

**DEPARTMENTS OF LABOR, HEALTH AND HUMAN  
SERVICES, AND EDUCATION, AND RELATED  
AGENCIES APPROPRIATIONS FOR FISCAL YEAR  
1998**

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**HEARINGS**

BEFORE A

SUBCOMMITTEE OF THE  
**COMMITTEE ON APPROPRIATIONS**  
**UNITED STATES SENATE**

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

ON

**H.R. 2264/S. 1061**

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR,  
HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED  
AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1998, AND  
FOR OTHER PURPOSES

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**Corporation for Public Broadcasting**  
**Department of Education**  
**Department of Health and Human Services**  
**Federal Mediation and Conciliation Service**  
**Nondepartmental witnesses**  
**Physician Payment Review Commission**  
**Prospective Payment Assessment Commission**  
**United States Institute of Peace**

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Printed for the use of the Committee on Appropriations

Available via the World Wide Web: <http://www.access.gpo.gov/congress/senate>

U.S. GOVERNMENT PRINTING OFFICE

39-860 cc

WASHINGTON : 1998

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For sale by the U.S. Government Printing Office  
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402  
ISBN 0-16-056239-2

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**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 1998**

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**TUESDAY, MARCH 4, 1997**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 10:01 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Gregg, Faircloth, Hutchison, Stevens, Harkin, Bumpers, Kohl, and Murray.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**OFFICE OF THE SECRETARY**

**STATEMENT OF HON. DONNA E. SHALALA, SECRETARY**

**OPENING REMARKS OF SENATOR ARLEN SPECTER**

Senator SPECTER. Ladies and gentlemen, the hour of 10 a.m., having arrived, we will begin the hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education. This morning, we greet the distinguished Secretary of Health and Human Services, Hon. Donna Shalala.

Welcome, Madam Secretary.

The budget for the Department of Health and Human Services is an enormous one, amounting to some \$200 billion in entitlements and discretionary programs, and included in that is a discretionary budget request of \$31.7 billion, which is a virtual freeze on the funds from last year.

The Department has an enormous number of vital programs in the health field, an evolving field with enormous changes, even before the introduction of the President's health care program in 1993. The health care field was seeing enormous changes with the President's program having been introduced and the analysis of that program, which ultimately did not result in legislation but has had profound changes, with the private sector responding in a variety of ways. With managed care programs and other efforts to try to contain costs we have seen tremendous changes in this field.

The advent of managed care has brought a new array of concerns: the so-called gag rule, the so-called capitation response by Congress with legislation on drive-by deliveries, requiring that

women stay at least 48 hours in the hospital, and now legislation to determine hospitalization coverage for mastectomies. There is a real area of concern that there may be micromanagement by the Congress.

This subcommittee and others in the Congress are searching for ways to have a generalized approach to these issues so that the decisions will be made by doctors, as opposed to insurance companies, and certainly not by Congress.

#### PREPARED STATEMENT

There is quite a long list of very important items to be covered in our hearings. So I will put my formal statement in the record, without objection, and we will turn at this time to our distinguished witness, the Secretary of Health and Human Services.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR SPECTER

This morning the Subcommittee on Labor, Health and Human Services and Education convenes the first of several hearings on the fiscal year 1998 appropriations requests. I want to once again welcome Secretary Shalala to the subcommittee.

Madam Secretary, your Department is charged with a formidable task: overseeing over \$200 billion in entitlement and discretionary programs that Congress appropriates to your Department for meeting the Health and Human Service needs of our Nation's citizenry.

No other Federal Department has more at stake in the balanced budget negotiations than yours. If the Congress and the President fail to reach agreement on entitlement reforms that stem the growth in spending for Medicaid and Medicare, these programs will soon consume virtually the entire Federal budget, leaving no room for funding medical research, preventive and primary health services and Head Start.

This committee will be taking a careful look at your recommendations for fiscal year 1998. Your Department's budget request for discretionary spending for this coming fiscal year totals \$31.7 billion, virtually a freeze in spending. I am sure you agree that something as critical as the health of our citizens deserves no less than the most reasoned review. In the year ahead, this Congress is expected to take action to assure:

- Medicare is financially sound;
- Poor children have health coverage;
- Health maintenance organizations provide quality care to beneficiaries;
- Women have access to regular mammography screening;
- Continued progress in fighting disease through prevention and medical research;

and

- A comprehensive review of the implications of genetic research.

We have an extremely tough job ahead of us, Madam Secretary. I look forward to working with you in the coming months to craft an appropriations bill that maintains the commitment to balancing the budget while preserving funding for high priority health and human service programs. This will necessitate each Federal agency within this subcommittee's jurisdiction sharing in spending reductions through identifying further efficiencies and savings.

#### SUMMARY STATEMENT OF SECRETARY DONNA SHALALA

Secretary SHALALA. Thank you very much, Mr. Chairman. I apologize for changing the time of the hearing.

I am pleased to appear before you today to discuss the President's 1998 budget for the Department of Health and Human Services.

Theodore Roosevelt once said nine-tenths of wisdom consists of being wise on time. This country remains the oldest and the finest democracy, not because we always agree but because we know

when it is time to agree. These are the moments that have always defined generations.

Mr. Chairman, we have reached one of those moments. Leaders on both sides of the aisle agree that we must balance the budget. The question is how.

At a time when our population is rapidly aging and our health delivery system is rapidly changing, a time when advances in technology and medical research offer new hope and new ethical dilemmas, how can we put our budget in the black and meet our health care challenges for the 21st century?

The President's plan will allow us to do just that. It puts us on a straight path to balance the budget by the year 2002, and our Department is playing a leading role in that effort.

Overall, the President's 1998 budget for the Department totals \$376 billion in outlays, of which \$34.7 billion is discretionary. Make no mistake about it—we believe this is a smart budget for a new century.

It acknowledges that we live in a time of scarce Federal resources and that government cannot do it all. But it makes it clear that when we target our resources responsibly and innovatively, when we team up with our private and public partners, and when we act as tough, savvy managers, the Federal Government can help lead the way to create a stronger and a healthier Nation, a Nation capable of meeting challenges both old and new.

#### MEDICARE AND MEDICAL CHANGES

Our first challenge is that we reserve our Medicare and Medicaid lifelines by modernizing, reforming and strengthening them. The President's plan would reduce projected Medicare spending by a net \$100 billion over 5 years and guarantee the solvency of the part A trust fund until the year 2007, a full 10 years.

The independent HCFA actuary has written a letter confirming these numbers and I will submit it for the record.

[The information follows:]

#### MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
HEALTH CARE FINANCING ADMINISTRATION,  
*Washington, DC, January 21, 1997.*

To: Administrator, HCFA.

From: Chief Actuary, HCFA.

Subject: Estimated Year of Exhaustion for the HI Trust Fund under the Medicare Legislative Proposals in the President's 1998 Budget.

This memorandum responds to your request for the estimated year of exhaustion for the Hospital Insurance trust fund under the Medicare legislative proposals developed for the President's 1998 Budget. Based on the intermediate set of assumptions in the 1996 Trustees Report, we estimate that the assets of the HI trust fund would be depleted early in calendar year 2007 under the Budget proposals.

In the absence of corrective legislation, trust fund depletion would occur early in calendar year 2001 based on the intermediate assumptions. Thus, the Budget proposals would postpone the year of exhaustion by about 6 years.

The financial operations of the HI trust fund will depend heavily on future economic and demographic trends. For this reason, the estimated year of depletion under the budget proposals is very sensitive to the underlying assumptions. In particular, under adverse conditions such as those assumed by the Trustees in their "high cost" assumptions. Asset depletion could occur significantly earlier than the intermediate estimate. Conversely, favorable trends would delay the year of exhaustion. The intermediate assumptions represent a reasonable basis for planning.

The estimated year of exhaustion is only one of a number of measures and tests used to evaluate the financial status of the HI trust fund. If you would like additional information on the estimated impact of the Medicare proposals in the President's 1998 Budget, we would be happy to provide it.

RICHARD S. FOSTER, *F.S.A.*

#### MODERNIZING MEDICARE

Secretary SHALALA. We are able to achieve these savings with real reforms, not with gimmicks, and without imposing new financial burdens on older Americans and people with disabilities. How? We do this by modernizing Medicare so that it fits the needs of older and disabled Americans both today and tomorrow—which is why we are expanding choices among private plans; which is why we are making sure that government is a more prudent purchaser of health care services; which is why we are tightening reimbursement rules, moving toward a new payment system and investing in prevention benefits like mammograms, vaccines, and colon screening, benefits that we know prevent illness and save lives.

Medicaid, too, needs a new look, but not a new soul. We keep Medicaid's historic promise of health care for our most vulnerable Americans. At the same time, the President's budget includes net Medicaid savings of \$9 billion over 5 years. Overall, we are saving \$22 billion over 5 years.

We are able to propose less savings than last year in part because of the great progress we have already made in reducing the Medicaid baseline, progress that could not have happened without strong management, without new legislation, and without increased flexibility, progress that must continue. This is why we are giving the States even more flexibility with Medicaid.

We are throwing away mountains of redtape for them and regulations by eliminating managed care waivers. We are also repealing the Boren amendment so States have more freedom to set provider payment rates, and we are dropping archaic payment rules. We are also eliminating regulations that tie States' hands on staffing and other matters.

#### CHILDREN'S HEALTH CARE

Our second goal is to lift up the lives of our children, and here the President's plan makes a firm, passionate commitment by, first and foremost, tackling one of this country's most pressing health care challenges, a challenge I know that members on both sides of the aisle want to meet.

Today there are more than 10 million children, 1 in 7, without health insurance. Most of these children are in families where parents work hard and play by the rules. This must end.

Our administration proposal is designed to cut the number of uninsured children by millions over the next 4 years. Let me outline how we are going to do it. And, Mr. Chairman, I am well aware that you have a significant recommendation in this area.

First, we will offer a hand-up to workers between jobs who need health insurance for their families while they get back on their feet. Our budget dedicates \$1.7 billion this year to help these families get up to 6 months of health care coverage. That will help to insure 700,000 children.

Second, we are proposing to spend \$750 million a year for a new partnership with the States so that we can insure children who fall through the cracks because their families earn too much to be eligible for Medicaid but not enough to afford private insurance.

Third, we are taking important steps to expand Medicaid coverage to reach more children through legislation the Congress has already passed.

We allow States to provide 1 full year of continuous Medicaid coverage for the 1.2 million children who qualify each year.

Mr. Chairman, this is an interesting proposal because what happens now is a child could be enrolled in Medicaid but one of their parents gets a job and moves above the Medicaid line. They have to be dropped by that HMO after the HMO has gone through the process of enrolling them.

Our proposal keeps that child in the Medicaid program and in that HMO for 1 full year. We will add 1 million adolescents to Medicaid by the year 2000. That is the regular legislation that has been introduced.

Finally, working with States and with health care providers, we put together an extraordinary public/private partnership to help find the 3 million children who are eligible for Medicaid but are not currently enrolled. We expect to enroll 1.6 million by the year 2000.

#### WELFARE REFORM

One of the President's highest priorities this year will be to move forward on the promise of welfare reform, changing our welfare reform program to a jobs program so that everyone who can work has the opportunity to work. But real welfare reform does not mean punishing people who cannot work. This is why our budget includes \$5.2 billion to restore Medicaid benefits to disabled children and to legal immigrants who are either children or disabled adults—people who cannot be expected to work.

These are important steps, steps we can take together.

But this budget commitment to children and families does not end there. If you look at the increase in our discretionary budget, what you will see is an intense focus on our children, a focus on the early foundations they need to get the right start in life and the guidance they need, as adolescents, to make the right choice with their lives.

#### HEAD START

You cannot live in Washington for more than a day without noticing that people tend to disagree about everything. But people do agree that the early years of a child's life are critical to his or her success in school and beyond, and to enrich those early years they do agree that Head Start works. It is part of the solution.

Our goal is to expand Head Start to reach more of the children who need it but do not get it now. To do this, we propose a \$324 million increase in Head Start.

#### NEW ADOPTION INITIATIVES

Today we have almost 500,000 children in foster care and 100,000 of them have no chance of returning back home. That is



100,000 children who want what every child deserves—a home, security, and love.

The President has issued our Nation a difficult but critical challenge. By the year 2002, we must double the number of children in foster care who are adopted or permanently placed each year. To reach this goal, the budget includes \$21 million for a new adoption initiative, to help States remove barriers that keep kids from finding loving, permanent homes.

Too often in the past, policymakers grouped children of all ages together. In this budget, we take a much more sophisticated approach by tackling the unique landmines that help keep many of our adolescents from making smart choices with the only lives they will ever have.

#### TEENAGE PREGNANCIES

After years of increases, there is some indication that teenage birth rates are inching downward, but not nearly enough. Each year, 200,000 teenagers, 17 and younger, have children. That hurts these children, it hurts their parents, and it hurts our entire Nation. That is why, as part of the new welfare law, we are implementing a new \$50 million initiative to send our children one clear and consistent message, that they must abstain from sex.

#### TEENAGE DRUG USE

There is a lot of talk lately about rising drug use rates among teens. But when you peel away the rhetoric and take a cold, hard look at the hard facts, what you see is our teenage drug problem in this country is, for the most part, a marijuana problem. The fact is that we have too many parents who do not feel comfortable talking to their kids about marijuana and sending them clear no-use messages.

We have a generation of children who are using marijuana earlier and earlier and are more and more likely to be armed with the dangerous misconception that it will do them no harm.

As part of the President's overall drug strategy, our 1998 budget makes a \$98 million commitment to fighting these dangerous trends—by countering pro-use messages, especially among 9- to 14-year-olds; by leveraging State resources; by gathering State by State data on substance abuse so that our country's Governors will know where they are succeeding and where they are not; and by dedicating an additional \$30 million to expanding research on drug treatment and prevention.

#### TEENAGE TOBACCO USE

There are a lot of different perspectives on the drug issue and certainly there are a lot of different perspectives on the issue of tobacco. But there is one thing we can agree on: children in this country should never smoke.

Every year, tobacco related illnesses claim the lives of 400,000 Americans, the vast majority of whom began smoking while they were teenagers, before their 18th birthday. That is why the President stood up to the special interests and proposed the boldest initiative ever to kick Joe Campbell and the Marlboro man out of our

children's lives. We made that promise to our children and to their parents. In this budget we include \$34 million to implement the regulation and to make that promise a reality.

We are also requesting \$36 million for CDC and \$22 million for NIH, to help States prevent cancer and encourage Americans, particularly kids, to put down their cigarettes and pick up their health.

The fact is that, when we work to cut teen smoking by one-half over 7 years, we are focusing on a huge public health challenge that, if successful, could save thousands of lives and dollars.

#### PUBLIC HEALTH AGENDA

That is our approach in this budget as we move ahead to meet our third challenge, to build a public health agenda for the 21st century.

Parents should not have to worry that the food or juice that they give their children will make them sick. They shouldn't have to worry that their families or communities will fall victim to deadly outbreaks of infectious diseases. But today too many do.

The CDC estimates that there are as many as 33 million cases of food-borne illnesses each year in this country and up to 9,000 deaths because of them. And emerging and reemerging infectious diseases, like ebola, are increasingly crossing continents and oceans to threaten all of us.

In both of these areas, we know that it pays to be smart on the front end to find innovative ways to prevent these tragedies instead of just responding to them after they have occurred. This is why the President has proposed a very sophisticated \$43 million early warning system so that we can stop food-borne illnesses before they stop us. This is why our budget increases funding by \$15 million to improve training and research and the ability of States to prevent and respond to deadly outbreaks of infectious diseases.

#### MEDICAL RESEARCH

Another cornerstone of our public health agenda is and always will be medical research. To make certain that the United States remains preeminent in research our administration proposes \$13.1 billion for the NIH as well as the second year of funding for NIH's new cutting edge clinical research center.

Because of the brilliant work that is being done at the National Institutes of Health, we have not only made important scientific breakthroughs, we have also learned that basic science can and should inform the choices we make about disease prevention and treatment. This lesson is important in the debate over mammography screening for women from age 40 to 49.

Last week, on February 25, the outside experts who make up the National Cancer Institute's Advisory Board began a discussion of the issues surrounding mammography screening. The advisory board, recognizing the importance and complexity of the issues, decided to form a working group to develop clear recommendations for the National Cancer Institute, including the messages that NCI should communicate to women in this age bracket about the benefits of mammography.

That board will report to the Director of NCI within 2 months.

Here, as in other areas, good science should prevail. Past NIH scientific research has already led to remarkable breakthroughs in the treatment and prevention of HIV AIDS. And now in this budget, NIH proposes to invest \$1.5 billion in additional research, including a substantial increase in funding for AIDS vaccine research, so we can use the light of science to finally reach the end of this dark tunnel. But until we do, our first priority must be prevention.

Our budget increases our prevention activities in the CDC by \$20 million to help prevent HIV among drug users, one of the groups at highest risk. And we continue our strong commitment to Ryan White activities by proposing \$1 billion, \$40 million more than last year, to empower those communities hardest hit to fight back.

#### TOUGH BUDGET

Preserving and modernizing Medicare and Medicaid, investing in the lives of children and families, creating a strong public health agenda for the 21st century, we have been able to make these commitments, Mr. Chairman, because of the strong management we have brought to the Department. We have reduced FTE's by almost 7,600 since 1993. We have cut bureaucracy, we have consolidated services, we have increased flexibility. That is what the American people want and deserve.

#### PREPARED STATEMENT

Barbara Jordan once said: "What the people want is very simple. They want an America that is as good as its promise." An America as good as its promise—that is the future we have tried to create with this budget, a budget that makes tough choices, a budget that shows tough management, a budget that cuts costs and invests in lives, especially in the lives of children and adolescents. That is the American future that all of us can create if we seize this great opportunity as we have done in the past and move forward together.

Once again, Mr. Chairman, I want to thank you for giving me this opportunity to testify and I would be happy to answer any questions you may have.

Senator SPECTER. Thank you very much, Madam Secretary.

[The statement follows:]

#### PREPARED STATEMENT OF HON. DONNA E. SHALALA

Mr. Chairman and Distinguished Members of the Subcommittee: I am pleased to appear before you today to discuss the President's 1998 budget for the Department of Health and Human Services.

As we move toward a new century, our Nation faces significant health and human service challenges. Advances in biomedical research and medical technologies, changing demographics, and transformations in the structure and delivery of health care and social services all present us with new opportunities and new demands. The President's fiscal year 1998 budget for the Department of Health and Human Services (HHS) ensures that our Nation's health and social services programs will have the flexibility to address these changes.

Our budget takes several critical steps toward creating a stronger and healthier nation:

- It puts us on a path to a balanced budget by 2002;

- It preserves Medicare and Medicaid by reforming, strengthening, and modernizing both programs;

- It helps provide health insurance to growing numbers of American families, especially children who do not have it;

It helps families raise strong and healthy children by strengthening our investment in Head Start, teen pregnancy prevention and abstinence education; increasing opportunities for adoption; and bolstering our efforts to reduce tobacco and drug abuse among youth;

It provides assistance and support to States as they assume new responsibilities under welfare reform and to families as they make the transition to work;

It creates a strong public health agenda for the next century by sustaining biomedical research at the National Institutes of Health, developing a new food safety initiative, combating infectious diseases and providing life-extending drug therapies to people with AIDS; and

It emphasizes tough management strategies that cut costs, ensure program integrity, create technological opportunities, promote effectiveness, respond to our customers and empower our partners.

The President's fiscal year 1998 budget proposes a balanced budget by fiscal year 2002 through a combination of program savings, responsible reforms and strong management. The Department of Health and Human Services plays a major role in this balanced budget effort. The President's fiscal year 1998 budget for the Department of Health and Human Services totals \$376 billion in outlays of which \$34.7 billion is discretionary spending. Of the total amount requested, \$223 billion in spending will be for programs that fall under this Subcommittee. This amount includes \$31.7 billion in discretionary spending, an increase of 1.5 percent over fiscal year 1997.

#### PRESERVING AND STRENGTHENING MEDICARE AND MEDICAID

##### *Medicare*

The President's Medicare plan preserves and modernizes the program, reducing projected spending by a net \$100 billion over five years while guaranteeing the solvency of the Part A Hospital Insurance trust fund until 2007. We are reforming Medicare to make it more efficient and responsive to beneficiary needs to make it a more prudent purchaser, to give seniors more choices among private health plans, to cut the growth of provider payments, and to hold the Part B premium to 25 percent of program costs.

In fiscal year 1998, HHS will continue to crack down on Medicare and Medicaid fraud and abuse through implementation of the Medicare integrity and anti-fraud and abuse programs that are authorized by the Health Insurance Portability and Accountability Act of 1996. Building on the successes of the HHS pilot project, Operation Restore Trust, HHS and the other Federal, State, and local partners will expand anti-fraud efforts to all 50 states.

##### *Medicaid*

The President's plan for Medicaid reforms the program but preserves the guarantee of health and long-term care coverage for the most vulnerable Americans—more than 37.5 million children, pregnant women, people with disabilities, and the elderly. The President's legislative proposals in Medicaid will achieve a net savings of \$9 billion over the five years from 1998 through 2002. This total is comprised of both spending and savings proposals that improve and strengthen the Medicaid program, while more appropriately targeting spending for our most vulnerable populations.

Recognizing that growth in Medicaid spending has declined significantly over the past two years, this budget seeks to maintain these lower spending levels in the out-years when spending growth is projected to rise more rapidly again. The President's Medicaid savings are achieved through the establishment of a per-capita cap and through the reduction and re-targeting of DSH spending, for a total of \$22 billion over five years. The budget also makes a number of improvements to the Medicaid program, including changes to last year's welfare reform law, costing \$13 billion over the same period.

The major spending initiatives include the children's health initiative and welfare reform related proposals. The plan also helps States meet the most pressing needs, while giving them unprecedented flexibility to administer their programs more efficiently. Finally, the plan retains current nursing home quality standards and continues to protect the spouses of nursing home residents from impoverishment.

#### MAINTAINING AND EXPANDING HEALTH CARE COVERAGE FOR WORKING FAMILIES

One of the best signs of a healthier tomorrow was passage of the Health Insurance Portability and Accountability Act of 1996 which addressed some of the problems workers face in getting, and holding onto, affordable health insurance. We must now take the next step to help the growing numbers of American families who

lack health insurance coverage. And that is exactly what this budget proposes to do.

An estimated 10 million children in America today do not have health insurance. The President is proposing these steps to help address this problem and reach the goal of reducing the number of uninsured children by up to 5 million by the end of fiscal year 2000.

First, the budget proposes \$750 million in annual grants to States to build on their recent successes in working with insurers, providers, employers, schools, and others to develop innovative ways to provide health insurance coverage to children who have neither Medicaid nor employer-sponsored insurance.

Second, the budget provides funds to allow States the option to extend one year of continuous Medicaid coverage to children, thus increasing continuity and security for children and families and reducing administrative burdens on States, families, and health care plans which now have to determine eligibility on a monthly basis.

Third, the budget includes a \$1.7 billion initiative to help about 700,000 children in the families of temporarily unemployed workers maintain health coverage between jobs. This program of grants to states will be available to recipients with incomes below a certain level, who had employer-based coverage in their prior jobs. States will have substantial flexibility to administer the demonstration program.

Finally, we will work with the Nation's Governors to develop new ways to reach out to the 3 million children who are currently eligible for Medicaid but are not presently enrolled. In addition, under current law, an estimated 250,000 14-year-olds will become eligible for Medicaid in 1998.

As a part of the President's health legislation package, our budget includes \$25 million in grants to States to establish voluntary health insurance purchasing cooperatives to take advantage of economies of scale to which small firms normally do not have access in purchasing health insurance.

#### BUILDING STRONG FOUNDATIONS FOR FAMILIES AND CHILDREN

The best gifts we can give our children are strong families, safe communities, and good health. Strong foundations are important for every child's future. Both research and the experiences of parents and caregivers tell us that a child's environment during the early years is especially critical to his or her ability to succeed in school and later in life.

In addition to expanding health care coverage for children, this budget includes many other special initiatives to help our children and families. It is sound fiscal policy to invest in our nation's children; the pay off obviously can be substantial. For this reason, the budget proposes a set of strategic investments.

*Head Start.*—Studies of children enrolled in Head Start and other similar programs continue to show that the Head Start experience has a positive impact on school readiness, increases children's cognitive skills, boosts self-esteem and achievement motivation, and improves school social behavior. Head Start has also been shown to help parents improve their parenting skills, increase participation in their children's school activities and, in many cases, helps parents on the road to self-sufficiency. In short, Head Start works and needs to be expanded to reach more Head Start-eligible children in families not currently served by the program. The budget includes \$4.3 billion, \$324 million more than in 1997, to ensure that Head Start stays on track to serve 1 million children by 2002. The additional funds will allow Head Start to serve an additional 36,000 new children and their families, bringing total Head Start enrollment to an estimated 836,000.

*Adoption Initiative.*—Each year, State child welfare agencies secure homes for less than one-third of the children for whom the goal is adoption or another permanent placement. These children wait an average of three years to be placed in permanent homes. President Clinton has challenged States and Federal agencies to at least double, by the year 2002, the number of children in foster care who are adopted or permanently placed each year. HHS will lead the effort to identify barriers to permanent placement, set numerical targets, reward successful performance, and raise public awareness. The fiscal year 1998 budget includes \$21 million for an adoption initiative. Funds will be used to provide training and enhanced technical assistance to States; support grants to States to assist them in removing barriers to adoption or permanent placement; engage business, church and community leaders in this initiative and develop and lead a public awareness effort to include public service announcements, print material and increase use of Internet to promote adoption. Our budget also proposes paying \$108 million between fiscal year 1999–2000 in incentives to States for increases in adoptions over the previous year which will be offset by corresponding reductions in foster care costs.

*Tobacco.*—Every year, tobacco-related cancer, respiratory illness, heart disease, and other health problems take the lives of 400,000 Americans—the vast majority of whom began smoking before their 18th birthday. Consequently, in August 1996, the Administration approved the boldest proposal ever made to kick Joe Camel and the Marlboro Man out of our children's lives. The goal of this initiative is to cut tobacco use among our young people by half over 7 years by reducing the ready access that teenagers have to tobacco products and by lessening the pervasive appeal that these products have for potential underage users. Our budget includes \$34 million to implement the regulation. The budget also provides \$36 million for CDC and \$22 million for NIH for financial and technical support to States for tobacco control and cancer prevention activities. In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA) is working with States to help them comply with the 1996 Synar regulation requiring that they reduce the availability of tobacco products to underaged youths.

*Reducing Substance Abuse Among Youth.*—After years of steady decline, marijuana use is rapidly increasing among American youth. As much a cause for concern is the fact that adolescents increasingly feel there is little or no risk to themselves or others in their abusing drugs. To attempt to reverse these trends, the Department is increasing the resources dedicated to preventing marijuana and other substance abuse. The fiscal year 1998 budget specifies \$98 million for a SAMHSA youth substance abuse prevention initiative which will allow HHS to mobilize and leverage Federal and State resources, raise awareness and counter pro-use messages, and measure outcomes. Approximately \$63 million will be dedicated to State Incentive Grants.

These grants will require Governors to develop comprehensive State-wide strategies for reducing youth substance abuse. In designing their plans, States may propose their own approaches but will be offered a menu of effective substance abuse prevention strategies and programs that are based on scientific research. SAMHSA will focus public education efforts on reaching youth and their caregivers by integrating and expanding its Girl Power! and Reality Check anti-drug use campaigns. To measure outcomes, approximately \$28 million will be used to expand the National Household Survey on Drug Abuse to capture state-level data. The Household Survey now provides data for making national estimates on the prevalence of substance abuse in the population age 12 years and older as well as information on behavior, attitudes, and household characteristics. The expansion will allow the Department to make state estimates of substance abuse for youth between 12 and 17 and for young adults, benefiting those who are designing state substance abuse prevention and treatment activities. The Administration also calls on Congress to enact SAMHSA's Performance Partnership proposal, which would give States more flexibility to design and coordinate their anti-abuse and mental health programs and target resources to community priorities.

*Preventing Teen Pregnancy.*—Teen pregnancy rates are going down, but more needs to be done. Each year, about 200,000 teenagers who are 17 or younger have children. Their babies are often low birth weight and are at high risk for infant mortality. They are also likely to be poor—about 80 percent of the children born to unmarried teenagers who dropped out of high school are poor. In contrast, just 8 percent of children born to married high school graduates aged 20 or older are poor. The fiscal year 1998 budget includes \$14.2 million for the Adolescent Family Life program, an abstinence-based education initiative which continues to build on the Administration's ongoing efforts to assure that communities are working to prevent out-of-wedlock teen pregnancies. This budget also includes \$13.7 million for CDC's program for the prevention of teen pregnancy. In addition, the new welfare reform law signed by President Clinton on August 22, 1996, provides \$50 million a year in new funding for the Health Resources and Services Administration (HRSA) to support State abstinence education activities, beginning in fiscal year 1998.

#### PUBLIC HEALTH FOR THE 21ST CENTURY

Investments in public health can yield substantial returns—fewer premature deaths, fewer and less costly illnesses, and healthier, more productive lives. The fiscal year 1998 budget invests in biomedical research and in public health initiatives that show great promise for improving critical health problems while controlling future costs.

*Biomedical, Behavioral and Health Services Research.*—The budget continues the Administration's longstanding commitment to biomedical research, which advances the health and well-being of all Americans. For the National Institutes of Health (NIH), it proposes \$13.1 billion for biomedical research that would lay the foundation for future innovations that improve health and prevent disease. The budget in-

cludes \$223 million to emphasize research in six areas NIH has identified as showing the most promise for addressing public health needs and yielding medical advances, including research on the biology of brain disorders; new approaches to pathogenesis; new preventative strategies against disease; genetics of medicine; advanced instrumentation and computers in medicine and research; and new avenues for therapeutics development. In addition, the request funds research on HIV/AIDS, breast cancer, drug abuse, spinal cord injury and regeneration, as well as many other diseases and disorders that affect the health, productivity, and quality of life of all Americans.

Of particular interest to members of this Subcommittee is the question of the advisability of routine mammography screenings for women between the ages of 40 and 49. On February 25, the National Cancer Advisory Board began a discussion of the issues surrounding mammography screening for women. The advisory board, recognizing the importance and complexity of this issue, decided to form a working group to develop clear recommendations for the National Cancer Institute, including the messages that NCI should communicate to women. The Board intends to complete the process within two months.

The budget request also includes the second year of funding for a new Clinical Research Center, which will give NIH a state-of-the-art research facility in which researchers can continue to bring the latest biomedical research discoveries directly to patients' bedsides.

In just the past year, NIH-sponsored research has produced many major advances, such as locating the first major gene that predisposes men to prostate cancer; pinpointing the location of the gene that researchers believe is responsible for familial Parkinson's disease; and unveiling a map which identifies the locations of over 16,000 genes in human DNA, about one-fifth of the estimated 80,000 genes packaged within the human chromosomes. This will give researchers a ready list of "candidates" for genes involved in human diseases.

Of particular note is an increase of \$30 million for NIH's National Institute on Drug Abuse which is part of the Administration's cross-cutting commitment to combat drug abuse. The increased funding will further the development of a medication for the treatment of cocaine addiction.

The budget includes an initiative devoted to improving health care quality. The Agency for Health Care Policy and Research (AHCPR) has requested \$5 million on the Quality and Cost Effectiveness Initiative to narrow the gap between what we know and what we do to improve health care. The initiative will focus on developing knowledge and strategies to improve the quality of clinical care. Research on quality and cost effectiveness also plays a crucial role in the continuing effort to decrease expenditures for the Medicare program, while providing quality health care.

*Food Safety.*—In recent years, new and serious food safety problems have occurred with increasing frequency, including illness outbreaks caused by food-borne pathogens such as *E. coli*, *Salmonella*, enteritidis, *Vibrio vulnificus*, and *Cyclospora*. The Centers for Disease Control and Prevention (CDC) has estimated that each year as many as 33 million cases of food-borne illnesses in the United States result in up to 9,000 deaths. To respond effectively to these food safety issues, the President has proposed a \$43 million food safety initiative, including \$34 million for CDC and FDA to strengthen surveillance systems for food-borne illnesses nation-wide, and to improve Federal-State coordination when food-borne disease breaks out. The budget would also further support a modernized system of food safety inspection in the seafood industry that quickly identifies potential food safety hazards in the production and processing of such food. In addition, the U.S. Department of Agriculture is a partner in this initiative, with an increase of \$9 million requested in fiscal year 1998.

*Infectious Disease.*—Recent outbreaks of various infectious diseases have shown that emerging and re-emerging infectious diseases are an important potential threat to public health. Preventing infectious diseases is far less costly, in human suffering and economic terms, than reacting with expensive treatment and containment measures once public health emergencies occur. To address this need, the budget includes \$59 million, \$15 million more than in 1997, for CDC's efforts to address and prevent emerging infectious disease. Funds will support training and applied research, and strengthen significantly the States' disease surveillance capability. The budget also includes \$88 million (which is \$5 million more than in fiscal year 1997); for NIH's efforts to expand research on new and resurgent infectious diseases as well as the development of vaccines. Funds will support basic and applied research on infectious diseases to facilitate the detection and control of infectious agents.

*HIV Treatment and Prevention.*—In 1996, the Ryan White CARE Act was reauthorized with strong bipartisan support. The budget proposes over \$1 billion for

HRSA's Ryan White activities, \$40 million more than in 1997. This will help our hardest hit cities, States, and local clinics provide medical and support services to individuals with HIV/AIDS. Under this Administration, funding for Ryan White grants has risen by 158 percent. The 1998 budget would fund grants to cities and States to help finance medical and support services for individuals infected with HIV; to community-based clinics to provide HIV early intervention services; to pediatric AIDS and HIV dental activities; and to HIV education and training programs for health care providers. The fiscal year 1998 Ryan White request includes \$167 million specifically for the AIDS drug assistance programs. In an effort to give states the flexibility to provide a combination of primary AIDS care services—AIDS drugs, insurance continuation and other medical and support services—to best meet their own needs, the budget provides a \$15 million increase to the overall Title II state grant program.

Finally, the budget proposes \$634 million for the CDC's HIV prevention activities, \$20 million more than in 1997, to help prevent HIV among injecting drug users, who are at great risk of HIV infection. While the outside experts on the NIH Consensus Conference recently recommended lifting the ban on the use of federal funds for clean needle exchange programs, the prevention activities funded by this budget do not include such programs. As the Department's report to Congress, dated February 18, indicated, clean needle exchange can be an effective component in community-based HIV prevention programs in communities that choose to include them. The science on this issue is evolving somewhat rapidly. And, as it does, NIH will continue to research effective programs that examine how to prevent HIV infection and decrease drug abuse.

#### STRONG MANAGEMENT

In keeping with the President's commitment to the American people to reinvent and reduce the size of Government, the Department has continued to streamline organizational structures and focus our efforts on reducing employment while preserving the resources necessary to carry out our missions. The Department as a whole ended fiscal year 1996 at a comparable level of 57,629 FTE which is more than 1,600 FTE under the budget target for the year. Since 1993, the Department has reduced staffing levels by approximately 7,600 FTE, or 12 percent. As we struggle to meet balance budget targets, we will be looking for innovative ways of financing our streamlining plans for this and future years.

The fiscal year 1998 budget request supports the continuation of our efforts to transform the Department into a high-performance, customer-focused organization. Our past efforts have led to better service to our customers, reduced bureaucracy and red tape, increased flexibility in the administration of our programs, and internal changes that help the Department work better and save taxpayer dollars.

#### CONCLUSION

The fiscal year 1998 budget for the Department of Health and Human Services accomplishes four major goals.

First, it makes a major contribution to the goal of a balanced budget through targeted reforms of our entitlement programs and by limiting discretionary program growth. It also contributes to this goal through continued effort to curb fraud, waste, and abuse in Medicare and Medicaid.

Second, it preserves, protects, and expands our health insurance system. Medicare is protected and trust fund solvency is extended. Medicaid will be reformed and expanded to cover up to 3 million more children. Two new programs will also extend health insurance to unemployed workers, their families and uninsured children.

Third, it provides much needed investments in programs—Head Start, teen pregnancy prevention, adoption programs, and tobacco and drug use control among our children—that help families raise their children.

Fourth, it proposes a public health system for the 21st century that will improve the nation's health by expanding medical research to ensure the safety of our food supply and strengthening our ability to respond to new and emerging infectious diseases and AIDS.

Thank you, Mr. Chairman, for the opportunity to present our budget to this Subcommittee. We look forward to working with this Subcommittee on our fiscal year 1998 budget requests. I will be happy to answer any questions you or Members of the Subcommittee may have.



## SUMMARY OF BUDGET REQUESTS FOR PROGRAMS UNDER THIS SUBCOMMITTEE

*Health Resources and Services Administration (HRSA).*—The fiscal year 1998 budget request for HRSA is \$3.3 billion. Over \$1 billion is proposed for Ryan White activities, a \$40 million, or 4 percent increase over fiscal year 1997. This will continue our commitment to improve the quality and availability of care for individuals and families with HIV and AIDS. The request for the Consolidated Health Centers cluster provides \$810 million for grants to local health centers that serve vulnerable under-served populations, including migrant workers, homeless individuals, and residents of public housing. This funding level maintains our commitment to ensure that they receive quality health care. The HRSA budget supports funding of several programs with the sole mission of improving the health of women of childbearing age and their children. These programs include the Maternal and Child Health Block Grant (\$681 million); and the Title X Family Planning program (\$203 million). In addition, HRSA will fund a new \$50 million mandatory abstinence education block grant to States which was authorized in the Welfare Reform Bill.

*Centers for Disease Control and Prevention (CDC).*—The fiscal year 1998 request for CDC totals \$2.45 billion in program level, a net increase of \$36 million over fiscal year 1997. Within this level, \$25 million will be targeted to improve infectious disease prevention and control; and \$10 million will be used to help ensure, in partnership with other government agencies, the safety of the food supply. Also included in the request are increased resources of \$20 million to target HIV prevention efforts toward injecting drug users, a growing segment of all new AIDS cases. The fiscal year 1998 budget also continues and enhances CDC's diabetes control program, with a requested increase of \$10 million. With this initiative, CDC will fund diabetes control programs in all 50 States. CDC is requesting an increase of \$15 million to conduct multi-faceted tobacco control programs in 32 States and the District of Columbia to reduce the use of tobacco, especially among our nation's youth. An added \$5 million is requested to begin to replicate model programs to conduct intensive chlamydia screenings across the country. Reducing chlamydia infections ultimately results in a much lower rate of reproductive health consequences including infertility of women.

Finally, the elimination of most vaccine-preventable diseases remains a major priority of the CDC. With the funds requested, CDC will be able to support the same level of State purchases of vaccine, as well as improvements to the delivery system, as was done in fiscal year 1997.

*National Institutes of Health (NIH).*—The fiscal year 1998 request for NIH totals \$13.1 billion, an increase of \$337 million, or 2.6 percent, over fiscal year 1997. Within this increase, \$271 million is devoted to providing a 3.9-percent rate of growth in funding for investigator-initiated research project grants (RPGs), NIH's highest priority.

These grants support new and promising ideas cutting across all areas of medical research. In fiscal year 1998, the NIH budget provides nearly \$7.2 billion to support a record total of 26,679 RPGs, including 7,112 new and competing RPGs. Overlapping with the RPG increase is the NIH request for an additional \$223 million to emphasize research in six areas NIH has identified as showing the most promise for addressing public health needs and yielding medical advances, including research on the biology of brain disorders; new approaches to pathogenesis; new preventive strategies against disease; genetics of medicine; advanced instrumentation and computers in medicine and research; and new avenues for therapeutics development. Also included within the request is an additional \$30 million specifically to expand research on drug abuse and drug treatment and prevention.

The development of a medication for the treatment of cocaine addiction is the highest priority for fiscal year 1998 of the National Institute on Drug Abuse. The fiscal year 1998 budget continues to request all of NIH's AIDS-related funds—\$1.5 billion—in a single account for the Office of AIDS Research (OAR), consistent with the provisions of the NIH Revitalization Act of 1993. The Director of OAR will transfer AIDS funds to the Institutes in accordance with the comprehensive plan for AIDS research developed by the OAR along with the Institutes. The Administration strongly supports a consolidated AIDS appropriation within NIH as a vital part of ensuring a coordinated and flexible response to the AIDS epidemic. In addition, \$90 million in total is requested, the same as in fiscal year 1997, for the second phase of construction funding for NIH's new Clinical Research Center.

*Substance Abuse and Mental Health Services Administration (SAMHSA).*—The fiscal year 1998 President's budget for SAMHSA totals \$2.2 billion, an increase of \$34.4 million or 1.5 percent over the fiscal year 1997 enacted level. This funding level will continue our commitment to improving the quality and availability of mental health and substance abuse services. The request dedicates additional resources

to substance abuse, including a \$10 million increase for the Substance Abuse Performance Partnership Block Grant and \$28 million for data collection activities to expand the National Household Survey on Drug Abuse (NHDSA) to individual States. A major component of SAMHSA's budget will focus on combating recent increases in teenage drug use. The 1998 budget request continues to expand funding for the Youth Substance Abuse Prevention Initiative by mobilizing and leveraging Federal and State resources to call upon Governors to develop State-wide prevention plans; raising public awareness and countering pro-drug use messages aimed at adolescents and families; and tracking youth drug use at a State-by-State level to measure progress of youth drug attitudes and use. This proposal directly addresses Goal No. 1 of the National Drug Control Strategy to "motivate America's youth to reject illegal drugs as well as the use of alcohol and tobacco."

*Agency for Health Care Policy and Research (AHCPR).*—The fiscal year 1998 request for AHCPR totals \$149 million in program level, an increase of \$5.5 million over the fiscal year 1997 level. The fiscal year 1998 request will fully fund previous research commitments, support the Medical Expenditure Panel Surveys (MEPS), and fund the Quality and Cost Effectiveness of Clinical Care initiative. This initiative will focus on developing knowledge, tools and strategies to improve the quality of clinical care. This research also plays a critical role in the continuing effort to reduce health care expenditures, while still providing high quality services. The \$36.3 million requested for MEPS will continue this major data survey, providing the public with timely national estimates of health care use and expenditures, private and public health insurance coverage, and the availability, costs and scope of private health insurance benefits among the U.S. population.

*Health Care Financing Administration (HCFA).*—HCFA is the largest purchaser of health care in the world. In fiscal year 1998, Medicare and Medicaid expenditures will be about \$311 billion for 71 million beneficiaries. The fiscal year 1998 request for program management, the budget responsible for administering these two programs is \$1.8 billion or a little over one-half of 1 percent of total Medicare and Medicaid outlays. Of this amount, almost 70 percent will go to 75 private sector insurance companies throughout the United States who process and pay the claims for the care given to Medicare beneficiaries. Only about 20 percent (\$359 million) of the requested amount will go to fund Federal employees and their activities (about one-tenth of 1 percent of total Medicare and Medicaid outlays). These activities maintain and strengthen the Department's commitment to develop more efficient operating systems; manage programs to fight fraud, waste, and abuse; and promote and monitor managed care spending and quality of care. To deal with the growth in new health care facilities joining the Medicare program, the Department proposes a user fee for new facilities to be collected by the States to cover the cost of initial surveys.

*Administration for Children and Families (ACF).*—ACF is the Department's lead agency for programs serving America's children, youth and families. It also has the lead in implementing the recently enacted Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193), including the Temporary Assistance to Needy Families (which replaces the Aid to Families with Dependent Children program), the child care entitlement program, and new research and evaluation activities.

The fiscal year 1998 budget for ACF totals \$34.6 billion, including \$19 billion appropriated under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. Our request includes \$8 billion for discretionary programs that promote safe and healthy children and youth and support our Nation's working families including: \$4.3 billion for Head Start to provide an additional 36,000 children with Head Start experience and establish strong foundations for a total of nearly 836,000 children and their families; \$1 billion for the Child Care and Development Block Grant; and \$410 million for a range of discretionary programs that help States and local communities protect children, including a new Adoption Initiative to bring more foster care children into healthy, stable homes.

The fiscal year 1998 budget also includes almost \$27 billion for entitlement programs. Of this amount, approximately \$17 billion is for the Temporary Assistance for Needy Families (TANF) program, which transforms welfare into a system that requires work in exchange for time-limited benefits. A total of \$2.2 billion (this includes \$107.5 million in estimated carryover from fiscal year 1997) is requested for child care programs to allow States maximum flexibility in developing child care programs. This amount combined with \$1 billion in discretionary spending requested for the Child Care and Development Block Grants, will further the Administration's commitment to supporting families and moving families from welfare to work. In fiscal year 1998, we estimate that Federal and State governments will spend about \$3.5 billion in order to collect over \$13.7 billion in child support payments—an 8 percent increase over 1997. The budget also includes \$4.3 billion for

Foster Care, Adoption Assistance and Independent Living programs. The President's Adoption Initiative proposes to pay incentives to States for increases in adoptions of children from State foster care systems. This new entitlement to States will result in no net increase in outlays because increases in Adoption Assistance will be offset by savings in Foster Care.

*Administration on Aging (AoA).*—The fiscal year 1998 budget for AoA provides \$838.2 million for programs aimed at maintaining or improving older Americans' quality of life. For fiscal year 1998, AoA requests \$291.4 million for Supportive Services and Centers, to provide funding for the nationwide network of 57 State units on aging, 661 Area Agencies on Aging, 6,400 senior centers, and more than 27,000 service providers. Also requested is \$469.9 million for Nutrition Services, to continue providing the 242 million congregate and home-delivered meals served to vulnerable senior citizens. In addition, AoA requests \$9.3 million for in-home services for the frail elderly, \$16.1 million for grants to Native Americans, \$15.6 million for preventive health services, and \$4.0 million for aging training, research and related programs. Finally, to improve service and streamline administration, the request includes three program changes: a consolidation of the various programs authorized under Title VII of the Older Americans Act into a single Grants to States for Protection of Vulnerable Older Americans program, with total funding of \$9.2 million; a transfer of the Alzheimer's Disease Demonstration Grants to States program (\$8.0 million) from the Health Resources and Services Administration (HRSA) to AoA; and the transfer of DOL's Community Service Employment for Older Americans program (\$440.2 million) to AoA.

*General Departmental Management (GDM).*—The fiscal year 1998 budget request provides a program level of \$192 million for General Departmental Management (GDM), including an appropriation of \$172 million and intra-agency transfers of \$20 million in one-percent evaluation funds. GDM supports those activities associated with the Secretary's roles as chief policy officer and general manager of the Department through nine Staff Divisions (STAFFDIVs): the Immediate Office of the Secretary, the Offices of Public Affairs, Legislation, Planning and Evaluation, Management and Budget, Intergovernmental Affairs, General Counsel, and Public Health and Science, and the Departmental Appeals Board. In fiscal year 1998, the GDM request includes funds for Policy Research—formerly a separate appropriation account—to support research on issues of national importance.

*Office for Civil Rights (OCR).*—The OCR requests \$21 million, an increase of \$1 million above fiscal year 1997. OCR has made significant progress in addressing issues such as race discrimination in access to health care and discrimination against persons with disabilities. The fiscal year 1998 budget request supports outreach and other compliance initiatives that seek new ways of preventing civil rights problems and addressing potential discrimination in HHS programs. This includes implementation of new nondiscrimination requirements covering adoption and foster care placements that will support the President's Adoption 2002 initiative.

*Office of Inspector General (OIG).*—The OIG requests a discretionary budget of \$32 million, a decrease of \$3 million below the comparable fiscal year 1997 level. OIG will focus its resources in the following areas: evaluating various options and methods to increase collections in the Child Support Enforcement Program; assessing the adequacy of the Food and Drug Administration's control over investigational new drugs; investigating grant and contract fraud, research fraud, and allegations of wrongdoing in the Department's public health programs; and auditing management control systems and financial operations.

In addition, the Health Insurance Portability and Accountability Act of 1996 appropriates funds to OIG for the Health Care Fraud and Abuse Control Program. OIG will receive between \$80 million and \$90 million in fiscal year 1998, to be determined by agreement between the Secretary of HHS and the Attorney General. Under this program, OIG will: build upon and expand the proven effective policies and practices of Operation Restore Trust; enhance general Medicare fraud and abuse enforcement activities; and develop innovative anti-fraud initiatives.

#### MAMMOGRAMS

Senator SPECTER. We will have 5-minute rounds for each member.

I begin, Madam Secretary, with the issue of mammograms. The National Institutes of Health panel finding that mammograms were not warranted for women in the age bracket 40 to 49 has caused quite a stir. I have had a series of field hearings in my own

State, and, as you know, we had Dr. Klausner of NCI and other witnesses appear here. You talk about a report which is coming in the course of the next 2 months. My own view is that the evidence is substantial, if not overwhelming, that mammograms for women 40 to 49 are very helpful and do save lives.

It seems to me that there ought to be a prompt conclusion to that effect.

When you take a close look at what the NIH panel did, they had prepared a press release which they had really not intended to disclose publicly and the matter sort of got out of hand. Dr. Klausner said he was shocked by it.

My question to you, Madam Secretary, is do you have the authority administratively to say that Medicaid will cover mammograms for women 40 to 49?

Secretary SHALALA. I think the answer is yes, I probably do have that authority. But let me tell you what we are going to do.

Senator SPECTER. Before you go on, there are some women under Medicare in the age 40 to 49 category, disabled, SSI. Could they also be covered by an administrative order?

Secretary SHALALA. Well, it is not necessary. Let me explain.

Medicare must cover all medically necessary services. If a doctor recommends that a disabled woman, who would be in the category covered by Medicare, needs a mammogram, that mammogram will be covered through the Medicare Program because Medicare covers all medically necessary services.

As you know, most of the people on the Medicare Program are the elderly, over age 65. Mammograms certainly are covered for them.

Senator SPECTER. I do know that. That is why I talked about the disabled.

The point I am coming to—and I would like to cover this within my first round of 5 minutes—is that if it is medically necessary, as you say for the disabled, under Medicare it will be covered. There is a strong message given here to the insurance world that mammograms are not warranted.

I chose my word carefully and I noticed you focused on the word. If there is a way to avoid coverage of the payment, I think it is reasonable to expect the insurance community will not cover those payments.

What I am looking for is a prompt determination that mammograms are warranted for women in the 40 to 49 category. You and I talked about this briefly when you returned just in time for the State of the Union speech. You had been traveling overseas and I had expressed an interest in having you appear the next day, when Dr. Klausner came. This is a matter which I think requires clarification early-on.

When Dr. Klausner was here in January, he said that he expected the meeting in February to resolve the matter, and it has not resolved the matter. When there is a public determination that mammograms are not warranted for women 40 to 49, many women are reading that beyond that age bracket to mean that mammograms are not really necessary.

I heard some very compelling testimony yesterday at the Hershey Medical Center from women who are very bitter about the de-

termination, saying that women were not using mammograms. A very distinguished African-American woman from Lancaster testified very forcefully about this point.

What I am looking for is an early message that mammograms are warranted for women of age 40 to 49. What I am trying to move toward is how that can be accomplished. That is why I asked you in a very pointed way if you have the authority, administratively, to do that.

Secretary SHALALA. In Medicaid, the States would decide what optional benefits there are. The National Cancer Advisory Board did not come to a conclusion at the February meeting. They did appoint a working group and do intend to give us a recommendation in 2 months, which is what they reported to us on this issue.

Senator SPECTER. Why so long?

Secretary SHALALA. Two months?

Senator SPECTER. Yes; why so long? I think 2 months is too long.

The panel came out several weeks ago. He testified here, I believe on January 21. They were supposed to have something done in February. Every day that passes is a day when women are not tested.

I think 2 months is too long.

Secretary SHALALA. Well, let me say that the National Cancer Advisory Board believed that they could make recommendations within a 2-month period. As you know, this is an area in which there has been controversy. But no woman should stop from going to her doctor or requesting a mammogram if she believes that she wants a mammogram.

Now in terms of the National Cancer Institute's recommendation, their advisory board has said that they would report back to us in 2 months. Dr. Klausner has referred it to that advisory board; 2 months does not seem to me to be a long period of time in an area in which we need as clear a response as we possibly can get from our experts.

Senator SPECTER. Madam Secretary, this will be my last question because the red light is on and I do want to observe the time. But I also want to follow up on your last statement.

When you say that women should get a mammogram if they need one, that won't even make a footnote anywhere. If you say that Health and Human Services will cover the payment for mammograms for women 40 to 49 because the Health and Human Services Secretary determines that they are warranted, that will make a headline. It will make an impression on a lot of women.

Secretary SHALALA. The Department will come to a conclusion on a scientific guideline. I will wait for a clear recommendation from Dr. Klausner, as to how the Department ought to act on this matter. It is extremely important that the Department rely on the advice of the scientists who have been empowered to advise the Secretary on this matter.

Senator SPECTER. Well, Madam Secretary, I respectfully disagree with you about the timing. The panel came to a conclusion on January 23 about saying that mammograms were not warranted for women 40 to 49. I think there was a lot of damage done in the interim between then and now. I think before the panel came to a conclusion or made the statement that it did that it should have

had a better basis for doing so before causing all of this angst among women. And I think that Dr. Klausner should have had an answer when he came before this committee in February, certainly by late February; 2 months is a very long time for millions of women not to have mammograms.

Secretary SHALALA. Senator, I think that the point I am making is that there has to be a clear scientific basis for the kinds of health requirements that the Department puts in place on the Government programs.

Senator SPECTER. Well, was there a clear scientific basis that mammograms were not warranted for women 40 to 49 when the NIH panel came to that conclusion?

Secretary SHALALA. Well, I am not going to substitute my judgment for Dr. Klausner's or for the National Cancer Institute's Advisory Board who are reviewing that particular standing ad hoc panel's recommendation.

What Dr. Klausner has told me is that the National Cancer Advisory Board working group will report back in 2 months. When we have that information, we will provide that to you and to the women in this country.

Senator SPECTER. Well, my question went to a different point.

You say there has to be a clear scientific basis to say that mammograms are warranted for women 40 to 49. I am asking you if there was a clear scientific basis for the NIH panel to say that mammograms were not warranted for women 40 to 49.

Secretary SHALALA. Dr. Klausner has said to me that he has a different reading of the literature than that particular NIH panel and, therefore, he wanted to refer to the National Cancer Advisory Board for a clearer basis and a clearer interpretation. I will rely on his judgment on that.

Senator SPECTER. Well, I am still on a different point. You are saying you want a clear scientific basis before you say mammograms are warranted for women 40 to 49. I am asking you if there was a clear scientific basis for the contrary conclusion, that mammograms were not warranted for women 40 to 49.

If you put it out in the field that they are not warranted without a clear scientific basis, I don't see the problem in retracting it. There was no clear scientific basis for the NIH panel finding that mammograms were not warranted for women 40 to 49.

Secretary SHALALA. Senator, that is your conclusion. I must rely on the National Cancer Institute.

Senator SPECTER. Oh, do you have a different conclusion?

Secretary SHALALA. I'm not saying that I have a different conclusion. I'm relying on the advice from the head of the National Cancer Institute. When he gives me that clear advice after consultation with his own advisory board, I will; obviously, the Department will pass that on in as clear a form as possible.

The trouble here is that there has been enormous confusion not just in that particular panel, but in a number of different statements that have been made. What I don't want to do is to reverse myself without the proper advice of the cancer specialists at the National Cancer Institute when they give me that information, and they said that they would give it to me within a reasonable time-

frame, within the next 2 months. Then we will communicate that as clearly as possible.

Senator SPECTER. Have you reviewed Dr. Klausner's testimony before this subcommittee?

Secretary SHALALA. I have and I know what Dr. Klausner said, and I know what he said afterward, after the initial NIH panel reported. What I am making very clear is that I intend to respect the process he has set up before we make additional public statements.

Senator SPECTER. Well, my question to you was whether you read Dr. Klausner's testimony before this committee. You said you did and then you said you knew some other things. Then you said you were going to wait for the scientific community.

His testimony before this committee was emphatic that there was not a clear scientific basis for the NIH panel's finding that mammograms were not warranted for women 40 to 49. Now that is what stands without a clear scientific basis. There may be some dispute as to whether there is a clear scientific basis for the contrary conclusion, that mammograms are warranted for women 40 to 49. I would ask you to review that.

I do not think there is a sufficient sense of urgency, Madam Secretary, with all due respect, in the approach you are taking and the approach Dr. Klausner is taking. He makes a public statement after the NIH panel's finding that he is shocked, and then he waters that down when he comes in here. He says there will be a determination by the end of February and now we are waiting for 2 more months.

Well, I have made my point. I wouldn't like to see the Congress act on these matters. But I don't think there is sufficient sense of urgency in your department on this.

Secretary SHALALA. I think that everything we have done for the last 4 years on breast cancer in relationship to women, on improving the quality of mammogram standards, on the national breast cancer action plan is an indication that we not only consider this a priority but the clarification and clear communication with women is at the top of our priority list.

The National Cancer Advisory Board is, in fact, the critical board on cancer issues. Dr. Klausner has indicated that they are reviewing the issue, and I don't think that any woman who has breast cancer—and all of us are worried about breast cancer—thinks that we should take more than 24 hours on an issue like this. But we want to make sure that that board, which is the supervising board for the National Cancer Institute, has given us a clear description of what they believe the position should be.

I cannot in any way disagree with your conclusion that we should not take more than 2 minutes on this. But I will respect the process and we will report back as quickly as we possibly can.

Senator SPECTER. Now, Madam Secretary, I am not talking about 2 minutes and I am not criticizing what you have done on breast cancer otherwise. I am commending you for it. But when it is a matter of dollars and cents and there is no clear scientific evidence, I think the word ought to come from the Secretary of Health and Human Services that, notwithstanding the cost, we are going to see to it that mammograms are made available for women 40 to 49.

We will proceed in order of arrival.

Senator Murray.

OPENING REMARKS OF SENATOR MURRAY

Senator MURRAY. Thank you, Mr. Chairman. I am delighted to be back on this committee after a 2-year-absence. The issues of this committee are very important to us and my constituents and many of the programs that we deal with are very high on my priority. So I am glad to be back and am anxious to begin work on the fiscal year 1998 appropriations bill.

Madam Secretary, I want to welcome you here today as well. I want to take this opportunity to commend you for your efforts over the years on behalf of our most vulnerable citizens, the children, the disabled, senior citizens. We all very much appreciate it. Your expertise and knowledge has really helped a lot of us go through these issues over the last 4 years.

I am especially delighted that you and I share many of the same priorities. I look forward to working with you as we try to enact some of the President's initiatives in this Congress.

I would like to focus my comments and questions on the issue of children's health.

UNINSURED CHILDREN

As you know, the Democratic leadership has really placed high on our agenda the enactment of a universal health insurance bill for children. I know that you have long been a champion for improving access to quality health services for our children and have helped in the last 4 years to improve access to immunizations, prenatal care, and well baby care. I really want to encourage you to continue in that direction. I think it is absolutely vital.

As I have gone around my home State, I have seen a lot of new, innovative programs that deal with those uninsured children, children whose parents are at work but whose income places them above Medicaid eligibility. But they still do not get access to health insurance.

I have heard of things like clinics that are supported by hospitals in an effort to reduce the cost of treating uninsured children. King County has a 1-800 number now for parents to call to ask for information about treating their child, instead of going to an emergency room. And I have seen some great school-based health clinics.

NEW INNOVATIVE PROGRAMS

I want to ask you this morning what kind of innovative programs you have seen out there to serve our children so that their only exposure to health care is not through the emergency room.

Secretary SHALALA. Well, there are a lot of programs, including the one in your own State, the basic health plan plus.

The way we are doing it now in this country is that each State is designing their own program to try to increase the amount of coverage for children. Some States are obviously trying to make certain that more children are covered by Medicaid, which is often the easiest way. Other States are trying to subsidize working parents to help them pay the premiums. Other States are expanding their community health centers so that more children know that



there is a community health center to come to, and by the expansion of school health programs, sometimes contracting with an HMO or other form of organized care.

So it is all of the above. And, in fact, the President's own initiative takes advantage of that as opposed to a single expansion of a program or developing a new entitlement. It takes advantage of the different strategies that are going on in States.

Washington, for instance, has 141,000 children who are not insured. Getting at that group, we suggest involves giving the State money directly so that they can improve on the programs they are already doing, as well as finding children that are eligible for Medicaid. It also, keeps some children in health insurance if they are enrolled on Medicaid and their parents get a job, and keeps them there for 1 year so that the State could find another way of getting them insured.

Many people have been concerned about what happens if employers start dropping health insurance for kids, if the State starts to cover kids. That is easy to take care of because you can simply have a rule that if the employer provides health insurance for the children of any employee, they have to provide it for their low income employees. That takes care of that issue.

Senator MURRAY. I appreciate that. I really want to work with you on that because one of the obstacles, I think, to welfare reform succeeding is young mothers in particular who go back to work, do not have health care, and drop out of the workplace because of that problem. So we need really to focus on this and to work all of us together to address that issue.

#### DISPROPORTIONATE SHARE FUNDS

I have one other quick question on my time. Many of our hospitals are currently using their disproportionate share moneys to fund services for the uninsured, especially our children. I am really concerned that efforts to reduce the disproportionate share moneys and retarget them could jeopardize especially children.

Can you talk about how the administration is going to deal with that?

Secretary SHALALA. I think our approach to disproportionate share, particularly in the Medicaid Program—and we do get some savings through that program—is an approach that is balanced. What we try to do is to retarget and to make sure that the money is actually going to hospitals that do serve people who don't have insurance; and, really, that the money is used for the purpose for which it was originally designed.

States have different levels of disproportionate share money, depending on how they participated in the program. But our effort is to keep that money in hospitals that, in particular, have a heavy burden.

So I think you would find that consistent with the points that you are making.

Senator MURRAY. Thank you.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Murray.

Senator Hutchison.

## REMARKS OF SENATOR HUTCHISON

Senator HUTCHISON. Thank you, Mr. Chairman.

I think that the chairman certainly covered the mammogram issue well. But I do want to say that I think the NCI jumped awfully quickly in 1993 on the basis of one study from Canada to take away the guidelines for women between age 40 to 49, and that since that time the preponderance of the studies have shown otherwise, that there are actual, quantifiable savings of lives when women have gotten mammograms between the ages of 40 to 49.

So I really hope and I will ask you if you will do everything within your power, understanding, of course, that you are looking to the experts, but, nevertheless, the buck stops with you. You really do have the power to issue the initiatives that will make sure that insurance does cover women between the ages of 40 to 49 in government programs.

## NCI GUIDELINES FOR MAMMOGRAMS

I just will ask you if you plan to take a leadership position to encourage NCAB and NCI to give us clear guidelines.

Secretary SHALALA. The answer is absolutely yes.

Senator Hutchison, I feel the way Senator Specter does and everyone else. I am profoundly irritated by the fact that we have not sent clear messages, that we appoint panels, and even if we agree with their conclusion, the balance and the tone of the discussion is often not very helpful.

While I fully want to back up the scientific leaders, they have to understand that these are real people with real lives that need to make informed decisions but that need some guidance from scientific leaders.

I will do everything I can both to make sure that we get this report as quickly as we possibly can, but, once having gotten it, it has to be as clear as it possibly can be.

Now science cannot always be as precise as we want it to be. But on this issue in particular, we have not distinguished ourselves. I will do everything I can to make sure of that, as will Dr. Klausner, who gets it.

Senator HUTCHISON. I must say that I agree with you.

Secretary SHALALA. I must say that he is really trying both to reflect the advice he is given, but understands that there are real lives involved here and that the women of this country and their families deserve straight answers.

Senator HUTCHISON. Madam Secretary, I do believe that there is great hope in Dr. Klausner. I do think he gets it. Besides the hearing that we have had, I have talked to him twice now about this issue. I think he gets it. I hope so. He must because I think that many of us—and I think you are in the same category—have been so frustrated that it has taken so long. And, frankly, I think that, particularly with our volunteer groups, really giving an initiative to educating women and making them more aware of the need for early detection, I think we were on a roll. Then, all of a sudden, in 1993 there is a muddled message and it is hard to keep the roll when all of a sudden now the scientists say well, it really is not

proven, it is actually that out of 10,000 lives, it may be only 34 percent of them.

Now give me a break—only 34 percent of 10,000 women might be saved with early detection.

So I am frustrated. I hope that you will do everything you can.

#### CDC SCREENING PROGRAM

Let me just ask you this question. One of the outflows of this kind of muddled message is the Centers for Disease Control which funds a full service early screening program to reach minority populations across our country. Currently, it targets women over the age of 50.

Now if we can get a clear message from the NCI, will you immediately take steps to lower that to targeting women over the age of 40?

Secretary SHALALA. Let me say that when we do get a recommendation, what we normally do is review all of our programs, and we certainly will review that.

The point of that particular CDC program is that we have a much smaller percentage of minority women, as you well know, who are getting mammograms, that we wanted to have a targeted program to try to increase the number of minority women who receive mammograms. That was the purpose of that. Whatever the standard is, we would want to extend our work to a different age group.

So let's hope that we get a clear answer. Now scientists in general give us clear answers. We expect confused answers from the economists, not the scientists. I think that is why we are all sort of thrown off on this issue. Normally, the scientists walk in here and they are pretty straight forward in terms of what they are recommending.

#### BENEFITS AND RISKS

Senator HUTCHISON. Well, excuse me, Madam Secretary, but it seems that in most other diseases they are straight forward and they will say here are the benefits of this treatment and, yes, here are the risks. We get that in every other disease treatment that I can remember. I mean, my gosh, every time you open up a medicine bottle it has the risks listed and what it is recommended.

Secretary SHALALA. Some more clearly than others.

Senator HUTCHISON. I think look, we are adult, intelligent people. We can take the benefits and also the risks, and that is a clear message because the risks are minuscule compared to the benefits. And I think that can be said clearly.

When you talk about the Centers for Disease Control funding, which I think is absolutely warranted—I was at Howard University a couple of weeks ago and I think the minority women should be our focus because they are the ones who end up not having early detection and, therefore, the disease is more fatal. I would just say that we really need to go to that 40 and above age group where early detection is so important because we know that the disease is generally more virulent in younger women.

Secretary SHALALA. I think Dr. Klausner agreed with you in his testimony because what he said about the NIH report was that it

overly minimized the benefits and overly emphasized the risks for the 40 to 50 population. He thought it should have been a better balance.

We will do our best.

Senator HUTCHISON. I just do not see why this disease is treated so differently when we have benefits and risks given and we can make judgments, as in every other disease I have seen. Why not this one? Why take a segment of the population that is a large segment that can be saved with relatively little expense and not do it? Why not do it?

Secretary SHALALA. I think that Dr. Klausner realizes that.

My point is and my reluctance to overrule people and pronounce on the science is that we have done a good job in a bipartisan manner over the years in building these first-class scientific enterprises. We have always, when we wanted to make a pronouncement of science, put the scientists in front of us to talk about it and to give people advice.

The American people trust these scientists when they speak on these subjects. I see no reason for us to change that process. But I think Dr. Klausner gets it. He communicates clearly himself, and he is going to be working with his advisory board, which is the premier advisory board on cancer, to make sure we get very clear messages out.

Senator HUTCHISON. Thank you, and thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Hutchison.

Senator Faircloth.

#### REMARKS OF SENATOR FAIRCLOTH

Senator FAIRCLOTH. Thank you, Mr. Chairman.

Madam Secretary, thank you for being here this morning. It is nice to see you.

Secretary SHALALA. Thank you.

#### MEDICARE SAVINGS

Senator FAIRCLOTH. I am particularly pleased to see that the President's budget numbers on Medicare savings come close to what was proposed in the Congress last year. But what bothers me is how the administration achieves the savings. That does concern me.

The budget extends the life of the Medicare trust fund for an arbitrary period of time through accounting maneuvers. I don't think it looks at the realistic long-term solution, and particularly the shift in home health costs from part A to part B looks like there has been fiddling with the books to prolong the life of a system that well could be near collapse and that is in desperate need of reform.

Over the next 60 years, the ratio of workers paying into the system to beneficiaries taking money out will be cut in half. I think it is important to be honest with the American people about the condition of the Medicare Program and the realistic options that we are going to have to face to fix it.

Secretary SHALALA. Senator—

Senator FAIRCLOTH. Wait a minute. I have a further statement that I want to finish.

Secretary SHALALA. Sorry.

## WELFARE SPENDING ON NONCITIZENS

Senator FAIRCLOTH. Further, I am troubled by the administration's proposal to increase welfare spending by \$21 billion especially to pay for welfare benefits to people who are not citizens of this country.

I was surprised and disappointed at the suggestion that we will start erasing about one-third of the savings we achieved from the welfare law passed last year. Almost one-third of our savings will be lost by so-called opening up the bill to increase benefits to non-citizens. It sends a wrong message. It clearly sends a wrong message to immigrants and potential immigrants, that in this land of opportunity, a nice package of taxpayer funded, taxpayer financed, government benefits awaits you upon arrival. I think that is sending the wrong message.

Madame Secretary, I look forward to working with you on solutions to the problems, and I am confident that we will find common ground.

## LOSSES FROM FRAUD AND ABUSE

Now here is my question. Madam Secretary, the General Accounting Office estimates the losses in the Medicare system from fraud and abuse, estimates that these two items cost taxpayers from \$6 billion to up to \$20 billion in fiscal year 1996.

Can you give me an update on the Department's efforts to stop the flow of money to those who cheat the system? By anyone's account, those billions of dollars could and should be used elsewhere.

I would like an answer.

Secretary SHALALA. Thank you very much, Senator. Let me give you three quick answers.

We have launched, as a demonstration, Operation Restore Trust, which is the largest effort in the history of the Medicare Program. It was launched 3 years ago to combat fraud and abuse in the system. It is a combination of the inspector general, the U.S. attorneys, as well as State officials—State attorneys general, for example, and State district attorneys—to investigate and prosecute fraud.

We have had the largest settlements in the history of the Medicare Program.

Second, we have launched an effort to change systemic problems in the Medicare Program. Some of them we have done administratively, some of them are in the bill as part of our Medicare reforms, which are critical. While they are not necessarily scored, they will, in the long run, according to our inspector general, produce real savings for the program.

The Congress last year in the Kennedy-Kassebaum bill extended Operation Restore Trust to a national program and finances it out of the Medicare trust fund. So we will have, for the first time, a beefed up effort to deal with fraud in the program.

I believe over the next couple of years that the trustees will be able to report—and I am a trustee—because of the actuaries that, for the first time in history, our fraud, our antifraud efforts, are starting actually to reduce costs in the trust fund. So I think we have done a first rate job getting our act together and actually get-

ting at both systemic fraud as well as through our investigations and through our teamwork in this area.

Let me comment quickly on the other two issues that you raised.

#### IMMIGRANTS

On welfare, we have no intention of reopening the welfare bill. The President believes that the welfare to work bill ought to be continued. We have asked for restoration of some funds for part of a population that was pulled in—not for new immigrants but for immigrants that were here, disabled immigrants that were here before August of last year, immigrants who often are sitting in nursing homes, some of whom were disabled after they arrived in the United States. They may have worked for 3 years and then been in a terrible accident, or they are elderly and frail and sitting in a nursing home. So we do not shift those costs on to the States.

We have also asked for coverage for children at the same time who are disabled, and in our judgment those costs should not be shifted on to the States.

But for new immigrants coming in, we have all agreed on the rules. For people who are able-bodied, we have all agreed on this new welfare program. We are talking about people who cannot work, who have no other means of support, often who are sitting in nursing homes, totally disabled. And we're talking about not shifting those costs on to the State.

Senator FAIRCLOTH. Did these immigrants not have sponsors when they came in?

Secretary SHALALA. Many of them did not. But the sponsorship was not legally binding as it is now. That has been tested in the court.

Only 40 percent of immigrants who came to this country before we rewrote the laws had sponsors. Some of them are refugees. So it is not a question of some legal entity that we can enforce. We can now because the law has been changed.

So we are talking about a narrow group of people who cannot work. This is not reopening the welfare bill.

Senator FAIRCLOTH. My time is up. Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Faircloth.

We are pleased to have the chairman of the full committee here today, Senator Stevens.

Senator STEVENS. Thank you very much. I don't have any questions, Mr. Chairman. I am pleased to see Secretary Shalala here and wanted to come in and listen to the testimony.

Secretary SHALALA. Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Mr. Chairman.

Senator Kohl.

Senator KOHL. Thank you very much, Mr. Chairman.

Secretary Shalala, it is always good to see you. Welcome to our panel.

Secretary SHALALA. Thank you, Senator.

#### REMARKS OF SENATOR KOHL

Senator KOHL. As you know, I have introduced legislation to expand and strengthen our Nation's child care system by creating a

\$150,000 a year tax credit for businesses. This credit would be used by any business or group of businesses to set up an onsite or a nearsite day-care center to cover operating costs of the facilities, to contract for child care resource and referral services, and community child care centers and for the training of child care workers.

We all understand the critical shortage of quality child care. I believe that this bill makes sense for families struggling to find care and it makes good business sense because workers will be able to concentrate on their jobs and not on the questions of child care for their children.

I would like to ask you if you have had the chance to review or think about this legislation and whether you think it makes sense; also whether you think the administration would be willing to throw its support behind this piece of legislation.

#### TAX CREDIT FOR CHILD DAY CARE

Secretary SHALALA. Senator, as you know, the President does have a tax credit, a bill with a number of different recommendations, and we believe this ought to be discussed as part of that. Obviously we share your view that quality child care in particular and getting businesses, encouraging businesses to get more deeply involved in providing child care is very important. It is going to be increasingly important as we move hundreds of thousands of people from welfare to work.

For some people, onsite child care is perfect. For other people, they will have to get it provided in other ways. We think this ought to be part of both that tax discussion as we get further along in the discussion.

But, obviously, we support efforts to encourage businesses to get more deeply involved in child care. Whether this particular tax credit, in light of some of the other things—you know, we obviously have a balanced budget bill. We certainly are prepared to discuss it, though, as part of that discussion.

Senator KOHL. Thank you.

#### TRAINING FOR CHILD CARE WORKERS

Madam Secretary, this subcommittee previously set aside a very small amount—it was only \$1 million—for scholarships to childcare workers who wish to be certified as child development associates. This CDA was not funded last year.

If the Federal Government is willing to spend over \$400 million a year training health care professionals, even when it is known that there is a glut of doctors, and if your department is able to send New York hospitals \$400 million not to train medical residents, then surely we can invest just a few million to help train childcare teachers when there is a severe shortage.

Do you agree that CDA scholarships are worthwhile investments and worthy of your support? Do you think that it makes sense for this subcommittee to, once again, set aside funding for these CDA scholarships, as modest as that funding is, \$1 million?

Now it does account for 4,000, 5,000, or 6,000 training slots.

Secretary SHALALA. Exactly. States are now using their block grants in part to send people to school. I was recently in South Carolina, for example, where the State is, in fact, supporting

former welfare recipients to get community college degrees, to get certified as childcare workers.

Senator, I don't think that any of us would object to a \$1 million program in the context. What we have tried to do with welfare reform, though, is to give the States the block grant and then encourage them to do the right thing, as opposed to increasing the number of specifically categorical programs. No one is going to object and I don't think the White House is going to yell at me if I don't object to a \$1 million program.

But I do want to make the point that this is exactly the direction in which we want to encourage the States to go, using their block grants, as childcare will be a new area of employment and a real opportunity, I think, for people who are coming off of welfare, as well as a Head Start expansion area for employment. Certification is important and, as I indicated, South Carolina is already doing this. I think a number of other States are, too.

#### CHILD SUPPORT

Senator KOHL. I have one more question.

Madam Secretary, the administration has made good progress on child support enforcement, collecting a record \$1 billion in 1996. But there are serious problems that still plague the system.

For example, an estimated \$60 million has been spent to develop an automated child support system in Wisconsin, to simplify and improve collections and disbursements. And yet, all the parties, including clerks, enforcement agencies, and parents, still report glaring problems with checks arriving weeks late.

When they do arrive, the checks are often too little or too much.

I imagine you would agree that this is a poor return on a very large investment. With an October deadline approaching for States' automated systems to be fully functional, I would like to ask what you are doing to assist Wisconsin and other States to overcome these glaring problems, with which I am sure you are familiar.

Secretary SHALALA. Right, I am very familiar with it.

As you well know, we just approved a waiver, which I notified you about and which you and I had talked about earlier before we approved it. Wisconsin, in essence, is providing for those who are on welfare the back child support so that they are going to be up to date on child support for those families that are currently on welfare, which is really a remarkable step.

But we are giving extensive technical assistance to the States to get their computer systems up and going. As you know, that deadline was extended for the States because they could not meet the earlier deadline.

I am crossing my fingers and the States need to pay more attention. We have been communicating clearly with the States. There may be some States where I need to pick up the phone and talk to the Governors and say you need to get on this.

It is in their financial interest to do that. But, more importantly, if we are asking people to go to work, the minimum we ought to do is be collecting that child support and doing it accurately.

We are both working carefully with the States and providing technical assistance. I am happy to continue to report back to the Congress specifically on that issue.



Senator KOHL. I thank you and I want to express my appreciation to you for the way in which you went out of your way last week to help Wisconsin set up a particular pilot program that you pioneered. It is going to be very helpful in Wisconsin.

I do not want to spend money or time here today talking about it in detail because it would take too much time to explain it, but I do appreciate your efforts in our behalf.

Secretary SHALALA. Thank you very much, Senator. As you know, I am no longer recused from Wisconsin.

I gave up my tenured appointment, Senator Harkin, to stay with all of you, for that opportunity.

Senator HARKIN. Good. I am pleased to hear that.

Secretary SHALALA. So I can now spend time on the Wisconsin issue.

Senator KOHL. Thank you, Madam Secretary and Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Kohl.

Senator Harkin, our distinguished ranking member, the floor is yours.

#### REMARKS OF SENATOR HARKIN

Senator HARKIN. Thank you, Mr. Chairman.

I apologize for being late. I had another hearing I had to attend to before I came over here, Madam Secretary. Again, I welcome you here today. Thank you for the great job you are doing. I want to state that publicly and for the record. It is an outstanding job.

I am delighted to hear that you have given up your tenure and you are staying here with us.

Have you now broken the record? Are you the longest serving Secretary of Health and Human Services we have ever had?

Secretary SHALALA. Yes.

Senator HARKIN. I appreciate that. I want to thank you for your work and your cooperation with this committee in every aspect.

#### NIH BUDGET

Madam Secretary, there are just a few items that I am really concerned about.

The President's budget provided for a 2.6-percent increase for NIH. This means that right now, 1.9 percent of our GNP will be spent on nondefense research, compared to 5.7 percent of GNP in 1965.

I think we are going in the wrong direction on NIH research funding.

As you know, I have worked in the past with Senator Hatfield and others, and now with Senator Specter, to try to find some dedicated funding sources for NIH. I know you have taken a lead on it, and whatever we can do to start getting the public aware of this we just have to do. We cannot continue to go in this direction.

#### HEAD START

I want just to mention Head Start again. Just prior to this hearing, I was at a hearing on school breakfast and school lunch programs. Of course, the Head Start Program is a program that precedes that and gets these kids ready for school. I think we just

need, again, to think about how we are going to focus more effort and energy on preschool education through programs like Head Start.

#### WASTE, FRAUD, AND ABUSE

But most importantly, I want to thank you and commend you for the recent successes that you and Inspector General Brown just had. Last week, it was announced that Medicare would recover \$325 million from a major supplier of clinical lab services that was found to be double billing and billing for tests that were never performed.

Thank you and keep up the great work. That is good. Go after them. Get that money back.

Again, I think eliminating the waste, fraud, and abuse is so important and what you have done there I think is just great.

#### OXYGEN

Let me ask a question about, again, waste, fraud, and abuse. I want to mention oxygen. This subcommittee held hearings in November 1994 in which it was revealed that taxpayers and beneficiaries are losing hundreds of millions of dollars a year in overpayments just for oxygen. We found that the Veterans Administration, which uses competitive bidding, was paying less than half of Medicare's payment for oxygen. At that hearing, Mr. Vladeck promised to initiate a process to try to reduce this excessive rate.

There is general agreement that there is waste here. The Republican budget plan agreed with my call for a 40-percent reduction. That is one of the parts of the Republican budget plan with which I agree. So you can see this crosses lines. This is not a partisan issue. Everyone agrees that there is a tremendous amount of waste there.

It is my understanding that the President's budget does not contain a recommended cut for oxygen because the Department is planning on moving forward with a reduction administratively using your inherent reasonableness authority.

But we wait and we wait, and every day we wait we lose another \$1 million. Can you tell us what is going to happen here?

Secretary SHALALA. It is going to happen shortly. We plan to publish our proposed notice before the next time you talk to me I hope it will be out. But it will certainly be out shortly. It is currently being reviewed and we do have our recommendation ready.

Senator HARKIN. When is the next time I am going to talk to you? [Laughter.]

We just have to move on this.

Secretary SHALALA. I agree, Senator. It will be done.

Senator HARKIN. On the positive side, let me just say that the President's budget does include a proposal for competitive bidding for all part B items. I know you had a hand in that and I compliment you for that. I look forward to working with you on it.

#### OFFICE OF ALTERNATIVE MEDICINE

Last, while I believe very strongly that we have to increase our funding for NIH, let me just say that I am greatly disappointed in

the leadership at NIH in one specific area. In 1991, we started the Office of Alternative Medicine at NIH. It has had quite a rocky existence since that time. The goal was to foster the evaluation of alternative or unconventional medical treatments, facilitate the collection and dissemination of information regarding alternative therapies. It is part of the Office of the Director.

The OAM is one of six special coordinating offices within the Office of the Director—the Office of Research in Women's Health, Rare Disease Research, Office of Dietary Supplements, et cetera.

Now I have tried to work with the leadership at NIH on this in a reasonable, straight forward manner, knowing that sometimes things take a little time. But after 6 years I can tell you, Madam Secretary, that there has been no leadership at NIH in this area.

As I look at NIH's budget this year, Mr. Chairman, the biggest cut in the Office of the Director, at his request, is in the Office of Alternative Medicine. It is the biggest single cut, from \$11.9 million down to \$7.5 million, which is where it was a couple of years ago. Everything else is either level funded or slightly increased.

#### NIH DIRECTOR'S DISCRETIONARY FUND

But I will note one other thing for the record. In the Director's discretionary fund, he is requesting an increase from \$8.4 million to \$10 million.

Senator SPECTER. Senator Harkin, may I interrupt you for just a moment?

I have to excuse myself for a moment. So when you finish your round, we will then go to Senator Bumpers. I will be back within that time.

Senator HARKIN. OK, thank you, Mr. Chairman.

Senator SPECTER. Thank you very much.

Senator HARKIN. For the Director's discretionary fund, you are asking for an increase from \$8.4 million to \$10 million. What is this all about? Why are they cutting that, when they want to increase the Office of the Director?

I am going to ask, Madam Secretary, that the Director give me some information. I know he is going to be up here and I see some of his people here in the audience. I want a full accounting of what that discretionary fund was used for last year, the year before, and the year before—every single, solitary penny of it, of that discretionary fund.

Secretary SHALALA. Dr. Varmus will be up here in a couple of days to go into this in detail. But let me say that we have proposed to continue funding at the 1996 levels.

What we did with the additional money in 1997 was we initiated several clinical studies. The out-years for those clinical studies, which are not reflected in the Office of Alternative Medicine, will be paid for by the various institutes themselves where those studies are located.

So I think it is somewhat misleading to look directly at the Office of Alternative Medicine budget when the out-years are being picked up in those other institutes. I will leave it to Dr. Varmus to go into that in some detail.

I think he is willing to take criticism at any time. But I think in this case they have actually done the right thing. The Office of

Alternative Medicine initiates the studies, and then the various Institutes actually provide the funding.

I think that you will see reflected in the followups to those actually a serious commitment to alternative medicine, which I know that both Dr. Varmus has and certainly the leadership of the Department has.

Senator HARKIN. Well, I will get into that more with Dr. Varmus when he comes up. But I just wanted you to know, Madam Secretary, since you are his boss. Also I want you to know that I have followed this since I started it in 1991. My patience is gone and I am going to ask what clinical trials they have really been engaged in. I am going to ask, also, what the Office of Alternative Medicine has done directly.

A meeting was held in my office a couple of years ago and certain statements were made about the Department, about the Office of Alternative Medicine actually doing grants out of there to entities outside of NIH. I don't know of one that has happened yet—not one.

The foot dragging in this area has just been abysmal—abysmal. I will have more to say about that with Dr. Varmus. But I just thought, since his people were here, that I would give him a heads up.

But I do want to know for the record where every single penny of the Director's discretionary money went last year and for the last few years, and what that money is being used for, Madam Secretary.

Again, just for the sake of emphasis, we have a real problem with the Office of Alternative Medicine—a real problem. I intend to go into it at length with Dr. Varmus when he is here. If it takes all day I will go into it with him at length—not with you, Madam Secretary.

Senator Bumpers.

#### REMARKS OF SENATOR BUMPERS

Senator BUMPERS. Senator Harkin, are there any other Senators who have not had a chance to ask questions?

Senator HARKIN. I don't know. I don't think so.

Senator HUTCHISON [presiding]. I believe you are the next one.

Senator BUMPERS. I'm the only one left then. Thank you.

I just want to ask a couple of questions that I am quite sure have already been covered. But for my own edification, I will ask them, though I may be repeating here.

#### MEDICAID SAVINGS

I think about this Medicaid cut, which has been very troubling to me.

We are cutting Medicaid. We are capping Medicaid in some way that I do not understand. But it is supposed to save \$22 billion. But if you add the proposed health initiatives, children's health initiatives back in, then the saving is only \$9 billion. Is that fair to say?

Secretary SHALALA. I think the children's health initiative is—let me get the number—yes, \$9 billion, that's correct. The children's health initiative is \$13 billion. No; it's not. Excuse me.

Let me have the right sheet, please. [Pause.]

Oh, he has it right.

#### PER CAPITA CAP ON MEDICAID

Senator, if you would like, I would explain what the per capita cap does.

Senator BUMPERS. Please.

Secretary SHALALA. First of all, in the Medicaid Program, what you don't want to do is to in any way cut off the program from eligible people. The cap was put on as part of the balanced budget exercise because we need to make sure that we are not increasing programs beyond what their actual costs are.

In this case, we put a per capita cap on, which means that in the State of Arkansas, for instance, we will have a cost number for disabled children, for children that aren't disabled, for the elderly, and for adult disabled.

For each of those, Medicaid spends a differing amount of money, children that are not disabled being the cheapest. So there will be a growth rate for Arkansas and for every other State, but by category and by individual.

The point is to try to introduce some discipline and slow down the growth of the program but not to slow down the growth by cutting out individuals. If more people are eligible for Medicaid, they will be allowed to come into the Medicaid Program because they are eligible. What we are going to do is slow down the actual growth in spending. But we are going to do it in a pretty sensitive way because we recognize that if more disabled people come in, the State is going to be spending more money.

Now you can argue with whether these programs should be capped or should not be capped. This is a pretty sensitive cap because it has a growth rate, a cost-of-living plus some medical cost number on top of it. It does introduce some fiscal discipline into the program.

Two-thirds of the saving in Medicaid, though, are taken from the disproportionate share program. For a State like Arkansas, which gets very little DSH money, it would not be significantly effected. For some other States that get a lot of DSH money, they would be affected by the DSH reduction.

That, again, is our attempt to refocus the disproportionate share hospital payments, by protecting the neediest safety net providers. But, again, we are indeed trying to get some savings out of the program.

#### CHILDREN'S HEALTH INITIATIVE

Now the children's health initiative, I would argue, is on top of this. We did not cut the Medicaid Program and then, on the other hand, try to reinvest some of the resources. There is not a direct relationship. We tried to get some discipline in the Medicaid Program and then tried to figure out a way in which we could stop children from losing their health insurance and expand health insurance in this country, particularly for children.

So that is a separate effort.

In the area in which you have provided outstanding leadership, immunization, getting all of the kids in this country covered will help us on that overall issue. As you well know, that is the fundamental thing that a health insurance program must do.

Senator BUMPERS. Of course I understand precisely what you are saying. But everything you read, if you can believe it, is that the President has been so dismayed about the welfare reform proposal that the children's health initiative is a simple effort to rectify some of the wrongs, some of the damage that the welfare reform bill is doing. That is going to lead me to my next question.

Would we not just be better off to leave Medicaid alone than we would by cutting it and putting the \$13 billion back in?

#### NON-MEDICAID CHILDREN

Secretary SHALALA. Senator, one of the things that you all did last year was to separate Medicaid from welfare reform, and eligible children can continue because we did not block grant Medicaid.

Children that are eligible for Medicaid are eligible for Medicaid independent of their parents' work status if they are in that category.

The children's health expansion is for non-Medicaid children for the most part; 7 million of the 10 million that we are going after are non-Medicaid children.

What we are trying to get at is working class kids.

Senator BUMPERS. Would you say that again, Madam Secretary.

Secretary SHALALA. On the children's health initiative, of the 10 million kids that do not have health insurance, 7 million of them do not now have Medicaid; 3 million are eligible for Medicaid and are not getting Medicaid. We need to go out and find them.

Senator BUMPERS. So it is that 7 million that you are going after?

Secretary SHALALA. Our working-class kids. These are kids whose parents have jobs.

Senator BUMPERS. They simply have no health insurance?

Secretary SHALALA. They just don't have health insurance. They just make too little money, or they are in a job where they cannot afford the health insurance. I have some people that provide services to me. Their employers actually provide health insurance, but they cannot afford the premiums because their incomes are under \$20,000 a year. They are not eligible for Medicaid and they cannot afford health insurance.

This is for working class families, for low income workers. Sometimes they have two part-time jobs and they cannot get health insurance for their kids.

Senator BUMPERS. I have one additional question, if I may, Mr. Chairman.

Senator SPECTER [presiding]. I think it would be shorter just to let you go ahead. [Laughter.]

#### MEDICAID CAP

Senator BUMPERS. Thank you.

You have made a very good argument against what I perceived were the facts in this matter. But for a State like mine, which has

been raising the eligibility limits as best they could—they have been doing a magnificent job in Arkansas raising the eligibility limits—putting a cap on Medicaid is going to have a chilling effect on States doing that, isn't it?

Secretary SHALALA. I don't think so because it is a per capita cap; because they would not be penalized if they added someone to the Medicaid rolls; because they still will get the same amount of money per person.

Senator BUMPERS. I know, but that is my very point. They are going to be very reluctant to take on anything that increases the Medicaid roll because the money is not going to increase, and the only way they can make up the difference is to cut services for those who are already on it.

This is not Medicare. You cannot cut Medicare \$100 billion and not cut services.

Secretary SHALALA. Yes; but, again, we are cutting the growth rate. We think we have put in a growth rate that is good enough to continue to encourage the States to add people to their Medicaid rolls. They are going to continue to get the Federal match for the amount of money they match.

What we are doing is putting a cap on the growth rate in Medicaid, and we have put it softly on a per capita basis so that if a person is added in Arkansas, they will continue to get a Federal match for that and they will continue to have to put in their own money. But the growth rate is slowed down.

Senator BUMPERS. Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Bumpers.  
Senator Gregg.

#### REMARKS OF SENATOR GREGG

Senator GREGG. Thank you, Mr. Chairman.

Senator SPECTER. Senator Gregg, your timing is impeccable. I thought Senator Bumpers' was, but you only had to wait 20 seconds, whereas he had to wait 1 full minute.

#### DSH PAYMENT

Senator GREGG. I have been trained by Senator Bumpers in this. [Laughter.]

I was wondering if you could talk a little bit about the DSH payment process. A significant amount of your savings is projected in that area.

Have you formalized what your plans are in that area?

Secretary SHALALA. Basically, the gross savings from DSH is about \$7.7 billion. What we would like to do is to reduce some of the DSH money.

In high DSH States, we bring the reduction down a little more slowly than we do in low DSH States—and I think yours is one of them—have integrated that money into their whole health care system. We are squeezing down on the DSH payment.

We are doing some retargeting, asking the States to do so, giving them some flexibility to target toward safety net providers and making sure that we are targeting pretty sensitively to those areas that are really providing safety net services.

Senator GREGG. You have not decided on a formula then, have you?

Secretary SHALALA. I don't think we have. I think we can give you the outlines of what we would like to do.

Senator GREGG. Is it only \$7 billion? There is \$22 billion in savings, is my recollection, in Medicaid, and I thought a high percentage was coming from DSH.

Secretary SHALALA. That is the gross.

Senator GREGG. I thought a high percentage of that \$22 billion was coming from there.

Secretary SHALALA. It's about \$15 billion in total, because it is two-thirds the \$22 billion.

Senator GREGG. So it is \$15 billion that you expect to get from the DSH payments?

Secretary SHALALA. Right.

Senator GREGG. Your rate of growth on the per capita payment is what?

Secretary SHALALA. GDP plus two in 1998, plus one in 1999, into the year 2000.

#### STATE FLEXIBILITY UNDER THE CAP

Senator GREGG. What sort of flexibility will you be giving the States to function under the cap?

Secretary SHALALA. They will have full flexibility to move people into managed care. They will no longer have to come to us for waivers, which is the most important flexibility they have been asking for, to make managed care mandatory. In addition to that, they will have the authority to redistribute some of the DSH money to safety net providers. Then we waive the Boren amendment.

It is actually the usual suspects that the States have been asking for. We have now put it forward as part of this plan.

Senator GREGG. For which I congratulate you.

Secretary SHALALA. Thank you.

Senator GREGG. I also do not personally have a problem with your cap concept if there is enough flexibility given to the States. I think that the issue is the flexibility to the States.

Are you giving any flexibility on the individual coverage area relative to age and issues such as that?

Secretary SHALALA. The States now have tremendous flexibility. We simply ask them to guarantee the benefit package. Most of their growth has been in optional benefits, not in adding people to the basic benefit package.

So they have tremendous flexibility in adding benefits or subtracting benefits, and that will continue to be part of this. As I indicated, most of their growth really has been in these optional benefits that they have added on.

Senator GREGG. You then do not expect to give flexibility in the area of age, such as the fact that now people have to be covered, I think it is down to 3 and up to 21, or something?

Secretary SHALALA. No; you know, the last thing you would want to do is to reduce the number of people who have health insurance in this country. That is why the children's health initiative is so important.



We have 10 million kids basically left. What you don't want to do is to take away with one hand and then add with another hand. So what Congress passed is I think, we are up to 13, or something, that States are covering everybody under 13.

Senator GREGG. In what other areas will you not be giving the States flexibility?

Secretary SHALALA. Well, the basic benefit package. The basic benefit package is the one area that the States will have to continue, and fair and equitable treatment, so that they cannot provide a package to the same category of person in one part of the State and not in another part of the State.

The sort of fundamentals of the Medicaid Program will continue. The major thing they have been asking for waivers on, is to move people into managed care without waivers and the repeal of the Boren amendment. These are the critical areas so the States can properly price and pay for certain kinds of services.

#### FDA BUDGET

Senator GREGG. May I ask you about another area, which is in FDA? Are you comfortable with taking up that at this time?

Secretary SHALALA. Sure. This committee does not have jurisdiction, but I am happy to answer a question about FDA.

Senator GREGG. It is an area that I am interested in. I notice that the administration is suggesting I think a 7-percent increase in budget authority but an 8-percent cut in the appropriated amounts, with the difference being made up basically on fees that are assumed by OMB.

I was wondering if you could tell us how you are going to really do this.

Secretary SHALALA. Well, as you know, we do have an agreement with the pharmaceutical industry on fees, and that increase in resources has, in fact, helped us to reduce the turn-around times on drug approvals. That very much is an industry administration agreement which has been in place over the last few years.

The new OMB proposal extends that to cover a lot more, and it is, as you can imagine, quite controversial.

Senator GREGG. There is about a \$60 million gap between what is being suggested we appropriate and what was appropriated this year for FDA.

Secretary SHALALA. Right.

Senator GREGG. My sense is that it is going to be very hard to make that up with fees and that there are going to have to be cuts in FDA activity.

I am just wondering if you folks have a contingency plan for those cuts if we budget to the appropriated level that you want.

Secretary SHALALA. I think that what Dr. Friedman, the acting director, will say is that we will work with our Appropriations Committee on that issue. But, obviously, what the administration is recommending is a further shift to a fee structure.

Again, we had to make these decisions within the context of a balanced budget. These are not individual, free-standing. They are all connected. Senator Specter and Senator Harkin are concerned about the NIH increase not being sufficient. But we did our best within the context of having to bring down this budget.

The same answer I would give for the cap on Medicaid, the per capita cap on Medicaid. Again, we are working within the context of a balanced budget.

Senator GREGG. I guess my concern is that this number may end up being a bit of a plug in that it is probably not going to be a doable number. Therefore, either we hammer FDA or else this budget will be out of balance by about \$60 million in that area.

I would be interested in any other suggestions you have for addressing it as we go down the road.

Thank you.

Senator SPECTER. Thank you very much, Senator Gregg.

Madam Secretary, you have drawn more members than I can recollect at a hearing, certainly any that I have presided over. We have had nine members here today, and there are a great many questions to be asked. We began one-half hour late because you had the commitment with the President, which is certainly understandable. There are a great many more questions to be asked.

I am going to have to excuse myself shortly before noon. What I would like to do at this point is this. As chairman, there are a lot of questions which I need to ask which the staff needs to integrate into our budget. So what I will do is ask you the questions, which highlight what I would like your personal response to, contrasted with just submitting questions for the record, which is of a lesser qualitative level.

My prepared statement differed from yours slightly, Madam Secretary, on the total amount of your department, and I think we ought to specify for the record that when you cite \$376 billion, you include the Medicare benefits; and when we have used the figure of \$223 billion, that is appropriated entitlements, Medicaid, AFDC, black lung, matters of that sort; and my \$31.7 billion discretionary for this committee differs from your \$34.7 billion because you have included FDA and the Indian Health Services, which we do not include.

Let me go over the questions which I would like your personal attention to on responding.

#### MEDICARE REIMBURSEMENTS FOR SPECIALITY PROVIDERS

The question of Medicare reimbursements for specialty providers is an enormous one. HCFA's plan proposes to cut payments to thoracic surgeons by 40 percent, neurosurgeons by 30 percent, and cardiologists by 25 percent. We would like to get the specifics as to where HCFA stands.

In order to hold to the January 1, 1998, statutory implementation date, these proposed regulations have to be issued by May 1 with a final rule by November 1. This gives us a problem on comments. So the earliest you could provide that to us we would really appreciate.

There is an issue on the medical education carve-out—which I am now looking for.

Secretary SHALALA. It would be in our Medicare reform proposal.

Senator SPECTER. Looking at the graduate medical education, the question is how are we going to handle that with so many managed care providers. We will give you some specific questions on that. That is one which we hear about all the time.

The issue of Medicaid coverage for attendant care services is a big one. I sent you a letter on that just a few days ago and I understand that you have not had time to respond to it. I visited a home where people were in wheelchairs and their requests were very, very urgent asking that Medicaid provide this kind of service not in nursing homes but attendants in their own homes. It is hard to see on the face of the record why that flexibility would not be provided when it would appear to be much less expensive to provide them in that context.

I would very much appreciate your specific response on that question.

[The information follows:]

#### MEDICAID FOR ATTENDANT CARE SERVICES

Health and Human Services is currently considering attendant service programs as a policy option. The Robert Wood Johnson Foundation is funding a demonstration program that should be operational in January 1998. The Department is looking forward to seeing the results of this project for purposes of estimating the cost effectiveness of attendant services. In addition, the President's Medicaid proposal will enable States to offer home and community-based care without the need for a 1915(c) waiver. This new flexibility should encourage more States to adopt attendant service programs.

#### BREAST CANCER ACTION PLAN

Senator SPECTER. I wrote to you on a complicated matter involving the issue of the action plan back on November 1st of last year and you have not responded to that. I am concerned because we are moving through a good part of the fiscal year. I had a very specific letter from a very distinguished constituent of mine, Frances Visco, who is a breast cancer survivor and cochairman of the Action Plan Committee, dated October 10. I had responded to her and sent a letter to you. We had taken this up with Dr. Klausner. This involves the action plan, where the administration had requested \$14 million last year as a carryover from the preceding year, \$14,750,000. We had agreed with the administration's request.

The action plan includes quite a number of items which are not covered by the National Cancer Institute, legal and ethical issues regarding the gene on predispositioned cancer, clinical trials, publication of the problems, a biological research bank and other cross-cutting matters, the minority health issue, and the environmental clusters.

When Dr. Klausner was here, in a rather lengthy exchange we asked him just how much money he wanted. The funding is in excess of \$400 million now. On this action plan funding we have about \$14,750,000. It seems to me from what I have seen that the action plan or the alternative crosscutting matters have been very beneficial. One of the first things I saw when becoming chairman was the missiles to mammograms, where the CIA had put in \$2 million.

As I have had these field hearings on mammograms for ages 40 to 49, there is a big issue of informing women who simply do not know about mammograms, many more in the African-American community. Women's 2000 just had a very good forum a few feet from where we are in this building.

So I would like you to respond and give us your thinking on that.

[The information follows:]

#### BREAST CANCER ACTION PLAN

As Secretary, I am aware of the fiscal year 1997 Appropriations Conference Report language stating that \$14.75 million was available in the National Cancer Institute budget to be used to fund the National Action Plan on Breast Cancer (NAPBC), that this Plan was to be coordinated by the OPHS Office of Women's Health, and that the funds were to be used "to implement the Plan's activities and other cross-cutting Federal and private sector initiatives on breast cancer." I am also aware that the Action Plan's Steering Committee has recommended that \$14 million of the funds in fiscal year 1997 be "returned" to the National Cancer Institute and used only to fund research on breast cancer.

The Department of Health and Human Services has made breast cancer a top national health priority and supports a broad range of programs in research, early detection, service delivery, and education. Through its public-private partnerships, the Action Plan's efforts to date have been very successful in stimulating the scientific community to devote more attention to this dreaded disease, and helping to identify and address gaps in our scientific knowledge and health care policies, in ensuring consumer involvement, and improving the public's access to critical information about breast cancer.

As Secretary I intend to meet with the members of the Action Plan's Steering Committee before I complete my deliberations on their recommendation as to how best to use fiscal year 1997 appropriated funds. No final decisions have been made and of course the Department will keep the Committees informed of our plans. It is important that we work with the Congress to get the right things done. Our goal is to ensure that a wide range of public and private organizations continue to get involved and join together in efforts to eliminate breast cancer and its devastation to women and their families.

#### CLONING

Senator SPECTER. Then we have the issue of cloning, which is the matter where you were with the President earlier today. This committee had provided that there would be no funding for the creation of human embryo research. It may be that this committee will need a hearing on that subject because we do fund to make sure that there is a legislated determination as to what ought to be done on the cloning issue.

We may ask you to come back for that one. That seems to be a matter of enormous importance, enormous public concern at the moment. The President, of course, has addressed that today.

#### MARIJUANA USE FOR MEDICINAL PURPOSES

Then there is the issue of marijuana use for medicinal purposes. The New England Journal of Medicine has called for a revamping of marijuana laws to allow for medical usage. You have also the Arizona and California initiatives pass, which provides a classic conflict between Federal and State.

I think no one wants to legalize drugs, but there is a question as to where we head in that direction.

Let me deviate from my format and ask you for a response as to how you are looking at that and how you evaluate the New England Journal of Medicine conclusion as to where you see that issue heading. Is there a way to really have that dichotomy for legitimate medical purposes without getting into the legalization?

I notice the Attorney General said that she would not prosecute cases where there was legitimate medical treatment. How do you view that vis-a-vis a matter for your Department, contrasted with the Attorney General?

Secretary SHALALA. Let me say that there is currently no evidence that smoked marijuana has a strong medical use. There is evidence that some of the properties of marijuana in a pill form, which has been approved by the FDA, is useful for medical purposes.

We have had, I think, only one application in 10 years. The NIH has recently convened a group of people to talk about the possibility of more research in this area, in the area of smoked marijuana. But what we recently did was convene that panel to see whether NIH could expand and get more actively involved in research in this area.

But we have said very clearly what the scientific findings are in this area, and that is on smoked marijuana there is no evidence since there has been almost no research in this area and we know very little about dosage or anything else. We have objected to those referenda in part because they are not based on any kind of science.

In our judgment, they were, in fact, using the issue of marijuana for medical purposes as a cover for the legalization of marijuana. As you well know, the teenage drug problem in this country is essentially a marijuana problem, and we believe that that does, in fact, encourage smoking of marijuana by teenagers.

Our research already shows that marijuana harms the brain, the heart, the lungs, and the immune system. It limits learning, memory, perception, judgment, and certainly you would not want anyone driving a car who had smoked marijuana.

Senator SPECTER. Madam Secretary, I do not want to cut you off, but are you suggesting that there ought to be more research in this field?

Secretary SHALALA. Yes.

Senator SPECTER. Will your Department undertake such research?

Secretary SHALALA. We have, and, in fact, the National Institutes of Health, after convening its workshop—I'm not sure we have the final report on that workshop—are looking at the issue of expanding the existing scientific work on smoked marijuana.

#### NEEDLE EXCHANGE PROGRAM

Senator SPECTER. Let me move on because my time is moving on. There is a collateral issue where a comment from you I think would be helpful.

The February 18 report to the committee on studies reviewing the needle exchange program found:

Overall, these studies indicate that needle exchange programs can have an impact on bringing difficult to reach populations into systems of care. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood-borne infectious diseases in communities that choose to include them.

Here, again, it is a very difficult matter, where we do not want to promote drug use, beyond any question where there is something which will stem proliferation of drugs. What do you see as the next step?

I note that you stopped short of a certification here. What do you see as a followup to the current status of the matter?

Secretary SHALALA. Because the NIH convened a panel, they are going to report to me shortly. Obviously, our summary of these studies indicates that we have, in fact, made progress on the research.

As you indicated, what the studies do tell us is that needle exchanges as a strategy can be an effective component to prevent HIV and other bloodborne infections. It also tells us that these programs are good at pulling people into services.

Drug addicts who are out there that need services, the exchange programs themselves, because they put public health outreach workers out there, pull people in services.

But the fundamental finding is, as part of an overall strategy to reduce HIV AIDS, they certainly have been an effective part of that strategy. On the issue of the impact on drug use, because it is a social science versus science, it is self-reporting, and many people believe it is slightly less clear in that area. But I think our fundamental point is that communities could be reassured, who have funded these efforts themselves, that our research is now showing that as part of their overall strategy they are getting people into services, and on HIV AIDS the impact is increasingly clear.

The standards that I have been asked to meet are varying, depending on what program in the Department. I am in the process of reviewing those standards as to what the research tells us.

#### ABSTENTION PROGRAMS

Senator SPECTER. I have one final question, Madam Secretary, and that is relating to the abstention programs.

Your testimony is pretty explicit on discouraging premarital sex among teenagers. You and I will have to talk about your difference in approach contrasted to what Congress said as to where the administration would be, and that is too long a topic to take up now. But we will have to talk about that.

I have seen a fundamental conflict on education on abstinence, as to whether it is simply to abstain from sex or providing the alternative of, if you are going to have sex, to have condom availability.

Some of the programs go one way and some of the programs go another way. I would be interested in your answer to the question about dealing with teenagers, to counsel for abstinence or to give alternatives.

Secretary SHALALA. I would say two things. First, Mr. Chairman, we believe that the issue of the nature of health education or sex education in schools is a decision for the local community—for the parents, for the school board. The content of those programs are very much a local community decision based on the values of that community.

The Federal Government funds, with this committee's support, in the welfare bill a substantial amount of the abstinence education programs. We are in the process of evaluating those. But from what we know, these are effective ways of preventing teenage pregnancy.

Our position is that no teenager ought to be engaged in sex and no public official ought to be encouraging a teenager, either through programs or through words, to be engaged in sexual be-

havior before marriage. We ought to be clear and straightforward in our messages to teenagers on this subject.

But we do not dictate, nor do we think it is appropriate for the Department or the Federal Government to dictate the content of the total health education program in a school. That is a community decision. We provide resources on abstinence education. We also fund some demonstration projects that are local initiatives that come to us to be funded.

Senator SPECTER. So, if the local community wanted to have the additional option of condoms, it is up to them?

Secretary SHALALA. It is up to them.

Senator SPECTER. OK. Thank you very much.

Senator Hutchison.

#### TEACHING HOSPITALS

Senator HUTCHISON. Thank you, Mr. Chairman.

I wanted to go into the teaching hospital issue. This is becoming a great concern, especially as managed care moves in. We are losing the ability to train our future doctors.

The Health Care Financing Administration has granted New York a waiver for a demonstration project. But I would like to know what your thoughts are on how we can address this issue all over the country and make sure that we do have the ability to train our physicians, despite the managed care growth movement.

Secretary SHALALA. Thank you, Senator. Your State has some of the most remarkable teaching institutions in this country and some of the great academic health centers. We consider them among this Nation's most precious possessions.

It does cost more to maintain a great academic health center, whether it is the Duke University of North Carolina complex or the four or five Texas complexes.

We believe that the money ought to be carved out. We are now giving the money directly to managed care, for example. We do not believe that all that money is being given back to the teaching hospitals. The teaching hospitals have complained to us, often bitterly, that they are being asked to provide the same kind of discounts that any other hospital would, even though we have given additional money to organized care to provide for the teaching hospitals.

We believe it is time to carve out those resources and to set them up in a different fund. Some of your colleagues, Republican colleagues, on the House side have suggested that, rather than taking it out of Medicare, where we have put it, it ought to be a separate, free-standing allocation, a discretionary allocation, as opposed to pulling it out of an entitlement program and making it free-standing.

I think that our view is that it is so important that we get this done this year. We have moved ahead on one demonstration, as you noted. We are flexible about how we do it, but we think it should be done, so that the money is targeted directly to the academic health centers.

The resources are there in this case. We just have to make sure that they are carefully targeted, so we maintain these institutions of such great quality.

In the case of the New York demonstration, New York has 15 percent of all of the residencies in the country. They came to us with an application. There are a couple of other States in now.

Hopefully, before we look at other States, we will have an agreement, a bipartisan agreement, on this issue. But let me assure you that we also have told New York that, whatever the bipartisan agreement is, the New York demonstration, like the welfare demonstrations, are included as part of that.

Senator HUTCHISON. Well, I certainly think that it is a national problem and there is a finite number of medical schools that have these residency and internship programs. So we certainly need and hope that you will allocate that accordingly and fairly.

Senator SPECTER. Senator Hutchison, may I interrupt you for just a moment to hand the gavel to Senator Gregg, who is next in seniority. I will have to excuse myself.

Senator GREGG. I am going to have to leave, too. So please give it over.

Senator HUTCHISON. I am leaving also. So, Senator Faircloth will be the last one here.

Senator FAIRCLOTH. And I am leaving soon, too, after just a few questions.

Senator SPECTER. Well, may I hand you the gavel, then, Madam Secretary.

Senator GREGG. I think the Secretary would be happy to have us all leave. [Laughter.]

Senator HUTCHISON. We can handle this, Mr. Chairman.

Senator SPECTER. Well, we have established the priority.

Let me thank you, Madam Secretary. This is a very, very lively session with many members here, showing the importance of these issues. There will be, as there always is, tremendous followup among members with you, me to you, Senator Harkin and you, and our staffs to staff as we work through this very complicated budget on these matters that are of such priority. We have so many priorities that it is very, very difficult. Of course, it goes over into education, labor safety, and the Labor Department. But we will work it out, again.

We thank you for your cooperation and your great contribution.

Secretary SHALALA. Thank you very much, Senator, and thank you for the opportunity. I look forward to working with all of you over the next 4 years.

Senator SPECTER. Thank you.

#### DISPROPORTIONATE SHARE HOSPITALS

Senator HUTCHISON [presiding]. Madam Secretary, I just have one other comment. It is this.

I, like Senator Gregg, am very concerned about the policies that would be following on the disproportionate share issue. This is something that many States have used for serving the underserved populations. I hope that your policies will be very careful to understand that.

When you have those ready, I hope that you will give us a chance, before everything is in concrete, to comment on those. Is that your plan?



Secretary SHALALA. We would be happy to come and talk to you about that. Our goal is to make sure the disproportionate share money goes to hospitals that are safety net hospitals.

Frankly, within the context of a balanced budget, I think we have fairly treated the Medicaid Program. It is, in fact, in the entitlement programs, as you well know, where we have to slow down the growth.

I think we have done this very carefully. But we, of course, look forward to working with Congress with both parties in working through this issue.

Senator HUTCHISON. Let me just say that I served on the board of Parkland Hospital in Dallas, which is one of those that, frankly, gets dumped on by all of the other hospitals in the area because the others will refuse to serve those people. So Parkland does it because that is its mission.

We have others around our State and certainly around our country. But I want to make sure that those hospitals are able to continue giving that service because they are performing a function that, if they were not there, these people would be really in a hardship situation. We have done everything possible to get the other hospitals or the communities to pay for the service that is given. But what we cannot lose is that safety net in the hospitals that are doing that.

Secretary SHALALA. Senator, I share your view on Parkland. They have a nationally recognized emergency care service, in particular. We will do everything we can to protect those truly safety net institutions.

Senator HUTCHISON. Thank you.  
Senator Faircloth.

#### LOSSES FROM FRAUD AND WASTE

Senator FAIRCLOTH [presiding]. Thank you.

Madam Secretary, I will not delay your lunch.

I had a quick followup to an earlier question and you answered it quite extensively. The General Accounting Office estimates up to \$20 billion in losses. What I would like for you to do is to give me an estimate of what we can expect to lose next year from fraud and waste.

Secretary SHALALA. I think the only real number we have is the GAO study. But in our reform proposals, the waste in the system, where we should not have to pay, is part of the reform proposals.

Do we have the Medicare reform list?

Let me give you one specific example. Right now, on home health care, which is very heavily used in the Southeast, in your part of the country, we pay a home health care provider, a company, according to where their corporate headquarters is located, not according to where the service is provided.

Now there is a quirk in the law that allows the home health care business to bill us from their corporate headquarters. We pay on the basis of what the average salaries are. So locating your corporate headquarters in a larger city is in the interest of that company, even though the service could be provided in a rural area.

We need to pay them in the rural area. That is waste, as far as I am concerned. It is not fraud. They are simply taking advantage of a loophole in the law.

Throughout our modernizing proposal, we go after exactly that. That is what the inspector general and the GAO has been concerned about.

Senator FAIRCLOTH. Where are most of them located, in Palm Springs or Newport?

Secretary SHALALA. No; I think it is Atlanta and in larger metropolitan areas.

Senator FAIRCLOTH. Well, that's it.

Secretary SHALALA. That's an example of waste in the system that we take care of.

Senator FAIRCLOTH. I understand that. I would like for someone in your staff to send me a letter estimating what they expect it to be next year, and I would be back to talk to them about it.

Secretary SHALALA. Fine, sir.

Senator FAIRCLOTH. I just want a figure.

[The information follows:]

#### ESTIMATED COST OF HEALTH CARE FRAUD

The Office of Inspector General has never estimated the extent of health care fraud in our programs. The General Accounting Office issued a report which stated "estimates vary widely on the losses resulting from fraud and abuse, but the most common is 10 percent." We have used that estimate as a guideline for our projections of fraud in the Medicare and Medicaid program.

Health care expenditures represent nearly 15 percent of our national output. We know the vulnerabilities within the health insurance system allow unscrupulous health care providers, including practitioners and medical equipment suppliers to cheat health insurance companies and Federal programs out of millions of dollars annually.

#### SURGEONS AND MEDICARE

Senator FAIRCLOTH. The next one is this. The cut on surgeons—and I am supportive of any cuts. But for heart by-pass surgeons it is about 44 percent. Some of them are saying it is not feasible to treat Medicare patients.

Is there any possibility that this would lead to inferior care? Is that an unwarranted assumption?

Secretary SHALALA. I don't think so. In general, Medicare is now the best payer.

When I first came here to testify 4 years ago, Members of Congress said to me that they knew of hundreds of doctors who were going to move away from Medicare. Because the HMO's have gotten such severe discounts, we now are a much better payer. What we are trying to do is to bring our growth rate somewhere near the private sector growth rate for health care as a way of introducing some discipline in the system.

As a result, we do a number of different things in the Medicare Program, again, trying to get entitlements under control. But, in general, we have been a much better payer over the last couple of years than the private sector has been and the corporations, because they have negotiated such deep discounts with their managed care agencies.

Senator FAIRCLOTH. If I am not mistaken, we have turned out a lot of doctors, so there is not exactly a shortage of doctors ready to do most any procedure that is out there.

Secretary SHALALA. That's correct. But in the case of surgeons, they have been very disciplined by the number of residences and they have done a good job, I think, in keeping down the number of residencies.

The truth is that, as the private sector squeezed down on health care growth, as the public sector squeezed down, people just are not going to make as much money as they used to make. We have to make sure that we pay a reasonable price for high quality care, and if the surgeons are concerned that they won't be able to provide high quality care, I would be happy to carefully look at that information. But I think that what we have done is tried at the same time to protect quality as part of our overall Medicare cost savings.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator FAIRCLOTH. Madam Secretary, that is all I have. But I do have some questions from several Senators and I would like to submit those for the record. If you would, please see that they are attended to and answered.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing.]

#### ADDITIONAL COMMITTEE QUESTIONS

##### HUMAN CLONING

*Question.* Madam Secretary, the news that scientists have discovered the ability to clone adult sheep is troubling, especially when the possibility exists that human beings might also be cloned someday. The President announced that the National Bioethics Advisory Board will be investigating the legal and ethical issues associated with genetic cloning and asked the Board to issue a report in 90 days. Given the enormous scope of the questions and implications of this technology, will a report done in just 90 days be adequate?

*Answer.* A report developed within 90 days by the National Bioethics Advisory Commission should be sufficient to guide near-term policy making and to establish a valuable framework for further, more detailed review and public dialogue.

*Question.* Language contained in this subcommittee's bill prohibits your Department from funding human embryo research. Is this language sufficient to cover research involving cloning of human individuals?

*Answer.* The current Appropriations language prohibiting the Department of Health and Human Services from funding human embryo research does not cover all imaginable research involving cloning of human individuals. For example, the Appropriations language does not explicitly cover (a) all federal agencies or (b) human embryos created for implantation in a woman with the intent of establishing pregnancy and conceiving a child—whether the embryos be created by conventional in vitro fertilization techniques or by other means such as nuclear transfer (i.e., transferring the genetic material of one cell into an egg cell from which the genetic material has been removed), an early step in the process used by the Scottish scientists in cloning sheep. President's Clinton's action on March 4, 1997 to prohibit Executive Branch agencies from funding the cloning of human beings was designed to fill these gaps.

*Question.* If not, do you support legislation prohibiting funding for research involving human cloning?

*Answer.* I believe that legislation to prohibit funding of research involving human cloning would be premature. Once the National Bioethics Advisory Commission has completed its assessment of the pertinent issues, the Congress and the Executive Branch both should be better positioned to determine whether specific new legislation is needed and, if so, to define its scope and content.

*Question.* NIH recently discovered that a Georgetown University researcher was conducting human embryo research with NIH funds in violation of the prohibition in the Labor, HHS and Education Appropriations bill. That researcher lost his NIH grant and eventually resigned from Georgetown. I am troubled that there are people who could evade a ban on cloning research and conduct rogue research. Now that this technique has been published in the scientific press, do you believe there ought to be a comprehensive ban on human cloning to include privately funded research?

*Answer.* I believe that a comprehensive, statutorily mandated ban on human cloning, including privately funded research, would be premature at this time. The National Bioethics Advisory Commission should first be given the opportunity to complete its assessment of the relevant issues. In addition, because of Constitutional limitations, federal statutes alone may not be able to cover all private sector activities that involve cloning. State legislation may be required as well.

*Question.* Is it inevitable, given the power of this technology and how easily it can be disseminated, that someone will attempt to clone a human being?

*Answer.* I feel confident that strong leadership by the President and the Congress will do much to ensure that scientists within the United States do not undertake cloning efforts that are scientifically unjustified and ethically unacceptable. However, as much as I would hope otherwise, I cannot rule out the possibility that, within the next decade, someone will attempt to clone a human being.

*Question.* The authorization of the National Bioethics Advisory Board will be expiring this October—do you think the Board will have enough time to consider the major important issues?

*Answer.* I feel confident that, by the fall of 1997, the National Bioethics Advisory Commission will have additional findings and recommendations pertaining to the key issues associated with the prospect of cloning humans. Furthermore, I expect that the Commission will have important findings and recommendations about two other topics: (a) the implementation, across 16 federal agencies, of the so-called "Common Rule" for protection of human research subjects, and (b) the implications of the rapidly emerging genetic-testing technology for the way health-care providers obtain and use human-tissue samples.

*Question.* Cloning technology, whether for better or for worse, will be here to stay. Do you believe the National Bioethics Advisory Board ought to be made permanent?

*Answer.* The concept of a continuing, high-level advisory group to address complex issues in bioethics has much to commend it. I look forward to working with President Clinton in assessing how best to ensure that policy-making within the Executive Branch that involves bioethical concerns is supported by relevant data, thorough analyses, and sound recommendations.

#### MEDICARE REIMBURSEMENT FOR SPECIALTY PROVIDERS

*Question.* It has come to my attention that HCFA is planning to change the method for calculating Medicare reimbursements to physicians. As I understand it, the new system for calculating overhead costs, or "practice expenses," could result in very drastic changes in payments to physicians. For example, HCFA's plan would cut payments to thoracic surgeons by 40 percent, neurosurgeons by 30 percent, and cardiologists by 25 percent. Yet, the proposal also would increase payments by similar amounts for other providers, such as, dermatologists, rheumatologists, and podiatrists. What is the justification for such drastic changes in proposed reimbursement rates?

*Answer.* We note that changing the method for calculating practice expense portion of physician payments was mandated by Congress in the Social Security Act Amendments of 1992 and by Congress in the Social Security Act Amendments of 1994. Many of the hospital-based surgical specialties are startled by the magnitude of the reductions in their payments under the preliminary options. For example, as you indicated, the reductions in total payments to cardiac surgeons, thoracic surgeons, vascular surgeons and neurosurgeons under the preliminary options are in the 20 percent to 40 percent range. We must emphasize that these options are still preliminary options. We are exploring other options for allocating indirect costs. We would note, however, that the simulations of impacts we distributed to physicians are consistent with earlier studies by the Physician Payment Review Commission, completed in 1992 prior to passage of the resource-based practice expense legislation by Congress.

*Question.* What effect do you estimate shifts in reimbursement of this magnitude will have on the delivery of services to Medicare beneficiaries?

*Answer.* Changes in payments at the beginning of the Medicare physician fee schedule were large, yet no adverse impact on access to care was detected. Medicare assignment and participation rates are at all time highs. Further, we must empha-

size that the options and methodology are proposed, not final. As we consider further options and methodology, we will carefully consider the impacts on beneficiary access.

*Question.* In order to hold to the January 1, 1998, statutory implementation date, I understand that proposed regulations will have to be issued by May 1 of this year and a final rule by November 1. Given the fact that HCFA halted its survey of physician practices in favor of unspecified alternative methodology, how can Congress be assured that the new approach fairly recognizes what it costs providers to deliver services in both the office and hospital settings as Congress intended?

*Answer.* The data we are using are the best available. The survey, canceled because of unacceptably low response rates, might have provided more complete data on indirect costs of physician practices, had it been successful. However, the survey would have been only one of the data sources that HCFA would have considered for measuring and allocating indirect costs. The AMA Socio-economic Monitoring System data that we are using as a source of the aggregate direct and indirect cost information was always a viable option. Regardless of the data source, however, we would still have to design a method for allocating these costs to individual procedures. No universally accepted method for allocation exists, and we would still be faced with the need to determine which method to use.

HCFA has long supported the use of expert panels for Medicare fee schedule issues. We believe the use of such methods is valid and credible. We have repeatedly used panel methods for refinement of relative values for work. The Clinical Practice Expert Panel (CPEP) process was designed with the input of the medical societies. Nominees were solicited from specialty societies and societies submitted 100 nominees. There were over 150 participants in each of the two rounds of the CPEPs. In addition, specialty societies provided their own data and were present for consultation at the CPEP meetings.

We have also specifically asked the specialty groups to review carefully the Abt CPEP data and provide us with comments. We have conducted some "gross" internal checks on the CPEP data that confirm the general validity of the data. We would also emphasize that during the second round of the CPEPs, Abt added panelists with more specialized knowledge of certain codes.

*Question.* How will there be adequate time for review and comment to arrive at a meaningful final rule?

*Answer.* HCFA provided public access to the preliminary data for the practice expense fee schedule development by hosting a meeting on January 22, 1997. At that meeting we presented the data resulting from the Abt Associates contract and our preliminary projections for selected alternative practice expense fee schedules. In addition, we asked the physician groups to respond within two weeks, that is by February 5, to provide us with comments on the proposed methodologies and other specified issues that we agreed to consider in developing the proposal. Almost all the specialty groups have said that this time frame is too short, particularly with respect to review of the Abt data.

Actually, we have given the specialty groups far more than two weeks to comment on proposed methodologies. We are continuing to have open communication with all organizations as we develop the NPRM which is expected to be published in May. Following publication of the proposed rule there will be an additional 60 days for comment. Thus, in making this available prior to an NPRM we extended to nearly six months the period of time that medical organizations could analyze and provide input into the process.

#### NATIONAL ACTION PLAN ON BREAST CANCER

*Question.* I wrote you on November 1st of last year regarding the need to resolve promptly the controversy that has arisen regarding funding for the National Action Plan on Breast Cancer. What action have you taken regarding this matter?

*Answer.* The fiscal year 1997 Appropriations Conference Report stated that "\$14,750,000 shall be used to fund the National Action Plan on Breast Cancer. Sufficient funds have been provided within the NCI for this expenditure. The conferees further agree that this plan shall be coordinated by the PHS Office on Women's Health and shall be used for implementation of the plan's activities and other cross-cutting Federal and private sector initiatives on breast cancer." However, the NAPBC Steering Committee voted on November 7, 1996, to recommend to me "\* \* \* that \$14 million of its \$14.75 million fiscal year 1997 appropriation be returned expeditiously to the National Cancer Institute for breast cancer research." Of the \$14.75 million, \$750 thousand was approved by the Steering Committee to support administrative costs for the NAPBC incurred by the OWH, and these funds were transferred from NCI to the OWH. Since the Steering Committee's rec-

ommendation, I have asked the NCI and the OWH to develop a proposal of activities that reflect the broader interests in breast cancer issues that I share with the Appropriations Committees. The OWH and NCI have identified 16 activities (see attached proposal) to be supported by fiscal year 1997 funds. These activities build on the accomplishments of the NAPBC, further priority initiatives of NCI and the OWH, and address a broad range of critical breast cancer issues. Accordingly, an additional \$3 million will be transferred to the OWH specifically to support innovative, cross-cutting projects on breast cancer developed by diverse agencies of the Federal government, with an emphasis on public/private sector partnerships. The remaining \$11 million will be spent by the NCI to begin or expand the other breast cancer research and collaborative initiatives.

*Question.* Why has it taken so long?

*Answer.* I met with the NAPBC Steering Committee to hear first hand the basis for their recommendation. After this meeting, I directed the OWH and NCI to identify breast cancer initiatives that reflect the broader interest and intent of the Appropriations Committees. The OWH and NCI have been refining initiatives to be supported by these funds to ensure that critical issues in breast cancer are being addressed and that activities supported by these funds will bring rapid progress in our fight to eradicate this disease.

*Question.* What do you view as the role of the Plan and whether the Steering Committee should move ahead with identifying additional areas of priority for action?

*Answer.* The NAPBC serves a unique role as a catalyst for action, bringing together public and private sector partners to ensure a unified and focused effort to eradicate breast cancer. The NAPBC's role in stimulating action to fill gaps in our efforts is critical. The Steering Committee of the NAPBC is currently examining whether to add new priority areas to the Plan, and I expect to receive their recommendations along with a proposed fiscal year 1998 budget by the end of June. They continue to make substantial progress in addressing the six priorities identified four years ago and have numerous accomplishments to their credit (see attached).

#### ATTACHMENT 1

##### BREAST CANCER PROPOSAL

*Activity 1: Cancer Genetics Network (CON)—\$1 million.*—The Cancer Genetics Network (CON) will serve as a dynamic informatics and research infrastructure linking institutions that test individuals for hereditary cancer susceptibility as well as provide counseling and interventions to prevent cancer in these individuals. Research projects will be funded to achieve the CON objectives to: (1) develop and disseminate high-quality information about genetic susceptibility and testing; (2) develop and assess approaches to informed decision-making, counseling, and laboratory testing procedures; (3) collect and pool data linking specific mutations with phenotypes; and (4) enhance participation in cancer genetics research. The NCI will serve as the lead agency for this activity in collaboration with the PHS OWH.

*Activity 2: Breast Cancer Genome Anatomy Project (C-GAP)—\$1 million.*—The goal of the Breast Cancer Genome Anatomy Project is to scan a human tumor for all the genetic alterations present in it and to develop clinical tools that will be of direct use in making diagnoses, estimating prognosis, and selecting treatments for patients with breast cancer. Projects will be supported to prepare cDNA libraries from tumor cells and to develop sensitive, accurate, and economical high-throughput technologies to use for scanning tumors. The NCI will serve as the lead agency for this activity in collaboration with the PHS OWH.

*Activity 3: Clinical Trials Partnership on the World Wide Web—\$200,000.*—Funds will be provided to enhance the NCI Physician Data Query (PDQ) system to establish a national resource of user-friendly descriptions of breast cancer clinical trials. The NAPBC has conducted a workshop to begin to address the broader issue of the need for integration of the numerous different sources of information about clinical trials, including trials sponsored by pharmaceutical companies, hospitals, CROs and the government. PDQ was identified as one of the more credible existing repositories and support will be provided to enhance this system to establish a central repository of user-friendly cancer clinical trials information. The NCI will serve as the lead agency for this activity in collaboration with the PHS OWH.

*Activity 4: New Approaches to Breast Cancer Imaging—\$3.5 million.*—Ongoing efforts to explore the application of imaging technologies from the intelligence, defense and space fields to improve the early detection and diagnosis of breast cancer will be expanded and broadened to hasten the clinical application of newly developed

and experimental breast imaging techniques and to foster collaborations between imaging scientists in other fields and investigators in molecular and cell biology, oncology, and radiology. The PHS OWH and NCI will jointly lead this activity.

*Activity 5: Federal Coordinating Committee on Breast Cancer Supplement Program—\$3 million.*—The Federal Coordinating Committee on Breast Cancer (FCCBC) is in a unique role to mobilize all federal agencies to address issues in breast cancer, to identify areas of overlap and gaps in our federal approach, and to identify areas in need of additional resources. Support will be provided to complete a searchable, Internet-accessible gateway to information about federal breast cancer programs. Using the searchable gateway of Federal breast cancer initiatives, the FCCBC will identify research, education, policy and service delivery gaps in current federal breast cancer efforts. Based on these gaps, support will be provided for a supplement program for DHHS agencies and other Federal departments for innovative, cross-cutting projects on breast cancer, including an emphasis on public/private sector partnerships. The PHS OWH will serve as the lead agency for this activity.

*Activity 6: Minority Breast Cancer Initiative—\$2 million.*—Collaborative activities will be supported to address research, service delivery, and education issues related to disparities in breast cancer incidence and mortality among women of color. Specifically, a workshop and related scientific reviews will be conducted to assess current knowledge of potential differences in tumor biology among minority groups and the potential implications for cancer prevention, control and treatment and to develop specific recommendations for future research initiatives. Additionally, education initiatives will be designed and conducted specifically targeting minority women to stimulate increased mammography screening, especially for older women and women at risk, utilizing public/private sector partnerships. Finally, a workshop will be conducted to identify barriers to the effective translation of intervention research and to provide specific recommendations for actions to address these barriers. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI.

*Activity 7: Communicating Risks and Benefits about Cancer and Cancer Control—\$500,000.*—Risk communication is becoming increasingly critical to efforts to responsibly inform the public and health care providers about the benefits and potential risks of various cancer treatments and preventive behaviors. Based on information from a literature review and market research a workshop will be conducted to formulate specific recommendations about how to better communicate risks in the context of cancer treatment and control, and to define future research needs in the area. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI, through its Office of Cancer Communications.

*Activity 8: Collaborative Research on Hormones, Hormone Metabolism and Breast Cancer—\$500,000.*—NCI, working in collaboration with the CDC, will address research needs identified at the NAPBC Etiology Working Group conference on hormones, hormone metabolism and breast cancer. Specifically, support will be provided for research to develop better (more sensitive, more specific, more reproducible, faster, less invasive, and less expensive) analytic methods for measuring steroid hormones and their metabolites in body fluids and tissues which could be applied to large scale epidemiologic studies and validation/reproductivity studies of new and existing assays. The NCI will serve as the lead for this activity in collaboration with the PHS OWH.

*Activity 9: Establishment of a Working Group on Environmental Clusters of Breast Cancer—\$250,000.*—A national working group involving Federal and state representatives, consumers, health care professionals and researchers will be convened to evaluate data concerning breast cancer clusters, to determine whether they are real or artifactual, to examine potential causative factors, and to develop mechanisms to further investigate the reported higher incidence of breast cancer in certain areas of the country. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI.

*Activity 10: Alternative Medicine and Breast Cancer Workshop—\$200,000.*—Increasingly, women are using alternative medicine approaches for treatment of breast cancer. A review of current literature and issues in the use of alternative medicine for breast cancer and a workshop on the use and effectiveness of alternative medicine interventions among breast cancer patients will be conducted. The workshop proceedings will provide the foundation for identifying further education and research initiatives. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI and the NIH Office of Alternative Medicine.

*Activity 11: Adiposity, Physical Activity and Breast Cancer Workshop—\$150,000.*—A workshop will be supported to set a research agenda on the role of diet, obesity, and physical activity in breast cancer etiology and recurrence. A special focus will be placed on Asian immigrant and Asian American women in considering the basis

for variations. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI.

*Activity 12: Prophylactic Mastectomy and Prevention of Breast Cancer—\$150,000.*—A research workshop will be supported to review available data on the effectiveness of prophylactic mastectomy in the prevention of breast cancer and potential policy implications. The results of this workshop may lead to future research initiatives and public and health care provider education strategies. The NCI will serve as the lead agency for this activity in collaboration with the PHS OWH.

*Activity 13: Breast Cancer Risk in Female Flight Attendants—\$250,000.*—Ongoing studies at the National Institute of Occupational Safety and Health (NIOSH) of environmental exposures, including exposures to cosmic ionizing radiation, in airplane cabins and disruption of circadian rhythms that may alter endogenous hormone levels, thereby influencing breast cancer risk in populations with high exposures will be supplemented. This supplement will assess increased breast cancer risk among female flight attendants to provide the foundation for follow up studies that will evaluate sources of risk and the impact of certain exposures on hormone levels, providing important clues about potential increased risk of breast cancer among flight attendants, female frequent fliers, radiation workers, and women who work nights or rotating shifts. Funds will be transferred to NIOSH for conduct of the study.

*Activity 14: Reproductive Status, Hormone Levels, and Breast Cancer Conference—\$250,000.*—Significant changes in reproductive patterns, such as delaying childbirth and having fewer children, as well as increasing use of hormone replacement therapy among the growing elderly population of women in the United States is raising a large number of unanswered questions about reproductive status, hormone levels and breast cancer risk. These will be addressed at a research conference to assess what is known about the role of these factors in the development of breast cancer and the changing patterns of breast cancer incidence and mortality in the United States. The PHS OWH will serve as the lead agency for this activity in collaboration with the NCI.

*Activity 15: Silicone Breast Implant Rupture Study—\$200,000.*—Ongoing collaborative studies by the NCI and Food and Drug Administration (FDA) are addressing problems of symptomatic rupture of silicone breast implants often used in reconstructive surgery for breast cancer patients. Rupture of silicone gel breast implants may be one of the most prevalent complications associated with breast implants, however, current prevalence estimates vary considerably across studies. This supplement will estimate the level of symptomatic rupture which has resulted in explant, rupture of implants explanted for other reasons, and silent rupture of implants which may have occurred. This study will allow more accurate determination of the total rupture rate of silicone breast implants, both symptomatic and silent. NCI will be the lead agency for this study in collaboration with the FDA and PHS OWH.

*Activity 16: Breast Cancer Survivorship Initiatives—\$250,000.*—The new NCI Office of Cancer Survivorship has held a series of planning activities and workshops to identify and prioritize future initiatives on the medical, psychosocial and economic issues for cancer survivors and their families. Support will be provided to further explore specific medical and psychosocial aspects of breast cancer survivorship and potential initiatives to address identified needs. The NCI will serve as the lead agency for this activity in collaboration with the PHS OWH.

*Question.* Are there priority areas beyond the six currently identified by the Steering Committee that should be pursued in the future?

*Answer.* Among the activities proposed by the OWH and NCI to be supported with fiscal year 1997 funds are a number of critical priorities including: (1) minority health issues and breast cancer, including differences in tumor biology and special issues in prevention and education; (2) genetic susceptibility to breast cancer, and (3) continued refinement and development of new imaging technologies and treatment strategies.

*Question.* How much does your budget recommend spending on the Action Plan's Activities in fiscal year 1998?

*Answer.* A specific amount has not been earmarked for the Plan for fiscal year 1998. I have asked the NAPBC Steering Committee to bring the Plan into the same budget cycle as the rest of the Department, so that funding requirements can be coordinated with the DHHS and the Congressional appropriations process. The Committee is currently in the process of doing this, and will forward their request for fiscal year 1998 to me by this summer.

*Question.* How much was expended on the Plan's activities in Fiscal year 1996 and how was it spent?

*Answer.* The Plan spent \$10 million in fiscal year 1996. These funds were spent on Working Group activities, highlights of which include:



- Funding the second year of the NAPBC grant program (\$3.5M).
- Funding a support contract that will ensure the availability of needed technical and logistical support for Program activities (\$3.5M).
- Funding a series of Working Group initiatives (\$2.8M), including, for example:
  - Developing an educational curriculum on hereditary susceptibility for health care providers.
  - Evaluating the need for and beginning the establishment of a tissue bank for research.
  - Conducting a workshop on Hormones, Hormone Metabolism, Environment and Breast Cancer and initiating development of meeting proceedings.
  - Initiating development of a breast cancer core questionnaire that will provide consistent data and enable meta analysis of survey data, thus providing sufficient power to address some of today's toughest questions about the causes of breast cancer.
- Additionally, the NCI provided support for research activities they identified to be related to Plan priorities (\$4.9M)

*Question.* How much do you estimate spending in fiscal year 1997 and for what purpose?

*Answer.* Of the total \$14.75 million available through the fiscal year 1997 appropriation, \$14 million will be spent for the 16 breast cancer research projects identified by NCI and the OWH and for continuing obligations of the NCI. We also anticipate that we will spend approximately \$750 thousand of fiscal year 1997 funds on coordination of Plan activities conducted this year.

#### MEDICAID COVERAGE OF ATTENDANT CARE

*Question.* Under Medicaid, all states are mandated to provide institutional nursing home care for eligible persons, but community-based attendant services are only a state optional service. Would you support legislation to require all states to develop attendant service programs for disabled persons of all ages as alternatives to nursing homes?

*Answer.* HHS believes that attendant service programs might be able to help reduce Medicaid costs. The Department is currently examining this policy option, and there will be a recommendation in the future.

*Question.* Has your Department developed estimates on whether cost savings could be achieved by getting people out of nursing homes and into home-based care?

*Answer.* No, HHS has not developed a cost savings estimate for this policy.

*Question.* Would you be willing to create a Personal Attendant Services Task Force, consisting of members from State Planning councils, Independent Living Councils, and Aging councils, to look at such issues as financing and eligibility standards?

*Answer.* HHS is currently considering attendant service programs as a policy option. The Robert Wood Johnson Foundation is funding a demonstration program that should be operational in January 1998. The Department is looking forward to seeing the results of this project for purposes estimating the cost effectiveness of attendant services.

#### JANUARY 30 LETTER ON MEDICARE PROPOSALS

*Question.* On January 30th, I wrote you a letter encouraging your support for carving out graduate medical education payments to Medicare managed care providers and for making provider sponsored organizations (PSO's) eligible to contract with Medicare for managed care services. Both of these proposals were brought to my attention during meetings with health care providers in Pennsylvania. Although you have not yet responded to my letter, I note that the President's budget proposes carving out graduate medical education. Would you clarify the President's proposal in this area?

*Answer.* Under the President's proposal, payments for IME, GME, and DSH would be carved out of the local payment rates over a two-year period (50 percent in 1998; 100 percent thereafter) and provided directly to teaching and disproportionate share hospitals for managed care enrollees and to entities with recognized teaching programs.

This policy would guarantee that payments designed to compensate hospitals for conducting teaching programs and for caring for the neediest citizens are made directly to such hospitals for managed care enrollees. The carve out does not represent a reduction in payment for managed care enrollees.

—Managed care plans can consider these funds available to such hospitals when they negotiate their rates.

—A current law provision that requires non-contracting hospitals to accept the Medicare DRG amount as payment in-full would be modified to require non-contracting hospitals to accept the DRG amount, minus the IME/GME/DSH carve-out, as payment in-full.

*Question.* What have you done with regard to provider sponsored organization?

*Answer.* Under the Administration's proposal, Medicare beneficiaries could enroll in a new type of managed care plan, provider sponsored organizations (PSOs). The 1995 Balanced Budget Act also permitted Medicare beneficiaries to enroll in PSOs.

PSOs would be held to all of the same standards as existing HMO's related to quality, access, marketing, beneficiary liability, benefits, and appeals and grievances.

Because of differences between the PSOs' and HMOs' delivery systems, PSOs would be subject to special standards in two areas—(1) fiscal soundness and solvency and (2) private enrollment requirements (e.g., 50/50 rule and minimum private enrollment requirements).

Unlike HMOs which provide services through contracts, PSOs would provide a substantial proportion of services directly through their own physician and hospitals. As a result, both the Congress' balanced budget bill and the Administration's proposal would subject PSOs to special standards for fiscal soundness and solvency.

The Administration's proposal would also permit PSOs to meet the 50/50 rule and the minimum private enrollment requirements in a different manner than HMOs.

—The PSO could "count" as commercial enrollees those individuals for whom the PSO was at substantial financial risk. For example, if the physician group of the PSO contracts with another HMO and receives capitated payments from that HMO on behalf of the HMO's enrollees, those individuals would count towards meeting the PSO's 50/50 requirement or the minimum private enrollment requirement for the PSO.

The Administration's bill would provide federal pre-emption of State licensing requirements in limited circumstances.

—Prior to approval of a State's certification and monitoring program for PSOs, the Medicare program would not require PSOs to be state licensed in order to obtain a Medicare contract.

—State licensing requirements would be preempted unless the State's requirements were identical to federal contracting standards.

—However, once the State has a certification and monitoring program approved by the Secretary based on its standards being substantially similar to federal standards, PSOs would be required to obtain a license from the State.

—After 1999, the State could impose more stringent standards, but these standards would have to be approved by the Secretary.

#### AVOIDING MICRO MANAGEMENT OF MANAGED CARE

*Question.* There are a growing number of bills pending in the 105th Congress aimed at resolving specific problems in the rapidly growing field of managed health care, including: "drive through" mastectomies; gag rules; emergency room care; and access to specialists. Last Congress, we enacted legislation requiring health plans to cover a minimum stay of 48-hours following child birth. But is this the best means of insuring access to quality health care for managed care participants?

*Answer.* The HCFA Office of Managed Care has analyzed many of the issues you raise in your question, including "drive through" mastectomies, gag rules, and coverage of emergency room visits. As a result of our attention to ensuring appropriate access to quality health care services for all Medicare beneficiaries, we have recently sent several letters interpreting this policy to both Medicare managed care plans and to fee-for-service contractors. We have reiterated that the law requires Medicare managed care contractors to provide their Medicare enrollees with the full range of services that are covered under Medicare and available to fee-for-service Medicare beneficiaries residing in the geographic area covered by the plan. Medicare managed care plans have been instructed that they may never establish "gag rules" that might prevent providers from advising beneficiaries of treatment options. And, in the most recent policy interpretation, HCFA sent a letter to all Medicare managed care plans, and to fee-for-service carriers and intermediaries, advising these entities that it is never appropriate for a provider—whether it be a hospital, and HMO or a physician, to adopt arbitrary coverage policies, disease management protocols, or utilization review criteria that do not take into account individual patient circumstances. All Medicare providers must make decisions about the coverage of health care services using an objective, evidence-based process that addresses the needs of the beneficiary.

Establishing specific coverage and benefit mandates by legislation should not be necessary when all providers are abiding by these guidelines. In fact, coverage requirements may not be appropriate in all circumstances, and in some cases it may not be in the beneficiaries best interest to mandate a certain minimum length of stay. Optimally, treatment decisions should be made by physicians in consultation with beneficiaries, and without interference from a third party administrator. Assuring that Medicare managed care providers have the freedom to provide enrollees with all medically necessary covered benefits and services will continue to be a focus of HCFA's routine oversight of contracting managed care organizations.

*Question.* What are your views on whether Congress should continue to micro-managed health care coverage problem by problem, or would it be better to take a "macro" management approach that sets broad standards, such as: access to specialty providers; grievance procedures; and disclosure of financial arrangements between health plans and providers?

*Answer.* Please see previous response.

#### ALTERNATIVE MEDICINE

*Question.* Madam Secretary, I wrote you on February 14th concerning the need in our country to develop a comprehensive clinical research database on alternative and complementary medical therapies with great numbers of Americans reporting the use of alternative and complementary therapies it is imperative that the federal government incorporate research and information dissemination on such practices with its traditional medical research activities. The letter requested your Department to undertake two reviews:

- (1) Review, by agency, the level and type of federal research on alternative and complementary therapies that has, and is, being supported by the federal government; and
- (2) Review the existing clinical databases that include alternative and complementary therapies, and provide an assessment to the Committee of the time and cost required to consolidate into a central database all relevant clinical literature on alternative and complementary medicine.

What is the status of this review?

*Answer.* I have recently responded in writing to your letter of February 14th. The essence of the letter is as follows:

The review you request is a large undertaking; yet there are activities that have begun in some of these areas. The Offices of Alternative Medicine and Dietary Supplements at the National Institutes of Health (NIH) have already begun development of three databases. These databases, when completed, will cover the majority of the research published in the world literature, and will encompass research supported by the NIH and other Federal agencies. The databases and the plans for their development are as outlined:

- (1) The Office of Alternative Medicine (OAM) is developing a comprehensive compilation of NIH funded research in complementary and alternative medicine (CAM). A database of research being supported by all Federal agencies and departments requires a search by hand of all relevant data sources since the available keywords are usually not useful for identifying projects in complementary and alternative medicine. This search has been done for fiscal year 1996 and is being expanded to comprise the last three years of NIH-funding. This information can be completed by NIH by the time of the August 1, 1997 interim report that you request. A plan will be developed and presented to expand this effort to other Health and Human Services agencies. In addition, other agencies, like the National Aeronautics and Space Administration, the Central Intelligence Agency, and the Department of Veteran's Affairs may have contributions to the database.
- (2) A bibliographic database of scientific literature covering all national and international publications has been started by the OAM with over 60,000 citations already entered. Construction of a worldwide database of scientific literature is a major undertaking but is being aggressively pursued. The OAM has reviewed and characterized existing bibliographic databases in alternative and complementary medicine. There are 70 such databases and about two-thirds are international in scope, providing worldwide representation. Several important impediments have emerged, including the use of multiple languages, diversity in the quality of studies, lack of uniformity of the abstracts provided, and the incorporation of proprietary data. Currently, the best strategy seems to be to create a "database of databases" allowing the user to move seamlessly across the existing databases using common search terms and technology. This approach poses challenges, but is an option which is compatible with the longer

term strategy of translating and evaluating selected scientific papers. The goal of this work is to create a valid source of information, accessible to the public, to health care providers, and to researchers through the Internet. The OAM is working closely with the National Library of Medicine on this project. An update regarding this strategic approach will be provided in the interim report.

—(3) The Office of Dietary Supplements (ODS) is working collaboratively with the OAM and the Department of Agriculture as well as with the private sector in developing two databases on botanicals and dietary supplements, one of published research and one of ongoing Federal research. The ODS expects to have an initial version of available information regarding Federal research on the Internet this spring. This activity responds to a mandate in the Dietary Supplements Health and Education Act (DSHEA). The ODS has considered the addition of research being supported by other agencies. Currently there are scientists from the Food and Drug Administration and the Centers for Disease Control and Prevention working on a detail to the ODS to implement this project. Considerable work remains, particularly in regard to the foreign literature. The bibliographic database is progressing and an early version should be available on the Internet by summer. Information about the status of these databases can be provided for the interim report and strategies for a more comprehensive databases with rough estimates of the costs, and timelines as well as the positive and negative aspects of the project can be provided for the final report on January 1, 1998.

—(4) There is currently no central entity coordinating all complementary and alternative medicine activities across the Federal government. NIH is the only Federal agency having a specific mandate to address these areas. NIH focuses its activities on biomedical research and related information dissemination. It has provided assistance, however, in coordinating joint activities with the Agency for Health Care Policy and Research, Health Care Financing Administration, the Centers for Disease Control and Prevention, state licensing boards, some sections of the Department of Defense, NASA, VA, CIA and the Department of Agriculture in other areas pertinent to CAM practice such as medical education, licensure, reimbursement and product regulation.

*Question.* Can this committee expect to have an interim report on the clinical database review by August 1st?

*Answer.* An interim report can be compiled by August 1, 1997. It will present information on: Federal research being conducted at the NIH on CAM for the years 1993–1996 and the methods of contact with other agencies; a plan for collecting information from other Federal agencies on their research support of CAM; a summary of the status of two databases on dietary supplements in the Federal government and information on the types of worldwide databases regarding published research on CAM.

By the final report on January 1, 1998, we expect to provide: an estimate of the cost and of the timelines required to gather information from other Federal agencies on their CAM research; a description of several strategies for compiling a worldwide database of published research on CAM with rough estimates of the costs and timelines as well as the positive and negative aspects of the project; a timeline for a formal needs assessment of an accessible worldwide research database; and, a demonstration of the use of databases on dietary supplements.

*Question.* Madam Secretary, given the findings reported in the January 28, 1993 issue of *The New England Journal of Medicine* that 34 percent of the people surveyed in a national sample of adults had used at least one unconventional therapy in the previous year, what justification is there for cutting the budget of the Office of Alternative Medicine at NIH by \$4.5 million?

*Answer.* Decisions on the allocation of resources within the budget of the Office of the NIH Director were determined solely by the NIH Director within the context of the overall NIH budget. It is my understanding that the fiscal year 1998 and other outyear costs of clinical studies initiated with the increases provided in fiscal year 1997 for the OAM will be picked up by the various Institutes and Centers where the studies will actually be located. I know that the Committee has a strong interest in this field and that the Committee plans to discuss this issue further with Dr. Varmus and his staff.

*Question.* What will be cut in order to absorb a reduction of 40 percent?

*Answer.* Primarily, funds for cooperative agreements for clinical studies would be reduced by \$4.1 million, or by about 50 percent, within the OAM budget compared to fiscal year 1997, with smaller reductions in the OAM support for evaluation and liaison activities. However, as discussed above, this reduction represents the fact that the outyear costs of CAM research awards initiated with the fiscal year 1997 increase will be assumed by the Institutes and Centers where the studies will actu-

ally be located. The remaining \$7.5 million included in the fiscal year 1998 request for OMB would be used for administrative costs, the clearinghouse activity, for initiating a database, and for seed money to further stimulate CAM research within the Institutes and Centers.

*Question.* How are the funds being used in fiscal year 1997?

*Answer.* A summary of fiscal year 1997 funding is shown on the table below:

*National Institutes of Health—fiscal year 1997 estimated funding for the Office of Alternative Medicine*

<i>Activity</i>	<i>Thousands</i>
Complementary and alternative medicine centers and grant cofunding .....	\$8,247
Clearing house and public information .....	550
Database and evaluation .....	350
International and professional liaison .....	150
Intramural research, research training, program support .....	2,629
Research development and investigation .....	68
<b>Total .....</b>	<b>11,994</b>

PAIN RESEARCH

*Question.* People with chronic, debilitating cancer pain often are shortchanged in getting the pain medicines they need to cope with their illness. Doctors may not be getting the information they need to make sure that their patients receive enough medication to substantially alleviate their pain. The NIH recently created a new office in pain research and the Agency for Health Care Policy Research has been conducting studies on how well doctors are informed about pain management. With millions of individuals suffering from some level of pain, I believe that this is an area that deserves substantially more attention and resources. Madam Secretary, what can be done to improve our research efforts on pain and to better the information physicians receive about treatment?

*Answer.* A number of steps have been taken to address the issues you raise. The Agency for Health Care Policy and Research has issued a series of clinical practice guidelines on pain management—for cancer pain, acute post-operative pain and low back pain. These have been widely distributed and were publicized in the news media at the time of their publication. The World Health Organization has also published cancer pain guidelines and similar recommendations on pain management have been developed and distributed by various institutes at the National Institutes of Health (NIH) as well as professional organizations such as the American Pain Society. In addition, NIH uses consensus development conferences and other forums to educate providers and members of the public on a variety of health issues, including the management of chronic pain conditions. It is important to note that part of the resistance to appropriate management of pain comes from many pain patients themselves, who either believe that it is better to be stoical in the face of pain or else fear—mistakenly—that they will become addicted.

In new efforts to enhance research and education on pain, NIH Director Harold Varmus has established an NIH Pain Research Consortium chaired by the Directors of the National Institute of Neurological Disorders and Stroke and the National Institute of Dental Research. The Consortium is made up of 21 Institutes and Offices at the NIH and has been charged to provide coordination of pain research activities across NIH, to promote collaborations, and to ensure that the results of pain research are widely communicated. This fall, the Consortium is planning a major workshop on New Directions in Pain Research that will bring together pain research investigators, and leaders in other fields of neuroscience or in related areas such as genetics and immunology. Representatives of patient groups will be invited as well.

*Question.* Several doctors have been investigated by their state medical boards, prosecuted, and even had their licenses revoked because they believed that their patients needed higher doses of medicines than what is considered normal. California, Florida, and North Carolina have issued new practitioner guidelines on pain management. Madam Secretary, is it time for your Department to think about developing a comprehensive recommendation on pain management for providers nationwide?

*Answer.* The management of pain is generally handled on a case-by-case basis. The health care provider must take into consideration the characteristics of the patient—age, health status, use of other medications, side effects and so on. The Department fully supports the clinical practice guidelines published by the Agency for Health Care Policy and Research on cancer pain, acute post-operative pain and low

back pain as well as recommendations from consensus development conferences at the National Institutes of Health. While the Department has no jurisdiction over state medical or dental boards, we can inform physicians in clinical practice through dissemination of research results, promotion of research training, and distribution of educational materials regarding best practices. Ultimately, this could lead to a broadening of the curriculums of health professional schools to include more comprehensive programs on pain problems and their management. I expect that the activities of the newly formed NIH Pain Research Consortium, as well as those of individual agencies in the Department, can be instrumental in focusing attention on management of chronic pain problems and in this way encourage adoption of appropriate guidelines nationwide.

MEDICARE PAYMENT SAFEGUARD ACTIVITIES

*Question.* As you know, Medicare contractor payment safeguard activities are sound investments for the federal government because they help to detect and reduce fraud and abuse in the Medicare program. Last year, the Kassebaum/Kennedy bill included a provision that moved the payment safeguard activities from the appropriations process to a mandatory program—to ensure an adequate and stable funding source. I am concerned by reports that although the Office of Management and Budget released the full \$440 million in fiscal year 1997 these important activities, HCFA has not subsequently disbursed the full amount to the Medicare contractors. Can you please explain why HCFA has not released the full funding and when it intends to do so?

*Answer.* As of March 26 1997, approximately \$425.4 million of the total \$440.0 million payment safeguard funds was released to the Medicare contractors. The remaining undistributed balance—\$14.6 million—supports specific program integrity special projects, and is released as the contractors complete this work. We believe that providing this funding at the time of work completion reflects our unwavering commitment to fiscal responsibility.

*Question.* Please provide an accounting of exactly how the money is being spent region by region.

*Answer.* The regional breakout of the payment safeguard funding is as follows:

*Regional breakout of the payment safeguard funding*

<i>HCFA region</i>	<i>In millions</i>
Boston .....	\$71.5
New York .....	42.4
Philadelphia .....	38.7
Atlanta .....	67.4
Chicago .....	79.9
Dallas .....	37.7
Kansas City .....	31.5
Denver .....	6.6
San Francisco .....	35.2
Seattle .....	7.9
RRB/BCA .....	5.6
Funding in transit .....	1.0
Undistributed projects .....	14.6
<b>Total .....</b>	<b>440.0</b>

VENTILATOR REHABILITATION UNIT

The Health Care Financing Administration is currently providing demonstration funding to Temple University Hospital in Philadelphia for the hospital's Ventilator Rehabilitation Unit (VRU). As the original sponsor of this demonstration, I am delighted that the project is, by every measure an unqualified success: it saves lives and money.

The VRU's innovative methods for weaning ventilator-dependent patients have had remarkable results: over 79 percent of patients, who previously would have been relegated to long-term care facilities, go home and are able to lead active, productive lives. Further, health care dollars are saved because patients do not remain in long-term care facilities for extended periods of time. The funding for this demonstration, regrettably, expires on June 30, 1997. Temple, HCFA, OMB, and the Commonwealth of Pennsylvania have been engaged in an intensive, but ultimately unproductive, effort to find a permanent funding source for the VRU. It is my hope that you will work with us to resolve this funding dilemma. I have some questions and would very much appreciate your submitting answers for the record.

*Question.* Have you had the opportunity to review this project?

*Answer.* As part of the original four-site demonstration project, HCFA contracted with Lewin-VHI to conduct an evaluation of the Ventilator Dependent Unit (VDU) (also known as Ventilator Rehabilitation Unit (VRU) Demonstration. The report was finalized in April of 1996. With regard to effects on Medicare costs, the report found that:

—Mean Medicare and total expenditures for the VDU cases during their hospital stay was substantially higher than for the non-VDU cases. This was largely due to the longer lengths of stay for VDU patients; expenditures per day for VDU cases were lower than for non-VDU cases.

More generally, based on the evaluation's analysis of costs, outcome and other factors, the report recommended that:

—National implementation with the demonstration's most effective controls on admission (following the Temple model) would have increased Medicare expenditures in 1994 by about \$0.4 billion, while implementation with ineffective controls on admission would have increased Medicare expenditures by about \$1.25.

—The findings from this study provide little support for national implementation of TEFRA cost-reimbursement for VDU-type rehabilitation units. Given admission findings, it is unlikely that sufficiently effective means can be found for limiting admission to VDUs to patients who will benefit from this type of care.

—Further, given outcome findings, it is likely that Medicare and total expenditures for patients treated in many new units would be much higher than under PPS, and that they would benefit little from that type of care.

Based on these and other interim findings, HCFA determined that it would not continue this demonstration project, and would not recommend that the VDU model be developed as part of the national Medicare program.

*Question.* Would you consider whether the VDU at Temple could be designated a Center of Excellence under the expanded definition contained in the Administration's budget proposal?

*Answer.* The goals of the Medicare Center of Excellence projects are not consistent with the current design of the VDU demonstration project at Temple University. The Center of Excellence concept, as it is described in the Administration's budget, aims at realizing savings to Medicare while improving quality of care through a bundled payment arrangement and closer coordination of care across providers for certain complex procedures. Since the VDU demonstration, in essence, permits a separate—rather than bundled—payment for VDU services, the Temple VDU model is different than the Center of Excellence concept. Therefore, it does not appear to be consistent with the goals of expanded Center of Excellence projects to include continued funding for the Temple VDU.

*Question.* Neither a SNF nor a Rehab unit designation appears appropriate for the VRU. Could your staff suggest any further funding alternative?

*Answer.* When HCFA and HHS staff originally reviewed Temple University's request to extend the VDU demonstration to June 30, 1997, it was with the understanding that this 3 year extension was to allow the Temple VDU to continue uninterrupted operations while integration with Temple's existing hospital-based skilled nursing facility was accomplished. At the time of Temple's request for this 3 year extension (in 1995), it anticipated that this 3 year extension would be sufficient to obtain State SNF certification. HCFA staff continues to believe that integration with the existing Temple skilled nursing facility is the most appropriate long term funding option for the VDU.

*Question.* Would you consider extending the demonstration authority while a permanent funding source is sought?

*Answer.* The difficulty with this suggestion is that the previous extension to June 30, 1997, was granted with the expectation that this additional time would be used to secure permanent funding through integration with Temple's SNF facility. Given the findings of the evaluation of the overall demonstration, particularly the fact that the Temple VRU project represents an additional cost to the Medicare program above that which would be expected under non-demonstration rules, it is difficult to justify further continued funding through demonstration authority. Typically, HCFA's demonstration authority is reserved for short-term policy and/or operational policy test projects which are anticipated to generate savings to the program, or at least be budget neutral while accomplishing other program improvements and innovations.

*Question.* Would you and your staff continue to work with my office to help resolve this issue for Temple?

*Answer.* We will continue to work with your office, recognizing that our primary concern must always be with the value of an arrangement to Medicare beneficiaries and to the program overall.

## HCFA/MEDICARE COVERAGE/LVRS

*Question.* Given this Committee's mandate for you to submit a report by January 1, 1997 describing a method and schedule to provide Medicare coverage and reimbursement for lung reduction volume surgery, and the multitude of favorable peer reviewed data published about the procedure since HCFA's January 1, 1996 non-coverage decision, please provide us with a preview of the report you intend to submit to Congress by April 1, 1997 regarding the timing of coverage and reimbursement for lung volume reduction surgery.

*Answer.* The report will address two major issues. The first is a review of recent published articles on LVRS. The second is the structure of the NHLBI/HCFA clinical study and how new Medicare coverage decisions will occur as new data become available from that study. Our initial conclusion from the published articles, which will require AHCPH assistance and review, is that current data support Medicare coverage only within the clinical study as is reflected in current policy. Many questions concerning outcomes and risks remain unanswered. The second issue will be concluded, as will the report, when the study protocol is completed in May. This will determine how the surgery will be provided in the study. Most importantly, if at any point in the study there is conclusive proof of benefit, Medicare will begin expanding coverage immediately.

## MEDICARE: INADEQUATE FEDERAL REIMBURSEMENT FOR CLAIMS

*Question.* I support increasing efficiencies, but I'm concerned about your proposed reductions to the Medicare contractor claims processing budget. You propose large cuts in fiscal year 1998 for claims processing unit costs, about a 15 percent cut for Part A and 18 percent cut for Part B. Considering the number of contractors that have exited the program over the past year—several, including Aetna and Many Blues Plans—and have complained about inadequate Federal reimbursement for claims processing activities, do you agree that funding for claims processing activities should at the very least, remain stable, to prevent many more contractors from dropping out the program which could hurt beneficiaries who rely on the stability of the program?

*Answer.* Providing a stable level of funding for the Medicare contractor claims processing function is an essential element of this year's request. While claims processing costs have decreased \$15.3 million from the fiscal year 1997 appropriation level, we expect that an increase in managed care enrollment will continue to slow the growth associated with fee-for-service claims processing. Moreover, HCFA expects that continued increases in operational efficiencies will allow Medicare contractors to process claims without interruption.

In the event of a contractor non-renewal, HCFA staff will work closely with each departing contractor and each replacement contractor to assure a smooth transition of Medicare workload. Medicare beneficiaries and providers in the affected States will not experience any disruption in service.

## MEDICARE TRANSACTION SYSTEM (MTS)

*Question.* In your congressional justification, you state that the "continuation of the Medicare Transaction System (MTS) is a wise decision." It is my understanding that many concerns have been raised by the Office of Management and Budget and the General Accounting Office about your management of MTS. Additionally, Bruce Vladeck was recently quoted in BNA as stating that MTS implementation probably would be delayed as a result of under funding. Can you please tell me how long a delay you expect as well as the expected total cost of MTS and how you are addressing concerns of HCFA management of MTS?

*Answer.* We are currently reassessing the MTS design in order to mitigate risk, conform to the budget pressures of fiscal year 1998 and beyond and the constantly changing Medicare operating environment. Currently we are in the process of updating cost estimates based on the latest information and when the results of that are complete, we would like the opportunity to share them with you.

OMB, HHS and HCFA have engaged in numerous discussions concerning MTS development and implementation. Both OMB and HHS agree with HCFA that significant changes need to be made in the operation and management of the Medicare program and that improvements to the program's information and processing infrastructure are necessary. Although we may sometimes disagree on methods, there is no argument on the goal. HCFA continues to work with OMB to develop an implementation strategy that balances risk and cost factors.



## MEDICARE: DISPLACED EMPLOYEES FROM CLAIMS PROCESSOR'S OFFICES

*Question.* In light of the increasing number of carriers and intermediaries who decided to scale back or end their contractual relationships with HCFA as a claims processor, what efforts will HCFA undertake to ensure that employees who may be displaced by such activities are given an opportunity to work for a new contractor who may enter that particular service area?

It seems to me that one of the criteria that HCFA should consider while making a decision is the impact that the new provider will have on these employees' jobs. The valuable services they provide should be protected as much as possible. The long-term dedication these people have demonstrated should be honored, with attention and care given to their futures. Lastly, it would be advantageous to utilize these employees because of their knowledge of the Medicare program and the low training costs which would be required rather than having to train an entirely new workforce while HCFA continues to decrease its cost per claims reimbursement.

*Answer.* HCFA recognizes the value these employees have brought to the Medicare program over the years. We work with the contractor leaving the area/program to identify those employees dedicated to Medicare activities, who are losing their jobs. We encourage the incoming contractor to offer comparable jobs to the displaced employees. Where the incoming contractor is not opening an office in the affected area, we work with the contractor leaving to find new employment opportunities for the displaced Medicare employees.

We believe that these efforts are good for the employees and for the economy of the local community.

## HEPATITIS C

*Question.* Last year the Appropriations Committee Report accompanying the Labor HHS bill noted the Centers for Disease Control and Prevention's (CDC) recent estimate that 3.9 million people are infected with Hepatitis C. The National Institute of Allergy and Infectious Diseases estimates that there are 150,000 new cases of acute Hepatitis C per year, resulting in 8,000–10,000 deaths per year. Despite these alarming estimates, I am astonished to learn that acute and chronic Hepatitis C specifically is not a reportable disease. Why isn't Hepatitis C specifically a reportable disease?

*Answer.* Acute hepatitis C is a reportable disease in all U.S. States and Territories. Chronic diseases are not reportable in any of the U.S. States and Territories primarily because available diagnostic tests for hepatitis C do not distinguish between acute and chronic or past infection.

The main purpose of acute disease reporting is to monitor trends in the rate of newly acquired disease and changes in risk group specific transmission patterns in order to determine where prevention measures should be targeted and to evaluate their impact. The cited estimates on the acute disease burden are derived from studies conducted by CDC, which has been actively involved in the surveillance for acute hepatitis C (and non-A, non-B hepatitis) since the late 1970s. The number of newly acquired (acute) infections with hepatitis C virus (HCV) has declined from 180,000 in the mid 1980s to 30,000 in 1995 for an average annual number of 120,000. Contributing to this overall decline is a decrease in transfusion-associated infections, most of which occurred prior to 1911 and a decrease in injection drug use-associated infections, most of which occurred since 1911.

*Question.* Without valid numbers, how can the prevalence and severity of hepatitis C be analyzed and how can resources be directed to persons most in need?

*Answer.* Reliable data regarding the prevalence of HCV infection is available from the National Health and Nutrition Survey conducted by CDC from 1988–1994. Based on this survey, we are able to examine both the prevalence of HCV infection, which in the United States is 1.8 percent, an estimated 3.9 million infected persons, and, thus, determine the relative severity of the disease. The prevalence of infection was higher in males than in females, and higher in African Americans than in Caucasians. The highest rates of HCV infection were found in adults aged 30–49 years. In addition, two population-based studies of patients with chronic liver disease conducted by CDC found that 40 percent to 60 percent were associated with HCV, with the most severe disease in patients with combined HCV and alcohol-related liver disease.

Though problems exist in the full reporting of Hepatitis C, data captured in the National Health and Nutrition Survey has provided meaningful information with regard to the populations most at risk. As a result, we have been able to address some of the many concerns and needs of these vulnerable populations based on the resources available.

*Question.* What is being done to ensure full reporting of chronic and acute hepatitis C?

*Answer.* Complete and reliable reporting of patients with acute hepatitis C is limited because: (1) persons with acute HCV infection are usually asymptomatic and only 25 percent to 30 percent will have signs and symptoms of illness and seek medical attention; (2) available diagnostic tests for hepatitis C do not distinguish between acute and chronic or past infection; (3) up to 20 percent of patients with symptomatic acute hepatitis C cases will have a negative diagnostic test for hepatitis C when they initially see their doctor; and (4) state and local health departments lack the resources to carry out surveillance for this disease. Thus, CDC has relied on a sentinel surveillance system involving selected counties in the U.S. to provide reliable estimates for the incidence of acute hepatitis C. However, the current number of study sites (5) do not provide an adequate number of cases of hepatitis C and we need to expand their number to accurately determine the number and source of these infections.

To address the issue of HCV-related chronic liver disease, CDC is attempting to establish sentinel surveillance. It is projected that at least five sites would be required to provide valid surveillance data. Such surveillance would provide information on the various causes of chronic liver disease, determine disease trends, and provide a means to evaluate the effectiveness of various prevention or treatment strategies. It is anticipated that funding for one surveillance site will be awarded in fiscal year 1997. Currently, death certificate data are our only means of monitoring this disease. As a result, an accurate determination of the magnitude of the problem or the etiology of chronic liver disease has been difficult to ascertain.

*Question.* It is vital that on this and all infectious diseases we educate the public as far as prevention and disease recognition. Is the CDC developing appropriate educational tools to educate physicians and health providers on effective detection and treatment strategies?

*Answer.* The Public Health Service is using three approaches to identify and educate persons at risk of HCV infection: verbal, written, and visual material directed to the public; educational efforts directed to health care and public health professionals; and development of community-based prevention programs. These educational programs are being developed through partnerships with non-governmental voluntary organizations, such as the American Liver Foundation, the Hepatitis Foundation International, the American Digestion Health Foundation, and with professional societies. Public service announcements have the potential to reach a broad population. The educational messages directed at the public will include information on who is at risk for HCV infection, the consequences of infection, the need for early diagnosis and possible treatment, and recommendations to prevent infection and transmission. Educational efforts directed at physicians and other health care professionals will include the appropriate medical management of HCV infected patients, known and potential risks for HCV infection and transmission, need to ascertain complete risk factor histories from their patients, and appropriate evaluation of high-risk patients for evidence of infection.

NIH and CDC cosponsored a Consensus Development Conference on Management of Hepatitis C that was held March 24–26, 1997, and the results will be widely disseminated. CDC is developing an interactive satellite teleconference, scheduled for broadcast November 22, 1997, to educate primary care providers regarding the screening, diagnosis, management, and prevention of hepatitis C. Written educational materials are being developed for conference attendees and will be available for wider distribution. Informational packages are also being developed for health care providers, policy makers (e.g., state and local health departments, managed care organizations, insurance companies). In addition, CDC is working with patient support groups to evaluate currently available education materials for the general public, and to develop new educational materials where needed, with a special emphasis on materials for high risk populations (e.g., injecting drug users).

*Question.* What research is CDC pursuing based on last year's Senate report?

*Answer.* An RFA will be issued this spring to provide financial assistance to a voluntary agency in fiscal year 1997 for development and dissemination of educational materials on hepatitis C.

#### HEPATITIS C: COSTS

*Question.* In this era of health care cost containment, what prevention and treatment is the department recommending to effectively minimize this catastrophic expense for end stage liver disease?

*Answer.* Hepatitis C is a major public health problem in the United States. Currently, prevention and treatment options for hepatitis C are limited. No vaccine is

available for hepatitis C. Post-exposure prophylaxis with immune globulin does not appear to be effective in preventing HCV infection, and is not recommended by the Advisory Committee on Immunization Practices. In the absence of vaccine or postexposure prophylaxis, recommendations to prevent transmission of HCV to others are limited by the extent of our understanding of the risk of HCV transmission in different settings. Although all infected patients should be considered infectious and informed of the possibility of transmission to others, no reliable tests are available that can determine infectivity. Counseling recommendations to prevent transmission of HCV to others were published by the United States Public Health Service in 1991 and disseminated widely. They were reiterated by the recent Consensus Development Conference, and they will be included in newly developed educational materials directed at both the public and health care professionals.

High-risk drug and sexual behaviors appear to account for most of the HCV infections transmitted in the United States. Unfortunately, persons with these behaviors are the most difficult to reach with prevention efforts, and there is no funding for programs aimed at the prevention of hepatitis C in these high-risk populations. Our greatest unmet need in this area is the initiation of studies to determine the dynamics of HCV infection among injection drug users. HCV is the most common infection among this risk group, even more common than hepatitis B virus and HIV. Data from such studies are needed to better target and evaluate prevention strategies.

Interferon is the only treatment licensed by the Food and Drug Administration for treatment of chronic hepatitis C. However, interferon is effective in only 10 percent to 20 percent of persons treated, it can cause severe side effects, and there is no available evidence that treatment has any effect on quality of life, disease progression, or long term outcome. In addition, this therapy has been ineffective in eliminating HCV infection in persons with more advanced stages of disease or in persons with no biochemical evidence of active liver disease. Thus, at the recent National Institutes of Health Consensus Development Conference, a panel of experts recommended interferon treatment only for a selected group of patients with chronic hepatitis C who are at greatest risk of progression to cirrhosis.

#### ALLERGIES AND ANTIHISTAMINES

*Question.* I am informed that allergies and subsequently certain treatments for allergies, impact negatively on children's learning. Educating parents and teachers as to the signs and symptoms of allergies could alleviate the problems incurred by children in whom allergies are undetected. What do you think HHS should do through the CDC to ensure that the inappropriate treatment of allergies is not contributing to the incidence and severity of asthma?

*Answer.* Asthma is the leading chronic disease among children. More than 10 million days of school are missed each year in the United States by children with asthma. CDC estimates that asthma accounted for 400,000 missed school days in Pennsylvania alone. Asthma related illnesses contribute to a child's inability to fully participate in educational, extracurricular and social activities. The effects of asthma are compounded by the fact that many symptomatic children are forced to attend school, because their parents are unable to take off from work. An additional complication of asthma is that the attacks occur without warning. This poses a problem in that most schools, as a matter of policy, do not allow children to carry their medications on them. To receive the medicine, the child needs to go to the school clinic.

Over the past several years, CDC and other HHS agencies have funded several pilot projects directed at improving medical management of asthma and reducing the number of exacerbations that often result in hospitalizations or emergency room visits. One key element of an effective asthma prevention program is to educate parents and health care providers about the appropriateness of medical management with regards to asthma and how to avoid an exacerbation triggered by allergens. CDC's goal is to expand its asthma prevention program over the next several years.

A preliminary review of the medical literature conducted at CDC in response to this inquiry did not identify any peer-reviewed publications that linked the treatment of allergies with children's learning in school.

*Question.* I am informed that Dr. Gary Kay, of the Georgetown University School of Medicine Department of Neurology, has studied and documented the adverse effects of sedating antihistamines on children's learning and worker's performance. Has the Department of HHS, or NIOSH, looked at the safety issues involved in workers taking sedating antihistamines?

*Answer.* NIOSH has not conducted research on safety issues regarding workers taking sedating antihistamines.

## H. PYLORI PUBLIC EDUCATION

A 1994 NIH Consensus Development Conference concluded that the bacterium *helicobacter pylori* causes most ulcers, not stress or diet as previously believed, and that most ulcers can be cost-effectively cured by eradicating *H. pylori*.

In response, the Senate included in its Committee Report accompanying the Fiscal 1997 Labor, HHS, Education Appropriations bill, funding for the Centers for Disease Control and Prevention to conduct a public education campaign on *H. pylori* eradication on and its link to ulcer disease. Furthermore, the Committee Report requested that CDC submit to Congress a report within 120 days on its plan to conduct such an effort and the appropriate design of the campaign. The full Congress endorsed funding for the *H. pylori* public education campaign by including language similar to the Senate's in the Conference Report accompanying H.R. 1360.

I understand that the CDC has made significant progress toward complying with the Congressionally-mandated *H. pylori* public education campaign. Consistent with Congress' recommendations, CDC organized a day long conference in January on *H. pylori* and the public education campaign where representatives from other Federal agencies, consumer organizations and the private sector met to discuss issues involved in the conduct of this campaign. I commend CDC for all its efforts to date in implementation of the Congressional recommendations.

I look forward to receipt of this report on CDC's plans for implementation of the *H. pylori* public education campaign.

*Question.* What is the timing for submission of CDC's report to Congress?

Answer. The draft plan has been developed in collaboration with public and private sector representatives and is presently in clearance for submission to Congress.

*Question.* What is CDC's calendar for full implementation of the Congressionally mandated *H. pylori* public education campaign?

Answer. CDC has begun examining existing private sector *H. pylori* communications campaigns. When this is complete, CDC will design its *H. pylori* educational campaign, with collaboration and input from private and public sector partners. It is anticipated that funds for the investigation of audience information preferences, message design, production/distribution of materials and evaluation will be obligated fiscal year 1997. The campaign is anticipated to begin in early fiscal year 1998 with evaluation commencing by the end of fiscal year 1998.

## SAMHSA AND HRSA

*Question.* Regarding the National Women's Resource Center, identify the amount of funds SAMHSA and HRSA that has been supplied to NWRC under contract for fiscal year 1997 and projected for fiscal year 1998.

Answer. SAMHSA initiated the National Women's Resource Center (NWRC) in fiscal year 1994 under a 3 year contract, originally scheduled to end in July 1997. However, SAMHSA will provide an additional \$272,000 in fiscal year 1997 to support activities and services under this contract. Also, SAMHSA is currently discussing inter-agency agreements with other Federal agencies designed to continue aspects of this program into fiscal year 1998. HRSA is expected to provide \$40,000 for fiscal year 1997 but no decisions have been made on funding for fiscal year 1998.

*Question.* Describe the chief activities and services supported by Federal funds and major increases or decreases in the level of such services, if any, anticipated for fiscal year 1998.

Answer. The National Women's Resource Center serves an important role as a focal point for information, referral, policy, research, dissemination, training, service design, technical assistance and evaluation findings of programs targeting substance using pregnant and postpartum women and their infants. The Center stimulates effective policies and practices for prevention and addresses maternal use of addictive substances and the negative consequences of maternal substance use on their infants and children.

The Center is currently developing a state-of-the-art report to the field on prevention, intervention, and treatment approaches deemed successful in combating mental illness and substance abuse in women across their life cycle. Additionally, the Center supports the following activities: develops and disseminates resource packages to the substance abuse and mental health prevention and treatment field; conducts a community team development institute designed to foster national leadership in the substance abuse and mental health areas critical to women; and maintains a 1-800 help line for appropriate information and referral. In fiscal year 1998, as the contract phases down, the Center will continue to support the community team development institute and provide limited technical assistance.

## CDC: BLOOD SAFETY

In last year's report language, the Senate Appropriations Committee expressed deep concern over the safety of our nation's blood supply and included in CDC's fiscal year 1997 appropriations increased funding to ensure that steps were being taken to address emerging infectious disease problems and to respond to critically important blood safety issues affecting all Americans, with particular concern for people with hemophilia. On blood safety, CDC was called upon to implement a strengthened blood safety surveillance system, including a serum bank for blood product recipients and patient-related outreach activities.

*Question.* How has CDC allocated funds in the National Center for Infectious Diseases to carry out the objectives set forth by Congress for fiscal year 1997?

*Answer.* In fiscal year 1997, \$400,000 of Emerging Infections resources has been provided to address blood safety issues. In addition, CDC is providing \$2.2 million in extramural funding to State and local health departments to monitor the complications of hemophilia, including safe blood and blood products. CDC is committed to ensure the safety of the nation's blood supply and is enhancing its surveillance systems to better monitor and detect adverse events among blood product recipients.

*Question.* What progress has been made in creating an active surveillance system to monitor, detect and warn of adverse effects among blood product recipients?

*Answer.* A national surveillance system is currently being established to monitor infectious disease complications among the approximately 13,000 persons with hemophilia A or B who receive care at federally funded hemophilia treatment centers (HTCs). This system will provide prevalence and incidence rates of seroconversion for viral illnesses including HIV and hepatitis (A, B, C). Cases of seroconversion will be investigated for possible association with clotting factor, which has implications for blood safety. Establishment of a serum bank is an integral part of this surveillance system. Implementation of the project will begin in the first quarter of 1997 with a gradual phasing in of the system on a national basis as resources permit. Investigational Review Board (IRB) approval has been obtained at CDC and IRB approval is currently being obtained at the local level for these activities.

*Question.* What is the status of the serum bank for blood product recipients? How much funding has CDC allocated to carry out this project?

*Answer.* Establishment of a serum bank is an integral part of this surveillance system among persons with hemophilia. CDC is working with HTCs to provide patients with free testing for bloodborne infections and to monitor and investigate possible infections. As part of these efforts, CDC also provides assistance for storage of samples for potential investigations of infectious agents. Through cooperative agreements, CDC has awarded approximately \$6 million to HTCs; approximately half of this money is being used for implementation of a national surveillance system, which includes the establishment of a serum bank for blood product recipients.

*Question.* Describe how CDC is coordinating with the hemophilia treatment centers to establish the serum bank?

*Answer.* CDC is working closely with HTCs to identify and prioritize prevention efforts for the complications of hemophilia, develop and evaluate interventions, and obtain input into the development of educational programs for health care providers and the public. CDC is also working with HTCs to determine the best means of obtaining the information needed to establish and implement the serum bank while providing the least amount of disruption to current HTC operations.

*Question.* The Committee also requested that the CDC work with the National Hemophilia Foundation in moving forward with this expanded blood safety effort. What discussions have been held to plan outreach activities with its patient groups and treatment centers as part of this strengthened surveillance system?

*Answer.* Persons who currently use blood products or who are at risk for future use should understand the purpose of CDC's blood safety efforts as well as the importance of their participation in surveillance activities. The National Hemophilia Foundation (NHF) and CDC have been working closely with consumers, health care providers, and local hemophilia organizations to plan a national conference to examine key prevention education messages and identify innovative strategies for their implementation on the local and national levels. This conference, The National Conference on Prevention Education; Health Strategies for the New Millennium, will take place in June 1997 in Louisville, Kentucky. The NHF and CDC recognize the importance of collaboration among health care providers, consumers, and peer organizations in developing a strong prevention program. Each of the 40 NHF chapters or hemophilia organizations will select four key representatives to attend the conference. These representatives will include a chapter board member or staff professional, two peer coordinators, and an HTC provider. These individuals will compose a core "team" whose members will return to their communities with information and

resources to help expand prevention education programs and practices. The conference will include a) plenary sessions with leading experts; b) breakout sessions on defining needs of audiences and strategies to influence behavior change; c) a learning center with reference materials and innovative educational techniques; d) networking opportunities; and e) a customized workbook and education guide for program planning.

CDC staff are also participating in each of the 12 regional meetings of HTC providers throughout the country to introduce the universal data collection system and provide information about CDC's surveillance activities. These meetings provide an opportunity for health care providers to offer input to CDC in the development of its programs. Consumers and health care providers are also obtaining information about CDC's prevention efforts through publications distributed by NHF, local chapters, and the Hemophilia Research Society.

*Question.* How is CDC coordinating its blood safety efforts with other Public Health Service agencies, including the Food and Drug Administration and the National Institutes of Health?

*Answer.* CDC is coordinating its efforts with other Public Health Service agencies through participation in the monthly interagency conference calls of the PHS Interagency Working Group on Blood Safety and Availability and participating in the FDA Blood Products Advisory Committee, the Blood Safety Committee, and, the soon to be convened, Advisory Committee on Blood Safety and Availability. Also, CDC has worked collaboratively with the FDA in the epidemiologic and laboratory aspects of several recent investigations related to the safety of blood products (e.g. bacterial contamination of intravenous albumin, hepatitis A contamination of clotting factor concentrates). CDC has co-sponsored, planned and participated in recent PHS public meetings related to blood safety (e.g., Notification of Plasma Product Withdrawals and Recalls and Workshop on Incentives for Volunteer Donors).

#### PROVIDER SPONSORED ORGANIZATIONS

In Southeastern Pennsylvania, Medicare managed care penetration 18 months ago was less than 10 percent. Today, it's over 30 percent and should increase to more than 50 percent by the year 2000. But the marketplace is limited to major managed care plans. Seniors have little choice. Providers say they can provide a community-based alternative to the commercial health plans that will provide equivalent service while keeping health care dollars in the community. The alternative plans would be called Provider Sponsored Organizations. The providers say they cannot contract with HCFA to be direct Medicare health plans.

*Question.* Do you support Provider Sponsored Organizations as another option for Medicare enrollees?

*Answer.* Yes, the Administration has long supported giving Medicare beneficiaries the option to enroll in Provider Sponsored Organizations, provided there are appropriate standards in place to protect beneficiaries. The President's 1998 Budget proposal contains a new PSO contracting option which will require that contracting PSOs meet existing HMO standards in the areas of quality, access, marketing, beneficiary liability, benefits, and appeals and grievances. Because PSOs have different delivery systems than HMOs, new standards for fiscal soundness and private enrollment would be applied to these entities.

*Question.* Since HCFA supports PSOs, and has in fact started a demonstration project, why have you only granted approval for six plans throughout the nation?

*Answer.* At this time, the Social Security Act does not permit HCFA to contract with any commercial managed care plan unless the plan is licensed by a state as an HMO. Therefore, the only way for HCFA to contract directly with PSOs is through the Medicare demonstration authority. HCFA has accepted 11 PSOs for participation in the Medicare Choices demonstration, a project which will give us some experience in overseeing these new managed care organizations while allowing us to test unique standards related to certification, quality monitoring and risk assumption. Four of the eleven PSOs approved for participation in the Medicare Choices demonstration have been awarded a contract and have begun enrolling beneficiaries, with the remaining 7 plans are scheduled for further review before they may begin marketing and enrollment.

*Question.* Can't we speed up the process? Can this best be accomplished through the regulatory process, or will it require legislation?

*Answer.* As stated in the previous response, HCFA does not currently have the legal authority to begin contracting with PSOs on a national basis. It is imperative that legislative standards and regulatory authority be in place before we allow PSOs—which may not be licensed as insurance products by the state, to provide services to the vulnerable Medicare populations.

*Question.* Are there statutory barriers to PSO development?

*Answer.* The primary barrier to PSO development at the federal level is the statutory requirement that all Medicare managed care plans be state-licensed HMOs. In cases where a PSO has obtained the required state licensure, federal law requires minimum commercial enrollment standards that may be difficult to meet. The Administration's PSO proposal will address these statutory barriers by amending the Social Security Act to allow direct contracts with PSOs, and by establishing federal pre-emption of State licensing requirements under certain circumstances.

*Question.* Do you support a federal process for certification of PSOs immediately upon enactment of PSO authorization for the purpose of providing care to Medicare Patients?

*Answer.* The President's budget proposal will expand the options for Medicare beneficiaries by allowing them to enroll in the same types of managed care organizations that are available in the commercial market, including PSOs. Since we will allow private enrollment determinations to be based on the number individuals for whom the PSO network providers assume "substantial" financial risk, PSOs will not have to wait for a certain level of commercial participation before applying for a Medicare contract. In addition, limited federal pre-emption of state licensure requirements will also encourage the immediate participation of PSOs. Provided that the legislative authority includes sufficient beneficiary protections, HCFA should be able to approve qualified Provider Sponsored Organizations relatively quickly, using the knowledge gained from the Medicare Choices demonstration and our extensive experience monitoring the operations of more than 300 Medicare HMOs.

*Question.* One obstacle for PSO development is HCFA's "50/50" rule which requires managed care plans that contract with HCFA to limit Medicare recipients to no more than 50 percent of their overall enrollees. Since commercial markets are already dominated by existing managed care plans, this rule can in effect keep PSOs out of certain key markets. Do you believe that the 50/50 rule needs to be changed in order to accommodate PSOs that are doing federal-only business?

*Answer.* The "50/50" rule and a minimum level of commercial enrollment are two contracting standards that were established to ensure a certain level of quality. The existence of a commercial enrollment base gives the contracting plan a basis for an accurate adjusted community rate proposal, and assures that Medicare and Medicaid beneficiaries receive high quality care that results from market competition for commercial accounts. In addition, the requirement that Medicare managed care contractors operate successfully in the commercial market demonstrates to us that the plan has experience with risk assumption and a moderately mature provider network.

As managed care has grown, and as the population ages, the 50/50 requirement has become less effective as a measure of managed care quality, and is in fact a hindrance to competition in some parts of the country. Therefore, the Administration's budget proposal will give the Secretary the authority to establish regulatory quality standards to replace the obsolete private enrollment requirements. HCFA is currently working on several broad quality initiatives such as requiring managed care plans to report HEDIS performance measures, conducting a beneficiary satisfaction survey, and testing the use of encounter data by beneficiaries in the Choices demo. The data that we glean from these projects will help us to develop a state-of-the-art quality measurement system to replace the 50/50 rule. We will continue to work closely with beneficiary advocacy groups, consumer organizations and other health care purchasers to define outcomes measures and other quality indices which will may eventually replace the 50/50 requirement.

#### CONTRACT ROLLOVERS

As I mentioned, the growth of Medicare managed care, particularly in my home state, has been spectacular. Insurers in my state say they have been signing up seniors at the rate of 10,000 a month. Current contracts between providers and managed care plans were signed before Medicare managed care gained significant market share, and those contracts are based on an enrollee base that is younger than 65, healthier, and less likely to be hospitalized. However, as Medicare managed care grew, the managed care plans rolled this new population onto existing contracts. Because this growth was not planned when contracts with providers were signed several years ago, providers have been hit with unplanned reimbursement consequences. Providers believe that Medicare managed care products should be subject to new contract negotiations with providers, rather than rolled onto existing contracts. Since Medicare managed care products are relatively new, serve a different population demographic, and are composed of enrollees that are higher-utilizers in general, this makes sense.

*Question.* Why has HCFA permitted the managed care plans to roll their new products into existing HMO contracts?

*Answer.* HCFA requires separate provider contract arrangements for the provision of services to Medicare beneficiaries served under contracts with managed care organizations. HCFA does not allow contracting managed care organizations to “roll” the requirements for coverage of Medicare beneficiaries into existing provider contracts established for commercial networks.

All Medicare contracting managed care plans must obtain separate agreements with network providers that apply only to the Medicare contract—either in the form of a new provider contract, or by amending the existing (commercial) provider contract. This separate contract or amendment gives every provider the opportunity to negotiate terms and reimbursement for the services they will provide to Medicare beneficiaries.

*Question.* (Follow-up question). In greater Philadelphia, Medicare is about 30 percent of the overall market. Given the marketplace dynamics, with most markets dominated by a few large managed care plans, providers cannot afford to be excluded from an HMO network. They have little choice but to be part of these emerging networks. But, shouldn't HCFA level the playing field as part of its role as providing oversight over the Medicare program?

*Answer.* The health care marketplace is rapidly changing for both Medicare and commercial insurers, and these systematic changes are having a dramatic effect on health care providers. As you point out Senator, Medicare makes up a significant proportion of the health care market in much of the country, and managed care program participation is increasing commensurately. Just as with the federal government's switch to prospective payment systems in the 80s, the current shifts to managed care are changing the competitive landscape for all health care providers.

Managed care companies can compete in the market by lowering prices and increasing benefits as a result of the savings they get through negotiating rates with a limited number of providers. In this competitive market, providers agree to obtain lower payment for services in exchange for a guaranteed patient volume. Individuals who join managed care plans are lured by lower premiums and increased benefits that the plan pays for with the money saved in provider payments. Given these considerations, it is obvious that there is a financial benefit to providers only when they are able to receive a certain level of capitation based on a defined number of patients. It is in the provider's best interest to keep the ratio of enrollees to providers relatively high, in order to collect more premiums from the plan. Therefore, particularly in markets with high managed care saturation like Philadelphia, some providers will not be invited to contract with certain managed care plans. But, it is just as likely that certain providers will never be willing to give up an independent practice in order to join an HMO network. In the existing health care environment, it seems logical that providers in both cases—those that are unwilling to participate in a managed care network, as well as those that are not invited to join, will face reduced fee-for-service patient volume along with decreased revenue.

One thing that HCFA cannot do is to “level the playing field” by establishing market controls that could have the effect of reducing beneficiary choice. For example, if all beneficiaries in a certain market were to choose to enroll in a Medicare managed care plan, HCFA could not deny that option to some, in order to ensure a clientele for fee-for-service providers. On the other hand, the Administration proposes to make a more level playing field for all providers in an environment of increasing managed care by expanding the types of organizations that are eligible to receive a direct contract with HCFA to provide services to Medicare beneficiaries. The President's budget proposal includes provisions which will allow provider owned managed care organizations such as preferred provider organizations, or PPOs, and Provider Sponsored Organizations, PSOs, to contract with HCFA on a capitated basis to provide eligible beneficiaries with all Medicare benefits and services.

#### AVERAGE ADJUSTED PER CAPITA COST

Medicare managed care organizations are reimbursed according to the Average Adjusted Per Capita Cost (AAPCC), which is approximately 95 percent of the PPS rate for Medicare. However, included in the AAPCC calculation is reimbursement for medical education and for treating the poor (disproportionate share). Managed care organizations do not provide these services, yet they do not generally pass on these fees to providers. In Pennsylvania, the Medicaid program this January began to reimburse providers directly for medical education and disproportionate share.

*Question.* Is it your view that graduate medical education and Medicare disproportionate share should be carved out of the current AAPCC payment?

*Answer.* Yes.



Under the President's proposal, payments for IME, GME, and DSH would be carved out of the local payment rates over a two-year period (50 percent in 1998; 100 percent thereafter) and provided directly to teaching and disproportionate share hospitals for managed care enrollees and to entities with recognized teaching programs.

The local rates are used to determine blended payment rates. Under the President's proposal, plans are paid the greater of—(1) a blend of the local and national rate, (2) a minimum payment amount (\$350 in 1998) or (3) a minimum percent increase over the previous year's rate (0 percent in 1998 and 1999 and 2 percent thereafter).

This policy would guarantee that payments designed to compensate hospitals for conducting teaching programs and for caring for the neediest citizens are made directly to such hospitals for managed care enrollees. The carve out does not represent a reduction in payment for managed care enrollees.

—Managed care plans can consider these funds available to such hospitals when they negotiate their rates.

—A current law provision that requires non-contracting hospitals to accept the Medicare DRG amount as payment in-full would be modified to require non-contracting hospitals to accept the DRG amount, minus the IME/GME/DSH carve-out, as payment in-full.

*Question.* What payment mechanism should be used to pass these dollars on to providers?

*Answer.* We believe that we already have systems that would be appropriate for making these additional payments to hospitals. Basically, when a hospital treats a Medicare managed care enrollee, it will file a bill with Medicare that contains most of the information as a regular fee-for-service (FFS) bill. These bills for managed care enrollees are commonly referred to as "shadow bills" since they are more for informational purposes. Using this bill, Medicare will be able to calculate how much GME/IME/DSH the hospital would have been entitled to under FFS, and will send that amount to the hospital through the regular billing process. We believe this is the simplest and most efficient way to make the extra payments.

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#### QUESTIONS SUBMITTED BY SENATOR COCHRAN

##### PUBLIC POLICY CHANGE: RURAL TO OTHER URBAN

*Question.* In October 1996, the Health Care Financing Administration implemented a policy that eliminated the opportunity for rural hospitals to be reclassified from "rural" to "other urban." These 28 hospitals serve a disproportionate share of indigent clients and provide needed services to rural communities. What is the public policy reason behind this public policy change?

*Answer.* When the original prospective payment system was put in place, the base payment rates for rural hospitals were lower than those for urban hospitals. The geographic reclassification process, which permitted rural hospitals to be designated "other urban" for base payment rate purposes, was designed to correct inequities arising in instances where a rural hospital shared a labor market with urban institutions, or where rural hospitals for other reasons experienced the same cost pressures as urban institutions. A legislative change effective October 1994 eliminated the base payment differential between rural and urban hospitals, except for "large urban" hospitals serving urban areas with a population greater than one million. Because of the legislative change, there is no longer any need to reclassify rural hospitals to "other urban" for the purposes of equalizing base payment rates, and the policy change put into effect in fiscal year 1996 reflects that fact.

##### FDA PROPOSES USER FEES

*Question.* The President's fiscal year 1998 budget request for the Food and Drug Administration proposes new user fees on industry. Many of us are concerned that the administration has begun funding the FDA through user fees in areas that traditionally have been mandated by the government and have been funded through the appropriation process. Could you explain the administration position?

*Answer.* The Administration's fiscal year 1998 budget request does include new user fees to partially cover the cost of FDA activities that Congress has traditionally funded through appropriations. However, FDA is not being singled out for these new fees. The President's fiscal year 1998 budget proposes new and expanded fees across many Federal programs, which serve as an integral part of the President's overall plan to balance the budget by fiscal year 2002.

FDA provides a public service by protecting consumers from unsafe and impure foods and ensuring that drugs, medical devices, and biological products are safe and effective. Industries with products under the regulatory jurisdiction of FDA benefit from increased consumer confidence in their products, and from a strong and efficient agency capable of conducting product reviews in a timely manner.

We are prepared to work with the Congress and our many constituencies, including FDA regulated industries, to develop these proposals for actual implementation. We plan to make every attempt to structure the new fees in such a way as to minimize any additional burdens on industry.

#### NHLBI: CARDIOVASCULAR DISEASE

*Question.* Mississippi has a very high rate of chronic illness such as cardiovascular disease, diabetes and stroke. What is being done at the National Heart, Lung, and Blood Institute (NHLBI) to combat cardiovascular disease and what in particular is being done to study the disproportionately higher rates of cardiovascular disease among African Americans?

*Answer.* As examples of NHLBI's efforts to combat cardiovascular disease, the Institute has several clinical trials addressing the treatment and prevention of hypertension, with a particular focus on the African American population. The Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack (ALLTPHA) is comparing four commonly used antihypertensive medications for their effectiveness in reducing the rate of heart attacks in older patients with additional risk factors. ALLTPHA has enrolled more than 10,000 African Americans among more than 26,000 patients entered to date. A second program supports a series of five coordinated grants through which investigators in five major cities are conducting trials aimed at improving hypertension control among inner-city populations. A third program, Dietary Programs to Stop Hypertension (DPSH), is conducting a series of carefully controlled dietary studies in persons with high normal or slightly elevated blood pressure, 50–60 percent of whom are African Americans, and is likely to report some important positive findings. A fourth trial, called PATHWAYS, is targeting another minority group, American Indians, in an attempt to prevent obesity in childhood.

Trials focusing on heart disease in women are evaluating the effects of aspirin, antioxidant vitamins, and hormone replacement therapy on first or recurrent heart attacks or progression of coronary heart disease. The Activity Counseling Trial seeks to learn the best of several approaches to increasing physical activity through counseling delivered in doctors' offices and clinics, for both men and women. The Rapid Early Action for Coronary Treatment Trial, is targeting whole communities, including several with large minority populations, to reduce the time for seeking acute medical care. Other ongoing trials are addressing the use of antiarrhythmic drugs compared to an implantable defibrillator to prevent sudden cardiac death in high risk cardiac patients; beta-blocking medication to prolong survival in congestive heart failure; alternative strategies for the management of atrial fibrillation, and the use of an angiotensin-converting enzyme inhibitor to prevent recurrent heart attack and death following first heart attacks. All of these trials have minority representation.

NHLBI has also been working with the NIH Office of Research on Minority Health and three institutions in the Jackson, Mississippi area (University of Mississippi Medical Center, Jackson State University, and Tougaloo College) to identify scientific priorities and implementation steps for an expansion of the ongoing Jackson component of the Atherosclerosis Risk in Communities (ARIC) study. The Institute envisions such a study, if successful in its planning and pilot phases, to become a community study in a predominantly African-American cohort similar to the Framingham Heart Study. Areas of scientific priority include: (1) studies of high rates of complications from hypertension in African-Americans, including stroke, renovascular disease, and congestive heart failure; (2) expanded studies of genetic factors related to cardiovascular disease in African-Americans; and (3) examination of cardiovascular disease and its risk factors in younger middle age (35–44) and older (70 and above) adults, to complement study subjects in the ongoing Jackson ARIC cohort.

Further, NHLBI has several health education activities as part of its national education efforts to help reduce cardiovascular risk factors in minority populations. For example, the NHLBI has funded 11 state health departments in the southeastern U.S. with high stroke death rates. A large number of African Americans reside in these states. The objectives of the projects were to implement health education activities to prevent and control risk factors of cardiovascular disease. These States

are conducting one or more of the following programs: high blood pressure control, smoking cessation, weight reduction, healthy eating, and physical exercise.

Another activity is the National Physicians' Network, a group of physicians and other health professionals who provide care to African Americans. This group has agreed to work with the NHLBI to conduct professional education training programs as well as community education programs in African American communities. Members of the Association of Black Cardiologists and the National Medical Association are the key participants in these activities.

The NHLBI has developed professional education and public education materials to help facilitate the professional education training and community outreach activities to reduce cardiovascular disease risk factors and to encourage the adoption of healthy-heart behaviors. The NHLBI has also developed an extensive public education campaign targeting African Americans. A series of 39 one-minute radio programs was developed on issues of particular interest to African American audiences as part of NHLBI's "HealthBeat Radio Network." "HealthBeat" is distributed to more than 900 radio stations across the U.S.

#### NCRR AND IDEA ASSISTING NIH GRANTS

*Question.* This subcommittee has included report language over the last several years endorsing the activities of the National Center for Research Resources (NCRR) and the IDEa program. This program is designed to assist states that traditionally have been unable to effectively compete for regular NIH grants. Please update the Subcommittee on the status of the IDEa program and any progress in improving the ability of participating states in obtaining NIH grants.

*Answer.* The fiscal year 1996 appropriation for the Institutional Development Awards (IDEa) program was \$2.1 million. A Program Announcement was issued in December 1995 for applications, which could request up to three years of support for no more than \$200,000 per year in direct costs with a requirement of matching funds by the institution. Applications were received from 12 of the 15 eligible States; they were peer reviewed for scientific merit and nine of these applications were funded. The appropriated funds for fiscal year 1997 (\$2.6 million) will be used to meet the commitments of these existing awards, and, based on peer review, to award some additional grants in the area of science education to institutions in States eligible for IDEa grants.

An evaluation of the impact of the IDEa program is being performed. Reports at meetings and discussions with grantees suggest that the program has been important in providing seed support for junior investigators until they can obtain independent funding, and in linking senior investigators with new faculty members, particularly in areas of clinical or basic science which are narrowly focused.

#### QUESTIONS SUBMITTED BY SENATOR BOND

##### EDUCATION AND TRAINING FOR CHILD CARE PROVIDERS

As we have known in Missouri for years, the early years of a child's life are a critically important time for learning. The quality of the care and education that a child receives before age five can influence all learning later in life. Children who are not cared for in an environment conducive to their growth and development often arrive at kindergarten unprepared to learn. We must provide a safe, healthy environment so that young children can grow and develop and enter school ready to learn.

*Question.* What is the Department doing to improve the training and quality of personnel providing child care services?

*Answer.* As you know, the Child Care and Development Fund (CCDF) provides states wide flexibility in setting standards for child care. States decide what kind of licensing requirements they will hold providers accountable to, and which providers will be exempt from licensing. The CCDF does, however, assure that all providers caring for children funded by the program, even license exempt care, must meet basic health and safety requirements as set by the state.

The CCDF also offers training and other supports to providers. The Act requires that states dedicate a minimum of 4 percent of their CCDF resources to building the quality and availability of child care. States can use those funds to recruit, train and support providers. Resource and Referral agencies and provider organizations play an important role in this regard by helping to link individual providers to critical resources.

The Department supports the efforts of child care grantees to improve the implementation and administration of their child care systems through a national tech-

nical assistance effort. Our technical assistance activities promote promising practices and provide information on a variety of quality activities and services.

In 1995, in addition to our national State and Tribal child care conferences and regional meetings, we held a National Child Care Health Forum through which we launched the Healthy Child Care America Campaign, a nationwide effort by health care and child care providers to improve the health and safety of children and families. Using the Blueprint for Action developed at the Forum, states and communities all over the country are making linkages between health programs and child care. We also held a national leadership forum "Including Children with Disabilities in Child Care Settings: Connections for Quality Care" in which national leaders addressed the development of an inclusive child care system for children with disabilities and shared strategies and models that can be adapted by providers in states, territories, and tribes.

In 1996, we held a similar leadership forum promoting family-centered child care to develop guidelines for state, territorial, and tribal administrators, parents, and child care providers to effectively communicate with, support, and involve families in full-day child care programs. This year we are planning a leadership forum focusing on child care as a job, which we hope will provide tools to support existing child care providers as well as those newly entering the profession.

In addition, ACF promotes quality comprehensive services and public awareness through a National Child Care Information Center that compiles and disseminates information on a variety of quality and training activities and services. We also publish a bi-monthly Child Care Bulletin that is distributed to over 2000 individuals and organizations and is available electronically on the World Wide Web and at a gopher site. The Bulletin highlights timely ideas and information to improve child care systems, program operations, and child care quality, and to expand child care services.

#### TEENAGE PREGNANCY

Teenage pregnancy has emerged as one of the most severe problems facing children and parents today. Among unmarried girls age 15–19, the birth rate has risen from 15 to 45 births per 1,000 teenagers, and more than 40 percent of young women in the United States become pregnant before they reach the age of 20, producing the highest teenage pregnancy rate of any industrialized nation. These statistics are extremely alarming, given the multiple and complex problems of adolescent pregnancy and parenthood.

I believe abstinence is the most sound teenage pregnancy approach. Also, the education and promotion of strong family values are critical in combating the teenage out-of-wedlock birth crisis. The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 establishes a new program on abstinence education.

*Question.* Has the Department established the guidelines for this program and how will this program affect existing programs?

*Answer.* On February 27, 1997, the Maternal and Child Health Bureau of the Health Resources and Services Administration published draft guidelines for the Abstinence Education provision of The Personal Responsibility and Work Opportunity Reconciliation Act of 1996. The comment period ended March 19 and final guidelines should be published by early April. Funds for the Abstinence Education Program must be used exclusively for the teaching of abstinence and may not be used for any other purpose. The Abstinence Education Program's guidance has been developed in consultation with other existing programs.

*Question.* What resources will you provide for teenagers?

*Answer.* The Abstinence Education Program was provided a mandatory appropriation of \$50 million for each fiscal year 1998 through 2002. The \$50 million appropriation will be awarded annually by a formula determined by the proportion that the number of low-income children in the state bears to the total of such numbers of children for the states. The states will be required to match every 4 dollars they receive of Federal abstinence education funds with 3 state dollars. The law says that the purpose of the funds are to enable the state to provide abstinence education, and at the option of the state, where appropriate, mentoring, counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups which are most likely to bear children out-of-wedlock. This law does not specify a specific targeted age group, but discussions with states suggest that most of the resources will be spent on preteens and young teens in the 9–14 year old range.

## QUESTIONS SUBMITTED BY SENATOR FAIRCLOTH

## SYNAR AMENDMENT

*Question.* In 1992, the Congress passed the Synar Amendment, which requires states that receive federal funds for substance abuse prevention and treatment to enact and enforce laws prohibiting the sale of tobacco to minors. HHS issues a proposed rule implementing the Synar Amendment in August 1993 but did not issue final regulations until January 19, 1996. Why did the Administration delay so long in issuing the Synar regulation?

*Answer.* Over a two year period, we carefully analyzed the public comment (over 3,000 received) and sought to develop a reasonable regulatory scheme. The comments received on the regulation prompted us to rethink our approach, in particular the issue of imposing requirements on States that would have been costly to carry out. Because of concerns about unfunded mandates, we made changes to avoid an overly burdensome regulation while fulfilling the propose of the legislation. In addition, we tried to be as thorough as possible in our planning, review, and implementation process to ensure a strong, quality regulation.

*Question.* The delay in issuing final regulations means that state enforcement efforts have only recently begun. Given this Administration's emphasis on preventing underage tobacco use, how can the delay in implementing the Synar Amendment be justified? (CSAP)

*Answer.* SAMHSA and the Department fully supports the implementation and enforcement of the Synar Amendment. Given the number and complexity of the issues raised during the public comment period on the Notice for Proposed Rulemaking, SAMHSA drafted an implementing regulation that is both responsive to the concerns of the States, retailers, anti-tobacco advocacy organizations, etc., as well consistent with the intent of the legislation. The delay in implementing the Amendment was necessary, in order to ensure that the final rule would result in effective enforcement of State youth tobacco laws and ultimately a reduction in youth access to tobacco.

*Question.* The delay in issuing final regulations means a delay in measuring the effectiveness of the Synar Amendment on youth smoking rates. Why was not the FDA rule deferred until the initial effectiveness of the congressionally-mandated solution could be determined?

*Answer.* The Department did not delay the implementation of the FDA rules (in order to measure the effectiveness of the Synar Amendment) because it considers both the FDA rules and the Synar Amendment critical components of a comprehensive approach to reduce tobacco use nationally. This approach consists of a three pronged strategy—limiting the accessibility, availability and appeal of tobacco products to minors. The implementation of the Synar Amendment addresses only one needed piece of this larger strategy—access.

The Department supports the careful coordination and implementation of all three elements of this strategy in order to achieve the targeted reductions in youth tobacco use set by this Administration (reduce youth use of tobacco by 50 percent in the next seven years). This comprehensive strategy requires the effective enforcement of State laws, limitations on the placement of vending machines, banning of self-service displays, restrictions on tobacco advertising that appeals to children, and strong community mobilization efforts. It also requires the coordination and cooperation of resources at the Federal, State and local levels.

*Question.* HHS took two-and-one-half years to review fewer than 400 comments filed in response to its proposed regulations implementing the Synar Amendment. The FDA, however, reviewed 710,000 comments filed in response to its proposed tobacco regulations in only a little more than a year. How can you explain this vast discrepancy, especially since the Synar Amendment was passed by Congress, while FDA was never given congressional direction to promulgate its tobacco regulations?

*Answer.* Youth tobacco use is a public health issue of major importance to the Department and to SAMHSA. We believe limiting youth access to tobacco is only one of many strategies that are necessary to reduce youth tobacco use. Many factors contribute to youth tobacco use, including access, availability, and appeal. A comprehensive approach is necessary to reduce youth tobacco use. The Synar Amendment is one aspect of that approach.

As such, SAMHSA received and carefully analyzed over 3,000 comments from the public and sought to develop a reasonable regulatory scheme. We tried to be as thorough as possible in our planning, review, and implementation process in order to ensure a strong, quality regulation.

In particular, the comments prompted us to rethink our approach to implementation of the Synar Amendment to allow for greater state flexibility and to address

the issue of unfunded mandates. We tried to balance flexibility for the states with the need for scientifically sound methodology in conducting inspections and collecting data. We believe this ultimately resulted in a quality regulation that will reduce minor's access, while providing states with the flexibility they need.

Since the Synar Amendment was passed in 1992, we have taken our responsibility seriously and continue to do so. Following the release of the regulation in 1996, we conducted two technical assistance conferences and provided states with three guidance documents to assist with sampling, inspection, and implementation strategies. We have been in regular contact with the states and have worked closely with states having difficulties implementing the regulation. We anticipate that all states will have a failure rate of no more than 20 percent by the year 2003 and that this will, in turn, reduce youth tobacco use by approximately 15–20 percent.

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QUESTIONS SUBMITTED BY SENATOR INOUE

RESEARCH CENTERS IN MINORITY INSTITUTIONS

*Question.* What has been the changes in co-funding for the RCMI program since fiscal year 1995 and what has been the budgetary impact of the downturn in co-funding on the RCMI program since that time?

*Answer.* Collaborative efforts between NCR's RCMI Program, the NIH Office of Research on Minority Health, and the National Institute of Allergy and Infectious Diseases (NIAID) provided co-funding respectively for fiscal years 1995, 1996 and 1997 as follows: \$5.37 million in 1995; \$2.33 million in 1996; and \$2.25 million is anticipated in fiscal year 1997. This downturn in co-funding has necessitated making the RCMI program more competitive. This is consistent with the goals of the program since each RCMI faculty investigator is expected to generate independent research support in order to decrease dependence on the RCMI support. This frees up resources; the grants received by RCMI faculty generate resources to support RCMI-provided core facilities through fees for services.

*Question.* What efforts are under way to increase co-funding available to the RCMI program?

*Answer.* As indicated above, NIH does not anticipate an increase in co-funding support for the RCMI program in fiscal year 1997. However, plans are evolving between the RCMI community, NCR, and six NIH Institutes (the National Institute of Neurological Disorders and Stroke, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Child Health and Human Development, the National Eye Institute, and the National Institute on Drug Abuse) to develop partnerships with RCMI institutions. Cofunding to develop NIH's neuroscience initiative at RCMI institutions is a possibility.

*Question.* One of the elements in all of the RCMI applications is pilot projects. What happens to the faculty investigators after they are no longer supported by the RCMI program?

*Answer.* Approximately one-third of the support provided through the RCMI program is for pilot projects. Support for these pilot projects is augmented through collaborative efforts with the National Institute of Allergy and Infectious Diseases (NIAID), which co-funds many of the AIDS and AIDS-related research projects. The published RCMI program policy allows support for these pilot projects for five years. From our experience with the RCMI program, as well as other programs, this should allow sufficient time for researchers to develop productive laboratories that can compete for independent research support.

*Question.* Are there ways within the NCR that these individuals could be provided an intermediate step to more competitive grants?

*Answer.* The NIAID has expanded its collaboration with the RCMI grantee community by providing transitional support for many of the RCMI investigators that they have supported to collaborate with some of their more experienced investigators.

*Question.* Is there adequate representation of RCMI institutions on the RCMI review committee?

*Answer.* Presently, two out of sixteen members of the Research Centers in Minority Institutions (RCMI) Review committee are from RCMI institutions. Proposed plans are to increase RCMI membership to three. Present and proposed minority representation on the committee exceeds 60 percent. Since the purpose of the review committee is to review the scientific merit of the proposals and to evaluate the overall organization and functioning of these centers, NIH regards the proposed membership (nearly one-fifth) from RCMI institutions as adequate to provide appropriate input into the review process about RCMI institutions.

*Question.* Since service on study sections is very educational, are faculty from the RCMI institutions routinely used as members of all the NCRR committees and site visit teams?

*Answer.* Members of standing committees are selected according to the expertise needed to review applications submitted to that particular committee, paying attention to appropriate representation of women and minorities and geographical distribution of the members. For membership on review committees, candidates must have an established publication record and active peer-reviewed grant support, except for administrative reviewers.

Currently, the RCMI Review Committee has two members out of sixteen from RCMI Institutions; the General Clinical Research Centers (GCRC) Review Committee also has two; the Comparative Medicine (CM) Review Committee has one; and the Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities has one member. The Special Emphasis Panel (SEP) does not have a set membership. When SEPs review applications for NCRR, faculty from RCMI and other minority institutions are regularly asked to participate in the review process. Representation may vary between one and eight per meeting, depending on availability and nature of applications that are being reviewed. However, to avoid conflict of interest, as part of the NIH peer review policy, program directors and principal investigators of competing applications may not serve on the committee when their application is being reviewed. Minorities, including those from RCMI institutions, are invited to serve as Temporary Members on the standing committees to augment the expertise needed to review grant applications.

Members of site visit teams are selected for their expertise in a narrow or broad area of biomedical and behavioral sciences, paying attention to selection of women and minorities, within our ability to identify such scientists. For the most part, site visit team members are expected to be established scientists, physicians, and veterinarians with an excellent publication record, who have no conflict of interest with the institution to be site visited or protocols to be reviewed. Current peer-reviewed support is preferred, but is not required.

In addition, architects, computer specialists, and hospital administrators may be invited on site visits as needed. The CM Review Committee does very limited numbers of site visits, one or two per year, and minority investigators, some of whom are from RCMI institutions, are routinely asked to participate in the site visit. Site visit teams for the RCMI Review Committee always have several RCMI institution representatives on the site visit team. The GCRC Review Committee has the most site visits, and scientists from minority institutions are invited to participate. The two members from RCMI institutions actively participate in site visit. The Office of Review invites scientific reviewers from RCMI institutions who have the appropriate scientific expertise for protocols under review and are available to attend the site visit when they are scheduled.

*Question.* How many institutions are now supported by the RCMI clinical initiative?

*Answer.* The purpose of the RCMI Clinical Initiative is to assist eligible grantees with affiliated medical schools to develop an expanded capacity for clinical research by providing some of the resources that are needed to develop the relevant infrastructure. The long-range objectives of this initiative are to (1) assist the participating institutions to conduct clinical research which will improve the health of the Nation's citizens, especially racial and ethnic minorities; (2) enhance the clinical research capacity of RCMI-eligible institutions with affiliated medical schools; (3) position these medical schools to compete successfully for clinical research support; and (4) enhance the probability of success in competing for resources to establish a productive, free-standing Clinical Research Center (CRC).

Six RCMI grantees with affiliated medical schools are supported through this RCMI clinical initiative, including Meharry Medical College; the Morehouse School of Medicine; the Medical Sciences campus of the University of Puerto Rico; Universidad Central del Caribe; Charles R. Drew University; and the University of Hawaii. These awards have five year commitments. Another RCMI grantee institution with an affiliated medical school, Howard University, is now receiving support for developing its clinical research capacity through NCRR's General Clinical Research Centers Program. Thus, seven of the eight medical schools are receiving support for expanding their participation in clinical research from NCRR.

*Question.* What is the annual cost and what impact has this had on the RCMI program since no additional funds have been requested for this special initiative that the Congress urged?

*Answer.* The costs for RCMI clinical this initiative were \$4.5 million in fiscal year 1996 and \$4.6 million in fiscal year 1997. This initiative is a natural outgrowth of

the mission of the RCMI Program and a logical redirection of program funds supports this initiative.

*Question.* Since the RCMI program is in its eleventh year, are steps on the way to evaluate the program? Please provide some examples of additional scientific highlights that have emerged from the grantee institutions?

*Answer.* The NCRP has requested funds from the 1 percent program evaluation set-aside to evaluate the RCMI program in fiscal year 1997. We hope to assess the areas of success and failure so that the program can be modified to take the fullest advantage of the best ways to enhance competitiveness.

The following are some examples of recent scientific accomplishments at RCMI institutions:

RCMI investigators, collaborating with scientists at Albert Einstein College of Medicine, have demonstrated significant inhibition of HIV-1 replication by nontoxic doses of L-cycloserine (L-CS) in a CD4+ cell line. They discovered possible mechanisms of action, which appears to be indirect, via interactions with cellular components rather than through direct antiviral action. It appears that drugs that interfere indirectly with viral production are less likely to be rendered ineffective due to rapid viral mutation. The in vitro effective dose of L-CS was also nontoxic in animal experiments. These results are encouraging and may lead to new strategies for viable complementary or alternative treatments for HIV-1 infections in humans.

Other RCMI investigators, studying the mechanisms involved in the major increases in programmed cell death observed in peripheral blood lymphocytes (PBLs) in HIV-positive patients, found a high correlation between the extent of apoptosis and impaired production of the cytokine lymphotoxin. This study supports the hypothesis that all HIV-positive patients have defective immune systems and provides evidence that apoptosis is an important factor contributing to the massive depletion of CD4+ cells during the progression of the HIV-disease. These observations represent an important step in further understanding the mechanisms ultimately responsible for apoptosis induction in lymphoid cells from HIV-positive patients, which could eventually lead to effective preventive or therapeutic treatments.

RCMI faculty using molecular endocrinology techniques, including hybridization histochemistry, have identified the cells making the hormone relaxin. They have shown also that relaxin acts on the cells of the fetal sac surrounding the baby by producing enzymes which degrade the structural collagen in the membrane. If this sac breaks, the baby is born prematurely. Therefore, too much relaxin production may result in weakening of the membrane, predisposing it to premature rupture and consequent premature birth. These studies provide insights at the molecular level which are essential to developing strategies for preventing preterm births, which occur with significantly higher frequencies in minority populations in this country.

Scientists in the RCMI-supported neuroscience program at Meharry Medical College, exploring the functions of a newly isolated brain peptide, have found that nociceptin appears to inhibit pain. The new findings suggest that nociceptin's effects on brain neurons are similar to those of other opioid molecules that relieve pain, which is critically important in addressing both economic and quality of life issues associated with chronic and intractable pain.

*Question.* What percent of the NCRP budget has a direct affect on minority institutions? How does this compare to National Institute of General Medical Sciences where the MARC and MBRS programs are housed?

*Answer.* About 8 percent of the NCRP appropriation has a direct impact on minority institutions. About 6 to 7 percent of the National Institute of General Medical Sciences total appropriation has a direct impact on minority institutions.

*Question.* Since the budget request for construction is \$16 million less than what was appropriated last year, is this based on a reduced need that is evident by a decrease in the number of applications?

*Answer.* While there is a strong demand by universities and institutions for funds for research facility construction, NIH chose to reflect its higher priority for the support of research project grants. Much if not all of this demand is met through the \$3 billion the Federal Government spends on indirect costs of research grants, which support research facility construction requested in the fiscal year 1998 budget.

*Question.* Does this mean that there was limited participation in the grantsmanship workshop which the Congress urged to level the playing field for minority institutions by providing them the proper "coaching"?

*Answer.* The grantsmanship workshop which was conducted by NCRP in December was attended by representatives of over 70 institutions, including seven from Centers of Emerging Excellence. The NCRP has received 80 applications for the fiscal year 1997 program.



## QUESTIONS SUBMITTED BY SENATOR BUMPERS

## MEDICAID CAP

I understand you plan to use a portion of the savings from the Medicaid cap for several children's health initiatives. One is the proposal to provide continuous Medicaid coverage for children—that is, to allow states to provide continuous coverage for one year after eligibility is determined, regardless of a change in the family's income status.

*Question.* How many states will exercise this option, and how many children will be affected?

*Answer.* There is no way to determine how many states will participate in this program. However, we estimate that about half of the eligible children—1 million—will benefit from these provisions.

*Question.* What is the estimated cost of this proposal?

*Answer.* Our cost estimate is \$3.7 billion over five years, with an initial cost of \$3 billion in 1998.

## HEAD START

*Question.* You are proposing another large increase in funding for Head Start. I am concerned again this year about the fact that spending on this program has grown dramatically over the past 5 years without a parallel growth in the number of children served. Since 1992, Head Start funding has grown from \$2.2 billion to nearly \$4 billion—an 80 percent jump in spending. But the enrollment has increased from 30 percent to just 40 percent of the eligible children. I realize some funds have been devoted to quality improvements, but how do you explain such a disappointing rate of enrollment growth in the face of such generous increases in funding?

*Answer.* Over the past five years, the Department has worked to balance the goal of reaching more of the unserved children who need Head Start services with the goal of ensuring that Head Start programs provide effective, high quality services. In 1993, the "Report of the Advisory Committee on Head Start Quality and Expansion" laid out a series of recommendations that included improving staffing and career development, improving the management in local programs, providing better facilities, providing longer services and strengthening the role of research. Steps were also taken to improve Federal oversight and better assure program accountability. The report also recommended expanding services in a way that better meets the needs of children and families, such as providing more full-day services so families can enter the work force.

The expansion and improvement of Head Start has been an important goal of the President and the Congress in recent years. The program has received \$1.8 billion in increased funding since 1992. Approximately 40 percent that amount has been used for statutorily mandated increases to (1) offset the rise in the cost of living, (2) improve program quality and (3) fund training and technical assistance activities. Beyond these mandates, grantees were given the authority to use approximately 10 percent of the total funding increase to make further needed improvements in program quality. These improvements included:

- increasing staff salaries and benefits, for example, average teacher's salaries have increased by over 25 percent to approximately \$17,500;
- hiring needed and better qualified staff to work with families;
- improving facilities and replacing equipment such as school buses; and
- extending the program day for more than 100,000 children to allow children to remain in Head Start for longer periods of time.

The remaining half of the funding increases since fiscal year 1992 have been used to serve additional children, increasing enrollment from 621,078 to a projected 800,000 children in fiscal year 1997, an increase of almost 30 percent. Approximately 22,000 of these additional children are infants and toddlers, who are provided Head Start services under the authority of the recently established Early Head Start program.

In fiscal year 1998, we are proposing to increase enrollment by another 36,000 children above the projected fiscal year 1997 enrollment of 800,000. This will enable us to continue our progress towards meeting the President's goal to serve 1 million children in Head Start by fiscal year 2002.

## GLOBAL POLIO ERADICATION

I want to commend the administration again this year, and particularly you and Dr. Satcher, for the fine work you have done on global polio eradication. My only concern about the program at this point is in the area of staffing. Last year we were

given a commitment by CDC to increase staffing the polio by 25 FTEs. I understand that CDC intends to honor the commitment but that there has been some administrative delay.

*Question.* Is this the case, and when do you anticipate allocating those new positions?

*Answer.* Immunization, in particular global eradication remains a high priority at CDC. CDC has allocated 25 additional FTEs to the National Immunization Program in fiscal year 1997 for global polio eradication.

#### VACCINE EXCISE TAX

The Administration has an unusual request regarding excise tax for pediatric vaccines. As I understand it, you are proposing to exempt the federal government from its statutory obligation to pay excise tax to the vaccine injury compensation fund for the vaccine it purchases, but continue to require state and local governments as well as private providers to pay taxes into the fund. Further, you score this proposal as a savings and then assume that the savings will be reallocated for discretionary spending. I have a number of questions about this proposal, which, I understand, did not originate with your Department:

*Question.* What is the justification for exempting federal purchases from the current statutory requirement?

*Answer.* The proposal to exempt the Federal government from the current statutory requirement of paying excise tax on purchases of vaccine is proposed for one year only. With this exemption, CDC would only need \$365 million in fiscal year 1998, as opposed to \$427.1 million—and still meet all the vaccine needs for States. The excise tax for vaccines is intended to provide funding to compensate children and their families who suffered certain adverse events following immunization. The vaccine compensation trust fund currently has a balance of over \$1 billion. Therefore, excise tax revenue from non-federal vaccine purchases would be more than sufficient to compensate potential claims.

*Question.* How would the savings referred to in the budget be scored—wouldn't a reduction in payments by CDC also be treated as a reduction in receipts to the compensation fund and therefore yield no overall budget savings?

*Answer.* Because the President's Budget proposes to exempt Section 317 from payment of these taxes, funding for its operations can be reduced by this amount without affecting the amount of vaccine the program purchases. Receipts lost by the exemption of Section 317 from the excise tax are not scored, since the effects on tax receipts of changes to discretionary programs normally are not scored under the Budget Enforcement Act.

*Question.* Have you done calculations to determine how long it will take under your proposal for the compensation fund to show significant losses and jeopardize the viability of the injury compensation program?

*Answer.* As stated above, this proposed exemption is requested for one year only. As a result of the sizable balance in the vaccine compensation trust fund, currently \$1 billion, excise tax revenue from non-federal vaccine purchases would be more than sufficient to compensate potential claims. At the beginning of the next fiscal year the Administration expects that federal payment of excise tax would resume, and the substantial balance in the compensation fund would continue to grow. As a result, the viability of the injury compensation program would not be jeopardized in any way.

*Question.* Have you consulted with parent and child health advocate groups about the significance of federal government abrogating its responsibility for contributing to the injury fund?

*Answer.* As stated earlier, the proposed exemption is requested for one year only. To date, since this proposed exemption is limited to one year child health advocate groups have not been consulted regarding this request. It is expected that federal payments will resume in fiscal year 1999. The sizable balance in the vaccine compensation trust fund, currently \$1 billion, excise tax revenue from non-federal vaccine purchases would be more than sufficient to compensate potential claims. As a result, the Administration is committed to protecting the viability of the injury compensation program.

*Question.* What is the status of the "flat tax" proposed by the administration during the last Congress?

*Answer.* The Administration is no longer pursuing the "flat tax" proposal.

#### PRICE CAP ON VACCINES

*Question.* I understand that CDC has used an administrative mechanism to lift the price cap on a number of vaccines covered under the Vaccine for Children au-

thorization legislation. What are the criteria for determining whether the price cap should be lifted?

Answer. There is no administrative mechanism for lifting the price cap and CDC has never “lifted” the price cap, but rather has not applied the price cap for some vaccines, because the product in question was not being purchased as of May 1, 1993. CDC examines the language of contracts in effect in May 1993 to determine if it is necessary to change the description of product indications in order to receive the desired product(s). If a change in the language is needed, the CDC believes it is negotiating a price for a new vaccine, i.e., “a vaccine for which the CDC had no contract in effect under section 317(j)(1) of the Public Health Service Act as of May 1, 1993, in children 2 months of age and older.” Therefore, imposition of a price cap would be inappropriate in accordance with paragraph (C) of 42 U.S.C. 1396s, cited below.

*Negotiation of Discounted Price For Current Vaccines.*—With respect to contracts entered into under this subsection for a pediatric vaccine for which the Centers for Disease Control and Prevention has a contract in effect under section 317(j)(1) of the Public Health Service Act as of May 1, 1993, no price for the purchase of such vaccine for vaccine-eligible children shall be agreed to by the Secretary under this subsection if the price per dose of such vaccine (including delivery costs and any applicable excise tax established under section 4131 of the Internal Revenue Code of 1986) exceeds the price per dose for the vaccine in effect under such a contract as of such date increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from May 1993 to the month before the month in which such contract is entered into.

*Negotiation of Discounted Price For New Vaccines.*—With respect to contracts entered into for a pediatric vaccine not described in subparagraph (B), the price for the purchase of such vaccine shall be a discounted price negotiated by the Secretary that may be established without regard to such subparagraph.

*Question.* Please describe the review and decision process within CDC and the Department for making such determinations.

Answer. CDC examines the language of contracts in effect in May 1993 to determine if it is necessary to change the description of product indications in order to receive the desired product(s). When CDC makes a decision about whether the price cap should be applied to the product, the Department is notified.

*Question.* Does CDC consider a change in FDA labeling or a change in the recommended use of the vaccine a legitimate basis for lifting the cap?

Answer. In accordance with Paragraph (B) of 42 U.S.C. 1396s, there has been no instances in which the CDC has renegotiated a price cap for a vaccine which under contract language of May 1, 1993 could have been purchased for the new indication or labeling change. No “exceptions” have been made because of changes in recommendations or FDA labeling changes. Indeed, most vaccines have undergone these kinds of changes since the passage of OBRA 1993. Had the CDC been renegotiating price caps based upon such factors, virtually none of the vaccines being purchased today would fall under a price cap.

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#### QUESTIONS SUBMITTED BY SENATOR KOHL

##### UNLICENSED CHILD CARE SERVICE UNDER THE WELFARE REFORM LAW

The welfare reform law encourages states to put welfare recipients in unpaid, unsupervised child care community service jobs. It’s hard to believe, but there are no training or licensing standards for these child care workers and the care could occur in unsupervised settings. Probably no other community service job would be allowed without supervision, yet the assumption is that it’s O.K. for child care workers to go it alone.

Scientific research on early childhood development is proving again and again that to maximize a child’s learning potential, they must have access to productive, educational care in their early years. If we are ever going to break the cycle of poverty, we must not skimp on the quality of child care.

*Question.* There is nothing wrong with welfare recipients becoming child care providers, but shouldn’t there at least be some level of training and supervision?

Answer. We agree. Not only should there be appropriate training and supervision, but providers must also have an interest in providing child care. Welfare recipients who do not want to be child care providers and who have not received proper training may not provide appropriate care. Research has demonstrated that child care providers who are committed to taking care of children offer more responsive and overall better quality care than those who are not committed to the profession of

child care. Group child care is work that takes dedication, skill and specialized preparation.

Although there is no federal training standard for child care, the Child Care and Development Fund program requires that each state, at a minimum, set standards for health and safety training for providers. There are a number of recognized credentialing programs for providers in the field of early care and education that states can draw from in developing their standards. The Head Start program, for example, includes performance standards requiring each classroom to include at least one teacher who has a Child Development Associate credential, an early childhood degree, or a state early childhood certificate.

In addition, the American Public Health Association and the American Academy of Pediatrics, under a grant from the Maternal and Child Health Bureau, has developed the Caring for Our Children—National Health and Safety Performance Standards: Guidelines for Out-of-Home Child Care Programs. The National Performance Standards is a comprehensive set of recommended national standards for health and safety of children in child care that includes training of child care providers. This document represents a consensus of the various disciplines involved with child care, with particular emphasis on the health specializations.

*Question.* Do you believe that this provision should be amended to require training and supervision for welfare-to-work activities that involve child care?

*Answer.* We believe appropriate training is critical for all child care providers. At a minimum, all child care providers should meet State requirements for training and supervision, particularly pertaining to health and safety. To create a planning and regulatory analytical tool from the comprehensive volume of National Health and Safety Performance Standards, the Maternal and Child Health Bureau recently developed Stepping Stones to Using Caring for Our Children. Stepping Stones identifies those standards most needed for the prevention of injury, morbidity and mortality in child care settings. Stepping Stones supports state licensing and regulators, state child care, health and resource and referral agencies as well as other public and private organizations that need to focus their efforts in order to target limited resources effectively. These standards provide a critical and sensible starting point for state administrators planning policy and regulations revisions. We recommend that all States adopt the Maternal and Child Health Standards.

*Question.* Congress will be considering legislation to make technical corrections to the welfare law. Do you plan to include changes to this provision in the Administration's recommendations?

*Answer.* No, we did not propose technical corrections to require training and supervision for those child care workers. While we believe training is critically important, we did not believe that such an amendment would be considered strictly a technical correction.

#### CHILD SUPPORT SAVINGS

As you know in December 1996, the HHS' Inspector General's (HHS-IG) office issued a report regarding noncustodial parents incorrectly claiming custody of children on Federal income tax returns. The report suggested that we could solve this problem administratively and cost-effectively by exchanging information between IRS and the Office of Child Support Enforcement (OSCE). Furthermore, the report suggested that the necessary information is readily available, or will be by the end of 1997, on most state database systems.

*Question.* What problems or concerns have you encountered as an administrator of the current tax refund offset program?

*Answer.* The program runs smoothly and has been very productive. For tax year 1995, the Federal government collected a record of over \$1 billion in delinquent child support by intercepting income tax refunds of parents owing past due support. The amount was 23 percent higher than the previous year, and up 51 percent since 1992.

*Question.* What would be the pros and cons of exchanging custodial data between the IRS and the OCSE?

*Answer.* The major advantage of providing the IRS with data from the Office of Child Support Enforcement is improved tax compliance. Such information will allow the IRS to improve compliance with tax laws involving duplicate or erroneous claims for dependency exemptions, earned income tax credits and head of household filing status. We believe that the use of this data as part of ongoing revenue protection programs could prevent a significant portion of the \$1.4 billion per year that is lost to the tax system through these inappropriate filings. We also believe that such a program could have a significant positive effect on payment of child support on the part of non custodial parents. Once it is made clear to these individuals that child

support payments must be made before any tax advantages are allowed, compliance with support orders may increase.

The main disadvantage is the administrative cost of obtaining the data and providing it to IRS. However, we believe this cost would be relatively small compared to the savings that would be achieved. The State Child Support Enforcement agencies are working toward implementing their child support management information systems. When these systems are certified, States will have centralized, computerized files containing the information needed by IRS, at least for the VI-D population. We recommend using only data from certified systems. This will not only reduce the cost, but will also ensure the accuracy of the data. Additionally, with the implementation of the Federal Case Registry of Child Support Orders, as required by The Personal Responsibility and Work Opportunity Reconciliation Act of 1995 (Public Law 104-193), some information will be available from State court orders on all dependent children. Through appropriate planning, information for dependent children can be available to aid in the construction of appropriate revenue protection programs by the IRS.

*Question.* What additional statutory authority would be required for OCSE, in coordination with State agencies, to compile this data for use in a reimbursable program modeled after the current child support refund offset program?

*Answer.* Legislation is needed to allow transmission of the necessary data to IRS from a privacy standpoint—i.e., that the privacy of personally identifiable information about the children and their parents would not be violated by the transfer of data to IRS. Language could be added to minimize the amount and safeguard the privacy of the data transmitted. Above and beyond that, requirements for OCSE to transmit the data and for IRS to receive and use it for tax collection oversight would also be needed.

It is important to note here that we would not necessarily recommend a program modeled on the current child support refund offset program. The IRS is best suited to determine the most efficient way to use this data; and we would defer to IRS to propose the specific approach to be used.

#### NATIONAL INFERTILITY PREVENTION PROGRAM/CDC

The National Infertility Prevention Program currently does not allocate funding to Regions and States in proportion to the need. For example, Region V States currently have 19 percent of the total number of women ages 14-44, yet it receives only 9 percent of the total allocation for Infertility Prevention.

*Question.* With the plan to expand the National Infertility Prevention Program nationwide, how does CDC propose to allocate the funding to the Regions and States to achieve an overall balance in funding?

*Answer.* The Infertility Prevention Program was initiated as a result of the Preventive Health Amendments of 1992. At that time, the CDC estimated the annual cost of a nationwide program to reduce preventable infertility by controlling chlamydial infections to be \$175 million. This included an estimated \$90 million in federal, public sector funds, with the recognition that a substantial portion of chlamydia detection and treatment currently occurs in the private sector and that an augmented public-private prevention partnership must continue into the future.

Initial chlamydia prevention efforts have been implemented in a phased approach due to limited resources. To date, of the \$90 million required for public sector coverage, only \$13.2 million has been appropriated to begin to build chlamydia prevention efforts.

A demonstration project focusing on screening for chlamydia in reproductive age women was initiated in 1988 in PHS Region X (AK, ID, OR, WA) and by 1995 had reduced the rates of chlamydial infection by 65 percent. In 1994, through a combination of grants to state STD prevention programs and an interagency agreement with the Office of Population Affairs, CDC supported expansion of the successful model in Region X on a demonstration basis to three additional PHS regions, a total of 20 states (III—DE, DC, MD, PA, VA, WV; VII—IA, KS, MO, NE; VIII—CO, MT, ND, SD, UT, WY). In 1995, with a total budget of \$12.2 million, services were expanded to initiate capacity building and small pilot projects in family planning clinics for infertility prevention services in the six remaining regions (30 States). These remaining 30 states include large, highly populated areas such as states in Region V, as well as states such as California, New York, and Texas.

In fiscal year 1995, with a total budget of \$12.2 million, Region V states (IL, IN, MI, MN, OH, WI) received approximately \$0.5 million to support initiation of the collaborative service delivery model of providing chlamydia screening and treatment services to women attending family planning and STD clinics. By 1997, with a total budget of \$13.2 million, Region V states will receive at least \$1 million, almost a

doubling in funding for Infertility Prevention services with very limited increases in overall national program funding. CDC remains committed to providing increased funds to Regions and States with the greatest unmet need for chlamydia screening and treatment services, as new resources become available.

QUESTIONS SUBMITTED BY SENATOR BYRD

APPALACHIAN LABORATORY FOR OCCUPATIONAL SAFETY AND HEALTH

*Question.* What is the number of Full Time Equivalents for the Division of Safety Research and the Division of Respiratory Disease Studies at this facility in fiscal year 1997 and the number projected for fiscal year 1998?

*Answer.* The fiscal year 1997–98 Full Time Equivalents for the Divisions of Safety Research and Respiratory Disease Studies are as follows:

FISCAL YEAR 1997–98 FULL-TIME EQUIVALENTS FOR THE DIVISIONS OF SAFETY RESEARCH AND RESPIRATORY DISEASE STUDIES

Name of division at Morgantown Research Laboratory	Fiscal year—	
	1997 FTE's	1998 FTE's
Division of Safety Research .....	86	<sup>1</sup> 96
Division of Respiratory Disease Studies .....	125	125

<sup>1</sup>The fiscal year 1998 proposal includes +10 FTE's and \$2.5 million for the firefighters initiative outlined in the President's Budget.

*Question.* Please provide the funding level for the above mentioned Divisions in fiscal year 1997, and the projected level for fiscal year 1998.

*Answer.* The fiscal year 1997–98 funding levels for the Divisions of Safety Research and Respiratory Disease Studies are as follows:

FISCAL YEAR 1997–98 FULL-TIME EQUIVALENTS FOR THE DIVISIONS OF SAFETY RESEARCH AND RESPIRATORY DISEASE STUDIES

Name of division at Morgantown Research Laboratory	Fiscal year—	
	1997 estimate	1998 President's budget
Division of Safety Research .....	\$12,250,000	<sup>1</sup> \$14,750,000
Division of Respiratory Disease Studies .....	11,219,600	11,219,000

<sup>1</sup>The fiscal year 1998 proposal includes +10 FTE's and \$2.5 million for the firefighters initiative outlined in the President's Budget.

THE NEW OCCUPATIONAL SAFETY AND HEALTH LABORATORY

*Question.* How many Full-Time Equivalents are at this facility in fiscal year 1997, and what is the projected number of FTE at this facility for fiscal year 1998?

*Answer.* As of December 31, 1996, NIOSH had filled 180 of the 303 positions authorized for the advanced laboratory. Openings exist for engineers, industrial hygienists, laboratory technicians, and statisticians in the Health Effects Laboratory Division. Leadership positions have been filled, facilitating recruitment for the remaining positions. We anticipate that the facility will be fully staffed by the 4th quarter of fiscal year 1997.

*Question.* Please furnish the funding level required for staffing and research for fiscal year 1998 at this facility.

*Answer.* In the fiscal year 1998 President's Budget a budget of \$36 million and 303 FTE's have been requested to support this facility.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

*Question.* The Senate Report accompanying the fiscal year 1997 Department of Labor, Health and Human Services, Education, and Related Agencies Appropriations bill, urges the National Institute for Occupational Safety and Health (NIOSH) to be prepared to report to the Committee in fiscal year 1998 on implementing test-

ing and certification of emergency response personnel. Is it feasible for NIOSH to perform the testing and certification of personal protective clothing and equipment for emergency personnel and firefighters?

Answer. NIOSH intends to complete its feasibility study on performing the testing and certification of personal protective clothing and equipment for emergency personnel and firefighters by June 1.

*Question.* If so, at what cost?

Answer. The cost estimates are part of the feasibility study which will be completed by June 1.

#### SUBCOMMITTEE RECESS

Secretary SHALALA. Thank you very much, Senator.

Senator FAIRCLOTH. We will do that. I thank you for being with us this morning.

Secretary SHALALA. Thank you very much. It is always nice to see you.

Senator FAIRCLOTH. It has been a pleasure to talk to you. Thank you.

The subcommittee will stand in recess to reconvene at 2 p.m., Wednesday, April 16 in room SD-124. At that time we will hear testimony from the Secretary of Education, Hon. Richard Riley.

[Whereupon, at 12 noon, Tuesday, March 4, the subcommittee was recessed, to reconvene at 2 p.m., Wednesday, April 16.]

**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 1998**

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**WEDNESDAY, APRIL 16, 1997**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 2 p.m., in room SD-124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Craig, Byrd, Harkin, Bumpers, Reid, Kohl, and Murray.

**DEPARTMENT OF EDUCATION**

**OFFICE OF THE SECRETARY OF EDUCATION**

**STATEMENT OF HON. RICHARD RILEY, SECRETARY OF EDUCATION**

**ACCOMPANIED BY THOMAS P. SKELLY, DIRECTOR, BUDGET SERVICE**

**OPENING REMARKS OF SENATOR SPECTER**

Senator SPECTER. Good afternoon, ladies and gentlemen. It is 1½ minutes past 2 o'clock, the starting time for this meeting of the Subcommittee on Labor, Health and Human Services, and Education of the Appropriations Committee.

We are honored today to have the distinguished former President pro tempore, former chairman of the Appropriations Committee, currently the No. 2 man in seniority in the conscience of the Senate, Senator Robert Byrd of West Virginia, and I want to comment about his presence before I do anything else which I think is the appropriate protocol.

This afternoon our subcommittee continues its series of hearings on the President's fiscal year 1998 appropriations request. We are pleased once again to welcome the distinguished Secretary of Education, Richard Riley, to discuss the budget for the Department of Education for the upcoming fiscal year.

The Department of Education's budget request for discretionary spending for fiscal year 1998 totals \$29.1 billion, an increase of \$2.9 billion, or 11 percent over fiscal year 1997. Mr. Secretary, your budget includes some new initiatives, including \$5 billion for school construction, an increase of \$260 million for the America Reads Challenge, and an increase of \$300 on the maximum Pell grant



award, an array of tax proposals, as well as increases in the core education programs.

I look forward to working with you in the coming months to craft an appropriations bill which maintains the commitment to a balanced budget while keeping education funding at the highest possible levels.

All of the funds contained within this subcommittee's jurisdiction are by far most importantly directed toward the investment in education in the Nation's youth. Over the past several years, Senator Harkin and I have fought the large cuts in education spending proposed by the House and have worked together to increase the Federal investment in education.

#### PREPARED STATEMENT

There is a statement which will be included, without objection, in the record, and we will economize on time and note the bipartisan cooperative effort which Senator Harkin and I have made. We added a \$2.6 billion amendment in 1996 which broke the logjam to enable the subcommittee's bill to be enacted, and over the past several years, Senator Harkin and I have worked jointly with the very able staff to eliminate or consolidate some 134 programs to liberate \$1.5 billion to allocate resources on a priority basis to education and health research, NIH, which is where I think our priorities are, along with worker safety.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR ARLEN SPECTER

This afternoon, the Subcommittee on Labor, Health and Human Services and Education continues its series of hearings on the President's fiscal year 1998 appropriations requests.

We are pleased to once again welcome Secretary Richard Riley to the subcommittee to discuss the budget for the Department of Education for the upcoming fiscal year.

The Department of Education's budget request for discretionary spending for fiscal year 1998 totals \$29.1 billion, an increase of \$2.9 billion or 11 percent over the fiscal year 1997 amount. Mr. Secretary, your budget includes some new initiatives, including \$5 billion for school construction, an increase of \$300 in the maximum Pell grant and an array of tax proposals as well as increases in the core education programs. I look forward to working with you in the coming months to craft an appropriations bill that maintains the commitment to a balanced budget while keeping education funding at the highest possible level.

Mr. Secretary, of all of the funds contained within this subcommittee's jurisdiction, by far the most, direct, rewarding, and important investment we can make is in the education of this Nation's youth.

Over the past several years, Senator Harkin and I have fought the large cuts in education spending proposed by the house and have worked together to increase the Federal investment in education. We first eliminated 126 programs within this subcommittee's jurisdiction that were either duplicative or had proven to be ineffective. We then captured the funds from these program eliminations and combined them with savings achieved in other areas of the budget. Funds were then redirected to increase our investment in the core elementary and secondary and higher education programs, including increasing the maximum Pell grant. In fiscal year 1996, we offered the amendment on the Senate floor that broke the logjam on funding and restored \$1.7 billion in education funding. Then again, in fiscal year 1997, Senator Harkin and I fought hard during consideration of the Senate budget resolution and through the appropriations process to ensure adequate funding for education programs, yielding an increase of \$3.5 billion in Federal education spending for that fiscal year. Again this year we will continue to invest in the future of this Nation's youth.

Today we are also pleased to have a second panel of witnesses who will testify following Secretary Riley. I want to welcome to the subcommittee Governor Bob Miller of Nevada, Governor George Voinovich of Ohio, Dr. Bruce Perry, professor of child psychiatry at the Baylor College of Medicine, and Mr. Robert Reiner of Castle Rock Entertainment.

These witnesses will give testimony on the importance of early childhood education with a focus on the critical formative period from birth to age three. I want to commend you gentlemen for your hard work in this area and in launching the "I am your child" campaign. We look forward to hearing about the efforts underway across this Nation to promote family and community involvement in a child's development and the reports by early childhood experts on the research findings on brain development for children in the very earliest stages of life. I am particularly interested to hear your views on the connection between neglected children and its consequences in later years such as criminal behavior, dropping out of school and teen pregnancy.

Senator SPECTER. I would be pleased now to yield to our distinguished senior Democrat, Senator Byrd.

Senator BYRD. Mr. Chairman, you are very thoughtful and courteous to do so. I just came by today as an ex officio member, and I will await a later turn.

Senator SPECTER. Fine. Thank you very much, Senator Byrd.

We have been joined by Senator Cochran who is a senior member on this subcommittee.

#### PREPARED STATEMENT OF SENATOR COCHRAN

Senator COCHRAN. Mr. Chairman, thank you. I am going to put a statement in the record with your permission and join you in welcoming the Secretary and thanking him for his cooperation and assistance to our committee as we review this budget request.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, the administration's proposal that every child in America should be able to read well and independently by the end of third grade is laudable. We recognize the necessity of basic reading skills in order to meet life challenges in a more confident and successful manner.

I am disturbed by the data that suggest at least 40 percent of our children are not reading as well as they should by the end of third grade. Additionally, research studies show that fewer than one child in eight who is failing to read by the end of first grade ever catches up to grade level.

In 1985, responding to parents, teachers and other child advocates, the Health Research Extension Act (Public Law 99-158) was passed by Congress and signed into law by the President. As a result of the act, the National Institute of Child Health and Human Development (NICHD) initiated a collaborative research network with multidisciplinary research programs to study genetics, brain pathology, developmental process and phonetic acquisition. NICHD has spent over \$100 million to follow about 2,500 young children in rigorous scientific research to understanding not only the causes but the consequences of reading problems and related cognitive difficulties.

The results are in. The bitter debate over "whole language approach" vs. "phonetic drill approach" need not continue.

NICHD's results conclude that both literature and phonics practice are necessary for impaired and unimpaired children alike. Techniques for early identification of problem readers and intervention strategies are now known as a result of this research, but many administrators, teachers, tutors, and parents are not aware of the key principles of effective reading instruction.

The NICHD findings underscore the need to do a better job of teacher training. Researchers found that fewer than 10 percent of teachers actually know how to teach reading to children who don't learn reading automatically.

I hope the administration will include in its reading initiative the NICHD research findings and help ensure they are used in federally supported education programs.

## SUMMARY STATEMENT OF HON. RICHARD RILEY

Senator SPECTER. Secretary Riley, we welcome you again. It has been a pleasure to work with you for the past—this is the fifth year of your secretaryship, and it has been a cordial, cooperative working relationship and we look forward to that again this year. The floor is yours. Your full statement will be made a part of the record, and you may proceed as you choose.

Secretary RILEY. Thank you very much. If I could do that, Mr. Chairman, and Senator Byrd, Senator Cochran.

## CARNEGIE FOUNDATION TASK FORCE ON YOUNG CHILDREN

I am pleased, of course, to answer any questions you have asked in your letter about early childhood education, which of course is something that I have taken a great interest in. And I would point out to you, Mr. Chairman, that I was the chairman of the Carnegie Corporation Task Force on meeting the needs of young children that you referred to in your letter. I had to give that chairmanship up when I took this job and I had to give up about everything else I belonged to also. [Laughter.]

But I have been seriously involved in that issue of early childhood for a long time.

I am also pleased to say that the President and the First Lady have also been deeply involved in early childhood issues. I actually first worked with the First Lady on the southern regional education board task force on infant mortality over 15 years ago, and the upcoming White House Conference on Early Childhood is a culmination of a lot of years of concern and effort on the part of the President and the First Lady.

## FISCAL YEAR DEPARTMENT OF EDUCATION BUDGET REQUEST

Now let me turn to the education budget. For fiscal year 1998, we are asking for a total of \$29.1 billion, as you indicate, in discretionary funds, an increase of \$2.9 billion, or 11 percent, over the 1997 level, of course, all that being part of the balanced budget provisions sent by the White House.

## NEW BUDGET INITIATIVES

This budget request seeks to respond to recordbreaking enrollment increases with a significant investment for two new initiatives, the America Reads Challenge and the school construction initiative.

President Clinton is also proposing tax cuts that would save students and families an estimated \$36 billion in postsecondary education expenses over a 5-year period.

## GOALS 2000—RAISING EDUCATIONAL STANDARDS

Our effort to improve education begins with a focus on high standards. We are requesting \$620 million for our Goals 2000 Program, an increase of \$129 million over 1997. I would like to thank you, Mr. Chairman, especially for your leadership in making Goals 2000 be effectively used in all 50 States. Your leadership was very helpful in that. The standards movement I am absolutely convinced is one of the most important things that this country could move

forward with. We are doing it in all 50 States. Goals 2000 serves that purpose directly, and I am very proud of that and I appreciate your leadership in doing it.

Goals 2000 also has an early childhood connection that often goes unnoticed. We have established 28 parent resource centers, including one in Washington, PA, that allow parents in poor areas to help other parents to be better parents. This type of assistance is a very direct way to help new parents in their children's preschool years, and we plan to open 14 more of these centers this year.

#### AMERICA READS CHALLENGE

Another way that we are trying to raise standards is to maintain a strong focus on reading and literacy. We want all of our young people to be reading well by the end of the third grade. That is why we are proposing the America Reads Challenge, led by Carol Rasco, and my submitted testimony outlines our budget request in some detail.

I believe there is a strong link between this initiative and the new thinking on early childhood development. The years before a child arrives at school cannot be spent in just any fashion. It is not simply a waiting period before a child is dropped off at school one day to start learning. It does not work that way. Good parents do make a powerful difference. To my way of thinking, it makes a great deal of sense to have the parents as first teachers component of our America Reads Challenge.

When I was Governor of South Carolina back in the 1980's, we found that 40 percent of our entering first graders were simply not ready for academic work. Perhaps not coincidentally we also found about 40 percent of all of our students were dropping out of school before graduating from high school. There was a direct connection there that got our attention.

#### INCREASES FOR PROGRAMS THAT DEVELOP READING SKILLS

I want to emphasize that the assistance offered through the America Reads Challenge supplements the reading instruction provided in the regular classroom, and that is why we have asked for increased support for existing programs that make a significant contribution to improving reading skills such as title I, Even Start, bilingual education, adult literacy, and special education.

#### TITLE I

For title I, we are asking for \$7.5 billion, an increase of \$347 million. Here again we have a very strong link to early childhood development. Our whole school approach in title I allows schools to help with the transition from Head Start to kindergarten and the first grade. Research from our Even Start Program tells us that children whose parents have taken parenting education increased their vocabulary. In addition, our early intervention efforts under IDEA, the Infants and Families Program, will enable us to reach some 191,000 children with disabilities.

## NATIONAL VOLUNTARY TESTING PROGRAM

Another strong focus in our effort to raise standards is our proposal for challenging but voluntary testing in fourth grade reading and eighth grade mathematics. Right now 40 percent of our young children are not reading as well as they should, and this Nation is below the international average when it comes to eighth grade math.

The test will be based on the widely accepted fourth grade National Assessment for Education Progress—NAEP—in reading, and the eighth grade NAEP and TIMSS—the international math and science test—in mathematics. That eighth grade test would include algebra.

## PROFESSIONAL DEVELOPMENT AND TEACHING STANDARDS

Better teaching is also high on our agenda. We cannot raise standards unless we have better teachers, and that is why we are including \$360 million for our Eisenhower Professional Development Program, up \$50 million from 1997.

We are also asking for a \$16 million increase for the National Board for Professional Teaching Standards. We want 100,000 master teachers in our Nation's classrooms. And that is why I will be hosting a national forum this week in attracting and preparing and retaining teachers for the 21st century. As a nation we have a very real question before us: How do we improve the quality of teaching at a time when we have to raise quantity? Two million new teachers in the next 10 years must be trained. Too often in the past we have lowered teaching standards to meet the demand for more teachers, and now is the time to get it right, to step back and rethink how we recruit, prepare, and support America's teachers.

## EDUCATIONAL TECHNOLOGY AND INNOVATION

A third strong emphasis in our budget is technology and innovation. We are requesting \$500 million to support educational technology.

## CHARTER SCHOOLS

The President's budget also doubles funding for public school choice through our support of charter schools. A \$100 million request would support the start-up for as many as 1,100 new schools created by teachers and parents and other community members.

## SCHOOL CONSTRUCTION INITIATIVE

Finally, I urge the Congress to recognize that many school districts are very hard pressed because of rising enrollments I referred to. You do not get a lot of learning done when 30 to 40 young people are crowded into a single classroom and often with a roof leaking or whatever. That is why the President is requesting a one-time appropriation of \$5 billion in 1998 to jump start school construction. Our goal is to stimulate at least \$20 million in new construction or renovation projects.

## FEDERAL PELL GRANT PROGRAM

Now, let me turn one moment to higher education. President Clinton seeks to significantly expand college access for low-income students, while providing new help to that part of the middle class that seems to have been forgotten and is struggling to pay for college. The request includes \$7.6 billion, an increase of \$1.7 billion, or 29 percent, to support two significant changes in the Pell Grant Program.

The first is an increase in the maximum Pell grant award to an all-time high of \$3,000, up from \$2,700 in 1997.

The second is an expansion of the eligibility of independent students with no dependents, and this will allow an additional 218,000 students to be eligible to participate in the Pell Grant Program.

## POSTSECONDARY TAX PROPOSALS

The President's budget also includes two major tax initiatives that together would save more than 12 million postsecondary students and their families an estimated \$4 billion in 1998.

American's HOPE scholarship proposal would help make 2 years of postsecondary education universally available by providing a tax credit of up to \$1,500 a year during the first 2 years of college.

President Clinton is also offering a middle-income tax deduction proposal that would allow students and families to deduct up to \$5,000 in postsecondary tuition and fees from their taxable income, and this deduction would rise to \$10,000 under this proposal in 1999. More than 8 million students would benefit from the tax deduction in 1998, with total savings reaching \$17.6 billion by 2002.

Our data tells us that low- and middle-income students are less likely than higher income students to earn bachelor's degrees within 5 years. One of the main reasons these students drop out of college is the lack of money. What we have here is a forgotten part of the middle class I referred to that could use our help.

Other postsecondary education priorities include a \$27 million increase for work-study, an additional \$25 million for TRIO to support almost 37,000 more aspiring students, and our \$6 million request for the Advanced Placement Fee Program that will allow many more low-income students the opportunity to reach for excellence.

## PREPARED STATEMENT

In conclusion, I point to history in considering our proposed investment in education. For most of the industrial age, we used the Tax Code to encourage business to invest in plant and equipment. For the information age, what I call the education age, I believe we should provide incentives, including tax incentives, that encourage people to invest in themselves by getting a quality education. This type of investment policy, Mr. Chairman and members of the committee, is the best insurance we can have for long-term economic growth and a growing middle class that is eager to participate in our free enterprise system and strengthen our democracy.

Thank you, Mr. Chairman. I will be happy to respond to questions.

[The statement follows:]

## PREPARED STATEMENT OF RICHARD W. RILEY

Mr. Chairman and Members of the Subcommittee, I am pleased to have this opportunity to talk about the President's 1998 budget request for the Department of Education. I have a statement that I would like to submit for the record, Mr. Chairman, and then I will briefly summarize it for the Subcommittee.

Let me begin by saying how pleased I am that education is a top priority for both President Clinton and the Congress. The Nation is already responding to the President's call for action on education in his State of the Union address, and I believe that we here in Washington need to give the American people as much help as we can in their efforts to demand more of schools and students.

This is my fourth Congressional hearing this year, and I have been greatly impressed by the broad and bipartisan agreement among Members in both Houses of Congress on what we need to do in education. The President's commitment to high standards; expanding public school choice; safe, disciplined, and drug-free schools; bringing technology into the classroom; improving the quality of teaching; and increasing access to postsecondary education is shared by nearly everyone.

There are, of course, some differences on how best to achieve these goals, but they are not insurmountable differences and I am hopeful that we will work together this year in a bipartisan fashion to move the country forward in education.

## THE PRESIDENT'S REQUEST

I have often said that money alone is not the answer to the challenges we face in education. Motivated students, talented teachers, and supportive parents and communities are what really leads to outstanding performance in the classroom. But money makes a difference too, particularly at a time when a record number of students are in our Nation's classrooms. This is the Education Age, and America must have an education budget right for the times.

The President's budget lives up to our education challenge. For fiscal year 1998, the President is asking for a total of \$29.1 billion in discretionary funds for the Department of Education, an increase of \$2.9 billion or 11 percent over the 1997 level.

The President's budget also includes a significant investment of mandatory funds for two new initiatives: the America Reads Challenge and the School Construction initiative. And to complement the education funds in our budget and help Americans pay for college, President Clinton is proposing tax cuts that would save students and families an estimated \$36 billion over five years.

The President's budget directs new resources into four priority areas: putting standards of excellence into action, improving reading for all Americans, providing help to schools and students with special needs, and expanding access to higher education.

## PUTTING STANDARDS OF EXCELLENCE INTO ACTION

As I said in my State of American Education speech earlier this year, it is not enough to have high expectations or set challenging standards. We must put standards of excellence into action. This is the first priority of the President's budget for education.

Over the past four years, President Clinton has worked with Congress to build bipartisan support for effective assistance to states and communities using standards of excellence to improve their schools. The 1998 budget would expand this assistance.

For Goals 2000, the cornerstone of Federal support for schools and communities that are working to raise standards, we are requesting \$620 million, or \$129 million over the 1997 level. This increase would permit grants to an estimated 16,000 schools, or one-third more than the 12,000 currently receiving Goals 2000 assistance.

We are also requesting \$6 million for the Advanced Placement Fee program. This program would support higher academic standards by paying some or all of the cost of advanced placement tests for low-income students, thus encouraging these students to challenge themselves and take tough courses.

The President's budget includes \$400 million for School-to-Work Opportunities, \$200 million each from the Departments of Education and Labor. These funds would help all 50 States to fully implement their strategies for preparing students for work and further education.

In addition, we would nearly double funding for Educational Technology. The \$500 million request emphasizes linking rural and inner-city schools to the Internet, and would help us reach the President's goal of connecting all schools to the Information Superhighway by the year 2000.

The President's budget would promote innovation and accountability and expand the range of choices available to parents and children within public school systems by nearly doubling funding for Charter Schools. The \$100 million request would support planning and start-up costs for as many as 1,100 new schools created by teachers, parents, and other community members.

We also are seeking new resources to improve the quality of teaching. The request includes \$360 million for Eisenhower Professional Development State Grants, up \$50 million over 1997, to help teachers better deliver instruction in the core subjects. And the budget would provide a \$16 million increase for the National Board for Professional Teaching Standards to greatly speed up the development of standards and assessments in over 30 teaching fields. This increase also would enable teachers to go through the rigorous National Board evaluation process—a key step in identifying and rewarding master teachers.

One of the most important proposals for putting standards of excellence into action—one that did not make it into our budget documents but about which you are well aware—is the plan to develop and support the administration of new national tests in 4th-grade reading and 8th-grade mathematics.

As you know, President Clinton announced this plan in his State of the Union address to the Congress. The decision to support such testing was made after our 1998 budget documents had gone out for printing, and reflects the President's conviction that after much emphasis on higher standards in recent years, it was time to put such standards into action in every State, school district, and school.

President Clinton believes that we will never reach standards of excellence until we have "recognized high standards for math and science and other basic subjects that are national in scope, measured by national and international standards, adopted locally, implemented locally, but nationally recognized and nationally tested throughout the United States." And while he acknowledges that Federal involvement in such testing should be limited, he doubts that it will happen "unless we get out here and beat the drum for it and work for it."

As a result, we are now proposing to use 1997 and 1998 funding available through the Fund for the Improvement of Education (FIE) to develop and begin pilot-testing of the national tests in reading and mathematics. FIE funds for this purpose will be reallocated from planned development assistance to States working on their own assessments. Additional funding to support full administration of the tests by the States in the spring of 1999 will be included in the 1999 budget request.

The tests will be based on the widely accepted National Assessment of Educational Progress (NAEP), with the math test also linked to the Third International Mathematics and Science Study. The Department has been seeking guidance in developing the tests from parents, teachers, governors, and State and local leaders. These tests will show how well students are meeting rigorous standards and how well they compare with their peers around the country and the world. They also will help parents know if their children are mastering critical basic skills early enough to succeed in school and in the workforce.

I hope we do not cloud our children's future with arguments that are not really relevant about Federal government intrusion. Reading is reading and math is math, as Governors in Michigan, Maryland, and North Carolina have recognized by already accepting the President's challenge to participate in these voluntary national tests. I urge you to join me in encouraging other states and school districts to follow their example. Many of our children, schools, and States may not make the grade at the beginning, but these tests will be a very serious tool for showing them where and how they need to improve.

#### HELPING ALL AMERICANS TO READ WELL

Our second priority is helping all Americans to read well. Learning begins with reading, but 40 percent of fourth graders read below the "Basic" level on the NAEP reading test. Research shows that if students can't read well by fourth grade, their chances for later success in school are significantly reduced.

The goal of the America Reads Challenge is to ensure that all children read well and independently by the end of the third grade. The President's budget includes \$260 million in mandatory funding for two components of the Challenge: America's Reading Corps and Parents as First Teachers. We plan a total of \$1.75 billion for this initiative over the next five years, with the Corporation for National and Community Service contributing an additional \$1 billion.

Most of the funds would be used to begin enlisting and training one million volunteer tutors for the Reading Corps, who would work with teachers and provide reading assistance after school, on weekends, and during the summer for children in grades K-3 who need assistance.



I want to emphasize here that the assistance offered through the America Reads Challenge would supplement the reading instruction provided in the regular classroom. We will continue to support existing programs that make a significant contribution to improving reading skills, such as Title I and Special Education. Our budget includes increases for each of these programs.

A Parents as First Teachers component of America Reads will support programs that assist parents in helping their children to read. These programs put a strong emphasis on helping children before they enter school. And that is so important, because new scientific findings about the brain tell us that it is essential for children to start learning as early in life as possible. Before I came to the Department of Education, I had the privilege of serving as chairman of the Carnegie Foundation Task Force that collected these findings in a report called *Starting Points: Meeting the Needs of Our Youngest Children*.

I was especially pleased, therefore, to learn that you will be discussing early childhood development with a panel that follows my testimony, because I believe this new research has important implications for how we teach our children. The White House Conference on Early Childhood Development and Learning that begins tomorrow will also help to raise awareness of how critical the early years are for learning.

This conference builds on President Clinton's investment in children and families, which has included a 25-percent increase in children's research at the National Institutes for Health, a 43-percent increase in funding for Head Start, and raising participation in the Woman, Infants and Children Supplemental Nutrition Program by 1.7 million or 30 percent.

At the Department of Education, we have increased funding for the Special Education Infants and Families program by 48 percent, helped to establish Parent Information and Resource Centers in 42 States, and encouraged greater understanding of the important role families play in education through our Partnership for Family Involvement in Education.

I think we have made a good start in supporting the child development and learning in the earliest years, but I am certain that the White House Conference—as well as this afternoon's hearing—will suggest additional steps we might take in this important area. I welcome those suggestions, and would be pleased to work with the Committee to help make sure our youngest children receive the support they need for later success in school.

The 1998 request also provides increases for other programs focused more specifically on reading. We are seeking a \$6 million increase for Even Start, for a total of \$108 million. This would expand local family literacy programs that combine early childhood education for preschool children with instruction in basic literacy skills for their parents.

Our \$199 million request for Bilingual Education, up \$42 million from the 1997 level, would help ensure that students who speak a language other than English receive the extra help they need to learn to read English. And a \$42 million increase for Adult Education State Grants would help adult Americans improve their literacy skills.

#### EXTRA HELP FOR SCHOOLS AND STUDENTS WITH SPECIAL NEEDS

All across the nation, schools are struggling to make room for new students while they provide services for students with special needs. These students include low-achieving and limited-English-proficient students, and students with disabilities. Helping these schools and students is the third priority in our 1998 budget request.

For Title I Grants to Local Educational Agencies, we are asking for \$7.5 billion, an increase of \$347 million, to help low-achieving students in the poorest school districts meet the same challenging standards expected of all children. The request would target a larger share of Title I resources on communities and schools with the highest concentrations of children from low-income families.

The budget would provide \$3.2 billion for Special Education Grants to States, an increase of \$141 million or 4.5 percent over the 34-percent increase in 1997. The request would help States cover the increased costs of serving additional children with disabilities.

We also recognize the additional costs faced by school districts that serve large numbers of recently arrived immigrant students. To help districts pay these costs, the request includes \$150 million for Immigrant Education, a \$50 million or 50-percent increase over the 1997 level.

Children cannot be expected to reach high standards in schools where they are threatened by drug abuse and violence. To help fight these threats, we are asking

for \$620 million for the Safe and Drug-Free Schools programs. This is an increase of \$64 million, or nearly 12 percent, over the 1997 level.

I want to be clear here that I am very concerned about the enormous variation in the effectiveness of the drug prevention activities funded by this program. Our schools must do a better job of getting the anti-drug and anti-violence message across to young people. We know a lot about what works when it comes to drug prevention, and we also know that the proven models are not being used as much as they should. That is why we are proposing appropriations language for the Safe and Drug-Free Schools program that would require the use of proven, research-based approaches to drug and violence prevention.

The Department also is proposing a new initiative to support safe learning environments for our children. The \$50 million After-School Learning Centers program would help hundreds of rural and inner-city public schools stay open after school hours and serve as safe, neighborhood learning centers where students can do their homework and obtain tutoring and mentoring services.

In addition, the President is requesting a one-time appropriation of \$5 billion in 1998 to stimulate state and local efforts to repair and modernize school facilities, particularly in urban areas, which often have the greatest need.

The new School Construction initiative would pay for up to half the interest on school construction bonds or similar financing mechanisms, with a target of stimulating at least \$20 billion in new construction or renovation projects. Projects could include emergency repairs to ensure health and safety, technology upgrades, building new schools to serve growing enrollments, ensuring access for disabled individuals, and improving energy efficiency.

#### MAKING COLLEGE MORE AFFORDABLE

The point of our efforts to put standards of excellence into action, improve reading, and help students with special needs is to raise our expectations of educational achievement for all Americans. As a result, more and more people will be reaching for higher education to meet their educational and career goals. That is why the fourth priority in our 1998 budget is to make college more affordable.

President Clinton is proposing a combination of budget and tax initiatives for 1998 that would significantly expand college access for lower-income students, while providing new assistance to working families and middle-class families struggling to pay for college.

The request includes \$7.6 billion, an increase of \$1.7 billion or 29 percent, to support two significant changes in the Pell Grant program. The first is an increase in the maximum Pell Grant award to an all-time high of \$3,000, up from \$2,700 in 1997. The second is an expansion of the eligibility of independent students with no dependents. This need-analysis change would make 218,000 additional independent students—generally defined as over age 24—eligible for Pell Grants.

We also are proposing changes to the student loan programs that would save billions of dollars for both students and taxpayers. Our proposal would cut origination fees from 4 percent to 2 percent for need-based loans, and to 3 percent for other loans, thus saving 4 million low- and middle-income students \$2.6 billion over five years. We would further reduce Federal and borrower costs by lowering the interest subsidy to lenders and the interest rate for students by 1 percentage point during in-school, grace, and deferment periods—when lender costs are very low. Finally, we would save taxpayers \$3.5 billion over five years by streamlining the guaranty agency system to clarify the federal government's role as sole guarantor of all student loans and by linking agency fees to performance in collecting on defaulted loans.

In addition to these changes in Department programs, the President's budget includes two major tax initiatives that together would save more than 12 million postsecondary students and their families an estimated \$4 billion in 1998.

The America's HOPE Scholarship proposal would help make two years of postsecondary education universally available by providing a tax credit of up to \$1,500 each year during the first two years of college. Students would have to stay drug-free and maintain at least a "B-minus" average (2.75 GPA) to qualify for the tax credit in their second year of postsecondary study. We expect 4.2 million students to benefit from HOPE Scholarships in 1998, with total savings to students and families reaching \$18.6 billion by 2002.

President Clinton is also proposing an education and job training tax deduction. This would allow students and families to deduct up to \$5,000 in postsecondary tuition and fees from their taxable income. The deduction would rise to \$10,000 in 1999. More than 8 million students would benefit from the tax deduction in 1998, with total savings reaching \$17.6 billion by 2002.

Some have argued that HOPE Scholarships would do little to increase access to postsecondary education, and instead would merely subsidize those who would attend college anyway. I believe such critics are ignoring evidence that we need to improve access to college for both low- and middle-income students, who have much lower rates of participation in postsecondary education than higher-income students. In 1994, only 45 percent of high school graduates from low-income families and 58 percent from middle-income families went directly to college, compared to 77 percent of students from high-income families.

Our data also show that low- and middle-income students are less likely than higher-income students to earn bachelor's degrees within 5 years, and one of the main reasons that students drop out of college is lack of money. HOPE Scholarships can help close both of these gaps—in access and completion—by changing the expectations of many Americans who still do not consider a college education to be within their reach and by putting more resources into the hands of students and families.

Other postsecondary education priorities in the Department of Education's budget include a \$27 million increase for Work-Study to keep us on course toward funding 1 million work-study jobs by the year 2000, a \$25 million increase for TRIO to provide outreach and support services to almost 37,000 more students, and \$132 million to give Presidential Honors Scholarships to the top 5 percent of graduating students in every high school in America.

#### CONCLUSION

The President's 1998 budget request supports real and dramatic improvement in education at all levels. I believe the Nation is ready to do what needs to be done to raise educational achievement for all Americans to the levels needed for success in the 21st century. This budget will help, and I hope you will give it your fullest consideration.

Thank you, and I will be happy to respond to any questions.

#### INTRODUCTION OF ASSOCIATE

Secretary RILEY. Let me point out Tom Skelly, who is with me, my Director of Budget Service.

Senator SPECTER. Thank you very much, Mr. Secretary, and we welcome Mr. Skelly here again.

Mr. Secretary, we have a great many questions for you. As usual, our time is going to be limited.

We are having an unusual second panel today which we are featuring with Gov. Bob Miller who currently serves as chairman of the National Governors Association, along with Gov. George Voinovich—Governor Miller from Nevada, Governor Voinovich from Ohio—along with Dr. Bruce Perry and Mr. Rob Reiner, chair and founder of the I Am Your Child Program. Mr. Reiner is in town for other activities today and activities tomorrow at the White House, and we thought this would be a good opportunity to focus on the issue of education for the very young.

We will proceed now with 5-minute rounds for the members.

#### EARLY CHILD DEVELOPMENT RESEARCH FINDINGS

My first question to you, Mr. Secretary, relates to this growing body of information that children have fairly developed aptitudes by the age of 3, which I found somewhat surprising. I focus with particularity on two grandchildren which my wife and I were recently the beneficiaries of: Sylvi, 3; and Perry, 1. Their mother is a product of the new age and has them in school already. Perry at 1 goes to music school. I would like your insights into that approach.

Secretary RILEY. Well, I think the fascinating research that was recently documented in several major magazines and newspapers and TV articles of all kinds very clearly shows the importance of

brain development at a very early age. I guess it ought not to be such a shock to us, the fact that hundreds of thousands of these positive connections develop for young children in their brains when they have the kind of nurturing, the kind of attention that your children and my children are giving to our grandchildren. It is very exciting research and findings.

Our Department, when we reauthorized OERI, Mr. Chairman, provided for an Institute on Early Childhood, and there is now a National Center to Enhance Early Development and Learning working under that institute which we think will provide some very, very helpful additional information. It is looking at some of the specifics, the connection between this early stimuli and how it impacts kindergarten and school and thereafter. So, I am very interested and excited about it.

#### TAX INITIATIVES

Senator SPECTER. Mr. Secretary, I applaud the initiatives on tax credits and tax deductions. Those will, of course, go to the Finance Committee, but I think that it is very important to set the foundation so that every young man and young woman who wants to go to college and graduate school can do so, with education being our best capital investment, and beyond the young people, adult education as well.

I also commend the addition on charter schools, all within the public school system, as a supplement to provide some competition with the public school systems.

#### PUBLIC SCHOOLS' USE OF PAROCHIAL SCHOOLS' FACILITIES

We have a great many questions, Mr. Secretary, which we are going to be submitting for the record, and in the remaining time on my round, I want to explore with you a subject that is controversial but, I think, has very substantial potential, if it can be worked out, and it relates to a request which the Congress made to your Department to provide a report on public urban schools and the possibility of utilizing facilities from parochial schools.

To summarize in a nutshell, within the past year Cardinal Bevalaqua of Philadelphia visited me on another subject and raised the issue about 25,000 vacant seats in the parochial schools of Philadelphia where the average cost of education is \$7,000. The Cardinal stated that he would be willing to make those seats available to public school children for \$1,000. That was at about the same time that New York City with Mayor Guliani was considering a similar proposal.

There has been some suggestion that the parochial schools would take the most difficult of the public school children to educate. Another suggestion is to take them by lottery.

The issues are complex, obviously, on the question of separation of church and state. Ultimately New York City has proceeded with this program with public funding—with private funding, rather, as opposed to public funding. There are some cases, none really dispositive of this kind of a complex issue, suggesting that public funds may be used in certain ways.

I know you are going to be submitting a more detailed response by the September date which we had requested, but I would be

very much interested in your preliminary thinking on that subject today.

Secretary RILEY. Well, I think the determination in New York, as you point out, was that they had some real concern about public funds being used to pay for scholarships into parochial schools.

I strongly believe in quality private and parochial schools, and we work very closely with them in a lot of ways through title I, and we are trying in every way we can to make that more workable and to make it work better for them.

You have to be very, very careful with the constitutional issue in my judgment, Mr. Chairman, on that particular issue. When you get into private funds, that is a different situation. Private funds—people can do basically what they want to do with them. But again, if you go into public schools and you are talking to students and parents who might not be well educated, with the idea of moving them from a public school into a parochial school, really again, I think you have to be very careful with regard to having them involved in a religious learning experience.

Senator SPECTER. Do you think there is a way it can be worked out?

Secretary RILEY. I think with private funds. It is a very interesting question, and I think all of us need to be pondering that. But how you choose the students, how they end up there, and whether they belong to that religion or not, are issues that are central to the question when you are taking kids out of a public school setting and putting them in a private or parochial setting. So, I wish I could answer yes or no. I would say this, I would have very serious concerns about how it is done to make sure the constitutional issue is avoided.

Senator SPECTER. Thank you very much, Mr. Secretary.

The Senator from West Virginia, Mr. Byrd.

Senator BYRD. Mr. Chairman, if I might suggest, I will wait until the member of the subcommittee has reached his turn.

Senator SPECTER. Very well, the Senator from Mississippi, Mr. Cochran.

#### OPENING REMARKS OF SENATOR COCHRAN

Senator COCHRAN. Mr. Chairman, one of the issues that I think we are all aware of and would like very much to work to influence is the problem of college costs and the difficulty that continues to mount for parents and students alike to meet these ever-increasing costs. I have been impressed with the administration's attention to this, even though I do not agree with the limited approach it is taking to deal with it with the tax changes which do not seem to have enough support in the Congress to make it into law. But I do applaud the effort and the leadership to cause others to look at alternatives.

#### PREPAID TUITION PLANS—ONE ANSWER TO RISING COST

One of the alternatives is a prepaid tuition program which I know the Secretary is aware of. Our State of Mississippi has just passed legislation to authorize a prepaid tuition program where you can pay current costs by joining the program now and so that increases over the future years will not work to make it impossible

for those who have children who will be college age later to meet those costs.

#### INCREASE IN TUITION VERSUS MEDIAN INCOME

Here is, in a nutshell, the problem. Over the last 15 years, I am told that college tuition costs have increased 234 percent while median income has increased only 82 percent. In our State the cost of just 1 year at a 4-year college rose 215 percent between 1985 and 1995.

#### MISSISSIPPI'S PREPAID TUITION PLAN

Under this new tuition plan, I think we are going to see a lot more participation by parents and the business sector in helping to encourage early investments in college education, helping to make it possible for more students to get a college education.

We are introducing legislation here that will make the internal buildup of value of those funds tax-free, much like an IRA, and we hope that will be a big help too.

I wonder whether or not this kind of initiative is the kind of initiative the administration is supporting and what efforts you are making to try to help encourage other States to do like our State and 16 others have done to put this kind of law on the books.

Secretary RILEY. Well, the answer, Senator, is absolutely we favor prepaid plans. You have to be careful about how those are done. States have done them differently, some working very well, some working fairly well. So, we would be very happy to provide technical kinds of advice to States on how to set these plans up and would advise Congress on any benefit here. But I strongly would favor the tax-free approach that you refer to. I think that makes great sense.

#### FEDERAL STUDENT AID APPROACH

I would urge you to look at our full higher education approach. Pell grants cover the very poor, as you well know, and are kind of the backbone of really all Americans having some chance to go to college. To extend this we have proposed a Pell grant increase and an eligibility expansion. Then on top of that, where the Pell grant lets off, we have the HOPE scholarship, which is a \$1,500 tax credit, to cover middle-income students, and then after 2 years, the up to \$10,000 tax deduction for lifelong learning.

If you take those three as a package and put with them efforts to encourage savings, as you propose, and the prepaid tuition plans, which are very helpful, and then the IRA changes which make great sense too—to expand upon those so you can withdraw funds without penalty—I think it will go a long way toward helping all Americans have a good chance at college. So, I would urge you to take another look at those.

#### AMERICA READS CHALLENGE AND NICHD RESEARCH RESULTS

Senator COCHRAN. Well, we will review them very carefully.

In connection with the administration's reading initiative, I hope that you will look at the results of research that was done by the National Institute of Child Health and Human Development. This

was done after a bill was passed in 1985 called the Health Research Extension Act. It resulted in collaborative research to study genetics, brain pathology, developmental processes, and other matters to try to learn more about how young children learn to read and why some of them do not, why some do it better than others; \$100 million has been spent on that research and 2,500 young children were studied in a way that no other research has undertaken to do.

But anyway, the point is: techniques for early identification of problem readers and intervention strategies are now known as a result of this research, but many administrators—I would say very few—or teachers or parents or tutors know about these results or are aware of what the key principles are that were developed so that effective reading instruction can occur.

I hope that any effort to push the reading initiative, again a subject which is very important—I hope the administration will include the research findings by the NICHD in any federally supported instruction programs that you support.

Secretary RILEY. Well, thank you, Senator, and that is a solid suggestion. Carol Rasco, I am told, has met with the researchers, and she is very much involved in that. She is heading up the America Reads Challenge, and she is very much into that and I will be myself. That is a grand suggestion.

#### NATIONAL WRITING PROJECT AND TEACHER TRAINING

Senator COCHRAN. The only other question I have is a complaint about your failure to put in the budget the national writing project. This is a project that the National Council of Teachers of English recognized last year as one of the most successful teacher training programs in America; 44 States have sites. It was funded several years ago as a result of a bipartisan congressional initiative which we started here in the Senate and the House went along with it.

We hope you will take another look at that. We are going to try to convince this committee and others in Congress to support funding. It is a modest amount of money, but I get the impression that the administration does not put money in the program in its budget just because it did not think it up. It was a congressional initiative. But it is a really fine program from everything I have heard about it, and I hope the administration will take a close look at our suggestion.

Secretary RILEY. Well, thank you. Senator, as you know, we had it zeroed out by our recommendation some 4 years ago. Our emphasis this year has been on reading, really, and math, but again—

Senator COCHRAN. This is teaching them how to read. This is teacher inservice training based on research that was done by this study that I talked about.

Secretary RILEY. And it was just a \$2 million program.

Senator COCHRAN. That is right. It is small, \$3.8 million, but it is modest.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Cochran.

We have been joined by our distinguished ranking member. We will call on Senator Harkin for an opening statement and a 5-minute round of questioning.

## PREPARED STATEMENT OF SENATOR HARKIN

Senator HARKIN. Mr. Chairman, thank you very much. I apologize for being a little late, and I will not take the time to read my statement. I will just ask it be made a part of the record.

Senator SPECTER. Without objection.

[The statement follows:]

## PREPARED STATEMENT OF SENATOR HARKIN

Mr. Chairman, first I would like to thank you for holding this important hearing. There is no issue that is of greater significance to our Nation's future than the one we are here to discuss today—education, especially the education and development of young children. We have a tremendous list of witnesses and I extend a warm welcome to Secretary Riley, Governors Miller and Voinovich, Rob Reiner, and Dr. Bruce Perry.

Over the years, this subcommittee has provided significant investments in research at the National Institutes of Health. During this hearing we will learn more about brain research and its implications for the education and development of young children. We have been reading a great deal lately about this research and it seems like we are learning more every day.

The research provides the scientific evidence which validates what many parents and children's advocates have been saying for years—the greatest potential for learning happens during the first years of a child's life. Therefore, we need to make sure that all children have enriching learning experiences during that critical time.

The first National Education Goal states that by the year 2000, all children will start school ready to learn. I strongly support all of the goals, but believe that the first goal is essential for achieving the rest. Without a strong foundation in the early years, children, particularly children from low-income families, start school behind their peers and often find it very difficult to catch up.

Several years ago I read a report by the Committee on Economic Development. This is a group of CEO's from some of the Nation's largest companies and they called on us to fundamentally change how we think about education. They said education is a process that begins at birth and that preparation must begin before birth. I believe this statement should be the cornerstone of how we think about education in America.

Early intervention also makes good economic sense. A dollar invested in quality preschool programs such as Head Start saves as much as \$7 in future costs by increasing the likelihood that children will be literate and employed rather than dependent on welfare or engaged in criminal activities.

This subcommittee provides funding for a number of very important initiatives devoted to improving the education and development of young children. Chairman Specter, over the years we have worked together on a bipartisan basis to support these activities and I look forward to our continued partnership in the future.

I know that we will face serious limitations on the amount of funding for programs under the jurisdiction of our subcommittee. However, I hope that we can agree to provide increased funding for Head Start for children from birth through age 3; provide increased funding for the Part H early intervention program for infants and toddlers with disabilities and to make sure that what we learn from research is reflected in our spending priorities.

The President's 1998 budget provides significant increases in funding for college aid programs. This funding is vitally important for students and their families who are struggling to meet college costs. I fully support these initiatives.

However, we must not lose sight of the importance of investments in the education of young children. After all, high quality educational activities during a child's first years often alleviates the need for more expensive interventions later on. I hope that we will be able to work together to create the infrastructure which truly redefines how we view education—as a process that begins at birth, with preparations beginning before birth.

Thank you, Mr. Chairman.

## IMPORTANCE OF EARLY CHILDHOOD EDUCATION

Senator HARKIN. I just want to again say that this hearing today is just vitally important not only just because of education, but because we are also focusing on early childhood education. All of the



goals that we want to meet in this Nation in terms of education, whether it is college education, finishing high school, job training, it really goes back to the early childhood.

We have had so many studies done in the last 20 years—I can stack them up on my desk and they would cover my entire desk—about the importance of investing in early childhood education. Every study that has ever been done shows that we get the most bang for the buck there.

The Committee on Economic Development that was set up under former President Reagan that pulled together a number of our leading CEO's in the United States to study education spent I think probably 3 years or more looking at this. They set up a panel. They spent a great deal of time, and they wanted to look at it from the approach of a nonsocial scientist. They wanted to look at it from a hard business standpoint, what did we need in education in this country. So, they put together all these CEO's.

Here is the report that came out. In 1990 I think it came out. But the commission was set up under President Reagan.

You know what they said? This was all these hard-headed CEO's. What they said about education, they said, we have to understand that education begins at birth and the preparation for education begins before birth. They said in their report that if we really want to move this country forward, we have to put it down in early childhood education. Usually you hear that from social scientists, but this is from the business community of America.

So, I am all for college loans and making sure that kids can get into college and everything, but if that is all we are going to focus on or focus most of our attention there, there are a lot of kids that are not ever going to get that far. So, we have to again go back to that early childhood education.

I know that you in particular have been one of the greatest proponents of this, and I appreciate that very much. You have provided great leadership in this.

I make that statement only because we cannot lose sight of that. We have to keep coming back to that initial early childhood education.

#### SPECIAL EDUCATION—EARLY INTERVENTION PROGRAMS

Now, some of that of course is under a different Department. Part H of the early intervention program for infants and toddlers with disabilities is under the jurisdiction of the Department of Education. Part H has involved families. It has brought the parents in for early intervention programs. I believe it has been a great success. It has been very effective.

I guess my first question is have you looked at it or would you have your people look at this, and what is it in Part H that has been so successful that we might be able to adapt or adopt in other programs, in early childhood education programs?

Secretary RILEY. Well, first of all, I agree with you that the infants and toddlers program, the 0 to 2 age range which we refer to as part H, has been very effective. The preschool incentive grants for 3- to 5-year-olds likewise has also been very effective.

APPLYING SPECIAL EDUCATION INTERVENTION TECHNIQUES TO  
READING

So, I think when you work with a young child who is having difficulty learning and who has a disability, how you work with that child is multiplied by the same effects as how you would work with a child who had no difficulties. In other words, what works well for a child that is having learning difficulties would work extremely well for a child who is having no difficulties.

I think of everything in the world that we can do, early childhood should be one of the strong emphases—and I discussed early childhood some, Senator, before you arrived. But, I say our emphasis on reading and concern with the special education numbers are really in a lot of ways related, because of the connection between reading difficulties and learning disabilities, and so forth. I think that when you look at the impact that part H of IDEA and the preschool incentive program under IDEA is going to have on reading, on special education numbers on up the line, it is going to be very significant. I think you can take a lot of the things that we learned there and reduce the number of these young people who are special ed students in the second and third grade if we handle them early enough and prepare them for their learning.

## FEDERAL ROLE IN EARLY CHILDHOOD EDUCATION

Senator HARKIN. Mr. Secretary, my time is out. I just want to follow up on just one point.

We in this country have devised a system of education whereby elementary and secondary education is basically State and local based, and I think it has been a good system and I want to keep that control in the local level.

When it comes to postsecondary school, the Federal Government has stepped in, going clear back to the old land grant colleges in the last century, the Pell grants, guaranteed student loan program. So, the Federal Government has stepped in very heavily in postsecondary education.

But in elementary and secondary education, the Federal Government shares I think now less than 6 percent of the total amounts of money.

But it also seems the Federal Government has stepped in on a national basis before in elementary education with things like part H, and with Head Start programs, of course, again which are not under your jurisdiction.

I guess philosophically I am saying that perhaps we ought to envision a stronger role for the Federal Government nationally not so much in elementary and secondary education which is primarily—and has been for a long time—a function of States and local government, but using the same philosophy that we use on a national basis for postsecondary education. Using that to reach down to early childhood education with perhaps even new systems, providing education in day care, expanding part H, expanding the Head Start Program, so that the national goal of every child being ready and able to learn by the time they enter first grade is met by the year 2000.

I just throw that out for your consideration. Maybe we ought to think about that as a prominent role for the Federal Government.

IMPORTANCE OF FAMILY INVOLVEMENT IN EARLY EDUCATION

Secretary RILEY. Well, I think that is a very interesting idea. Of course—in thinking about your previous question, one of the strong things that we pick up when we give special attention to especially disabled young people is family involvement. That is the most significant part of part H. It gets the family involved and that clearly is beneficial to everybody. It's what works.

I will think about that. The role of the family has to be such a critical part of these preschool years.

Senator HARKIN. Absolutely.

Secretary RILEY. So long as everything that was done puts the family at the head of the attention that the child will be given, I think your suggestion is very, very interesting.

As you know, the State constitutions require the State to provide free public education for all children in the State, and that is perceived to be K through 12. Your question is very interesting: How about before K? Certainly after 12 it is very clear that it cuts off.

I will ponder that, but I would say this, that you have to be very careful about making sure the family is first, especially for those very young children.

Senator HARKIN. Absolutely. I agree with you wholeheartedly.

My staff just gave me the figure here. For Federal funding for child care and early childhood education 2 years ago—I guess that is the latest data we have—it was \$4.8 billion. Total State funding for the same programs was \$2.4 billion. So, we have already moved ahead in that area from the Federal standpoint.

Senator SPECTER. Thank you very much, Senator Harkin.

The Senator from Idaho, Mr. Craig.

PREPARED STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Mr. Chairman, thank you very much. Let me ask unanimous consent also that my opening statement be made a part of the record.

Senator SPECTER. Without objection, it will be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR LARRY E. CRAIG

Thank you Mr. Chairman. I would first like to thank the Chair, Senator Specter, and the ranking member, Senator Harkin, for holding this hearing and giving the subcommittee the opportunity to hear from the administration and others on both the education budget for 1998 and early childhood education.

I applaud the President for making education a top priority during his second term. As a member of the Republican leadership in the Senate, I have worked with my colleagues to insure wide bipartisan support, where possible, for a number of issues relative to education and am pleased with the progress we have made.

I believe all would agree with his goal of making our schools the best in the world and providing every American student the skills necessary to compete in the global economy of the next century. Indeed, the President's budget contains many items which rise above partisan debate and which I intend to fully support. For example, the administration's plan to expand Head Start is long over due. Similarly, I believe we have made progress on Pell Grants, special education, and many other items of concern.

However, I was disappointed to see that for all the rhetoric on reform and bipartisanship, there are still too many areas where the President's proposal falls short.

Chief among these is impact aid. Signed into law by President Truman in 1950, impact aid underlines the Federal Government's commitment to assist local school districts for lost revenue in cases where Federal ownership or Federal activity adversely interferes with a traditional revenue sources.

After making great progress last year, the President's request for impact aid includes a \$31.5 million reduction. No funds are provided for "b students" which make up a significant portion of the student population in impacted areas. Simply put, the President's budget fails to live up to our commitment in this area.

Another issue of great concern to me is bilingual education. The administration has requested an additional \$3.3 million over last year for instructional services and \$14 million for support services even though it was made very clear last year that Congress does not support these programs.

Likewise, for all the talk of promoting technology and helping rural schools, the administration has requested a \$4 million reduction in funding for Star Schools. This important program provides distance learning tools such as two way video and audio communications. The rural schools in my state rely heavily on this program and would be severely disadvantaged if the President's budget was adopted.

Again, thank you, Mr. Chairman, for this opportunity to hear from the administration. I have several questions to be submitted for the record and look forward to the testimony here today. While I believe there is much we can agree on, there remain several areas where I believe the President has missed the mark. However, I do believe that what we have here is an opportunity to do great things for America's school children while remaining within a balanced budget.

#### FEDERAL FUNDING OF HIGHER VERSUS ELEMENTARY EDUCATION

Senator CRAIG. Mr. Secretary, thank you so much for being with us today.

Let me say at the outset I think all of us were pleased with the President's new initiatives announced in the area of education and the priority that this administration has given it. We recognize that that would cause the Congress to move, and for those of us who value and see this as an important part of our responsibilities, we were pleased. Now, that is the end of the good side of the story.

Now, Mr. Secretary, I will cut to the chase: in two areas that you led in last year you are not leading in this year. I am frustrated because, while Senator Harkin is absolutely right—most of our Federal dollars are in higher education and less than 6 percent in primary and secondary—there are some areas where the Federal Government has helped, is helping.

#### PROPOSED CUT IN IMPACT AID FUNDING

But in one instance, impact aid, your budget represents a slash of about \$31 million over last year's totals. Those are real dollars on the ground, in the classroom, in areas where a large Federal presence is real. Of course, you know the issue and you know it well.

The President's budget provides no funding for B students. I am from a Western State; 63 percent of my land mass is caretakered from Washington, DC. It is Federal property. I have native American reservations as well as military installations, and yet while the President takes great credit for an educational program, when we begin to look at it, the dollars flow where the dollars have always traditionally flowed: into the higher education levels as a percentage of the total.

And you have cut back in the area of impact aid. That is one.

## PROPOSED CUT IN STAR SCHOOLS PROGRAM

The other that is such a remarkable tool for the true rural school is the Star Schools Program. We all go around here talking about advancing technology and the application of education. I drove 55 miles through the forest on a gravel road about 1 year ago to a small community and I walked into the doors of the school and every child was sitting at a computer with a satellite up-link on a Star Schools Program, and they were getting a quality of education comparable to or greater than children in the wealthiest of suburban America. Why, even though they were in one of the ruraest of school districts in the State of Idaho? Because of the Star Schools Program.

Your budget represents a cut in star schools funding this year.

My two questions are: Why impact aid and why star schools funding, if in fact this President wants to participate in primary and secondary education at a level where our Government has historically had very real impact?

Secretary RILEY. Thank you, Senator, and I appreciate your positive comments in the beginning.

Senator CRAIG. I meant them. [Laughter.]

Secretary RILEY. And I understand your inquiry. I think it is very legitimate.

The star schools budget was a reduction from \$30 million down to \$26 million.

Senator CRAIG. A \$4 million reduction. That is right.

## EDUCATIONAL TECHNOLOGY PROGRAM INCREASES

Secretary RILEY. But compare that, if you would, with the significant increase in technology that would be provided to the States, a total of \$500 million in addition to this. In other words, the budget includes the technology innovation challenge grants, which the President proposes to increase to \$75 million, that are leveraged out many times that, and they are wonderful, wonderful programs that get whole communities into technology. Then the technology literacy challenge fund would provide \$425 million to the States based on their share of title I dollars. This would mean technology funds would be available for every school to be used for the same kinds of things. Distance learning, that the Star Schools Program has proven effective, could certainly be part of it.

Senator CRAIG. Was your reduction in anticipation of a transition then to these new programs?

Secretary RILEY. Well, it is anticipation of the combination of those, and we really wanted to have a major boost in technology funds for the schools. Talking about what the Federal Government does, in terms of technology in the schools, the Federal Government provides some 25 percent of that. In other words, it is kind of an accepted thing that the Federal Government is going to help in that area at more than its average share for elementary and secondary education generally, which is, as was pointed out, 6 or 7 percent.

So, I think the commitment to technology is very great, and the star schools budget was kept almost level, even considering the tremendous increase in the other technology challenge areas.

Senator CRAIG. Well, for rural States, Idaho being one. We are going to be hearing from Governor Miller from Nevada. He has got schools that are probably even more rural than some of ours in Idaho, and I am sure they implement and utilize star schools funding, which is just an excellent tool.

Secretary RILEY. Well, and he does, and he also has probably the greatest growth, for example, in Las Vegas of any city in America, a combination of problems.

I want you to understand we are not diminishing star schools. We think it has been a grand program. But we felt more or less level funding it, with a slight reduction, combined with a significant increase in the technology programs would be a good move for the country.

#### IMPACT AID

Now, impact aid. I strongly understand the value and need for impact aid in areas where it applies, but we have, for a number of years, attempted to target those funds more to A students and less to B students. Again, that was not a large reduction—\$615 million down to \$584 million.

Senator CRAIG. As you know, though, Mr. Secretary, certainly with your background in education, in schools that are almost wholly dependent on some of this kind of funding, those that have no ability to raise their tax base revenue because it is a Federal base—

Secretary RILEY. Yes; and they depend on this.

Senator CRAIG [continuing]. They depend on this. You have cut their budgets and they have little or no alternative but to apply to the State or to the Federal Government for additional dollars because it is the Federal impact that they experience.

Secretary RILEY. Well, it is a relatively small reduction and it is an attempt again to target funds. Of course, as we all are struggling with the balanced budget effort, it is part of that effort.

Senator CRAIG. I hope we did not fall in the trap that not only this administration has used but others before you, that because it is important and because it is often tied to defense, well, Congress is going to supply the money anyway. So, this is your way of acting frugal but we know it is going to get put back in. I hope that was not the logic because we should be emphasizing the importance of these programs.

Secretary RILEY. The programs are important and they are important for education.

Senator CRAIG. Thank you.

Secretary RILEY. And we did not in any way intend to demean the programs, but it was an attempt to target our funds.

Senator CRAIG. Mr. Secretary, thank you much.

Secretary RILEY. Thank you, Senator.

Senator SPECTER. Thank you very much, Senator Craig.

The Senator from Arkansas, Mr. Bumpers.

#### OPENING REMARKS OF SENATOR BUMPERS

Senator BUMPERS. Thank you, Mr. Chairman, and welcome to the committee, Mr. Secretary.

Secretary RILEY. Thank you, sir.

Senator BUMPERS. It is always a pleasure to have you here.

#### AMERICA READS CHALLENGE

Mr. Secretary, first, let me ask you a question regarding the America reads proposal, which is designed to improve the reading skills of K through third grade children with 1 million-person voluntary army of tutors. This is a very laudable thing for a lot of reasons. No. 1, presumably it will help the reading skills of the children, and No. 2, it will give 1 million people a sense of participation.

But as you may or may not know, for years I have promoted a teacher training program through the National Endowment for the Humanities—I think you are familiar with it. The Carnegie Foundation started this many years ago by educating teachers during the summer months, paying them a stipend to attend—not just to be trained in a particular discipline that they taught—but trained in a whole host of things, for example, the value of the Constitution, the sacredness of the Constitution, and so on.

As I looked at this America reads proposal I still have this strong hankering to do a much better job of educating the present cadre of teachers in this country. After all, education is not going to get better as long as the same people are doing the teaching unless they improve their skills. Would you comment on that?

#### TEACHER PROFESSIONAL DEVELOPMENT

Secretary RILEY. Well, that is absolutely right. Education will only be as strong as its teaching force. As you know, Senator, we are having this week a teachers forum here and we are having the 50 Teachers of the Year from the 50 States that were chosen by the States, and we are having around 50 of the deans and presidents of the teacher colleges in here for them to have a dialog for 2 days and for us to really glean as much as we can out of these best teachers talking to the leaders in teacher preparation.

Now, of course, the Eisenhower program, which we do recommend an increase in, is the program that goes to exactly what you are saying, and that is for the professional development of teachers who are teaching now.

The President also has proposed to increase the funds for national teacher certification, a very difficult, rigorous effort to have master teachers, and this is to help poorer teachers and others get into that opportunity. We would like to see 100,000 of those, 1 perhaps in every single school—a master teacher in every school.

But I thoroughly agree with you, that we should do everything we can to help teachers—and that is what teachers want.

Senator BUMPERS. They do indeed. Every time they offer one of these programs, it is oversubscribed immediately.

Secretary RILEY. Absolutely. Absolutely, and people really ought to know that. Teachers really want the opportunity to improve themselves, to work together, to develop lesson plans together. So, I thoroughly agree with you and I am in support of that concept 100 percent.

## EDUCATION TAX PROPOSALS

Senator BUMPERS. Mr. Secretary, I guess this is more a statement than a question, and as you know, it causes me great pain to disagree with the President because I know he is a thoughtful person, and he is especially thoughtful in educational matters.

But I am going to have a very difficult time voting for the tax proposals that he has suggested because those tax proposals are designed to help people, in my opinion, whose children are going to go to college anyway. It is not a refundable tax credit, and that means only the people who pay taxes will benefit. And I am interested in the people who have fairly good-sized families and do not pay taxes who are going to get no benefit out of this. When I look at the cost of the two tax proposals, the two educational tax proposals, the cost is \$36 billion over 5 years.

## PELL GRANT PROPOSALS

Now, that is a big hunk of change. I know you also plan on increasing the Pell grant which actually does help poor students. We are increasing the Pell maximum award from \$2,700 to \$3,000; that's a \$300 increase in the Pell grant awards which will cost about \$1.7 billion in 1 year, and then the cost of expanding the eligibility, that is, allowing people to have slightly bigger incomes and still be eligible for Pell grants, is going to cost \$3.9 billion over 5 years.

I do not mind telling you, Mr. Secretary, I would 10 times rather forgo the tax cut and put that money in Pell grants where I know—student loans or Pell grants or both, but Pell Grants especially—it is going to go to the people we are trying to help.

Secretary RILEY. Senator, the \$1.7 billion increase for Pell over 1997 to 1998 includes the eligibility expansion too.

Senator BUMPERS. Is that both eligibility and increased award?

Secretary RILEY. Yes; so, it is a total of \$1.7 billion which is a substantial increase in Pell, as you observed.

Senator BUMPERS. Based on history, it is.

Secretary RILEY. Yes; it is the highest increase I think over the last 20 years.

I ask you please to stand back from the situation, and I realize what you are saying about middle-income people. The refundability really does not become much of an issue because if you are not making any income, generally you would qualify for Pell. In other words, if you are not making income, then the refundability does not mean anything to you.

So, when we expanded eligibility for the independent student, the 24-year-old or older student who does not have dependents, then you cover 90 plus percent of those who would get refundability and cover them under Pell, which is tremendously more helpful.

So, that whole student aid package is a very strong, well thought out package, and we think that really covers an awful lot for the poorer, the very poor students.

## EDUCATION TAX PROPOSALS

When you come to \$30,000 for a family or \$40,000 or \$50,000 and you have one or two or three children in school, you are what I call



educationally poor if you are trying to send your children to college. We think this enormous number of people who are in this category, this middle-income category—and as you know, the President has pledged for tax cuts in middle-income people—to have tax cuts targeted for higher education in this category of people we think is a very solid proposal which will enable all young people to have a shot at college.

Then the lifelong tax deduction up to \$10,000 is a strong statement that education is important all of your life. The nontraditional student that is out of school can come back and get 2 years of training and then come back for another year and that \$10,000 tax deduction would be applicable.

So, I would urge you to take a look at that whole package. I think with Pell included and with the IRA and all of the other aspects of it, it is a wonderful package for higher education.

Senator BUMPERS. Thank you, Mr. Secretary.

Senator SPECTER. Senator Bumpers, if you have one more question, proceed.

Senator BUMPERS. I just want to ask a quick question, if I may, Mr. Chairman.

Senator SPECTER. I would like to make the questions as brief as possible, the answers too.

Senator BUMPERS. Yes.

Senator SPECTER. We have many Senators here this afternoon.

Senator BUMPERS. Yes; I am sorry. I do not want to impose on my colleagues.

#### SCHOOL-BASED HEALTH CLINICS

But you know, I am married to the secretary of peace and childhood immunizations, and for many years she has told me that we ought to have school-based clinics in every school, particularly elementary school, in America. I did not pay much attention to that because it did not sound like a very plausible thing, even though when I was growing up poor in the South, the only shots we got were when the county health nurse came to the school.

Now, you probably saw the story the other day that reported the number of school-based clinics in this country have gone from 500 to 1,000 in 2 years. That is all happening at the local level. The Federal Government has nothing to do with that. But I am beginning to think that Betty and Rosalyn who travel together, as you know, across this country on their Every Child by Two Program, are on to something, and obviously the local school districts of this country think they are on to something because when the exponential increase of school-based clinics occurs like this, it is obvious that a lot of school districts think this is very effective both from a health standpoint and from an educational standpoint.

Are you familiar with what I just said?

Secretary RILEY. Yes, I am; and though that is not directly under my Department, of course, I am very aware of what happens out there in the schools. I would say in very poor areas especially, local people are making those decisions and that is a local decision, but it does seem to be working in many cases for them. I am seeing the same thing you are, especially in very, very poor areas.

Senator SPECTER. Thank you very much, Senator Bumpers.

The Senator from Nevada, Mr. Reid.

REMARKS OF SENATOR REID

Senator REID. Mr. Chairman, I will be very brief. I just want to say I hope that you have given the attention to the other 49 States that you have to Nevada. If you have, our country has been served well. You have been a great Secretary of Education for Nevada. You have come there and you have been concerned about rural Nevada in addition to our urban centers. So, I publicly extend my appreciation to you for your concern about the students of Nevada.

Secretary RILEY. I thank you and I thank you for your concern for the same students.

Senator SPECTER. Thank you very much, Senator Reid.

The Senator from Wisconsin, Mr. Kohl?

Senator KOHL. Thank you very much, Mr. Chairman, and Secretary Riley, it is good to see you again.

EARLY CHILDHOOD EDUCATION FOR CHILDREN AGED 0 TO 3 YEARS

I am pleased that Chairman Specter and Senator Harkin have called this hearing to look at the Education Department's budget with a particular focus on early childhood education. Recent research on the brain has confirmed what scientists have been talking about for years: The most significant period in a child's development is between the ages of 0 to 3.

Mr. Reiner's efforts to publicize these findings has brought into our living rooms an issue that was previously only debated in laboratories; namely, what could we do to make sure that our youngest children are receiving the care and education that will shape the rest of their lives?

Unfortunately, the Federal commitment to early childhood education has not caught up with our understanding of how important the first 3 years of life are. Early education and child care receives fewer resources, teacher training, salary, and even respect than the rest of the educational system.

A new commitment to quality child care is necessary as a response to the fact that children between the ages of 0 and 3 are spending more time in care away from their homes. An enormous percentage of women in the work force have children under the age of 3 requiring care. Many of these working families will not be able to find quality child care for their young children, and while Federal, State, and local governments have built an educational system for 5- to 25-year-olds in our country, care and education for 0- to 5-year-olds is largely unstructured, undervalued, and scarce.

PROPOSED CHILD CARE TAX CREDIT FOR PRIVATE SECTOR

Resolving this inequity will require solutions from the public and the private sector. I have recently introduced legislation to encourage the private sector to invest in quality child care for their employees through a new tax credit that would total up to \$150,000 a year for construction and operation of quality child care centers for the children of these employees.

## PROPOSED INNOVATIVE CHILD CARE BLOCK GRANT

Today I am announcing a new initiative to set aside funding under the upcoming budget to enhance innovative early childhood programs. This budget amendment would provide flexible funding in the form of block grants to allow States to focus on the educational needs of children in the 0 to 3 age group. This initiative will be mandatory spending paid for by cuts in other entitlement programs or minuscule reductions in the size of this year's proposed tax credit.

I would like to hear from you, Secretary Riley, on your own reactions to this proposal as well as your interest and concerns about the 0- to 3- to 5-year-old child care problem in this country.

Secretary RILEY. Senator, suffice it to say, I think it is extremely important, and we did have some extensive discussion about it earlier and I will not go into repeating all of that. But it is absolutely critical, and the recent brain research information just makes it more and more important really by the day, as things are being developed.

As I indicated to the committee, I was chair of the Carnegie task force dealing with children aged 0 to 3 that came out originally with the serious recommendations about the same thing you are talking about, these young children. The main crux of their findings was that if we have some shortcoming in this country, it is in the area of child care. So, I think your idea of prioritizing attention to child care makes great sense and certainly is consistent with the research.

Senator KOHL. Thank you. Thank you very much.

Senator SPECTER. Well, thank you very much, Senator Kohl.

The Senator from Washington, Mrs. Murray.

Senator MURRAY. Thank you very much, Mr. Chairman, and thank you, Mr. Secretary. Good to see you again.

I commend Senator Kohl for his emphasis on early childhood education. As the only Senator in the history of this country who was a preschool teacher before being a Senator, I wholeheartedly recommend that we look at early childhood education and the impacts that it has.

Secretary Riley, maybe you can comment further on the fact that we really focus on funding K-12 education, but we do not look at the public involvement in early childhood education, and perhaps we need to look at our commitment to funding early childhood education in the future.

## FEDERAL PROGRAMS FUNDING EARLY CHILDHOOD EDUCATION

Secretary RILEY. Well, that fits of course into several other issues. Let me just mention a couple of things that we do do, and I am inclined to agree with you, Senator.

But title I, for example, addresses early childhood education requirements for State and local plans, and those funds can be used for preschool.

The parents as first teachers component under our reading proposal is very significant, modeled after the Parents as Teachers Program in Missouri and other places, as well as the HIPPIY Program.

The parent resource centers under Goals 2000, 28 of them in very poor areas of this country, also provide help. It is kind of parents helping parents.

For Even Start, which is a very popular and very sound program, we recommend an increase to \$108 million.

IDEA, that we had a significant discussion about, includes part H and also the preschool incentive grants.

Goals 2000. The first goal in Goals 2000 is that children enter school ready to learn, which looks back at the whole idea of preschool.

So, when you add all of these together, it comes to about \$1.5 billion. That is not any great amount of money, but it is more probably than people realize when you put all of these factors together. So, we do have some significant involvement on the part of the Federal Government, but I would certainly agree with you that it is a critical area that we should be looking at in the future.

Senator MURRAY. A lot of what I hear back from my own peers is that we really need to really look at the quality of training and the quality of pay for early childhood education.

Secretary RILEY. Absolutely.

Senator MURRAY. I know that it is a significant factor in the amount of people who go into the field, the staying power of those who stay in and the quality of what our kids learn that are in our preschool programs.

As I listened to all the questions here, it really struck me that your job is very complex, Mr. Secretary. What we demand of our education system today is incredible. All of the diversity of the questions really points that out.

#### EDUCATIONAL TECHNOLOGY

One of the coming challenges that we have that is upon us is the area of technology and the fact that today we have over 180,000 jobs that are open in information technology, going unfilled, good paying jobs, and that we are looking to our schools to educate students in technology so that they have the skills to go into the jobs.

#### TECHNOLOGY TRAINING FOR TEACHERS

One of the areas you and I have talked about before is the fact that we need to train teachers to teach who understand technology and how to use it, not just turning on a computer but integrating it with their curriculum. I have introduced a bill called the Teacher Technology Training Act that will require teachers to have technology training in order to get their certificate and also to have that as part of their professional development for all those teachers out there who have not had any technology training.

Can you take a few minutes to tell us about what is in this budget in terms of technology and what you think we need to be doing and investing in most importantly?

Secretary RILEY. Well, when you talk about technology, I think the part that a lot of people do not pay near enough attention to is teacher preparation. You have all the computers and the Internet and everything in the world, and if you do not have teachers who understand how to use that technology, it is really not that valuable.

So, we are recommending \$500 million total—\$425 million in the technology literacy challenge fund, which would go down to the 50 States based on their share of title I dollars, and \$75 million that would be technology innovation challenge grants.

It has tremendous leverage. The funds that go down to the States in the fund, that is a large request and it is significant, \$425 million. When a State develops its plan for using this money, teacher preparation should be a large part of that plan. The money does not have to go just to buy computers or buy wiring, connections, or whatever. They can use that for teacher preparation, for any of the other aspects of technology to make it work well for children.

Star schools again is a little less than level funding, but we are maintaining that.

#### EISENHOWER

The Eisenhower Teacher Development Program, of course, can be used for teacher preparation and development in technology.

Goals 2000, under the State plan can, of course, be used for that also.

So, we have designed these funds to be flexible so that the States and the local schools are not hamstrung in their use and they can really use these funds as they see fit. Title I also can significantly be used to help with this area of technology.

Senator MURRAY. Thank you.

Are we going to have a second round?

Senator SPECTER. No.

Senator MURRAY. OK.

Senator SPECTER. Would you like to ask another question?

#### TRAINING OF AMERICA READS TUTORS

Senator MURRAY. I just wanted to make a quick comment on the America Reads Program and I will make it real short, and that is that I hope that as you look at the America Reads Program, which I think is really a good way to go, that we make sure that we put in training for those tutors and training money. We cannot just send people out and say, teach kids to read. We need to teach them how to teach.

Secretary RILEY. Thank you very much. We have in there, in answer to that, Senator, the funds for 25,000 reading specialists, and their primary purpose is to train the reading tutors and make sure that they know what they are doing, what to look for, eye problems or whatever. Thank you very much.

Senator MURRAY. Thank you. Thank you, Mr. Chairman.

Senator SPECTER. Senator Murray, I would like to have another round, but we just do not have time. We have another panel and not unexpectedly, we have had a very large turnout of Senators because of the very important subject.

Now, I would like to turn to the distinguished Senator from West Virginia, Mr. Byrd. We welcome you here especially, Senator Byrd, as an ex officio member, and I had some comment as to why I had skipped over you. I did not say at the time that it was at your request to go last.

## REMARKS OF SENATOR BYRD

Senator BYRD. The chairman certainly gave me, at least, two opportunities to ask questions. I thank him for the work that he is doing as chairman of this subcommittee. He spends a lot of time and he is a very able chairman, and as the ranking member of the full committee, I feel that we are all in his debt.

And I say also good things with respect to Mr. Harkin.

Well, Mr. Secretary, I have been in Congress now 45 years. I have been a great supporter of funding for education. During the years I was chairman of the Appropriations Committee, I supported funding for education, and I am still a supporter of funding for education.

But as one who started out in a two-room schoolhouse where we did not have high-technology, but we had dedicated teachers who knew how to teach and who knew how to exact discipline in the schoolroom and where we had students who wanted to learn, and when we had parents who wanted to back up the teachers and be supportive of the teachers, and whose foster father did not say, now, if you get a whipping in school, I will go up and whip your principal, but he said, if you get a whipping in school, I will whip you again when you get home. Now, that is the kind of school era in which I grew up.

But, as I say, as one who has come out of that long-ago environment, as one who like James A. Garfield believed that if he had his old teacher, Mark Hopkins, on one end of the log and he himself on the other, there was a university.

## PROGRESS OF EDUCATION IN THE UNITED STATES

Having said all that, to say that I voted for all the funding that Republican and Democratic Presidents have requested for education, yet with all of this high-technology and all of the reports that the various groups are able to turn out from year to year and make available to committees on appropriations and to the teachers and to the administrations and the schools of the country, with the significant Federal financial investment that we make in the Nation's education system—and I understood you to say that you were asking for \$2.9 billion more than last year—why is the United States not turning out better students?

Secretary RILEY. Senator, you and I could talk for several hours on that question, but it is a very profound question.

I would say this. First of all, when you look at the \$2.9 billion, a good portion of that is Pell, \$1.7 billion, and you were here when we were talking about that earlier. So, the significant increase in Pell is a good part of that.

The country is doing a much better job in education. I am absolutely convinced of that. If you look back when I finished high school in the 1950's, the dropout rate was around 40 percent. Kids who were not so-called college material, dropped out and went to work in the mill or on the farm or whatever, and that was all right during that period because those jobs were there and that is all they called for.

Today the dropout rate is still too high, but it is down to about 11 percent, and we have got to get it on down from that. Today a

young person coming out as a dropout—as you well know, there are just very few jobs out there for them. They really do not have much of a chance to reach their so-called American dream.

The complications—the exponential increase in knowledge that has exploded every year since the 1950’s—really makes education so much different now than what it was. The requirements are different. The competition is different. The whole nature of education is different.

#### COMPARATIVE STANDING IN INTERNATIONAL TESTING

In terms of testing and international testing in reading, we are now second in the world to Finland even though we have not increased our own testing levels significantly over the past 20 years, but we have a different cohort of students being tested. We’ve got more students in high school now than we did.

In terms of math and science, we do not do as well. We are slightly above average in science, slightly below average in math. We then are trying to center in on math and science, centering in on reading, those basics, to master the basics. Just as you would have us do, is what I am trying to do. The President is also.

#### RAISING STANDARDS AND ACADEMIC EXCELLENCE

Raising standards is, Senator, exactly what you and I have talked about for several years now—raising the notch of what young people learn in school and what they are able to do when they come out of school. That is what the standards movement is all about. That is hard work. That is parent involvement. It might not be getting the spanking that you talked about, but it is very much the same kind of tone.

So, I think we are coming along well in a complex time. We need to do more and we need to do it faster, but, I think we are doing that.

Senator BYRD. Well, I thank you, Mr. Secretary, but you yourself said earlier that we are below the international average in math and many other subjects. I do not think we are doing so well.

And I am getting just a little bit tired of voting for funding for the public schools of America when we cannot exercise discipline in those schools, and if there is not discipline, the students cannot study, those who are there to study and who want to study, and the teachers cannot teach. So, I am becoming a little bit discouraged.

I hope that we will put greater emphasis on getting a true education, and I hope that we will learn to reward academic excellence.

Now, I enjoy watching sports on television and I find myself getting on the edge of my seat just like other people do when they want to waste time watching football games and basketball games. And when you have watched one, you have watched them all. I came to that conclusion quite a long time ago. I do not say that in derogation of sports, but I think we have got our values turned on their heads in this country. We reward the athletes, and I do not begrudge the recognition they get, but I think we ought to reward

good spellers and children who can read and write and add and subtract and divide and multiply.

I think we ought to get back to the basics, as you say, but also get back to the basics in teaching. When I was in school, we had a spelling match every Friday afternoon. I looked forward to that. We had adding matches and other arithmetical matches. We are not putting the emphasis on excellence in education, academic excellence.

#### BYRD HONOR SCHOLARSHIPS

And that brings me to my question. Some years ago, when I was earlier in the Senate, 1969, I started a program called the Robert C. Byrd Scholastic Recognition Award in which I gave to every valedictorian in every parochial and public high school in West Virginia a savings bond. I paid for it out of my own pocket. And it went on like that for some years, and then I established a trust fund so that I no longer have to pay that out of my pocket. But each valedictorian in each West Virginia high school, parochial and public, gets a Robert C. Byrd Scholastic Recognition Award, a handsome certificate, and a savings bond.

I know in one case there were seven schools in one county in which students achieved a 4-point average, so I gave each of those seven students a bond.

Now, in the 1980's I started a program in the Congress in which I sought to award merit, to award academic excellence. I did not care whether they were a doctor's son or a coal miner's son or daughter. I wanted to reward excellence and let that valedictorian, that student who strove to get ahead who worked hard in the laboratories and in the libraries and in the schoolrooms, I wanted him or her to get recognition because they were striving to achieve excellence. That is what enabled America to put a man on the moon first because of excellence in academics.

So, Ted Stevens and some others here sought to name that program 2 or 3 years after I had gotten it started, and it provided a \$1,500 scholarship to 10 students in every congressional district in this country chosen by the school administrators, teaching profession, and so on, in all of the States. So, Ted Stevens and others named that through a resolution the Robert C. Byrd Honor Scholarship Program.

Two questions. Over the life of the program, how many students have received Byrd scholarships and how many new and continuing awards have been made?

Mr. SKELLY. Approximately 60,000 students, Senator Byrd. In 1998, we will have 26,000 students getting awards.

Senator BYRD. Thank you.

In 1996 how much did the Department of Education support in need-based student financial assistance?

Mr. SKELLY. About \$28 billion in need-based aid for college students was supported, and it cost approximately \$10 billion.

Senator BYRD. And how much did the agency spend for the same year for merit-based student financial assistance?

Mr. SKELLY. Our only merit-based program, Senator Byrd, is the Byrd Scholarship Program and we used \$29 million.



## MERIT AID—REWARDING ACADEMIC EXCELLENCE

Senator BYRD. Well, I thank you, Mr. Secretary, for supporting the Byrd Scholarship Program. I thank the administration. I think for the first year the administration has put into its budget the full amount of funding for the Byrd Scholarship Program, which is based on merit, which seeks to reward academic excellence so that students will feel that they are getting recognition. And whether, as I say, they come from the home of a lawyer, coal miner, doctor, minister, or whatever, if they can show that they have got the right stuff, they are going to get some recognition. I hope you will continue to support that program.

Secretary RILEY. Thank you, Senator. I wish you could make that same statement to every parent in America. I think that is grand.

The whole idea, though, of the standards movement, Mr. Chairman, that you have supported and all of us have supported is very much in keeping with that. It is not intended to be soft. It is not intended to be easy, but it is raising standards in very many ways and I think it is the right way to go.

Thank you, sir.

Senator BUMPERS. Mr. Chairman, I noticed when Senator Byrd was talking about professional athletes being overpaid, I could not help but notice Senator Kohl was nodding in agreement. [Laughter.]

Senator SPECTER. When Senator Byrd was commenting about time spent on football, I thought of my father's comment, Senator Byrd. He was watching a football game one day and the ball eluded one player after another, as some of those fumbles do down the field, and he watched it for a while and he said, why do they not give those fellows another ball? [Laughter.]

Senator BYRD. Mr. Chairman, one holiday season I decided I was going to watch all the football games, and I watched them through the Christmas season and New Year's Day. And I became so tense and so interested in the games that I just could not pull myself away. Of course, when I was in high school, I rooted for the home team also. I liked athletics.

But after this period was over of several days, I turned to my wife and I said, what have I got to show for my time? [Laughter.]

In every one of those football games, they did the same thing. I can describe a football game right now that will keep your attention and keep you on the edge of your chair.

Senator SPECTER. After the second round, Senator Byrd. [Laughter.]

Senator BYRD. But I decided that I ought to spend my time doing something else. And I say that not in derogation of athletics.

Senator SPECTER. Senator Byrd, we welcome you here. We now know how to get full funding for a program. [Laughter.]

Be in the Congress for 45 years and ask very pointed questions.

We are privileged to have Senator Byrd here. For those who do not know, Senator Byrd spends a good bit of his time on soliloquies on the Senate floor and has published four volumes now, Senator Byrd, on the history of the Senate. And we are indeed fortunate to have him. When the red light is on and Senator Byrd goes over-time, we enjoy it. [Laughter.]

Thank you very much, Senator Byrd.

PREPARED STATEMENT OF SENATOR BOND

The subcommittee has received a statement from Senator Christopher Bond which will be inserted into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF SENATOR CHRISTOPHER S. BOND

Mr. Chairman, it is always a pleasure to hear and learn from the U.S. Secretary of Education, Mr. Richard Riley.

As I have traveled through Missouri and around the country, parents have told me, without exception, that they are concerned about their children's education, from kindergarten to the college level. If, like me, you see college tuition cost looming on the horizon—my son Sam will enter college in less than two years—you are wondering how in the world you are going to pay for it. And you are probably wondering why college tuition costs have gone up so much in the last few years. Since 1980, average tuition costs at public universities have increased 234 percent, but the general rate of inflation and the average household income have increased only about 80 percent (GAO Report). This is astounding and it seems to me that we need to be asking why.

If you are a parent of an elementary, middle-school or high-school student, you may be concerned that they are not learning enough to compete in today's world or you may be concerned about their physical safety getting to and from school and even while in school.

That is why I am a cosponsor of S. 1, the Safe and Affordable Schools Act of 1997. This legislation provides solutions to nearly all of these problems. I am pleased that the President's education budget contains several similar tax proposals included in S. 1.

Mr. Chairman, as we all know, parents are the primary teachers of children and play a vital and enduring role in their education. I am pleased with the President's proposal for preschool children, particularly, the initiative to promote parental involvement in the early learning of their children. I am proud to say that in 1994 Congress passed Parents as Teachers legislation to expand the acclaimed Missouri program nationally, and has since provided funding for school districts to implement the program. This program, which I advocated as Governor and signed into law for all Missouri school districts, has a proven track record of increasing a child's intellectual and social skills that are essential when he or she enters school, and involving parents in creating a healthy and safe learning environment for their children. I hope that we will work to ensure increased funding for the Parent as Teachers program so that the program can be expanded into more communities.

Mr. Chairman, I am delighted that Mr. Rob Reiner (television and movie director) will have the opportunity to testify before the Committee today. Mr. Reiner has launched the "I am Your Child Campaign," and I am proud to be a part of this important new national effort to raise awareness about the first 3 years of life and how this critical period of development may shape a person's future success in school, work, families, and society as a whole. Mr. Reiner has produced a wonderful television special, "I Am Your Child." I hope everyone will tune in on April 28 to this entertaining and informative show. Mr. Reiner, I appreciate your hard work to promote education in the earliest years of a child's life and to improve the care children get in those earliest years and look forward to continuing to work with you on programs that are an investment in our future.

I am sure the White House Conference on Early Childhood Development and Learning: What New Research on the Brain Tells Us About Our Youngest Children will be successful. Fortunately, Missouri has known for years what research is now showing that the greatest capacity to learn is found in a child's early years. I am just glad to see that we are moving in the right direction and look forward to learning more about the new discoveries of brain development.

I am also pleased that the Committee will have the opportunity to hear the testimony of our other distinguished panelists: Governor Bob Miller (D-NV) and Governor George Voinovich (R-OH) and Mr. Bruce Perry of Baylor School of Medicine.

Mr. Chairman, I thank you for your consideration and look forward to a successful appropriations process which will enhance educational opportunities for all students and benefit parents and communities as well.

## ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. We now turn to our second panel. We thank you very much for coming, Mr. Secretary. There will be quite a few questions in writing because there are many subjects we could not cover. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing.]

## ADDITIONAL COMMITTEE QUESTIONS

## PRIVATE SCHOOL VOUCHERS

*Question.* What have been the effects of private school voucher programs in Milwaukee, Cleveland, and possibly elsewhere in the Nation on the achievement of participating children?

*Answer.* Three separate studies of the Milwaukee voucher program have drawn contradictory conclusions about the program's impact on student achievement. The evaluation by John Witte of the University of Wisconsin/Milwaukee found that virtually all participating parents expressed satisfaction with the program, but students' achievement did not improve significantly from their previous achievement in public schools. Greene and Peterson claim to have found evidence that the Milwaukee voucher program had a substantial positive effect on the math and reading scores of students who remained in the program for 3–4 years; however, these results are not significant when adjusted for family background or prior achievement. A third study, conducted by Cecilia Rouse of Princeton, found that participating students made gains in math but not in reading. No data are available yet on the Cleveland voucher program; however, the Ohio Department of Education will be conducting an independent evaluation.

*Question.* Might such programs be a partial solution to the serious problems faced by disadvantaged pupils in high poverty school districts?

*Answer.* Based on a limited number of studies of school choice programs, there is no conclusive evidence that these programs have a positive impact on student achievement. In general, most differences between performance in public and private schools can be explained by the family background of the students—such as family income and parents' educational attainment. Some research indicates that public schools of choice show as large a benefit (if not larger) than private schools in producing better student achievement. For example, a recent analysis comparing 10th graders in Catholic schools, nonreligious private schools, and magnet schools found that magnet schools showed the strongest achievement benefit, with significantly higher achievement in reading, social studies, and science.

In general, probably the most effective educational choice that parents and students can make is to choose to take more challenging courses. Gamoran found that after controlling for course-taking and other student factors, both Catholic and nonreligious private schools showed no significant advantage in any subject, while public magnet schools showed a significant advantage in reading, social studies, and science.

## USE OF PRIVATE SCHOOL FACILITIES TO RELIEVE CROWDING OF PUBLIC SCHOOLS

*Question.* Some school systems are exploring using religiously-affiliated private schools as a means to relieve overcrowding in public schools. What legal and policy issues are raised by such efforts?

*Answer.* Some school districts may consider using private schools as a quick and easy way to deal with overcrowding. However, it is not clear that there are sufficient spaces available in private schools to have a substantial impact on overcrowding. In addition, inclusion of religious schools in any plan to address overcrowding concerns would raise constitutional issues. The study that the Department is undertaking in response to a directive in the 1997 Conference Report will examine these important issues. We believe that a more effective approach to relieving overcrowding in public schools is not short-term use of available spaces in private schools but for States, localities, and even the private sector to meet the responsibility to provide adequate public school facilities.

## SCHOOL CONSTRUCTION INITIATIVE

*Question.* Does your school construction proposal address the overcrowding problems faced by these school districts?

*Answer.* Yes, one of the objectives of our school construction legislation, the Partnership to Rebuild America's Schools Act, is to help school systems build the additional schools they need, or will need, to serve increasing enrollments. In addition, under the legislation, approximately one-half of the funding would flow to the 100 districts that serve the largest numbers of children from low-income families. Districts in this group, such as New York and Houston, are the same ones that have been considering using private schools to relieve overcrowding.

## FEASIBILITY STUDY ON USE OF PRIVATE SCHOOL FACILITIES TO ALLEVIATE PUBLIC SCHOOLS OVERCROWDING

*Question.* Last year, I included language in the conference report accompanying the omnibus appropriations bill requesting that your Department provide to the Committee by September 1, 1997 a feasibility study outlining the benefits of using private and parochial schools as an alternative to alleviating the overcrowding in public schools and barriers to using public school dollars for tuition reimbursements. What is the status of your work on that study?

*Answer.* The study is somewhat behind schedule due to extended consultations with private school and public school organizations and with the Office of Management and Budget over the study design and questionnaires. OMB cleared the data collection instrument on May 2, and the Department sent out surveys the following week. This data collection consists of the following components:

- A survey of urban school districts to determine the extent of overcrowding, and the status of efforts to alleviate overcrowding. This survey went to 24 large urban districts that have identified a problem with overcrowding.
- A survey of private schools to determine their capacity to serve additional students and to obtain information about their tuition and fees, admissions policies, student diversity, and interest in participating in a program to help the public schools reduce overcrowding. This survey went to a representative sample of private schools located in the geographic areas covered by the above 24 school districts.
- A survey of private school organizations to explore potential issues and concerns for private schools that might participate in such a program.

Although we will make every effort to complete the study as quickly as possible, it seems unlikely that we will be able to deliver the final report to Congress by the requested date of September 1. If we cannot provide the complete report by that date, we will submit an interim report by September 1 that discusses the legal issues surrounding the use of public dollars for the education of students in private and religious schools, implementation and program design issues based on the experience with publicly funded voucher programs in Milwaukee and Cleveland, and issues raised by the private school organizations.

## FUNDING FOR THE VOLUNTARY NATIONAL ASSESSMENT TESTS

*Question.* Would you provide the Committee with details on the proportion of fiscal year 1997 appropriations, and of the fiscal year 1998 budget request, that you propose to use for the development and administration of "national tests" in reading and mathematics for fourth and eighth grade students?

*Answer.* We will use funds made available for the Fund for the Improvement of Education (FIE) in the appropriation for Education Research, Statistics, and Improvement to develop these tests. We expect to use up to \$10 million in FIE funds for this purpose in 1997, and up to \$12 million in 1998, infinitesimal portions of the \$29 billion fiscal year 1997 appropriation and the \$39 billion fiscal year 1998 request. Funds will not be needed for implementation (or administration) of these tests until 1999 when they first become available for use by States and districts.

*Question.* Since there was no mention of using these funds for this purpose in your fiscal year 1997 budget, don't you feel that a formal reprogramming request is in order if these funds are to be used to develop these national tests?

*Answer.* No. We think the FIE authority and funding is so broad that no reprogramming is necessary.

*Question.* What is the Department's statutory authority for conducting your proposed national testing program?

*Answer.* We believe that authority exists under the Fund for the Improvement of Education authorized by Title X, Section 10101 of the Elementary and Secondary Education Act (20 USC 8001).

## SCHOOL CONSTRUCTION INITIATIVE—PROPOSED AS MANDATORY APPROPRIATION

*Question.* The Administration's initiative for school construction would provide a program of \$5 billion over 4 years to pay Federal interest subsidies for construction projects for school districts repairing existing K-12 schools or building new schools to meet overcrowded conditions. Why is the funding for this proposal being requested as a "mandatory", rather than a "discretionary" appropriation?

*Answer.* In order for this program to have its intended impact on State and local activity, it is important that the States and communities know that the money will be available up front. Without a guarantee of funding—that is, if annual funding is subject to the regular appropriations process—States and communities may be unable to initiate bonds and other financing actions, which would undermine the purposes of the program. For this reason, the Administration has proposed making the School Construction program a mandatory expenditure.

## FINANCING THE SCHOOL CONSTRUCTION INITIATIVE

*Question.* For what length of time will Federal funding be required to meet commitments under the proposed school construction program?

*Answer.* The Administration has proposed a one-time, \$5 billion mandatory appropriation in fiscal year 1998. In order to give States and school districts sufficient time to develop their school construction plans and go forward with bonds and other financial activities, the funds would be available for obligation for four years.

*Question.* How do you anticipate financing the school construction program?

*Answer.* The Administration has proposed to finance the program through a one-time, \$5 billion mandatory appropriation.

*Question.* If you are using spectrum sales, what is to prevent other competing interests from using the same source of money? Also, how stable will the money source be?

*Answer.* We are no longer proposing to finance the program through spectrum sales. When the President announced this initiative during the course of Congressional deliberations over the 1997 budget, he was required to identify an offset because the program had not been included in the Administration's budget submission. At that time (July of 1996), we identified the sale of a portion of the VHF television spectrum as the offset.

Now, because the proposal fits within the President's overall plan for eliminating the budget deficit, as enunciated in the 1998 budget, a specific offset is not needed, and the proposal is no longer tied to spectrum sales.

## IDENTIFYING DISTRICTS WITH CRITICAL CONSTRUCTION NEEDS

*Question.* What criteria will be used to determine which schools are "in greatest need?"

*Answer.* Under our proposal, States would give priority to construction projects in localities with the greatest needs, as demonstrated by inadequate educational facilities coupled with a low level of resources to meet school construction needs. The States would measure the needs of different communities through a survey undertaken with the involvement of school officials and experts in building construction and management. The 100 urban districts that would receive direct grants from ED would undertake a similar survey of their school construction needs and would use the Federal subsidy to fund their highest-priority needs.

*Question.* Where do "technology needs" rank in the list of "needs" for schools in the President's school construction proposal?

*Answer.* The Administration recognizes that improving school infrastructure to enable the use of advanced educational technologies is one of the major challenges facing school districts. Our bill would thus authorize States and districts to use the Federal funds to support construction that facilitates the use of educational technologies. It would not, however, make this type of construction a higher or lower priority than repairs to meet health and safety needs, disability access, improvement in energy efficiency, or other types of eligible construction activities. That decision would be up to local and State officials.

It is likely that most construction projects will meet more than one need; a school renovation can, all at once, upgrade building systems (such as plumbing and heating), increase energy efficiency, remove architectural barriers to disability access, and provide the wiring needed for new computers and other technologies. It would be cumbersome, and thus inappropriate, for the Federal Government to specify one or more of these activities as priorities.

## EBONICS AND FEDERAL PROGRAMS

*Question.* Mr. Secretary, on January 23, 1997, this Subcommittee convened a panel to discuss the issue of Ebonics. Unfortunately, your schedule did not permit you to attend that hearing. Are there any current Federal education programs that either might be used or are presently being used to support school programs based on Ebonics?

*Answer.* Because we do not view Ebonics as a language, we do not believe that the objective of teaching or maintaining Ebonics as a language would come within the purposes of any of our programs.

*Question.* Is it possible for schools to use their funds under Title I of the Elementary and Secondary Education Act for an Ebonics-based program?

*Answer.* Schools have the flexibility to decide how to use Title I funds to help disadvantaged students meet high standards in core academic subjects. They can use the teaching tools and approaches that they believe make the most sense in helping raise their own students' performance. However, the bottom line is that Title I requires schools to show that their students are meeting high standards in core academic subjects.

## WHITE HOUSE CONFERENCE ON EARLY CHILDHOOD DEVELOPMENT

*Question.* What role is the Department playing in tomorrow's White House Conference on Early Childhood Development?

*Answer.* Department staff participated in the interagency planning meetings for the conference, helped identify participants, developed lists of potential invitees to the conference, and provided early childhood research reports and other materials for use in planning the conference. In response to the White House Executive Order, the Department prepared a detailed report of its early childhood research and program activities.

The Department's Office of Educational Research and Improvement (OERI) is assisting with the editing and production of the conference proceedings, in conjunction with the Department of Health and Human Services (HHS).

## RELATIONSHIP BETWEEN A CHILD'S EARLY EXPERIENCES AND SCHOOL SUCCESS

*Question.* Do you have any information on the relationship between a child's experience during the first three years of life and later success in school?

*Answer.* The National Institute on Early Childhood Development and Education, within OERI, is supporting a number of projects that are examining the relationship between children's early experiences and their success in school. Examples include:

- (1) Research conducted by the National Center for Early Development and Learning on how quality in early childhood programs for young children affects school performance and behavior by second grade; how early childhood experiences at home and in preschool settings influence children's transitions to kindergarten; and how family-centered, community-based intervention models improve outcomes for young children with a variety of risk factors.
- (2) A multi-site, randomized study of the short- and long-term effects of the Parents As Teachers (PAT) program, and whether it affects parent knowledge, attitudes, and behaviors; parent-child interactions; and early development and later school readiness, school performance, and attendance of young children. This study will assess the effectiveness of early parenting education and the support provided through home visiting for families with young children.

In addition, OERI and HHS's Maternal and Child Health Bureau are currently funding a follow-up of the Abecedarian Study, one of the best research studies on the relationship between a child's earliest experiences and his or her later success in school. The study has found that "educational intervention very early in the life span had greater impact than experiences provided later" (Campbell & Ramey, 1995). The study has found that children who received an intensive preschool program continued to have higher intelligence test scores, significantly higher test scores in reading and math, fewer cases of retention in grade (39 percent vs 59 percent), and fewer special education placements (24 percent vs 48 percent) than children who did not receive the intervention. Currently, 74 of the original 111 Abecedarian children are taking part in the follow-up investigation. To date, they have been evaluated at ages 8, 12, and 15. The follow-up will look at the role that fathers played in the children's learning and social development; community-level influences; and individual differences among the sample population.

While there has been little research that begins with children during the first three years and assesses their later school success, the Carnegie Corporation's 1994 report, *Starting Points*, documents the importance of the first three years in how

children and adults function. The brain develops rapidly and extensively prior to age one and is vulnerable to environmental influence, including nutrition, health care, and how parents and other caregivers treat the baby. The major implication is that experiences in the earliest years must be enhanced regardless of the settings children are in, including family and child care environments. A failure to invest resources in education and development until a child reaches kindergarten, or even 3 and 4 years old, may be penny wise and pound foolish.

Studies related to children with disabilities also provide important information. The Infant Health and Development Program, a national multi-site study completed in 1992, found that low-birth weight, premature infants who received comprehensive early intervention and preschool services scored significantly higher on tests of mental ability, and experienced lower mental disability rates, compared to children who received only health services. The Early Intervention Collaborative Study also found developmental gains after one year of intervention in children with identified disabilities or who were at risk for developmental disabilities (Shonkoff, et al., 1990). In 1996, the Early Intervention Research Institute completed work on a number of longitudinal studies of the effects and costs of early intervention with children with disabilities. These studies indicate that positive differences continued as children progressed through elementary school.

RECOGNIZING THE IMPORTANCE OF EARLY BRAIN DEVELOPMENT IN DEPARTMENT OF  
EDUCATION PROGRAMS

*Question.* How is the importance of brain development in the first three years of life recognized in education programs and activities?

*Answer.* In the Special Education area, we know that the earlier you intervene, the more positive effect you can have on the cognitive development and functional abilities of infants and toddlers with disabilities. In recognition of the importance of the first three years on the physical and mental development of the child, we support a number of early intervention activities. For example, the Infants and Families program, for which \$324 million, an increase of \$8 million, is requested in fiscal year 1998, assists States to implement coordinated, comprehensive statewide inter-agency systems to make available early intervention services to all 0 to 3 aged children with disabilities and their families. To promote effective implementation of this program, we also conduct a comprehensive program of early childhood research and technical assistance on best practices related to early intervention for infants and toddlers with disabilities or at risk of developing disabilities. We also provide information to parents on early intervention and early childhood education through Department-funded clearinghouses and our parent training program.

ONGOING RESEARCH ACTIVITIES ON EARLY DEVELOPMENT

OERI's National Institute on Early Childhood Development and Education sponsors many activities that focus on how to use the results of brain research in programs or practices aimed at young children. Specifically:

- (1) The National Center for Early Development and Learning at the University of North Carolina conducts research that examines the relationship between the quality of child care environments and children's learning and development. The work is focusing on intervention models currently used with infants who have "failure-to-thrive syndrome", young children who have early onset of aggressive and antisocial behaviors, and children whose families have low literacy levels. It aims to determine if new, family-centered, community-based models of supports and services reduce risk factors and improve outcomes for these young children and their families.
- (2) A study of the Prevention of Reading Difficulties in Young Children is being conducted by the National Academy of Sciences, with funding from the Early Childhood Institute, the Department's Office of Special Education Programs, and the National Institute on Child Health and Human Development in HHS. The effectiveness of existing models of prevention, program intervention, and instructional techniques used with populations of children at-risk for reading difficulties will be compared. Major policy implications of the research will be highlighted, as will future directions for research and practice. Materials also will be prepared for practitioners and parents.
- (3) A project to identify, describe, and disseminate information about promising school-based or school-linked programs that reduce the number of low birth weight babies (under 5½ pounds) born to adolescent mothers. HHS reports that 22.5 percent of babies born to teenage mothers in 1992 were low birth weight. We do not know how low birth weight is related specifically to brain development. However, the Packard Foundation's 1995 report on this topic found that,

after controlling for other factors, low birth weight children are 50 percent more likely to be placed in special education programs than normal birth weight children. In addition, 31 percent of low birth weight children repeat a grade compared to 26 percent of normal birth weight children.

PLANNED RESEARCH ACTIVITIES RELATED TO BRAIN RESEARCH AND EARLY CHILDHOOD DEVELOPMENT AND LEARNING

Additional activities are planned, including:

- (1) A Study of Early Childhood Pedagogy by the National Academy of Sciences. This two-year activity will convene leading early childhood researchers and educators to determine what young children should know, when they should know it, and how they can learn best what they need to be prepared for and successful in school. How to translate neuroscience findings to everyday practice will be part of the discussions and deliberations.
- (2) A National Forum on Neuroscience Research and Early Learning: Implications for Educational Practice and Public Policy sponsored by the Early Childhood Institute, the Danforth and Dana Foundations, the Parents As Teachers National Center, and the Graduate Department of Neuroscience Research at Washington University (St. Louis). The Forum, to be held in the fall of 1997, will examine recent neuroscience research findings and their relationship to the development of language, literacy, and reading in young children. Discussions will focus on the implications these findings have for States and communities as they design early education and child care policies and programs for young children and their families.
- (3) The National Center for Early Development and Learning will sponsor, in September 1997, a research synthesis conference to determine what infant-toddler child care practices and policies will maximize learning and development. For very young children, the average age of entry into child care is 3 months, and research shows that infant-toddler care is usually of the poorest quality. Invitees will include a mix of leading neuroscience and early childhood researchers and practitioners.
- (4) The Early Childhood Institute will sponsor a conference on Developmentally Appropriate Practices and Early Brain Development that will include neuroscience, child development, and early childhood researchers, family organization representatives, and practitioners to discuss young children's learning and development. The purpose will be to develop a document that presents a summary of some key brain development findings related to young children; includes a section to help parents and educators understand these findings; and includes examples of developmentally appropriate activities that educators and parents can use in everyday activities with young children.

INTERAGENCY COORDINATION TO DEVELOP EDUCATION POLICIES RECOGNIZING THE IMPORTANCE OF THE AGES 0-3

*Question.* To what extent does the Department of Education coordinate with the Department of Health and Human Services and other Federal agencies to develop comprehensive education policy that recognizes the importance of ages 0-3?

*Answer.* The National Education Goal of school readiness, with its emphasis on nutrition and health care, access to preschool, and parenting, provides a natural link for interagency coordination of early childhood education efforts, and we are working closely with other agencies to ensure that young children start school ready to learn. To help achieve this goal, we are collaborating with the Department of Health and Human Services and other Federal agencies to develop a coordinated approach for planning future directions for early childhood research, practice, and policy. For example, in the Special Education area, the Secretary heads a Federal Interagency Coordinating Council related to infants, toddlers, and children with disabilities, the purpose of which is to ensure effective coordination and minimize duplication of Federal early intervention and preschool programs and policies; coordinate technical assistance and support activities to States; identify gaps in Federal programs and services; and identify barriers to Federal interagency cooperation. The Council includes representatives from Federal, State, and other agencies, and parents. Representative HHS agencies include NIH, Maternal and Child Health, the Administration for Children and Families, the Administration on Developmental Disabilities, and the Health Care Financing Administration, and others.

The Department's National Institute on Early Childhood Development and Education, in February 1995, convened the Early Childhood Research Working Group, which is comprised of agencies across nine Federal departments and the Government Accounting Office. The agencies have research, data collection, and service de-



livery responsibilities focusing on children from birth through 8 years of age and their families. The purposes of the Working Group are to share early childhood research, development, and policy information across Federal agencies; offer opportunities for professional development for agencies' staff; and develop a mechanism for building a collaborative research, development, and policy agenda for children from birth through 8 years of age and their families.

We co-fund research and technical assistance activities to promote broad understanding of what children should know and be able to do at various developmental levels from birth through age 8. For example, the Early Childhood Institute supports collaborative research efforts with other Federal agencies, including an inter-agency study of the effect of comprehensive interventions on young children's learning and development, and a project on the prevention of reading difficulties in young children. The Institute will also join the National Institute of Justice and the MacArthur Foundation in a nine-year study, following 7,200 children in Chicago, to learn how aggressive behaviors develop and what interventions, beginning in infancy, might reduce the behaviors. In addition, the Institute will join the National Institute on Child Health and Human Development's study of the Health and Mental Health Adjustment of Immigrant Children, which will have major implications for the public schools.

We also carry out other collaborative efforts with HHS such as joint monitoring of the Infants and Families program.

#### TITLE I, EVEN START AND HEAD START COLLABORATION

Our efforts also include building continuity between Head Start, Title I, and Even Start programs so that they more effectively address the developmental and educational needs of the children they serve. For example, beginning in 1998, Title I preschool programs must meet several requirements for developing early childhood curricula that also apply to Head Start programs. We worked closely with HHS to help schools and districts implement those standards. Also, the Even Start family literacy program reinforces early learning by integrating early childhood education for children from birth through age seven, parenting, and adult literacy activities that help parents take a more active role in their children's learning. By networking a variety of services for families, Even Start projects link families with Head Start and other early childhood programs, as well as family health and nutrition assistance, English language classes, day care, and job training.

#### PROPOSED POSTSECONDARY EDUCATION TAX CREDITS AND DEDUCTIONS

*Question.* The Administration has proposed Federal tax credits and an alternative tax deduction for postsecondary education tuition and fees. What do you consider to be the advantages of this form of assistance compared to the more traditional form of authorization and annual appropriations for student assistance through grants and loans?

*Answer.* The primary goal of our tax credit and deduction proposals is to reduce the tax burdens faced by middle-income families who are struggling to help pay the college bills of their children. Our tax credit and deduction proposals complement our proposals for substantially increased direct need-based grant aid to students, including the highest Pell Grant maximum award in history. These traditional programs tend to provide more help to poorer families than to the middle class.

*Question.* Is there any way to control budgetary costs of such tax expenditures since these would not go through the annual appropriations process?

*Answer.* The budgetary costs of these tax provisions would be controlled by eligibility limits on family income, costs of attendance, and other criteria. These are not open-ended policies. In addition, the provisions could be modified during a budget reconciliation process if necessary. The higher education tax proposals are consistent with the President's and the Congress's goal of reaching a balanced budget. The President's proposals for the HOPE Scholarship and the education tax deduction can be paid for fully within the fiscal year 1998 President's Budget.

#### IMPACT OF TAX PROPOSALS ON ACCESS AND COLLEGE COSTS

*Question.* Do you have any information that would suggest which form of assistance—tax credits or deductions versus grants or loans—would more likely increase access to postsecondary education and strengthen educational opportunities in general? What is the basis for claims that the proposed tax credits and deductions would increase access to postsecondary education?

*Answer.* I do not think you should look at this situation as a choice between higher education tax proposals and traditional student aid. We need both. All these forms of assistance would improve access to postsecondary education. Need-based

aid would be available to students from low-income families. The tax provisions would be available to students from middle-class families, as well as for workers returning to school to acquire additional skills. Finally, loans would be available to students who come from families which have a variety of income levels.

*Question.* Do you have any information that would suggest which form of assistance would be more likely to curtail the constantly rising costs of tuition and fees for postsecondary education? Is there any evidence to suggest that state legislatures would not use the availability of tax credits and deductions as an opportunity to raise tuition at state colleges and universities by an equivalent amount?

*Answer.* Federal assistance for postsecondary education has little to do with postsecondary tuition costs. Postsecondary cost increases are driven by such factors as the need for technological and academic facilities improvements, increasing faculty salaries, and institutional financial aid.

I do not believe that state legislatures will raise tuition at state colleges and universities because of the proposed tax provisions. Many factors enter into a state legislature's decision to set tuition at a certain level. Those factors include the level of subsidy the state believes is equitable for all of its citizens as well as its willingness to tax and its ability to pay. Typically, states have a clear policy to maintain low tuition levels at its public institutions.

#### PROPOSED AMERICA READS CHALLENGE

*Question.* What is the rationale for the proposed "America Reads Challenge" program? We already have major programs for young children that focus largely on developing reading skills—Head Start, Title I, Even Start, and smaller efforts such as the Parental Assistance program authorized by Title IV of Goals 2000—so why do we need another program in this area?

*Answer.* The proposed America Reads Challenge will be devoted exclusively to helping children read well and independently by the end of the third grade. Although Head Start, Title I, and the Goals 2000 Parental Assistance program devote resources to helping develop children's reading skills, these programs have a much broader purpose. The whole idea behind the America Reads Challenge is to work with parents and educators to complement and support these other, essential programs so they can be even more effective in helping children increase their skills and achievement levels, and by extending the on-task learning time of children who need special help in reading, particularly before and after school and in the summer.

Even when students receive the very best in-class instruction, some will always need extra time and assistance to meet the high levels of reading skills needed in today's economy. A significant part of the America Reads Challenge, Parents as First Teachers, will provide grants to organizations that assist parents, including those with children in Head Start, to help their children become successful readers. The Reading Corps portion of America Reads, which will provide tutoring to students after school, on weekends, and during the summer, will coordinate its tutoring efforts with each child's in-school reading program. One-on-one instruction is a key component in enhancing reading skills. Study after study finds that sustained individualized attention and tutoring after school and over the summer can raise reading levels when combined with parental involvement and quality school instruction.

For our Nation to achieve its full potential, we must make sure that every young child can read. Far too many of our young people are struggling through school without having mastered this most essential and basic skill. On the 1994 National Assessment of Educational Progress, 40 percent of all 4th graders scored below the "basic" reading level. This is just not good enough. By the start of 4th grade, students must be able to read so that they can learn science, history, literature, and mathematics. If they can read then, they can read to learn for a lifetime. Students who fail to read well by 4th grade have a greater likelihood of dropping out and a lifetime of diminished success.

#### LEGISLATION DESIGNED IN RESPONSE TO NEEDS IDENTIFIED BY SCHOOL AND COMMUNITY LITERACY PARTNERSHIPS

*Question.* Is the "America Reads Challenge" largely an effort to link AmeriCorps with much more popular, less controversial programs in an effort to secure its future? What are the truly new elements of the America Reads Challenge?

*Answer.* We have designed the America Reads Challenge legislation in response to the needs of school and community literacy partnerships, not as a strategy for boosting AmeriCorps. Last fall, officials at the U.S. Department of Education met with individuals from parent groups, businesses, leading principals and teachers, literacy groups, and community organizations and asked them what they thought was needed to help America's children learn to read successfully. The general and over-

whelming response focused on two things: 1) the need for trained reading specialists to train volunteer tutors; and 2) the need for organized tutor coordinators to help match tutors with children. What is unique about the America Reads Challenge legislation is that it builds on this feedback and will provide the resources necessary to implement and carry out successful school and community reading programs that extend learning time for children who need extra help to read well. These school and community partnerships are doing a good job, but they are reaching only a few of our children who need help.

In the America Reads Challenge Act, the Corporation for National and Community Service would help local reading programs recruit and organize volunteer tutors. The tutors, coordinating with the in-school reading program, would provide individualized after-school, weekend, and summer reading tutoring for children who want and need the extra help. We expect these tutors to help link the reading program, teacher, school, child, and family. The funding for the Department of Education will provide the technical and training expertise of reading specialists. Together, the two will fill a void and a real need to provide after-school and summer reading help.

AMERICAN READS CHALLENGE—JOINT INITIATIVE OF ED AND THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

The Administration designed America Reads as a joint initiative between the Department of Education and the Corporation for National and Community Service in order to leverage existing Federal resources and provide tools to communities that need and want them. The America Reads Challenge legislation would build on the strong track record of national service in tutoring and literacy. More than half the 25,000 AmeriCorps members now serving work with children and youth by tutoring, mentoring, and running after-school and summer programs. Learn and Serve programs mobilize hundreds of thousands of K-12 and college students in service projects; many tutor younger children. The Senior Corps, RSVP volunteers, and Foster Grandparents work extensively in school settings. The America Reads Challenge calls for 11,000 additional AmeriCorps members each year to recruit and train volunteers, and thousands more Senior Corps volunteers and Learn and Serve students to manage tutoring programs or provide tutoring.

SCHOOL-TO-WORK

*Question.* Some parents and interest groups are concerned that school-to-work programs steer students away from college and tracks them into specific jobs. What evidence do you have to the contrary?

*Answer.* It is unfortunate that anyone would have these misperceptions. Today's high-skill job market demands that high school graduates have both advanced academic knowledge and workplace skills. Far from tracking students into specific careers, School-to-Work systems provide students and their parents with options, so that they can make informed choices—both about further education after high school and about careers.

Many students learn better and retain more when they learn in context, rather than in the abstract, and integrated work-based and school-based learning can be very effective in motivating students to learn. School-to-Work does not “track” students into set career paths. No one chooses a student's career path, and no student is asked to make final high-stakes occupational decisions. Last month, through the School-to-Work program, we identified five urban high schools that are on the cutting edge of education reform. I visited one of these schools—the Central Park East Secondary School in New York City. This school and others like it show that teachers, students, parents, the community, and businesses can join forces to produce outstanding schools that stress:

- High academic standards and career skills;
- A curriculum of high-level academics linked with career experiences;
- Career exploration and work experiences linked to classroom teaching;
- Strong partnerships between the high school and postsecondary institutions;
- Adult mentors to assist students with classroom and on-the-job learning;
- A safe, supportive learning environment within the school.

*Question.* What steps is the School-to-Work Office taking to ensure parents that school-to-work programs won't preclude or discourage their children from going to college?

*Answer.* School-to-work aims to improve the way students are prepared for college, careers, and citizenship. The authorizing statute contains numerous provisions referencing the important role of postsecondary education in any school-to-work system. For example, the school-based learning component of a school-to-work system

must include a program of study designed to meet the same academic content standards the State has established for all students—standards that meet the requirements necessary to prepare a student for postsecondary education. In evaluating applications and plans from States, peer reviewers look specifically at the extent to which the State's school-to-work plan includes effective strategies for establishing linkages between secondary and postsecondary education.

PROGRAMS NOT AUTHORIZED UNDER THE IDEA ACT WHICH SERVE CHILDREN WITH DISABILITIES

*Question.* In addition to programs authorized under the Individuals with Disabilities Education Act (IDEA), what Federal programs provide assistance to school districts to educate students with disabilities? In particular, what role does Medicaid play in serving children with disabilities in public schools?

Answer. Several Federal programs provide support for educating children with disabilities as part of their program mandates to help educate children in general or to provide particular services such as health services. For example, about 5 percent of the children served through Title I of the Elementary and Secondary Education Act are children with disabilities.

MEDICAID PROGRAM SERVICES FOR THE DISABLED CHILD

Medicaid is a major resource for financing health-related services, that are necessary in order to provide children with disabilities with access to special education services. In 1988, the Medicare Catastrophic Coverage Act amended the Medicaid law to make clear that Medicaid funds are available to pay for health-related services and that nothing under the Medicaid statute is to be construed as prohibiting or restricting the payment for services covered under a Medicaid State plan simply because they are on a disabled child's individualized education program.

The use of Medicaid funding is most important in districts with limited financial resources and where large proportions of the children served are poor. For these districts, Medicaid funding can be a critical resource in serving children with disabilities.

AMOUNT OF LEA ASSISTANCE FOR DISABLED STUDENTS PROVIDED BY NON-IDEA AUTHORIZED PROGRAMS

*Question.* What is the total amount of assistance that flows to local educational agencies (LEA's) under these other Federal programs for disabled pupils?

Answer. We do not know how much funding from other large programs is provided to schools or is used by schools to pay for services. However, we believe that Medicaid and other health programs provide substantial support for related services necessary to provide children with disabilities access to education. The way many programs are structured would make accumulating such information very difficult. For example, Medicaid costs are supported from State and Federal funds; and the Head Start program requires that 10 percent of class spaces be made available for children with disabilities, but does not indicate any particular level of funding for services to these children.

Most assistance from the Department of Education for children with disabilities is provided through Part B of the Individuals with Disabilities Education Act and through Title I Grants to Local Educational Agencies.

Under Title I, funding is not tracked to individual children, and we do not have information on the amount that schools actually spend on children with disabilities. In fiscal year 1996, the Title I Grants to Local Educational Agencies program provided services to an estimated 9.6 million children at an average Federal per-child cost of \$700. Based on State-reported data for 1994–95, about 5 percent of children receiving Title I services were identified as having disabilities. Assuming that schools spent an average of \$700 on each of the 9.6 million children estimated to be served by the program in fiscal year 1996, then of the \$6.730 billion in total funding, \$336 million would have been for children with disabilities. The actual amount used for disabled children receiving Title I services may be greater or less than this amount.

IDEA—LEA USE OF GRANTS TO STATES PROGRAM FUNDS

*Question.* What is the most important use of IDEA funds by LEA's?

Answer. Under the Grants to States program authorized by the Individuals with Disabilities Education Act (IDEA), Federal funds are provided to assist in paying for special education and related services for children with disabilities. For fiscal year 1997, the appropriation for Grants to States represented only about 8 percent

of the excess cost of providing these services. Local educational agencies have great flexibility in determining which expenses will be paid for from Federal versus State or local funding sources. One LEA may use Federal funds to pay for special transportation costs while another uses the Federal funds for teachers' salaries. We do not collect information on which services local educational agencies have chosen to use Federal funds to pay for.

*Question.* Are IDEA funds being effectively used by school districts?

*Answer.* Funds from IDEA are used in conjunction with State and local funds to provide children with disabilities with free appropriate public education. The effectiveness of the use of these funds varies from local educational agency to local educational agency and from State to State. One area of concern relates to the use of funds to support placements in separate schools, which can involve high transportation costs, and, in the case of private school placements, tuition.

#### LEGISLATION PROPOSED TO CAP STATE ADMINISTRATIVE FUNDS UNDER IDEA

*Question.* Should Congress require that a greater proportion of IDEA funds flow through to LEAs?

*Answer.* Congress has addressed this issue in the Individuals with Disabilities Education Act Amendments of 1997, which passed the House on May 13, 1997, and the Senate on May 14, 1997, and is now awaiting the President's approval. This bill, which is supported by the Administration, would increase the proportion of funds to be flowed through to local educational agencies by capping the amount of funds that may be retained by the State educational agency. In years in which the percentage increase in a State's allocation exceeds the rate of inflation, the State may reserve an amount up to the amount it was authorized to retain in the previous year plus inflation. The balance of funds must be provided to local educational agencies.

*Question.* What type of activities do State education agencies (SEAs) support with their set aside?

*Answer.* Most States do not retain all of their set-aside funds at the State level, but pass a portion of these funds on to local educational agencies according to the Federal formula for distributing funds or targeted to specific local purposes. Other major uses of funds include operating Statewide and regional resource centers and staff development activities.

#### EQUITABLE FEDERAL SHARE OF EXCESS COSTS TO SERVE CHILDREN WITH DISABILITIES

*Question.* What is the equitable share of excess costs that should be borne by the Federal Government?

*Answer.* The President's budget request for fiscal year 1998 for the Special Education Grants to States program is over \$3.2 billion. This amount would provide about 8 percent of the excess cost for serving children with disabilities, the same level as in fiscal year 1997, and would provide support for an additional 101,000 children with disabilities requiring services. We believe that this is an appropriate level of funding for fiscal year 1998 under the current Federal funding restraints. In addition, children with disabilities will benefit from the other initiatives for which we have requested funds.

#### IMPACT OF INCREASED APPROPRIATIONS ON STATE AND LOCAL SERVICES

*Question.* If Congress increased appropriations for IDEA, will that provide fiscal relief at the State level or local level?

*Answer.* Increases in the appropriations under IDEA above the requested level could be used at State and local discretion to provide fiscal relief, subject to the requirement that, for each local educational agency, the spending for children with disabilities cannot be reduced below prior year spending levels. Additional Federal funding might be used to cover increases in costs or to expand services for children with disabilities. Under the IDEA Amendments that are now awaiting the President's approval, LEAs will have the authority to use a portion of their Federal funds to replace local funds once the appropriation for the program reaches \$4.1 billion.

#### PUBLIC CHARTER SCHOOLS PROGRAM

*Question.* You propose a doubling of the appropriation for charter schools, from \$51 million for fiscal year 1997 to \$100 million for fiscal year 1998. This compares to an \$18 million appropriation 2 years earlier, for fiscal year 1966. How effectively can these rapidly increasing appropriations be used?

*Answer.* The increase requested for Charter Schools in 1998 is consistent with the remarkable growth in the number of States with charter school laws and the num-

ber of charter schools across the country. Between 1991 and 1994, 12 States passed charter schools laws. In the past two years, an additional 14 States plus D.C. adopted charter legislation. Today well over 400 charter schools are in operation, up from 250 in January 1996. The number of charter schools will continue to grow rapidly as new States adopt legislation, States with recently adopted laws begin to implement their charter schools programs, and States that have had laws for some years reconsider restrictions on the number of charter schools permitted. This growth, combined with the fact that the Federal program is designed to provide schools with the start-up funding their developers say they need most in order to succeed, would ensure the effective use of a \$100 million appropriation. In addition to stimulating the creation of additional schools, a \$100 million appropriation would enable States to increase the size of per-school awards from an average of around \$35,000 to between \$80,000 and \$100,000. This boost would help provide sufficient funds, per school, to facilitate the development of high-quality programs.

*Question.* Is there evidence that the Public Charter Schools program is effective in stimulating the establishment of charter schools or adoption of charter school laws?

*Answer.* While it is difficult to establish a direct link between the enactment of the Public Charter Schools program and an increase in the number of charter schools, the availability of Federal funds for planning and initial implementation of charter schools does seem to have generated more interest in starting these schools. For example, Kansas, which last year received an \$850,000 Federal grant, has chartered its first school and awarded 23 planning grants after several years of no chartering activity. In Georgia, the number of charter schools has grown from three to 12 since the State received a Federal grant.

It is also not clear what impact, if any, the existence of the Federal law has on States' decisions to adopt charter school laws. We would not encourage States to pass such legislation solely as a means of accessing additional Federal funds. Rather, we would urge States to develop carefully considered charter school laws, and, once that work is complete, Federal funds may provide some assistance to those people interested in developing and implementing charter schools.

#### DISTRIBUTION OF PUBLIC CHARTER SCHOOLS PROGRAM FUNDS

*Question.* What proportion of the States with charter school laws are receiving grants under this program?

*Answer.* About 80 percent of States with charter school laws received Federal Charter Schools funding in the first two years of the program. The Department has not yet conducted the competition for fiscal year 1997 funds.

*Question.* How are you allocating funds among these States—in proportion to their number of charter schools, their overall enrollment levels, or simply at your discretion?

*Answer.* Public Charter Schools is a discretionary grant program. Peer reviewers use the statutory selection criteria to rate the quality of the applications submitted to the Department. The Department makes awards to States and other eligible applicants in accordance with the peer reviewers' scores.

#### CHARTER SCHOOLS GUIDANCE ON APPLYING FOR FEDERAL FUNDS

*Question.* What guidance are you providing to States on the allocation of all Federal funds—not just those under the Public Charter Schools program—to charter schools?

*Answer.* All program offices within the Department provide assistance to States and school districts on the distribution of Federal funds to public schools, including charter schools. In addition to this ongoing help, the Department plans to issue a guide to help charter schools apply for Federal program money.

#### TERMINATION OF THE EDUCATION BLOCK GRANT

*Question.* The Administration has proposed the termination of funding for the education block grant, the Innovative Education Program Strategies State Grants authorized under Title VI of the Elementary and Secondary Education Act of 1965 (ESEA). How do you justify the elimination of one of the most flexible and popular forms of federal assistance for elementary and secondary education?

*Answer.* The Innovative Education Strategies Program, like its predecessor Chapter 2, is not well designed to support the types of State and local efforts most likely to result in real improvements in teaching and learning. The Department continues to believe that a more effective way to utilize scarce resources lies in targeting funds on comprehensive systematic reform and areas of high need.

The most recent evaluation of the Chapter 2 program, released in 1994, concluded that:

- In most cases, the program had not been an impetus for systemic educational reform.
- The majority of activities supported by Chapter 2 funds would have continued without Chapter 2 funds because these funds typically constituted a small percentage of any program's funding.
- 40 percent of local district funding went to the purchase of instructional materials which were often not tied to the improvement of an instructional program.
- While nearly 75 percent of districts who used funds for instructional materials purchased computer hardware/software, only 70 percent used those computer purchases for instructional use.

More recent annual reports of the program have shown no real change in how States and districts use their program funds.

While the Goals 2000 program provides the same flexibility as the Title VI program, it makes the critical link between expenditures and standards-based educational reform that Title VI does not. There is no reason to have two separate flexible educational improvement programs, and Goals 2000 is clearly the authority more likely to result in real improvements and reforms. Therefore, the Administration proposes to terminate the Title VI program.

*Question.* The education block grant program appears to achieve its popularity through being one of the few types of funds from any source that can be used for improvement purposes as determined by local educational agencies (LEAs). Do your program evaluations show the extent to which local schools have any other source of funds to meet locally determined improvement and innovation priorities?

*Answer.* As noted in the previous response, the most recent evaluation of Chapter 2, released in 1994, found that most of the activities it funded would have continued without Chapter 2 funds because these funds typically constitute only a small percentage of any program's funding.

Additionally, the Department has several programs that provide LEAs with funds to meet locally determined improvement and innovation priorities. For example, Goals 2000 provides funds to assist schools, communities, and States in developing and implementing their own strategies for improving elementary and secondary education. The Eisenhower State Grants program provides funding to States and school districts to support professional development in all the core academic subjects. The program gives schools the flexibility to set their own staff training and development priorities. The Technology Literacy Challenge Fund provides grants to States to assist them in implementing the strategies they have developed to integrate technology into the curricula of their schools. States have a great deal of flexibility in using these funds.

#### REDUCTION IN FEDERAL REGULATORY PAPERWORK REQUIREMENTS

*Question.* The education block grant program has reduced Federal regulatory paperwork burdens to a minimum. Why not modify other Federal education programs to be more like it, rather than proposing block grant termination?

*Answer.* The Department has made efforts to keep the Federal regulatory paperwork burdens associated with its programs to a minimum. The Department has attempted to maintain the flexibility afforded State and local educational agencies through block grant programs while maintaining a connection between the funds it provides and school reform efforts.

An example of an effort by the Department to reduce the regulatory paperwork burden associated with its programs is Goals 2000. While the Goals 2000 program promotes the same flexibility heralded in the Title VI program, it makes the critical link between expenditures and standards-based educational reform that Title VI does not. Further, States have found the program to be "user-friendly" because of its regulation-free administration and the flexibility it affords them to build upon pre-existing reform efforts.

Other Departmental programs, such as the Eisenhower Professional Development State Grants, Safe and Drug-Free Schools and Communities, and the Technology Literacy Challenge Fund, are also administered without regulations and provide State and local agencies with flexibility while ensuring that program funds are used to advance educational reforms and address critical national needs.

#### FEDERAL FAMILY EDUCATION LOAN AND DIRECT LOAN PROGRAMS

*Question.* Your Budget Justifications indicate that you intend to comply with the goal of an even (50–50) split in future student loan volume between the Federal

Family Education Loan and Direct Loan programs. How do you intend to assure that this goal is reached and maintained?

Answer. The Department plans to continue its strong customer service orientation and its support for both FFEL and Direct Loans. Our approach would let schools choose which program best suits the needs of their students. We currently project a 50 percent split in loan volume for academic year 1999–2000—the sixth year of the Direct Loan program. These are, of course, estimates, and will be adjusted based on experience.

*Question.* Have you abandoned your previous goal of eliminating the FFEL program?

Answer. Yes. That was a fiscal year 1996 proposal, and it was abandoned last year. While we continue to believe that the Direct Loans program has substantial inherent advantages to students, schools, and the taxpayer, as long as there is demand for the FFEL program we will support it to the best of our ability. The Administration is committed to preserving borrower and school benefits fostered by competition between the two student loan delivery systems.

*Question.* Is your stated goal of a 50–50 split in loan volume between the Federal Family Education Loan and the Direct Loan programs consistent with several of your specific proposals that would reduce the incentives of lenders and Guaranty Agencies to participate in the Federal Family Education Loan program, such as reduced interest subsidies and default repayments to lenders, and reduced revenues for Guaranty Agencies?

Answer. Our projection of a 50–50 split in loan volume between FFEL and Direct Loans in fiscal year 2000 is entirely consistent with our recent 1998 budget proposals to restructure the guaranty agency system for greater efficiencies and increase lender risk-sharing. We view these policies as strengthening the overall delivery and management of guaranteed student loans. Both students and taxpayers are the primary beneficiaries of these policies, but most participating lenders and guaranty agencies would also continue to earn substantial returns. For instance, lenders would still enjoy a 95 percent Federal guarantee against default, compared to 98 percent under current law—a reduction of only 3 percentage points. Default collection rates up to 18.5 percent paid to guaranty agencies would be similar to the actual average cost the Government incurs, instead of offering what has been considered a perverse incentive to let loans go into default by allowing guaranty agencies to keep some 27 percent of every dollar they collect.

#### STUDENT LOAN GUARANTY AGENCY PROPOSALS

*Question.* The Guaranty Agencies are an important element of federal-state partnership in administering the Federal Family Education Loan program. Why do you offer a series of proposals to undercut the Guaranty Agencies, eliminating them from some of their current roles and reducing their revenues? Is this part of a strategy to indirectly weaken the Federal Family Education Loan program in favor of Direct Loans?

Answer. The Department's proposals are not designed to undercut guaranty agencies, but to increase efficiency and hold guaranty agencies to performance-based standards.

Our proposed changes to the guaranty agency system recognize that these State and private nonprofit entities currently act only as agents of the Federal Government perform any substantial insurance function. Guaranty agencies currently use Federal funds they hold in reserve to pay a small portion of each lender default claim; while the balance is funded through Federal subsidy payments. Under our proposals, the Government would pay all eligible lender default claims—greatly simplifying the process.

We propose to replace the current administrative cost allowance (ACA), under which guaranty agencies are paid .85 percent of new loan volume regardless of costs incurred in relation to that volume. In its place, we propose two new sources of revenue: a one-time issuance fee based on each new loan insured by the Secretary through the agency, and an annual maintenance fee related to each outstanding borrower account. Under this approach, Federal funding would be more aligned with agency costs. We estimate that, in the aggregate, agencies would actually receive more under our proposal than they would under the current ACA formula.

The Department's proposals are not intended to weaken FFEL in favor of Direct Loans. Our proposals to restructure the guaranty agency system and increase risk-sharing by lenders are designed to increase FFEL efficiency, reduce costs, and create an even more customer-service driven program. This would result in an even stronger, not a weaker FFEL program.



## CENSUS DATA AND FISCAL YEAR 1997 TITLE I ALLOCATIONS

*Question.* Has the Department yet made its decision regarding what population data to use in calculating fiscal year 1997 grants for Part A of Title I, Elementary and Secondary Act? If not, what problems are being created for State and local educational agencies by this delay? If so, what is the decision, and the rationale for making it?

*Answer.* The Department announced 1997 Title I allocations to States without any delays in mid-April, shortly after the Secretaries of Commerce and Education made the decision to follow the recommendation of the National Academy of Sciences with regard to the use of poverty estimates for fiscal year 1997 allocations. State and local educational agencies received notice of their allocations on the normal schedule and should have ample time to plan their Title I programs for the upcoming school year, hire staff, and purchase necessary materials and equipment.

Consistent with the Title I statute, the Secretaries of Commerce and Education sought expert advice from the Academy on whether the Census Bureau's 1994 updated poverty estimates are appropriate or reliable for use in making fiscal year 1997 Title I allocations. Based on that advice, our decision was that it would be inappropriate to use either the updated estimates or the 1990 decennial census estimates alone for making fiscal year 1997 Title I allocations. Further, we agreed with the Academy's recommendation to utilize a combination of the 1990 census data and 1994 updated poverty data for these allocations, following the procedure outlined in the "Executive Summary" of the Academy's report, released March 21, 1997. Specifically, the procedure allocates Title I funds to counties on the basis of estimates that are obtained by averaging the poverty rates for 1989 and 1993 and then applying the average rate to the 1994 population estimate for school-age children in each county. Our decision is explained further in the "Report of the Secretary of Education and the Secretary of Commerce Concerning the Use of Updated Census Bureau Poverty Estimates for Title I Allocations in fiscal year 1997," transmitted to the Congress on April 18, 1997.

## RECOMMENDED BASIS FOR ALLOCATION OF FISCAL YEAR 1997 ESEA TITLE I, PART A GRANTS

*Question.* A National Academy of Sciences advisory panel has recommended that a specific combination of 1990 Census and 1993 updated estimates of school-age children in poor families be used as a basis for allocating fiscal year 1997 ESEA Title I, Part A grants. Do you agree with their recommendation?

*Answer.* Yes. The Secretaries of Commerce and Education agree with the Academy's conclusion that using either the 1990 census poverty data or the 1994 updated poverty data alone would not be appropriate for 1997 allocations, and that the allocations should use poverty data blended from the two data sources.

The Title I statute requires that the Department use the "most recent satisfactory data available from the Department of Commerce" for Title I allocations. For the reasons given by the Academy's panel and in our report, these composite data are the most recent satisfactory data from the Department of Commerce.

*Question.* Do you believe that you are authorized to follow such a recommendation to use neither the 1990 Census nor the 1993 updated population estimates alone?

*Answer.* Yes. We have looked very closely at the issue and believe there is ample authority under the statute to follow the NAS recommendation.

## QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

## INDIVIDUALS WITH DISABILITIES EDUCATION ACT—FEDERAL PER STUDENT ALLOCATION

*Question.* Secretary Riley, what is the fiscal year 1997 Federal per student allocation under the statutory pass-through requirement to the school districts for IDEA Part B, State Grants?

*Answer.* We estimate that the average amount provided per student served with a disability to each State, the District of Columbia, and Puerto Rico from the fiscal year 1997 appropriation will be \$525. Of this amount, at least 75 percent, or \$394 must be passed through to local educational agencies.

## PER STUDENT EVALUATION AND IEP DEVELOPMENT COSTS

*Question.* What is the average per student cost, based on available information and studies from the Department of Education, for initial identification, evaluation, and development of the IEP?

Answer. The Special Education Cost Study conducted by Decision Resources Corporation for the Department of Education indicated that the average cost of the initial evaluation and Individual Education Program (IEP) development for a student with a disability was \$1,200 in the 1985–86 school year. Based on increases in the average per pupil expenditure for educating children and inflation rates, the cost for these activities in the 1997–98 school year would be about \$2,200.

STATE ASSISTANCE FOR DISABLED STUDENTS FROM NONEDUCATIONAL AGENCY RESOURCES

*Question.* Can the Secretary discuss the reasons why some States provide inter-agency financial assistance to school districts for the costs of health and other related services of disabled children, while other States provide virtually no such financial assistance from noneducational agencies of the State?

Answer. There are many reasons why States vary in the amount of assistance provided from noneducational agencies that is used for the cost of health and other related services. One of the major factors is the extent to which State educational agencies and State health agencies have been able to work together to coordinate their efforts to provide services. Billing procedures between educational and health agencies are not always clear and there is often a lack of agreement regarding which services various agencies are responsible for providing. Another factor that limits health agency support for education related services is that educational and health agencies often have different standards for services. For example, IDEA often requires that services be provided by personnel that meet higher standards than would be required for providing Medicaid services.

States' policies regarding programs such as Medicaid also have a direct impact on the extent to which States provide assistance for health and other related educational services. States that provide Medicaid coverage for families at higher income levels have a more extended range of children who can be provided health related educational services from Medicaid funds.

The IDEA Amendments of 1997 would require States to take specified actions to ensure that LEAs have access to funds from noneducational agencies which have been assigned responsibility by Federal or State law, State policy or by interagency agreement to provide special education or related services. These services include assistive technology devices and services, supplementary aids and services, and transition services.

PUBLIC COMMENT AND NOTIFICATION OF DEPARTMENTAL POLICY LETTERS

*Question.* How does the Department provide for public comment and timely notification to school districts of interpretive rules issued through Department policy letters?

Answer. The Department's Office of Special Education Programs (OSEP) issues policy letters in response to specific inquiries it receives from Federal, State, or local legislators; State or local educational agencies; parents; teachers; advocacy organizations; or other interested parties. When asked a specific question, OSEP provides its interpretation of the particular statutory and regulatory requirements of the Individuals with Disabilities Education Act (IDEA) in the context of the particular factual situation or request presented by the inquiry. These responses explain how OSEP would apply the relevant legal requirements to the particular issue presented, and, in a given context, describe what OSEP considers to be necessary to comply with the IDEA requirements.

While regulations must be promulgated through certain procedures prescribed by the Administrative Procedures Act, including notice and comment, these procedures do not apply to OSEP policy letters, which interpret the application of current rules to particular situations. Regulations create new law, rights or duties while policy letters only give the Department's interpretation of what the underlying statutes and regulations mean.

Policy letters are sent to the individual, organization, or entity who requested OSEP's opinion. Generally, a copy of the policy letter is also sent to the relevant State educational agency. OSEP policy letters that include new policy clarifications that might be applicable to more than one discrete situation have been widely disseminated to States and organizations representing interested parties, such as school districts, and have been published by a widely used commercial reporting service.

Under the IDEA Amendments of 1997 that were passed by the House on May 13, 1997, and the Senate on May 14, 1997, and are now awaiting the President's signature, the Department will, on a quarterly basis, publish in the Federal Register, and widely disseminate to interested entities through various additional forms of com-

munication, a list, including topic and other summary information, of all policy letters sent during the previous quarter. In addition, the Department will widely disseminate to State and local educational agencies, parent and advocacy organizations, and other interested organizations all policy letters that raise an issue of general interest or applicability of national significance to the implementation of IDEA and will, within one year, issue written guidance on that policy or interpretation through such means as the Secretary determines appropriate.

#### EVALUATIONS REQUIRED BY IDEA REGULATIONS

*Question.* What is the average per child cost and the total national expenditure for triennial evaluations required by the IDEA regulations? Also please cite the statutory authorization for this administrative requirement.

*Answer.* The Department does not collect data on the costs of triennial evaluations. However, a study conducted several years ago in the State of Michigan found the average cost of these evaluations to be about \$750. Estimating a national average cost from this study has many inherent problems. We do not know whether the costs in Michigan are typical of other States though we do know the average per pupil educational expenditures for children in Michigan are higher than in the Nation as a whole. At the same time, the cost of evaluations in Michigan and the Nation has probably increased since the study was done. About 5.6 million children with disabilities were served by States under the IDEA in the 1995–96 school year. However, in any given year only a small proportion of children would receive a triennial evaluation. Many children would have been receiving services for less than three years. Others may have received evaluations more frequently than every three years because such evaluations were deemed appropriate. For others, their triennial evaluations would have been conducted in a prior school year. Taking all of these factors into consideration, we believe that the total expenditure for triennial evaluations was probably about \$500 million for the school year 1995–96.

The triennial evaluation required in regulations at 34 CFR 300.534 ensures that a child who has been identified as eligible for special education and related services continues to be eligible for those services, and that the services provided in accordance with the individualized education program are appropriate for addressing the unique needs of the child. The statutory basis for this requirement is section 612(2)(C) of the Individuals with Disabilities Education Act, which requires all children in need of special education and related services to be evaluated, and sections 602(18) and 614(a)(5), which require that special education and related services be provided in accordance with an individualized education program that addresses each child's unique needs.

#### DEPARTMENTAL ADMINISTRATIVE EXPENSES

*Question.* Mr. Secretary, what percentage of funds appropriated to the Department of Education are used for administrative costs? Furthermore, what percentage of the funds the Department of Education allocates to the States are reserved for administrative purposes?

*Answer.* A very small proportion of Federal education funding goes to administrative costs at the Federal or State levels. Less than 2 percent of the Department of Education budget is spent on Federal administrative costs. Over 98 percent of Federal education funds are sent to States and local communities, and roughly 93 percent of Federal funds for elementary and secondary education reach school districts and other agencies that provide services.

Overall, States retain about 3.6 percent of the funds for State-level activities, including program administration, technical assistance, and State-operated programs. For example, States retain only 1 percent of Title I, but somewhat larger percentages for Safe and Drug-Free Schools (6 percent) and the IDEA programs serving children with disabilities (7 percent). Finally, to help get more dollars to the classroom, in our legislative proposals we have recommended reducing the funds that States and localities can use for administration.

#### AMERICAN READS CHALLENGE

*Question.* The America Reads program consists of \$2.75 billion in mandatory spending over the next five years, of which \$1.75 billion would be used to fund 30,000 after-school reading specialists and materials. Over the same period, an additional \$1 billion from the Corporation for National Service will fund AmeriCorps volunteers to recruit and organize one million reading volunteers. Why do we need two separate programs to accomplish the same objective?

*Answer.* The Administration designed America Reads as a joint initiative between the Department of Education and the Corporation for National and Community

Service in order to leverage existing Federal resources and provide tools to communities that need and want them to help children learn to read independently and well by the end of the third grade. We have developed the America Reads Challenge legislation in response to the needs of school and community literacy partnerships. Last fall, officials at the U.S. Department of Education met with parent groups, businesses, leading principals and teachers, literacy groups, and community organizations and asked them what they thought was needed to help America's children learn to read successfully. The general and overwhelming response focused on two things: (1) the need for trained reading specialists to train volunteer tutors; and (2) the need for organized tutor coordinators to help match tutors with children. What is unique about the America Reads Challenge legislation is that it builds on this feedback and will provide the resources necessary to implement and carry out successful school and community reading programs that extend learning time for children who need extra help to read well, by bringing together the Education Department's knowledge and expertise with reading programs and the Corporation's demonstrated success in developing and coordinating effective tutoring and volunteer programs.

Under the America Reads Challenge Act, the Corporation for National and Community Service would help local reading programs recruit and organize volunteer tutors. The tutors, coordinating with the in-school reading program, would provide individualized after-school, weekend, and summer reading tutoring for children who want and need the extra help. We expect these tutors to help link the reading program, teacher, school, child, and family. The funding for the Department of Education will provide the technical and training expertise of reading specialists. Together, the two will fill a void and a real need to provide after-school and summer reading help. At the local level, however, reading programs will function as a single, integrated effort.

We estimate that our budget request for the America Reads Challenge will support 25,000 reading specialists and tutor coordinators—including 11,000 AmeriCorps members. Under the recent budget agreement between the White House and Congressional leadership, America Reads would be paid for entirely with discretionary funds.

#### EFFECTIVENESS OF TECHNOLOGY IN IMPROVING STUDENT ACHIEVEMENT

*Question.* Computers are rapidly becoming more and more important to the everyday functioning of millions of Americans. They are also, however, very expensive to purchase and maintain. The Administration proposes spending more than \$2 billion for technology over the next five years. What information does the Department of Education have regarding the ways in which technology improves academic achievement?

*Answer.* The evidence is strong that, used properly, computers and other educational technologies can be effective in expanding students' opportunities, motivation, and achievement. Technology can change the content of instruction and enable the learner to develop skills not possible through conventional instruction. Technology can also affect student achievement indirectly, by improving student assessments, professional development, and family involvement. While many of the Department's technology programs are too new to provide conclusive evaluative data, a number of independent studies indicate that technology has proven effective in the following areas:

*Basic Skills.*—Computer-assisted instruction (CAI) allows students to proceed at their own pace, and provides instruction and instant feedback based on the student's individual needs. In a long series of studies, students in classrooms with CAI outperformed their peers without CAI on standardized tests of basic skills achievement by as much as 30 percent. Evaluations have demonstrated that technology improves basic literacy, math, and science skills, by engaging students in multidisciplinary tasks, and by bringing material "to life," enhancing students' ability to both remember and understand what they read and hear.

*Advanced Skills.*—Educational technology helps students develop more advanced skills, such as the ability to conduct research, organize information, recognize patterns, draw inferences, and communicate findings.

*Accommodating Student Needs.*—Assistive technologies can help students with special needs to function in mainstream classes and communicate with their peers. In one study, learning disabled adult students receiving videodisc-delivered algebra instruction significantly outperformed students receiving textbook instruction on two different tests. Technology has also improved the ability to teach English and other second languages. Distance learning allows students in small and geographically remote schools to take a wide range of courses, including Advanced Placement

courses. It also allows migrant students to continue their education without interruption, resulting in higher completion rates.

*Access to Instruction and Information.*—Networks and the Internet provide students with access to world-wide libraries and information resources. In addition, linking schools through telecommunications networks allows geographically dispersed classes to work collaboratively to develop and implement projects and to learn more about the social, cultural, and physical world. An evaluation of one such project demonstrated significant gains in students' ability to organize, represent, and interpret data, as well as gains in knowledge of specific content areas.

*Processing and Presenting Information.*—Software tools such as word processors, spreadsheets, databases, encyclopedias, and graphics/presentation programs increase the ability of students to prepare studies, projects, and homework, and to communicate this information to others. Technology also makes it easier for students to edit written work, resulting in higher quality writing.

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#### QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER S. BOND

##### PREPARATION OF HIGH-SCHOOL STUDENTS FOR POSTSECONDARY EDUCATION

*Question.* The Federal Government spends \$7 billion in remedial education. Statistics show that 29 percent of all freshmen take a remedial course when they enter college. Remedial courses are required by 41 percent of the freshmen at community colleges, 26 percent at two-year private colleges, 22 percent at four-year public institutions, and 13 percent at four-year private institutions (Forbes, February 10, 1997).

These statistics are extremely alarming and send the message that our young people are not being properly prepared during their high-school years. What is the Department doing to encourage better preparation at the high-school level?

*Answer.* First of all, Department programs are encouraging better preparation at the high-school level by helping States and school districts build a strong foundation for better student achievement at all levels of education. Programs authorized by the Elementary and Secondary Education Act (ESEA), the Goals 2000: Educate America Act, and the School-to-Work Opportunities Act are based on the recognition that significant achievement gains at any education level are not likely to occur without fundamental education reforms to create and use high standards as the starting point for improving school and student performance. These programs are helping States and local communities create high expectations for all their elementary and secondary students, and providing resources for reshaping local curriculum to reflect high State standards and to train teachers to lift students up to those standards. Title I, the largest Federal elementary and secondary program, is an important part of this effort. In 1995, the \$7 billion Title I program shifted its focus away from providing remedial instruction intended to bring low-achieving students up to minimal levels of competency in basic skills to a completely new objective of helping disadvantaged students benefit from educational reforms stressing high standards.

##### PROVIDING EXTRA EDUCATION PROGRAM RESOURCES AT KEY MILESTONES IN EDUCATION

Second, since the pathway to academic success is set long before students enter high school, Department programs are providing the extra resources that poor and low-achieving schools and students need to perform well at key milestones in their education. One of the first objectives is that all students need to be able to read independently and well by the fourth grade, or they will be unable to read to learn other subjects. They also need a strong background in challenging mathematics by the eighth grade, or they will be unable to take the rigorous courses in high school that prepare them for college. Also, to help schools meet the standards and measure their progress in these important areas, the Department is leading an effort over the next two years to develop the national tests of student achievement in reading and math proposed by the President. These voluntary national tests for fourth grade reading and eighth grade math will go a long way toward ensuring that challenging standards become a reality for all students.

##### PREPARING STUDENTS FOR KNOWLEDGE-DRIVEN ECONOMY OF THE 21ST CENTURY

Third, in addition to strengthening the foundations for learning that affect student achievement in high school, some Department programs are focusing specifically on helping high-school students obtain the knowledge and skills to pursue and complete post-secondary training and compete for high-paying jobs in the knowl-

edge-driven economy of the 21st century. For example, in the fiscal year 1998 budget we are requesting:

- \$202 million for the Upward Bound program, which prepares high-school students and veterans to pursue and complete their education beyond high school. The typical Upward Bound experience is a highly structured, demanding program of supplemental academic instruction. The average program participant receives 160 hours of supplemental instruction a year. In contrast to the early 1970s, when most Upward Bound instruction had a remedial focus, the program's current emphasis includes course work that supports the high-school curriculum and advanced instruction. Services also include Saturday classes, tutorial and counseling sessions, cultural enrichment activities, and a 6-week summer component. Also, some funds are used to establish mathematics and science regional centers to encourage students to pursue postsecondary degrees in these fields.
- \$200 million for School-to-Work Opportunities, to help all 50 States fully implement their strategies for preparing students for work and further education. School-to-work is a promising educational strategy that aims to improve learning by connecting what goes on in the high-school classroom to future careers and to real work situations. Through the School-to-Work Opportunities Act, operated through a partnership between the Departments of Education and Labor, every State has access to seed money to design and implement a comprehensive school-to-work transition system for their students. Students in School-to-Work systems are expected to meet high State academic standards and, in addition, earn portable, industry-recognized skill certificates.
- \$6 million for a new Advanced Placement Fee program to supplement State efforts to subsidize or, in some cases, pay the full cost of advanced placement tests for low-income high-school students. The program will help raise academic standards by encouraging all students to challenge themselves and take the tough courses. It will also help fight the tyranny of low expectations, which keeps so many students from developing to their full potential.

#### HOPE SCHOLARSHIPS

*Question.* Will the Hope Scholarships proposal encourage grade inflation by linking the "B" average to the \$1,500 tax credit?

*Answer.* I do not believe this proposal will encourage grade inflation. As with numerous private and institutional merit grants and scholarships, professors would be unlikely to know which students are first-year HOPE Scholarship recipients.

In addition, in enacting the current "satisfactory academic progress" requirement for participation in all of the Department's student aid programs, i.e. maintaining a "C" average, or its equivalent, Congress had some concern about possible grade inflation, and requested a study by the Department. The resulting study found that the "C" average rule has not resulted in grade inflation.

Georgia reports no evidence of grade inflation related to the Georgia Hope Scholarship. In fact, some 50 percent of Georgia Hope recipients lose their aid in the second year due to failure to meet the "B" average requirement.

*Question.* How will this proposal prevent further tuition inflation which could result by schools raising tuition to capture new funds?

*Answer.* There is no evidence to suggest that increases in student aid result in increases in tuition. In fact, the Federal student aid programs have increased their greatest during those periods of time when tuitions have remained the most stable.

Furthermore, the tax credit would be targeted to specific populations, leaving unaffected large segments of students, including upperclassmen, graduate and part-time students, and those with family incomes above the cutoffs. Out of some 14 million postsecondary students, there would be only 4 million HOPE recipients.

*Question.* What is your response to criticism from the higher education community that your plan will increase access to higher education for low-income students but will simply subsidize students who would have attended college regardless.

*Answer.* The HOPE Scholarship is targeted towards middle-class families who are struggling to pay their children's college costs. Middle-income students are only half as likely to attend college as students from upper-income families, showing that financial barriers to college continue to exist. The HOPE proposal will help reduce the increasing amount of debt families have incurred to pay these costs by providing needed tax relief and will induce students to attend college who otherwise would not have.

## IMPACT AID

*Question.* The Department's budget substantially increases funding for general Federal assistance to school districts at the same time it proposes to dramatically reduce Impact Aid payments and eliminate Federal property payments which represent an obligation of the Federal Government to mitigate the adverse effects of its activities on local school districts. Missouri would be greatly impacted by the reduction and elimination of funding for Impact Aid payments. What is the Department's reason for such a reduction and elimination of funding for Impact Aid payments and what will happen to local school districts?

*Answer.* Our budget request would not increase funding for general Federal assistance to school districts. Rather, we have proposed to terminate those programs that provide general, untargeted support, such as the Title VI education block grant and the portions of the Impact Aid program that provide assistance on behalf of students whose enrollment does not impose a significant burden on school districts. And we have proposed increases for programs that focus on the needs of the disadvantaged, children with disabilities, and other special populations, or that address national priorities like educational technology, safe and drug-free schools, and professional development.

The relatively small reduction for Impact Aid (10 percent) would adequately fund a better targeted program. It would limit Basic Support Payments to those on behalf of children living on Indian lands and children of members of the uniformed services who live on Federal property. These two categories of children present the greatest burden to local educational agencies, and our request would provide at least level funding, and in some cases increased payments, for school districts that educate them. We have also proposed to level-fund the Impact Aid disability payments and to provide badly needed funds for the maintenance and upgrading of federally owned schools. We do not propose to fund the Section 8002 Payments for Federal Property program because it duplicates the 8003 payments on behalf of federally connected children.

## SCHOOL CONSTRUCTION INITIATIVE

*Question.* The President has proposed a \$5 billion new Federal program for local school construction. I believe we all recognize that many schools are in dire need of repair and renovation. However, I do have some concerns about the proposal. Would this initiative increase school construction costs by imposing costly government mandates like the prevailing wage requirement (Davis-Bacon) to be paid on federally funded projects, ultimately costing taxpayers more providing students with less?

*Answer.* As is commonly the case with Federal construction programs, our program would be covered by the Davis-Bacon Act, which requires that laborers and mechanics who work on the construction projects be paid wages at rates not less than the prevailing wages for the same type of work on similar construction in the locality.

The purpose of the Davis-Bacon rules is to ensure that federally funded construction activities do not have the unintended effect of depressing wages in a community. According to the Department of Labor (DOL), there is no real evidence that the Act drives up local wages; studies that purported to show such a cost are over a decade old and do not reflect changes in the construction practices and in DOL's administration of the Act. Moreover, 30 States, and a number of localities, have their own prevailing wage laws and would not be affected, at least to some extent, by the inclusion of Davis-Bacon coverage in our construction program. Nor would school districts that receive funding from our Impact Aid program; their school construction activities are already covered by Davis-Bacon rules.

## PARENTS AS TEACHERS AND HOME INSTRUCTION FOR PRESCHOOL YOUNGSTERS PROGRAMS

*Question.* As you know, Secretary Riley, the purpose of Title IV of the Goals 2000: Educate America Act is to increase parents' knowledge of and confidence in child-rearing activities, to strengthen partnerships between them and professionals in meeting educational needs of children aged birth through 5, to enhance the developmental progress of those children, and to fund at least one parental information and resource center in each State. To accomplish the parenting goals, the statute requires that grantees use part of their funds to establish, expand, or operate Parents as Teachers (PAT) or Home Instruction for Preschool Youngsters (HIPPI) programs.

Three-quarters (21 to 28) of the original grantees chose to implement the Parents as Teachers program, a model for which staff receive training from the Parents as Teachers National Center at locations around the nation. Despite the substantial size of the grants, however, many grantees appear to be making only minimal efforts to implement Parents as Teachers programs, as indicated by participation in that training.

I am disappointed in this outcome, and it is particularly surprising in light of the President's new emphasis on birth to three and the PAT program. What steps will the Department take with new grantees being awarded this spring to assure that Parents as Teachers programs are more faithfully implemented?

#### FLEXIBILITY IN PARENTING PROGRAM IMPLEMENTATION

Answer. In implementing education legislation passed by the 103rd Congress, the Department was guided by a policy of ensuring that grant recipients have greater flexibility than they have had in the past to design and implement programs suited to their particular needs. Consequently, we did not issue regulations for many of these programs, including the Parental Assistance Program authorized under Title IV of Goals 2000. Applicants for grants under the program must comply with statutory requirements, but are permitted to conduct a variety of activities to meet the needs of preschool and school-aged children throughout the State or a large region of the State. To meet these needs, Parent Centers generally allocate resources for awareness and information dissemination activities as well as parent training.

The statute does not specify the amount or percentage of grant funds to be spent on the Parents as Teachers or Home Instruction for Preschool Youngsters programs, and the Department has not gone beyond the statute to impose such a requirement. The amount of funds budgeted for PAT or HIPPO varies widely among the Parent Centers and, in fact, Centers in some States (for example, Iowa, New Jersey, and Oklahoma) have increased or are planning to increase the amount of funds initially budgeted for these activities.

We continue to advise grantees that the PAT and HIPPO programs must be an integral part of a Center's overall activities, and we will review this aspect of project performance in the annual reports that the grantees will submit this summer. Also, as we review the applications currently under consideration for funding, we will ensure there is a clear plan to fund and implement these elements as substantial program components.

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#### QUESTIONS SUBMITTED BY SENATOR LARRY E. CRAIG

##### IMPACT AID BUDGET REQUEST

*Question.* Since 1950, the Federal Government has recognized its commitment to local school districts whose tax base is heavily impacted by a Federal presence. Yet, the Administration's proposal slashes over \$31 million from last year's total and provides no funding for "b students." What is the Administration's explanation for turning its back on these students?

Answer. We are requesting payments only for those children for whom the Federal Government has a primary responsibility: children of military families who live on Federal property and children living on Indian lands. Most of the "b" children live on private property, the taxes from which support their local schools. Because local property taxes are the principal source of local funds for schools, we believe that communities are adequately compensated and do not require additional Federal assistance.

##### IMPACT OF PRIVATIZATION OF MILITARY HOUSING ON IMPACT AID REQUEST

*Question.* What impact does the Administration anticipate the privatization of military housing to have on its impact aid request?

Answer. Section 8003 of the Impact Aid statute authorizes payments to school districts to compensate partially for the costs of educating federally connected children. The principal justification for these payments is that the Federal Government has removed local property from the community's tax rolls, thus reducing the local property tax base available to support education. In general, the current Impact Aid formula provides larger payments on behalf of children who live on Federal property and whose parents work on Federal property or are in the uniformed services. Smaller payments are provided for federally connected children, including military dependents, who live on privately owned property in the local community.

In recent years, the Department of Defense has pursued a variety of arrangements to provide housing for military families. Some of these arrangements have



characteristics of “on-base” housing but are not actually located on tax-exempt Federal property. For example, Section 801 of the Military Construction Authorization Act of 1984 authorized an arrangement under which a branch of the military could contract with a private developer to build family housing. The military branch then agreed to lease the housing for a number of years. When housing was built under this authority, the developer sometimes leased base property on which to construct the housing and continued to own the housing but not the underlying land. In such a case, the housing is eligible Federal property for Impact Aid purposes because the underlying land is tax-exempt due to its Federal ownership. In other cases, however, developers built section 801 housing off-base on privately owned or other non-federally owned land. In those instances, the housing does not qualify as Federal property for Impact Aid purposes because the land on which the housing is located generates, or could generate, local property taxes. The Departments of Education and Defense agree that housing facilities that generate taxes or revenue are not placing a burden on these school districts that would warrant higher Impact Aid payments.

*Question.* If students living in privatized military housing were reclassified as “b students,” how would the Administration’s request be changed?

*Answer.* If military families live in houses located on tax-exempt Federal property, their dependents are eligible to be counted as “a” students for Impact Aid purposes. If their housing is off-base on privately owned land that could generate local property taxes, their children would be classified as “b” students. The possible changing status of any of these children should not necessitate an amended budget request for 1998.

#### STAR SCHOOLS FUNDING

*Question.* The administration’s proposal suggests that cuts in Star School funding might be made up by other technology-based programs. What specific programs did the administration have in mind and is there any guarantee that current Star Schools would receive funds through these other programs?

*Answer.* The reference in the budget request was primarily to the Technology Innovation Challenge Grants program, for which the Administration requested \$75 million, an increase of \$18 over the fiscal year 1997 level. This program supports the development of innovative educational technologies and their integration into the classroom. In light of recent developments in network and satellite technologies, the Department is carefully examining how the Challenge Grants, Star Schools, and other technology programs can work together for the greatest impact. However, no current Star Schools projects will be discontinued because of the decreased funding request. The funds requested for fiscal year 1998 will be used to continue the school completion grants awarded in 1996, as well as funding dissemination and leadership activities and a large-scale evaluation. The request will also fund the second year of the grants to be awarded this summer. The decrease simply reflects the Department’s decision not to make any new awards, because the grants awarded in 1997 will be in the first year of five-year awards.

#### TECHNOLOGY TRAINING FOR TEACHERS

*Question.* The University of Idaho is part of a consortium, which has submitted a proposal through the Fund for Improvement of Post Secondary Education (FIPSE) program to examine means of integrating the use of technology into teacher education programs. It is very important that our teachers, both those currently teaching and those studying to become teachers, learn how to use the new technologies. What is the administration doing to ensure that this training is available?

*Answer.* Training teachers in the effective integration of technology in the classroom is one of the Department’s four main technology goals. In the area of preservice training, the Department is currently working on proposals for the reauthorization of Title V of the Higher Education Act that focus on the recruitment, initial preparation, licensure, and induction of K–12 educators. Although the details have not yet been determined, technology training may be part of this proposal. In addition, FIPSE will continue to solicit applications that improve education through the use of technology.

#### FEDERAL PROGRAMS PROVIDING TECHNOLOGY TRAINING FOR TEACHERS

The Department is supporting technology training, primarily for existing teachers, through the following programs:

—Technology Innovation Challenge Grants: These grants support partnerships of business, industry, and local schools in the development of innovative approaches to improving student achievement with technology, in part through new and more effective professional development.

- Technology Literacy Challenge Fund: The Fund provides state formula grants in order to help build the infrastructure necessary for integrating technology into the classroom. States must submit comprehensive proposals which include teacher training in order to receive funding.
- Regional Technology in Education Consortia (RTEC): These consortia provide professional development, develop training resources, and work with institutions of higher education to establish preservice programs in the use of educational technology.
- Star Schools: These grants support partnerships which use distance learning to provide training for teachers in both core subject areas and the effective use of technology in the classroom.
- Telecommunications Demonstration in Mathematics: Funds support PBS Mathline, a program that provides professional development through high-quality video, online teacher networks, and other online interactions.
- Eisenhower Regional Mathematics and Science Consortia and Eisenhower National Clearinghouse (ENC): The consortia and ENC have created a national network to support mathematics and science reform. As a part of their work, they help educators use technology to access information on science and mathematics and, to a lesser extent, provide assistance in using technology in the classroom.

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QUESTIONS SUBMITTED BY SENATOR HERB KOHL

AFTER-SCHOOL LEARNING CENTERS

*Question.* I am interested in the 21st Century Community Learning Centers program. Your budget proposes \$50 million for that program to provide comprehensive after-school programming. Given the new welfare law work requirements and the limits of child care availability to children under six, kids over six could basically be left home alone or on the streets. Structured after-school care is critically needed and this program could help. In many areas comprehensive community based after-school programs have been working to involve the schools and secure needed resources. Would you agree that in some cases it might make more sense to encourage collaboration with quality programs off school grounds, rather than starting up totally new programs?

*Answer.* The After-School Learning Centers program would encourage collaboration between schools, existing centers, and other community-based organizations. However, there are several reasons why schools are the designated location for the centers. First, schools are convenient and accessible to students and parents. Second, schools have much of the resources needed for such a program, resources which are often underutilized during non-school hours. Third, school-based centers result in increased community and parent involvement in the school. Finally, locating centers within schools will help ensure that the centers maintain a strong academic focus. The after-school centers are intended to provide academic assistance in core subjects and enrichment activities, in areas such as art, music, and technology.

*Question.* Will this initiative seek or require collaboration where community centers already exist?

*Answer.* The program strongly encourages collaboration between various community entities, regardless of whether community centers already exist. If community centers exist within schools, they may apply for funding to expand their current programs. The law requires schools to describe their collaborative efforts in their applications.

*Question.* Will funding be available through this initiative for community-based after-school programs off school grounds?

*Answer.* No. The authorizing legislation defines learning centers as existing within a public elementary or secondary school building.

INTERAGENCY COLLABORATION ON SCHOOL-AGE DAY CARE PROGRAMS

*Question.* Are you collaborating with the Department of Health and Human Services (HHS) on this and other opportunities to expand availability of school-age care?

*Answer.* The Department has worked extensively with HHS to coordinate currently existing programs and to avoid duplicative efforts. In support of this program, HHS has advised on the program priorities and will assist the Department in reviewing applications and planning a technical assistance network that can help grant recipients share effective strategies. The Department is communicating with other agencies as well.

## TITLE V, HEA—PROGRAMS FOR TEACHER TRAINING

*Question.* Title V of the Higher Education Act has received scant attention and minimal funding. Programs within Title V have the potential to enhance the training of teachers and encourage talented individuals to pursue a career in teaching. Does the Department of Education support reauthorization of Title V, and will you push for funding to enhance teacher training?

*Answer.* The Department is preparing a reauthorization proposal for Title V, and we do plan to seek funding for it in fiscal year 1999. Because the professional development needs of the existing teaching force are addressed by the Eisenhower Professional Development program, we are planning to focus our Title V proposal on the “front end” of the process; that is, on recruitment, preservice education, licensure, and induction. While the existing array of (largely unfunded) Title V programs are not well targeted on needs in this area, we believe that well-conceived Federal programs can help strengthen teacher education and attract more talented students into teaching. We are also looking for vehicles through which to attract more minority candidates to the teaching profession, improve the training of school principals and other administrators, enable teacher aides and other paraprofessionals to achieve full certification, and help more teacher training institutions adopt the practices and programs of the best institutions.

## TEACHER TRAINING NECESSARY AT ALL LEVELS OF EDUCATION

*Question.* Do you believe that teacher training programs should have an emphasis on early childhood education?

*Answer.* We believe that the preparation of preschool teachers can be one focus of the new Title V, particularly because of the new research on the importance of learning in the earliest years of life and the well-documented problems that preschool programs encounter in finding qualified staff. But early childhood education should not be the only focus. Recent reports on teaching, such as the report of the National Commission on Teaching and America’s Future, have found problems with the recruitment, preparation, licensure, and induction of teachers at all levels, not just early childhood. In addition, public schools will need to hire some two million new elementary and secondary teachers in the next decade, and there has been no national response to this problem. Because of these concerns, we have elected to look at issues pertaining to the preparation of the entire continuum of preschool, elementary, secondary teachers.

## FEDERAL STUDENT LOAN FORGIVENESS PROGRAMS

*Question.* One of the main problems affecting the quality of early childhood education is the lack of access to training for educators and the lack of rewards when training is completed. As a result, the field of early childhood education is characterized by high turnover and low pay. An option to create incentives for service in early childhood education is to expand loan forgiveness for those who make a commitment to teach. Has the Department considered expanding loan forgiveness through the Perkins Loan Program, the Direct Lending Program, or other programs?

*Answer.* The Department is considering various alternatives to attract early childhood educators. Currently, there are two primary Federal vehicles for assisting individuals who have college debt and take, or want to take, low-paying jobs such as may be the case for early childhood teachers and educators. The first is income-contingent repayment of student loans through the Direct Student Loan program. Flexible Direct Loan repayment terms allow students to choose their occupation based on their own interests and abilities, without fear of being overwhelmed with debt and defaulting on their loans. Additionally, students holding guaranteed student loans are entitled to consolidate into the Direct Loan program and gain access to income-contingent repayment.

The second statutory vehicle is the “economic hardship deferment,” under which borrowers may suspend payments for up to three years; meanwhile, the Federal Government pays borrower interest on subsidized loans while interest accrues on unsubsidized loans. This benefit is available to any Direct or FFEL loan borrower whose income or combination of income and debt subjects them to economic hardship.

## LEVEL OF LOAN FORGIVENESS AVAILABLE TO EARLY CHILDHOOD EDUCATORS

*Question.* What level of loan forgiveness is currently available for early childhood educators?

*Answer.* The Perkins Loans program offers nine criteria for which loans may be partially or fully canceled. Three of these are targeted on early childhood educators:

- 1. Borrowers teaching special education classes to young children.
- 2. Borrowers providing early intervention services that combat developmental problems facing infants and toddlers with disabilities.
- 3. Head Start educational staff.

The Perkins Loan cancellations occur in increments over a period of time. Those teaching special education classes or providing early intervention services have their loans fully canceled after five years of service, while Head-Start educational staff have their loans fully canceled after seven years.

#### EFFECTIVENESS OF LOAN FORGIVENESS PROGRAMS

*Question.* What is the experience of the Department on loan forgiveness programs, and what are your views on an expansion of loan forgiveness for early childhood teachers with a strong service requirement?

*Answer.* The Department does not have comprehensive data showing how effective Perkins Loan cancellations have been in attracting early childhood educators. However, several evaluation studies of Federal and State programs that have used loan forgiveness provisions to attract teachers, or to encourage physicians and lawyers to serve underserved communities, have concluded that loan forgiveness provisions generally are not effective in achieving these goals.

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#### QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

##### ROBERT C. BYRD HONORS SCHOLARSHIPS

*Question.* Is rewarding excellence in achievement, the purpose of the Byrd Scholarships, consistent with the Clinton Administration's goals?

*Answer.* The Administration believes that students should be recognized and rewarded for their academic achievement by giving them tangible resources for post-secondary education. This is consistent with the intent of the Byrd program. The Administration is also requesting funds for the proposed Presidential Honors Scholarship program, which would also reward high academic achievement.

*Question.* With increasing global competition, and a continuing need for innovative technological leadership, does the Administration believe the Byrd Scholarship program to be a wise investment for the Nation?

*Answer.* The Administration believes that the Byrd Scholarship program is an important investment for the Nation. The Administration believes that it is important to encourage students to strive for academic excellence. Students need to develop more skills than ever in order to compete in the global economy and meet the challenges of the next century.



## NONDEPARTMENTAL WITNESSES

### STATEMENT OF HON. BOB MILLER, GOVERNOR OF NEVADA, CARSON CITY, NV

Senator SPECTER. I would like to call Gov. Bob Miller, Gov. George Voinovich, Dr. Bruce Perry, and Mr. Rob Reiner. This panel is a part of a series of events highlighting the importance of early childhood education, including a White House Conference on Early Child Development, which will be held tomorrow. Time magazine issued a special report on how a child's brain develops, and this week Newsweek published a special edition devoted to the first 3 years of life. All of these events are designed to get the word out to parents about the importance of early childhood education.

Governor Miller and Governor Voinovich are cochairs of a bipartisan National Governors Association task force studying State and Federal policy options to strengthen programs and support for families with young children. They will outline what the task force is doing as well as activities being carried out in their respective States.

Dr. Bruce Perry will tell the committee the outcomes of brain research and how early intervention can have a profound impact on the development of young children.

And we are privileged to have Mr. Reiner here with us today, and he will discuss the public awareness campaign entitled "I Am Your Child." Mr. Reiner is chairman and campaign founder and he, along with his wife, Michele Singer Reiner, have produced a prime time television special designed to bring public attention to the importance of early childhood experiences. This special will air on April 28, this month, on ABC TV.

We turn now to the distinguished Chairman of the National Governors Association, Gov. Bob Miller. A former Lieutenant Governor of Nevada, Governor Miller assumed the Governor's office in 1989 fulfilling the term left by Gov. Richard Bryan who joined us here in the Senate. Governor Miller and Governor Voinovich serve as cochairs of a bipartisan National Governors Association task force studying State and Federal policy options to strengthen programs and support for families with young children.

If Senator Reid would care to give a special word of introduction, we would be delighted to recognize him at this time.

Senator REID. Thank you very much, Mr. Chairman.

Governor Miller has a unique career. He will be Governor longer than anyone in the history of the State of Nevada. He will be Governor for 10 years. That is a result of Senator Bryan leaving in midterm. We have had for 25 years or more term limits in the State of Nevada, but every day that goes by, he breaks the record for longevity as a Governor.

As you indicated, he was Lieutenant Governor. He is the only person in the history of the State of Nevada to be reelected district attorney of Clark County. That is where Las Vegas is.

Senator SPECTER. So, he once had a really important job. [Laughter.]

Senator REID. He has been a judge. He has been a prosecutor. He is really one of Nevada's finest, and I am very proud to have him represent not only the State of Nevada, but the National Governors Conference today.

Senator SPECTER. Well, we welcome you here, Governor Miller. The floor is yours. We look forward to your comments.

#### SUMMARY STATEMENT OF HON. BOB MILLER

Governor MILLER. Thank you, Mr. Chairman and Senator Harkin and other distinguished members of the subcommittee. I am representing the State of Nevada in my role as Governor of Nevada, and maybe some components of what I say are not shared unanimously by all the National Governor Association members. But I am honored and happy to be able to be here on a matter that concerns our very young children, especially the ages of 0 to 3.

Tomorrow the President and Mrs. Clinton will be hosting the first White House Conference on Early Childhood Development and Early Learning. This conference may be one of the most important meetings in recent memory.

This meeting of scientific experts, one of whom at least is with us on this panel, policymakers, and other professionals will bring to light critical research on how babies and very young children learn and grow and how the human brain develops in healthy, productive environments.

Conversely, the conference will also show how medical science has recently proved that a negative environment actually hinders brain development during the critical first 3 years of life, and this results in a child losing his or her opportunity to thrive, to learn, and to grow to be happy and healthy.

I believe we as leaders have a duty as policymakers, as protectors of America's children, to take heed of the latest research about early childhood brain development. We have the duty to act on this research and a duty to do all that we can to enable every child to receive the nurturing and positive stimuli he or she must experience from the first days of life through the third year.

The Carnegie Foundation in New York was one of the first to tell us a comprehensive story on early childhood development, releasing a breakthrough study in 1994 which documented the compelling body of literature on young children's emotional, social, physical, intellectual, and brain development. It concluded that how children function from the preschool years all the way through adolescents and even adulthood hinges in large part on their experiences before the age of 3. This is a critical time, and the amazing physical developments that occur in the brain happen only once during those years.

Today's medical technology dramatically illustrates how the growth of a child's brain will flourish in a healthy environment or how a child's brain will be stunted in a deprived or abusive environment. I am told by experts that even a short period of abuse

during a young child's life will require hundreds of thousands of hours of remediation later in that same child's life, and if a child is deprived of a healthy, secure, and nurturing environment during his 3-year window of brain development, then the negative consequences may very well last a lifetime.

But if we assure a healthy, stimulating, and caring environment, we can expect positive results for that child's entire life. There is no second chance. What is missed in the first 3 years is very, very difficult and costly to make up later on.

These discoveries are so compelling that through Mr. Reiner's efforts that ABC Network will devote a week of programming to the subject and will begin at the end of this month—and that is virtually unprecedented. The "Today Show," "Good Morning America," Newsweek, Time magazine, and most importantly the special which I will leave to Mr. Reiner's description I think are almost unprecedented in the coverage on a single issue in the history of this country by the Nation's media.

This type of intense focus on America's young children is vitally important to the future of the Nation. Here are some statistics that help define the issues facing us.

Between 1979 and 1994 the number of children under age 6 in poverty grew from 3.5 to 6.1 million. During the same period, the percentage of young children living in poverty rose from 18 to 25 percent. Even more striking is nearly one-half of all of our children under age 6 live in poverty or borderline poverty.

More than their poverty, these children often have no health care, sometimes go to bed hungry, are more likely to come from single parent households, some are on welfare, often their parents are poorly educated. They are more prone to child abuse and neglect, and they have limited prospects for education or employment.

We are faced with a stark scenario of contrasts across the land. Many of our children do benefit from a positive environment that stimulates learning and healthy emotional development. Their future is bright. They are poised for life's successes.

But an alarming number of children, due to a variety of negative factors, do not share in those happy prospects. For them the first 3 years of life will start a pattern of difficulty and disadvantage, and they are poised to fail.

My wife and I have found watching and raising each one of our three children exhilarating, as I am sure all of you have, and as a parent, we all know those experiences, both good and bad. We were fortunate to have a supporting network of friends and relatives nearby. Not everyone is so fortunate in this day and age.

As a policymaker, I have the opportunity to create, promote policies and programs that can help parents and care givers when they need it most, and there has been a great deal of debate about what is the role of government. Well, let me share with you my beliefs.

We can all agree that raising a child is the responsibility of the parents or primary care giver. However, I think we can also agree that when families and communities are unable to meet those needs, government does have a role to play. Simply put, government should not take the place of a family or a community, but it can stabilize the environment in which children are being raised and it can empower families. It can lend a helping hand.



As people elected to provide leadership, I think we can work together to determine how and when government should be involved and we should decide it together. Local government and civic leaders also need to be part of this dialog. We should work collectively to identify public/private partnerships and innovative financing structures and should allow flexibility for creativity to help design the services that are needed most and tailored to specific needs of the community.

In our State, the 35-percent increase in Federal funding has resulted in a 91-percent increase in State funding. I have outlined a program in our State called family to family for the next 2 years which will be optional for all parents. An overwhelming majority we believe from recent research will participate—some 87 percent, in a poll we put out recently have indicated they would like to—in which they will receive some consultation both in hospitals and in their neighborhoods on a voluntary basis. No eligibility or means test. If you have a newborn, you qualify. The intent is to concentrate on baby wellness and to make sure parents are fully informed about the importance of a child's early years.

Programs like that exist in Vermont, Hawaii, Minnesota, Kansas, and others, and many other States are following suit after the proposals that we heard from Mr. Reiner and Dr. Perry and others at our winter meeting. In Hawaii, those evidences are very strong, as they were in Vermont. In Hawaii, the incidence of repeat child abuse dropped from 62 to 3.3 percent. In Vermont, 82 percent of families with newborns participated and also a dramatic decrease in child abuse and neglect, as well as higher immunization levels rose dramatically.

#### PREPARED STATEMENT

I think that is what it is all about. What can we as government do to work together with the private sector to work together with families and with hospitals in ensuring that each child has an equal opportunity to grow and develop in a healthy and nurturing environment.

I appreciate your time and attention.  
[The statement follows:]

#### PREPARED STATEMENT OF GOV. BOB MILLER

Senator Specter, Senator Harkin, distinguished members of this subcommittee. I am Governor Bob Miller of Nevada and Chairman of the National Governors' Association. As I present this testimony, I am representing the State of Nevada and not the National Governors' Association. I am honored and happy to be here today to discuss a matter of grave importance to my state and to the nation. The matter concerns our very young children, especially during the ages of zero to three.

Tomorrow, the President and Mrs. Clinton will be hosting the first White House Conference on Early Childhood Development and Early Learning. This conference may be one of the most important meetings in recent memory. This meeting of scientific experts, policymakers and other professionals will bring to light critical research on how babies and very young children learn and grow, and how the human brain develops in healthy, productive environments. Conversely, the Conference will also show how medical science has recently proved that a negative environment actually hinders brain development during the critical first three years of life. This results in a child losing his or her opportunity to thrive, to learn, and to grow up happy and healthy.

We have a duty as leaders, as policymakers, as protectors of America's children, to take heed of the latest research about early childhood brain development. We

have the duty to act on this research. We have the duty to do all we can to enable every child to receive the nurturing and positive stimuli he or she must experience from the first days of life to age three.

The Carnegie Foundation in New York was one of the first to tell a comprehensive story on early childhood development. It released a breakthrough study in 1994 which documented the compelling body of literature on young children's emotional, social, physical, intellectual, and brain development. The study concluded that how children function from the preschool years all the way through adolescence, and even adulthood, hinges in large part on their experiences before the age of three.

This is a critical time. The amazing physical developments that occur in the brain happen only once, from age zero to three.

Today's medical technology dramatically illustrates how the growth of a child's brain will flourish in a healthy environment \* \* \* or how the child's brain will be stunted in a deprived or abusive environment. I am told by experts that even a short period of abuse during a young child's life will require hundreds or thousands of hours of remediation later in that child's life.

If a child is deprived of a healthy, secure, and nurturing environment during this three-year window of brain development, then the negative consequences may well last a lifetime. But if we assure a healthy, stimulating, and caring environment we can expect positive results for that child's entire life. There is no second chance. What is missed in the first 3 years is very, very difficult—and costly—to make up later on.

These discoveries are so compelling that the ABC Network will devote a week of programming to the subject. This coverage will begin at the end of this month, I'm told this level of coverage is virtually unprecedented in TV history.

This type of intense focus on America's young children is vitally important to the future of the nation. Here are some statistics that help define the issues facing us.

Between 1979 and 1994, the number of children under age 6 in poverty grew from 3.5 million to 6.1 million. During this same period, the percentage of young children living in poverty rose from 18 percent to 25 percent. Even more striking is that nearly one-half of all our children under age 6 live in poverty or borderline poverty.

More than their poverty, these children often have no health care; they sometimes go to bed hungry; they are more likely to come from single-parent households; some are on welfare; often, their parents are poorly educated; they are more prone to child abuse and neglect; and they have limited prospects for education or employment.

We are faced with a stark scenario of contrasts across the land. Many of our children do benefit from a positive environment that stimulates learning and healthy emotional development. Their future is bright. They are poised for life success.

But an alarming number of our children, due to a variety of negative factors, do not share in those happy prospects. For them, the first 3 years of life will start a pattern of difficulty and disadvantage. They are poised to fail.

As policymakers, we can not tolerate this situation. We must face the challenge of helping every family meet the needs of every child during the first 3 years of life.

In Nevada this year, I have proposed a program called Family-to-Family Connection that addresses early childhood development. The program is optional for all mothers and fathers with a newborn baby. Our research shows that the overwhelming majority of parents, from all stations in life, are interested in participating in the Family-to-Family Connection.

It provides hospital, home and neighborhood visits for every family who wants to participate.

There are no eligibility resections or means tests. If you have a newborn, you qualify. The program is largely administered by communities through nonprofit organizations, one-stop family resource centers, the religious community and other local groups.

The intent of the Family-to-Family Connection is to concentrate on baby wellness, and to make sure parents are fully informed about the importance of a child's early years. The program strives to assure that all participating parents will have ready access to the information they need. It also connects families with essential services in the community they might need to succeed as parents.

Programs like Family-to-Family Connection have started in states such as Vermont, Hawaii, Minnesota, Kansas, and others. The results are dramatically successful. In Vermont, 82 percent of families with newborns participated last year. And their program has resulted in reduced occurrence of child abuse and neglect, and higher immunization levels.

In Hawaii, similar positive results are evident. The incidence of repeat child abuse dropped from 62 percent to 3.3 percent. In Nevada, we hope to do as well. Family-to-Family Connection and these other programs are not ends, but beginnings.

And maybe that's been our problem all along: we don't know where to begin. I am here today, Senators, to say that the beginning must be now. We have to draw a line in the sand and say this next generation of children will not suffer as past generations have suffered.

We have to fight back against the conditions that undermine the ability of families to provide the healthy environment each child must have.

Once again, let me say how honored I've been to speak here today. I thank you for the committee's generous time, and I will answer any questions that you might have.

#### GOALS 2000

Senator REID. Mr. Chairman, I have to go to a meeting in the Capitol. Could I just say a brief word? I know it is out of turn.

Senator SPECTER. Go ahead, Senator Reid.

Senator REID. I want to also indicate for the record that not only has the Governor been involved in education matters, but his wife, who has been the chairperson of Goals 2000 in the State of Nevada, is responsible for having a scientific advisor now for the State of Nevada.

I had the good fortune to sit through one of our Democratic conferences and hear Mr. Reiner speak, and it was very stimulating.

Thank you very much.

Senator SPECTER. Thank you very much, Senator Reid.

#### STATEMENT OF HON. GEORGE VOINOVICH, GOVERNOR OF OHIO, COLUMBUS, OH

Senator SPECTER. We now turn to the distinguished Governor of Ohio, Gov. George Voinovich, Vice Chairman of the National Governors Association, who will serve as the Chairman beginning in 1998. The Governor is a former Ohio State legislator, assistant attorney general, and county commissioner. He was elected Governor of Ohio in 1990 after serving 10 years as the mayor of Cleveland.

The improvement of education is the top priority for Governor Voinovich. The Schoolnet Program he initiated is now bringing 21st century computer technology into all Ohio classrooms.

Thank you for joining us, Governor Voinovich. The floor is yours.

#### SUMMARY STATEMENT OF HON. GEORGE VOINOVICH

Governor VOINOVICH. Thank you, Chairman Specter and Senator Harkin, for the opportunity to testify before you today.

As Governor of Ohio and Vice Chairman of the National Governors Association, it is exciting to be part of the I Am Your Child campaign and I would like to congratulate Mr. Reiner and his team for using television to bring to the American people the importance of 0 to 3 in this country, which I think is long overdue.

I am proud that Ohio is often recognized for our efforts to meet the first national education goal of having all children enter school ready to learn. I shared that vision in my first state of the state address back in 1991 when I said our aim is to make an unprecedented to one priority that I believe ranks above all others, the health and education of our children.

The only way to do it is to pick one generation of children, draw a line in the sand, and say to all, this is where it stops. I am grateful that in partnership with the Ohio General Assembly—and they have been very, very cooperative on a bipartisan basis—and

through dedicated efforts of many citizens and organizations, we have turned this vision into a measurable goal.

We have also worked to expand the definition of education in Ohio to lifelong learning that starts at conception and recognizes what doctors and researchers have said about the importance of positive early childhood learning experiences.

It is discouraging to me that too often many of the educators in traditional education fields fail to see the learning value of childhood programs and so often view them as strictly competitive with scarce funds that are available for education.

As Congress contemplates the importance of early childhood development, I hope you will follow Ohio's fiscal investment strategy. Since taking office in 1991, our biennial budgets have grown at the lowest rate in 40 years. We have a good budget stabilization fund, and we continue to look at programs in State government to ensure they are necessary and they are cost effective.

But within that fiscally conservative program, we have prioritized programs benefiting family and children. For example, between 1991 and 1998, which will be the years I am Governor, we will have increased funding for children and families approximately 50 percent while inflation has gone up during that same period about 27 percent.

Today, our State leads the Nation in the percentage of eligible children served and State investment in Head Start, and I just looked at the numbers. In 1990-91, we spent \$18.9 million on Head Start. Today, we spend \$181 million. We had 6,300 kids in Head Start. Today, we have 67,750 kids, and when you combine our public preschool, special education, 83 percent of the eligible kids in our State whose parents want them in the program are there, and by the end of 1998, all of them will have an opportunity to participate in the Head Start Program.

We have also done something else that you would be interested in and that is we have funded a program called Early Start, which now serves about 4,000 infants and toddlers. In fact, thanks to the flexibility granted to Ohio by the temporary assistance to needy families welfare reform package, my administration is working with our State legislature to invest \$6 million of TANF funds over the next 2 years to provide Early Start for an additional 2,500 young families on public assistance. Since families with children under age 1 are going to be exempt from the work requirements that you have in the legislation, we want to focus on their children's early development, and that emphasizes the importance of quality child care. In pilot counties, families will have access to services ranging from parent education to respite care to speech therapy and counseling. Just as with our non-TANF clients, home visitors will help each family meet its parenting goals.

I just want to say to you that the flexibility that you have given us in that block grant has enabled us to do some things that we would not have been able to do under the traditional categorical programs.

Senator SPECTER. Governor Voinovich, may I ask you to summarize? I have just been informed that we are going to be voting within the next 10 minutes and I would like to reach both of our witnesses before we conclude.

Governor VOINOVICH. I think in a nutshell what I would like to say to you is, in terms of national policy, I think education is primarily the responsibility of the States.

I think that if Congress is going to give consideration to doing something in this area on a pilot basis or otherwise, that what you ought to do is look at the programs that you are already spending money on and see if there is not some way that maybe you could reprioritize some of the money that you are spending and putting it into an area that I think is going to give you a larger return on your investment.

PREPARED STATEMENT

And last but not least, I want to tell you something. You spend a lot of money on the Head Start Program. It has been in there for 26 years, it is a great program and you ought to think about trying to encourage States either through a carrot or through a stick to get more involved in this Head Start Program which I think is so important to this country, particularly with our children at risk.

Senator SPECTER. Thank you very much, Governor.

This committee concurs with you. We have allocated resources to prove it.

[The statement follows:]

PREPARED STATEMENT OF GOV. GEORGE V. VOINOVICH

Thank you Chairman Specter and Senator Harkin for the opportunity to testify before you today.

As the Governor of Ohio and Vice-Chairman of the National Governors' Association, it's exciting to be part of the "I Am Your Child" campaign.

From the beginning of my administration, we've made the education and well-being of our children our highest priority. I'm proud that Ohio is often recognized for our efforts to meet the first national education goal of having all children enter school "ready to learn."

I laid out our vision in my first State of the State Address in 1991 when I said: "Our aim is to make an unprecedented commitment to one priority that I believe ranks above all others \* \* \* the health and education of our children.

The only way to do it is to pick one generation of children—draw a line in the sand—and say to all: This is where it stops."

I'm grateful that in partnership with the Ohio General Assembly—and through the dedicated efforts of many citizens and organizations—we've turned this vision into a measurable goal.

We've also worked to expand the parameter of an education beyond K-12 to "life-long learning" which includes what doctors and researchers have said about the importance of positive early childhood learning experiences.

It is discouraging that so many professionals in traditional education fields fail to see the learning value of early childhood programs and view them strictly as competition for scarce funds.

As Congress contemplates the importance of early childhood development, I hope you will follow Ohio's fiscal investment strategy.

Since taking office in 1991, Ohio's biennial budgets have grown at the slowest rate in over 30 years. Within this low growth, the state has built a responsible rainy day fund. State funded programs have been constantly reviewed to ensure that they are necessary and cost-effective.

Within this fiscally conservative framework, Ohio has prioritized programs benefiting families and children. Between fiscal years 1991 and 1998, our spending on children and education is \$5 billion higher—that's a 45.5 percent increase at a time when inflation equaled 26.4 percent.

Today, Ohio leads the nation in the percentage of eligible children served—and state investment in—Head Start. (54,645 or 75 percent, \$145.6 million expenditure in fiscal years 1996-97.)

Ohio is also becoming a leader in state-funded Early Start which now serves 4,000 infants and toddlers. In fact, thanks to the flexibility granted Ohio by the TANF (Temporary Assistance to Needy Families) block grant, my administration is working with our state legislature to invest \$6 million in TANF funding over the next 2 years to provide Early Start for an additional 2,500 young children in families on public assistance.

Since families with children under age 1 will be exempt from work requirements, we want them to focus on their children's early development.

In pilot countries, families will have access to services ranging from parent education to respite care to speech therapy and counseling. Just as with our non-TANF clients, home visitors will help each family meet its parenting goals.

Without the flexibility of the TANF block grant, Ohio wouldn't have been able to fund Early Start for the families of these infants and toddlers.

Ohio's Help Me Grow program demonstrates the power of the public/private partnership. With my wife, Janet, as spokesman, corporate partners combine their financial and creative resources with the expertise of the health care community to support a statewide health promotion initiative designed to encourage prenatal care and preventive health care for babies and toddlers.

A free wellness guide provides families with valuable parenting information and discount coupons redeemable for a variety of goods and services following health care visits.

Since 1995, Ohio's distributed 633,000 free wellness guides. Our Help Me Grow helpline (1-800-755-GROW) has answered 117,000 telephone calls, providing information ranging from health care to family-related support services, adoption and foster care. As part of our outreach, Help Me Grow has handed out 7,000 P.J. Huggabee bears to children in foster care.

A key piece of our public/private partnership is that we measure our impact. We need to be able to show our partners that Help Me Grow is making a measurable difference. As a result, we can prove that it is \* \* \*.

Ninety-three percent of all women receiving a wellness guide reported they began their prenatal care within the crucial first trimester \* \* \* this exceeds the state average by 10 percent.

Ohio's rate of fully immunized 2-year-olds is up from 66 percent when Help Me Grow started, to 71 percent today.

Ohio's also reduced the number of babies born with chemical dependence. (1,291 babies since fiscal year 1993, \$59 million saved.) And, our overall infant mortality rate is down.

What I've just outlined are programs and partnerships which we believe qualify as national best practices. Throughout our 50 states we can find numerous other quality efforts for children. The goal is to foster more \* \* \*.

When I become NGA Chairman next July, I intend to build upon the leadership of Governor Miller. I've already indicated to him and Executive Director Ray Scheppach that I will continue our current efforts under the banner of "Zero to Three: Our Future." One of our first efforts will be to host a national conference to share the step-by-step best practice programs already achieving results.

In the meantime, the NGA's Leadership Group on Children will continue to educate us all about the need for early childhood development while serving as a powerful catalyst for new partnerships for young children. The NGA's work also reinforces the need to baseline and benchmark programs so we can monitor our efforts.

In closing, I want to reiterate today that the efforts we support for early childhood development address one of the two major deficits facing the nation today.

The "I Am Your Child" effort focuses our national attention on what I call the "human deficit." I am a firm believer that prioritizing early childhood development will help our states address the ongoing problems of too many high school dropouts, dependence on public assistance and ever burgeoning prison inmate populations.

However, while we discuss these problems we cannot overlook our first national priority \* \* \* the need to reduce the federal budget deficit. The fact is, if we don't get this under control, there won't be anything left for anyone.

We have a brand-new grandchild, Mary Faith Voinovich. This country's gift to Mary Faith was a bill for \$187,000. This is the interest cost she will have to pay in taxes on the federal deficit.

While we deal with the human deficit, we must deal with the federal deficit. Just as we did in Ohio, we need to slow the growth in spending in order to free up the funds to invest in programs which give us the best return.

I firmly believe this can be accomplished. The federal government now funds more than 600 separate categorical programs, many of which serve the same client base. This is not effective. Every functional categorical area of federal aid should be explored to find more cohesive and efficient program structures.

As incoming Chair of the NGA, I intend to devote our association's resources to undertaking a thorough and comprehensive review of these programs.

We would like to work with the Congress and the Administration to rationalize and consolidate these programs so that we increase the efficiency of government programs, devolve responsibilities to the states, protect long-term investments, and ensure that the benefits of federal programs outweigh the costs.

Ultimately, I believe this review would facilitate a re-ordering of priorities which would benefit our nation's children.

Again, I thank you for the opportunity to share my thoughts with you today. I have every confidence that by all of us working together we can ensure that our nation's young children receive everything they need to develop to their God-given potential. Thank you.

**STATEMENT OF DR. BRUCE PERRY, PROFESSOR OF CHILD PSYCHIATRY AND VICE CHAIRMAN FOR RESEARCH, DEPARTMENT OF PSYCHIATRY, BAYLOR SCHOOL OF MEDICINE, HOUSTON, TX**

Senator SPECTER. I would like to turn now to Dr. Bruce Perry, senior fellow and vice chairman for research in the Department of Psychiatry and Behavioral Sciences at Baylor College of Medicine, Houston, TX. Welcome, Dr. Perry, and the floor is yours. To the extent that you could abbreviate your statement, we would appreciate it.

Dr. PERRY. Thank you very much. I appreciate the opportunity to be here. I will try in a few minutes to try to help you understand, if I can, this incredible sense of frustration I feel by knowing things that I think if you knew, you would change the way you do things.

That is the wonderful thing about this public engagement campaign is that there are bodies of information that relate to brain development and child development that literally have the capacity to transform our culture, and they have been out there for some time.

Through the efforts of Rob and Michele and the team they put together, they have put people in the same room that speak different languages. They come from different disciplines, but they all see the same thing, whether they are cops, social workers, child development specialists, lawyers. They all see that these children that are costing us so much and these children who we do not provide opportunities so that they can realize their potential come from environments that are devoid of certain characteristics.

Now, obviously there are so many aspects of this that need to be addressed, and I will let Rob talk about some of those things.

But what I would like to say is that this is a Government place and we are here talking about this, but I think it is crucially important that everybody understands that these problems will never be solved by Government. These problems will never be solved by families alone. These problems will never be solved by business. These problems will never be solved by any segment of our society working alone, and the only way that things will change, the only way that we can create these environments that we now know can develop a healthy, flexible brain is by creating novel, cross-institutional, atypical, synthetic solutions.

I think there are places where that is taking place. In Houston, for example, the Civitas initiative is funding and leading a novel public/private partnership that is focusing on high risk kids from 0 to 6. It has already had tremendous impact on the dollars that are spent and where we put these abused and neglected kids, the

services we provide for them, and it is making a difference. There are many, many other examples of that going on across the country.

I will close with one request, that you take time, and I know many of you have, to learn about the brain. It seems like that is a silly thing for Senators to learn about, but the reality is the brain is the organ that allows us to think, to act, to believe, to hate, everything we do. The fact that you can believe in a democracy, the fact that you can understand anything is related to how your brain develops.

And it does not develop in a magical way. It just does not pop up and happen that way. The brain develops because there have been specific, patterned consistent experiences that are characterized by nurturing, predictability, structure, and the crucial element of that is that 85 percent of this foundational capacity to think, to act, to be a citizen, to pay taxes, to have a job occurs in the first 3 years of life.

When you miss that window of opportunity, if we continue to have this mismatch between the potential for when the brain is changeable and when we put our money into programs, we will continue to have problems meeting the potential of our culture.

And I thank you for that and I pass it on to Rob.

Senator SPECTER. Thank you very much, Dr. Perry.

**STATEMENT OF ROBERT REINER, CASTLE ROCK ENTERTAINMENT,  
BEVERLY HILLS, CA**

Senator SPECTER. We now turn to Mr. Rob Reiner, chair and founder of the I Am Your Child campaign, intended to increase public awareness of the importance of early childhood development. An Emmy Award winner for his role in the landmark television series, "All in the Family," he is one of the film industries top directors with such credits as "Stand by Me," "The Princess Bride," "When Harry Met Sally," "Misery," "A Few Good Men," "The American President," and "Ghosts of Mississippi." It is a privilege for us to welcome you here, Mr. Reiner. The floor is yours.

Mr. REINER. Thank you very much, Chairman Specter, and Senator Harkin for allowing me to come here.

I had a statement prepared but I am not going to issue it now because I know we are short for time.

I feel bad that Senator Byrd is not with us at this moment because he asked a very important question that we have the answer to. He was talking to Secretary Riley and he said:

With all of the years that he has spent in the U.S. Senate—he has been here 45 years and he has voted for every appropriation for every educational bill that has come down—why have we not produced better students.

Well, we now know the answer to that and we are fools, absolute fools, if we do not invest in this answer.

The answer is very clear. Science now points the way and tells us that it is in the first 3 years of life. What happens to a child, what a child experiences in the first 3 years of life, lays the foundation for who that child will be, how that child will function later on in school and later in life, and whether or not that child will be able to integrate positively or negatively into society. We know this. We have the answers. The answers are here. We just have to



act on how to implement those answers. We know what to do. It is a question of how to do it.

I feel bad that there is not one single Republican member of this committee sitting here today. I know the chairman is here. You have to be here, sir, and I am glad you are here. [Laughter.]

I am glad you are here and I know these other gentlemen will get this information at some point, but whether they do or not, whether what I am saying here gets past this committee or not, this will happen. This will happen because the public will make it happen.

We must address the first 3 years of life if we want to impact crime, teen pregnancy, drug abuse, child abuse, welfare, homelessness, and every other societal ill. If we do not, we are fools.

Senator Byrd also said we have to applaud academics. Well, there is a man sitting at the end of this table who is a professor of psychiatry, who is a neurobiologist at Baylor University. This man is telling us something, along with many other people who are going to be represented in a report that is going to be released at the White House tomorrow called: "Rethinking the Brain." That tells us very, very specifically what happens in those first 3 years.

We have done a lot now. We have all sat in these rooms. I have been civically minded and politically active my entire life. I have sat in rooms like this and I have sat in rooms across the country with groups of people trying to figure out how to solve problems. We have been beating our heads against the wall for as many years as I can remember.

We always come to the same answer, and every person in this room knows it. Education is the key. We always say that, but then what does that mean? How do you educate? Who do you educate? What form does that education take?

Well, science now tells us where to look. It tells us that the education has to happen in the first 3 years, and that does not mean reading Tolstoy to a 2-year-old, and it does not mean issuing flash cards. It means providing a nurturing environment for a child from the time they are born to 3 years old.

And that is what the I Am Your Child campaign is all about. It is about getting that information out to the public, making the public aware of it.

I can guarantee you once everybody understands this, we can all sit here and knowing what we know now, we are not going to defund anything. There are programs that we need and they are important, but if we were to take Head Start, which is a good program that has been around for 32 years, has been funded at the level of \$4 billion a year, and we take Early Head Start, which is relatively new, that I think is funded at \$150 million a year—we are trying to ramp it up hopefully with some legislation to double that. Knowing what we know now, we would be fools to say that we would reverse that. If we had to wipe the slate clean and start from the beginning, we would put the \$4 billion in the first 3 years and the \$150 million later.

Obviously, we are not going to do that, but what I am trying to impress on everybody is how critical those first 3 years are. And we are not saying to the Federal Government, you are the answer. We are not saying the Federal Government has to issue a one-size-

fits-all program, but we are saying that the Federal Government has to play a part. We see it as a partnership. As Governor Miller points out, it is a partnership between the Federal Government, State governments, local communities, and the business community.

We are going to host a CEO summit in the fall with Kaiser Permanente. We are going to bring CEO's from all over the country to talk about what can be done in the first 3 years of life. There are a lot of other activities that we have planned with our campaign.

But we have to start rethinking, we have to start reprioritizing and looking at problem solving through the prism of 0 to 3. We have to understand that there is a direct nexus between what happens to a child in the first 3 years and social ills that come down the road.

#### PREPARED STATEMENT

We are also having the Rand Corp., do a study, a cost-benefit study, on the intervention programs that are working, and that study will be made available in the early part of the summer. The preliminary findings are very, very encouraging. What it says basically is we can pay some money now and save a lot of money later or not pay the money now and it costs us a lot of money later. It is very, very clear. Do we want to spend the money now and reduce people's taxes and have tax infusion into the economy, or do we want to skip these first 3 years and build more prisons and have more crime and more teen pregnancy and more child abuse—

Senator SPECTER. Mr. Reiner, we are now 4 minutes into the vote.

Mr. REINER. That is the end of my statement. Thank you very much. [Laughter.]

[The statement follows:]

#### PREPARED STATEMENT OF ROBERT REINER

I want to thank Chairman Specter and Senator Harkin for inviting me to appear before this committee this afternoon.

I'm here as a representative of "I Am Your Child," a national awareness and engagement campaign designed to shed light on the vital importance of the first 3 years of life.

With the startling new research in brain development, science now clearly tells us that what a child is physically, emotionally, and intellectually exposed to from the prenatal period through age three has a far-reaching effect on how a child's brain organizes itself. And since we now know that 90 percent of a person's brain growth and development occurs in the first 3 years, how a child's brain organizes itself in those critical early years will have a profound impact on what kind of an adult he or she will turn out to be. Whether he or she will become either a toxic or nontoxic member of society is in large part determined by a child's experiences in the first 3 years.

The implications of this with respect to public policy are eminently clear. If we want to make a truly meaningful impact on crime, teen pregnancy, drug abuse, child abuse, welfare, and a variety of other societal ills, we must focus on the first 3 years of life. If we truly want every child to enter school with a readiness to learn, we must provide him or her with the proper foundation. How do we do this?

The implications of science are clear, but what are the applications? First, we must recognize that in order for each child to reach his or her full potential, children and their parents must have access to health care, quality child care, parenting services, and intervention programs when necessary.

As far as parenting services and intervention programs are concerned, there are a number of approaches that have been proven effective. We have commissioned the

Rand Corporation to do a cost-benefit analysis of these programs, and the results are more than encouraging. We can provide the committee with some preliminary findings of the Rand study if requested. The full report will be made public this summer.

We've all sat in rooms like this trying to find ways to solve society's problems. Science now clearly shows us what we've suspected all along: If we are truly interested in making a significant difference, we must attack the problems at the roots. The first years last forever.

#### GOOD HEALTH CARE

Senator SPECTER. Let us see if we have time for one question from each member and a brief answer.

Mr. Reiner, could you give us some insight as to what ought to be done during 0 to 3?

Mr. REINER. OK. We look at it as a four-pronged approach. First we need good health care. There are too many children without good health care. If they are not taken care of physically, they are not going to develop properly. That we know.

The second is child care. That has been touched on. Senator Kohl talked about child care. We need good quality child care to help empower parents to do the right things for their children the first 3 years.

The third thing we need is good parenting programs and information for parents to help them be better parents.

And the fourth thing are intervention programs when necessary for children at risk. We can identify. We know what those programs are. You have all done the studies and we can identify and help you identify those programs.

So, those are the four areas we need to provide every community.

In the special that we are doing, I Am Your Child, we focus in on Hampton, VA, a community that was at risk that came together over this issue because they found it a way to lift the community socially and economically, and they have done a tremendous job. It will give you a blueprint of what we are talking about.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

Again, I appreciate all your statements, Mr. Reiner and Governors, Dr. Perry.

We live in the political world, the realm of the possible of what we can accomplish. I would like to ask you, Governor Voinovich. I am very encouraged by what you have done in the State of Ohio during your tenure as Governor.

I said earlier that we have all I think as Republicans and Democrats accepted the separation that elementary and secondary education is the primary function in State and local communities and that is where local control ought to stay, right there.

We have also accepted I think from both parties that the Federal Government has a very significant role in postsecondary education with Pell grants and guaranteed student loans and land grant colleges and everything else. We could debate how much, but basically politically we have agreed on that.

Do you think it would be possible for us to have a bipartisan agreement that there is a proper role and a significant role for the Federal Government to play in early childhood education before they get to that elementary school which is primarily under local

and State jurisdiction, in other words, looking at early childhood education from a Federal standpoint, as we look at postsecondary education from a Federal standpoint? Is that possible?

We have made some inroads here, Head Start Programs, WIC Programs, part H for kids with disabilities, things like that. I am trying to think if we cannot get some kind of a national consensus politically among the two leading parties in this country. Do you think that would be possible? I do not know what you think of that.

Governor VOINOVICH. What I think of it is that again you need to look at what you are doing. You have 600 categorical programs here that deal with the same people, and we always look at those programs in light of the budget crunch instead of looking at them without the framework of the budget. How can we do a better job of providing services to people in this country? I think that by doing that, you could find more money that you could invest in the kinds of things that I think are important in this Nation.

But you got a real problem here. There are two problems in this country—big problems. One is the Federal deficit and the other is the human deficit. What I am saying is that at the time you want—we have got lots of things that need to be done, but if we keep going the way we are going, there will not be anything left for anybody. If you look at, for example, money for discretionary programs and the interest we are paying, it is disappearing.

So, what I am saying is that we ought to sit down and figure out who is doing what, what resources we have, and I think picking up on Dr. Perry and I think on Rob, how do we galvanize the resources of our local communities, our States, the Federal Government, the private sector to figure out how we can come down and get this job done. That is where I come from.

Senator SPECTER. One question, Senator Bumpers.

Senator BUMPERS. Dr. Perry, we have been told, since the memory of man runneth not, that how a child develops in the first 3 years, and how the child's brain develops depends on what kind of protein diet the child has, among other things. That is the reason we have the WIC Program, one of the most cost-effective programs that we have.

Some of the things you are saying here are fairly new to me and I have been involved in childhood education since I was first elected Governor of my State. What you are saying I do not disagree with and I do not think anybody on this committee would, but there is a socioeconomic problem that almost has to precede this.

When my daughter was 2 years old—she had a very ominous condition. We lived in a community of 1,200 people. I was the only lawyer in town, and by just outhouse luck, we wound up with her in the hands of the best pediatric neurosurgeon in the world, Boston Children's Hospital. Now she is a very successful, magnum cum laude lawyer.

I can tell you that 99 percent—98 percent of the people in that community would have watched their child die, and it was pure luck that we did not.

So, I agree with you as to how important it is to give these children this sort of thing—you know, my brother and sister are both rich Republicans. I am the only Democrat left in the family. [Laughter.]

I keep reminding them that what we did that most children do not get a chance to do is to choose our parents well. I mean, we are doing the best we can to make people economically secure and give them better housing, better health care, all of those things. But it seems to me that that almost has to precede some of the ideas you've discussed. I do not care whether I make this vote or not. [Laughter.]

Dr. PERRY. We think about these things all the time, and what you are saying is absolutely critical to this whole process of understanding how we are going to live together now with these evolutions that are taking place in technology, in economics, and all kinds of things are changing in our world.

I think that what we have to do is sit down and talk about what were the elements of living that way that created consistent predictable nurturing experiences, and are there any ways with the new changes in the way we live together, the fact that mom and dad are both working, the fact that there are socioeconomic pressures that take parents away from the ability to provide that kind of optimal experience sometimes, are there ways to bring in grandparents? Well, we do not live that way anymore. Are there ways to bring in the elderly? Are there ways to be creative about this? We literally need to think—

Senator SPECTER. This concludes the hearing. Senator Bumpers is on his own.

Dr. PERRY. Sorry.

Senator SPECTER. You go ahead, Dr. Perry. [Laughter.]

Dr. PERRY. I think we literally need to rethink a lot about the way we live together, about literally the recreation—we need to create spaces where people can be together. We have this tremendous I think destructive compartmentalization where the elderly are here and the infants are here and the work people go over here and education takes place here, here, here, and here so fifth grade kids do not see first graders and first graders do not hang out with babies. We really need to think about the way we live together.

I think when we do that and when we begin to create—and I think one way that we can start to use this is I think that we need to think about some public spaces being redesigned and utilized in innovative ways like school-based clinics. You could also have school-based technology resources. You could have places for adult education in the public school settings. You could have an after-school program where the elderly could come and tutor at a school. You could do all kinds of things utilizing the resources we already have.

But I really think what it requires is well-meaning people who are smart sitting down and being willing to be flexible and work together.

Senator BUMPERS. Gentlemen, thank you all very much. I am sorry we do not have more time.

SUBCOMMITTEE RECESS

The subcommittee will stand in recess until 2 p.m., Wednesday, June 11, when we will meet in SD-192 to hear testimony from Dr. Harold Varmus, Director, the National Institutes of Health.

[Whereupon, at 4:07 p.m., Wednesday, April 16, the subcommittee was recessed, to reconvene at 2 p.m., Wednesday, June 11.]



**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 1998**

WEDNESDAY, JUNE 11, 1997

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 2 p.m., in room SD-138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Gorton, Bond, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. HAROLD VARMUS, DIRECTOR, NIH

ACCOMPANIED BY:

DR. RUTH KIRSCHSTEIN, DEPUTY DIRECTOR, NIH  
DR. RICHARD KLAUSNER, DIRECTOR, NATIONAL CANCER INSTITUTE  
DR. CLAUDE LENFANT, DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
DR. HAROLD SLAVKIN, DIRECTOR, NATIONAL INSTITUTE OF DENTAL RESEARCH  
DR. PHILLIP GORDEN, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES  
DR. ZACH HALL, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE  
DR. MARVIN CASSMAN, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES  
DR. DUANE F. ALEXANDER, DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT  
DR. CARL KUPFER, DIRECTOR, NATIONAL EYE INSTITUTE  
DR. KENNETH OLDEN, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES  
DR. RICHARD J. HODES, DIRECTOR, NATIONAL INSTITUTE ON AGING  
DR. STEPHEN KATZ, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES  
DR. JAMES B. SNOW, JR., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS  
DR. STEPHEN HYMAN, DIRECTOR, NATIONAL INSTITUTE ON MENTAL HEALTH  
DR. ALAN I. LESHNER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE



**DR. ENOCH GORDIS, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM**  
**DR. PATRICIA GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH**  
**DR. FRANCIS COLLINS, DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE**  
**DR. JUDITH VAITUKAITIS, DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES**  
**DR. PHILIP SCHAMBRA, DIRECTOR, JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES**  
**DR. DONALD LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE**  
**DR. WILLIAM PAUL, DIRECTOR, OFFICE OF AIDS RESEARCH**  
**DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. The Subcommittee of Labor, Health, Human Services, Education will proceed. We have an extraordinarily distinguished group of scientists who are assembled here today as we proceed for our hearing on the budget of the National Institutes of Health.

This is an occasion where President Kennedy's famous statement comes to mind when there was an enormous group of artists and scholars and intellectuals at the White House, and he is reported to have said that: "this is the greatest assemblage of intelligence in the White House since Thomas Jefferson dined alone." That might be appropriate here as well.

I think it is safe to say that the Congress, the administration, and the American people are enormously impressed with the contributions which NIH, all the contributions which you have made, with tremendous advances and so many lives, and I will not stop to particularize them with all of the Institutes represented here, and the budget of the NIH has gone up consistently over the years in recognition of the tremendous work you have done and the tremendous challenges there and the tremendous additional opportunities.

We have set some high targets for NIH with a goal articulated by some of doubling in the next 5 years. Congressman Porter and I have set a goal of achieving a 7½-percent increase this year, which would provide \$952 million extra, but it will not be easy to find the money.

We had the budget resolution before the Senate a couple of weeks ago, and we passed a sense of the Senate amendment calling for \$2 billion extra for NIH. What is not universally known is that a sense of the Senate amendment is a statement of druthers as opposed to real dollars. I knew instantly that a variety of interest groups would be coming to me as chairman of this subcommittee asking for their share, which was not really there, so I offered a hard money amendment to add \$1.1 billion, offset with an across-the-board cut of four-tenths of 1 percent, but that was not passed.

So we face a situation where there is a sense to give NIH more money, but there is not a reservoir to fund it. That will be our task, and we will do our best. We are pleased to have the NIH leader-

ship here today, and we will proceed with your testimony after giving a chance for other subcommittee members to make an opening statement if they care to do so.

Senator Cochran.

OPENING REMARKS OF SENATOR COCHRAN

Senator COCHRAN. Mr. Chairman, let me just say the NIH budget request is always a high priority for consideration by this committee. This year the passage of the budget resolution and the emphasis in that resolution on increasing the NIH budget makes it even more so this year, and we appreciate very much your being here to help us understand how that money can be used effectively to deal with the health problems of our country.

Mr. Chairman, I also want to just thank you for including a second panel in today's hearing on the subject of funding under the Drug Assistance Program for the Ryan White Health Act. We have seen a shortfall of funding occur in our State of Mississippi, and we understand that that problem is going to spread to other States if it has not already, and we need to explore the options for dealing with that problem.

A lot of people are in some jeopardy because of the shortfall in funding, and there was no request for supplemental funding from the administration, and we are eager to explore with administration officials and others—the State health officer from Mississippi, Dr. Ed Thompson is here; Dr. Earl Fox, who is Acting Administrator of the Health Services Administration is here; and someone who has been dropped from the program is here to talk about the consequences. We appreciate very much your cooperation with our problem.

Senator SPECTER. Thank you very much, Senator Cochran.  
Senator Bond.

OPENING REMARKS OF SENATOR CHRISTOPHER BOND

Senator BOND. Thank you very much, Mr. Chairman. I am looking forward to the budget discussions and the many, many funding issues we'll get in here today, but I want to take a moment on something that has hit the headlines since this committee acted, and that is on the issue of cloning.

As we all know, the National Bioethics Advisory Committee reported that it is morally unacceptable at this time for anyone to try to create a child through cloning. Well, I agree it is unacceptable, but I disagree with the recommendation that it may become acceptable later on.

I do not think we are dealing with something that depends upon better technology. I think we are dealing with a moral imperative, and I do not think we can put a sunset on morality or ethical conduct.

I happen to believe that human cloning is wrong and unethical now and always will be, regardless of whether technology for cloning is perfected. It is either immoral, or it is not, and I think we ought to quit talking about the issue and continue at least through this committee the very strong message that we have put forward to ban any such funding on cloning.

I think it ought to go beyond that, that this committee clearly can do that.

The President in his press conference on Tuesday suggested other nations should follow our country's lead banning human cloning. Well, the news is, we have not banned it. All we have done is said no to Federal funding, and a number of countries have instituted a permanent, complete ban on human cloning. I think it is wrong to send a message that we are only banning Federal funding of human cloning research, and that only for a short time period.

I also am concerned that the commission punted on the issue of what is possible and what can be done, leaving open the possibility of cloning human embryos as long as the embryos are not implanted. It seems to me by allowing cloning research on human embryos to continue in the private sector, the commission said go ahead as far as you can. When it gets dangerous, then we will try and stop you.

If we permit the cloning of human embryos, or the experimentation of cloning techniques on human embryos, then we risk sliding very far down the slope to human cloning, and once you get the cloning done, that is the hard part. The very easiest part would be to take the process one step further and implant an embryo in a woman's uterus, and I think that once the human embryos are cloned somebody will take that next step, and I think that there ought to be an effort to stop the private sector from doing it as well.

There are some who have said we cannot put the genie back into the bottle and stop progress. I suggest that if that is the case our technological capability may be outrunning our moral sense.

I continue to support biotechnology. I support the work taking place in the NIH Human Genome Center. There is a long list of things we can say about the progress made in the human genome project, the pace of gene discovery, everything from dealing with cystic fibrosis, colon cancer, and all these things. I think there is tremendous progress to be made, but I think we ought to continue our efforts and seek to expand the ban that this committee has put on the use of Federal funding for research on human cloning and urge other bodies and other areas to make that permanent.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Bond.

I noted in the recent report that this subcommittee had considered a separate hearing on the cloning issue some time ago, and then the hearing was held, I believe it was in the Commerce Committee, and I know that your testimony at that time——

Senator BOND. Senator Frist chaired it. I thought it was in Labor.

Senator SPECTER. Well, I know that Senator Frist did chair that, and today's hearing might post some opportunity for some discussion as to what impact, if any, such a ban would have on the NIH human genome line, or other research. It is something that we might get into at least to some extent today, or perhaps that would be a subject for a later hearing. It is obviously a matter of enormous importance.

## PREPARED STATEMENT OF SENATOR CRAIG

I have received a statement from Senator Craig, it will be inserted into the record at this point.

[The statement follows:]

## PREPARED STATEMENT OF SENATOR LARRY E. CRAIG

I would like to thank the chairman for holding this hearing today regarding budget requests for the National Institutes of Health (NIH) for fiscal year 1998. I look forward to learning more about some of the scientific advances that have been made over the last year at the NIH, as well as the goals and long-term projects planned for the coming year. Past accomplishments, as well as future plans should be taken into account as we look at ways to appropriately allocate funds to the various programs within the NIH.

For the last several months, my staff and I have been hearing from various groups representing a broad range of diseases that get their research dollars through the NIH. The resounding message we hear from all of these groups is that their interests are not being adequately addressed in the way of funding. Each group has extremely valid reasons for wanting more funding and I find it difficult to pick and choose which disease should get more research money.

All of the groups I met with felt they should be given a higher priority-level for funding when the time came for us to make these decisions. This is not an easy thing to do. Each disease is important and each one has far-reaching impacts on our country. I think it is crucial that they decide on what level of funding is appropriate and then distribute those funds with a sense of fairness.

I applaud the NIH for the work they have done in developing new therapies and cures for diseases that will help resolve some of our country's greatest health problems. The long-term investments they have made in the areas of medical research and training will help to achieve many more new discoveries.

I do believe the NIH should be given funding adequate to support research that moves us toward cutting-edge treatments and prevention efforts, while helping to reduce overall health care costs. However, as we all know, there are harsh budget realities that we must work within and that is why we are here today. We must find a way to provide the appropriate level of funding for these programs while being fiscally responsible.

I am strongly committed to fiscal responsibility. I also realize that the subcommittee is operating under significant budget constraints and will have to make difficult choices among competing programs. My hope is that the recommendations for NIH funding are made with the objective of searching for cost-effective solutions.

We can make significant strides in the field of medical research while still working toward a balanced budget. Balancing the budget is all about setting priorities. Setting priorities is more important now than ever before because the debt has grown to the point where it is the major threat to programs most Americans consider to be most important. If we discipline ourselves and set priorities now, while moving toward and keeping a balanced budget, that is the best way to preserve our ability to fund our priorities in the future.

I hope we will be able to shed some light on what these priorities must be as we continue to look for ways to adequately fund these very important programs, while working within our means. I look forward to hearing the testimony of all of our witnesses here today. Your expertise will be extremely valuable to me throughout this process.

## SUMMARY STATEMENT OF DR. HAROLD VARMUS

Senator SPECTER. Well, Dr. Varmus, we welcome you and your colleagues here. Let us begin with your testimony. The floor is yours.

Dr. VARMUS. Thank you, Mr. Chairman. I am very proud and pleased to be here representing the NIH for the fourth time at appropriations hearings. In view of the short amount of time allotted for this hearing, I prefer to submit my opening statement for the record.

I will devote just a few minutes to introducing four vivid images used by the Institute and Center Directors at the House appropria-

tions hearings to illustrate the productivity and potential of the investigators we support.

#### UNDERSTANDING DISEASES THROUGH GENES

The first image reflects the pace of gene isolation, which is accelerating, as well as new ways to visualize the genetic blueprint and to store images and make use of them for understanding diseases.

The beautiful pictures of chromosomes displayed here illustrate a method devised and used by intramural scientists at the NIH for painting each human chromosome a distinct, unique color. This allows easy analysis of abnormal—that is, recombined—chromosomes in cancer cells, as shown at the bottom of this chart, facilitating diagnosis and leading to the identification of new genes that are involved in causing cancer.

#### USE OF MOLECULAR INFORMATION

The second image tells us a little bit about how we are now using molecular information to benefit patients with disease. This picture reflects the three-dimensional structure of an enzyme you have all heard about, the protease of HIV. Determination of the structure some years ago both in industry and by NIH-supported scientists assisted in the development of the current protease inhibitors you will be talking about with Dr. Fauci and others in the next panel. This image is helping in the design of improved versions of those drugs as well.

#### NONINVASIVE IMAGING TECHNIQUES

The third image reflects our ability to use noninvasive imaging devices to understand the function of many organs, including, very importantly, the nervous system. What is shown here is a scan using positron emission tomography, or PET scanning. It shows the prolonged effect of short-term high dose amphetamines, a drug of abuse, on the production of a neural transmitter, called dopamine, in one part of the brain.

At the start of this experiment, the monkeys can be shown to be producing dopamine, as you can see from the intensely colored dot that represents a certain area of the brain where dopamine is produced. Shortly after receiving amphetamines for about 10 days, that part of the brain's ability to make dopamine is suppressed, and it remains suppressed for a year after the amphetamine treatment. This suppression of dopamine production is also associated with profound behavioral changes. Importantly, after a year or so the ability to make the neurotransmitter reappears.

The fourth image reflects our ability to use noninvasive imaging techniques to develop earlier and cheaper diagnostic procedures than we have currently available. In this case, the target is heart disease, disease of the coronary arteries. The image on the left, developed by a noninvasive procedure called magnetic resonance imaging, or MRI, shows a better picture of the coronary arteries than that obtained with the more expensive conventional and invasive procedure referred to as an angiogram.

In the MRI image, you can actually see blood vessels that are the width of the lead in your pencil, and appreciate abnormalities—

from a procedure which can be done repeatedly and at less cost than current angiography.

#### BUDGET REQUEST

Well, Mr. Chairman, to continue work of this kind and to do a multiplicity of other things we do not have time to describe today, the President is requesting \$13.078 billion, \$337 million more than in fiscal year 1997, a 2.6-percent increase. This budget includes an additional \$90 million for the Mark O. Hatfield Clinical Research Center, but that is not part of the \$337 million increase, because we received \$90 million for the Center last year.

Most of the increase—

#### BUDGET INCREASE

Senator SPECTER. Dr. Varmus, let me interrupt you for just a moment. You say there is a \$338-million increase, but where does that increase fit in when the overall health function in the President's budget has been reduced by \$100 million?

Dr. VARMUS. Well, that is a question I think you would have to address to OMB. I do not know how to answer that question.

Senator SPECTER. Well, I think it is important when talking about an administration request for an NIH increase when the overall budget request for the health account, of which NIH is a part, is \$100 million less.

Dr. VARMUS. I have been assured by the administration that the President's request stands as originally proposed.

Senator SPECTER. That is why I want to assure you that it does not add up in the current state of the record, and I think that one of the things we have to understand in this hearing are those hard facts. What we propose to find out today from each of the people here is what you have been able to do with your funding, what you could do with more funding, and specifically how many applications you are not able to handle.

There are too many people talking about druthers and too few people talking about dollars. What I propose to do here today is to talk about dollars, so I do not want anybody to be under any illusion that the administration has \$338 million extra for you.

You may proceed.

Dr. VARMUS. Actually, I am reaching the end of my comments. I was simply going to point out that the vast majority of the increased dollars would go to research project grants. We expect that the increase requested for fiscal year 1998 would allow the NIH to support the largest number of grants in its history—nearly 27,000. My prepared statement gives several reasons why we are able to do this.

#### PREPARED STATEMENT

Simply, I would conclude by saying that we are proud of what we have achieved with the generous appropriations we have received in the past from Congress and the administration, and we are optimistic about our future prospects. My colleagues and I would be happy to answer any questions you might have.

[The statement follows:]

## PREPARED STATEMENT OF DR. HAROLD VARMUS

I am pleased to present the President's budget request for the National Institutes of Health for fiscal year 1998, a sum of \$13.078 billion, an increase of \$337 million (or 2.6 percent) above the fiscal year 1997 appropriation.

*The pace of medical research: Retrospective*

This is the fourth year that I have been privileged to represent the NIH at this Committee's proceedings. As on previous occasions, the Institute Directors and I will soon provide you with a summary of remarkable scientific accomplishments from the past year and a description of some exciting paths our research is likely to take in the coming year. This annual process of recounting our performance and predicting future productivity is important, stimulating, and necessary. But it should not obscure some essential features of our activities: that our ultimate task, the conquest of disease, is formidable; that the course of progress is best measured over many years or decades, rather than over a single year; that scientific advances require a long-term investment in training and facilities, as well as research projects; and that the benefits of research are unpredictable, demanding work on a broad range of topics to achieve success with even a single problem.

Some of these features are dramatically illustrated by recent events in our battle against the human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS). In the past year, the world has learned that many people with AIDS can experience dramatic improvement after treatment with a new class of anti-HIV drugs, called protease inhibitors, especially when combined with another class of drugs, called reverse transcriptase inhibitors. Although far from perfect, such potent anti-viral agents are unprecedented in the history of virology, and the achievements have been appropriately heralded in many news stories, including New Year cover stories in the lay press (Time magazine) and the science press (Science magazine).

But the history of these accomplishments encompasses much more than a single year; it reaches back over many years and in many directions. It extends to the early isolation of retroviruses from birds and rodents, as long ago as 1910. To the identification in the 1970's of retroviral enzymes—reverse transcriptase and protease—that now serve as targets for the anti-viral drugs. To the determination of the three-dimensional structure of these enzymes a few years ago. To the development of inhibitors of cellular proteases over twenty years ago for the treatment of hypertension. To the lengthy training of investigators competent to pursue basic science, drug discovery and development, and clinical testing. And to the strength of our nation's laboratories, developed over decades, in governmental, academic, and industrial sectors.

*The pace of medical research: Prospective*

The breadth and depth of the investments required for the success of protease inhibitors underscore the importance of the strong bipartisan support that the NIH has received for the past fifty years. It is our responsibility to bring here each year new signs that such continued confidence is warranted and likely to produce future dividends. Thus, while we can take pride in end products, such as protease inhibitors, it is even more important to showcase recent discoveries, especially those findings from which many lines of investigation are likely to grow and measures to combat disease are likely to develop.

To illustrate this point, I would like to refer again to the field of HIV research, this time to describe a recent, long-awaited finding that holds special promise. Soon after the discovery of HIV in the early 1980's, investigators found that CD4, a well-known protein on the surface of certain T lymphocytes, was required for HIV to attach to and infect target cells. But it was also learned that at least one other protein was required, and those proteins—the so-called co-receptors—remained elusive for many years.

About one year ago, a research group in the NIH intramural program used an ingenious detection method to unveil co-receptors as members of a class of cell-surface proteins we already knew a great deal about—proteins that normally allow cells to detect secreted signaling molecules called chemokines. This discovery was especially exciting because another group of NIH intramural scientists had shown that certain chemokines could interfere with infection by HIV. Now we recognize that the interference is due to blockade of a co-receptor. Recently, some individuals were found to carry mutations that prevent production of a co-receptor. Because these people are actually resistant to infection by HIV, yet otherwise normal, co-receptors have emerged as prime targets for therapeutic and preventive strategies against HIV, stimulating a frenzy of experimental activity towards those goals.

*Recent culminations and inspirations*

For dramatic purposes, I have chosen to present in detail two paradigms of success—one representing culmination, another inspiration—from the domains of AIDS research. But other examples abound.

The culminations are visible as practical health benefits, often accompanied by economic benefits:

- The first successful treatment for stroke, using recombinant tissue plasminogen activator (tPA).
- Increasing use of cell growth factors to protect patients against the bone marrow toxicities of cancer and AIDS therapies.
- Declining mortality rates for many cancers, including some common ones.
- Reduction in disability rates among the elderly.
- The virtual elimination of Hemophilus influenza as a cause of childhood meningitis, due to widespread use of a new vaccine.

Recent inspirational discoveries are also legion, especially in the fields of genetics, molecular biology, and neurosciences:

- The genomes of baker's yeast and several bacteria (including the experimental warhorse, *Escherichia coli*) have been fully sequenced; a detailed map of the human genome as been assembled and posted on the Internet; and innovative technologies are being harnessed to understand this genetic cornucopia.
- The locations of still unknown genes implicated in Parkinson's disease, prostate cancer, and other diseases, have been narrowed to small chromosomal regions, implying imminent isolation; and genes involved in many other disorders (such as retinitis pigmentosa, polycystic kidney disease, many birth defects, basal cell carcinoma, hemochromatosis, and some forms of diabetes) have been isolated and characterized.
- The precise changes that occur in genes during our lifetimes are telling us how environmental agents, like tobacco and sunlight, cause cancer by inducing mutations, and how normal mechanisms for correction of DNA can fail, allowing harmful mistakes to persist in our genetic material.
- Experimental manipulation of genes in mice has produced new animal models for studying many diseases (including Alzheimer's Disease, cardiac and vascular diseases, developmental defects, drug abuse, cancers, and others).
- New imaging methods are informing our understanding of the central nervous system during early development, behavioral change, learning, pain, and emotion, and in a variety of disease states, including drug addiction.
- Recently-identified molecules that govern the behavior of nerve and muscle cells are providing new prospects for repairing injury and degeneration in the brain and spinal cord.

Such advances inspire further work and support our request for appropriated funds for fiscal year 1998. To help you see what these funds are likely to accomplish in the immediate future, the Institute Directors and I have identified many of the most exciting topics of on-going and anticipated research and grouped them within six broad Areas of Research Emphasis: the biology of brain disorders, new approaches to pathogenesis, preventive strategies against disease, therapeutics and drug development, genetics of medicine, and advanced instrumentation and computers. These categories of research reach beyond Institute boundaries to highlight the disciplines that we judge to show special promise for further discovery and practical application. You will be hearing from individual Institute Directors during the next two weeks about many specific examples that illustrate why we believe these topics to warrant such high priority.

*Clinical research and the new Clinical Research Center*

In my appearance before this Committee last year, I emphasized my concerns about several aspects of clinical research, especially the need to reinvigorate, reorganize, and rebuild the Clinical Center at the NIH. Since then, we have received \$90 million in fiscal year 1997 appropriated funds that allow us to proceed with the detailed planning and initial construction of what will be the Mark O. Hatfield Clinical Research Center. We have established a Board of Governors to oversee management of the Clinical Center, in accord with the recommendations of last year's report by Dr. Helen Smits and her colleagues to the Secretary of HHS and we have initiated plans to collect third party payment for care at the Clinical Center. We have continued to recruit outstanding clinical scientists, improve instruction in clinical research, toughen the review of protocols for clinical experiments, expand outreach to extramural clinical investigators, and forge stronger ties with nearby academic health centers. In the past few months, we have also developed a program to bring medical students to the NIH campus for one or two years to participate in patient-oriented research, in accord with a recommendation by the NIH Director's



Panel for Clinical Research. (This important training program, to begin this Fall, is our first collaborative effort with the newly-constituted Board of the National Foundation for Biomedical Research, which received its first appropriated funds, \$200,000, in fiscal year 1997.)

The prospect of a new Clinical Research Center has re-energized clinical investigators at the NIH. Several months ago, we held a full-day celebration of our clinical research activities, with many presentations of past, present, and future projects on metabolic, infectious, and genetic diseases; diagnostic methods developed with molecular and novel imaging tools; therapies involving immune manipulation and gene transfer; and various approaches to disorders of the nervous system. For this occasion, Institute Directors prepared statements of their goals for patient-oriented research for the next several years; post-doctoral fellows showed posters outlining recent work; and architects and administrators described plans for the form and function of the new facility. In addition, the intramural clinical research community has proposed measures to strengthen our ability to recruit clinical investigators and to ensure a nurturing environment for them at the NIH.

*Other aspects of administrative oversight*

Clinical research is only one of many areas that have benefited from increased administrative oversight during the past few years. The Institutes have recently pledged to develop more interactive information systems, and the NIH is in the process of hiring a Chief Information Officer. Directives from both this Committee and the Administration to limit administrative costs have stimulated the adoption of streamlined methods for peer review, accounting, and other activities; more widespread use of electronic communication; sharing of resources through service centers; and reduced use of FTE positions. In response to your request, Mr. Chairman, we are currently undertaking an extensive study of all of our administrative functions, looking for opportunities to achieve even greater efficiency, without impairing support of the research enterprise and our traditional stewardship of Federal funds.

We have also been vigilant about oversight of our research activities. In the spirit of the 1994 report on intramural research by the Marks-Cassell Committee and the 1995 Bishop-Calabresi report on the NCI, we have continued to review individual intramural research programs; a report on the NIMH program was recently completed, and four others are in progress. Complex activities—gene therapy, the AIDS program, and clinical research—have been subjected to detailed review, and many trans-Institute areas of investigation—nutrition, pain, sleep, and several specific diseases—are being monitored by special coordinating committees. In addition, we have initiated a process for evaluating the performance of Institute and Center Directors every five years; panels are currently reviewing the activities of the seven Directors with the longest terms of service.

*Plans for the proposed budget for fiscal year 1998*

The President's fiscal year 1998 budget for the NIH provides an increase of \$337 million over the current NIH appropriation. In line with our traditional priorities, we plan to allocate about 80 percent of the additional funds (\$271 million) to research project grants (RPGs), increasing support for these awards by nearly 4 percent over fiscal year 1997. We expect to increase the average size of both continuing and new awards by 2 percent, rather than the usual 4 percent, allowing us to support about 7100 new and competing grants and to achieve an all-time high total of nearly 27,000 research grant awards. (Note that the Department of Commerce has determined the Biomedical Research Development and Price Index [BRDPI] to have been 2.6 percent in 1996, the lowest rate in many years, consistent with the recent decline in the consumer price index ; we project BRDPI values of about 3 percent for 1997 and 1998.) The Budget also requests a \$30 million increase for the National Institute for Drug Abuse as part of the Administration's efforts to address the problem of drug use.

We also request \$90 million to support continued construction of the Mark O. Hatfield Clinical Research Center in fiscal year 1998, along with advanced appropriations of \$90 million for fiscal year 1999 and \$40 million for fiscal year 2000, for a total of \$310 million, which is required to complete the project by 2002.

I will be pleased to answer any questions you and your colleagues might have.

SUMMARY STATEMENT OF DR. STEPHEN HYMAN

Senator SPECTER. What I would like to do, Dr. Varmus, is proceed around the table and get a brief statement from each of the distinguished administrators who are here as to how much money each has, how many grants they are able to give, how many grants

have to be turned back, and if they had, say, a 7½-percent increase, what that would do for them.

Let us start with you, Dr. Hyman.

Dr. HYMAN. I do not have in front of me our precise budget number, but I can tell you.

Senator SPECTER. Give me a generalized number.

Dr. HYMAN. We are just over \$700 million, including nearly \$100 million for our AIDS budget, which is focused on AIDS behavioral prevention, in the National Institute of Mental Health.

Do you want me to give you the precise numbers?

Senator SPECTER. I do.

Dr. HYMAN. Our—

Senator SPECTER. If you do not have a precise number, give me an approximation, please.

Dr. HYMAN. The non-AIDS budget proposed is \$629,739,000, and then the AIDS budget is \$98,510,000. This is in the President's proposal.

Senator SPECTER. With respect to research grants, can you tell me how many that allows you to have, and how many you turn down?

Dr. HYMAN. In the current budget year we expect to be, because we are not at the end of the budget year, to be funding about 24 or 25 percent of our grant applications, and turning down, therefore, about 75 percent of our grant applications.

Senator SPECTER. Could you give us an estimate as to what you think you could accomplish if you could have more of those grant applications? Suppose you were able to double them. Let us take the figure of doubling over 5 years. What could you accomplish with that kind of a doubling?

Dr. HYMAN. Let me give you some highlights, Senator Specter.

Brain research, especially with respect to mental disorders, has undergone a recent revolution in our ability to understand how the brain functions and how things go wrong with mental illness.

Areas that we would like to be able to invest in include understanding the genetics of mental disorders. This is extremely complex. In no case in mental disorders does a single gene cause vulnerability.

It turns out that for diseases like schizophrenia, manic depressive illness, serious depression, and others, multiple genes interact with the environment to produce illness. We would like to be able to invest in no small part to be able to capitalize on the findings of the human genome project.

A second important area that has received inadequate focus in the past but which is absolutely critical is children's mental health. There have been an inadequate number of clinical trials in children. As you may or may not know, there is very little in the way of approved psychotropic drugs for children, and yet we recognize that the age of onset of major depression, for example, in the United States is getting earlier and earlier.

We also have paid inadequate attention historically to important diseases like autism, and would like in general to be able to increase our efforts in childhood mental health.

In addition, we need to engage in large-scale clinical trials of the kind that will validate comprehensive treatments for diseases like

schizophrenia or manic depressive illness in an era of managed care. This is a critically important area for us.

I will not go on, because you want to talk to everybody else, but I think it is very important to state that we are in an era now where using a combination of molecular biology tools and neuroscience tools we are beginning to understand how the brain works in forming both normal and abnormal cognition, or thinking, and normal and abnormal emotion, and what we would like to be able to do is to use these tools to understand how the brain functions and then rapidly translate these discoveries into novel treatments for people with mental disorders.

Senator SPECTER. I have started the clock for 5-minute rounds so that I will not detain my colleagues, but I intend to go around the room so that each of you who will follow will know where I am heading on the questions.

Dr. Hyman, if you were to put it in layman's language, what could you accomplish with a 50-percent increase? What could you do on the issue of mental illness if you had that funding?

Dr. HYMAN. I think that over time we would discover vulnerability genes, so we would know who was at risk. We would be able to intervene earlier. We would have better treatments for adults. We would have a fundamental knowledge base for the treatment of children, and we would also improve the dissemination of the knowledge that mental disorders are real, diagnosable, treatable brain diseases throughout, for example, primary care settings where these diseases are often underrecognized and undertreated.

Senator SPECTER. Would you give us in writing a more precise statement as to what you could accomplish?

Dr. HYMAN. Yes.

Senator SPECTER. Focus on how we would translate that to brief floor statements to persuade our colleagues to increase funding, and if it is possible also for you to add in the calculation as to what money would be saved, how cost-effective it would be. We hear that on Alzheimer's, for example, saving so much money.

We will come to Alzheimer's, but to the extent you can quantify it, and what will happen to your program if there is no increase but a slight decrease, if you have a proportionate share of the \$100 million cut on the health account, what will happen to your unit.

Dr. HYMAN. I would be happy to do that. I can say we have just had some help from the World Bank and World Health Organization, which have calculated that mental illnesses, most notably diseases like major depression, schizophrenia, obsessive-compulsive disorders are among the absolute leading causes of disability, and disability adjusted life years lost. This is true in the United States and Europe already and soon will be worldwide. There are immense social costs to our inability to treat these diseases fully at this time.

Senator SPECTER. Well, if you could quantify that on a cost-effectiveness basis I think it would be of interest to Congress as well as to the public.

[The information follows:]

*Accomplishments*

Throughout its fifty years, the NIMH has conducted and supported research that has made possible the development and use of many new treatments for mental illnesses—where previously there were no effective treatments. This time span saw the first medications that could alleviate mental illness, establishing that these illnesses are biological in origin and providing a powerful weapon against stigmatization of patients.

Effective treatments have greatly improved the lives of people with mental illness and have also produced significant economic benefits. For example, lithium therapy for manic depression has saved the U.S. economy almost \$6 billion per year since 1970; and clozapine maintenance treatment for schizophrenia saves approximately \$1.4 billion annually, primarily by preventing hospitalizations of the estimated 60,000 patients receiving clozapine.

Continuing improvements in psychotherapies have replaced or augmented pharmacologic treatments for some patients. In 1990, one mental illness, unipolar major depression, was the leading cause of disability. This disability has a major and growing impact on both the direct costs of health care and the loss of economic productivity; it is a potent incentive to accelerate efforts to reduce the burden of mental illness.

Decades of painstaking research have brought neuroscientists to the threshold of understanding the structure and operation of that most complex of human organs, the brain. To understand cognition, emotion, and what goes wrong to produce the brain disorders that we call mental illnesses will require progress at the levels of molecules and genes, cell, circuits, and psychology.

This is an enormous challenge because mental illnesses don't appear to have any single cause; rather they result from multiple vulnerability genes acting at different times during brain development combined with influences of environmental factors. Using genetic engineering and cell recording techniques in mice, researchers have begun to describe the underlying biology that constitutes the molecular basis of memory formation in the brain. Other scientists have made major advances in discovering how the brain functions in emotions such as fear; this progress will revolutionize our understanding of the neurobiology of emotion and how best to treat severe anxiety disorders, such as panic disorder and obsessive-compulsive disorder.

Another group of scientists, using advanced molecular techniques and basic behavioral science, have identified a gene named clock, that controls daily biological rhythms. This work will help understand human problems ranging from mood disorders, such as depression, to sleep disorders to jet lag. A recent study, which illustrates the potential usefulness of neuroimaging techniques for understanding mental illnesses, found that people with schizophrenia had a decreased density of dopamine D1 receptors in the prefrontal cortex and that the extent of decrease correlated with the severity of the illness.

*What could be accomplished in the future with additional funds*

Expansion of research on the complex genetics of the major mental disorders would lead to a much more complete understanding of the roles of genetic factors in mental illnesses—schizophrenia, schizoaffective disorder, manic depressive illness, major depression, autism, panic disorder, and obsessive-compulsive disorder—which would lead, in turn, to clearer insights into the origins, optimal treatments, and ways to prevent these illnesses.

Increased emphasis on the use of modern molecular and integrative neurobiology to understand the basis of mental disorders would discover new targets for novel therapeutic agents.

Acceleration of research on the application of modern genetic techniques in animal models would enable scientists to understand how the brain processes cognition (including memory) and emotion, while neuroimaging techniques will allow scientists to translate the findings of this animal research into humans.

Expansion of research on the prevention and treatment of mental disorders in children would yield critically needed information on the best and safest ways to reduce the terrible consequences of mental illness for our youngest citizens.

Initiation of clinical trials of new drugs recently approved for the treatment of manic depressive illness and psychotic disorders would allow NIMH to advise mental health care providers on the most effective treatments for each type of patient.

Finally, research on imaging techniques could lead to an integration of pharmacologic and behavioral approaches to treatment.

## PREPARED STATEMENT

Dr. HYMAN. If I may, Mr. Chairman, I have a prepared statement which I would like to have inserted into the record.

Senator SPECTER. Your statement will be inserted into the record at this point.

[The statement follows:]

## PREPARED STATEMENT OF DR. STEPHEN HYMAN

It is my pleasure to appear before you to discuss the research programs of the National Institute of Mental Health (NIMH). My first year as Director of the NIMH has reinforced my perception that this is a period of extraordinary scientific opportunity for understanding the brain, its role in behavior, and what goes wrong in the brain to produce mental illness. The knowledge we are gaining should improve our capacities to treat and, eventually, prevent an array of mental disorders.

In this statement, I will comment briefly on the burden of mental disorders; highlight key scientific accomplishments and opportunities; and describe several administrative steps we are taking to speed our progress as efficiently as possible.

Schizophrenia, major depression and manic depressive illness, severe anxiety disorders, obsessive compulsive disorder, anorexia nervosa, and other severe mental illnesses affect some 5 million adults. Additional millions of Americans suffer other disorders that occur across the lifespan, from childhood autism to dementias in the aged. All told, mental disorders cost the United States more than \$148 billion each year. The U.S. experience is not atypical. A study sponsored by the World Bank and World Health Organization recently forecast that by the year 2020, as we effectively meet the challenge of infectious disease in developing countries, major depression alone will rival chronic ischemic heart disease as the single leading cause of disability worldwide (Table 1). The study makes it clear, moreover, that the courses of the top five diseases from all causes are heavily influenced by human behavior.

Given the immense public health burden of brain disease and its impact on our Nation's productivity, I am encouraged that mental illness has emerged as a prominent theme in our Nation's efforts to set health care priorities, as evident, for example, in the debate concerning insurance parity. Americans are increasingly aware that serious mental illness is not a moral failing or weakness, but a disorder of a specific organ, the brain, just as coronary artery disease is a disorder of a specific organ, the heart. Mental illnesses are brain disorders that will be understandable in terms of molecular and cellular processes in the brain and the brain's interaction with the environment. With this recognition, the stigma once associated with mental illness is fading.

Independent analyses show that research is an effective response to the economic and social burden of mental illness and to the needs of patients and their families. For example, a study published in the journal, *Science*, 1994, documents savings of \$145 billion to the U.S. economy since 1970 when the FDA approved lithium for treating manic depressive illness. In addition, a study in the *American Journal of Psychiatry*, 1993 showed that clozapine maintenance treatment for schizophrenia, approved by the FDA in 1990, yields annual savings of \$1.4 billion for the estimated 60,000 patients receiving this medication. I believe these treatments, and the resultant savings, reflect a return on a sustained research investment.

Modern mental health research relies on many of the same methodologies and technologies used in other areas of medicine, but applies them to an array of questions that extend from the cell to society: from studies of the genetics of complex human disorders, to molecular neurobiology, to brain circuits and behavior, to clinical trials of new treatments, to sophisticated services research designs needed to understand the effectiveness of treatments in complex, real-world settings.

The human brain is the most complex structure in our known universe. If we are to understand the roots of mental illness, we must press on with fundamental investigations of the brain. The truly novel and effective treatments of tomorrow will be based on the investments in basic science that we make today. The dividends of our investment are seen in recent NIMH-supported basic science advances:

—We have identified a molecule—a protein found on the surfaces of nerve cells—that early in brain development appears to guide specific emerging cells to become part of the brain's limbic system, which is involved in the control of emotion and motivation. Any alterations in such guidance systems in the developing brain could lead to a cascade of abnormal circuit formation and could be the cause of illnesses such as schizophrenia or autism.

- Another accomplishment is the deciphering of a cellular mechanism that may be responsible for pruning of excess cortical neurons that are purposely over-produced in early phases of brain development. Here too, the discovery helps to flesh out a suspected developmental cause of the brain defects in schizophrenia.
- In yet another discovery, scientists using advanced molecular techniques in the mouse, coupled with basic behavioral science, have identified a gene that controls daily biological rhythms. A behavioral test, which exploits the tendency of mice to be highly active during the night and less active in daytime, enabled isolation of a mutation in a gene named *clock*, which controls the duration of daily biological rhythms. This work, and related research in the fruit fly, is clarifying a complex chain of events that regulate our sleep/wake cycle, a cycle that is disrupted in mood disorders, and also is crucial to understanding human problems ranging from sleep disorders to jet lag.

Such advances make it clear that innovative animal models and the molecular biological approaches constitute an essential foundation of our “bottom up” efforts to understand larger-scale brain systems, their role in behavior, and what it is that goes awry in brain function that leads to mental disorder.

Human genetics is a vital component of our efforts. As molecular genetics comes of age in medical science, we see that disorders such as schizophrenia and manic depressive illness are complex disorders, much like diabetes and hypertension. We know that certain genetic patterns, while not directly causing an illness, can lay a foundation for increased vulnerability to illness. We know that individual vulnerability to mental disorders and other complex traits is due to the interaction of multiple genes rather than to a flaw, or mutation, in a single gene. Moreover, it appears that no single genetic mutation is necessarily shared by all individuals with a given disorder—indeed, there likely are multiple genetic pathways to vulnerability. Environmental factors may then interact with the genetic vulnerability to lead to the onset of a specific illness.

Modern genetics also permits us to understand brain-behavior relationships in animal models. Scientists now can manipulate the mouse genetic code by adding or deleting single genes, and soon will be able to deactivate genes in specific brain locations at a predetermined time in the animal’s development. These same approaches will help us understand human disease vulnerability genes whenever we find them.

Of course, what we glean from molecular genetics and other basic research will be most relevant to clinical concerns only when we understand these processes against a backdrop of social context, interpersonal interactions, individual psychology, and neural circuits. Thus, each advance in understanding genetic mechanisms opens opportunities for basic and clinical investigation. To ensure that we capitalize fully on these opportunities, the NIMH attaches high priority to research that translates basic findings into the realm of clinical investigation and application.

NIMH-funded research on childhood and adolescent mental disorders illustrates our commitment to clinical and treatment research. As many as 20 percent of young Americans between the ages of 7 and 14—approximately 10 million children—suffer from mental health problems severe enough to compromise their ability to function.

While any interruption to normal developmental processes is of concern to us, we attach particularly high priority to research on autism, a severe disorder of communication and behavior that affects more than 100,000 Americans. Family and twin studies point to a genetic cause in autism, particularly when multiple cases occur in a family. Among siblings of an autistic person, the prevalence rate for the disorder is 75 times higher than in the general population. The importance of finding the genes responsible for autism lies in their value in diagnosis as well as in providing essential information about the regulation of brain development. NIMH researchers at three different locations now are studying families using a combination of strategies, and the likelihood of identifying susceptibility genes in the next several years is high. As this search progresses, neuroimaging studies are providing evidence of abnormalities in several brain regions in persons with autism. Such findings strengthen hypotheses that a genetically-triggered disturbance in brain development early in fetal life is responsible for the devastation of autism. Our research complements an NIH-wide effort focused on autism, with other concentrated activities in the neurology, child health, and communicative disorders institutes.

For all childhood mental disorders, we must have a full range of interventions; that is, treatments based on behavioral approaches such as psychotherapy as well as medications. In one recent project, investigators developed a 16-week cognitive-behavioral intervention specific to the needs of children with anxiety. Untreated, childhood anxiety disorders tend to persist into adulthood and are associated with a range of psychological and social impairments. The psychotherapeutic approach reduced anxiety, and these benefits were maintained for more than three years.

Such advances do not permit us to rest on our laurels. Recognizing that resources are limited, in my first year at NIMH, we have worked to identify and prioritize research challenges. Let me report briefly on progress in three major areas to strengthen our programs and make them even more cost-effective.

First, our Intramural Research Program Planning Committee, which was created in response to congressional interest in the revitalization of intramural research across the NIH campus, has completed its work, and I have begun to implement the nearly 80 recommendations it developed. These call for making many labs smaller; apportioning funds in a way that will offer incentives for translational research; creating incentives for excellence; and freeing up resources so we can recruit and support the most outstanding young and mid-career investigators. A top quality intramural program can create a superb complement to our extramural program by bringing together a critical mass of both basic and clinical researchers and, by stability of funding combined with rigorous review, permitting them to undertake long-term-, higher risk-, and interdisciplinary projects.

Secondly, with extensive consultation from our extramural community, I have undertaken a fundamental restructuring of our extramural research funding divisions. The first impetus for this change is fundamentally scientific—that is, our divisional structure, developed for a previous scientific era, today impedes our efforts to encourage and make necessary scientific connections—for example, between basic and clinical neuroscience. Changes we are making also will yield greater administrative efficiency; a structure that more closely reflects the contemporary scientific process will permit us to use our administrative funds in the most streamlined and effective manner.

A third area of change concerns the role of our National Advisory Mental Health Council. The breadth of interests and expertise of our Council members is impressive, as is the intensity of their commitment to mental health issues. I have been immensely gratified by the enthusiastic and productive response of our Council members to my invitation to take a more active working role in conducting in-depth, hands-on reviews of the operations of various NIMH's programs: Our science communications and prevention research portfolio are now being examined by Council work groups and more will follow.

Let me conclude by returning to the most important aspect of our work, which is the science. Our efforts in the coming year will be aimed at new initiatives in the genetics of vulnerability to mental disorders, using the tools of molecular biology and neurobiology together to understand the function of the normal brain and how things go wrong with mental disorders, and development of programs to translate what we learn from basic brain and behavioral research to clinical applications. In addition we will begin reforming our approach to clinical trials and adapting what we learn to people in the real world. An important task for the mental health services research community will be to study the impact of managed care on the mentally ill, a particularly vulnerable population.

For the scientific activities I have highlighted here and for related programs, NIMH requests \$629,739,000 for fiscal year 1998. Thank you Mr. Chairman. I will be pleased to answer any questions.

*Table 1.—Worldwide burden of disease*

<i>Rank and cause</i>	<i>Percent</i>
<i>Estimate 1990:</i>	
1 Lower respiratory infections .....	8.2
2 Diarrheal diseases .....	7.2
3 Perinatal conditions .....	6.7
4 Unipolar major depression .....	3.7
5 Ischemic heart disease .....	3.4
<i>Projection 2020:</i>	
1 Ischemic heart disease .....	5.9
2 Unipolar major depression .....	5.7
3 Road traffic accidents .....	5.1
4 Cerebrovascular disease .....	4.4
5 Chronic obs pulmonary disease .....	4.2

Note: Global Burden of Disease 1996—WHO, Harvard School of Public Health, World Bank.

SUMMARY STATEMENT OF DR. STEPHEN KATZ

Senator SPECTER. Dr. Katz, your unit is arthritis.

Dr. KATZ. Yes, sir; it is the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Our budget for 1997 is \$257 million, and our proposed budget for 1998 is \$263,242,000.

Senator SPECTER. So you have a reduction.

Dr. KATZ. No; it went from \$257 million for 1997 to \$263 million requested for 1998. Our success rate anticipated for this year is 25 percent. That is, 25 percent of the applications will be funded, for an estimated total of 167 successful applications. That means we are turning down approximately 503 applications this year.

There are many exciting areas of research within the broad range of diseases that the Institute covers. In the area of osteoarthritis, as the aging population increases, the impact and frequency of osteoarthritis, as well as the disability associated with osteoarthritis are also increasing.

Another major public health problem that we have an interest in and commitment to understanding is osteoporosis. There have been major advances in understanding osteoporosis, including the diagnosis of osteoporosis using ultrasound or x-ray, as well as recent important advances in understanding how drugs affect osteoporosis.

Senator SPECTER. Dr. Katz, if you were to double your budget, what more could you accomplish?

Dr. KATZ. We could move at a faster pace with regard to our understanding of the process of bone formation and bone breakdown as well as the process of cartilage breakdown. We would also improve our understanding of how implants that are used for hip replacement and knee replacement can be improved so that the bone that surrounds these implants does not break down—a major complication.

We can also better understand many of the skin diseases and arthritic diseases where inflammation is a major process, and the pace would move much, much more rapidly with an increase in funding.

With an increased understanding, of course, comes an increased likelihood for better therapeutic interventions. Many of the therapies that are used in the arthritic diseases and skin diseases are nonspecific. That is, they not only decrease inflammation, but they also have adverse effects, or negative effects in other areas.

With increased knowledge investigators around the country and around the world are identifying very specific markers to target for specific interventions that will decrease the side effects from some of the drugs that are being used today.

#### SUMMARY STATEMENT OF DR. PHILLIP GORDEN

Senator SPECTER. I would like to turn now to Dr. Phillip Gorden, Director of the National Institute of Diabetes, Digestive and Kidney Diseases.

Dr. Gorden, what is your budget for last year and what for next year projected?

Dr. GORDEN. Mr. Chairman, our budget for current fiscal year 1997 is \$815.982 million. Our requested budget for fiscal year 1998 is \$833.802 million.



Senator SPECTER. Dr. Gorden, if we were able to project ahead a doubling of your budget, what will you project that you could accomplish?

Dr. GORDEN. Mr. Chairman, we have responsibility for some of the most serious chronic diseases in the country, including diabetes, obesity, kidney disease, liver disease. And in many of these areas—for instance, in diabetes—we have made really a major discovery of the efficacy of treatment. Now, our ability to follow up on that really is a question of what resources are going to be available to us. And so these are areas that we have immediately moved into. We have moved into areas of prevention in both noninsulin dependent and insulin-dependent diabetes. And we have only just begun to explore the opportunities that are available to us.

Senator SPECTER. What prospects do you see for the success of prevention?

Dr. GORDEN. Well, we have two major trials underway at the present time. And we are very optimistic about at least partial success. I have to modulate that, because the nature of these trials is not going to completely prevent the disease. But if we can simply make inroads into prevention, this will be a major step forward.

We have discovered very recently a major hormone regulating energy metabolism called leptin. The ramifications of this research are just beginning to emerge. This is a burgeoning area of research.

We just discovered the genes that are responsible for important diseases such as polycystic kidney disease—two very important genes that lead to this important form of end-stage renal disease. The ramifications of that are just beginning to emerge. We cannot really see exactly where this is going, but we clearly know that these are major areas of progress.

So that there are issues that are clearly on the table now, that represent real progress and represent the kind of thrust of the future. And we are just really beginning to understand where these particular opportunities and avenues are leading.

Senator SPECTER. Thank you very much, Dr. Gorden.

I will yield to my colleague, Senator Cochran.

Senator COCHRAN. Mr. Chairman, just in time. I was going to point out that Dr. Gorden is one of our favorite sons from the State of Mississippi. [Laughter.]

All the way from Baldwin, MS, to Washington, DC, where he is respected as one of the Nation's finest research scientists and physicians. We appreciate the good work that he is doing. And it is a pleasure to see him and Dr. Varmus and all of you who are here today to review with us this budget request.

I am going to defer any questions to specific members of this panel, and let them all have a chance to make their presentation before I ask any questions, if that is all right.

Senator SPECTER. Senator Bond.

#### SARCOIDOSIS

Senator BOND. Mr. Chairman, I have a question, a specific area question, either to Dr. Varmus or Dr. Lenfant. I understand that sarcoidosis is a common chronic disease of unknown cause which affects all races, both sexes and can appear in almost any body organ. The NIH Heart, Lung and Blood Institute provides about \$4

million for research on this mysterious disease. And I would just like to find out where we are in the research on it. Are we getting any closer to identifying the cause and perhaps the cure of it? And is this an area where there is a significant opportunity for the advancement of scientific knowledge?

Dr. VARMUS. Thank you, Mr. Bond. I would like to defer to the true expert, Dr. Lenfant, on this one. And if time permits, I would like to make a few comments about your opening remarks.

Senator BOND. I did not doubt you would.

Dr. LENFANT. Thank you, Senator.

Yes; the National Heart, Lung and Blood Institute has a research program on sarcoidosis, on which we spend a little bit more money than what you say. I think the expenditure for this year is on the order of \$6 million.

Your question of whether there are some opportunities which are before us for significant progress, I think the answer to that is yes. We have come to learn, during the last few years, that there may be some very significant genetic factors which control this condition.

I should say that it is a condition which affects mostly African-Americans and also the Scandinavian countries. Elsewhere in the world it is very rare to see sarcoidosis.

We have initiated, last year, a program to uncover what genes might be intervening in this disease. And, thus far, the work is progressing quite well. And I am quite confident that within a few years we will have some very significant progress to report to you.

Senator BOND. Well, is it a question of just time or the lack of resources? And we are talking about a significant number of people who are affected by it.

Dr. LENFANT. Indeed. Indeed.

Senator BOND. And I understand that the cause of death in many of these cases has been identified as lung problems or something. So it is really overlooked, the basic, underlying disease.

Dr. LENFANT. Your question is quite timely actually. Years ago, there was lots of work which was going on, on this condition, which had been relatively unsuccessful. Now we see an advance of the molecular and genetic approaches and molecular biology. There is a resurgence of activity. And sure enough, the research on this disease competes with the research on all the conditions. And within the resources that we have, we have allocated some resources to it. Whether we could do more beyond that, the answer is "yes." Whether we could do it faster, I suppose we would if we had the opportunity to invest more resources into this project.

#### NATIONAL ACADEMY OF SCIENCES REPORT ON RESOURCE ALLOCATION

Senator BOND. Dr. Varmus, I guess this brings me to the broader question. A couple of years ago, the National Academy of Sciences came to me because I was the chairman of the committee that funds NSF. And the NAS was going to come up with a means of evaluation of how we spend our scientific dollars.

Now, I know you have your own priority system within NIH. They were telling me that for funding scientific research across the board, including NIH and perhaps within it, they were going to develop, I guess last year, a better scientific protocol for allocating the

research dollars. And I wonder, have you heard anything about it? Where is it? And how can we get a handle on it?

Dr. VARMUS. Mr. Bond, there was a report presented by Frank Press, the previous President of the National Academy of Sciences, about a year and a half ago, I believe. It did not deal with priority setting at the level of specific diseases, but instead proposed another way to look at the nondefense part of the research portfolio, as a consolidated evaluation process—not consolidating all the agencies, but consolidating the budget-forming process. And that has been very widely discussed among science policy people.

We could provide you a copy of the report if you would like.

Senator BOND. I would appreciate it.

Thank you, Mr. Chairman.

Senator SPECTER. I thank you very much, Senator Bond.

[CLERK'S NOTE.—Due to its volume, the above mentioned report is being retained in subcommittee files.]

#### SUMMARY STATEMENT OF DR. CARL KUPFER

Senator SPECTER. Let us turn at this point to Dr. Kupfer, Director of the National Eye Institute. Would you tell us your budget for this year and the proposed budget for next year, please?

Dr. KUPFER. Yes, sir; for fiscal year 1998, the budget request is \$330.955 million. With that, we would be able to fund 228 competing grants and turn back about 400 grants.

Senator SPECTER. And if you had a doubling of your budget, what would you anticipate being able to accomplish?

Dr. KUPFER. I think two of our major challenges deal with the age-related macular degeneration, which is rapidly becoming of epidemic proportions, and the complications of diabetes, specifically diabetic retinopathy. With respect to the age-related macular degeneration, I think we would be able to move more rapidly into the areas of transplantation of tissue into the back of the eye to try to rescue the degenerating cells, and to explore more fully, growth factors that again would maintain these cells.

With respect to diabetic retinopathy, we are on the verge of finding more effective and safe inhibitors of a particular enzyme which we think brings about the complications of diabetes. And I think we could accelerate finding this inhibitor and then employing it in clinical trials.

I think those would be two of our major activities with additional resources.

Senator SPECTER. Thank you, Dr. Kupfer.

#### PREPARED STATEMENT

Dr. KUPFER. If I may, Mr. Chairman, I have a prepared statement which I would like to have inserted into the record.

Senator SPECTER. Your statement will be inserted into the record at this point.

[The statement follows:]

#### PREPARED STATEMENT OF DR. CARL KUPFER

Mr. Chairman, I am pleased to report that the NEI continues to conduct and support research leading to treatment for blinding eye diseases, including glaucoma, cataracts, and diabetic retinopathy. Furthermore, we also are pursuing exciting new

avenues of research for one particular eye disease that is causing increased concern among older Americans, age related macular degeneration, or AMD.

The American eye is aging. The first group of "baby boomers", those born between 1946 and 1964, turned 50 last year. This group, by their sheer numbers, has changed, and continues to change, the fabric of American society. In 1995, these "baby boomers" numbered more than 79 million.

As this group of Americans marches toward their golden years, they will become more susceptible to serious eye diseases, such as AMD. AMD is a common eye disease of the macula, a tiny area in the retina that helps produce sharp, central vision required for "straight ahead" activities such as reading, sewing, and driving. A person with AMD loses this clear, central vision. AMD is the leading cause of severe visual impairment and blindness in the United States. It is estimated that AMD already causes visual impairment in approximately 1.7 million of the 34 million Americans over age 65, and its prevalence is expected to reach 6.3 million by the year 2030. Since fiscal year 1989, the NEI has devoted an increasing percentage of its annual appropriation to AMD research.

Technology has advanced greatly in recent years, and as a result, the NEI has identified several areas of research to learn what causes AMD and how it can be treated more successfully. Through NEI's Age-Related Eye Disease Study, researchers at 11 clinical centers around the country are assessing the aging process, potential risk factors, and quality of life of 4,700 patients to pinpoint the earliest signs of AMD. Once such studies have helped us to determine how macular degeneration develops, we might be able to change its course; when we know for certain what risk factors contribute to development of the disease, we can caution patients to avoid them. This same study also includes clinical trials that will help determine the effects of certain vitamins and minerals in preventing or slowing the progress of AMD. In particular, researchers are examining whether vitamins C and E, beta-carotene, and zinc can provide the macula with greater protection, thereby preventing or slowing progression of the disease. If dietary supplements prove effective, it would have a huge impact on AMD treatment and reduce our nation's risk of visual impairment or blindness.

Another study begun last year is evaluating genetic and environmental factors related to AMD and examining an underlying hypothesis that genetic factors play a significant role in this complex chronic disease. Participating families in this study include those with both a single case of documented AMD and those who have at least two living siblings (or a parent) with documented AMD.

One of the risk factors that may be associated with AMD and vision loss is the presence of drusen, which are white, clumpy deposits that lodge under the retina. Early investigations suggest that these deposits might be a precursor to AMD, and this hypothesis is undergoing careful study to determine if drusen play a role in the development of macular degeneration.

Other approaches to solving the problem of AMD include laboratory, or basic, research. This research includes studies of genetic factors to gauge the role of heredity in the development of AMD. Genes involved in AMD already have been identified in three less common types of macular degeneration. In addition, genes associated with several other forms of macular degeneration have been localized to specific chromosomes. Knowing the genes will enable researchers to determine the gene product and how it brings about the degeneration.

NEI scientists also are trying to identify genes that could help regenerate damaged areas of the retina. This strategy may help to prevent much of the visual loss from later stages of AMD. Researchers are exploring the effects that gene replacement therapy may have on the treatment of macular degeneration, and scientists have already successfully placed genes into the retina of laboratory animals. Replacing diseased retinal cells with healthy ones is another promising area of research. NEI scientists are working to apply retinal cell transplants to treat retinal degeneration caused by AMD.

The NEI also sponsored a workshop that led to shared research ideas and consideration of the future direction of AMD research. This workshop, held last June, brought together academicians, clinicians, and representatives from biotechnology companies, all of whom were knowledgeable in growth factor cell biology. The discussion centered around the potential use of neurotrophins, or biological survival factors, to delay clinical indications of retinal cell degeneration in AMD and other eye diseases.

In addition to being a leading cause of blindness in the United States, AMD is also a leading cause of low vision, broadly defined as a visual impairment interfering with an individual's ability to perform activities of daily living. There are approximately three million Americans who suffer from visual conditions that are not correctable by standard glasses or contact lenses. People with low vision often can-

not perform daily routine activities, such as reading the newspaper, preparing meals, or recognizing faces of friends.

As the leading source of vision research funds in the United States, the NEI is committed to furthering progress in the area of low vision research. During 1996, the NEI supported 18 extramural research projects related to low vision. In addition, the NEI, through the National Eye Health Education Program, is developing an education program aimed at addressing the needs of people with low vision. This new program will increase public awareness about the impact of low vision on daily living. Approximately 21 percent of those who have low vision and are aged 45 and older are unfamiliar with low vision clinical services. The low vision program will play a key role in informing Americans about the use of optical and adaptive low vision devices and services.

The NEI has been very active in pursuing treatments for a wide spectrum of eye diseases, including those affecting the youngest Americans. Last year we confirmed that a freezing treatment helps save the sight of premature babies with a potentially blinding condition called retinopathy of prematurity. After 5½ years of follow-up, this treatment increased the possibility of saving sight in affected eyes by about 24 percent. These results present solid evidence that this freezing treatment significantly reduces the number of infants who are blinded by retinopathy of prematurity.

NEI's fight against uveitis, a severe inflammation in the eye, is continuing. Uveitis causes about 10 percent of the severe visual impairment in the United States, and affects primarily children and young adults. Treatment of uveitis has usually revolved around potent drugs that block the immune system. In a recent intramural NEI study, we found that when a purified protein is fed to patients suffering from uveitis, they were able to be weaned off the strong drugs, with no negative side effects. A larger, more focused clinical trial is underway.

The NEI is also studying the effect of apoptosis, or "cell suicide," in retinal degeneration. Apoptosis is a controlled, orderly process by which the body eliminates unwanted cells; it is a mechanism to eliminate damaged cells, without harming healthier neighbors. Apoptosis appears to play a role in several retinal degenerative diseases. By understanding the process by which this programmed cell death occurs, scientists may be able to develop a method to inhibit the process and thus treat these diseases.

The NEI also is active in the area of cell rescue and regeneration. Severed nerve cells in the peripheral nervous system can survive and regenerate to some extent, but most central nervous system nerve cells do not. For years researchers have been trying to determine the basis for this difference, so that damage to either system could be repaired. Recent research on the development of the visual system indicates that the signals that promote the survival and growth of neurons in the central nervous system and peripheral nervous system may differ significantly. Studies have demonstrated that specialized nerve cells in the retina that are similar to brain cells, including those cells in the spinal cord, do not survive in a serum-free culture medium. However, these cells do survive in culture when the medium contains the required combination of growth factors and other constituents. Related experiments in animals show that the survival of these specialized retinal cells after damage is significantly increased by injection of these factors into the eye. These findings demonstrate that the retinal nerve cells have similar survival requirements in the living organism and in the test tube, suggesting central nervous system neurons can be rescued by activating the appropriate signaling pathways.

As the NEI continues its research, it is becoming apparent that many eye diseases and disorders share common denominators. For example, new blood vessel growth in the retina is associated with both diabetic retinopathy and age-related macular degeneration. The NEI is looking at the way these pathologic processes cut across many diseases and can be controlled by blocking new blood vessel growth.

Our investment in high quality clinical research has little real benefit unless the results and recommendations from such studies are widely and suitably incorporated into patient care. Results of research must be disseminated to the public so people can take more proactive approaches to ensure their own health. One way this happens is through the National Eye Health Education Program (NEHEP), which is playing a role in educating Americans on the early detection and treatment of eye disease. For the past three years the National Eye Institute, through the NEHEP, has joined forces with the American Diabetes Association to make diabetic eye disease the major focus of National Diabetes Month activities, held in November. Through this successful public-private partnership, 11 organizations have disseminated important information to the 16 million Americans with diabetes and conducted community activities nationwide that emphasized the importance of an annual dilated eye examination. A related media campaign focusing on the connection between diabetes and eye care reached over 80 million people.

NEI's research program does more than fight eye disease, it also helps inventors with ideas on low vision aids develop those ideas for the marketplace. Inventors have few resources available allowing them to develop products that help people suffering from low vision. NEI's Small Business Innovation Research Grants Program gives inventors the opportunity to see their ideas turned into reality. For example, through this program, telescopic systems were developed that help those with low vision perform common tasks, such as walking down the street or reading signs. Another idea, a system called "Outspoken," magnifies text on a computer screen, making it easier for people with low vision to read. This product was recognized by the Smithsonian Institution for its unique way of using technology for the common good. A sister program, called the Small Business Technology Transfer Grant, encourages inventors in universities or research centers to form partnerships with small businesses. Between both programs, NEI expects to fund approximately 50 projects this fiscal year.

Mr. Chairman, the fiscal year 1998 budget request for the National Eye Institute is \$330,955,000. I will be happy to answer your questions.

#### SUMMARY STATEMENT OF DR. RICHARD HODES

Senator SPECTER. We now turn to Dr. Hodes, Director of the National Institute on Aging, can you tell us your budget for this year and your proposed budget for next year?

Dr. HODES. The budget for this year, Mr. Chairman, is \$483.952 million. The proposed budget is \$495.202 million.

Senator SPECTER. And if your budget were to be doubled, what would you anticipate being able to accomplish?

Dr. HODES. One of the National Institute on Aging's areas of emphasis is that which you mentioned earlier in your own remarks, Alzheimer's disease. Its urgency is put in the context of the changing age profile of the American population, in which particularly, the oldest old population will be increasing at a great rate over the next decades. This takes on relevance for all age-related disease, Alzheimer's disease among them, where studies have shown that percentages as high as 47 percent, or nearly one-half of those individuals age 85 and older, are affected.

With an increase in resources we would increase our efforts from the most basic level, to try to unravel the molecular basis of disease, an area where enormous progress has been made in terms of defining genes which are risk factors for Alzheimer's, as well as translating that information into development of new therapies. There has also been progress over the last years in identifying risk factors from epidemiologic studies. At present, the confluence of these epidemiologic, or risk factor studies, together with basic science, has brought us to the point of readiness for clinical trials of currently available and evolving agents.

Senator SPECTER. What is the reality, Dr. Hodes, of being able to find the cause and cure for Alzheimer's?

Dr. HODES. I think the reality is that eventually the cause or multiple causes will be found. The pace of progress, identifying mutations and individual genes, which cause inheritable disease, is symbolic of the way in which we are understanding the molecular pathways involved in Alzheimer's disease.

However, the complete translation of this into therapies and interventions is a task which is still formidable and should not be underestimated. In the interim, even prior to having this complete molecular understanding, there are data coming from risk factor analysis, which have suggested that histories, for example, of use of anti-inflammatory drugs, or history of estrogen use in women

has very substantial effects on the risk of Alzheimer's development. These are epidemiologic studies. They do not demonstrate directly the ability of these agents to act as therapeutic agents, but they are compelling evidence, provoking the initiation of such therapeutic studies, some of which are in progress and others of which are in the planning stages.

Senator SPECTER. Well, when the layman asks what are the prospects for finding the answer to Alzheimer's and some projection as to time, is it realistic, from your point of view, to give a projection as to how long it might take?

Dr. HODES. I think that it is wise to be most cautious in making promises that specify years. I think it is likely that over the course of the next 5 years that the time span of clinical studies now in progress and at planning stage have the potential to determine the effectiveness of treatments which are promising on the basis of basic science and epidemiologic analysis. I think that is a time-frame over which we will have the next answer to the effectiveness of the next generation of therapeutic agents.

Senator SPECTER. Well, if that answer is positive, what impact does that have on curing Alzheimer's?

Dr. HODES. I think, again, one has to be cautious about the use of the term "cure." What we have learned already about Alzheimer's is the multiplicity of factors which contribute to it. We are working to identify risk factors which, as suggested by certain epidemiologic studies may be able to reduce the risk of Alzheimer's by as much as 40 or 50 percent, if properly addressed. If that risk factor analysis were to be translated into actual effectiveness for therapeutic intervention, even if we had not yet understood the entire molecular etiology of disease and prevented it in absoluteness, there would be clearly an enormous public health and human impact upon Alzheimer's.

Senator SPECTER. Well, I understand the difficulties of being more precise. To the extent that it is possible to give some projected timetable, albeit tentative or albeit speculative, it would be enormously helpful. I have seen some statistics on Alzheimer's, for example, which say that if you delay the onset of Alzheimer's by 5 years, you save \$40 billion. Is that figure accurate or in the ballpark, Doctor?

Dr. HODES. I think it is clear, because of the late onset of disease, that if a 5-year delay in Alzheimer's should be accomplished, that there would be an enormous savings. I would certainly stop short of a precise dollar figure, but as a ballpark in order of magnitude, I think indeed it is reflective of the enormous savings that would result from that kind of delay.

Senator SPECTER. Well, when you submit followup answers to the subcommittee, to the extent you can quantify savings, it would be helpful. I know it is not possible to do it with precision, but when we are talking to the American people about the importance of the research it is very hard to give them a feel for if it cannot be quantified to some greater extent.

#### SUMMARY STATEMENT OF DR. ZACH HALL

Let me turn now to Dr. Hall, neurological disorders. We had Christopher Reeve in last week, and Christopher Reeve talks about

a doubling of the budget and a solution to the issue of severing the spinal cord. And of course, when Christopher Reeve testifies, there is an enormous amount of attention paid. What is the reality of finding an answer to spinal cord regeneration, to the extent you can answer that?

Dr. HALL. Let me begin by saying that the problem of regeneration after spinal cord injury is one of the most difficult that we face. The spinal cord carries literally millions of nerve fibers that exert control of the brain over our movements and, in contrast, also bring in sensations and information to the brain. To try to reestablish that wiring is a major challenge.

We are, however, making progress. And I think it is important to say that we do not have to completely be able to regenerate the spinal cord in order to provide substantial benefit for patients, people such as Mr. Reeve, who have spinal cord injury. Even a 5- or 10-percent increase in function can make an enormous difference in the quality of life for these people.

What we have found is that one of the major factors inhibiting regeneration in the spinal cord is that—two things. There are agents that promote growth of nerve fibers and there are agents that inhibit it. We know that the central nervous system, which traditionally does not allow regeneration, is a nonpermissive environment normally for nerve regrowth. And what we are beginning to learn how to do is how to manipulate that environment in order to remove the inhibitory influences and to add influences that stimulate nerve growth.

There have been some very promising early experiments in rat spinal cord injury, which suggests that limited regrowth is possible. And we are keenly interested in that and wish to push that work ahead as quickly as possible.

The major areas that we are interested in are understanding the injury that occurs, promoting regrowth, trying to increase the insulation of those newly regrown fibers, and our Institute also has a large program in providing help for patients with spinal cord injury. One of the recent triumphs, for example, is a device which lets patients with certain kinds of injury hold a glass or hold a pen or use their hands by movements of their shoulder muscles.

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And I cannot tell you what a tremendous improvement in just being able to manipulate one's way through daily activities, being able to hold a glass or hold a fork and to move that, involves. And so we are working, then, both in terms of trying to increase regeneration, prevent damage and also trying to devise mechanisms and devices that will restore some function to people with these injuries.

Senator SPECTER. Thank you.  
[The statement follows:]

#### PREPARED STATEMENT OF DR. ZACH W. HALL

Mr. Chairman and committee members: Thank you for the opportunity to appear before this Committee. These appearances are a pleasure for me because we are in an era of unprecedented progress in research on the brain and its diseases, and I appreciate the opportunity to share with you some of the important advances of the last year. There is a growing awareness of the importance of diseases of the brain



in our society. In part this arises because our population is aging, and diseases of the brain become more prevalent as one gets older. In part it is also due to the growing awareness of the importance of the nervous system for many problems that have not traditionally been considered as biologically based diseases, conditions such as autism or addiction or Tourette's syndrome. We share responsibility for brain research with a number of other Institutes and Centers at NIH, and we cooperate with them in areas of mutual research interest, including pain, sleep disorders, and neurological aspects of AIDS. Our own Institute has responsibility for more than 600 neurological disorders, ranging from those well-known, such as stroke, Parkinson's disease and epilepsy, affecting millions of Americans, to those less common, such as Batten disease, Friedreich's ataxia and ataxia-telangiectasia, that may affect a only few hundred Americans, but are nevertheless devastating to the patients and their families.

These are exciting times in research on neurological disease, as we stand on the threshold of an era in which the treatment of brain disease will become not just a promise, but a reality. In the past, we have had few treatments to offer patients with brain disease. When I was in medical school and became interested in neurological disease, I was told by my advisors that if I was interested in the intellectual challenge of diagnosis, neurology was a wonderful specialty, but if I wanted to make patients well, I should look for something else. Fortunately, that distressing situation is about to change. As we make progress in understanding the mechanisms at work in brain disease, as we identify genes that cause or predispose to brain disease, as we understand more about how the normal brain works, we are better able to devise treatments to prevent, slow or stop the disease process. Today, I want to tell you about our progress in three important disease areas: stroke, Parkinson's disease and spinal cord injury.

#### STROKE

Stroke is a major health problem in the United States; 500,000 Americans have a stroke each year; of these approximately 150,000 die. Those who survive are often left with major disability, at great emotional and financial cost to their families and to our society. Last year at this time I reported that NINDS, working with leading investigators across the country, with the private sector, and with the patient community, had organized a clinical trial showing for the first time that prompt administration of a clot-buster to those with the most common form of stroke gives a 30-percent increase in the chance for full recovery. This finding heralds a new era in stroke medicine, by showing that acute treatment can be effective.

Widespread use of the new treatment will not follow automatically, however, because to be effective, therapy must be delivered within three hours after symptoms first appear. To insure such prompt treatment requires that physicians, patients and their families be educated, and that paramedics and hospital personnel be organized to give urgent care. Our clinical trial provided a model for this change by showing that a rapid response could be organized in a variety of health care and emergency settings. To help bring about the change, NINDS convened a major symposium involving doctors, nurses, paramedics, and patient representatives, to provide guidance for health care providers implementing acute stroke therapy. We will continue to work with patient and professional organizations to publicize the results of the symposium, helping public and health care professionals organize acute stroke treatment in a variety of settings.

#### PARKINSON'S DISEASE

Parkinson's disease (PD), which usually strikes in late middle age and affects more than a half million Americans, impairs control of movement, progressing from symptoms such as tremor and muscular rigidity to total disability and death. Parkinson's disease, like Alzheimer's disease, amyotrophic lateral sclerosis (ALS), and Huntington's disease, is a neurodegenerative disease with an unknown cause.

—In 1995 NINDS and three other institutes sponsored a Parkinson's Disease Research Planning Workshop to identify new directions of research. A major conclusion of the Workshop was that PD likely has a large genetic component. In response, NINDS initiated a collaboration with the National Human Genome Research Institute and extramural researchers which quickly showed that in a single large family PD was caused by an alteration in a gene on chromosome 4. This discovery was published in last November's issue of the journal, *Science*. Current investigations are aimed at identifying the gene and determining whether genetic alterations would benefit patients. Most importantly, identification of the genes responsible for familial Parkinson's disease may help solve the mystery of what triggers the degenerative processes in both familial and non-

familial Parkinson's disease and provides the tools for testing new treatments. As a result of the 1995 Workshop, NINDS also issued a program announcement calling for applications on the mechanisms of cell death and injury in neurodegenerative disorders including PD, jointly sponsored by the National Institute on Aging, the National Institute of Environmental Health Sciences, and the National Institute of Mental Health.

- Clinical trials are underway to evaluate a surgical technique called pallidotomy to treat PD. Other trials are investigating the use of nervous system tissue implanted into the brain to halt or delay the process of degeneration, and to evaluate improved drug therapy for people with advanced PD.
- Trophic, or nurturing, factors are important for the survival of neurons in the growing brain and are essential for a healthy nervous system in adults. Promising results using trophic factors as therapies for PD have now been extended to primate models. Further research is required to overcome obstacles to human administration.

#### SPINAL CORD INJURY

One reason trauma to the central nervous system has such severe consequences is that neurons in the brain and spinal cord fail to regenerate after damage. Now we know they make unsuccessful attempts to regenerate, and in some circumstances can be coaxed to regrow. In 1996, NINDS with other NIH components sponsored a major workshop to foster new ideas and collaborations. Following that meeting, NINDS issued a program announcement to encourage research in several areas with potential for success:

- Neuroprosthetic devices connect with the nervous system via electrodes to stimulate muscles or provide sensory input. For example, a neural prosthesis developed with NINDS support and recently recommended for approval by an FDA advisory panel restores significant hand function to quadriplegics. Realistic future targets include a splint-free system to allow a paraplegic person to rise, stand, and sit again without assistance, and technologies to control muscles using direct brain signals.
- High dose methylprednisolone, the first therapy to improve the outcome of spinal cord injury, is now regularly used in emergency rooms. The effects of longer methyl-prednisolone treatment and of a new class of cortico-steroid drugs are now being studied.
- Efforts to repair damaged spinal cords in animals are continuing, using grafts, nerve bridges, cell implants, cell survival factors, antibodies, and genetic engineering. An NINDS grantee in Sweden has been able to use nerve grafts successfully in animals to bridge gaps in injured spinal cords. The potential use of newly-discovered neural progenitor cells, nerve cells that may have the capacity to replace cells lost because of trauma, is also under investigation.

#### DISEASES OF CHILDHOOD

More than a third of all genetic disorders affect the nervous system, and hundreds affect infants and children. In the past several years, research has rapidly progressed in identifying genes for a number of brain disorders. Approximately 50 genes have been identified. Finding the defective gene that causes a disease is only a beginning towards developing a therapy, but it allows scientists to develop diagnostic tests, create animal models, learn how the gene and its protein function to promote health or disease, and pursue a reasoned strategy towards counteracting the defect. Examples of progress in understanding neurogenetic disorders of infancy and childhood include:

- In neurofibromatosis 1, a common hereditary disorder of the nervous system, tumors, called neurofibromas, develop along nerves. Most of these tumors are benign but some become malignant. A defective NF1 gene results in the disease, and the normal gene is thought to be a tumor suppressor. This is an important clue to tumor formation in NF and perhaps will help predict which tumors will progress to malignancy, a valuable tool for planning surgery or other treatments.
- Recently scientists discovered that a defect in a gene for a previously unknown protein causes Friedreich's ataxia, a neurodegenerative disease of childhood. This should lead to a test for screening carriers of the gene and also to effective treatments.
- Turner syndrome, a genetic disorder of the X chromosome causing a lack of sexual development and a variety of cognitive and motor deficiencies, occurs in about 1 of every 3000 live-born females. Ongoing clinical trials are examining the effects of estrogen and androgen on cognition and social development. Be-

sides providing information about the effectiveness of hormone replacement therapies for girls with Turner syndrome, these studies present a unique opportunity to study the effects of hormones on brain development and function, with implications for children's and women's health.

Last year we reported exciting evidence that the administration of magnesium sulfate to mothers at risk for premature delivery was associated with a reduced risk of cerebral palsy in their infants. Now, NINDS is collaborating with the National Institute of Child Health and Human Development on a prospective clinical trial designed to validate this finding. In another study published in 1996, NINDS-funded researchers linked low levels of the hormone thyroxin in premature infants to cerebral palsy, suggesting another avenue for preventing this disabling illness.

#### FUTURE RESEARCH

Despite the astonishing progress of neuroscience, there is much we do not understand about the brain. Continued support of fundamental neuroscience research will undoubtedly yield important insights. Progress in molecular biology, genetics, imaging, and other areas has accelerated the flow of knowledge between basic and clinical neuroscience. NINDS is taking steps to enhance the Institute's ability to respond to emerging clinical research opportunities. While relying primarily on investigator-initiated ideas and peer review to ensure the best quality science, the Institute uses other important tools for stimulating research. In fiscal year 1996 NINDS solicited new research proposals from extramural investigators in the genetics of Parkinson's disease, mechanisms of cell death and injury in neurodegenerative disorders, Batten disease, immune system mediated diseases, central nervous system injury, and the effect of HIV in the brain. NINDS additionally organizes and funds workshops either directly, as in the case of recent workshops on Parkinson's disease and spinal cord injury, or through grants to investigators or organizations. The Institute will continue to take appropriate active steps to stimulate submission of research ideas in areas identified as high priority and to participate in the NIH special emphasis areas: Biology of Brain Disorders, Preventive Strategies, Therapeutics/Drug Development, and Genetics of Medicine.

Mr. Chairman, the fiscal year 1998 budget request for this Institute is \$722,712,000. I would be pleased to answer any questions you might have.

#### SUMMARY STATEMENT OF DR. WILLIAM PAUL

Senator SPECTER. Dr. Paul, Office of AIDS Research, what is your budget for last year and what do you project for next year?

Dr. PAUL. Mr. Chairman, our budget for this fiscal year is \$1.501 billion and the request for fiscal year 1998 is \$1.54 billion, an increase of approximately \$39 million.

Senator SPECTER. What could you accomplish with a doubling of your budget, Dr. Paul?

Dr. PAUL. As you probably know, Mr. Chairman, we have recently conducted an extensive review of our program and attempted to identify those areas of greatest need and greatest scientific promise. That group's advice and our own knowledge of the area as well, strongly pointed to the need to make major investments in efforts to prevent transmission of HIV by two main mechanisms: the development of a preventive vaccine, which is currently receiving the greatest emphasis and, second, the implementation and development of other techniques to allow people to avoid HIV infection.

Senator SPECTER. A preventive vaccine?

Dr. PAUL. We certainly regard a preventive vaccine as—

Senator SPECTER. Whom would that be administered to?

Dr. PAUL. Initially, the target population would be very much dependent on the nature of the actual vaccine that is developed. A vaccine of great power, with very limited side effect, I think would probably be targeted to a very wide population. By contrast, the

vaccine that might have some risk associated with it would obviously be targeted to those individuals of greatest risk of disease.

Senator SPECTER. How far along are you on developing such a vaccine?

Dr. PAUL. Well, the NIH has made vaccine development an important priority for some time, but within the last 2 years the rate of our increase of investment has been very substantial. As you know, the President has challenged us to accomplish this within a decade. And my colleagues and I at NIH and throughout the Nation are working very hard to try to meet that challenge. It is a very formidable challenge, but we do hope we can report a degree of success within that period of time.

Senator SPECTER. Is it not possible to answer the question, how far along you are?

Dr. PAUL. Yes; we have several vaccine candidates, one of which is in phase 2 trials at this time. That candidate is the so-called prime boost mechanism. We will know the results of the phase 2 trials approximately within a year. If those trials are promising—and I must argue we cannot determine that in advance—we would then move to efficacy trials that would begin, I would say, within a period of about 18 months, and would take approximately 2 to 3 years to complete.

Senator SPECTER. Dr. Paul, what response would you recommend that we give when people say that the allocation of Federal funds for AIDS is very disproportionate to the number of people involved, contrasted with other major ailments?

Dr. PAUL. This is a question of course which I understand that people are quite concerned about. Our position on this, and I think the Nation's position, is that we are dealing here with a new infectious agent, an agent which has only appeared in large human populations within the past 20 years. We are facing an entirely different situation than we do for measles, for influenza, for other viruses.

This virus has already become the leading cause of death of young adults in the United States, and will shortly be the leading infectious cause of death in the world. What we are particularly concerned about, however, is as this virus epidemic moves throughout the world, the virus will continue to evolve. And the form it will take is still unpredictable.

While we have an enormous epidemic today and one we need to meet immediately, we have the concern that we may face a more serious problem in the future. So that unless we use this window of opportunity that we have now, we may discover that our children and grandchildren are faced with an even more severe challenge.

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So it is our position that HIV and AIDS constitutes an unusual problem, one that is not easily quantifiable based simply on the number of infected individuals in the United States today, but one whose threat to us is based on its potential for damage. It seems to us we need to respond and meet that potential today.

Senator SPECTER. Thank you very much.

[The statement follows:]

## PREPARED STATEMENT OF DR. WILLIAM E. PAUL

Mr. Chairman, this has been a year of progress and promise in AIDS research, a year clearly demonstrating the dividends made possible by our national investment in biomedical science. So striking was this progress that Science Magazine named the "New Weapons Against HIV" as the breakthrough of the year, and Time Magazine named Dr. David Ho, an NIH-supported investigator and a member of our OAR Advisory Council, as its Man of the Year, the first time a scientist has been so honored since 1960.

After many years of slow and incremental advances against a relentless epidemic, we can take collective pride in the dramatic changes that have occurred just since our hearings here last year. Protease inhibitors, a new class of drugs, used in combination "cocktails" with other antiretroviral therapies, have been shown to dramatically diminish the amount of HIV in the blood of an infected individual. Receptors for molecules called chemokines have been identified as critical co-factors for HIV infection. Individuals who have defects in one set of these receptors are protected from HIV-infection despite exposure to the virus. These findings provide an entirely new approach for the development of anti-HIV therapies.

These critical advances have brought a sense of hope and renewed vigor to the AIDS research community and to our patients. But it is essential to point out that the news, while good, cannot lead to complacency. The covers of some magazines may fantasize about the "end of AIDS," but, Mr. Chairman, the end of this pandemic is nowhere in sight.

The new drugs, while promising, are not a panacea. We do not know how long the benefits of the drugs will last, whether the virus will become resistant to the drugs, or whether such drug-resistant strains of the virus could be transmitted. It is far from clear that immune function of treated individuals will be restored without additional intervention. There are many people for whom the new drug regimens have not been effective or for whom the side-effects are not tolerable. Access to and affordability of the therapies is also problematic. Although the virus has been brought to undetectable levels in the blood and in some lymphoid tissues, it is still not known whether there are other sanctuaries where the virus may reside in the body.

The sobering fact is that we have made virtually no progress against the devastating spread of the epidemic around the globe. AIDS is the number one cause of death among young adults in the United States. Rates of increases in AIDS cases in the U.S. are greatest for women, adolescents, persons infected through heterosexual contact, minorities, and injecting drug users. More than 29 million men, women, and children around the world have been infected with HIV; over 3 million of those infections occurred in just the past year. More than 90 percent of these infections occur in the poorest parts of the world, in countries without the resources or the health care systems to benefit from our successes in the development of anti-HIV drugs. AIDS has brought about a significant decline in overall life expectancy in many African countries, threatening the economies of these already poor nations and robbing them of their workforce. A safe and effective AIDS vaccine is an urgent global public health imperative. Without a vaccine, AIDS will soon overtake tuberculosis as the leading infectious cause of death in the world. Thus, we can take no solace from our advances nor can we diminish our urgent search for better therapies and for a protective vaccine.

Three years ago, the prospects in AIDS research appeared dim. The International AIDS Conference in Berlin left many scientists and patients dismayed. After the initial burst of knowledge about the virus and development of the original reverse transcriptase inhibitors, progress had slowed, and the pipeline of new potential drugs or vaccines seemed empty. The OAR convened a small group of eminent scientists, including a number of Nobel Laureates. We asked them to help us identify the critical gaps in our knowledge about AIDS and to suggest what steps could be taken to open new scientific opportunities and move the science forward.

That meeting was held at the Stone House of the Fogarty International Center, and has proven to be a pivotal moment for AIDS research. At the meeting, the late Dr. Bernard Fields stated his firm conviction that further advances against the virus would require the NIH to shift its priorities and its resources to bring about what he termed a "rededication to fundamental science." Without this basic knowledge, the pipeline would remain empty.

The OAR examined all NIH AIDS research funding to determine the best way to bring about this rededication to fundamental science. In every budget since that year, we have increased the proportion of funding for basic research. The OAR has placed greater emphasis on investigator-initiated science, increasing the number of

research grants by 50 percent between fiscal year 1994 and this fiscal year 1998 request. This has encouraged innovation from a wider group of investigators.

Another important initiative emerged from the "Stone House" meeting. Dr. Phillip Sharp, a Nobel Prize winner, presented the idea that in order to plot a course for the future, we needed to understand all of the facets of the existing AIDS research program, which by then already had spanned all of the NIH institutes and centers. He suggested that a critical evaluation of the entire program was necessary, to assure that the most promising areas of science are being supported, that the critical scientific questions are being addressed, and that the most effective use is being made of federal AIDS research resources.

As you know, that discussion led to the evaluation of the entire AIDS research program, a review of unprecedented scope and breadth, lead by Dr. Arnold Levine of Princeton University. The report of that review, commonly known as the Levine Report, has provided guidance to the NIH for strengthening our AIDS research program to move more effectively and efficiently toward our goal of preventing and curing AIDS. This report is not sitting on a shelf gathering dust. The recommendations helped frame the OAR's final distribution of the fiscal year 1997 appropriation, and are reflected in our research plan and budget request for fiscal year 1998. An implementation process is underway. I would like to update you on some of the changes that have already occurred.

The highest recommendation of the Levine Report confirmed what OAR had already set in place, that is, the need to increase investigator-initiated research. The report also recognized that only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS. Thus, the next priority of the reviewers was the need to restructure and reinvigorate the AIDS vaccine program, with leadership and guidance from eminent non-government scientists.

We have taken two important steps to carry out this critical recommendation. Nobel Laureate Dr. David Baltimore has been recruited to lead this effort, and he has gathered a group of outstanding scientists to serve with him. Their charge is to stimulate the integration of basic research advances in immunology and vaccine science to energize the development of new HIV vaccine strategies. To facilitate this effort, OAR has made a major financial investment in AIDS vaccine research. The fiscal year 1998 budget request represents a 33.6-percent increase for vaccine research over fiscal year 1996, a sign of our commitment to this effort. The President also highlighted the importance of this effort in his State of the Union address.

Some have argued that a protective anti-HIV vaccine is simply not possible because of the variability among the viruses that are being transmitted in any given population, because of the high mutation rate of the virus, and because the principal cells that are infected are themselves essential to a highly effective immune response. But, as an immunologist, I believe there is persuasive evidence that a protective immune response can be induced and that an effective vaccine is possible. I also believe that the government has a unique role and obligation to support the basic research needed for the development of a successful vaccine.

The Levine Report stresses the need for greater emphasis on prevention of HIV infection. In addition to a stronger vaccine research effort, the report urged NIH to develop a Prevention Science Agenda combining biomedical interventions—such as microbicides, female-controlled barriers, methods to prevent mother-to-child transmission, and STD prevention and treatment—with behavioral interventions. OAR convened a group of experts, chaired by Dr. James Curran of Emory University, to assist us in identifying the most promising areas for additional investment. OAR will provide additional resources to the institutes to fund proposals devoted to HIV prevention.

With these actions, OAR believes that the necessary balance has been established between research to develop treatments for those who are infected and to develop vaccines and other prevention methods for those who are at risk. This balance is a delicate one, and may shift as science progresses.

Thus, the fiscal year 1998 budget request for AIDS research has been crafted to reflect the recommendations of the Levine Report and the broad consensus on the current scientific opportunities. The scientific priorities that have framed this request are:

- A rededication to fundamental science, emphasizing investigator-initiated research;
- A stronger vaccine research and development effort with the goal of bringing products to clinical trials as soon as warranted;
- An augmentation of research efforts to better understand the human immune system;
- An emphasis on prevention science research, including enhanced studies of risk-taking behavior and the development of strategies to avert infection; and

—A vigorous therapeutic research program, emphasizing both drug discovery and an efficient clinical trials system, with additional emphasis on increased participation of women and minorities.

Mr. Chairman, we are reaping the rewards of years of work by dedicated scientists. Those who met at the Stone House set a new course for AIDS research, building a stronger foundation of basic science and relying on the ingenuity and creativity of investigators. Following that course, we have gained new knowledge of the basic biology of HIV and developed new targets for therapies and vaccine development. But we cannot diminish our efforts, for we are just beginning to unlock the mysteries of this disease. The science of AIDS is moving forward and opening whole new areas of research that can advance the treatment and prevention not only of AIDS, but of a vast number of other diseases as well.

The Office of AIDS Research requests a consolidated appropriation of \$1,540,765,000 for NIH AIDS research through the OAR. The budget authorities provided to the Office of AIDS Research, allowing us to make resources available where the greatest opportunities lie, are even more critical today as the scientific opportunities are constantly changing. We are grateful to the Committee for your continued support for AIDS research and for providing us the flexibility critical to meeting these enormous scientific challenges. I would be pleased to answer any questions.

#### SUMMARY STATEMENT OF DR. FRANCIS COLLINS

Senator SPECTER. Dr. Collins, Director, National Human Genome Research Institute, what is the down side, if any, to the proposals to prevent cloning of humans? To what extent would that impact on your general research?

Dr. COLLINS. I suspect Dr. Varmus may want to comment as well, but I will start out. I think statements that were made this week with the release of the National Bioethics Advisory Commission's recommendations were quite careful to point out that the cloning of genes and of cells is a very different thing than the cloning of a human being. The human genome project is very dependent on the cloning of genes. In fact, the project is intended to determine the entire genetic blueprint of human beings by the year 2005. And I am glad to say we are running ahead of that schedule at the present time and have now begun to ramp up seriously into the sequencing part.

Were this anxiety, which I understand, about human cloning to spill over into an anxiety about that same word, "cloning," being applied to genes, it would be an enormous tragedy for America, for the public, for the biotechnology sector, for the NIH, for all of us. So we have to be quite careful about what it is we are discussing.

When it comes to the cloning of genes or the cloning of cells—that is, a copying of a gene or a cell that is growing in a laboratory—the ethical issues have been dealt with quite successfully and broadly over the course of the last several decades. And the arrival of Dolly on the scene should not cause us to become anxious about those biotechnology aspects of recombinant DNA that involve cloning of genes.

#### PREPARED STATEMENT

The short answer to your question is that human cloning, while it is a fascinating topic, is really quite different than what the human genome project is all about.

[The statement follows:]

## PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman, it is truly an exciting opportunity to testify before you today, for the first time, as director of the NIH's newest research Institute, the National Human Genome Research Institute (NHGRI). On January 14, after consultation with you and other Congressional leaders, Secretary Shalala signed documents that gave the National Center for Human Genome Research (NCHGR) a new name and new status. We are proud the NCHGR has been recognized for its successful leadership of the Human Genome Project, the accomplishments of its cutting-edge intramural laboratories, and its active policy research programs. As an Institute, NHGRI looks ahead to completing the Human Genome Project and to playing a leading role in 21st-century health science based on understanding the instructions encoded in our DNA.

As in the past, we continue to make remarkable strides toward our goals, and in the process, spin off new ways to approach the study of genetic disease. The genetic maps are complete, the physical maps nearly so, and both are in wide use by the scientific community. The slowest part of a disease-gene hunt nowadays is sorting through all the genes in the target region on a chromosome and determining which one is responsible for the disease. To help solve this, scientists at NHGRI-supported research centers, the National Library of Medicine, and genome centers in England and France, created an on-line map that pinpoints the locations of over 16,000 human genes—about one-fifth of the estimated 80,000 total. With it, the number of mapped human genes has tripled in less than two years; that number will likely double again over the coming year. Taking full advantage of cutting-edge information technology, the electronic map is a mouse click away from on-line references in the medical and research literature, which will aid scientists in linking information about a likely disease gene to its role in cell function.

Human genome maps and technologies are now making the difficult “needle in a haystack” search for genes much easier. As a result, the number of disease genes isolated nearly doubles every year. In 1996, 21 disease genes were isolated using genome maps—almost twice as many as the year before and nearly five times the number isolated the year the genome project began. Among them are genes that contribute significantly to human diseases, including polycystic kidney disease, an adult form of diabetes, and hereditary hemochromatosis (HH).

HH is a common disorder of iron metabolism, affecting about 1 in 400 individuals of Northern European descent. It occurs when both parents contribute a mutated HH gene to their child. About 1 in 10 individuals carries a single mutated HH gene. The major symptoms of HH—liver cirrhosis, heart deterioration, and other organ failures—don't occur until mid-life, and untreated, the disease causes early death. But treatment by simple blood letting allows people with HH to live a normal lifespan. Because HH is so common and easily treatable, it provides an excellent example for offering genetic testing on a large scale to identify people at risk for a disease and enabling them to avoid becoming ill. NHGRI and the Centers for Disease Control and Prevention are planning a workshop this spring to examine the scientific, ethical, social, and medical implications of widespread testing for HH.

The ultimate map of the human genome will spell out all 3 billion letters that make up human DNA. Ongoing projects to sequence the DNA of non-human organisms have provided an opportunity for scientists to practice sequencing genomes much smaller than that of the human, but bigger than anything sequenced before. This past year, an international consortium of scientists finished spelling out the entire genetic code of a species of yeast valuable to biologists and commonly used by bakers and brewers. At 12,057,500 bases, the yeast genome is the largest to be completely deciphered so far and is the most advanced organism yet to be sequenced. Having the entire yeast DNA sequence now paves the way for scientists to study how all the genes in a complex cell similar to human cells function as a system.

With progress in sequencing moving so rapidly, NHGRI has launched pilot studies at six U.S. research centers to explore the feasibility of large-scale sequencing of human DNA—the most technologically challenging phase of the Human Genome Project. This initiative is projected to produce the sequence of about 3 percent of human DNA in the first two years and will help to streamline and cut the cost of DNA sequencing in order to finish the entire human genome by the year 2005.

Using current mapping technology to understand the inheritance of single-gene disorders—the so-called “Mendelian” disorders—is usually relatively straightforward. Current genetic maps are now dense enough to place a disease gene within reach in a matter of weeks. This past year, these maps led NHGRI scientists to a gene associated with Parkinson's disease in a large Italian-American family and to a gene associated with prostate cancer in another study of 91 American and Swed-



ish families. Although these genes have not yet been isolated, “linking” them to specific chromosomes gives scientists the first direct evidence that genes play an important role in these disorders.

But most diseases of modern life—cancer, heart disease, diabetes, arthritis, and a host of neuro-psychiatric disorders—seem to result from the activities of several genes and the interplay between a human body and its environment. NHGRI is supporting several initiatives to make the complex genetic and environmental components of these disorders easier to decipher and understand, and thereby easier to prevent or treat.

In a creative government-university partnership, eight components of the NIH, led by NHGRI, and the Johns Hopkins University School of Medicine, have established a new research center to facilitate analysis of the complex genetics of these common disorders. The new Center for Inherited Disease Research (CIDR) is located on the Johns Hopkins Bayview Medical Center in Baltimore and is expected to be fully operational this spring. Under full capacity, CIDR researchers expect to study six to nine complex disorders per year.

In other studies of complex disorders, NHGRI and the NIH Office of Research on Minority Health are collaborating with scientists at Howard University to study why people of African descent seem to develop adult-onset diabetes and prostate cancer more frequently than do many other population groups. Understanding the genetic basis of an increased risk for these diseases could lead to better strategies to prevent them from causing serious health problems.

Tracking down all the genetic components of a complex disorder requires analysis of the entire genomes of hundreds and perhaps thousands of individuals. For this to be possible, genome maps must be easily adapted to highly automated strategies. In the coming years, NHGRI will begin improvements on the existing maps, which have been so useful in finding single-gene disorders, to increase their usefulness in ferreting out the multiple genes that contribute to so many of today’s common disorders.

The impact on the future of biology of knowing the order of all 3 billion human DNA bases has been compared to Mendeleev’s establishment of the Periodic Table of the Elements in the 19th century and the advances in chemistry that followed. The complete DNA sequence of the human—the biologic periodic table—will make it possible to define a unique ‘signature’ for every gene. Rapidly evolving technologies, comparable to those used in the semi-conductor industry, will allow scientists to build detectors that trace hundreds or thousands of these gene signatures in a single experiment. Scientists will use the powerful new tools to reveal the secrets of disease susceptibility, create broad new opportunities for preventive medicine, and provide unprecedented information about the origin and migration of human populations.

One example of this kind of experiment was recently carried out by NHGRI-supported scientists who developed an automated method for determining differences as small as one base pair in comparisons of the entire 16,000 base-pair mitochondrial genome among 10 human volunteers. The scaled-up technique could potentially be used to analyze the entire 3 billion base-pair nuclear genome of the human in a single experiment. NHGRI scientists are using similar technologies to identify the broad range of genes possibly activated during cancer development.

While scientists are discerning the secrets once buried in the human genome, concerns about how the information will be used outside the laboratory call for new public policies about privacy and discrimination. An NHGRI-supported study showed that individuals from families with genetic disorders experience frequent discrimination in health insurance. Some do not even apply because they believe they will be turned down because of their condition.

NHGRI has established productive partnerships among consumers, scientists, and policy makers to help reduce the possibility that genetic information will be used to harm an individual or family members. The Ethical, Legal, and Social Implications (ELSI) Working Group in collaboration with the National Action Plan on Breast Cancer (NAPBC), has created a successful model for policy development through a series of workshops on genetics issues. The first of these resulted in recommendations on genetic information and health insurance that were later incorporated in part into the Health Insurance Portability and Accountability Act of 1996. While it is a laudable first step, the law is not the final solution since it still allows insurers to set exorbitant premium rates for holders of individual policies, which for many consumers amounts to denial of coverage. A second ELSI-NAPBC workshop developed recommendations relating to genetic discrimination in employment. The ELSI-NAPBC team is also interested in addressing privacy issues.

The Task Force on Genetic Testing (TFGT) of the ELSI Working Group has been examining the strengths and weaknesses of current practices and policies for devel-

opment and delivery of safe and effective genetic tests in the United States and the quality of laboratories providing the tests. Last March, the TFGT released a set of interim principles for public comment. The final principles and recommendations of the task force have just been published in the Federal Register for public comment and will be reported to the Working Group this spring.

In another ELSI project on genetic testing, NHGRI is co-sponsoring a consensus development conference this spring to look at issues related to testing for cystic fibrosis mutations and to determine whether such testing should be a standard part of medical care.

The broad range and critical importance of ELSI issues prompted NHGRI last spring to establish an outside group to evaluate the role of the ELSI Working Group in these functions. To provide the best attention to these important issues, the evaluation committee recommended dividing the Working Group's responsibilities among different committees and at various levels within the government, including a newly established ELSI Research Evaluation Committee to oversee the ELSI grant portfolios at NHGRI and DOE, an NIH-wide process to coordinate the ELSI activities of the various institutes engaged in genetics research, and a federally chartered committee at the DHHS level to formulate public policy resulting from advances in genetics.

As the demand for genetic tests moves from the medical genetics specialty into general practice, it is imperative that health care professionals across disciplines understand the technology and its potential benefits and risks. NHGRI has played a leading role, along with the American Medical Association and the American Nurses Association, in forming the National Coalition for Health Care Professional Education in Genetics. This Coalition brings together leaders in medical professional organizations, consumer groups, government agencies, and industry to develop and implement a national genetics education program for health care professionals. An organizational meeting was held last July, and the first meeting of the full Coalition will be held this spring.

Mr. Chairman, I am rewarded and astounded by the strides human genome research has made and the unprecedented opportunities it offers biomedical science to improve the lives of people in this country and around the world. The President's request for fiscal year 1998 for the National Human Genome Research Institute is \$202,197,000. I am happy to answer your questions.

#### ISSUES FOR THE NATIONAL CANCER INSTITUTE

Senator SPECTER. OK. Thank you very much.

We are not able to go through each one of the Institutes, but I wanted to proceed with as many as we could cover here. We are going to have a hearing on Thursday, June 19, involving issues for the National Cancer Institute and the recent study completed by Dr. John Bailar, so we will take up NCI at that time.

Dr. Varmus, what I would like to receive from everybody who is here, is a short statement, beginning with last year's budget, through next year's requested budget, summarizing what has been accomplished; then include what could be accomplished with a doubling of the budget. My colleague, Senator Tom Harkin, refers to all the doors which are not open; please include an estimate, as to what would be present if those doors could be opened. And as I stated earlier, specify what the cost-effectiveness would be to the extent that can be articulated.

I well understand the difficulty, perhaps impossibility, of precision along this line. But to the extent that it could be done, it would be very helpful.

Two years ago, when the House came in with the reduction of the NIH budget of \$900 million, we convened a hearing with everybody present and talked very much about the same line. We were able to restore that money on the Senate side, as well as increase it. We have to make our case. This is the toughest of times. It is the best of times for what you can accomplish, but the toughest of

times for what funds are available. So I would like you to respond to those questions as best as possible, so that when we put them in the Congressional Record, people will read them and be inspired by them.

[The information follows:]

#### NIH RECENT ACCOMPLISHMENTS AND FUTURE DIRECTIONS

##### *New vaccines*

For many years brain damage caused by Hemophilus influenza type B (Hib), a bacterium with a polysaccharide (sugar) outer coat, was the leading cause of acquired mental retardation in the U.S. Since the incorporation of an NIH-developed vaccine into the routine required childhood immunization series, the number of cases of Hib meningitis has fallen from about 20,000 a year to fewer than 100. The disease is on the verge of elimination.

Scientists are using the novel polysaccharide concept to develop a new generation of vaccines against other infectious diseases, such as typhoid fever, whooping cough, dysentery, and pneumonia.

##### *Biological link between smoking and lung cancer*

Scientists have unveiled how a chemical in cigarette smoke—long known to be a risk factor for lung cancer—can cause the disease. This work provides a definitive link between smoking and lung cancer.

The technology scientists used to make this discovery is revealing how cancer begins and what mechanisms future cancer treatment must target.

##### *Disability rate down in the elderly population*

Epidemiologic studies have revealed that disability among elderly people decreased at a striking rate in the 1980s. Research has shown that a small number of conditions—including stroke, hip fracture, pneumonia—lead to many of the hospitalizations that precede disability.

Continued research can define how to further reduce disability rates, even in the oldest old, to improve quality of life and reduce national health care costs as the elderly population increases.

##### *Reducing stroke and heart attack*

Treatment with a low-dose diuretic to reduce high systolic blood pressure cuts strokes and heart attacks by a third in older patients. This finding is especially important for older patients with diabetes who have a higher risk of cardiovascular disease and therefore benefit more from the treatment. Diabetes affects an estimated three to five percent or more of the U.S. population.

Additional research will investigate the use of other antihypertensive drugs to reduce stroke and heart attack rates among people with diabetes.

##### *Hemophilia treatment*

Advances in gene therapy research led to the recent development of recombinant factor IX, the first treatment for hemophilia B that is totally free of blood products, thus creating a minimal risk of infection. The clotting factor has been shown to be effective in clinical trials not only for bleeding episodes, but also for use in surgery.

Genetic engineering techniques are being used to create new “combination” clotting factors that have high activity and can be given in low doses, thereby reducing today’s high treatment costs for hemophilia.

##### *Treatment for drug dependence*

Heroin use remains a serious problem in the U.S. The number of heroin-related visits to hospital emergency departments rose from 38,100 in 1988 to 63,000 in 1993, an increase of 65 percent. A recent study of a treatment known as LAAM, just approved in 1993, has shown that heroin-dependent individuals can reduce their use of the opiate by up to 90 percent. Those receiving high doses of LAAM were able to achieve full abstinence over the study period (30 days).

This NIH-supported study shows that heroin addiction can be treated effectively. It is an important step in the ongoing efforts to develop effective medications that will enhance behavioral and psychotherapies used in drug treatment programs.

##### *Mouse model for diabetes developed*

Some degree of insulin resistance is thought to affect about 25 percent of the population, predisposing such individuals to development of overt diabetes later in life. Adult-onset diabetes, known as non-insulin dependent diabetes mellitus (NIDDM),

affects about five percent or more of this country's population. Studies suggest that the disease may be due to multiple genetic defects. NIH researchers recently developed a mouse model that will allow them to study the interaction of a string of such defects.

Because there is no cure for the disease, there is an urgent need for such animal models, both to investigate the cause of the disease and to develop new therapies. Similar animal models may apply to other common disorders such as hypertension and cancer.

#### *Vaccine development*

Rotaviruses cause 35 to 50 percent of the world's severe diarrhea cases in infants and young children, resulting in more than 800,000 deaths annually, mostly due to dehydration. In the U.S., more than 1 million cases of rotaviral diarrhea and 50,000 hospitalizations occur each year. NIH scientists designed a vaccine to prevent the disease that has been found safe, and effective 80 to 90 percent of the time.

The vaccine has been submitted to the FDA for approval, and once licensed, will have a major impact on the health of the world's children.

#### *Spinal cord injury*

Some 10,000 Americans experience spinal cord injuries each year—more than two-thirds of them under age 30. NIH-supported clinical trials demonstrated the effectiveness of methylprednisolone, the first effective treatment for acute injury. Giving the drug over a 48-hour period results in improved function in patients with spinal cord injury if treatment begins within three to eight hours following injury, helping them to recover a substantial degree of independence.

NIH expects that a new initiative to encourage research on spinal cord injury will result in similar findings in other important areas of spinal injury research.

#### *Reducing disability after stroke*

Some 500,000 Americans suffer a stroke each year. It is the third leading cause of death (after heart disease and cancer), killing about 150,000 Americans each year; 80 percent of these strokes result from blood clots that reduce blood flow to the brain. NIH-supported clinical trials have shown that treatment with a clot-dissolving drug known as t-PA in the three hours following a stroke can increase by 30 percent the likelihood that a patient will recover with little or no disability.

NIH is leading a public education campaign in an effort to make more medical professionals aware of the kind of care that will increase their patients' chances of leaving the hospital without disability.

#### *AIDS medications*

Decades of basic research into proteases—crucial enzymes made by cells and viruses, including HIV—led to the development of the powerful new class of anti-HIV medications known as protease inhibitors. These drugs are now widely prescribed as part of combination therapies for HIV-infected people.

NIH recently released a document outlining principles to guide physicians on how to use these drugs in treating HIV patients. Research continues on how best to use existing drugs, as well as on new therapies that may offer advantages over existing drugs.

#### *NIH and private industry*

NIH intramural scientists have negotiated over 270 Cooperative Research and Development Agreements with private organizations to support a wide range of research activities. Research efforts by NIH intramural scientists have resulted in the award of over 550 patents on inventions, with over 700 licenses to develop commercial applications based on them. Products resulting from these patents include a simple, accurate and inexpensive screening test for HIV infection which may also be used to monitor the safety of public blood supplies; two major therapeutics against HIV-infection; and a vaccine for Hepatitis A—commonly spread by food and water contamination.

These are only a few examples of the opportunities that become available when the public and private sectors collaborate.

#### *Sickle cell disease*

Sickle cell disease is the most common serious inherited blood disorder in the U.S., affecting an estimated 80,000 Americans, primarily African-Americans. With NIH support, researchers identified an effective treatment for adults with the disease—hydroxyurea, a relatively inexpensive compound. The drug is effective in relieving the severe pain of sickle cell crises and reducing the number of episodes. The treatment significantly reduces the need for costly blood transfusions and hos-

pitalizations. Another NIH-supported study has demonstrated that bone marrow transplantation in children with sickle cell disease can provide a cure for young patients who have a matched sibling.

These are two important steps in ongoing efforts to find a potential cure for the diseases.

*Gene identified for prostate cancer*

A team of NIH scientists and grantees found the first proof that genes conferring hereditary predisposition to prostate cancer exist. They identified a gene that when mutated may be responsible for at least a third of the cases of prostate cancer in families.

This finding should shed light on how and why prostate cancer develops and suggest ways to prevent and treat it.

*Scientists identify gene for Parkinson's disease*

NIH scientists have found that an abnormal form of a gene that codes for a protein in the brain causes some cases of Parkinson's disease, particularly those that occur before the age of 60.

This discovery will lead to a genetic test for the disease in high-risk families and help researchers find ways to slow or stabilize the disease. Such preventive measures may eventually be useful in other forms of Parkinson's disease.

*New targets for drugs against HIV*

NIH grantees and others have discovered two proteins on the surface of the immune cells that are the targets of HIV, the virus that causes AIDS. These "cofactors" allow the virus to fuse with the cell and infect it. People who have defects in one set of these cofactors don't get infected with HIV even though they are exposed to it.

These cofactors are potential targets for developing either drugs to block the virus from infecting cells or a vaccine to confer resistance against the virus.

*Strokes may make Alzheimer's symptoms worse*

Scientists have found that strokes may play an important role in the presence and severity of symptoms of Alzheimer's disease. In a group of patients who had changes in their brain that are characteristic of Alzheimer's, those who suffered strokes had more dementia and poorer cognitive function than those who didn't.

Prevention or treatment of vascular diseases—like hardening of the arteries due to cholesterol—could delay or diminish the development of symptoms in many patients with Alzheimer's disease.

*Genetic research is paying off*

A team of scientists from NIH, university and commercial laboratories around the world have developed a map that pinpoints 16,000 genes in human DNA—one-fifth the estimated total 80,000. A massive computerized database of the map is available to everyone over the Internet through NIH, providing students and scientists with an online educational tool.

Scientists are now working on creating more detailed maps of the human and other biological systems (i.e., zebra fish and rat) to tackle diseases caused by the interaction of multiple genes.

*Free easy access to MEDLINE*

NIH is now providing all Americans with free access to MEDLINE—the world's most extensive collection of published medical information—over the Internet. Patients and their families, students, doctors and health professionals will all have at their fingertips the most current and credible medical information. This is often the critical link in reaching the right diagnosis, resulting in lives saved, unnecessary treatment avoided, and hospitalization reduced.

Through MEDLINE, NIH is helping to ensure that the results of research benefit all Americans.

*New hope for repairing the brain and spinal cord*

NIH scientists and others have found that stem cells are present in the adult brain and spinal cord. Stem cells are "mother cells" that can divide to form other kinds of cells. For decades, scientists believed that the adult central nervous system could not repair itself, in part because it lacked stem cells. They can be grown in the laboratory and ultimately manipulated and used to replace cells that have been lost to injury or disease.

With additional research, this could provide new hope for people with Parkinson's disease, spinal cord injury and a host of other disorders.

## NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

*Accomplishments*

This year, as the NHLBI reaches its 50th anniversary, Americans can celebrate the great advances in public health made possible through their longstanding investment in biomedical research.

In 1948, a heart attack signaled the end of an active life. One-third of the patients who reached the hospital died within weeks, and survivors still faced a long ordeal. Nowadays, most patients return to normal activities within weeks of a heart attack, and many heart attacks are being prevented through control of risk factors, blood pressure, cholesterol, smoking). In the last 30 years, the national age-adjusted death rate from coronary heart disease has decreased by more than half.

Until recently, many premature infants died within hours of birth from neonatal respiratory distress syndrome. U.S. infant mortality is now at an all-time low due, in great part, to research that has enabled us to treat and prevent this lethal disorder.

Average life expectancy of sickle cell disease patients has more than doubled in the past 25 years, as research has uncovered strategies to prevent the devastating complications of this disease and treat its painful symptoms.

*What could be accomplished in the future with additional funds*

*Stemming the epidemic of heart failure.*—As increasing numbers of Americans survive acute episodes such as heart attacks, heart failure has become our modern epidemic, and research needs in this area are pressing. Tremendous opportunities now existing to explore such approaches as grafting healthy muscle cells onto failing hearts, turning on the ability of heart muscle cells to reproduce themselves as occurs in wound healing, or interrupting the programmed death of heart muscle cells that appears to play a role in this fatal chronic disease.

*Preventing asthma.*—Notwithstanding excellent progress in controlling asthma, the public health burden of this disease is increasing. Intensive modern research efforts have placed us on the threshold of unraveling the genetic basis for asthma and understanding the mechanisms by which environmental exposures render individuals susceptible to asthma or, conversely, protect them from it. Progress in this area will, in turn, open up new approaches for the primary prevention of asthma—a considerable advance over current practice, which is limited to preventing symptoms in patients who have already developed the illness.

*Finding heart disease before it finds you.*—Researchers have recently developed new magnetic resonance imaging (MRI) techniques to visualize the coronary arteries, map blood flow through all major arteries of the circulatory system, and measure heart function. This technology offers enormous potential for safe, inexpensive, accurate diagnosis of disease long before symptoms occur. With the wealth of new information cardiac MRI can provide, we will be in a much stronger position to intervene early to delay, arrest, or even reverse heart disease.

## NATIONAL CANCER INSTITUTE

*Accomplishments*

*Decrease in cancer death rates.*—Overall cancer mortality rates, which had been rising all century, have finally begun to fall. The 1–2 percent drop in age-adjusted mortality rates since 1991 appears to be just a beginning—representing thousands of lives saved per year that would have been lost.

*Improvements in the prevention of cancer.*—Smoking education and cessation programs have helped cut tobacco use, the major cause of lung cancer. About 37 percent of adults smoked cigarettes in 1971 compared with about 25 percent in 1994. NCI is currently testing 24 agents in 78 clinical trials aimed at preventing cancer. The identification of infectious causes of cancer provides another type of prevention opportunity. Based on major breakthroughs at the NCI, a vaccine against human papilloma virus, the major causative agent of cervical cancer, is being developed.

*Improvements in cancer detection and diagnosis.*—Over the past 25 years, remarkable improvements in cancer detection and diagnosis have occurred. These include Computed Tomography (CT), Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI). Today, 65 percent of breast cancers are found as localized disease compared to less than 40 percent of 20 years ago. As a result, 5-year survival rates are over 90 percent for patients with these localized cancers.

*New drugs for cancer treatment.*—In the past year alone, 12 new drugs were approved by the FDA for the treatment of cancer, and were 10 New Drug Applications are anticipated in 1997. In the biotechnology industry, over 40 new agents are in clinical trials for cancer. Notable results of clinical trials over the past year include

the demonstration of a 30-percent reduction in cancer mortality for adjuvant therapy in stage C colon cancer translating into approximately 4,000 lives saved each year, and as these benefits may extend to stage B patients, the benefits may be even greater.

*Improvements in quality of life for cancer survivors.*—There have been critical advances in the quality of life for our 7.5 million cancer survivors. Longer survival time after diagnosis—time to spend with family and community, less destructive and disfiguring surgery, better control of pain and other disabilities, so that people who would have lost their voices can speak, those who would have lost limbs can walk, and many others can keep the function of their bowel and bladder.

*What could be accomplished in the future with additional funds*

*More ideas about cancer prevention, early detection, and treatment could be pursued.*—The NCI is able to fund less than one in four of the grant applications. Pursuing more ideas will speed the reduction in the burden of cancer.

*More access to clinical trials and state-of-the-art cancer care at cancer centers could be provided.*—Only about 2 percent of eligible adult cancer patients are participating in clinical trials for new therapies. This condition slows the progress and keeps promising new drugs waiting in line for testing. The NCI currently supports 55 cancer centers around the Nation. Increasing this number to 75 or more such centers would put more Americans close to a cancer center.

*More ways to prevent cancer could be tested.*—A National Prevention Clinical Trials Program would permit the testing of emerging ideas arising from breakthroughs in the understanding of the causes and development of cancer.

*More cancers could be detected earlier to improve chances of better outcomes.*—It is known that early detection and effective screening can save lives because cancers caught early are more treatable. Even the best screening methods like mammography and PSA (prostate specific antigen) can and must be improved upon. Detection of pre-cancerous conditions would enable the treatment of these pre-cancers.

*More immediate response to breakthroughs in cancer genetics could be possible.*—Most of the genes that are involved in cancer will soon be understood in more detail than ever before. Developing NCI's Cancer Genetics Network would speed the benefits of the genetic revolution in cancer to more and more Americans.

#### NATIONAL INSTITUTE OF DENTAL RESEARCH

##### *Accomplishments*

NIDR has taken the lead to improve the plight of patients with oral, pharyngeal and laryngeal cancers. Over 42,000 Americans are diagnosed with these cancers every year and the death toll is approximately 9,000 people annually. Those who survive are often disfigured and have suffered the consequences of chemo- or radiation-therapies which can seriously impair such vital functions as speaking, tasting, chewing and swallowing. Moreover, the prognosis for survival of cancer after 5 years is only 50 percent.

To help remedy this situation, NIDR established four Oral Cancer Research Centers in fiscal year 1996: The University of Alabama, Birmingham; University of California, San Francisco; University of Chicago with Northwestern University; and University of Texas-M.D. Anderson Cancer Center in Houston. The first three are co-funded with the National Cancer Institute (NCI). The center approach, combining basic and clinical research by teams of investigators, will lead to improved diagnosis, better methods of reducing known risk factors and "smarter" therapies—such as those aimed at restoring tumor-suppressing gene activity or causing cancer cells to self-destruct.

NIDR has also assumed leadership in a National Plan to Combat Oral and Pharyngeal Cancer; the Institute also collaborates with NCI in a number of health promotional activities to discourage young people from using smoked or smokeless tobacco products.

*What could be accomplished in the future with additional funds*

A doubling of our investment in oral cancer research over the next 5 years might profoundly reduce the number of new cases of oral cancers and lower the annual death rate and with that, the burden of extensive medical costs (surgery, radiation, chemotherapy, rehabilitation).

*Cost savings resulting from medical research*

Research demonstrating how to prevent dental caries (tooth decay) has paid off in saving Americans billions of dollars in their dental bills every year. Indeed, the accumulated total funding to NIDR since its establishment 49 years ago is less than the \$4 billion a year now being saved in the Nation's dental bill. In 1948, the year

NIDR was established, half the population was toothless (edentulous). Today that figure is down to 10 percent—with a corresponding increase in the quality of life.

A recent economic analysis (Brown, Beazoglou & Heffley, 1994) is the source for these data. The investigators identified a slowing in the growth of U.S. dental expenditures for the periods 1979–1989, estimating that this resulted in savings of more than \$39 billion (1990 dollars). Their analysis attributed these savings to improved oral health resulting from preventive measures developed through a sustained agenda of oral health research. Benefits have come from the adoption of community water fluoridation, the widespread use of fluoride tooth pastes and mouthwashes, the application of dental sealants and improvements in public knowledge and adoption of good oral hygiene and sound diets. A more recent update of this analysis to cover the years 1979–1992, found total estimated savings of \$60 billion (1992 dollars) for the 14-year-period, or approximately \$4 billion in savings per year.

#### NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

##### *Accomplishments*

*Pinpointing the causes of disease.*—Impressive progress has been realized in identifying disease-causing genes. Research has narrowed the quest for multiple genes believed to be implicated in diabetes, a complex genetic disease. Advances in single-gene diseases have been remarkable, including the landmark discovery of the cystic fibrosis gene and its protein product, which paved the way to previously impossible research on promising drug and gene-based therapies. Recently, genes for obesity, hemochromatosis, hereditary pancreatitis, and major forms of polycystic kidney disease (P.K.D.) have been discovered. Paralleling these genetic advances are impressive new insights about metabolic, infectious, inflammatory and immune-mediated bases of diseases.

*Preventing and treating disease.*—The multicenter Diabetes Control and Complications Trial demonstrated that the eye, nerve and kidney complications of diabetes can be prevented by intensive management of blood glucose levels—a vitally important and potentially cost-effective public health finding. The demonstration that blood-pressure lowering drugs can prevent the kidney disease of diabetes has likewise produced another important advance in diabetes management, with major implications for reducing the enormous Medicare costs of treating end-stage renal disease. The national investment in acquiring an extensive body of knowledge about diabetes has enabled the NIDDK to launch its first clinical trials aimed at primary prevention of both forms of the disease in high risk individuals, including Native Americans, African-Americans and other minority populations disproportionately affected by the non-insulin dependent form. In other prevention-related research, new insights into bionutrition and discoveries of novel proteins, hormone analogs, and endocrine growth factors abound. Newly found peptides may have potential in protecting against digestive tract injury, and transforming growth factor may play an important role in prostate enlargement and breast tumors.

*Harnessing basic science and new technologies to combat disease.*—Success in detailing the molecular architecture of cellular proteins is providing new tools of molecular medicine. NIDDK structural biologists contributed to elucidating the structure of the p53 tumor suppressor gene—widely believed to play a protective role in cancer—and the structure of integrase, a protein essential to the cellular integration and replication of the AIDS virus. Tools of molecular hematology are shedding light on cellular differentiation, important to developmental diseases of children, cancer, and other diseases.

##### *What could be accomplished in the future with additional funds*

New initiatives would rapidly exploit the unprecedented opportunities for diagnosis, treatment and prevention made possible by the recent discovery of genes for diseases such as obesity and PKD, and progress in the search for diabetes genes. In each major NIDDK disease area, similar new initiatives would be framed to maximize scientific opportunities.

Researchers would undertake full and immediate pursuit of the explosion of new knowledge generated by elucidation of the genetic basis of obesity—a major risk factor for non-insulin-dependent diabetes—and the hormonal regulation of body metabolism, weight, and appetite. Such intensified genetics research would promote spin-off research and development by the U.S. pharmaceutical and biotechnology industries.

In diabetes, molecular genetic techniques would be applied at an accelerated rate to propel the promising quest for diabetes genes to successful completion. A major new diabetes initiative would focus on the development of new therapies by which



patients could more easily control their blood glucose levels and reap the benefits of preventing diabetes complications. Primary prevention trials in diabetes would be expanded, and potential antigens in insulin-dependent diabetes would be scrutinized.

Parallel initiatives would be launched for other major diseases where compelling needs and opportunities exist, including research to prevent or delay the progression of end-stage kidney and liver disease, inflammatory bowel disease, and urologic diseases such as interstitial cystitis, benign prostate hyperplasia and prostatitis. Researchers would exploit new insights into the role of growth factors in prostate and breast cancer, and in thyroid, blood and bone diseases.

The tremendous momentum of fundamental science—in structural biology, molecular hematology, and other fields—would be harnessed to design new clinical applications, including the development of designer hormone analogs, which would have all the benefits of hormones without unwanted side effects. Concomitantly, basic science would be propelled forward, to ensure an uninterrupted stream in the acquisition of new knowledge for future clinical application.

#### NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

##### *Accomplishments*

The NINDS research mission includes more than 600 neurological disorders that affect the brain, spinal cord, and peripheral nerves. Until recently, often the best that could be offered to people with a neurological disorder was a name for their disease and the prospect of lifelong disability or inevitable deterioration. However, we are now entering a new era with the development of treatments for neurological disorders including stroke, epilepsy, multiple sclerosis, and spinal cord injury.

*Stroke.*—Stroke is now viewed as a “brain attack” which, like a heart attack, in many cases may be prevented or promptly treated. For example, clinical trials supported by the NINDS have demonstrated the benefits of aspirin and warfarin for stroke prevention in specific patients. In 1996, the first emergency treatment for stroke, the clot-dissolving drug t-PA, was approved by the FDA based on the results of an NINDS-supported clinical trial that showed a 33-percent increase in the number of patients that are free of disability 3 months after stroke.

*Spinal cord injury.*—A multi center clinical trial under the direction of an NINDS grantee demonstrated the effectiveness of methylprednisolone for the treatment of acute spinal cord injury, and set a new international standard of treatment for these patients. The results from a second trial completed this year have shown that giving the drug for a longer period of time can significantly improve recovery over the standard treatment among patients who start treatment between three and eight hours of injury.

*Multiple sclerosis and epilepsy.*—NINDS-supported research led to the development of two new drugs to slow the progression of multiple sclerosis, and a new drug that reduces seizure frequency over 80 percent in selected patients with epilepsy.

##### *What could be accomplished in the future with additional funds*

With increased understanding of how the normal brain develops and functions, coupled with new insights about what causes neurological disorders, improvements in diagnosis, prevention, and treatment are on the horizon. Areas of opportunity, that could benefit from additional resources:

*The growing brain.*—Dramatic progress in understanding how experience and genetic influences shape the developing brain has profound implications for treating disease. Further research into how nerve cells survive, develop, specialize, and communicate with each other will benefit not only disorders of childhood, but also adult disorders such as stroke, brain injury, and neurodegenerative disease.

*Inherited brain diseases.*—Over 100 defective genes linked to neurological disorders have been discovered so far. Finding the defective genes causing disorders such as Friedreich’s ataxia, Batten disease, neurofibromatosis, and some inherited epilepsies allows for the development of new or improved diagnostic tests, the development of animal models for the disease, and investigations of how the genetic defect translates into human disease.

*Parkinson’s disease.*—The recent discovery of the gene location for some cases of Parkinson’s provides a powerful new tool for research on understanding nerve cell death. Increased funding would support efforts to further investigate and develop therapeutic and prevention strategies, including the use of cell survival molecules (trophic factors), surgical interventions such as pallidotomy and deep brain stimulation, and the growth of engineered cells to produce dopamine, the essential brain chemical that is not adequately produced in Parkinson’s disease.

*Mending the nervous system.*—A century of pessimism about whether damaged nerve cells in the brain and spinal cord can ever regrow after damage is giving way to guarded optimism. Demonstrations in animals have shown that regrowth can be achieved under certain conditions, for example, when natural barriers to growth were neutralized with antibodies, treated with x-rays, or bypassed with peripheral nerve grafts. Further work is needed to understand how to coax useful regeneration of damaged brain and spinal cord cells.

*Saving nerve cells.*—Surprisingly, similar mechanisms kill nerve cells in disorders as diverse as stroke and acute injury as well as slow degenerative diseases, such as amyotrophic lateral sclerosis and Parkinson's. Understanding these destructive processes that involve free radicals, cell suicide, and excess release of calcium and nerve cell signals provides targets for the development of new therapies.

#### NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

##### *Accomplishments*

Fundamental research into the structure and function of the human immunodeficiency virus (HIV) led to the development of a powerful new class of anti-HIV medications protease inhibitors—that have revolutionized the treatment of HIV-infected people.

NIAID-supported scientists clarified the process by which HIV infects its target cells and uncovered important clues about why some individuals appear to be immune to HIV infection. These findings provide the scientific basis for developing new treatment and vaccine strategies.

NIAID scientists and their collaborators developed a safe and effective vaccine against rotavirus, the cause of more than 800,000 diarrhea-related death worldwide each year. This vaccine is now nearing licensure.

Investigators in NIAID's National Cooperative Inner-City Asthma Study identified important factors involved in the recent increase in asthma prevalence, such as high levels of cockroach allergen in the home. Subsequently, they designed and proved the effectiveness of asthma intervention strategies for inner-city children.

NIAID-supported researchers and their colleagues developed highly sensitive and non-invasive tests for gonorrhea and chlamydia, the leading causes of pelvic inflammatory disease and sterility. Used in the context of large-scale screening programs, these tests hold promise for dramatically reducing the incidence and health and economic burden of these sexually transmitted diseases.

##### *What could be accomplished in the future with additional funds*

Accelerated progress in developing new vaccine strategies, such as "naked DNA" vaccines. This vaccine approach has shown promise for several diseases for which no effective vaccine currently exists, including HIV and tuberculosis.

Further progress toward understanding the mechanisms of the emergence of infectious disease.

Expanded research into the growing problem of drug resistance, with the goals of understanding the biological mechanisms of resistance, preserving the effectiveness of currently available antibiotics, and developing new classes of antibacterial agents.

Increased support of basic immunology research, which continues to yield the fundamental insights needed to develop interventions for preventing transplant rejection and for treating immunologic diseases such as allergic and autoimmune diseases.

Accelerated support to develop a vaccine effective against malaria.

#### NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

##### *Accomplishments*

*Otitis media.*—Otitis media (OM) is a bacterial infection of the middle ear common in young children 3 months to 3 years of age. OM is the major reason cited for taking infants and young children to emergency rooms or, to physicians' offices. Scientists funded by the NIDCD have recently been successful in developing a candidate vaccine to prevent OM.

*Hereditary hearing impairment.*—Twelve different genes on 10 different chromosomes have been located for various forms of autosomal dominant nonsyndromic hearing impairment, and 11 different genes on as many different chromosomes have been identified for autosomal recessive nonsyndromic hearings, impairment. Additionally scientists have recently found mutations in mitochondrial genes to be associated with a variety hearings disorders including aminoglycoside ototoxicity.

*Regeneration in the auditory system.*—Cochlear hair cells that are destroyed are not replaced, resulting in permanent hearing loss. Research efforts are focusing on the role of molecular events in promoting hair cell regeneration following experimentally induced damage. In a new approach to understanding hair cell regeneration, an NIDCD-supported scientist investigating hair cell has succeeded in generating new hair cells by adding protein kinase A that stimulates cAMP signaling pathways.

*What could be accomplished in the future with additional funds*

*Otitis media.*—With the promising candidate vaccine in hand, scientists are now ready to move into phase I clinical trials that will assure safety, and later a phase II trial in children to determine clinical effectiveness. An increase in the budget at this time would accelerate the testing of this vaccine and allow its delivery to the public in 6 years. Accelerated further development and testing of the candidate vaccine would ensure that infants and children would be spared the severe pain and sometimes serious side effects of these middle-ear infections, and in so doing would be expected to save \$5 billion per annum in health care costs.

*Hereditary hearing impairment.*—Further investigations would apply advances in the field of molecular genetics to hearing health problems; and assure the prevention of late onset hereditary hearing impairment. It is anticipated that having this type of genetic information will also aid in the early identification of hearing impairment in infant, thereby helping parents to plan for the educational and habilitation needs of their children at the earliest possible opportunity and ensuring the acquisition of language, spoken or signed, on a normal schedule.

*Regeneration in the auditor system.*—Additional funding would accelerate approaches that promote hair cell regeneration and repair in mammalian systems, thereby promising to hasten the delivery of therapeutic agents for the restoration of hearing and balance in individuals with sensorineural hearing loss and balance disabilities.

#### NATIONAL INSTITUTE ON DRUG ABUSE

##### *Accomplishments*

*Anti-addiction medications.*—The development of new medications to treat addiction is critical to solving, this Nation's drug problems. This is particularly true for cocaine addiction, for which we currently have no medications—either for overdose, or to help people stop using drugs or to help them stay abstinent once they do stop. Brain research over the past decade has provided phenomenal insights into both addiction generally and into the mechanisms of cocaine's actions in particular. Basic research has identified many molecular targets for strategic medications development and numerous compounds are in various stages of development as potential medications, including some being tested in early clinical trials.

*Child and adolescent drug exposure and use.*—Illicit drug use affects this Nation's children in many different ways and at all ages, from before birth through adolescence and beyond. Drugs impact our youth both through their exposure during the prenatal periods, as well as through their own drug, use as early adolescents. We are particularly concerned that drug use among youth is increasing and occurring at earlier ages. Research has clarified much about the nature these problems and suggested strategies to begin to deal with them. Within the past 3 years scientists have identified in detail quite subtle but important effects of fetal exposure to barbiturates, marijuana and cocaine on later emotional and cognitive development. For example, we are now seeing that so-called "crack babies" do not recover nearly as well as previously thought, and we are beginning to understand in detail the brain mechanisms mediating prenatal exposure effects on later behavior. Scientists have developed far more sensitive assessment techniques to detect prenatal drug exposure effects and begun to outline remedial strategies. Research has also revealed much about general principles and strategies effective in preventing children from beginning to use drugs themselves, as articulated in NIDA's recently published science-based guide to drug prevention.

*What could be accomplished in the future with additional funds*

*Anti-addiction medications.*—NIDA-supported research has provided the base in effective medications development. Questions remain, however, including the factors underlying powerful phenomena like drug craving and relapse after periods of abstinence. We know the major questions and many of the right strategies. Moreover, many candidate medications are now in line awaiting various stages of testing, from initial activity screening, to toxicity testing, to actual multi-site clinical trials. The rate limiting factor is the resources needed to support further and faster research

and development efforts. Additional funds clearly would accelerate the pace of anti-addictions medications development and provide for the first time an array of truly effective treatments.

*Child and adolescent drug exposure and use.*—The existing science base has begun to clarify exactly what the problems are and what appropriate approaches might be to reduce the impact of drug exposure both prenatally and by young people themselves. There is a critical need to develop more effective remedial strategies to reverse the subtle cognitive and emotional effects of early exposure to drugs. We need to know more about how the effects of drugs on the immature brain differ from those later in development and then what to do about them. Furthermore, in prevention research there is a great need to move from research on general principles to research on effective implementation strategies that can be used in diverse communities. Because we know the critical questions and how to begin to answer them, additional resources would greatly accelerate progress in decreasing drug use and the effects of drug exposure on our Nation's youth.

#### NATIONAL HUMAN GENOME RESEARCH INSTITUTE

##### *Accomplishments*

The Human Genome Project was initiated in the belief that creating detailed maps of the human genome and understanding the makeup and exact DNA sequence of all the human genes would speed the discovery of genes involved in human disease. This, in turn, would dramatically improve the ability to develop tests that can identify an individual's risk for disease and enhance early detection and prevention. Ultimately, this knowledge will lead to radically new and more effective therapies.

The promise of the Human Genome Project has been fulfilled beyond all expectations. Even before completion of all the original goals, the effects of the genome project have pervaded all of biomedical research. Gene discoveries have increased experientially and great progress has been made in the understanding of the underlying mechanisms of many diseases.

At this point, work on the original mapping goals of the genome project is nearing completion. Work on the next challenge, the systematic sequencing of the entire human DNA is beginning. In parallel with the sequencing research on methods to facilitate the interpretation of all the DNA sequence is gaining momentum.

In fiscal year 1996, NHGRI started a series of pilot projects to explore the feasibility of large-scale sequencing of human DNA. These projects have now demonstrated feasibility and are ready to ramp up their activities to achieve greater through-put. NHGRI has also recently issued two requests for applications to stimulate innovative research on technology for large-scale analysis of DNA function. Several approaches to this show promise. One is to compare DNA sequence between different organisms and deduce functional information from the similarities and differences. Another is to measure the rate of expression of the different genes in different tissues and under different conditions. A third is to use mathematical approaches to study the characteristics of the DNA sequence in comparison to sequence of known function. These areas of research promises to explode with opportunities in the near future.

##### *What could be accomplished in the future with additional funds*

If additional funds became available, NHGRI would invest them in several closely linked areas.

The human DNA sequencing effort at this stage is limited by budget, not technology. An increased investment in this area could speed up sequencing and complete the human sequence earlier than the current target date, which is 2005. Increased funding would also allow sequencing of some mouse DNA, which would greatly assist in the interpretation of human DNA sequence.

Now that DNA sequence is accumulating faster than it can be analyzed, there is a great need for technology for large-scale analysis of gene function. Many promising approaches are ripe for further development. The availability technologies would open up new frontiers of research on many diseases.

While the current genome maps have been a boon for mapping single disease genes, they are of limited usefulness for tackling diseases caused by the interaction of multiple genes. Much more detailed maps composed of markers that can be analyzed in large numbers in automated fashion are needed. The technology for developing such maps is now available. Increased funding would allow the production of these maps.

*Accomplishments*

The enormous amount of information generated by biomedical research must be disseminated efficiently and widely if the Nation is to realize fully the benefits from this investment. New communications technology can help bring this about. The growth of the National Information Infrastructure and the increasing access to high-speed computers and communications by the public, health professionals, and biomedical scientists, can have a fundamental impact on health and human services throughout the Nation.

In October 1996, NLM announced the award of 19 multi-year telemedicine projects that will demonstrate and evaluate the use of this technology in a variety of settings: rural, inner-city, and suburban. Each project will review and apply recommendations from two National Academy of Sciences studies on criteria for evaluation of telemedicine and practices to ensure confidentiality of electronic health data. Summaries for these projects and links to their web sites are available.

Internet Grateful Med (IGM) and PubMed are two new ways for NLM users to search MEDLINE over the World Wide Web, using the familiar interface of their web browsers instead of special software. Launched April 16, 1996, Internet Grateful Med is a newer member of NLM's Grateful Med family of programs. NLM's goal with this program is to help users find what they need in multi-million record medical databases. PubMed not only provides access to MEDLINE, but links to the full-text of journal articles at publisher's web sites. NLM's Board of Regents has recently approved free access to the MEDLINE database to users of the web, thus greatly expanding the availability of this information to health professionals and to the general public.

The Visible Human Project, begun by NLM in the early nineties, has resulted in complete, anatomically, detailed, 3-dimensional representations of the male and female human body. It is freely available to researchers. Current applications of the Visible Human data include non-invasive colon cancer screening, simplified plastic surgery, prostate cancer surgical rehearsal, surgical simulation, the study of anatomy, radiation absorption modeling, and crash testing.

On Thursday, October 24th, with a few keystrokes on a computer, a whole new world genetic information was unleashed on the Internet. "The Human Gene Map" project united 104 genemappers from three continents in a common goal of charting the location in the genome of tens of thousands of human genes. The fruit of their efforts is a database and web site of 16,354 human genes, roughly one-fifth of all human genes. The timing of the introduction coincided with the publication of "A Gene Map of the Human Genome" in *Science*. The massive computerized gene map database, available online to anyone with access to the web, is a pivotal development in the 15-year, \$3 billion international human genome project.

The Internet clearly offers a major strategic opportunity for the dissemination of NLM and other biomedical databases in the U.S. and globally. The Next Generation Internet will allow connections that are 100 to 1,000 times faster than today's Internet, along, with better quality of service and the opportunity to demonstrate new applications. NLM is a leader in developing health care applications for the Next Generation Internet effort.

*What could be accomplished in the future with additional funds*

The present success and impact of the Library's high-technology programs could be multiplied with the addition of resources. The widening accessibility of biomedical information as a result of Internet Grateful Med and PubMed, the Library's pioneering Visible Human Project, the recently announced Human Gene Map, and NLM's significant effort in telemedicine represent extraordinary contributions to the world of medicine and research. Remarkable opportunities related to the President's Next Generation Internet initiative would accrue from:

- Increased support for prototype telemedicine applications;
- Expanding the coverage of Internet Grateful Med and PubMed;
- Expanding existing grant assistance programs so that more institutions—including small and rural hospitals, medical and some public libraries—can have access to health information via the Internet; and
- Ensuring that the necessary computer software and hardware resources are available to support the vital GenBank database of molecular sequence information. Such resources are needed to keep up with both the data being added as a result of human genome research funded by NIH and the rapidly expanding usage by the worldwide scientific community.

## NATIONAL CENTER FOR RESEARCH RESOURCES

*Accomplishments*

Investigators depend on NCRR to create, develop, and provide the infrastructure of modern science to keep science moving forward. That infrastructure takes many forms—from sophisticated instrumentation and technologies, clinical research environments, and animal research models of human disease. Examples include:

Development of the first magnetic resonance images using hyperpolarized gas in living systems. This technology produces a signal many times more powerful than traditional MRI, with no added cost to the MRI system and only a moderate cost for polarized gas; this new approach will significantly enhance the diagnostic capability for clinicians;

Visualization of the 3-D structure of cytomegalovirus' protease enzyme required for CMV replication, thereby providing a new target for antiviral drug design. Cytomegalovirus (CMV) infects up to 70 percent of the U.S. population and can cause life-threatening infections in immunosuppressed individuals;

Using a noninvasive imaging technique, known as single photon emission computerized tomography, provided additional proof that increased transmission of the neurotransmitter dopamine causes the symptoms of schizophrenia;

Investigators identified a gene that, with others, controls the regularity of a person's heartbeat. Sudden, unexpected cardiac arrhythmias cause a staggering death toll each year. By detecting individuals who have a mutated form of this gene, physicians will be able to prescribe medications that protect against this pernicious disorder.

*What could be accomplished in the future with additional funds*

NCRR's programs provide research infrastructure and cost-effective shared resource facilities for investigators supported by the other NIH components. Additional funds could support the development of and access to technologies to examine the structure of proteins involved with disease. This would allow support for increased access to high energy x-rays at synchrotron facilities and other high-end technologies for imaging of molecules and structures within cells or organs to study an array of diseases, ranging from diabetes, Alzheimer's, Parkinson's and many others. NCRR could also extend its program for supporting bioengineering approaches to decrease health care costs, as well as extend its support of investigators conducting innovative, high-risk research to develop new technologies to understand basic processes at the molecular and cellular levels and to develop novel therapeutic interventions for AIDS, diabetes, autoimmune diseases, cancer and others.

Separately, NCRR could enhance the research capacity and investigator access to the Regional Primate Research Centers' specially-adapted biosafety laboratories to facilitate AIDS-related and other research with dangerous viruses and bacteria. Other rapidly evolving needs include repositories for genome-related studies of the mouse, rat, zebrafish, and other species. Those shared repositories will expedite research among investigators in a cost-effective way and facilitate studies to understand genes that impact human health.

NCRR could extend support for clinical research through clinical research facilities at several RCMI-supported clinical research centers as well as through the national network of General Clinical Research Centers (GCRCs) which host nearly 8,000 investigators supported by the other NIH components for studies on cancer, asthma, neurological diseases, AIDS and many other diseases. Increased support for junior career development of clinical investigators would also be possible to assure that the research advances at the bench reach the patient.

## FOGARTY INTERNATIONAL CENTER

FIC was established to advance the biomedical research priorities of the United States through international scientific cooperation. Foremost is the need to protect American citizens from health threats that transcend national boundaries. Through research training programs, small grants, individual fellowships and institutional partnerships FIC enables U.S. universities to increase their capacity to meet global health challenges.

Through FIC programs, technical skills and conceptual insights are shared with scientists worldwide. U.S. scientists are able to extend the geographic scope of their research to confront health concerns that require international cooperation due to disease distribution and other factors. Well-trained teams of scientists are fostered in regions of the world that provide unique opportunities to understand disease etiology and risk factors and devise new diagnostics, drugs, vaccines and other prevention methods.

*Accomplishments*

The model for FIC's global health efforts is its AIDS International Training and Research Program (AITRP) established by Congress in 1988. Since its inception, over 1,000 foreign scientists from over 80 countries in Africa, Asia, Latin America, and Central and Eastern Europe have received training in the United States. Many of these scientists are now co-investigators on NIH-supported research projects in developing countries where HIV/AIDS is epidemic. This past year the program documented a substantial decrease in the prevalence of HIV in the population of one foreign country as a result of a systematic prevention strategy. The geopolitical as well as scientific benefits of AITRP are significant. Many FIC trainees represent the future scientific leadership of their countries.

*What could be accomplished in the future with additional funds*

With additional funds, FIC would strengthen its new programs created in consultation with Congress to meet other global priorities—emerging and re-emerging infectious diseases; population and health; environmental and occupational health; and biodiversity. The objective would be to increase the capacity of U.S. institutions and foreign counterparts to (1) identify risk factors and develop prevention strategies for new and emerging pathogens, such as drug resistant forms of tuberculosis and streptococcus; (2) improve maternal and perinatal health through biomedical research and increase demographic and behavioral research capabilities; (3) reduce chronic diseases through a greater understanding of the adverse effects of exposures to environmental chemicals and other agents; and (4) examine the potential therapeutic properties of plants and microorganisms derived from rain forest and other natural ecosystems.

## NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

*Accomplishments*

*Genetics.*—An important benchmark in the history of alcoholism research was the demonstration that a significant portion of the susceptibility to alcoholism is inherited. NIAAA scientists are searching for the relevant genes using family studies, genetic research, and techniques of molecular biology. Initial findings in NIAAA's genetics research have identified promising chromosomal locations relating to alcoholism, colloquially referred to as "hot spots." The hot spots that may influence the development of alcohol dependence are located on chromosomes 1, 4, 7, and 16. Other identified locations on chromosomes 1 and 4 suggest a genetic basis for factors that may provide protection from the development of alcoholism. Genes influencing a brain wave deficit pattern may link to areas on chromosomes 2, 6, and 8.

*Fetal alcohol syndrome (FAS).*—Maternal alcohol consumption can induce congenital defects, growth retardation, learning disabilities, and other behavioral deficiencies in a fetus. NIAAA was responsible for establishing the fact that FAS is caused by alcohol and for galvanizing efforts to alert women and the medical community to the dangers of drinking during pregnancy. Recent research on motor training and how it affects the child's ability to learn has implications for overcoming deficits resulting from fetal alcohol exposure. Additional recent findings delineating the mechanism of cell injury from alcohol-induced free radicals yields the promise of developing treatments that use free radical scavengers or antioxidants to ameliorate or prevent FAS. Expanding research in FAS will contribute to early identification and treatment and help the Nation to deal with a disorder that costs about \$2 billion per year.

*Medications development.*—Based on NIAAA supported clinical trials, naltrexone became the first FDA approved medication for the treatment of alcoholism in 40 years. This medication has shown impressive results in helping the alcoholic to stop drinking. It decreased craving and reduced the relapse rate by 50 percent. The development of naltrexone in the United States and acamprosate in Europe is based on the important convergence of basic neuroscience and clinical research. Major advances in cellular and whole brain research are enabling the characterization of specific alcohol-mediated changes at both the cellular and gross level and facilitating the development of effective medications. This success presages a new era in medications development.

*What could be accomplished in the future with additional funds*

*Genetics.*—The next step is to identify the genes located within the identified chromosomal hot spots. Additional funding would significantly accelerate NIAAA's efforts. Once the genes are identified, more effective prevention and treatment medication can be designed—yielding meaningful gains for the Nation's health.

*Fetal alcohol syndrome (FAS).*—One of the most important goals of FAS research is prevention. Previous research has shown that socially and economically disadvantaged women continue to drink heavily despite warning labels and other public health efforts. Increased funding would greatly expedite our currently planned prevention efforts in this community.

*Medications development.*—Additional funding would permit NIAAA to accelerate clinical trials on the promising medications: naltrexone, nalmefene, and acamprosate. Funding will also facilitate the development of the recently introduced drug, amperozide. Funds are needed to permit the conduct of clinical trials to determine which groups of patients are most responsive to naltrexone and to identify the benefits and side effects of long-term use. Nalmefene is another opioid antagonist with several potential advantages over naltrexone, including less liver toxicity and more complete blockage of specific brain receptors. Acamprosate has been extensively tested in Europe and now under an FDA investigational new drug protocol. NIAAA is providing consultation on methodology and trial design to pharmaceutical companies planning clinical trials on acamprosate.

#### NATIONAL INSTITUTE OF NURSING RESEARCH

##### *Accomplishments*

*Pain.*—Research shows that gender may play a key role in pain relief. A new study demonstrated that women can obtain relief from acute pain from kappa-opioids, such as Stadol or Nubain, while men receive less benefit from these drugs. Earlier clinical testing of kappa-opioids was conducted primarily in men, thus obscuring evidence that these painkillers may be a good analgesic choice for treating acute pain in women.

*Wound healing.*—Chronic wounds such as diabetic ulcers and pressure sores can be life-threatening consequences of many diseases and conditions. Research in this area has resulted in the development of risk assessment measures that have been incorporated into national guidelines on the management of pressure ulcers.

*Cognitive functioning.*—Research on the disruptive behaviors that accompany Alzheimer's disease and other forms of dementia demonstrates that cognitive stimulation exercises can be used by family caregivers in the home to decrease behavioral problems, improve overall mental functioning, and reduce stress for the caregivers. Improvements lasted up to 9 months, allowing patients to remain at home longer, with greater patient and caregiver satisfaction.

*Heart disease.*—Adult heart disease can be influenced by behaviors that begin in childhood. An eight-week program to improve health behaviors was tested in more than 2,200 children in urban and rural schools. Twenty percent of the participants were African-Americans. At the end of the study, children in the intervention program showed a significant increase in reported physical activity and reductions in total cholesterol levels, body mass index, and body fat.

##### *What could be accomplished in the future with additional funds*

*Pain.*—Additional funds would allow NINR to involve more investigators in research to understand the influence of gender on response to pain. Research would focus on issues such as the role of hormones and differences in cell receptors and other neurological factors. This research has critical implications for future drug development and therapy.

*Organ transplantation.*—Organ transplantation, an increasingly successful procedure, is often accompanied by long-term complications and compromised quality of life. With increased funding, NINR would be able to develop assessment tools to be used in the home to monitor early signs of organ infection and rejection, to determine the status of gastrointestinal and heart function after transplantation, and to measure exercise capability following transplantation.

*Cognitive impairment.*—With additional funding, NINR could engage in further clinical and basic studies of (1) the neurobehavioral and cognitive effects of dementia, delirium, and confusion, and (2) nonpharmacologic approaches to the management of behavioral, physical, and functional problems associated with cognitive impairment, especially Alzheimer's disease.

*Heart disease.*—The burdens of heart disease and stroke remain higher for minorities and persons of low socioeconomic status than for the overall population. Additional funds would allow NINR to fund research to develop national programs tailored to minority groups that have not experienced improvements in morbidity and mortality from cardiovascular disease.



Alzheimer's disease is a devastating condition that destroys the lives of those who have the disease and disrupts the lives of their caregivers. The fastest-growing segment of the U.S. population, those over age 85, is also the most susceptible to Alzheimer's disease. The Nation could, therefore, face a growing public health crisis unless the progression of Alzheimer's disease is slowed or prevented. Research can move us closer to this goal at only a small fraction of the estimated \$100 billion yearly cost of caring for patients with Alzheimer's disease.

#### *Accomplishments*

Research on the basic biology of Alzheimer's disease, such as the remarkable series of genetic discoveries of the past few years, has resulted in major advances in our understanding of this disease. These findings, together with the results of epidemiologic studies, have led to the identification of risk factors and of potential protective interventions for Alzheimer's disease.

Epidemiologic studies have suggested that estrogen replacement therapy, use of non-steroidal anti-inflammatory drugs (such as ibuprofen), and use of anti-oxidants (such as vitamin E) may decrease the risk of developing Alzheimer's disease. These promising leads are being investigated. Epidemiologic research also has identified differences among various ethnic groups in the risk of developing Alzheimer's disease. Studies such as these are expected to yield leads to other environmental and genetic factors that may account for these differences in risk.

A recently completed clinical trial of people with moderately severe Alzheimer's disease showed that the drug selegiline and vitamin E, either separately or in combination, may delay important milestones such as entry into nursing homes by about 7 months. Such a delay would greatly reduce the burden of caring for Alzheimer's disease patients and has the potential of saving billions of dollars for nursing home care.

Research results have improved supportive, community-based services for Alzheimer's disease patients and their families. Improved behavior management techniques have reduced disruptive, agitated behavior in Alzheimer's disease patients and have contributed to a decreased use of both physical and chemical restraints, leading to a better quality of life for patients and caregivers.

The coexistence of Alzheimer's disease with vascular disease in a study population of elderly U.S. nuns was found to result in more severe dementia than expected on the basis of Alzheimer's disease neuropathology alone. These findings suggested that prevention or treatment of vascular disease may delay or reduce the development of symptoms in many Alzheimer's disease patients.

#### *What could be accomplished in the future with additional funds*

We are at the threshold of further discoveries that will lead to:

Finding additional clues to the genetic or environmental factors that may contribute to the development of Alzheimer's disease, and improving our ability to predict who is at risk for developing the disease.

Developing safe, effective, and reliable methods of early diagnosis for Alzheimer's disease.

Improving our understanding of factors that contribute to nerve cell death in Alzheimer's disease and thereby identifying means of preventing onset of symptoms.

Developing more effective treatments and preventive interventions to reduce the tragic impact of Alzheimer's disease on patients and their families.

#### *Accomplishments*

*Genetic basis of rheumatoid arthritis and systemic lupus erythematosus.*—Six distinct genetic regions that control inflammatory arthritis were identified by researchers in the NIAMS intramural program, who reported that the genetic basis in the inflammatory arthritis bore a striking similarity to what is known about the genetics of rheumatoid arthritis. Most significantly, researchers have located several of the particular genes that affect arthritis susceptibility and severity in this animal model. Other genetic studies have provided important clues about systemic lupus erythematosus (SLE), including the identification of a genetic risk factor for lupus kidney disease in African Americans, as well as the localization of a gene that predisposes people to SLE. The exciting dimension of this latter advance is that it appears in multiple ethnic groups, making it a very significant research finding.

*Osteoporosis.*—Osteoporosis is the leading cause of bone fractures in postmenopausal women and older people in general. Recently, investigators have shown that estrogen induces the death of the cells responsible for the breakdown

of bone. However, the effects of estrogen are complex, and since not all women are suitable candidates for estrogen replacement, it is important to determine the mechanism of estrogen action and to devise alternative therapies. This discovery opens up an exciting new avenue of research opportunities for investigators to discover whether other drugs can also affect the death of the bone-degrading cells, making them potentially useful as bone-protection treatments.

*Skin cancer.*—In a significant advance in our understanding and treatment of skin cancer, scientists have identified the gene involved in basal cell (skin) cancers, the most common human cancer. This work in genetic medicine identifies a new gene that is important in human development as well as tumor suppression, and may lead to novel, nonsurgical treatments for basal cell carcinoma.

*What could be accomplished in the future with additional funds*

*Total hip replacement.*—Total hip replacement provides pain relief, improves quality of life, and results in economic benefits. However, osteolysis, the disappearance of bone around the implant, can result in significant pain, implant loosening, and the need for additional surgery. Research to reduce osteolysis will improve the long-term wear of implants and result in tremendous cost savings.

*Low back pain/repetitive motion disorders.*—Seventy to 85 percent of Americans will develop back pain; and this problem may be recurrent and disabling. The term “repetitive motion disorders” describes a constellation of conditions that primarily affect the soft tissues, including nerves, tendons, and muscles. Both of these conditions have a significant impact in the workplace, resulting in pain and disability, as well as economic costs. The NIAMS has issued Program Announcements in both of these areas, signaling our interest in increased research focus to address these public health problems.

*Wound healing.*—The inability of certain wounds to heal in a timely fashion is the cause of great disability and immobility in the United States, particularly among the elderly and those suffering from certain injuries or diseases including spinal cord injury and diabetes mellitus. Additional research is needed on all aspects of chronic wounds to develop new and effective treatments.

*Osteoarthritis.*—Osteoarthritis, the most prevalent disease of the joints, takes a staggering toll in human suffering and economic costs. Additional resources would allow enhanced research on the biological responses of cartilage and bone to various mechanical forces and how those responses affect the onset and progression of osteoarthritis. The identification of ways in which mechanical forces lead to tissue damage could open new possibilities of drug therapy for osteoarthritis patients.

*Bone and the immune system.*—Recent advances in understanding bone remodeling indicate that the regulation of bone formation and resorption involves a number of factors that are also important in the regulation of the immune system and the system that controls blood cell formation. The NIAMS is co-sponsoring a workshop to identify research opportunities ripe for investment.

#### NATIONAL INSTITUTE OF MENTAL HEALTH

##### *Accomplishments*

Throughout its fifty years, the NIMH has conducted and supported research that has made possible the development and use of many new treatments for mental illnesses—where previously there were no effective treatments. This time span saw the first medications that could alleviate mental illness, establishing that these illnesses are biological in origin and providing a powerful weapon against stigmatization of patients.

Effective treatments have greatly improved the lives of people with mental illness and have also produced significant economic benefits. For example, lithium therapy for manic depression has saved the U.S. economy almost \$6 billion per year since 1970; and clozapine maintenance treatment for schizophrenia saves approximately \$1.4 billion annually, primarily by preventing hospitalizations of the estimated 60,000 patients receiving clozapine.

Continuing improvements in psychotherapies have replaced or augmented pharmacologic treatments for some patients. In 1990, one mental illness, unipolar major depression, was the leading cause of disability. This disability has a major and growing impact on both the direct costs of health care and the loss of economic productivity: it is a potent incentive to accelerate efforts to reduce the burden of mental illness.

Decades of painstaking research have brought neuroscientists to the threshold of understanding the structure and operation of that most complex of human organs, the brain. To understand cognition, emotion, and what goes wrong to produce the

brain disorders that we call mental illnesses will require progress at the levels of molecules and genes, cell, circuits, and psychology.

This is an enormous challenge because mental illnesses don't appear to have any single cause; rather they result from multiple vulnerability genes acting at different times during brain development combined with influences of environmental factors. Using genetic engineering and cell recording techniques in mice, researchers have begun to describe the underlying biology that constitutes the molecular basis of memory formation in the brain. Other scientists have made major advances in discovering how the brain functions in emotions such as fear; this progress will revolutionize our understanding of the neurobiology of emotion and how best to treat severe anxiety disorders, such as panic disorder and obsessive-compulsive disorder.

Another group of scientists, using advanced molecular techniques and basic behavioral science, have identified a gene named clock, that controls daily biological rhythms. This work will help understand human problems ranging from mood disorders, such as depression, to sleep disorders to jet lag. A recent study, which illustrates the potential usefulness of neuroimaging techniques for understanding mental illnesses, found that people with schizophrenia had a decreased density of dopamine D1 receptors in the prefrontal cortex and that the extent of decrease correlated with the severity of the illness.

*What could be accomplished in the future with additional funds*

Expansion of research on the complex genetics of the major mental disorders would lead to a much more complete understanding of the roles of genetic factors in mental illnesses—schizophrenia, schizoaffective disorder, manic depressive illness, major depression, autism, panic disorder, and obsessive-compulsive disorder—which would lead, in turn, to clearer insights into the origins, optimal treatments, and ways to prevent these illnesses.

Increased emphasis on the use of modern molecular and integrative neurobiology to understand the basis of mental disorders would discover new targets for novel therapeutic agents.

Acceleration of research on the application of modern genetic techniques in animal models would enable scientists to understand how the brain processes cognition (including memory) and emotion, while neuroimaging techniques will allow scientists to translate the findings of this animal research into humans.

Expansion of research on the prevention and treatment of mental disorders in children would yield critically needed information on the best and safest ways to reduce the terrible consequences of mental illness for our youngest citizens.

Initiation of clinical trials of new drugs recently approved for the treatment of manic depressive illness and psychotic disorders would allow NIMH to advise mental health care providers on the most effective treatments for each type of patient.

Finally, research on imaging techniques could lead to an integration of pharmacologic and behavioral approaches to treatment.

#### NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

##### *Accomplishments*

The multi-billion dollar biotechnology industry is a consequence of decades of NIGMS investment in basic research. This research has provided an understanding of the basic biological processes of living cells, a knowledge of the structure and function of the compounds that make up the fabric of life, and tools for synthesizing and evaluating drugs. The result has been the production of many new drugs, including human growth hormone, new orally active asthma medications; and EPO, which boosts production of red blood cells in individuals undergoing chemotherapy. A striking demonstration of the contribution of NIGMS-sponsored research to the development of new drugs comes from the patent literature, which shows that a significant percentage of patents for new drugs cite NIGMS-funded research as providing essential information leading to the patents.

Advances in chemical synthesis have led to drugs that are safer for patients and are effective at lower dosages.

Progress in rational drug design enables scientists to use the structures of the enzymes needed by disease organisms to design small compounds that will fit into, and jam the action of the enzymes. The protease inhibitors that have been so successful in treating AIDS were the result of an understanding of protease structure and function developed over several decades.

Achievements in identifying the pathways by which signals are transmitted from the outside of the cell to the cell nucleus, resulting in a change in gene expression, now make it possible to design drugs to block or enhance signal transmission.

*What could be accomplished in the future with additional funds*

The development of new targets for drug design and new approaches to identifying and creating drugs depends on additional funds to stimulate research. There are several areas that would particularly benefit.

One is increasing understanding of the key elements in the cell that can be used as targets for the control of disease. For example, there is growing evidence that compounds containing sugars may be important in many cellular activities and that many possible therapeutics could be realized by targeting these compounds. Because of many difficulties in working with these materials, progress has been slow. However, new developments in chemical synthesis have increased the likelihood that novel therapeutics will emerge in the near future, if resources are available to encourage this effort.

Further, although knowledge of detailed molecular structure has become an effective tool in the development of new drugs, it still has many shortcomings. An increased effort is needed to generate improved methods for the determination of the structure of target molecules, for the generation of improved theoretical methods aimed at the design of molecules, and for a better understanding of how drugs get into the cell and interact with their targets.

## NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

*Accomplishments*

The research of the National Institute of Child Health and Human Development is distinguished by its sweep across the life span. The oldest questions of life are being studied using the latest tools of biomedical research and a multidisciplinary approach. Significant gains have been made in reducing infant mortality, birth defects, and in transmission of deadly infections.

Since the Institute was established in 1962, the Nation's infant mortality rate has declined by 70 percent. This decline is clearly linked to NICHD research advances, particularly to improvements in treating respiratory distress syndrome and other breathing problems in newborns and in reducing sudden infant death syndrome.

Intense study of preeclampsia—the most common fatal condition of pregnancy—has challenged standard treatments and led to new insights about uterine biology.

Research has led to promising opportunities to affect the factors involved in premature delivery, a condition associated with low birth weight babies, expensive prenatal care, and often permanent disabilities.

Mother-to-child transmission, which accounts for the vast majority of HIV infections in infants, has been markedly reduced. NICHD research also developed a vaccine against Hib meningitis that has nearly eliminated the disease, which was the leading cause of acquired mental retardation.

*What could be accomplished in the future with additional funds*

Prevention of serious conditions, particularly those that occur during early development, in the first months of life or during childhood, is a high Institute priority. A recent White House Conference on the Brain and Early Learning coined the phrase, "the first few years last forever." NICHD scientists would add the phrase, "prevention is forever." Additional funds could help fund studies of early development that may hold the key to a healthy baby free of birth defects.

Building on basic studies, clinical trials could be undertaken to develop a treatment for infections that add to the risk of premature labor and delivery of low birth-weight babies. Increased spending would speed the development of topical microbicidal agents to prevent the transmission of sexually transmitted diseases (STDs), including AIDS.

Additional funds would speed progress toward vaccines against damaging and life-threatening pathogens such as pertussis, typhoid fever, shigellosis (dysentery), E. Coli M 0157, antibiotic resistant pneumococcus, and tuberculosis.

The development of additional sophisticated animal models could speed our understanding of critical moments in development, as well as the timing and success of genetic changes. Intensified research on human fertility, prevention of birth defects, including genetic diseases and various developmental disabilities such as mental retardation or autism, could improve the prevention of many human and medical tragedies.

Increased research into specific areas of the brain, as well as rapid intervention in children with early signs of learning disorders could help prevent a lifetime of educational problems.

Many adult diseases, such as osteoporosis, obesity and diabetes, are associated with poor childhood nutrition. Increased funding would enhance our efforts to develop the means in childhood to prevent these serious adult diseases.

Injury prevention studies could lead to reduced disabilities and the development of new high technology assistive devices could dramatically restore function and mobility to many with physical disabilities.

NATIONAL EYE INSTITUTE

*Accomplishments*

*Age-Related Macular Degeneration (AMD).*—AMD is the most common cause of severe visual impairment in the U.S. approximately 1.7 million Americans have damaged eyesight from AMD and 100,000 of them are blind from the disease. The prevalence of decreased vision from AMD is expected to rise to 6.3 million by the year 2030. Recently, many of the genes involved in retinal degeneration have been identified or localized such as one type that afflicts younger people and causes tunnel vision and night blindness. Vast strides have been made in understanding the genetic basis of this specific form of the disease with over 78 gene defects having been identified. In certain forms of retinal degeneration, NEI researchers have already placed genes into the retinas of laboratory animals. Human treatment strategies based on these experiments are under development.

Replacing diseased retinal cells with healthy ones by tissue transplantation has also been a promising area of research. Groups of NEI-supported scientists have successfully transplanted healthy retinal cells as replacements for diseased cells in animals.

Other, recent studies that have shown promise involve a class of chemicals called biological survival factors which delay cell degeneration in AMD and other retinal diseases.

*Diabetic retinopathy.*—Diabetic Retinopathy is one of the most important causes of sight loss and a leading complication of diabetes. It accounts for 12 percent of all new cases of blindness each year in the U.S. Past research advances have documented the role of a specific enzyme and growth factors as possible cause of blindness from diabetic retinopathy. New research on the cell biology of the retina has shown that newly discovered growth factors might play a role in the development of abnormal and destructive blood vessels that occur later in the course of the disease. Additionally, the development of new drugs and molecular genetic techniques to block the enzymes thought to be a major cause of diabetic retinopathy complications, and to prevent abnormal blood vessel growth, hold great promise for the future.

*What could be accomplished in the future with additional funds*

*Age-related macular degeneration (AMD).*—Now that scientists have localized and identified genes causing various forms of retinal degeneration, the study of the cellular and molecular basis of the disease can be greatly accelerated. Additionally, NEI scientists can now try to identify genes that will help rescue the retina, which, if possible, might help prevent much of the visual loss from the later stages of AMD.

Additionally, based on the above research accomplishments, there is a real opportunity to develop human treatment strategies. These clinical trials will include evaluation of agents that relayed abnormal blood vessel growth, cell transplants to replace the diseased retina or portions of it, and, potentially, gene therapy to replace defective genes. As the “baby boomers” age and a higher percentage of Americans reach age 60, more older people will become blind from AMD than from glaucoma and diabetic retinopathy combined. In addition to the obvious quality of life issues faced by those with age-related macular degeneration, effective treatment of even 25 percent of all cases could lead to significant dollar savings to society and decreases in the number of social security disability payments.

*Diabetic retinopathy.*—New drugs to inhibit aldose reductase and protein kinase C enzymes whose malfunctioning is thought to be responsible for diabetic retinopathy, need to be further characterized and developed as therapeutic agents and tested in nationwide clinical trials. Likewise, animal studies of inhibitors of the growth factors that appear in later stages of retinopathy, first, need to be tested in animals and then, if successful, evaluated in human clinical trials.

In the U.S., these two diseases—age-related macular degeneration and diabetic retinopathy—account for over 50 percent of all visual disability and blindness. Diseases of the eye cost Americans over \$40 billion annually, so any treatment advances in these two areas could save billions.

*Accomplishments*

*Risk Assessment for the 21st Century.*—Human exposure standards are calculated based on a combination of toxicological test results, epidemiology studies, and mathematical modeling. The NIEHS, under the auspices of the National Toxicology Program (NTP), has assumed the leadership role in developing risk assessment methodologies that incorporate our evolving knowledge of the molecular mechanisms and cellular pathways by which environmental toxicants exert their effects. As these techniques are refined, they will lead to more rational, more precise risk assessments that protect human health without the need for default safety factors not founded on scientific data. New approaches also open the possibility of developing novel, inexpensive, more rapid animal assays for environmental influences on diseases such as cancer.

*Individual responsiveness to environmental exposures.*—Exciting work supported in part by the NIEHS has identified how individual differences in inherited genes can dramatically alter a person's susceptibility to environmental toxicants. Examples include a carcinogen metabolizing gene that renders an individual who smokes more likely to develop urinary bladder cancer, a vitamin D receptor gene that increases a man's risk of prostate cancer, and a detoxifying enzyme that renders Asians more susceptible to the nerve gas, Sarin, than are Caucasians.

*What could be accomplished in the future with additional funds*

*Environmental genome.*—The NIEHS is planning an Environmental Genome Project to provide a systematic analysis of genes critical to the development of environmentally-associated diseases. Additional funding would be used both to get this project underway earlier and to increase the power of the program by surveying more people and obtaining information on a wider variety of environmentally-related genes.

*Prevention research.*—All NIEHS-supported research has as its basis the goal of preventing disease development. Several important avenues are being explored that could benefit from increased funding. One is strengthening epidemiological research in linking diseases to environmental exposures. This increased capability would be possible by expanding exposure assessment capability in the U.S. population, by developing biomarkers of exposure and effect, and by incorporating our evolving knowledge of how individual differences affect responses to environmental exposures. These individual susceptibilities would include both genetic susceptibilities and susceptibilities based on developmental age, e.g., how infants and children serve as a uniquely vulnerable subpopulation. Another important avenue is expanded prevention research on childhood exposures leading to asthma, and development of culturally sensitive strategies for conducting population studies. Additional funding would allow expanded efforts in these critical research areas.

*Complex mixtures.*—Traditionally health effects of chemicals have been assessed individually, even though people are exposed to many different compounds. A major flaw of risk assessment science is its inability to predict the expected health effects arising from a multiplicity of exposures. To address this information deficiency, the NIEHS is releasing an RFA to recruit university scientists to address this problem. Molecular toxicologic approaches are being used to identify those mixtures which may pose the greatest human health risk. For example, two transgenic mouse models are currently being assessed which hold the promise of rendering carcinogenicity results in 6 months at a fraction of the cost of a traditional 2-year exposure assay. With more funding, the NIEHS would be able to fund a greater number of grants in response to its RFA.

## CLINICAL RESEARCH

Senator SPECTER. Dr. Varmus, one concluding question from me, and then I will yield again to my colleague, Senator Cochran.

Dr. VARMUS. Yes.

Senator SPECTER. We hear complaints about an insufficient emphasis on clinical research. Do you think there is any basis to that complaint?

Dr. VARMUS. There is certainly a basis for worrying about it. As you know, I have been hearing about it ever since I have assumed my responsibilities here. About 2 years ago, I established a clinical research panel, composed of distinguished leaders in medical re-

search from around the country and chaired by Dr. David Nathan from the Dana Farber Cancer Center. That group has studied many of the issues that have been raised by those concerned about the status of clinical research.

One of the things that they have found is that the NIH is strongly supporting clinical research, perhaps in excess of what had been anticipated by critics. For example, about 37 percent of our grant dollars and about 28 percent of our grants go to support clinical research.

We are concerned about recruitment and training of clinical investigators, especially given the burdens that medical students experience now. And we have devised a number of new training mechanisms, some of which are already implemented, to ensure that we have a healthy new cohort of clinical investigators.

We are also looking at the status of places where clinical research is done, trying to improve the way in which the general clinical research centers work and to improve both the facilities and governance of the clinical center at the NIH. We believe that many of the areas of concern are being addressed. Life is not perfect, but we think the situation is healthier than some of our critics may have thought.

Senator SPECTER. Senator Cochran.

#### READING DEVELOPMENT AND DISORDERS

Senator COCHRAN. Mr. Chairman, I appreciate your recognition of me again.

When we had our hearing with Secretary Riley, Secretary of Education, I asked a question about a study that had been done under the provisions of the Health Research Extension Act at the National Institute for Child Health and Human Development into research affecting the capacity of children to learn—particularly to learn to read—and how this affected our efforts to provide education and resources for those who may be difficult to teach or have learning disorders of some kind or another. And it was fascinating to me that we have spent over \$100 million on this research now, and nobody at the Department of Education had bothered to read the findings or to find out what had been learned as a result of this important research that we had funded and had been undertaken.

So I had asked Dr. Duane Alexander to give us a report so we could put it in the record at this hearing. And I just want to point out that he has prepared a written response to my inquiry, which I ask that we put in the record.

[The information follows:]

#### READING DEVELOPMENT AND DISORDERS

I think that it is important to point out that our intensive research efforts in reading development and disorders is motivated to a great extent by our seeing difficulties learning to read as not only an educational problem, but also a major public health issue. Simply put, if a youngster does not learn to read, he or she simply is not likely to make it in life. Our longitudinal studies that look at children from age five through their high school years have shown us how tender these kids are with respect to their own response to reading failure. By the end of the first grade, we begin to notice substantial decreases in the children's self-esteem, self-concept, and motivation to learn to read if they have not been able to master reading skills and keep up with their age-mates. As we follow them through elementary and middle school these problems compound, and in many cases very bright youngsters are

deprived of the wonders of literature, history, science, and mathematics because they can not read the grade-level textbooks. By high school, these children's potential for entering college has decreased to almost nil, with few choices available to them with respect to occupational and vocational opportunities.

In studying approximately 10 thousand children over the past 15 years, we have learned the following:

At least 20 percent, and in some states 50 to 60 percent, of children in the elementary grades can not read at basic levels. They can not read fluently and they do not understand what they read.

However, the majority of these children—at least 90 to 95 percent—can be brought up to average reading skills if:

—(A) children at-risk for reading failure are identified during the kindergarten and first grade years and,

—(B) early intervention programs that combine instruction in phonological awareness, phonics, and reading comprehension are provided by well trained teachers.

If we delay intervention until nine-years-of-age (the time that most children are currently identified), approximately 75 percent of the children will continue to have reading difficulties through high school. While older children and adults CAN be taught to read, the time and expense of doing so is enormous.

We have learned that phonological awareness—the understanding that words are made up of sound segments called phonemes—plays a causal role in reading acquisition, and that it is a good predictor because it is a foundational ability underlying basic reading skills.

We have learned how to measure phonological skills as early as the beginning of kindergarten with tasks that take only 15 minutes to administer—and over the past decade we have refined these tasks so that we can predict with 92 percent accuracy who will have difficulties learning to read.

The average cost of assessing each child during kindergarten or first grade with the predictive measures is between \$15 to \$20 depending upon the skill level of the person conducting the assessment. This includes the costs of the assessment materials. If applied on a larger scale, these costs may be further decreased.

We have learned that just as many girls as boys have difficulties learning to read. The conventional wisdom has been that many more boys than girls have such difficulties. Now females should have equal access to screening and intervention programs.

We have begun to understand how genetics are involved in learning to read, and this knowledge may ultimately contribute to our prevention efforts through assessment of family reading histories.

We are entering very exciting frontiers in understanding how early brain development can provide us a window on how reading develops. Likewise, we are conducting studies to help us understand how specific teaching methods change reading behavior and how the brain changes as reading develops.

Very importantly, we continue to find that teaching approaches that specifically target the development of a combination of phonological skills, phonics skills, and reading comprehension skills in an integrated format are the most effective ways to improve reading abilities.

At the present time, we have held several meetings with officials from the USDOE and have discussed how these findings can be used across the two agencies. As an example of this collaboration, NICHD and USDOE have been developing a preliminary plan to determine which scientific findings are ready for immediate application in the classroom and how to best disseminate that information to the Nation's schools and teachers.

#### SUMMARY STATEMENT OF DR. DUANE ALEXANDER

Senator COCHRAN. And I would like to ask him to make whatever comments that he thinks would be appropriate at this point in connection with that research and the need for continued funding for this kind of inquiry—whether there is a payoff here in terms of improved health and quality of life of our younger generation.

Doctor.

Dr. ALEXANDER. Senator Cochran, I appreciate your interest in this topic. You are quite correct, over the past roughly 15 years, the Institute has invested, at the request of the Congress, approxi-



mately \$100 million, studying over 10,000 children in a longitudinal way for their reading ability and disability.

What we have learned about this problem that affects not just education, but also the public health and welfare because of the impact on the children and on their ability to learn to read, as evidenced by longer-term problems and limitation of educational opportunity, lifetime skills and increased behavioral and delinquency problems, is that approximately 20 percent of children in the elementary schools overall, are basically not able to read. And in some areas this ranges even higher—50 percent or more. We have done studies that look at this population, in terms of our ability to identify them and intervene.

What we have found is that we are able to identify, by a screening technique in kindergarten age group, this approximately 20 to 25 percent of children who are at high risk for a learning disability, particularly for learning to read. And if we are able to identify them at this age and intervene with a program that is based on phonologic awareness, teaching phonics, and understanding of written text by trained teachers, we are able to achieve normal reading levels in about 90 to 95 percent of these children. This makes an enormous difference in their capabilities, both academically and socially as well.

This screening test is available now. We are able to administer it at a cost of \$15 to \$20 per child, select out the population at highest risk, focus our intervention on them, and produce pretty impressive results.

What we are trying to do now is demonstrate this on a larger scale in educational systems, and demonstrate whether, in fact, we can apply it in a broader way and show that it will be effective in a classroom setting.

We have been in communication with our colleagues in the Department of Education about the implications of these findings, for training of teachers and teachers in education colleges, as well as the actual application in the classroom of these findings.

#### GRANT AWARDS TO ALL STATES

Senator COCHRAN. Thank you very much, Dr. Alexander. And let me commend you for the excellent report and the fine work that is being done in this research.

Dr. Varmus, I just want to point out, too, that Congress declared the 1990's as the decade of the brain, and brain disorder research was something that you discussed in your opening comments. The National Institute of Neurological Disorders and Stroke has been at the forefront of this research, and I think it is very impressive to see the results. And I appreciate your reporting that to us.

We are interested, too, in helping to make sure that research dollars, to the extent that it is possible to effectively spend them in other parts of the country that do not usually get the big-dollar research investments—States like Mississippi—are treated fairly. I know there is this program, the IDEA program. My question is, is it worth continuing to make an effort to disburse some of these dollars to States like ours, where we can see effective use of those dollars made in medical research?

Dr. VARMUS. We believe there is talent in all States, and sometimes it is necessary for NIH to undertake special programs to help people who live in those States to be more familiar with the NIH system. We have two major programs that address some of those concerns. One is the IDEA program; the other is the AREA program. Two other programs also have a minor impact.

With respect to your own State, you will be pleased to know that in the current fiscal year there will be at least five, and perhaps more, AREA awards going to Mississippi.

Senator COCHRAN. Thank you very much.  
Thank you, Mr. Chairman.

#### CLINICAL RESEARCH

Senator SPECTER. Thank you very much, Senator Cochran.

Dr. Varmus, we will have quite a few questions to submit for the record, because we do want to move along to the next panel as soon as I yield to our distinguished ranking member, Senator Harkin. We have some questions specifically on autism. We have a variety of questions which we will submit for the record. And I would like some further specification on the issue of clinical research.

I note that our 1995 committee report requested NIH to act on the recommendations of the Institute of Medicine report with respect to the crisis on clinical research. And we requested NIH to use 1 percent transfer authority to implement the IWIMP-recommended initiatives, which was never done.

Last year the concern was expressed about, quote, "very few of the recommendations have been implemented." And you said that NIH would take action. I am advised by staff that that has not occurred.

And the NIH advisory panel, 3 years ago, the clinical advisory group to provide advice and guidance on the issue of clinical research, related to the IWIMP panel that the group is now entering its final year of a 3-year tenure. But as I am advised, to date, only draft and interim reports have been made and no final recommendations have been offered to the NIH and no implementation of any action has occurred.

Dr. VARMUS. Mr. Specter, I beg to differ. There are a number of actions recommended by the committee that have been taken. The committee is going to report to me in final form in the fall.

Senator SPECTER. Well, what has been done?

Dr. VARMUS. There has been a new program instituted at the NIH for training clinical investigators. There has been the recommended survey—actually a prospective survey of our support of clinical investigation. And we are designing other new programs for training of clinical investigators.

Some of the objectives are in motion, but they are in response to recommendations that will take some time.

Senator SPECTER. Well, would you give those to us in writing, Dr. Varmus?

Dr. VARMUS. Yes; they are available.

Senator SPECTER. We have to move on to the next panel. But I would like to get the specifics and your response to the written questions.

Dr. VARMUS. I would be very pleased to provide them.

[The information follows:]

#### NIH PROGRESS IN THE CLINICAL RESEARCH ARENA

Over the past year, several steps have been taken to strengthen clinical research at the National Institutes of Health (NIH). Some of these initiatives are in response to preliminary recommendations made in December 1996 by the NIB Director's Clinical Research Panel (CRP). Others have been developed independently by the Institutes, Centers and Divisions (ICDs). Highlights of these initiatives are summarized below.

*1. The CRP developed the following definition of clinical research:*

Patient-Oriented Research: Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes: Development of new technologies; Mechanisms of human disease; Therapeutic interventions; and Clinical trials.

Epidemiologic and Biobehavioral Studies;  
Outcomes Research and Health Services Research.

*2. Assessment of the extent of NIB's support for clinical research through extramural funds*

Based on the definition above and in response to a CRP recommendation, the Office of Extramural Research (OER) has developed a database to code NIH-supported clinical research awards and to track funding of clinical research prospectively. The data collected for extramural competing awards during fiscal year 1996, including clinical trials as a subset, show that 27 percent of such awards and 38 percent of the funds supported clinical research projects. Comparable data on clinical research for noncompeting awards has not been collected, but are believed to reflect similar levels for clinical research.

*3. The General Clinical Research Centers (GCRCs)*

(a) In fiscal year 1997, the National Center for Research Resources (NCRR) will provide the network of GCRCs and other related activities with a total of \$157 million. The NCRR made an award to one new GCRC in fiscal year 1996 at Howard University. Research will be related to diseases that particularly affect African Americans. In addition, NCRR funded a new satellite site at Children's Hospital in Seattle, Washington.

(b) In response to a CRP recommendation, changes to the GCRC Guidelines have been approved to encourage a leadership role by each GCRC in coordinating many vital clinical research functions in its institution.

(c) The NCRR is committed to the training of clinical researchers at GCRCs, through the Clinical Associate Physician (CAP) program (established in 1974), the Minority Clinical Associate Physician (MCAP) program (established in 1991) and the Clinical Research Scholar (CRS) program (established in 1996). The most recent analysis of these programs shows that its graduates have been successfully in competing for research funds from NIH and other Federal agencies as well as the private sector.

*4. The Warren Grant Magnuson Clinical Center (CC)*

(a) The CC is currently undergoing significant governance and management changes as recommended in a 1996 report entitled "Revitalizing the NIH Clinical Center for Tomorrow's Challenges." These include appointment of a Board of Governors, implementation of a strategic plan, more efficient financial planning, improved procurement and information systems and initiation of novel patient recruitment strategies.

(b) Planning continues for construction and utilization of a new hospital (the Mark O. Hatfield Clinical Research Center), for which Congress has authorized funding.

(c) Proposals and mechanisms for increased intramural/extramural collaborations at the CC are being developed with the advice of a high-level internal Committee on Extramural/Intramural Investigations. Membership of the committee includes ICD Directors, Scientific and Clinical Directors. Its specific charges are to explore opportunities for interactions between extramural and intramural investigators in the CC, to devise mechanisms to facilitate such interactions, and to recommend ways in which the Clinical Research Center can support these goals.

(d) Each Institute has developed its own Internal mechanism to ensure rigorous scientific review of clinical research protocols prior to submission to an NIH Institutional Review Board, thus ensuring that only studies of the highest merit and significance are undertaken.

(e) In February 1997 an internal NIH Committee on the Recruitment and Career Development of Clinical Investigators, composed of intramural clinical researchers, offered specific recommendations to NIH management to improve clinical research activities on the NIH campus. Some of the most important recommendations related to increased resources for clinical research, and improvements in tenure and promotion policies that will give added weight to training and clinical service activities by clinical researchers, and provide more time for consideration of a clinical investigator for tenure. The Committee also recommended that active clinical researchers serve on Boards of Scientific Counselors and ICD Promotion and Tenure Committees, and the establishment of an intramural Clinical Research Revitalization Committee to report to the Deputy Director for Intramural Research and the Associate Director for Clinical Research.

These recommendations are currently under active review by NIH management, and are pending implementation.

#### 5. *Review of Clinical Research Applications*

Fair and competent review of clinical research applications, as with all applications, is of fundamental importance to funding the best science. The issues surrounding the review of clinical applications are currently under discussion by both the Division of Research Grants (DRG) under its new Director, and by a working group of the Peer Review Oversight Group (PROG).

(a) Dr. Ellie Ehrenfeld, the Director, DRG, has made the review of clinical research a major focus since her arrival at NIH, and has solicited the input of the clinical research community. She has also recruited a clinical researcher from academia to spend the next year in DRG to work on these issues.

(b) A working group of the NIH Peer Review Oversight Group (PROG) has been formed to develop an evaluation procedure for determining whether scientific peer review panels that review clinical grant applications are adequately constituted to provide competent review of clinical research proposals. Specifically, the Group's initial activity focuses on the clinical expertise on the various review panels.

(c) The National Cancer Institute (NCI) has recently implemented an Accelerated Executive Review (AER) that allows a broader emphasis on funding new and competing research grant applications. In fiscal year 1996, the NCI Executive Committee reviewed 51 applications under the AER (31 on basic research and 20 on patient-oriented research [POR]), and recommended 23 awards, for a total cost of \$6.7 million, nine of which were for POR.

(d) The National Institute of Allergy and Infectious Diseases (NIAID) is applying newly-developed, streamlined procedures of grants management, including electronic peer review and early Council review, to expedite the evaluation and funding of clinical research grant applications.

#### 6. *Research Training and Career Development for Clinical Researchers*

(a) A new one to two-year Clinical Research Training Program (CRTP) will start in the NIH intramural program in the summer of 1997. Nine Clinical Research Scholars were chosen from 78 third-year medical and dental student applicants. A senior NIH clinician-researcher will mentor each Scholar through an individualized research program combining clinical protocols and laboratory studies. Scholars will also complete the NIH Core Course in Clinical Research, which is designed to provide basic knowledge and skills to new clinical investigators at NIH.

(b) The NIH is exploring a number of possible mechanisms to enhance the quality of clinical research training and career development. Projects undergoing discussion and design that could be funded within the fiscal year 1998 President's Budget request include the following:

(i) National Research Service Award (NASA) Research Training Grants.

The NIH is considering the expansion of clinical research training for medical and dental students supported by Institutional NASA Short-Term Research Training Grants (T35) and similarly training Ph.D.s in clinical research using NASA Institutional Research Training Grants (T32) and Individual Postdoctoral Fellowships (F32).

A program similar to the NIGMS MSTP program is being considered for developing research training for medical students, leading to the award of further advanced degrees. Educational programs of this type are already in place at certain institutions such as Johns Hopkins University and Yale.

(ii) Clinical Research Mentored Scientist Development Award Institutional (K12).

This award will allow institutions to attract highly qualified and highly motivated candidates into a training program in patient-oriented research. Such a program would offer courses in epidemiology, biostatistics, bioethics, experimental design and others, as appropriate. The institution may also offer short rotations with several

different faculty members so that candidates can explore a number of clinical studies before they select a project. This program would be designed to recruit clinicians into a patient-oriented research fellowship either at the end of their general medical or surgical residency or during the research fellowship portion of their subspecialty training.

(iii) Clinical Research Mentored Scientist Development Award: Individual (K08).

This award will support individuals who wish to engage in a period of closely supervised career development. It could be used in conjunction with the program award described above and also would permit candidates to engage in development of their capacity for clinical research at institutions that have not yet developed a mature institutional program.

(iv) Academic Clinical Enhancement Award (K07).

This award will provide "protected" time for fully trained young clinical researchers to focus a portion of their efforts on research and on the establishment of high-quality clinical research training programs at their institutions. Many young clinical faculty find that much of their time is spent seeing patients as a way of generating clinical income for their departments and institutions. Time remaining to develop and conduct research is limited and the time necessary to establish an academic program in the area of clinical research is even more limited. This award would permit young clinical faculty to devote 25 percent or more of their efforts to organizing a patient-oriented research training program. Candidates will be clinicians who have demonstrated a capacity to conduct independent patient-oriented research.

(c) NIAID is conducting a review of its research training programs in infectious diseases to ensure that they are producing investigators capable of carrying out independent research in clinical studies.

(d) NCI will announce shortly a Career Transition Award. It will support outstanding, newly-trained basic or clinical investigators in the development of independent research skills through a two-phase program: an initial appointment in the NIH Intramural Research Program and a period of support at an extramural academic institution. If successfully, this program may provide a model for other Institutes and Centers to follow.

#### *7. Loan repayment for clinical researchers*

The NIH loan repayment program is currently limited to scientists in the Intramural Research Program. To broaden the eligibility for the loan repayment program to include clinical researchers at academic health centers throughout the country would require a legislative change.

#### *8. Examples of Other Clinical Research Initiatives*

(a) The NCI and the Department of Defense (DOD) have signed an agreement to allow DOD medical beneficiaries to participate in NCI-sponsored clinical trials at various centers, reimbursed through TRICARE/CHAMPUS, the DODs health program.

(b) NCI plans to expand the Physician Data Query information system which allows physicians to have quick access to information about available cancer protocols at research institutions close to their medical practices.

(c) In collaboration with the Health Care Financing Administration, the National Heart, Lung and Blood Institute (NHLBI) is sponsoring a randomized trial, the Lung Volume Reduction Clinical Trial, to determine the effectiveness, the benefits and the risks as well as the long-term outcomes of such surgery for patients with end-stage emphysema.

(d) In fiscal year 1997, MAID will fund ten new clinical research initiatives and also will announce its intent to fund 12 additional initiatives in fiscal year 1998 for studies of AIDS, vaccine development and testing, chronic fatigue syndrome, immunological effects of aging, women's health issues, sexually-transmitted disease in adolescents, organ transplantation and emerging and re-emerging infectious diseases, including malaria. These initiatives range from small pilot studies to large phase II and III clinical trials.

#### *9. Partnerships in clinical research*

During 1996 and early this year, the Chair of the NIH Director's Clinical Research Panel, other members of the Panel and the NIH staff met with many of the partners who participate in clinical research, including representatives of the academic health centers, the pharmaceutical industry, managed care organizations, philanthropic foundations, biomedical associations, organizations such as the American Association of Medical Colleges and the American Medical Association, and members of Congress.

(a) Academic Health Centers (AHCs). The initial recommendations of the CRP were widely circulated to the AHCs and comments are under review.

(b) The pharmaceutical industry. The industry provides the largest support for clinical research in the U. S. It spends approximately \$4 billion each year. Meetings with representatives of nine large pharmaceutical companies have been held. Possible cooperation in areas of clinical research training and drug development was discussed.

(c) Managed care organizations. Under the aegis of the American Association of Health Plans, the umbrella organization for 1,200 managed care organizations (MCOs), meetings were held with seven MCOs that have extensive research portfolios and have received NIH funding for some of their research projects. A high-level MCO official, who is also a clinical researcher, has been appointed on a part-time basis as an NIH Fellow in Managed Care. He serves as liaison to enhance communications between the NIH ICDs, the academic health centers and the MCOs. Other goals are to advance clinical research through greater involvement of the MCOs and their patients in peer-reviewed research studies and to explore models of MCO collaborations with NIH and the ABCs. An NIH-wide Managed Care Workgroup with representatives from each ICD has been convened to serve as a focus for discussing and coordinating collaborations with the managed care community.

Dialog between NIH and its partners in clinical research continues with a goal of obtaining optimum national funding for clinical research, improving support mechanisms for and research training of young and mid-term clinical investigators and publicizing the benefits of U.S. clinical research. The NIH will maintain and increase its support for clinical research so that the health of the men, women, and children in this country and throughout the world is improved.

#### REMARKS OF SENATOR HARKIN

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I apologize to you and to the distinguished Director of NIH, and all the Directors of the various Institutes, for being here late. We had a very important press conference that I had to participate in. So I apologize.

I only really have one question that was spurred by an opening comment by someone that my staff told me about that I want to get to. But, again, I want to thank all of you, especially all of the Directors, for continuing to lead the Institutes under some adverse circumstances, in terms of funding, and for maintaining our pre-eminence in the world community, in terms of biomedical research.

You have heard me say many times that NIH is really, I think, the jewel in the crown of all of the research we do in this country. And I have been working for several years, first, with Senator Hatfield and now with Senator Specter, to try to find a new source of revenue and funding for NIH. I still think that we are going to get it done, and I hope ratchet NIH up to a higher level than what it has been in the past. But I will not get into that now, other than to say thank you to all of you.

And I am aware that in many circumstances, Directors have gone outside of their Institutes to speak to colleges and high schools and other entities like that to encourage young people to take up research. Dr. Varmus, I hope that you and all the other Directors will keep that up. And I hope that you will promote that even more. So if you need more money in your travel allowance for that, let me know. [Laughter.]

We need to get out and get these young people stimulated to take up research. There is just so much happening in medical research now. And I think if we can provide the funding in the future and get you people out to stimulate these young people, I think we will draw some of them into research. So keep up that good work, too.

Two things. First, new drug discoveries. I will not ask a question about that now. I will submit it in writing. Especially, Dr. Klausner, I want to talk to you about that. What are we doing in terms of new drug discoveries, and what is the structure and how are we proceeding? Is it good? Is it bad? Do you think what we are doing is sufficient?

#### CLONING RESEARCH RESTRICTIONS

The second question I had was—and I know that Senator Specter is anxious to get on to the next panel—you know from a previous meeting we had of my interest in cloning and why I think it holds great promise for us in the future. I would not want to see us, in any way, try to restrict legitimate scientific research and inquiry. And I do not believe we can. I believe this investigation is going to go forward.

Now, to have parameters on, as I have said before, how we conduct scientific research and what ends it is being used for, I think are legitimate discussions for public policy. But to try to put a noose around something and to end something, and say no, you cannot even go down that pathway, I think is wrong. And so I think there is a lot of promise in cloning. And I do not mean clone a person. That is not what I am talking about. I am talking about cloning cells and I am talking about cloning DNA. I am talking about the different things that we can use that can play a major role in quality of life and saving lives and curing a lot of illnesses.

I am curious, Dr. Varmus, as to whether or not you feel that the President's directives are not restrictive enough—as I understand the question or the statement that was put earlier when this panel met about an hour ago that one of my colleagues said that they did not think the President's proposal or the proposal coming out of this Commission was restrictive enough. I just wondered if you wanted to comment on that.

Dr. VARMUS. Thank you, Senator Harkin, for the opportunity.

Senator Bond made a couple of comments about the President's proposal that I think require some correction. First, the Senator objected to the sunset clause that is in the proposed Presidential bill, on the grounds that ethics would not change. Well, I think there are a couple of reasons to argue for reevaluation of the ban that he is asking for.

One, of course, relates to the point you just made—namely, that it would be important, some years after the bill was passed, to be sure that the bill had not infringed upon our ability to conduct science that we all believe is ethical. You have named a number of areas of research that might be excluded by a bill that was not properly framed.

We believe that the bill the President has sent to the Congress places appropriate walls of demarcation between what is being forbidden by the bill and the science that you and Dr. Collins have described—the cloning of cells, the cloning of DNA, the cloning of animals—that we believe is appropriate to pursue. And we would want to reevaluate a bill some years later to be sure that it was not excluding valuable and ethical research.

The second point I would make about Senator Bond's comments is that he argued that the bill would apply only to federally funded

research. That is not the case. The bill would apply to all efforts to use nuclear transfer to create a human being, regardless of how the cloning was supported.

Senator HARKIN. Thank you for clarifying that, Dr. Varmus.

Again, thank you, Mr. Chairman. Thank you again.

And thank all of you Directors for the great leadership you have provided in our country. My hat is off to all of you. Thank you.

Senator SPECTER. I join my colleague, Senator Harkin, in complimenting you on the work you have done. We want to be supportive. When you submit the supplementals, do it in a way which will be as helpful as possible to the objectives which we are looking for. You have great Institutes. We are very proud of the work you have done. We are very pleased. We want to support you to the fullest extent we can.

We will now turn to panel 2, to discuss the new age medications and their implications. Recently drugs called protease inhibitors have been found to be remarkably effective in suppressing the replication of the AIDS virus in infected individuals. This has meant literally a new lease on life for many people with AIDS.

This hearing is still in process. If you would exit quietly, we would appreciate it, so we can move on to panel 2. There have been four such drugs approved by the FDA out on the market. And we can anticipate additional anti-AIDS mechanisms.

#### PANEL 2

#### STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

#### ACCOMPANIED BY:

CLAUDE EARL FOX III, M.D., M.P.H., ACTING ADMINISTRATOR,  
HEALTH RESOURCES AND SERVICES ADMINISTRATION

F.E. THOMPSON, JR., M.D., M.P.H., STATE HEALTH OFFICER, MISSISSIPPI STATE DEPARTMENT OF HEALTH

DANYSE LEON, ON BEHALF OF THE CIRCLE OF CARE AND AIDS POLICY CENTER, PHILADELPHIA, PA

KIM WILLIAMS, ON BEHALF OF THE SOUTH MISSISSIPPI AIDS TASK FORCE, BILOXI, MS

#### SUMMARY STATEMENT OF DR. ANTHONY S. FAUCI

Senator SPECTER. We would now like to turn to our second panel. Our first witness is Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases. He began his career at NIH as a clinical associate at the Laboratory of Clinical Investigation. He is a graduate of Cornell Medical College. He made significant contributions to research on immune medicative diseases, including the understanding of how the AIDS virus destroys the body's defenses, leading to its susceptibility to deadly infections.

We are just a little late as we are proceeding, so we would ask our witnesses to stay within the 4-minute time rule, which we will establish on our clock, please.

Dr. Fauci, the floor is yours.

Dr. FAUCI. Thank you very much, Mr. Chairman. It is a pleasure to be here with you today.

What I would like to do is briefly outline for you the basis and the process for the development of recommendations for the treat-



ment of HIV-infected individuals. This slide here shows something that has been known for some time; namely, when HIV-infected individuals get infected, there is a burst of virus, as shown in the red triangles, which gets suppressed somewhat after a few weeks. But what was not known years ago is that the virus continues to replicate throughout the course of disease, even in people who are clinically latent and feel quite well.

This has now become critical to the philosophy behind the treatment of HIV-infected individuals because, as opposed to following the level of the CD-4 count, which is not necessarily a good prognostication of where the disease is going—it only tells you what the state of immunosuppression is now—the virus has become much more important because of its rapid turnover.

In fact, if you look at studies that have been done, it is very clear now that if you look at individuals who have high levels of virus, their course is much more aggressive and fulminant than those individuals who have a lower level of virus. So the philosophical basis of treating individuals based on the level and turnover of virus has been something that has now evolved over the past few years.

Historically, back in 1987, when we only had one drug, AZT, we were able to accomplish a bit of that by decreasing the virus, but that was for a very limited period of time. It would generally bounce back, usually in a resistant form. In 1994, with the two-drug combinations, we had a better effect on decreasing the virus, and it lasted a bit longer. But the long-term clinical benefit, and certainly the ability to suppress virus to completely below detectable level, was not successful. So what had been standard therapy in 1987 and 1994 is now generally considered suboptimum therapy.

In contrast, in 1996–97, with the triple combination, including the protease inhibitors, the level of virus could decrease now in most cases to below detectable level for a considerable period of time. We know now that in the short range, this is associated with a clinical benefit. What we do not know is what the long-range effect would be, balancing toxicity and other effects on lifestyle of an individual, compared to the potential beneficial effects of having this rather substantial decrease in virus.

So now we have a wealth of studies and a wealth of information. These are things I do not want to necessarily go through; they just emphasize the point that there are a large number of trials, most of which have shown virological beneficial effect, a few of which have shown short-term clinical effect.

What this has led to is an understandable confusion on the part of both patients and physicians on just how to use these drugs, including the protease inhibitors. Based on that and based on the need to have some guidance, flexible guidance, Secretary Shalala asked Eric Goosby of the Office of AIDS and HIV Policy at the Department, together with Mark Smith, who was then vice president of the Henry J. Kaiser Family Foundation, to put together a panel of experts, which was chaired by myself and Dr. Bartlett from Hopkins, including private and public sector individuals, patient advocates, patients themselves, insurers, and individuals interested in AIDS policy. Over a period of several months, they have evolved, based on principles that had been laid down by an NIH panel, to come up now with recommendations which will be available for

public comment sometime next week for a 30-day period of commenting.

The fundamental basis of the recommendations is to be aggressive in suppressing the virus to as low as possible for as long as possible. Once the decision is made, then a whole series of recommendations about how to start, what to start with, when to change, what to change to, all of these will be asked for public comment, as I mentioned, beginning next week.

PREPARED STATEMENT

Then, finally, let me close—I was asked by the staff to just spend one-half minute on something that is equally as important as therapy, and that is prevention because, despite the substantial advances in HIV therapeutics, a comprehensive approach to the HIV epidemic will have to include the development of a safe and effective vaccine, which you alluded to in the previous panel. As I can just summarize in a moment, we have had an acceleration of our effort, with a 33-percent increase in vaccine resources from 1996 to 1998, as well as a number of other efforts, which I would be happy to discuss during the question period.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

The impact of the AIDS pandemic is staggering. Worldwide, more than 29 million people have been infected with the human immunodeficiency virus (HIV), the cause of the acquired immunodeficiency syndrome (AIDS). An additional 8,500 people become infected with the virus each day. Globally, at least 8.4 million individuals with HIV/AIDS have died, including more than 360,000 people in the United States.

Despite the mounting toll of HIV in this country and abroad, recent advances in HIV research have provided a degree of optimism for HIV-infected people and for those of us working to understand and control this devastating disease. In particular, progress in understanding the fundamental mechanisms of the HIV disease process, and advances in AIDS clinical research have allowed us to formulate new strategies for treating HIV-infected people.

The rapidity of advances in AIDS pathogenesis and therapeutics as well as the recent availability of a large number of drugs for the treatment of HIV-infected individuals have led to uncertainty among many patients and their physicians regarding the optimal approach to the treatment of HIV infection. In particular, questions arise regarding when to initiate therapy, which drugs to use, how to monitor the effects of therapy, when to change drugs, and which drugs to change to. Since there are few, if any, clinical trials with long-term clinical endpoint results that have come to fruition, there is a need for a coherent set of flexible treatment guidelines upon which patients and their physicians can rely as they engage in the complex task of the treatment of HIV infection.

In this regard, two expert panels convened in 1996 by the National Institutes of Health ("Principles" panel) and the Department of Health and Human Services (DHHS) and the Henry J. Kaiser Foundation ("Guidelines" panel) have synthesized the recent advances and articulated principles of therapy and specific treatment recommendations for HIV-infected adults and adolescents. Two complementary draft documents, the Report of the NIH Panel to Define Principles of Therapy of HIV-Infected Adults and Adolescents, will soon be made available for public comment. Following consideration of comments and revision, the documents will be published in the *Morbidity and Mortality Weekly Report* of the Centers for Disease Control and Prevention and subsequently in a peer-reviewed medical journal.

As discussed in the draft documents, we have learned in recent years that HIV actively replicates throughout the course of HIV disease, even when a patient may feel perfectly well. The level of HIV replication is striking: billions of HIV particles may be produced and cleared from an individual's body each day. Epidemiologic cohort studies have demonstrated that the level of HIV in an individual's plasma soon

after infection is highly predictive of the rate of progression of HIV disease in that person; that is, patients with high levels of virus are much more likely to get sicker, faster, than those with low levels of virus. Certain short-term clinical trials have shown that reducing the levels of HIV in plasma is directly associated with a clinical benefit.

Potent drug combinations, notably three-drug combinations that include a protease inhibitor in combination with two other antiretroviral drugs, such as those in the AZT class of compounds, are now being used to control the replication of HIV in many patients to a degree and for a duration not previously possible with one- or two-drug antiretroviral regimens. Several studies of triple-drug antiretroviral therapy have demonstrated both virologic and clinical benefits to patients.

As delineated in the draft DHHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, these and other findings have provided the rationale for aggressive antiretroviral therapy for HIV-infected people, as well as for routinely using newly available blood tests to measure a patient's viral load when initiating, monitoring and modifying anti-HIV therapy. Today, the central tenet of antiretroviral therapy is to reduce the amount of HIV in a person's body to the lowest possible level for as long as possible, with the goal of forestalling disease progression.

The new draft documents reflect the current state of knowledge regarding the HIV disease process and the use of antiretroviral drugs, and will be updated periodically to reflect changes in the rapidly evolving field of AIDS research. The draft treatment guidelines are not intended to substitute for the judgment of a physician expert in the care of HIV-infected individuals. Indeed, they should be used in the context of an ongoing dialogue between patient and clinician, including discussion of the many uncertainties in HIV therapy. In this regard, although we are hopeful, we do not yet know for certain whether early treatment of asymptomatic, HIV-infected individuals will have long-term clinical benefits, or if cumulative toxicity and the development of drug resistance will ultimately outweigh the benefits of aggressive therapy for some patients.

Finally, despite important advances in HIV therapeutics it is still critical to pursue vigorously the development of a safe and effective HIV vaccine. At the National Institutes of Health, we have formulated a balanced strategy to HIV vaccine development. Basic research is helping to answer important questions about HIV and the immune responses that might protect an individual from HIV infection or prevent the progression of disease. At the same time, clinical researchers are testing candidate vaccine products in small-scale trials. Early studies of single product regimens have given way to more complex strategies, including priming the immune system with a recombinant vector vaccine expressing HIV proteins and then boosting the immune response with a purified HIV recombinant protein. A Phase II trial employing this approach recently opened to patient accrual and will enroll 420 volunteers in 13 U.S. cities.

The newly established NIH AIDS Vaccine Research Committee, headed by Dr. David Baltimore, plays a central role in advising the NIH on key scientific questions in HIV vaccine development. In addition, the NIH has begun development of a Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary research into basic and clinical immunology and virology, and ultimately vaccine design and production. NIH is also preparing for eventual large-scale efficacy trials of HIV vaccines by establishing community linkages and conducting the epidemiologic, virologic and behavioral research required to ensure the success of such trials.

Recent progress in HIV therapy has been extraordinary, and I am confident that development of an HIV vaccine that is safe and effective will be accomplished. In conclusion, in order to control the HIV pandemic in this country and abroad, an AIDS vaccine and effective antiretroviral drugs are essential.

#### SUMMARY STATEMENT OF DR. EARL FOX

Senator SPECTER. Thank you very much, Dr. Fauci. We will come to some more development during the questions and answers.

I turn now to Dr. Earl Fox, Acting Administrator of the Health Resources and Services Administration. Before joining HRSA, Dr. Fox was Health and Human Services Regional Administrator for region 3 in Philadelphia, and subsequently, the Department's Deputy Assistant for Disease Prevention and Health Promotion. He is

a graduate of the University of Mississippi School of Medicine. He comes with accolades in all directions—Mississippi, Pennsylvania.

Dr. Fox, we welcome you here and look forward to your testimony.

Dr. Fox. Thank you, Mr. Chairman. You have my statement.

As you know, HRSA administers all four titles of Ryan White, and first we want to thank this Congress and the administration for the titles I, II, III, and IV funding. As you know, there has been over a 200-percent increase over the last couple of years. We now have over \$1 billion in this program, and \$380-some-odd, \$368 million, that total amount that is spent in Ryan White, of which 167 is for ADAP.

We know that the combination therapy that is evolving is going to cost somewhere in the neighborhood of \$10,000 to \$13,000 a year, and that the support for these drugs actually has come from a variety of different programs. It has come from the Ryan White ADAP program that is administered by the State as well as from State Medicaid programs. There are some 31 States also that are voluntarily appropriating money from ADAP.

One of the problems in trying to look at the numbers is to put together all the figures to determine actually what is out there and what needs to be out there. We have been trying to piece together public and private data from CDC, from HCFA, from our own data, as well as the Office of the Secretary.

CDC estimates that there are probably—the midrange of the number they estimate is probably some 775,000 individuals that are living with HIV in this country. Probably 500,000 of those actually know their HIV status.

Current estimates would support the figure of about 200,000 that are currently paid for either from Medicaid or from ADAP. About 40,000 at any one time from ADAP and about 160,000 a year on Medicaid. The remainder, some 300,000, actually we do not know how much private insurance covers, and there is a lot of difficulty with getting this number.

We do know that with combination therapy there would be earlier intervention, and therapy with a large number of drugs. In addition to not knowing exactly how many people we will need to support, we also know that there is some difficulty in getting numbers from our existing programs. For instance, the eligibility criteria on the ADAP programs in all the States varies, and those are determined by the State. There is not a national criteria that is determined by the program.

The funding levels, the prescription restrictions, the number of prescriptions that are provided, the actual formulary for the ADAP programs are determined by State, and in fact one of the problems with trying to just add the numbers up is that States may not even keep a waiting list beyond those numbers of individuals that they know they have funding for, so because of restrictions at the State level around deficit spending, we feel like the waiting list is probably not a good reflection.

But it is clear that significant demand exists, and we know that this, again, will continue.

Just briefly to tell you, because it does impact on the availability of drugs, what HRSA has done around trying to get the best buy

for the dollar, which I know is of interest to Congress and this committee, we have had some technical assistance, contacts with the ADAP's, and we feel like over time that has resulted in some cost savings.

There actually is a section of the Veterans Health Care Act that provides for some lowering of the drug pricing around the same kinds of discounts that Medicaid gets, and we know that the number of States that have taken advantage of that has increased by over 50 percent.

There is a voluntary manufacturer rebate. States are receiving discounts. There are probably 40 States that have some mechanism, and it varies all over the waterfront, for some type of price reduction in the AIDS drugs.

In addition to that, we have just recently submitted a Federal Register notice to make available a national rebate. I was talking about this earlier with Senator Cochran about a national rebate that would be available to all State and ADAP programs that would hopefully further drive down the cost for these AIDS drugs.

So we are looking at trying to make every economy we can there.

Finally, in addition to that, we only have probably one-half of the States that participate in what is called the 3-40 mechanism, or a program that we have for discounts from manufacturers, and we plan to submit a proposal to the Federal Register to actually require participation of all States either through the direct discount or through the rebate mechanism so that we again get the best buy for the dollars.

And just in the closing comments let me say that the whole problem around drug funding we think is not just an ADAP problem. It is in part an ADAP problem. It is a problem with trying to get States to provide some funding. We know that 10 States contribute the bulk of State moneys, and there are some 20 States that do not put any State dollars in.

It is an issue of trying to look at Medicaid. There is a great variety of room for what Medicaid can fund, and in the States that have broader Medicaid programs Medicaid pays for every fourth patient that ADAP pays for one, so it is a problem with that.

We want to continue to try and encourage the drug companies, and as the Government buys more drugs we think the drug companies should increase the amount that they provide in free drugs, because we are obviously buying more drugs and hopefully adding to their bottom line as well, so we think they should provide more.

#### PREPARED STATEMENT

So we think that it is a joint problem, that ADAP alone is not the solution, and I have some other comments I would be glad to make later about some other ideas we have about ways this problem could be addressed, but the bottom line is, we appreciate the support of both the administration and this Congress and ADAP in addressing this problem.

Thank you.

Senator SPECTER. Thank you, Dr. Fox.

[The statement follows:]

## PREPARED STATEMENT OF DR. CLAUDE EARL FOX, III

Mr. Chairman, I am Dr. Claude Earl Fox, Acting Administrator of the Health Resources and Services Administration (HRSA). HRSA is the Agency that administers the safety net programs providing health care services to the uninsured and vulnerable individuals of our nation. These programs include Community Health Centers, the Maternal and Child Health Program, and the Ryan White Program.

I appreciate the opportunity to discuss the recent developments involving HIV/AIDS pharmaceuticals and the related health care policy and financing issues, because these will be critical for both the public and the private sectors.

*Administration's record on Ryan White and ADAP*

The Clinton Administration has worked diligently with both parties in Congress to increase funding for grants authorized by the Ryan White CARE Act. The Ryan White program has grown from \$386 million in fiscal year 1993 to \$1.036 billion in the fiscal year 1998 Budget, a 168 percent increase since the Administration took office.

In particular, the Administration has sought major funding increases for AIDS Drug Assistance Programs authorized under Title II of Ryan White. Since the FDA began approving protease inhibitors in the Winter of 1996, the Administration has proposed and supported specific funding increases for Title II ADAP activities. In March of 1996, the President proposed and the Congress enacted a \$52 million set-aside in fiscal year 1996 for ADAP programs. Just five months later, he proposed another Budget Amendment for fiscal year 1997 to increase this earmark by \$65 million to a total of \$117 million. However, the Congress appropriated \$167 million for the ADAP set-aside in fiscal year 1997, \$50 million above the President's request.

While we are proud of our record, we are also pleased with the efforts of our partners—States and local governments—who have contributed significantly to ADAPs and other AIDS treatment programs in expanding access to pharmaceuticals. Total funding for State ADAP programs in fiscal year 1997 is an estimated \$368 million, \$167 million of which (or about 45 percent of total ADAP funding) derives from the aforementioned ADAP earmark. So while the Federal government is a major contributor to State ADAP budgets, we will continue to look to our partners at the State and local level to play a major role in addressing this situation as well.

*Background*

The rapidly evolving standard of care for HIV, which holds great promise to extend the length and quality of the lives of people with HIV, comes with a high price tag. The more conservative estimates are that combination anti-retroviral therapy, including the newly approved protease inhibitors, costs at least \$10–12,000 a year per patient. The principal Federal programs supporting access to combination HIV therapy for the poor are Medicaid and the Ryan White CARE Act's AIDS Drug Assistance Program (ADAP). Both programs are administered by the States based on Federal guidelines that allow for significant variation in financial eligibility criteria and benefits. State contributions, which are required by Medicaid and are voluntarily appropriated for ADAP by 31 States, allow Federal expenditures to provide significantly more drug therapies for people living with HIV.

*The possible demand for combination therapy*

Limitations in available public and private data make it impossible to calculate the possible demand for these drugs with any precision. The Centers for Disease Control (CDC), the Health Care Financing Administration (HCFA), and the Health Resources and Services Administration (HRSA), as well as the Office of the Secretary have worked together to establish a reasonable estimate of the level of potential demand facing these Federal/State programs, and the private health care sector. Approximately 775,000 individuals in the United States are living with HIV disease (using the midpoint of the estimate of 650,000–900,000). The CDC estimates that about two-thirds (500,000) of those people know their HIV status. In the short term, therefore, while efforts are underway to encourage all at potential risk to learn their HIV status, the immediate demand for public and private primary care and drugs will probably be limited to those 500,000 people.

Some (albeit unknown) proportion of these individuals will likely be covered by private insurance; others are likely to be low-income and meet other categorical criteria for Medicaid coverage or other public programs. Medicaid and ADAP provide drugs for approximately 200,000 people. According to HCFA actuaries, Medicaid may be providing services to approximately 160,000 eligible people living with AIDS and HIV; ADAP currently serves approximately 40,000 people at any one time, and

over 80,000 cumulatively during the year. These 200,000 people constitute 40 percent of the 500,000 estimated by CDC to have HIV and know their status.

Not all people with HIV disease will use combination therapy, but the forthcoming release of treatment information which will recommend earlier intervention with combination therapy may motivate more people with HIV to learn their status, enter primary care, and seek clinically appropriate access to pharmaceutical treatment.

In addition, it is not known how many more individuals will financially need public support to access combination therapy. The variation in eligibility criteria, funding levels, and prescription restrictions for State Medicaid and ADAP programs, as well as variation in formularies among ADAP programs, make it hard to determine the potential demand for these drugs. Some State ADAPS report limited formularies, waiting lists, and more restricted access to specific drugs on formularies because of increased demand on these programs. Combined with the overall costs listed above, it is clear that significant demand exists, for both prescription drugs and underlying primary care services necessary to deliver the treatment.

#### *Promoting maximum effectiveness of ADAP*

While CARE Act AIDS Drug Assistance Programs can only be part of the response to this situation HRSA has taken multiple steps to assure that Federal funds appropriated for ADAPs achieve maximum results. For example, regular technical assistance conference calls for all ADAPs were initiated in September of 1996 and four of the first seven calls focused on cost containment approaches. The cumulative impact of these activities is summarized below:

Participation in the Section 602 Veterans Health Care Act Program (“ODP Pricing”) increased 53 percent from July 1996 to May 1997 (from 15 to 23 States).

The number of States securing voluntary manufacturers’ rebates increased from 27 to 36 during the same time period, a 33-percent increase.

The number of States receiving discounts from pharmacies or manufacturers also increased substantially, and the number of States using multiple cost containment strategies increased over 100 percent—from 20 to 41.

HRSA has developed a Federal Register Notice to establish a rebate component within the Section 602 Program which would make the program accessible to virtually all ADAPs.

HRSA continues to develop its capacity and refine its approaches to assisting States in managing their ADAP programs with maximum efficiency. Recent innovations have included joint ADAP and ODP site visits to facilitate participation in the Section 602 Program, convening a group of key State representatives to define a workable model for forecasting program utilization and costs, and proactive enrollment of all State ADAPs in the Section 602 program to provide non-participating States with maximum flexibility for participating in ODP in the near future.

Despite the progress made through these efforts, HRSA believes there are still greater economies to be achieved in ADAP programs.

#### *Policy responses*

In addition to the establishment of the rebate option in the Section 602 Program, HRSA intends to require all States to utilize the 340b mechanism to achieve reliable and consistent levels of cost-savings on all medications on their ADAP formularies. This is expected to reduce not only the cost of drugs purchased by ADAPs, but the level of burden on States associated with individually negotiating discounts with multiple manufacturers. We will publish a notice of our intent in the Federal Register to obtain comment before making this a condition of our Ryan White Grants.

*Encourage States to Contribute Additional Funds to ADAP.*—ADAP set-aside funds currently do not require matching funds from States. Currently, 10 States contribute the bulk, approximately 90 percent of the State contributions, (examples are: California, Illinois, Louisiana, Massachusetts, New York, Ohio, Pennsylvania, Puerto Rico, Texas, Washington.) About 20 States (Alabama, Mississippi, Arkansas, Arizona, Florida, Kansas, Michigan, and Minnesota for example) do not contribute any funding at all. These States should be encouraged to contribute to ADAP.

*Encourage ADAPs to Target Resources to Low-Income Individuals.*—HHS has been encouraging States to target low-income individuals in guidance that says standards should be anchored to federal poverty guidelines. Twenty-two states have focused their eligibility on low income. All States are encouraged to review their financial eligibility criteria and assure that they focus on providing coverage for low-income people with HIV.

While the potential demand for these medications is significant, we look forward to working with Congress, as well as our partners at the State and local government to address this situation.

It should be noted, however, that the ability of HRSA to respond to State-specific crises through ADAP is constrained. The formula by which any ADAP appropriation must be allocated among the States is established in the CARE Act. This formula, and therefore the Agency, cannot respond to specific disproportionate State-level difficulties that are very often compounded by factors such as State-defined limitations in Medicaid programs (in terms of both eligibility and benefits) and lack of State participation in the cost of ADAPs.

#### *Conclusion*

ADAP alone is not the solution to the AIDS drug issue. The solution must be a system-wide approach, combining private, state, and Federal resources. No single Federal or State program can provide a total solution. With the private sector, it is critical that State and Federal programs work together to maximize resources. Medicaid and the Ryan White program must be examined in light of this new hope offered by drug therapy.

The pressures on policy makers, clinicians, and service providers to expand access to care have been challenging for a decade-and-a-half. They have not ever lessened, but in the last 18 months their source has changed profoundly.

Up until very recently, the pressures we all felt were tragically linked to whether or not we had the will and the resources to assure that the most vulnerable members of our society who were infected with HIV or had AIDS would have a reasonable quality of life and would die with some level of dignity.

The question now appears to be how many people who could live longer and healthier will have access to the necessary treatments to achieve that potential.

I appreciate the opportunity to discuss these critical issues today.

#### SUMMARY STATEMENT OF DR. ED THOMPSON

Senator SPECTER. Now we will turn to Dr. Ed Thompson, State Health Officer with the State of Mississippi since 1993. Prior to that, he directed the Mississippi State Department of Health Disease Prevention, a graduate of the University of Mississippi School of Medicine, master's degree in public health from Johns Hopkins University.

Welcome, Dr. Thompson, and the floor is yours.

Dr. THOMPSON. Thank you, Mr. Chairman. I certainly agree with Dr. Fox that ADAP is not the complete answer. The answer has many parts. ADAP is, however, a major part of that answer, and it is primarily to address ADAP that I am here. However, my remarks go beyond just the ADAP and talk more also about a greater need than that.

Mississippi is a relatively average State with regard to AIDS cases. In 1996 we were 28th among States for AIDS cases and 22d in AIDS case rates.

We are 1 of only 26 States that require reporting of all HIV cases; 512 new HIV infections were reported in 1996. If our first quarter this year trend holds, just over 600 new cases will be reported in 1997.

HIV is now one of the five leading causes of years of potential life lost in Mississippi, behind unintentional injuries, heart disease, cancer, and homicide.

As with the rest of the country, AIDS is no longer a disease of gay men and IV drug users in Mississippi. In 1996, less than one-half our new AIDS cases fell into these categories. An estimated three-fourths of our new HIV cases were in heterosexuals.

Like many other States, Mississippi relies heavily on Ryan White Care Act funding to help cover the treatment needs of persons with



AIDS. Although we devote State funds to AIDS prevention, we, like 22 other States, have, heretofore, not spent State funds for drug treatment through the AIDS Drug Assistance Program, or ADAP.

Under the new guidelines about to be published for the use of protease inhibitor antiretroviral combination therapy—Dr. Fauci referred to these earlier—they cost 10 times more than all other therapies, and these funds will no longer even begin to cover the real needs.

Unlike many other States, because we have HIV reporting, Mississippi is able to have a real idea of what that need might be. There are at least 4,500 known persons in Mississippi with HIV or AIDS. The new protease inhibitor antiretroviral combination therapies are being recommended for many more HIV-infected persons than before.

At \$12,000 to \$18,000 a year for the three-drug regimen alone, the cost to treat just one-half of our cases could range from \$25 to \$40 million for 1 year. With 500 new HIV cases each year, the cost would continue to escalate.

Even to provide combination therapy to all the roughly 880 patients currently enrolled in the ADAP in Mississippi—and I call your attention to an error in my written testimony. It says, receiving assistance through. It should be, enrolled in—will require \$10 million.

Beginning April 1, our Ryan White funds increased to \$2 million, leaving a potential unmet need of \$8 million. Other States face similar situations. The average State contribution to the ADAP is 24 percent of total ADAP funding. The potential need for it outstrips the available State dollars.

Even if States radically increase their contributions, even now, in order to keep those patients already receiving protease inhibitor antiretroviral combination therapy from the ADAP in our State, around 200, on the combination we are having to remove from the program those patients who have Medicaid, and limit the number of drugs, other than those required for the combination therapy, for the remaining patients. Without substantial new funding, more patients will have to be cut from the program in 1998.

All States will have to consider contributing State funds for drug treatment of persons with HIV and AIDS, or sharply increasing their current contribution. We have recommended our State's legislature conduct hearings into AIDS treatment funding before and during the upcoming State budget development process, and I am confident they will do so. I anticipate that some State funding for AIDS drugs will be seriously considered in the next session, but it is not likely the State will be able to afford the multimillion dollar cost of treating the thousands of persons needing the new treatment.

Without increased Federal funding for the Ryan White Program, it may not be possible even to meet the needs of those already on the ADAP in many States. To meet the needs of the far greater number not now being treated presents a national challenge of immense proportions.

In closing, I would offer four recommendations to this committee and to the Congress. First, as you consider treatment and research needs for AIDS, maintain a focus on and funding for prevention.

If we do not, the need for treatment will become impossible to meet.

Second, at least some increase in Ryan White funds for AIDS drugs is needed now, in fiscal year 1997, and additional increases, likely substantial, should be considered in the future.

Third, in considering potential State contributions to AIDS drug funding, take into account the competing needs for States to address other serious health problems, including heart disease, stroke, cancer, and injuries.

PREPARED STATEMENT

Fourth and finally, as part of any consideration of Ryan White funding, address the issue of more equitable distribution of funding among States with and without Ryan White title I metropolitan areas. The current system penalizes more rural States without large cities heavily infected by AIDS.

Senator SPECTER. Thank you very much, Dr. Thompson.  
[The statement follows:]

PREPARED STATEMENT OF DR. F.E. THOMPSON, JR.

I am Dr. Ed Thompson, State Health Officer of Mississippi. As in most States, our State Health Department is primarily responsible for the prevention and control of disease and protecting the public's health through population and community based prevention. Direct provision of medical care has been largely limited to maternal and child health or to medically controllable diseases such as tuberculosis. The rapid increase in the number of persons with HIV and AIDS has faced us with issues regarding treatment of disease that are outside that usual focus and beyond the ability of many states to handle.

Mississippi is a relatively "average" state with regard to AIDS cases. In 1996 we were 28th among states for AIDS cases, with 450 reported to CDC, and 22nd in AIDS case rates, with 16.6 cases per 100,000 population.

For HIV without AIDS, we are above average, but not with regard to numbers. Mississippi is one of only 26 states that require reporting of all HIV cases. We began in 1988, in order to do contact follow up on all cases. 512 new HIV Infections were reported in 1996. If our first quarter trend holds, just over 600 new cases will be seen in 1997.

HIV is now one of the 5 leading causes of years of potential life lost in Mississippi, behind unintentional injuries, heart disease, cancer, and homicide.

*Years of potential life lost—leading causes*

Mississippi—1993

Unintentional injuries .....	1,631
Heart disease .....	1,048
Cancers .....	911
Homicide .....	575
HIV .....	300

As in the rest of the country AIDS is no longer a disease of gay men and IV drug users. In 1996 less than half our new AIDS cases fell into these categories. An estimated three-fourths of our new HIV cases are in heterosexuals.

As in the rest of the country, minorities are over-represented among our cases. In 1996 73 percent of our new AIDS cases and 77 percent of new HIV cases were in African Americans

Like many other states, Mississippi relies heavily on Ryan White Care Act funding to help cover the treatment needs of persons with AIDS. Although we devote state funds to AIDS prevention, we, like 22 other states, have heretofore not spent state funds for drug treatment through the AIDS drug Assistance Program, or ADAP. With the increasing successful use of protease inhibitor/anti-retroviral combination therapy, costing ten times more than older therapies, these funds will no longer even begin to cover the real need. Under the new guidelines about to be published, in order to keep those patients already receiving protease inhibitor combination therapy from the ADAP in our state, we will have to Move from the program

those patients who have Medicaid and limit the number of drugs other than those required for the combination therapy for the remaining patients.

Unlike many other states, because we have HIV reporting, Mississippi is able to have a real idea what that need might be. There are at least 4,500 known persons in Mississippi with HIV or AIDS. The new protease inhibitor/anti-retroviral combination therapies are being recommended for many more HIV infected persons than before. At \$12,000 to \$18,000 a year for the three-drug regimen alone, not any other needed medications, the cost to treat just half of them could range from 25 to 40 million dollars for one year. With 500 new HIV cases each year, the cost would continue to escalate.

Even to provide combination therapy to all the roughly 800 patients currently receiving assistance through the ADAP in Mississippi would require \$10 million. Beginning April 1, our Ryan White funds increased to \$2 million, leaving a potential unmet need of \$8 million. Other states face similar situations. According to information provided by the National Association of State and Territorial AIDS Directors, the average state contribution to the ADAP is 24 percent of total ADAP funding. The potential need far outstrips the available state dollars even if states radically increase their contributions.

All states will all have to consider contributing state funds to the drug treatment of persons with HIV and AIDS or sharply increasing their current contribution. We have recommended that our state's Legislature conduct hearings into AIDS treatment funding before and during the upcoming state budget development process, and I am confident that they will do so. I anticipate that at least some state funding for AIDS drugs will be seriously considered in their next session.

But it is not likely that the state will be able to afford the multi-million dollar cost of treating the thousands of persons needing the new treatments. Without increased federal funding for the Ryan White program, it may not be possible even to meet the needs of those already on the ADAP in most states. To meet the needs of the far greater number not now being treated represents a national challenge of immense proportions.

I offer four recommendations to this committee and to the congress.

First, even as you consider treatment and research needs for AIDS, maintain a focus on and funding for prevention. If we do not, the need for treatment will become impossible to meet.

Second, at least some increase in Ryan White funds for AIDS drugs is needed now, and additional increases, likely substantial, should be considered in the future.

Third, in considering potential state contributions to AIDS drug funding, take into account the competing needs for states to address other serious health problems, including heart disease, stroke, cancer, and injuries.

Fourth, as a part of any consideration of Ryan White funding, address the issue of more equitable distribution of AIDS treatment funding among states with and without Ryan White Title I metropolitan areas. The current system penalizes more rural states without large cities heavily affected by AIDS.

I'll be happy to answer any questions the Committee has, or address any issues not covered that you wish to raise.

#### SUMMARY STATEMENT OF DANYSE LEON

Senator SPECTER. We return now to Ms. Danyse Leon, an HIV-infected mother of two HIV-infected children. She lives with her children in Philadelphia, where they receive assistance from the AIDS Drug Assistance Program for coverage of their drug therapy. They also receive care services through the Circle of Care Project of the Family Planning Council of Southeastern Pennsylvania, a program supported entirely by the Ryan White Care Act.

Ms. Leon has been referred to us by a distinguished—Dorothy Mann from the Family Planning Council of Southeastern Pennsylvania. Welcome, Ms. Leon. We look forward to your testimony.

Ms. LEON. Good afternoon, Senator Specter, and fellow Members of the Congress. I am the mother of a 10-year-old son and a 7-year-old daughter from Philadelphia, PA. We are all living with AIDS. I receive Ryan White care and title IV services through the Circle of Care and the Family Planning Council of Southeastern Penn-

sylvania, which serves children, youth, mothers, and families living with HIV and AIDS in Pennsylvania.

My children and I receive AIDS drug benefits from the Pennsylvania State AIDS Drug Assistance Program. My family and I also receive AIDS services through the Opportunity for Persons with AIDS.

I am pleased to testify today on behalf of the Circle of Care and AIDS Policy Center for Children, Youth, and Families. I am here today to talk about the disease that upsets our lives, and I hope that you will hear my words and hold them close to your heart.

I have been living with HIV for approximately 10 years. We learned about our HIV status after the birth of my second child. Both of my children have been living with HIV all of their lives, and do not understand what it means to be HIV negative.

What they do understand is doctor's visits, demanding drug regimens, side effects, and HIV-related illnesses. In the past, my children have failed to thrive and were often ill, and recently something changed. At the suggestion of my physician at Strawberry Mansion Clinic, which is part of the Circle of Care, my children were prescribed Crixivan, one of the new AIDS drugs called protease inhibitors, combined with DDI and AZT.

They are doing much, much better, and for the first time I have hope. Their viral load has been reduced from a high count of 44,000 to just under 500 in 1 month. Access to these new drugs has literally helped to save our lives.

As a woman living with HIV, I have also been helped by the latest advances in AIDS treatments. After seeing the beginning stages of success for my children, my physician also prescribed Crixivan for me. I took it for about 6 months, and retreated due to kidney problems, but I am hoping to start again with Crixivan or other new AIDS drugs in the next few months.

The combination of new AIDS drugs has given me new hope that I will be able to live a healthier life with my family. For once in my life I have hope for the future of my children's lives, and I have hope that I will be here with them.

But Members of Congress, not all people have access to the new AIDS drugs. I am not a public policy expert, and I do not understand pricing issues or the Federal programs related to AIDS, but I do know that Congress, local communities, and the drug companies must do more to provide access to these new drugs for everyone. It costs me approximately \$3,000 a month for my family to be on the new combination drug therapy. This is expensive, but it must be less expensive than staying in the hospital or going for more doctor's appointments.

We must do more to test the results of the new AIDS drugs, and we must do more to test the drugs in children and pregnant women. You may not know this, but right now none of the new protease inhibitor drugs or combination therapies have been approved for pregnant women, and only two new protease inhibitor drugs have been formulated for use in children, and approved by the FDA for children with AIDS.

One of these drugs is only approved for children 2 years and older. The other drug is approved by the FDA for all children with AIDS. So that means that drugs like Crixivan and others are given

to my children by our doctor on an off-label basis. Children and moms need safe access to these new drugs, and more testing and research are needed.

I have heard other people today talk about the need to educate doctors and patients about the new AIDS drugs and what the new AIDS drugs means for the Ryan White Care Act Program, and I have learned about new AIDS drug treatment guidelines that will be released soon by NIH. Families and doctors need to be educated about how to use those new drugs. Doctors need to be trained on how to use the new drugs with children and youth living with AIDS.

I have been told that the new guideline that will be released by NIH will not include guidelines for children with AIDS, and that the guidelines will be released separately by NIH. I feel the pediatric guidelines should be included with the adult guidelines when they get released, so that everyone has the most current information, and families and other children and youth need to be educated about how to take those drugs together in partnership with the doctors.

My story is not different from other families across the United States. Often women and parents seek treatment only after their children have been diagnosed with HIV, and this is wrong. Too often families struggle with taking the new complicated regimen of AIDS drugs, and are confused about what to take. To change this, American families need the commitment to all Federal AIDS programs.

My family and my family from Philadelphia rely upon Medicaid and the Ryan White Care Act, which provide us with HIV care that helps us cope with the new AIDS drug regimen. Without care, without AIDS research to continue to study these drugs, without AIDS housing and without AIDS prevention we have no chance in succeeding with the new AIDS drugs or preventing further HIV infections.

#### PREPARED STATEMENT

I hope for the day that there will be a cure for HIV and AIDS. I hope that parents will not have to watch their children die from HIV. People suffering from HIV and AIDS need your help—the help they receive from Federal AIDS programs like the Ryan White Care Act and the AIDS Drug Assistance Program to pay for these drugs. This will save our lives and our families. Please continue to support me and my family.

Thank you.

Senator SPECTER. Thank you very much, Ms. Leon.

[The statement follows:]

#### PREPARED STATEMENT OF DANYSE LEON

Senator Specter, Representative Pelosi, and Members of the Senate and House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, my name is Danyse Leon and I am the mother of a ten year-old son and seven year-old daughter from Philadelphia, PA. We are all living with HIV/AIDS

I receive Ryan White CARE Act Title IV services through the Circle of Care Project of the Family Planning Council of South Eastern Pennsylvania, and my children and I benefit from the Pennsylvania state AIDS Drug Assistance Program. I

am pleased to testify today on behalf of the Circle of Care Project and AIDS Policy Center for Children, Youth & Families, which represents 350 HIV health care projects across the country.

I am here today to talk about a disease that dominates our three lives—and I hope that you will hear my words and hold them close to your heart.

I have been living with HIV for approximately ten years. We learned about our HIV status after the birth of my second child. Both of my children have been living with HIV all of their lives, and do not understand what it means to be HIV negative.

What they do understand is our continual doctor visits, demanding drug regimens, and bouts of drug side-effects, and, of course, HIV-related illnesses. In the past, my children have failed to thrive and were often ill. Then, recently, something changed

At the suggestion of our physician at Strawberry Mansion clinic, which is part of the Circle of Care Project, my children were prescribed Crixivan—one of the new AIDS drugs. Combined with DDI and AZT, they are doing much, much better and for the first time, I have hope, real hope. Their viral load has been reduced from a high count of 44,000 to just under 5,000. Access to new AIDS drugs has literally helped to save our lives.

As a woman living with HIV, I have also been helped by the latest advances in AIDS treatments. After seeing the beginning stages of success for my children on Crixivan, DDI and AZT, my physician also prescribed Crixivan for me. After six months I retreated from this therapy due to kidney problems—but I am hoping to start again with Crixivan, or other new AIDS drugs, in the next few months

The combinations of new AIDS drugs have given me new hope that I will be able to live a healthier life with my family. For once in my life, I have hope for the future of my children's lives, and I have hope that I will be here with them.

But, members of Congress, not all people have access to the new AIDS drugs. I am not a public policy expert and I do not understand pricing, issues or the federal programs related to AIDS. But I do know that Congress, local communities and the drug companies must do more to provide access to these new AIDS drugs for everyone. It costs approximately \$3,000 per month for my family to be on new AIDS drug therapies. This is expensive, but it must be less expensive than staying in the hospital or going for more doctors appointments.

We must do more to test the results of the new AIDS drugs, and we must do more to test the drugs in children and pregnant women. You may not know this, but right now none of the new protease inhibitor drugs or combination therapies have been approved for pregnant women, and only 2 new protease inhibitor drug has been formulated for pediatric use and approved by the FDA for children with AIDS. One of these drugs is only approved for children 2 years and older. That means that drugs like Crixivan and others are given to my children by our doctor on an off-label basis. Children and Moms need safe access to these new drugs and more testing and research needs to be done

My story is not different from other families across the United States. Often, women and parents seek treatment only after their children have been diagnosed with HIV and this is wrongs. Too often, families struggle with taking the new complicated regimen of AIDS drugs. To change this, American families need the commitment of Congress to all federal AIDS programs. Our families rely on Medicaid and the Ryan White CARE Act which provides us with comprehensive HIV care that helps us cope with the new AIDS drug regimen. Without care, without AIDS research to continue to study these drugs, without AIDS housing, and without AIDS prevention, we have no chance in succeeding with the new AIDS drugs or preventing further HIV infections.

I hope for the day that there will be a cure for HIV and AIDS. I hope that parents will not have to watch their children die from HIV. People suffering from HIV/AIDS need your help—the help they receive through federal HIV/AIDS programs, including the AIDS Drug Assistance Program, to pay for the new AIDS drugs and provide access to care. This will save our lives and our families.

Please continue to support me and my family Thank you.

#### SUMMARY STATEMENT OF KIM WILLIAMS

Senator SPECTER. We now turn to Ms. Kim Williams, who serves on the board of directors for the South Mississippi AIDS Task Force. She first learned she was positive when she was 17 and pregnant, and since that time, Ms. Williams unfortunately lost her child and the child's father to AIDS.

She is an American Red Cross HIV/AIDS educator, and speaks publicly about her experience as a person living with AIDS.

Thank you for joining us, Ms. Williams, and we look forward to your testimony.

Ms. WILLIAMS. Thank you. Good afternoon. My name is Kim Williams, and I am a person living with HIV from the State of Mississippi.

I would like to thank Senator Specter and Senator Harkin and my Senator, Senator Cochran, for asking me, and listening to me today, and the other people on this panel.

I would first like to thank Senator Specter and the members of his committee for the past support you have given to the ADAP programs. Through this support you have improved the lives of tens of thousands of people across the country who are infected and affected by HIV disease.

Also, it is my understanding that Senator Specter voted against the budget agreement because it failed to protect HIV research and health care programs like ADAP. On behalf of people with AIDS I would like to thank you again, Senator Specter, and others who have supported you, for your courage in allowing compassion rather than political policies to guide you and help change your vote.

My story is a simple one that has been made complex by HIV disease, for you see, without this disease I would be a regular working mom, taking care of my child and making the best lives for us. However, I have lost my child, Jeremy, to this disease and now I face my daily struggle to cope with living with HIV alone, without my son.

And in the midst of the struggle, even with medical complications from the one drug I took myself, just like her, it affected my kidneys, and right now I am not taking anything until my kidney gets stronger. I have had two surgeries because of the drug.

But there are a lot of people, and there are a lot of hope and a lot of light out there, that people with these drugs are still going to be able to take them. There are a lot of drugs I have not gotten to take yet, and I know they are going to help. There are a lot of drugs that I know now that are helping, and without these drugs people do not have much hope.

Now, since receiving my letters informing me of disenrollment from the Mississippi ADAP I sometimes have doubt whether I will survive, even though there are drugs out there. I have been cut off from the ADAP program because there is not enough money there.

You see, as of July 1, I will have no medical coverage whatsoever, and I will have to go back to work. Unfortunately, in addition to myself, there are 660 patients who will be dropped from the Mississippi ADAP program. Senator Cochran, as my Senator I want to ask you personally to help families and individuals around the country to gain access to these medications. They need to stay alive.

Senator Specter, you have the power at your disposal. I ask you to continue to make this one of the priority programs of your committee so that it can continue to help other families and individuals who will be able to survive this awful disease. We need your help.

I ask all of you to make my life and tens of thousands of other lives throughout this country simpler by committing the necessary

funding so that I and other people living with HIV can continue to receive medications that are extending lives and giving people hope and strength.

I understand the importance of balancing of the budget, but I do not understand how you can take someone's life-saving medication away. Is there not adequate funding for this program? People will die, if they are not poor enough for Medicaid, there will be no funding or no access to the AIDS drugs, so there is no hope, and without hope you might as well lay down and die, because that is what we are going to do.

We are a great Nation which can send ships into space much further than I can ever imagine, and we can place thousands of soldiers in a matter of days in foreign lands all across the world. Is helping to supply therapies which can save lives of citizens living in America more complex? I say no.

Please help my life, make it more simple, and other people like me. Please support the Nation's ADAP Program with enough money to allow families and individuals and children to have access to these drugs and have healthy and productive lives so these parents out here do not have to have their children die. Theirs do not have to die like mine did.

Thank you.

#### NEW AIDS DRUG THERAPIES

Senator SPECTER. Thank you very much, Ms. Williams. We very much appreciate your being here and sharing with us the intimate experience which you have had, and we thank you, Ms. Leon, for doing the same.

Let me begin with you, Ms. Leon, and ask you, how has the new medication helped you and your family?

Ms. LEON. First of all, my children, they used to be sick all the time, either with pneumonia or diarrhea, and not being able to go in a straight year of school, but since they started taking the medicine, it has been like a year ago, they went to school all year long, except, of course, they missed to go to the doctor's checkups. Otherwise, I did not have that complaint this year.

Senator SPECTER. So you see real benefits for your children.

Ms. LEON. Definitely.

Senator SPECTER. And how about for you, for you too?

Ms. LEON. Yes; I started feeling better, too.

And one more thing, because my kids were—because of HIV they were not growing, and in 1 year they all got 10, 15 inches more. They started gaining weight, and they do look like healthy children now, and that is a benefit, I think.

Senator SPECTER. Dr. Fauci, these new drugs show exceptional promise, but they have just come into widespread use. How long will it be before we will have a scientific base for reasonable certainty that protease inhibitors do, indeed, suppress the virus permanently?

Dr. FAUCI. That will probably take several years. For certain, we know that you could detect it—you could suppress the virus below the detectable levels of the sensitive assays that we have available today.



Biopsies of lymph nodes, or lymphoid tissue, which are the sanctuaries of the hidden places of the virus on people who have been on therapy for 1 to 2 years have shown that there is still residual virus there. The hope is that as those cells turn over and die and the antivirals, namely the triple combinations, continue to have their effect, that after a period of several years we will be able to know whether or not you can do that.

The projection ranges from 2½ to 3½ years. It might be longer than that, but the proof of the pudding, notwithstanding the projections, will be what happens when you stop therapy in someone and see if the virus does come back, and that will not happen for at least another few years.

#### MEDICAID POLICY ON MEDICATION

Senator SPECTER. Dr. Fox, current Medicaid policy only pays for medication if the patient becomes symptomatic and disabled. The effectiveness of protease inhibitors make it imperative that those affected should be treated earlier. What is the likelihood that the Medicaid policy will be changed to conform to that reality?

Dr. FOX. Well, Senator, I cannot speak for HCFA or Medicaid. I know that the Vice President is looking at some options under Medicaid, but those are not ready to be brought forward yet. There are some options under Medicaid, however, to provide coverage beyond what we provide now, but that is an individual State determination.

For instance, the 1,115 waivers that are available that allow States to go above the existing income guidelines are an option now for States, and even though that may require 6 to 12 months to actually get approved through the process, it does offer some opportunity, so I think there are some options under Medicaid now.

There are also some options under the medically needy to expand coverage for the disabled in ways that you take into account what their current medical bills are, so those options we would encourage States to explore as a part of their Medicaid Program.

Senator SPECTER. I yield now to Senator Cochran.

#### DRUG THERAPY FUNDING SHORTAGE

Senator COCHRAN. Mr. Chairman, thank you very much for including this panel in our hearing today. We deeply appreciate it because we are confronted with an emergency of substantial proportions in Mississippi because of the breakdown in the funding that has been available to help pay the cost of these drugs to deal with the consequences of HIV/AIDS.

Let me first start with Dr. Fox and ask you, if I can, how do we explain to people what happened? When we look at the facts that in Mississippi here we were participating in a Federal program to help pay the costs of drugs and we had included a large segment of the State's affected population who were eligible to participate, and then halfway through the fiscal year we have to really tell people that there is no more money to continue paying the cost of these drugs, how could that have happened? What happened?

Dr. FOX. OK. Senator, to begin with, there has been no funding reduction in this program. The dollars actually, as I said earlier, have increased quite substantially over the last couple of years.

What has happened has been the change in the therapy, the fact that you go from one-drug to three-drug therapy that you begin to cover a large number of patients. So it is the therapy and the implications financially of that that have actually changed. There has actually not been a reduction of funding from the Federal standpoint. There has been an increase over the last 2 years, but there has been a dramatic change in the treatment protocol, and I think that will become more so as the guidelines come out and become generally accepted.

Senator COCHRAN. Now, it seems to me that this is a matter of some emergency, and I wonder if you know why the administration did not include as a part of its supplemental budget request increased funds to help deal with the consequences of these events.

Dr. FOX. I do not think I have the information to answer that question, Senator.

Senator COCHRAN. Dr. Fauci?

Dr. FAUCI. I certainly do not.

Senator COCHRAN. Let me ask whose responsibility is it to alert the administration to a problem that has to be obvious to somebody in the management of health programs for this administration?

Dr. FOX. Senator, let me just comment again, we are working on trying to piece together the information from HCFA. We have to go to every individual State Medicaid program. We do not have a good picture of what private insurance pays for. We know that each State varies in its State support. Part of the problem is trying to put the total picture together so that we have an accurate reflection of what the need is.

We do know there is a budget agreement and there are going to be constraints on financing, so we are in the process of trying to put that together, and hopefully have an accurate number, and that is not an easy task to do. It is something that needs to be done, and we are working on it, but it is something that is very difficult to come by.

Senator COCHRAN. It seems to me that it is a matter of some urgency, and I would hope that a task force could be put together by the administration and selected State department health officials such as Dr. Thompson from our State to try to help map out a strategy for coping with this in the most humane and effective way possible.

How do we start that movement? Is this a good place to start today to put folks on notice that that is what we expect to happen?

Dr. FOX. Well, certainly, we have had this process. I have been at HRSA for 3 months, and we have been working on this from before I got out there, and we certainly tried to accelerate that since I have been there to try to put this together, and we are working toward trying to come up with a number. So there is a lot of effort going on. We have had several discussions with HCFA to try to get those numbers. Again, we have called around to individual States. So there is an attempt right now to do that, and I am hopeful at some point we will have that information.

## TERMINATION OF FUNDING ASSISTANCE

Senator COCHRAN. Dr. Thompson, I know it was a tough job for you to have to write a letter to 600 people in the State of Mississippi to tell them they were not going to be able to get funding assistance to help pay the costs of these drugs on this program. Tell me what that was like.

Dr. THOMPSON. First let me say that we have been able to locate and transfer sufficient funds from a variety of one-time noncontinuing sources that we are going to be able to retain 400 of those people on the program at the level of medication they were previously receiving, not for the new protease inhibitor combinations that they had not yet begun to receive.

So at this point we are only going to have to drop from the program those persons who have Medicaid coverage which will provide five drugs, not necessarily enough, but at least some, and those persons who had private insurance or whose incomes were too high for the program.

Still, even for those people who will have some coverage but not complete coverage, I hope I never have to participate in the writing of such letters again. It is not a pleasant thing. It is much less pleasant to receive one, I am sure.

The problem we have is a problem of success. Our money, as Dr. Fox said, has not gone down, it has actually gone up. It has not gone up fast enough. The cost of therapy has gone up tenfold. In 1996, the average cost per patient in our ADAP program was \$1,200 a year. The cost for the new therapy is \$12,000 a year. We are faced with the availability of something that shows great promise, but it comes at great, great expense, and that is the emergency that we have now. How do we take advantage of this new therapy, in our State, in other States, because of what it costs.

Senator COCHRAN. Ms. Williams, I appreciate very much your coming here today. You received one of these letters, did you not?

Ms. WILLIAMS. Yes, Senator.

Senator COCHRAN. Could you tell us in practical terms what the consequences for you and your life will be because of this development?

Ms. WILLIAMS. It helped, since I am not taking medicine right now, the AZT and I believe it was 3-TC I was getting from it. It will not affect it that much at this moment, but 1 month from now—I was planning on going in 1 month or so down the road—the doctor was planning on putting me back, and I was planning on going back to work, so, therefore, I lose my Medicaid, so, therefore, the money for those drugs are going to have to come out of my pocket now, and they are not cheap.

Senator COCHRAN. Dr. Fox, you and I did talk before this hearing started, and I commend you for your efforts to explore the options for dealing with this, not just in requesting additional funds from Congress, which, of course, we know we have had huge increases in allocations of Federal resources for this program. And I think right now the Federal Government is investing more per victim in AIDS research and other programs under the Ryan White CARE Act than any other illness in America. Is that not correct?

Dr. FOX. Well, I do not know how it compares, but certainly there is over \$1 billion that goes into this program now, Senator. I would just tell you there has been a recent study looking at cost per years of life saved, and the cost per years of life saved for a person with AIDS under this program is about \$10,000, in that range, per year. Compare that, a 50-year-old man, my age, who gets a coronary bypass. The cost per year of life saved is \$113,000. So we feel like that certainly this is a good buy, and we should be doing it. Again, the question is how to distribute the cost among the different sources.

#### ALLOCATION OF FUNDING ASSISTANCE

Senator COCHRAN. Dr. Thompson, one idea somebody advanced is that the formula for allocation of the funds really benefits the big cities, and States like Mississippi, which does not have really big cities in it, end up getting the short end of the stick. Is that true?

Dr. THOMPSON. Yes, Senator, it is. Although the formula, when it was devised, may have been very appropriate at that time because the epidemic was concentrated in large cities, that is increasingly not the case. Right now the problem is that in essence the formula allows persons with AIDS only to be counted, and the issue is no longer how many people with AIDS do we have and may need treatment, but how many people with HIV, many of whom have had HIV for a long time and may not get AIDS with these new treatments.

That is not taken into account, and in the case of the title I cities, the persons with AIDS who are counted are in essence counted twice in those States that have title I cities versus those that do not have title I cities, as 29 States do not.

Senator COCHRAN. We explored the possibility of directing, in language in our supplemental appropriations bill, the administration to reprogram funds from other parts of the AIDS Program, and those funds have already been obligated or allocated, and that is not a productive effort. And we have explored other options, as well. But it seems to me that we have got to get together and decide what to do about this, and the time for action is now, and your cooperation, your advice and counsel as we go through this process will be very valuable.

We appreciate your being here to help highlight the importance of the program and help us figure out what to do about it. Thank you all very much.

Senator SPECTER. Thank you, Senator Cochran, and thank you all for coming. I would like to recognize Congresswoman Nancy Pelosi, who is in the hearing room. Congresswoman Pelosi has been an outstanding advocate for AIDS research and AIDS treatment, and has consulted with the subcommittee very substantially on the hearing which we had today, and in fact had been the initial party requesting it, and we thank her for her contribution. And every now and then the Senate catches up with what the House is doing.

#### ADDITIONAL COMMITTEE QUESTIONS

Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### ADDITIONAL COMMITTEE QUESTIONS

##### NIH HUMAN GENE TRANSFER DATABASE

*Question.* Dr. Varmus, in November 1996 the NIH published in the Federal Register a notice regarding the reconfiguration of the Recombinant DNA Advisory Committee (RAC). The notice stated that the NIH intended to create and maintain public access to human gene transfer clinical trial information. What is the status of the development of this database? What specific data will be required for this database from sponsors pursuing human transfer gene therapy trials? When will the database be put in place?

*Answer.* Development of the NIH Human Gene Transfer Database is a critical component of my overall proposal to enhance NIH oversight of human gene therapy research. Access to timely information about these clinical trials will serve not only the needs of the NIH with regard to identifying gaps and overlaps in basic and applied research, but will facilitate rapid responses to adverse events by the Food and Drug Administration (FDA). This timely dissemination of adverse events by the NIH Office of Recombinant DNA Activities (ORDA) has been applauded by FDA representatives as an exemplary mechanism for communicating such events to the scientific community. This rapid communication process has allowed immediate implementation of appropriate study modifications in response to such events, without execution of a clinical hold on related studies. Public access to gene therapy clinical trial information has served as an exceptional public education tool that has fostered acceptance of this once "feared" novel area of biomedical research.

##### STATUS

An evolutionary development approach is being implemented in relation to this database to permit deployment of initial functionality and subsequent growth to the final system that will contain all essential query and reporting functionality. A brief chronology relevant to implementation of the NIH Human Gene Transfer Database is described below:

(1) June 1997—System requirements were completed by the Office of Recombinant DNA Activities (ORDA) and the Division of Computer Research and Technology (DCRT), NIH.

(2) July 1997—A task order was executed under the NIH Computer Equipment Resources and Technology Acquisition for NIH (CERTAN) contracting mechanism for system design and development of the client/server-based information management system; vendor responses are due July 23, 1997.

(3) August 8, 1997—Written and oral evaluations of vendor responses by the DCRT technical review panel will be completed.

(4) October 1, 1997 (fiscal year 1998)—Implementation of Phase I development. Phase I will consist of local database development including desk-top system interface and basic local query and reporting capabilities. Phase I will be developed for use by the ORDA staff and other local authorized offices and users.

(5) October 1, 1998 (fiscal year 1999)—Phase I development completed. Phase II development initiated. Phase II will consist of expanded local query and reporting tools; expanded data entry; incorporate additional database functionality; and World Wide Web (WWW) summary information.

(6) Date undetermined—Completion of Phase II and implementation of Phase III. Phase III will consist of WWW remote data entry and WWW query and reporting capabilities.

##### SPECIFIC DATA CAPTURED BY THE DATABASE

Data captured in the Submission Phase includes the following information: (1) title of clinical protocol; (2) principal investigators; (3) clinical trial sites; (4) sponsor; (5) local institutional contacts; (6) description of treatment groups, e.g., dose range and gender of subjects; (7) number of subjects proposed for treatment; (8) objectives and rationale of the proposed study; (9) funding sources; (10) vector name and components, e.g., functional or marker gene, parental vector, and vector type; (11) in vivo or ex vivo target cell; (12) gene delivery method; (13) indication; (14) route of administration; and (15) inclusion/exclusion criteria. Data captured in the Follow-up Phase include: (1) serious adverse events (with clear indication if such events are

directly related to the transgene); (2) evidence of immune response; (3) evidence of gene transfer into target cells (ex vivo and in vivo); (4) evidence of gene expression (ex vivo and in vivo); (5) evidence of persistence of transduced cells; (6) problems associated with gene transfer; (7) evidence of biologic activity; (8) number of subjects entered on the study; (9) number of deaths; (10) number of autopsies conducted and any relevant gene transfer data derived from post-mortem analysis, e.g., potential transmission to the germ-line; (11) relevant assays that were conducted to assess safety and gene transfer and expression; (12) evidence of replication-competent virus and viral shedding; (13) accomplished goals and objectives; and (14) any relevant publications resulting from the clinical trial.

It is important to note that data captured in the follow-up phase is submitted in summary format. This database is not intended to be a patient registry; therefore, there will be no access to patient identifiers that would undermine patient confidentiality. It is also recognized that the summary manner in which follow-up data is captured does not in any way jeopardize an investigator's ability to publish clinical trial results in peer-reviewed journals. Investigators are clearly cautioned against submitting in-depth results that could threaten publication of such results. An example of the summary information requested of investigators is evidence of gene transfer. Rather than require a full description of the assay conditions and subsequent results, investigators may summarize their findings as follows: 2 of 4 assays were positive demonstrating gene transfer by PCR analysis. Although this information implies a preliminary assurance that the investigators were technically capable of transferring the gene into the target cell, there is no information provided about the assay conditions or parameters that could jeopardize either patient confidentiality or peer-review publication.

#### SUPPORT FOR YOUNG CLINICAL RESEARCHERS

*Question.* Dr. Varmus, I continue to hear grave concerns expressed in the research community regarding our current system of grant funding and the lack of programs supporting young clinical investigators. What action do you recommend should be taken to shore-up support for clinical research and to ensure a cadre of trained clinical investigators in the future?

*Answer.* The NIH recognizes that attention is needed for beginning clinical researchers to ensure an appropriate cadre of research scientists for the next generation. Beginning clinical investigators are especially vulnerable because their ability to establish independent research careers is potentially jeopardized due to the increasing competition for research support and the substantial amount of debt these clinicians have incurred by the end of their training.

In order to enhance the quality of clinical research training programs and to attract beginning investigators to careers in research, the NIH is in the process of developing a number of possible strategies. These include possible new award mechanisms both for institutions and for individuals, as well as other strategies. First, the NIH is exploring the possibility of offering clinical research experiences for medical and dental students through the existing institutional training award and individual fellowship award mechanisms. In addition, some new possible mechanisms are being considered. The NIH is considering awards aimed at assisting institutions in attracting high quality, motivated candidates and encouraging the organization of institutional resources for training programs in patient-oriented research. We are also considering clinically oriented individual awards, both for those just beginning clinical research careers or to enhance the capabilities of young clinicians already involved in research.

In addition, NIH is examining the feasibility of establishing a loan repayment program for clinical researchers. The NIH loan repayment program is currently limited to scientists in the Intramural research program. To broaden the eligibility for the loan repayment program to include clinical researchers at academic health centers throughout the country would require a legislative change.

#### REVIEW OF TRANSLATIONAL AND CLINICAL RESEARCH APPLICATIONS

*Question.* Dr. Varmus, I have been informed that an imbalance still exists between basic and translational researchers on NIH peer review panels. What steps has the NIH taken to redress this issue and how have the composition of these peer review panels changed, or the peer review process been altered, in response to create a level playing field for the review of translational research proposals?

*Answer.* The Division of Research Grants is responsible for the review of greater than 70 percent of submitted applications. Since questions about review group composition are typically addressed to the Division of Research Grants (DRG), the DRG

Director, Dr. Ellie Ehrenfeld, has undertaken two initiatives to specifically address the issue of review of translational and clinical research applications.

Shortly after Dr. Ehrenfeld was appointed as the new Director of DRG in January of 1997, she hired a consultant, Michael Simmons, M.D., Professor of Pediatrics and former Dean of the University of North Carolina Medical School, to work with a committee of Scientific Review Administrators, involved primarily in the review of clinical applications, and to recommend how translational/clinical research might be better reviewed. Drs. Simmons and Ehrenfeld have met with the Directors of each Institute and Center with a clinical research portfolio to identify specific concerns, and have initiated selective outreach efforts to clinical professional societies. The committee has made some recommendations that soon will be tested and evaluated.

Because continued dialogue with the outside community is critical to the success of this activity, the second DRG initiative is the appointment of a Panel on Scientific Boundaries for Review, as a subcommittee of the DRG Advisory Council, to analyze the optimal way to organize, constitute, and direct review groups. The members of this blue-ribbon panel, consisting of persons with scientific stature in diverse fields, will be asked to consider whether or not reorganization of the study sections is needed, and if so, to recommend a strategy by which the breadth of disciplines supported by the NIH could be reconstituted into newly defined, intellectually defensible scientific domains to assure that all areas of science, including translational/clinical research receive due consideration. These recommendations may serve in turn as the basis for reorganizing scientific review groups.

In addition, the Peer Review Oversight Group (PROG), chartered in 1996 and charged with addressing issues of review policy common to the entire NIH, is working on this issue. PROG is made up of representatives from the ICDs and members of the extramural scientific community, and is chaired by Dr. Wendy Baldwin, the Deputy Director for Extramural Research. Dr. Ellie Ehrenfeld is a permanent member of PROG. This oversight advisory group has been carefully examining the issue of whether in fact there are differences in the review of different types of research, for example basic scientific research performed in the laboratory and clinical, patient-oriented research. At the present time, PROG has a subcommittee examining the composition of panels for the review of patient-oriented clinical research, and is still working to address the issue of composition of review panels; no recommendations for change have yet been made by these groups.

These three initiatives that are currently underway should provide us with answers to questions regarding any imbalance in the review of translational/clinical research, ways to redress any deficiencies that may be uncovered, and provide us with an analysis of the optimal way in which to organize, constitute, and direct review groups.

#### CLINICAL RESEARCH DATABASES

*Question.* Dr. Varmus, legislation requiring the Secretary to establish a resource information and clinical database for individuals with serious or life-threatening diseases is under consideration by the Congress (S. 87 and H.R. 482). I am advised that the legislation would require the NIH to establish and maintain this databank. Has the NIH done a review of the cost to establish and maintain a patient database outlined in the legislation?

*Answer.* The National Institutes of Health (NIH) has not conducted a review of the cost of providing a central resource for information on clinical trials as specified in S. 87 and H.R. 482. There are three dimensions to the scope of such a resource and NIH has experience with only one. The legislation calls for establishment of a database across the agencies of the Department of Health and Human Services (DHHS) to provide information on "research, treatment, detection and prevention activities related to serious or life-threatening diseases and conditions." There are several extant databases of NIH-supported clinical research developed and maintained by the Institutes or the Office of the Director and several are available to the public through the Internet. These databases and the responsible organization include: Physicians' Data Query (PDQ)—National Cancer Institute; AIDSTRIAL—NIAID; Clinical Center at NIH—Clinical Center; Rare Disease Database—Office of the Director; Alternative Medicine—Office of the Director; and Dietary Supplements—Office of the Director.

All can or will be accessible through the NIH Home Page or the National Library of Medicine site. Programs of other DHHS agencies are not represented as these contain only information on projects reviewed and financially supported by NIH. There are no publicly accessible databases for other conditions. The annual cost of creation and maintenance for each of these databases has ranged from \$1 million to \$30 million.

The second dimension of the legislation relates to providing an information system including toll-free telephone communications. The NCI and Clinical Center already provide this service. From their experience, the information must be provided from a decentralized source (e.g., at Institute level) for it to be correct, current and useful. We have not made an estimate of these costs.

The third dimension would be development of a database and information system for all clinical trials, whether Federally or privately funded. This would be an enormous undertaking and many private sponsors (e.g., pharmaceutical firms) have not been interested. The quality of the study and of the information would be dependent on the investigator and could not be verified by NIH, and thus would have doubtful validity.

Importantly, the information for all databases and telephone responses must be updated every six months. This means that annual maintenance costs of these data sources is as expensive as the original development. The principal costs are related to creation of a valid informational source and disseminating this information.

*Question.* How much is the NIH currently spending on databases of this nature?

*Answer.* The development and maintenance of databases of clinical research have been the responsibility of organizational components (Institutes, Centers) at the NIH. The current databases and information systems cover only NIH-supported research and they vary greatly in size and complexity (electronic database or toll-free telephone or both). These programs are integrated with other programs and it is not possible to determine specific costs without careful dissection. The range of costs for each information system is about \$1 million to \$30 million per year, depending on the size and services provided.

#### HUMAN CLONING

*Question.* Dr. Varmus, the National Bioethics Advisory Board has now deliberated and made recommendations concerning the use of human cloning to create a child—What is your reaction to their recommendations? Did NIH participate in crafting the legislation the President has submitted to the Congress?

*Answer.* I fully support National Bioethics Advisory Commission's (NBAC) recommendations on the need for restrictions on the use of human cloning to create a child. I also agree with NBAC's recommendation that research involving the cloning of human DNA and cell lines should be protected under any legislation to ban the cloning of human beings to create a child. NIH did provide comments on the legislation the President has submitted to the Congress.

*Question.* The recommendation would not ban all human cloning, what are some of the promising aspects of cloning technology for medical science and treatment?

*Answer.* I believe that this technology has the potential to yield great benefits in many areas of medical research and treatment. One application is in the use of animals for medical research. This technology could reduce the numbers of animals needed for experiments, since differences in genetic background that often lead to experimental variation would be eliminated. Cloning technology could also speed the reproduction of animals that have been engineered to produce therapeutic proteins in milk, or as important animal models for disease.

Another area of importance is the study of how human and animal genes are turned on and off. As the NBAC report notes, the basic cellular process that allowed the birth of Dolly by nuclear transfer using the nucleus from an adult somatic donor cell is not well understood. There are many questions about how this process occurred. How the specialized cell from the mammary gland was reprogrammed to allow the expression of a complete developmental program will be a fascinating area of study. Answers to these questions will contribute to our overall understanding of how cells grow, divide, and become specialized.

Basic research into these fundamental processes may also lead to the development of new therapies to treat human disease. The demonstration that, in mammals, as in frogs, the nucleus of a somatic cell can be reprogrammed by the environment in the egg, provides further impetus to studies on how to reactivate embryonic programs of development in adult cells. These studies have exciting prospects for regeneration and repair of diseased or damaged human tissues and organs, and may provide clues as to how to reprogram differentiated adult cells directly without the need for insertion and fusion into the egg. A potentially feasible approach is to direct differentiation along a specific path to produce specific tissues (e.g., muscle or nerve) for therapeutic transplantation rather than to produce an entire individual.

For example, it may one day be possible to use nuclear transfer technology to produce bone marrow cells in culture, using, for example, skin cells from a patient with cancer, who is undergoing chemotherapy which can deplete bone marrow cells. These bone marrow cells could then be returned to the patient, without the poten-



tial for rejection, after the patient has undergone chemotherapy. One could also imagine helping people who have been incapacitated by massive burns and need skin transplantations by taking any cell from the body and using this technology to make skin cells. This technology may one day also be used in similar kinds of experiments in neurodegenerative disease, remodeling cells to behave as mature nerve cells that will not be rejected by the recipient.

*Question.* Even with the President's executive order which bans all Federal funds for cloning of human beings, what safeguards exist to prevent unauthorized attempts?

*Answer.* In order to ensure that Federally-supported investigators are fully aware of the Prohibition, NIH took several actions. The Presidential Prohibition on Federal Funding for Cloning of Human Beings was copied and distributed to those NIH staff responsible for grant awards and was discussed at a March 5 meeting. The document was also attached to the minutes of that meeting, which were distributed electronically on the following Monday, March 10. These minutes (with attachments) are redistributed by the senior staff throughout the Institutes, Centers, and Divisions. In addition, in order to ensure that the information is also shared with the extramural community of scientists, the Prohibition was also posted on the Office of Extramural Research Home Page on March 5. For the intramural community, the Presidential Directive was published on March 10 in the Deputy Director for Intramural Research Bulletin Board, which is electronically distributed to intramural researchers across NIH.

Additionally, attempts to clone human beings would fall under the rubric of human subjects research. Human subjects protections are covered by many levels of Federally-regulated review and oversight.

Federal regulations (45 CFR 46) require that all institutions that conduct or support research involving human subjects set forth the procedures they will use to protect human subjects in a policy statement called an assurance of compliance. An assurance should include, at a minimum, (1) a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation; (2) designation of one or more institutional review boards (IRBs); (3) a list of IRB members (4) written procedures the IRB will follow; (5) written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials and the Department or Agency head of any unanticipated problems involving risks to subjects or other or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB. The Regulations also state that "Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects." This would include the President's Directive prohibiting the use of Federal funds for cloning a human being. NIH peer review committees and advisory councils/boards also review human subject protections in proposed research submissions.

NIH program directors provide oversight of award activities to ensure adherence to Federal laws and regulations. Intramurally, the Scientific Directors of the Institutes and Centers are responsible for conducting human subjects research in full compliance with the NIH Multiple Project Assurance under 45 CFR 46.

#### ALTERNATIVE AND COMPLEMENTARY THERAPIES

*Question.* Dr. Varmus, on February 14, 1997, I wrote Secretary Shalala requesting that her Department prepare for the Subcommittee a report on all federal activities involving alternative and complementary therapies. The Secretary responded on April 18, 1997 stating that the interim report will be available by August 1, 1997. I am particularly interested in the consolidation into a central database all relevant clinical literature on alternative and complementary medicine in a form that is accessible and understandable to researchers, practitioners and the public. What is the status of the Department's review?

*Answer.* The NIH has completed its review of the research literature items on complementary and alternative medicine as outlined in the letter to you from the Secretary on April 18, 1997. This report is being edited by the Office of the Director, NIH and will be forwarded to the Secretary for her review and approval.

*Question.* Will the interim report be completed by August 1, 1997 as outlined in the Secretary's letter?

*Answer.* We anticipate that the interim report will be completed by August 1, 1997 and forwarded to you.

## 5 A DAY FOR BETTER HEALTH INITIATIVE

*Question.* Dr. Klausner, what are the NCI's plans with regard to the 5-a-day program for fiscal year 1998 through 2001? How much did the NCI spend over the previous budget period?

*Answer.* The 5 A Day project is one of the largest and most successful public/private partnerships in nutrition to date, and the National Cancer Institute's investment in the 5 A Day Program has been a catalyst for substantial industry support. The produce industry partners estimate they spend approximately \$50 million yearly in promoting the 5 A Day message and logo. Also substantial is the amount of resources expended by the 55 state and territorial health agencies and their coalition partners (totaling over 2000 partners nationwide) in 5 A Day community interventions.

The NCI remains committed to the 5 A Day for Better Health Program. Lifestyle and behavioral change research programs, such as 5 A Day, are exceptionally important components of our broader efforts to prevent cancer and other chronic diseases in this country. NCI plans to continue funding for 5 A Day nutrition and behavior change research, particularly for research projects focusing on children and youth. In addition, to assure widespread adoption of knowledge gained through this project, the NCI will conduct technology transfer research.

Staff from 5 A Day are now in the process of evaluating the program and based on that evaluation and advice from our various advisory groups, a research and dissemination plan for fiscal year 1998 through 2001 will be developed. Current plans include convening an advisory meeting in the early fall to address future plans for 5 A Day and how best to collaborate with sister federal agencies and organizations who have similar public health, prevention, and research interests.

In fiscal year 1996, the NCI spent a total of approximately \$6 million on the 5 A Day for Better Health Initiative. About 70 percent of the funds were used to support the final portion of the 5 A Day behavior change research initiative, in which preliminary results show significantly positive results for increased fruit and vegetable intake in all 9 community projects. The nine 5 A Day behavioral change research interventions in specific community channels showed an average (preliminary findings) positive change in fruit and vegetable consumption between .3 and 1.5 servings daily.

The remaining funds were spent on an interagency agreement with the Centers for Disease Control and Prevention in which the NCI funded 6 small research grants to state health agencies to evaluate 5 A Day interventions at the community level, for an ongoing evaluation of the national 5 A Day Program, and for research on dissemination of 5 A Day health promotion messages conducted by the NCI Cancer Information Service.

## POLYCYSTIC KIDNEY DISEASE (PKD)

*Question.* Dr. Gorden, I understand that there has been great progress in understanding the genetics of PKD. What is the NIDDK doing to maximize opportunities for expanded research?

*Answer.* In the last two years, dramatic progress has been witnessed in understanding the cause of polycystic kidney disease (PKD). The genes that are mutated in the two commonest forms of PKD (PKD1 and PKD2) have been cloned, sequenced and the protein structures deduced. We are beginning to understand the possible function of the protein, called polycystin, which is defective in patients with PKD1. To further encourage scientifically meritorious research, the NIDDK will support both a scientific workshop and a Program Announcement (PA) on PKD in fiscal year 1997. The workshop will provide a forum for the exchange of scientific information among investigators working in the field, with particular emphasis on the function of polycystin, the PKD1 protein. The PA will solicit research grant applications from both established PKD researchers and investigators new to the study of PKD. The PA will encourage research to capitalize on the discovery and sequencing of the genes for PKD1 and PKD2 and the identification of protein regulated by these genes.

*Question.* What types of therapies or cures does the latest PKD research portend for this disease?

*Answer.* Researchers have begun directing their efforts to understanding the functions of the PKD1 gene product, polycystin. As the interactions and the functions of this protein become clearer, new avenues for the treatment and prevention of this devastating disease will arise. For example, treatment strategies directed at correction of the defects caused by absence of polycystin may prevent cyst formation. Alternatively, a number of compounds have recently been shown to reduce the rate

of renal cyst formation in experimental animal models of PKD, and studies are underway to assess their role in the treatment of PKD.

*Question.* How much does the NIDDK estimate will be spent on PKD research in fiscal year 1997?

*Answer.* Recent advances in understanding PKD are impressive and encouraging. The NIDDK is proud of our role in supporting much of the research that has formed the foundation for these discoveries. NIDDK expenditures on PKD research have increased from approximately \$1.5 million in fiscal year 1988 to an estimated \$7.9 million in fiscal year 1997. This five-fold increase over a ten-year period reflects the enormous strides that have been made in PKD scientifically.

*Question.* How much was spent in fiscal years 1995 and 1996?

*Answer.* In fiscal years 1995 and 1996 the NIDDK spent \$6.9 million and \$7.5 million respectively.

*Question.* Now that the protein product for PKD has been identified, do you expect to expand support for PKD research in fiscal year 1998?

*Answer.* The NIDDK will continue to make every effort to fund additional PKD research within available resources. We believe that it is important to not only support PKD research, but also to ensure that funded projects are of the highest scientific merit. We accomplish this through a two-step peer review process mandated by law to evaluate applications and to ensure high scientific standards among funded projects. Of course, applications compete for available funds.

*Question.* What are you doing to encourage applications in PKD?

*Answer.* In fiscal year 1997, the NIDDK will support both a scientific workshop and a Program Announcement on PKD. In 1995, we found that a similar approach following the discovery and sequencing of the PKD1 gene provided an important forum for researchers to exchange information and plan collaborative projects. This initiative resulted in 18 new PKD grants in fiscal year 1995.

*Question.* Are you collaborating with other Institutes at the NIH involved in PKD research?

*Answer.* PKD research is a very active area of investigation within the NIDDK. We continue to highlight recent impressive achievements in PKD research in congressional testimony and in scientific statements prepared for the Administration. We have also featured the PKD research portfolio whenever possible relative to trans-NIH research areas such as research on pediatrics, genetics, or developmental biology. The building of the PKD research portfolio is a mutual achievement of the PKD research voluntary health communities, and the NIH. We are enormously pleased to be a part of this burgeoning research area and are always open to new areas of investigation and collaboration.

*Question.* Do you have any plans to convene a scientific workshop on PKD? If so, when and for what purpose?

*Answer.* The NIDDK will be sponsoring a PKD scientific workshop on September 10–11, 1997, at the Crystal City Sheraton Hotel, Arlington, Virginia. Emphasis will be on the state-of-the-science. The workshop will provide a forum for the exchange of scientific information among prominent investigators working on PKD and among investigators with an interest in the different aspects of PKD-related research. There is a particular interest in fostering interdisciplinary research. The objectives of the workshop will be to gain an understanding of the future direction of PKD research; identify new research opportunities and the resources required to foster new research efforts; and to expand the cadre of investigators pursuing research in this area. The workshop will address five distinct topics: renal morphogenesis and cystogenesis; genetics of PKD; cell biology of PKD; PKD model systems; and genetic diagnosis and interventions. Each session will include an overview, an invited presentation, selected abstract presentations, and a discussion period. A summary document outlining the final research opportunities identified will be produced. This conference will be instrumental in framing future directions for PKD research within the PKD communities.

#### t-PA TREATMENT FOR STROKE

*Question.* Dr. Hall, I understand that if t-PA is administered within three hours of the onset of stroke there is a 33 percent increase in the number of patients that are free of disability three months after the stroke. In light of the limited window of opportunity, what has the Institute done to bring attention to the existence of this effective acute stroke treatment?

*Answer.* The NINDS is so deeply committed to ensuring that this major new finding is widely disseminated, that we have undertaken a unique role in spearheading an enormous national effort to educate professional and public audiences alike about

the availability of this treatment, and the need to consider stroke, or "brain attack", as a treatable medical emergency.

The results of the t-PA clinical trial, demonstrating that ischemic stroke can now be treated successfully and in some cases dramatically, were reported in December, 1995 in the *New England Journal of Medicine*, and announced at a national press conference held by the NINDS. The press conference, with all eight investigators from the t-PA clinical trial in attendance, was packed; there were nine television cameras, and the story appeared on all the major TV news programs, as well as making headlines in nearly every newspaper in the country the next morning. The publicity introduced the public to the fact that there was now a tangible treatment for stroke which offers eligible patients the hope of recovery, and informed physicians that they could now offer eligible patients something more than supportive care and rehabilitative therapy.

At the time of the FDA approval of t-PA in June 1996, the Institute issued a joint statement signed by the leaders of five major national professional groups concerned with stroke care, voicing their support for this historic new era in stroke treatment and expressing their hope for widespread public education about stroke as an emergency.

To build on the excitement of treatment advances in stroke, and to draft guidelines on how to treat stroke on an emergency basis, NINDS organized an historic meeting, a National Symposium on Rapid Identification and Treatment of Acute Stroke, which was held on December 12 and 13, 1996 here in Washington, D.C. The symposium drew more than 400 professionals representing the leadership of over 50 organizations from broad areas of the health care system. This marked a new commitment to work together to advance the treatment of patients with stroke. The participants made recommendations for changes in five key areas including pre-hospital systems, emergency departments, acute hospital care, hospital systems and public education. The proceedings from the meeting are being published and will be distributed nationally in an effort to increase the number of stroke patients who can benefit from treatment, and the number of hospitals who can offer rapid treatment to their patients. In addition, the symposium resulted in increased national publicity, and led to hundreds of calls from the public and health care practitioners and dozens of follow-up articles and news stories across the country.

In the spirit of cooperation generated by the symposium, the NINDS has also assumed leadership of the Brain Attack Coalition, an umbrella organization of several national organizations that is working together to develop and launch a major stroke education campaign.

#### PARKINSON'S DISEASE RESEARCH

*Question.* Dr. Hall, last year's Senate Report requested that the Institute give consideration to sponsoring additional scientific workshops, new funding mechanisms to recognize innovative approaches and attract new investigators, and establishing centers to advance our understanding of Parkinson's disease and related treatments. What has the Institute done in response to the recommendation of the Committee?

*Answer.* This has been a year of great progress and opportunity in Parkinson's disease research. The discovery of a gene responsible for one form of familial Parkinson's, coupled with the finding that the gene product is a known protein with a possible role in other neurodegenerative disease, has opened up new directions for research. To help build on these genetic discoveries, NINDS and the NHGRI plan a workshop focusing on the genetics of Parkinson's later this year. We have also had discussions with the National Parkinson's Disease Foundation about recruiting families for genetic studies.

We continue to take advantage of opportunities to provide additional funding for especially promising research in Parkinson's disease. Dr. Varmus asked this Institute to take the lead in organizing a process to identify projects to be funded with the \$8 million provided this year in the Office of the Director appropriation for research in neurodegenerative diseases. I am pleased to report that there was considerable enthusiasm on the part of the other Institutes for the idea of setting aside a portion of those funds for especially innovative research. We expect to complete that process shortly.

NINDS does not have a centers program specifically for Parkinson's disease. We do have authority to award center grants when appropriate and we are currently supporting one in Parkinson's disease. We also fund two multi project grants dealing with Parkinson's research, and three major surgical clinical trials. We believe, however, that a program of full-fledged centers may not represent the most efficient way to encourage research in a given area. What is most needed in Parkinson's research are new ideas that will clarify further the nature of the disease and point

the way to new treatments. Such ideas are most likely to come from individual investigators or as the result of activities such as the workshop we sponsored with other Institutes in 1995.

*Question.* What is the current estimate for direct and indirect Parkinson's disease research?

*Answer.* NIH expects to spend \$34,218,000 in fiscal year 1997 for direct research and \$47,223,000 for research related to Parkinson's disease for total funding of \$81,441,000.

*Question.* How does this compare to fiscal years 1995 and 1996?

*Answer.* The information follows:

#### NIH PARKINSON'S DISEASE FUNDING

[In thousands of dollars]

Fiscal year	Direct	Related	Total
1995 .....	27,925	44,868	72,793
1996 .....	32,353	44,805	77,158
1997 estimated .....	34,218	47,223	81,441

#### HEPATITIS C

*Question.* Dr. Fauci, the Committee continues to be concerned about Hepatitis C and commends the Institute and the NIDDK for sponsoring a recent consensus development conference. What actions has the NIH taken, and what recommendations are there for other PHS agencies, as a result of the conference?

*Answer.* NIH has considered hepatitis C virus infection and disease a serious health concern since the virus was identified in 1989. Last year, the National Institute of Allergy and Infectious Diseases (NIAID) funded four Hepatitis C Cooperative Research Centers which focus on multi-disciplinary, integrated research at both the basic and clinical levels. One of these investigators, Dr. Charles Rice, just reported the identification of an infectious clone making it possible to carry out new experimental approaches and develop systems to identify and evaluate new therapies and important antibodies arising during infection.

As a result of the conference, NIAID brought together an expert group representing basic and clinical research and multiple disciplines to assist with the further development of a broad-based strategy for progress in hepatitis C. The resulting agenda for the next few years was reviewed by the NIAID Advisory Council and a group of experts convened by the Digestive Diseases Interagency Coordinating Committee. The agenda forms a solid basis for future actions and activities by the NIAID. Although these research recommendations were made with NIAID's mission in mind, there is interest in having other Institutes, agencies and even public organizations join in this research agenda.

*Question.* What should be done to contain the spread of Hepatitis C and to identify and treat those afflicted with the disease?

*Answer.* The Consensus Panel at the Hepatitis C Development Conference was effective in identifying all means currently available to impact on hepatitis C virus infection and disease. It is important to recognize that many times symptoms are mild and common to many other illnesses, making diagnosis difficult. Currently, the primary mode of acquisition is through injection drug use. Certainly, decreasing this practice or providing means to circumvent transfer from person to person would have a tremendous impact on the number of new cases and future disease burden. The Panel strongly identified the need for new therapies. There is a great deal of activity underway in industry and NIAID grantees are working in this area. The recent infectious clone discovery opens the way for development of new systems with which to evaluate antivirals.

*Question.* Has research to date found an effective treatment for Hepatitis C and/or effective prevention methods?

*Answer.* At this point Hepatitis C research is in its infancy. Hepatitis C virus is itself complex as is its persistent relationship with the human host. Some of the questions that we are trying to answer include: 1) why some of those infected recover and others do not, and 2) why some have no symptoms for a long time and others become ill quickly. As more tools are developed and the focus changes from descriptive to mechanistic research, progress will occur more rapidly.

## EFFECT OF ALLERGY ON ASTHMA

*Question.* Dr. Fauci, if allergies are effectively treated in children, what impact do you estimate this would have on the incidence and severity of asthma?

*Answer.* Allergy is a major contributor to asthma severity and perhaps to asthma incidence. Effective treatment of allergy should substantially reduce asthma severity. A striking example of the importance of allergy is the very close association between allergy to cockroach and asthma severity that was recently uncovered in the NIAID-supported National Cooperative Inner-City Asthma Study (1991–1996). In this study, children who were both allergic to cockroach and exposed to high levels of cockroach allergen were hospitalized for asthma more than three times as often as children who were not allergic to cockroach, or who were allergic, but not exposed to high levels of cockroach allergen. In addition to the association with cockroach allergy, asthma attacks can be triggered by other indoor allergens (e.g., dust mites, cat and dog dander, rodents, and molds) and outdoor allergens, primarily grass pollens and molds. Furthermore, chronic exposure to these aero-allergens may cause patients with asthma to be hyper-sensitive to non-allergic triggers of asthma attacks, such as upper respiratory viral infections and environmental tobacco smoke.

Exposure to aero-allergens at an early age (0–2 years of age) may also contribute to the prevalence of asthma by inducing changes in immune function that predispose to the development of chronic asthma later in childhood. Thus, one attractive idea is to decrease the prevalence of allergies by eliminating exposure to allergens during infancy. NIAID recently funded a Demonstration and Education Research Project that will evaluate the effectiveness of a program for the primary prevention of asthma based on allergen avoidance in very early childhood. In addition, a continuation of the National Cooperative Inner-City Asthma Study (1996–2000) was recently funded by NIAID and the National Institute for Environmental Health Sciences. This multi-site study will evaluate the effectiveness of a comprehensive environmental intervention designed to reduce or eliminate indoor allergen exposure among inner-city children. This study will measure the amount of improvement in moderate to severe asthma that can be achieved by allergy control.

Other research is focusing on the cloning and molecular characterization of allergens and on the identification of previously unsuspected allergens that may contribute to asthma. Another important area of research involves manipulation of the immune system so that patients will have a reduced ability to mount allergic responses to allergens. Recent advances in basic research are suggesting some promising new methods for manipulating immune responses. Thus, further research may result in even more effective ways to control allergies and thereby treat asthma.

## ADVERSE EFFECTS OF ANTIHISTAMINES

*Question.* Dr. Fauci, I understand that allergies and subsequently the antihistamines that are prescribed have a significant impact on the performance of our nation's workforce, as well as on children's learning. Has your Institute researched the effect of allergies and antihistamines on children's learning?

*Answer.* NIAID research is not focused specifically on the relationship between allergies or antihistamine use and learning, cognitive abilities, or performance. However, data on cognitive ability were collected in the NIAID-supported National Cooperative Inner-City Asthma Study. A correlation between asthma severity and cognitive ability was not found among the 4–9 year old children enrolled in this study.

An estimated 15 million Americans suffer from asthma, 25 million from allergic rhinitis and approximately 35 million from sinus disease. Collectively, these diseases are responsible for millions of restricted activity days, missed days from school and work, significantly impaired quality of life, and impairments in cognitive function and learning ability. Antihistamines are the first line therapy for mild allergic rhinitis and are useful in certain forms of sinusitis. However, the most commonly used antihistamines cause a variety of adverse effects, including sedation, unrecognized drowsiness, impaired office and assembly line skills, impaired driving ability, impaired learning, and worsening in response times and performance to visual stimuli. Fortunately, newer, non-sedating antihistamines—which were introduced in the mid-1980s—penetrate poorly into the brain and generally lack these adverse effects. Indeed, the performance of allergic patients treated with non-sedating antihistamines is similar to the performance of non-allergic patients.

## MARIJUANA

*Question.* Dr. Leshner, the California and Arizona referenda favoring the use of marijuana in certain medical conditions points out how frustrated people can be when they feel they are not getting the right facts about marijuana as a medical

therapy. The New England Journal of Medicine recently endorsed the use of marijuana in certain limited instances in patients with a chronic, perhaps, moribund condition, who have not responded to standard pain therapy. Your Institute recently held a National Conference on Marijuana Use: Prevention, Treatment, and Research. What were the findings of this meeting?

Answer. The National Conference on Marijuana Use: Prevention, Treatment, and Research, was sponsored by the National Institute on Drug Abuse in collaboration with the Center for Substance Abuse Prevention and the Center for Substance Abuse Treatment, SAMHSA, in July 1995. The purpose of the conference was to provide scientifically based information on marijuana; to dispel commonly held myths surrounding marijuana use; to increase public awareness of the rising trends in marijuana use; and to educate the public about the consequences of marijuana use, especially for young people. This conference did not address issues of therapeutic uses of marijuana. A report of Conference Highlights is attached.

More recently, the NIH sponsored a workshop in February 1997 to see what research has been done on the medical utility of marijuana, to identify what scientific questions remain to be answered, to consider what diseases or conditions might have potential for medical marijuana and to consider what special issues have to be considered in conducting such research. This workshop was truly a trans-NIH event involving 10 of the NIH Institutes and Centers. A consultant review group is now considering the information presented at the workshop and will provide a report of its findings shortly to the NIH Director, to assist him in determining what actions NIH could take to fund needed research.

In addition, recognizing the dearth of scientific information on the medical utility of marijuana, the Director of the Office of National Drug Control Policy has committed funds for a comprehensive 18-month public review by the National Academy of Science's Institute of Medicine, of all scientific evidence on therapeutic marijuana.

#### MEDICAL USE OF MARIJUANA

*Question.* What is the view of research to date on the proposition that marijuana should not be approved for therapeutic use because there are other equally effective therapeutics that do not have the psychoactive effects of marijuana?

Answer. The Food and Drug Administration (FDA) is the Federal agency charged with the review and approval of drugs for the treatment of disease states. The role of the NIH is to conduct biomedical research.

The use of any substance for medical purposes, including marijuana, should be based on the scientific evidence. There are numerous instances (e.g., morphine for pain; amphetamine for weight loss; cocaine for local anesthesia) where illegal drugs are approved for medical uses. NIH welcomes applications for well-designed scientific studies to determine the safety and efficacy of marijuana for medical purposes. Well-designed clinical studies provide the findings to inform the scientific process whereby decisions regarding drug approval are made. The evaluation of marijuana for safety and efficacy for various medical conditions can and should be subject to this rigorous scientific process.

Sound research findings to support anecdotal claims of the therapeutic benefits of smoked marijuana are currently lacking. Recognizing the dearth of scientific information, the National Institutes of Health (NIH) recently organized a scientific workshop to see what research has been done, identify what scientific questions remain to be answered, consider what diseases or conditions might have potential for medical marijuana and what special issues have to be considered in conducting such research. A consultant review group is considering the information presented at the workshop and will provide a report shortly to assist me in determining what actions NIH could take to fund needed research.

It is important to note that there is scientific evidence regarding adverse health effects of smoked marijuana. It contains many of the same carcinogens and irritants found in tobacco and it produces profound changes in the brain and in behavior. Recent scientific findings have added to a growing body of evidence on the serious and harmful effects of marijuana, which many people mistakenly believe is a 'safe' drug. In pre-clinical studies, for example, scientists have determined a link between activation of the biological receptors that respond to cannabinoids, the psychoactive ingredients in marijuana, and abrupt interruption of pregnancy at a very early stage. Recent research also shows that long term use of marijuana produces changes in the brain that are similar to those seen after long-term use of drugs such as cocaine, heroin, and alcohol.

A synthetic form of marijuana's active ingredient, THC, is now available in capsule form and can be used for treating the nausea and vomiting that occur with cer-

tain cancer treatments. The oral THC also can be used to help AIDS patients eat more to keep their weight up as well.

#### BASIC NEUROSCIENCE

*Question.* Dr. Hyman, you have spoken considerably about your desire to increase basic neuroscience research at the NIMH. Would you further describe how you are moving forward in these areas?

*Answer.* Understanding the biology of the brain, and how specific biological processes in the brain go awry, is key to understanding the causes of mental disorders such as schizophrenia and depression. NIMH is moving to increase basic neuroscience research in order to increase our knowledge of the roots of mental illnesses and how these illnesses may be prevented and treated. Research areas of particularly high priority at this time include:

*Developmental neuroscience.*—This area holds the key to understanding how gene-environment interactions shape brain function and behavior. Basic conceptual issues concerning the development of many brain regions are poorly understood at present, especially for “higher” brain areas involved in cognition and the control of behavior, functions which go awry in some mental disorders.

*Molecular genetics.*—Our increasing ability to manipulate the mouse genome has created remarkable new scientific opportunities to understand the development of the brain, brain function, and the genetics of behavior. Genetic technologies have progressed rapidly, permitting a rapid expansion of research. NIMH proposes to expand research on molecular genetics, neurobiology, and behavior, using the mouse model as the most efficient, inexpensive, and rapid means of gaining information.

*Neurobiology of emotion and motivation.*—When combined with genetic approaches, new research on the neurobiology of emotion and motivation will provide cornerstones for research on depression, mania, and anxiety disorders, and—of interest to NIDA, a potential collaborator—on addictive disorders.

NIMH has been able to start planning to expand research in these areas because the NIH Director, recognizing the importance of this work, dedicated some funds in the budget development process from the “FY 1998 Areas of Emphasis” initiative. In addition, within NIMH, I have undertaken to reorganize and streamline both the Institute’s extramural and intramural research program staffs, with the objectives of better aligning our programmatic functions with the current directions of the neurosciences and behavior, and of bringing basic and clinical neurosciences closer together. As a key part of this reorganization, NIMH is currently recruiting a new Scientific Director, who will lead the reorganized intramural program.

#### CLINICAL AND HEALTH SERVICES RESEARCH

*Question.* Dr. Hyman, in this time of considerable change in our health care system, it is increasingly important that federal research programs assure the vitality of both clinical research and health services research. Would you outline the plans of the Institute to address these two important areas of research?

*Answer.* Both clinical and health services research have been areas of major emphasis for the NIMH and will continue to be important in the future. In the field of health services research we have supported a wide variety of grants that address the organization and financing of health services for people with mental disorders. These studies have shown us new models of how to organize our mental health services to ensure that they provide the services needed by people with mental disorders in a variety of settings. In addition, this research has been instrumental in providing data on the cost of a variety of options for financing mental health care for adults and children. A recent report by the NIMH Advisory Council, in response to a Senate request, has provided data on the feasibility of providing parity coverage for mental disorders. Research from our mental health services portfolio has shown us how managed care impacts on the quality of services delivered and ways to improve the quality of those services. The NIMH intends to continue to support our broad portfolio in health services research with particular attention to understanding how the rapidly changing health care market, especially managed care arrangements, impacts on the provision of quality mental health services.

NIMH sponsored research in clinical treatments has been important in the development of new and better treatments for a variety of mental disorders. This is highlighted in response to a question concerning NIMH clinical treatment research below. In addition, NIMH intends to expand its research portfolio to ensure that its clinical treatments have relevance to the diverse people who suffer from mental disorders. The Institute intends to reorganize the extramural science Divisions to bring the clinical treatment and services research portfolios together. We intend to put special emphasis on research that interfaces these two areas of science. The intent



of this is to ensure that our treatments will be applicable to broad populations with a variety of disorders. Also, findings from studies that interface these areas should help us in the formulation of treatment interventions that are cost-effective and high quality.

#### SCHIZOPHRENIA RESEARCH

*Question.* Dr. Hyman, I am advised that funding for schizophrenia research as a percentage of the overall NIMH budget has declined somewhat over the last few years. Given the severity of this illness, what accounts for this change?

*Answer.* Following the development and implementation in 1985 of the National Plan for Schizophrenia Research, NIMH-funded research relevant to schizophrenia—that is, epidemiologic, services and neuroscience research, as well as clinical and treatment studies, conducted both in our Intramural Research Program and through grants—increased some 250 percent over a six-year period, raising our annual investment in schizophrenia to approximately \$100 million. In more recent years, although NIMH's overall research funding has experienced a substantial slowing in the rate of growth that was commonplace through 1980s and early 1990s, we are maintaining funding for schizophrenia research in the \$110 million range. While the infusion of funds called for by the National Plan invigorated the field and raised our scientific investment in this disease to a more appropriate level, the National Plan-inspired rate of growth could not be maintained indefinitely without severely impeding our capability to respond to opportunities in other critical areas, particularly areas of fundamental science that are essential to our understanding of schizophrenia. Thus, while the Institute is maintaining its real-dollar investment, schizophrenia research as a percentage of total NIMH research funding has declined from 19 percent, 4 years ago, to about 17 percent today. However, the success rate for research grant applications relevant to schizophrenia is somewhat higher than the Institute overall success rate; also, schizophrenia applications are paid to a higher percentile. Both of these measures signal the continuing priority we attach to schizophrenia research.

NIMH staff now are in the process of analyzing our portfolio with respect to research focused directly on schizophrenia as well as basic neuroscience and behavioral science that is relevant to schizophrenia. For example, one of the most exciting areas of research is the hypothesis that schizophrenia is a neurodevelopmental disorder that has roots both in the formation of the brain in utero and in the neuronal changes that occur early in life, through adolescence and young adulthood. I am committed to supporting schizophrenia research by increases in absolute amount of funds—that is, over our current investment. I am committed as well to improving the already high quality of the research that we currently fund and expanding into areas which are currently under funded. The opportunities are certainly there. As new “atypical” antipsychotic medications come on the market after completion of industry-sponsored Phase III trials—a massive private sector investment, incidentally, that has been stimulated by our research funding over the years—we anticipate a significant number of investigator-initiated applications for research on these compounds to examine their use, dosage strategies, and comparative efficacy. In addition, we are seeing increasing activity in molecular genetics, particularly for complex disorders such as schizophrenia, as the power of this research approach is demonstrated in studies of simpler genetic disorders. NIMH now is providing to the field DNA samples contributed by families who have worked with investigators in our Diagnostic Centers Cooperative Agreement project. Also, I believe that outcomes research studying the effects of schizophrenia treatments in actual practice settings has been under funded in recent years, and I plan to rectify that.

#### TREATMENTS FOR MENTAL ILLNESSES

*Question.* Dr. Hyman, Congress has become increasingly concerned that there be adequate support for clinical research. What progress has been made in research on treatments for mental illness, what still needs to be done, and what steps is the Institute taking to ensure there is adequate support for clinical research?

*Answer.* Clinical treatment research continues to be a major emphasis of NIMH. We support a broad range of pharmacologic, psychosocial, and combined treatment strategies in all of the primary categories of mental illness: schizophrenia, major depression, bipolar disorder, and anxiety disorders. Recent studies with new “atypical” antipsychotic medications promise a reduction of the primary symptoms of schizophrenia (thought disorder, hallucinations, and paranoia) without causing the sometimes debilitating impairment in cognition and motor function that often occurs with the older antipsychotic medications. Other ongoing research suggests that natural substances such as the amino acid, glycine, may be used in conjunction with tradi-

tional antipsychotic medications to further reduce symptoms of the disorder while at the same time reducing their side effects.

Studies in bipolar disorder include newer mood stabilizers for treating acute episode and preventing relapses and recurrences. There is also an ongoing multi-site clinical trial of the antihypertensive drug verapamil, a calcium channel blocker antihypertensive medication, that has shown some preliminary evidence of efficacy as a mood stabilizer, without the sedation and kidney toxicity of current treatments for bipolar disorder. This study is being conducted with women of child-bearing potential because an added benefit of this medication is its apparent safe use during pregnancy.

Future directions for clinical research will include greater emphasis on effectiveness studies (those that more closely approximate real world use)—for example, treatment of mental disorders in individuals with comorbid illness or substance abuse. Testable strategies for prevention of mental disorders or of reducing their progress are also being developed. Additional effort is directed at combined pharmacologic and psychosocial interventions in mood and anxiety disorders, including Institute support for a new training program in this specialized area of treatment research.

#### RESEARCH ON CHILD AND ADOLESCENT MENTAL DISORDERS

*Question.* Dr. Hyman, what can you tell the Committee about mental illness in children and adolescents and what is the NIMH doing to better understand pediatric disorders?

*Answer.* Senator, through NIMH research we now know that mental illnesses strike children and adolescents, not just adults. Indeed, most of our major mental illnesses begin in the child and adolescent years. Community-based studies indicate that up to 21 percent of our nation's youth may be affected by mental disorders that involve mild to severe levels of impairment. Unfortunately, even the most severe early onset conditions such as autism may go unrecognized until children reach school age. Similar difficulties are encountered in the recognition and treatment of other conditions, such as manic-depressive disorder and Attention Deficit Hyperactivity Disorder. Failure to recognize and treat mental disorders puts children at risk for additional problems such as substance abuse, since these children with unrecognized mental disorders are at a severe disadvantage for keeping pace with their peers, with potential lifelong consequences.

Thus, to expand our efforts in developing effective identification and treatment services across multiple settings, NIMH is increasing its collaborative activities with other agencies, such as the Administration on Children, Youth, and Families, Head Start, the Department of Education, and the Center for Mental Health Services. In parallel, we are working proactively with the pharmaceutical industry and the Food and Drug Administration to increase the testing of psychoactive agents, in terms of their safety and efficacy in children and adolescents. This effort has a high priority, given the frequency of "off-label" prescribing for children and adolescents here in the United States. In the last 12 months alone, we have funded five new "Research Units on Pediatric Psychopharmacology" to address this urgent public health problem.

To better address the underlying causes of a number of the major childhood mental illnesses, we have accelerated our efforts to examine developmental neurobiologic and genetic mechanisms likely to be implicated in these conditions. For example, with support from Dr. Varmus' fiscal year 1997 one percent transfer funds, we have recently expanded our efforts to detect the genes that convey susceptibility for autism.

To "get the word out" to the Nation's health care systems, providers, and families, we are preparing a number of public health information initiatives that will reach many persons in need of our new information. For example, within the next year, we will host a Consensus Development Conference on the role of psycho stimulants in the treatment of Attention Deficit Hyperactivity Disorder. This conference will review all scientific data concerning the diagnosis itself, what is known about the efficacy of specific treatments, and make recommendations for clinical practitioners and policy makers.

#### GENDER DIFFERENCES IN MENTAL ILLNESSES

*Question.* Dr. Hyman, the Committee has noted in the past that some mental disorders, such as depression, seem to strike women more than men. What, if anything, do we know from research that may account for this?

*Answer.* From NIMH epidemiologic research, we know that, overall, mental disorders affect approximately equal numbers of men and women. However, higher

rates for affective and anxiety disorders are found among women; for example, major depression and dysthymia affect almost twice as many women as men. Also, of course, women are much more likely to suffer from eating disorders than men are. Among disorders in which there are similar prevalence rates for men and women, gender differences may be found in symptomatology, age of onset, course of illness, and response to treatment.

*Question.* What steps has the Institute taken to ensure that questions of gender differences in mental health treatment are investigated?

*Answer.* NIMH has been emphasizing research on these gender differences for a number of years now; however, the underlying biological reasons for the differences are complex and not yet well understood. Both hormonal and psychosocial influences are suspected and are being studied. Recent research by NIMH intramural scientists who were studying women with a particular type of depression, Menstrually Related Mood Disorder, has provided some of the first direct evidence of the regulation of both blood flow in specific regions of the brain and depressive symptoms by hormones associated with the menstrual cycle. This research also suggests that differential sensitivities to these steroidal hormones, rather than differences in hormone levels, underlie those mood disorders that are associated with the menstrual cycle. These studies open up very important directions for future research.

NIMH attaches high priority to research on gender differences in mental disorders and is actively working to stimulate basic, clinical, preventive, epidemiologic, and services research in this area. Two Program Announcements directed to women's mental health studies have been issued or expanded and updated: PA-95-061, Women's Mental Health Research, and PA-96-064, Mental Health Research in Eating Disorders. NIMH has also organized research workshops on women's mental health and has participated in women's health research workshops and conferences organized by the NIH Office of Research on Women's Health—activities designed to stimulate research.

#### EXTRAMURAL FACILITIES CONSTRUCTION—CENTERS OF EMERGING EXCELLENCE

*Question.* Dr. Vaitukaitis, during the last several years the Committee has provided funding for the extramural facilities construction program in which 25 percent of the funding is reserved for Institutions of Emerging Excellence. Would you please advise the Committee what progress has occurred to fulfill this requirement?

*Answer.* Since the inception of the extramural facilities construction program, there has been only one year in which the NCRF was unable to utilize 25 percent of the appropriated funds for Centers of Emerging Excellence. In fiscal year 1995 there were no highly meritorious applications received from these institutions. However, in every other year, these institutions have received at least 25 percent of the funds appropriated for this purpose; in fiscal year 1996, Centers of Emerging Excellence received 29 percent of extramural facilities construction funds. We expect and intend to award at least 25 percent of appropriated extramural construction funds to these institutions in fiscal year 1997. The quality of applications from these institutions has been steadily improving, and they are fully competitive with other institutions applying for the program.

#### VIOLATION OF THE BAN ON HUMAN EMBRYO RESEARCH

*Question.* Dr. Collins, the Chicago Tribune published a story on March 9 stating that a scientist receiving funds from NIH violated the legislative ban on human embryo research by concealing his real activities at Georgetown University and Suburban Hospital. It was reported that with these funds, he ran an embryo testing laboratory and committed a diagnostic error that apparently resulted in the birth of an infant with cystic fibrosis. These allegations are troubling because they imply that those who wish to evade the intent of Congress and the President could do so. If it were not for the actions by some of his employees who reported his activities to authorities, he would still be conducting this type of research. Dr. Collins, what actions did you take and what actions will the Department take to investigate these allegations?

*Answer.* In August and September 1996, when it became apparent that a problem might exist regarding Dr. Mark Hughes, through equipment inventory discrepancies at Georgetown University (GU) and statements of National Human Genome Research Institute (NHGRI), formerly NCHGR, employees, explanations were sought from Dr. Hughes. On September 23, 1996, Dr. Jeffrey Trent, the Scientific Director of NHGRI, and I met with Dr. Hughes to remind him that it was imperative that he comply with NIH policy not to perform pre-implantation genetics research. Dr. Hughes assured us at that meeting that no Federal resources were being used in that endeavor. He admitted that he had moved equipment loaned to GU to Subur-

ban Hospital, despite NHGRI insistence that no resources be used at Suburban, but said that he had recently moved the equipment back to GU. In September and October, Dr. Kate Berg, the Deputy Scientific Director of NHGRI, interviewed all personnel working under the direction of Dr. Hughes and determined that Dr. Hughes was using both NHGRI equipment and trainees to perform pre-implantation genetic diagnosis.

On October 10, 11, and 15, Dr. Berg sent letters to all of the personnel working under the direction of Dr. Hughes to clarify the NIH policy on human embryo research. On October 17, 1996, Drs. Trent and Berg sent a memorandum to the HHS Office of the General Counsel and NIH Office of Human Resources Management documenting their findings regarding Dr. Hughes' activities. As a result, NHGRI was advised to terminate its research relationship with Dr. Hughes. NIH terminated its research relationship with Dr. Hughes (verbally and in writing) on October 21, 1996 at a meeting attended by Drs. Hughes, Trent, Berg, and me.

Continuing efforts to collect information and reconcile equipment lists followed, and in January 1997 a conference call with the Regional Inspector General for Investigations, Philadelphia Field Office, and the NIH Deputy Director for Management Assessment met with the NIH Deputy Director for Intramural Research and the NIH Office of Human Subjects Research (OHSR) to determine the next steps in coordinating with the Office of the Inspector General, HHS. From March 6 to April 21, 1997, the OHSR conducted a review of activities related to Dr. Hughes and determined that the research conducted by Dr. Hughes should have been subjected to review by an Institutional Review Board.

*Question.* If it were possible for this individual to evade this ban for a significant period of time, how confident can you be about those who might conceal efforts at cloning human beings?

*Answer.* We are confident that this was an isolated incident. Dr. Hughes clearly was aware of the rules and purposely set out to evade them. The NIH's review of the activities related to the violation of the ban on embryo research by Dr. Hughes resulted in the identification of several management areas needing immediate and future enhancement to ensure that such incidents do not happen in the future.

The NIH already has policies and procedures in place in each of these areas and the follow-up actions taken or planned will supplement the existing requirement with revised new requirements or will involve further testing or review to assure that existing controls and procedures are working as intended. The actions are:

1. Assure that intramural staff and extramural grantees are officially advised of legislatively imposed conditions on research, once such conditions are enacted.
2. Assure that NIH trainees are properly mentored and are advised of rules regarding research and what steps to take when problems arise in carrying out their research responsibilities.
3. Assure timely communication of information to the Office of the Inspector General and the Director of the NIH, when violation of law or significant deviation from the NIH policy may have occurred.

The following chart identifies the actions NIH has taken to date and the further actions planned for each of these areas of concern.

## NIH FOLLOW-UP TO ADDRESS MANAGEMENT OVERSIGHT ISSUES

Management concerns	Action taken to date	Further actions planned
<p>1. Assure that all NIH staff and extramural grantees are advised of legislatively imposed conditions on research.</p>	<p>1. The Deputy Director for Intramural Research (DDR) issued a memorandum to all NIH intramural scientific staff reminding them of the continuing prohibition against conducting human embryo research at NIH. (Feb. 4, 1997).</p> <p>2. NIH posted a list of the legislative mandates contained in Public Law 104-208 on the NIH home page. (Feb. 97).</p> <p>3. The ASMB/HHS issued a letter to Institutional officials of universities reminding them that no Federal research funds may be used for the creation of a human embryo for research or for research in which a human embryo is destroyed, discarded, or subject to more than minimal risk. (Feb. 97).</p> <p>4. The Office of Extramural Research (OER) distributed the ASMB's letter to over 1700 officials. (Feb. 97).</p> <p>5. OER discussed the need to ensure compliance with the human embryo research ban at a meeting of the Extramural Program Management Committee. (Feb. 97).</p> <p>6. The NHGRI Scientific Director: (1) met with each NHGRI principal investigator (tenured or tenure-track scientist) to describe the importance of compliance with human subject regulations and publication clearance issues and (2) attended the individual lab meetings of each principal investigator (at which attendance was mandatory) to present to every research member of every NHGRI laboratory the critical nature of human subjects compliance and publication clearance. (March 97).</p> <p>7. NHGRI's Scientific Director discusses priority research oversight topics at weekly meetings with NHGRI Lab and Branch Chiefs including protocol procedures, publication approvals, and outside activities, as well as research administration oversight activities including property, space and facilities, contracting, and personnel. (Ongoing since 1993).</p>	<p>1. The Office of Legislative Policy and Analysis (OLPA) will advise the Director, ICD Directors, and NIH senior management in writing of all legislative provisions in appropriations acts within 5 days of enactment. (This is already done for authorizing statutes).</p> <p>2. NIH (OLPA) is preparing a manual chapter on legislative implementation plans which identifies specific NIH organizations accountable for implementing and monitoring compliance with mandates in appropriation laws. Plans will identify mechanisms for information dissemination to intramural staff and grantees, as needed. (Already complete for authorizing statutes.)</p> <p>3. Communication of important Administration, Secretarial, and NIH policies (non-legislative) will occur more vigorously at NIH ICD Directors', Executive Officers', and Scientific Directors' meetings.</p> <p>4. The DDR is preparing a new publication clearance form for use by all Scientific Directors to assure increased oversight over publishable work done in the intramural program. The NHGRI Scientific Director is developing criteria to provide increased oversight/review/clearance over scientific articles, including abstracts by its scientists.</p>

2. Assure that NIH trainees are properly mentored and are advised of rules regarding research and what steps to take when problems arise in carrying out their research responsibilities.
  1. Established a requirement for all NIH intramural staff to take a new computer-based human subjects research training program. (96-97).
  2. Under the direction of the Deputy Director for Intramural Research, the NIH Ethics and Conduct Committee has developed programs to improve mentoring and to encourage post-doctoral fellows to seek help if problems arise. One of these improvements is a pilot project to appoint an ombudsman to address concerns of laboratory researchers at the NIH. The appointment has been made, and the ombudsman will report to the Deputy Director, NIH. (March and June 97).
1. Continue development of a central database of all intramural scientists (including post-doctoral fellows and students) at the NIH which will include a description of the work being done by the scientist. This database will be fully text searchable and will enable identification of all research activities which might require follow-up, which will be the responsibility of the Deputy Director for Intramural Research.
  2. Complete development and begin implementation for all staff, including IPAs, of an NIH-wide orientation package which will be tailored to the area in which the employee works and will cover areas of human studies, research, technology transfer, safety in the laboratory, and to whom to express concerns about research-related or personnel problems.
  3. Preparation of succinct, clearly written guides covering rules/regulations and responsibilities for post-doctoral fellows and a "Primer for Scientific Directors."
  4. NHGRI will hold quarterly, or as needed, meetings with trainees and new Principal Investigators to provide an opportunity for feedback on the science and work experience in NHGRI's intramural program.
  5. An evaluation of the effectiveness of the ombudsman concept will be carried out after one year.
1. The OIG Hotline Tips Handbook was distributed to all senior staff and ICD Directors and Executive Officers. (Jan. 97).
  2. Senior staff and ICD Directors have been reminded that they need to report violations to the OIG or OMA and keep the Director informed. (Feb. 97).
  3. NIH staff at all levels have been reminded, through placement of a notice on the NIH home page and by desk-to-desk distribution of a memorandum from the Director, NIH, to report suspected violations of law or administrative policy to the Director, OMA or the OIG Hotline. Staff were reminded to report possible criminal violations immediately. (Feb. 97).
  4. A new NIH manual chapter on procedures for reporting allegations of criminal offenses, misuse of NIH grant and contract funds, or improper conduct by NIH employees has been issued desk-to-desk to all NIH employees. Electronic announcement of the chapter and OMA and OIG Hotline telephone numbers have been provided to all NIH staff. Staff were reminded to report allegations of criminal activity immediately. (June 97).
1. The DDM will report alleged violations of law or policy as necessary, but no less than monthly, to the Director and Deputy Director, NIH.
  2. ICD Directors, Executive Officers, and OD Senior Staff will be reminded to advise the Director, Deputy Director, NIH, and the Deputy Director for Management of violations in their areas of responsibility on a timely basis.

## UPHOLDING THE INTEGRITY OF SCIENTIFIC DATA

*Question.* Dr. Collins, the disclosure last fall that an assistant of yours confessed to a series of data misrepresentations and outright fabrications was very disturbing. What steps did you take to correct the fraudulent data and will you take to ensure the future integrity of scientific data?

*Answer.* In the Fall of 1996, I confirmed that a serious case of fabrication and falsification of data had occurred in my laboratory, involving a project on the mechanism of leukemogenesis. No patients were directly involved in the research. This situation first came to light when a careful reviewer noted that a figure in a manuscript submitted for publication appeared to have been altered. I instituted a review of the experimental efforts of the suspected individual, Mr. Amitav Hajra, who was no longer affiliated with the NIH laboratory. Analysis of the laboratory notebooks, photographs, x-ray files, and the student's Ph.D. dissertation uncovered additional examples where the authenticity of data could not be verified. When the individual was confronted about these discrepancies, he confessed to a series of data misrepresentations and outright fabrications, extending over a period of at least two years.

Once discovered, the necessary steps were immediately taken to report and investigate this case. Scientists working in the field were notified and retractions of all flawed manuscripts were submitted and have now been published. The DHHS Office of Research Integrity (ORI) and the University of Michigan, from which this student had come, were notified and a full and formal investigation has been completed. The ORI found that Mr. Hajra engaged in scientific misconduct by falsifying and fabricating research data in five published research papers, two published review articles, one submitted but unpublished paper, in his doctoral dissertation, and in a submission to the GenBank computer data base. Mr. Hajra has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the four (4) year period beginning July 7, 1997, to exclude himself from:

(1) Contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 CFR Part 76 (Debarment Regulations);

(2) Serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

To uncover such a blatant example of fabrication of data, carried out by a student of apparent great intrinsic talent, and who discussed his results and shared his data frequently with me and numerous other members of the laboratory, has been a deeply disturbing experience. I have gone out of my way to speak freely about the experience, feeling that such episodes of scientific misconduct, while fortunately rare, provide lessons for everyone. I and many other researchers who were affected by these events, have increased our own vigilance as a consequence. A ground breaking course on ethical behavior is now required of all intramural trainees at NHGRI. However, it is unlikely that any system will be fool proof. Fortunately, it is an inherent property of the scientific enterprise that it is self-correcting—important experimental results will always be verified by others as they build on these results to produce further new knowledge.

## NEXT GENERATION INTERNET MEDICAL APPLICATIONS

*Question.* Dr. Lindberg, as both Director of the NLM and former Director of the White House National Coordination Office for High Performance Computing and Communications, can you tell us a bit about medicine's role in the HPCC initiative and the Next Generation Internet program?

*Answer.* Medicine can benefit from and contribute to high performance computing and communication systems and applications requiring high speed network connections. Applications such as the analysis of biomolecular sequences and structures, the processing and visualization of biomedical images, the development of networks linking hospitals, clinics, libraries, and medical schools, the development of computerized patient records and telemedicine technologies, and the creation of virtual environments to assist in medical diagnosis are currently being tested and show great promise of improving the delivery of health services.

Next Generation Internet applications fall into the categories of advanced telemedicine, telehealth and distance learning or control applications. They would generally require the transfer of many gigabits of data in close to real time such as CT, MRI or PET scan studies. Other applications require the transfer of smaller amounts of data but with considerations such as very tight control of latency and/or jitter such as echocardiography, angiography, nystagmus gait analysis and func-

tional MRI. Still other applications require the retrieval of multimedia reference data from libraries. The availability of the Next Generation Internet will lead to a whole new set of applications, telepresence applications, which are based on the ability to control, feel and manipulate devices at a distance. Applications already being developed include remote microscopy for pathology, remote monitoring and control of devices for home health care. Eventually, these advances may even lead to telesurgery. All health care applications have a strong security and confidentiality component.

#### WORLD WIDE WEB—HEALTH INFORMATION

*Question.* Dr. Lindberg, the general public in great numbers are turning to the World Wide Web as a source of information to improve their own health. What is NLM doing to provide quality health information to consumers and what improvements could be made?

*Answer.* The Library recently announced that health professionals and the general public have free access to MEDLINE using the World Wide Web via PubMed or Internet Grateful Med. MEDLINE is the Library's premier database, containing citations to articles in about 3,900 biomedical and health care journals from all over the world. This is the database used by members of the general public to retrieve information which has been very helpful in treating a medical condition they or a member of their family had. Staff are working to identify some high quality journals specifically designed for consumers to add to MEDLINE in 1998. Other databases created by the Library, such as AIDSLINE and HealthSTAR, a database of citations to health care research and technology assessment reports, are or will also be accessible free via the Web.

The National Library of Medicine's home page links to the full text of documents, including HIV/AIDS resources; consumer brochures of clinical practice guidelines sponsored by the Agency for Health Care Policy and Research and treatment protocols; NIH Clinical Alerts; early releases of clinical information from NIH; and a number of hot links to Web-based sources of excellent health information from NIH, DHHS's healthfinder, CDC's prevention guidelines, etc. The Library is also beginning a pilot project to determine the requirements for an ongoing project to locate, bibliographically describe, monitor, and make available in a database Web sites containing information of particular value to consumers.

#### QUESTIONS SUBMITTED BY SENATOR GORTON

##### EXTRAMURAL RESEARCH FACILITIES CONSTRUCTION PROGRAM

*Question.* The status of equipment and core facilities available to support research can best be described as "fraying at the edges". The matching grants program which assisted universities in maintaining cutting edge facilities was an important program particularly for those research centers that are co-located with public hospitals and deal with trauma, infectious disease, and severe mental illness and/or substance abuse. If Congress succeeds in appropriating additional funds for the NIH, do you have plans to direct some of these funds towards this program?

*Answer.* The extramural research facilities construction program, administered by the National Center for Research Resources, supports highly meritorious projects which will enhance the research capacity of the nation's research institutions. In the past, awards have been made to institutions to enhance research capability in many areas, including trauma, infectious disease, mental illness and substance abuse. The study of the nation's research facilities by the National Science Foundation in 1996 found that the space available for research in this country is diminishing and deteriorating. Therefore, this could be one of NIH's priorities for using additional funds.

##### STREAMLINING AND REINVENTION INITIATIVES

*Question.* What are the results of streamlining efforts such as GPRA? How do you propose to keep from "growing back" to the levels of bureaucratic spending?

*Answer.* As a part of efforts such as the Government Performance and Results Act (GPRA), the NIH has initiated streamlining and reinvention initiatives. NIH has four major goals for reinvention: (1) maximize scientific opportunities through optimal use of resources; (2) enhance NIH interactions with the scientific community; (3) clarify and streamline decision-making processes; and (4) focus internal operations on outcomes and results. Examples of completed streamlining efforts include:

*Streamlined Review.*—Based on the original NIH application "triage" process, streamlined review procedures insure that there is a review and critique of each ap-



plication while allowing the review process to focus on those applications that are most competitive. Adding to the efficiency of this process, reviewers' critiques are transmitted verbatim, thus preserving the detail, substance, and complexity of the issues being addressed. This results in savings in staff time previously spent on editing reviewers' comments.

*Streamlined Noncompeting Award Process (SNAP).*—Under SNAP, the majority of noncompetitive continuation applicants are not required to submit certain application components if there are no significant changes to previously submitted data. SNAP has eliminated nonessential reporting of data which saves time for applicants as well as NIH staff. Following the success of the original SNAP, NIH followed with a Phase II in which requirements related to the Notice of Grant Award were reduced, and a Phase III was initiated to modify the financial reporting requirements. These have further increased efficiency.

*Electronic requests for research contracts.*—A number of NIH institutes have begun to post Requests for Contract Proposals (RFPs) on the NIH Gopher server. This provides savings in the costs of mailing and copying, and in contract staff effort.

The following are examples of current streamlining initiatives that are being pilot-tested. These streamlining activities build on previous efforts and are expected to relieve administrative burdens on both NIH staff and grantee organizations.

*Electronic Data Interchange (EDI).*—Under a Cooperative Agreement with the Department of Energy (DOE), the NIH and several Department of Defense (DOD) agencies are participating in a pilot study to test a new system for the submission of grant application information. This initiative is reducing the need for manual rekeying of data and duplicative paper processing of key grant administrative information.

*Electronic Streamlined Noncompeting Award Process (E-SNAP).*—An electronic version of the SNAP process is now being pilot tested. "E-SNAP" is an interactive World Wide Web based site for electronic submission of SNAP information. Using the interface, authorized grantees will submit all required information electronically. This initiative will save staff time and reduce mailing and copying costs incurred by paper transmission of data.

*Paperless Acquisition.*—A pilot test is being conducted to test the feasibility of "paperless" acquisition of research contract proposals. This "paperless" system is expected to reduce the time and expense of all parties involved in the acquisition process.

*Expedited Review and Award.*—A pilot test is being conducted that will streamline five features of the application-to-award process. Although the initial pilot test is limited to a single initial review group and a single awarding institute, the eventual results will likely streamline aspects of the receipt, referral, review, and award processes for all NIH applications.

NIH staff are continually working to identify ways to improve how we do business. We maintain an open dialogue with the extramural community and seek new ideas about streamlining and related activities. The feedback we have received about these efforts has been positive and we plan to build on past successes and continue to implement changes in policies and procedures that will improve our efficiency and effectiveness.

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#### QUESTIONS SUBMITTED BY SENATOR BYRD

##### ALCOHOL RESEARCH BUDGET REQUEST

*Question.* According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), alcohol abuse and alcoholism cost our nation approximately \$100 billion annually. While the current crusade about the dangers of smoking tobacco and the war on drugs are certainly important and worthwhile endeavors, I am concerned that the impact that the consumption of alcoholic beverages has on our nation and on our youth is receiving short shrift. Given the enormous toll that alcohol exacts on our nation, do you feel that the President's fiscal year 1998 budget request of \$208,112,000 for NIAAA is adequate?

*Answer.* The fiscal year 1998 President's Budget requested an increase of approximately \$7.5 million over the fiscal year 1997 appropriation to enable the Institute to sustain its research progress, address the most significant research opportunities and support high quality research grants in priority areas such as genetics, fetal alcohol syndrome, neuroscience, medications development, prevention, and treatment.

## ALCOHOL ADVERTISING AND CHILDREN

*Question.* Has the NIAAA explored the impact of alcohol advertising on our nation's children?

*Answer.* The Institute has supported research which explores the impact of alcohol advertising on our nation's children. The current research findings on alcohol advertising and youth suggest that alcohol advertising may influence adolescents' drinking beliefs and expectancies but, at this point, research has not established the final link between alcohol advertising and adolescent alcohol consumption.

*Question.* Do the findings, if any, warrant further study in working toward the Institute's goal of combating alcohol abuse and alcoholism?

*Answer.* Current research findings are inconclusive and the Institute is interested in obtaining more decisive evidence on the impact of alcohol advertising specifically addressing concerns about the initiation, use, and misuse of alcohol by youths and other vulnerable populations. A NIAAA program announcement continues to solicit applications to elucidate the connection between advertising, mass media portrayals and alcohol use and abuse by youthful and vulnerable populations and expects additional fiscal year 1998 research grant applications in this priority area.

## QUESTIONS SUBMITTED BY SENATOR KOHL

## NIH BUDGET INCREASE

*Question.* There's been a lot of talk about doubling the \$13 billion NIH budget. I also support boosting our nation's biomedical research investment. Unfortunately, the Senate rejected an amendment to the budget that would have provided a down payment toward that goal, even though it was fully offset by an across-the-board reduction in administrative costs from other federal agencies.

Now we are faced with trying to fulfill promises of a big increase when this Subcommittee is faced with a health budget that is \$100 million below a freeze from current funding levels. Therefore, any increase in NIH would potentially have to come at the expense of other public health or education programs, which, I am sure you would agree, is not a good choice.

Are there further reductions in NIH overhead or administrative costs that you are prepared to offer to help in this task? Do you have other suggestions for offsets?

*Answer.* In an effort to provide a better understanding of administrative cost allocations, the NIH is currently responding to a study requested by Mr. Porter, Chairman of the House Subcommittee on Labor, HHS, and Education appropriations. This study will advise the NIH on management improvement issues and it will help to improve service levels and to reduce costs. The study will focus on identifying best practices and opportunities to create administrative efficiencies. Other reinvention efforts are underway in the organizations responsible for awarding NIH grants and contracts, and we are continuing our efforts to review each Institute's intramural research program for effectiveness and efficiency, as well as best scientific practices.

## EARLY CHILD CARE

*Question.* I am very supportive of the research conducted by the National Institute of Child Health and Human Development on the impact of child care on child development. This research has shown that higher child care quality was consistently related to better outcomes in cognitive and language development in the first three year's of life. Just in case there was any doubt, I believe this research provides a clear justification for increasing our investment in quality child care, particularly for the zero-to-three age group. Did this research examine on-site child care arrangements provided by businesses for their workers?

*Answer.* The NICHD Study of Early Child Care selected for its investigation 1,364 newborn infants and their families from among the 8,986 infants whose mothers were contacted soon after giving birth. The infants were observed in the child care settings that their parents selected for them. These settings included relative care, in home non-relative care, child care homes and center care. Parents were asked if the care setting was a for-profit setting or not, and if it was non-profit, parents were asked if the setting was sponsored by a corporation, business, hospital or employer. Only a small proportion of non-profit settings fell into this general category of sponsorship. The settings which were sponsored were child care centers. However, when the children were very young the number of children in centers was small. The number increased as children matured. When the infants were 6 months, 19 of the 91 child care centers that provided care for study children were "sponsored".

At 15 months, 6 of the 70 child care centers were sponsored. At 24 months, 5 out of the 91 centers were sponsored, at 36 months, 12 of the 219 centers were sponsored and at 54 months only 19 of the 652 centers providing care for study children fell into the "sponsored" category.

*Question.* How will these studies help families and businesses deal with the critical need for high quality child care?

*Answer.* The findings from the NICHD Study of Early Child Care show that after controlling family characteristics (including the quality of mothers' interaction with their children), child care quality is associated with positive outcomes for children. The higher the quality of positive caregiving and language stimulation by child care providers, the better the cognitive and language development of the children at 15 months of age, at two and at three years of age. With quality of care controlled, being enrolled in child care centers contributed further to better cognitive and language outcomes, probably because child care centers are more oriented than other child care arrangements to preparing children for school.

These findings suggest that parents can influence the development of their children not only by the way they interact with their children but also by the quality of the non-maternal care they select for them. Businesses which offer child care for children of their employees can help parents and children by providing high quality of care. High quality care is focused on providing each child with sensitive, responsive and cognitively enriching child care.

#### RESEARCH UTILIZING EXPERIENCES OF COMMUNITY AND MIGRANT HEALTH CENTERS

*Question.* Community and migrant health centers fulfill an important role in our health care system by providing comprehensive care to those who are most at risk in our society—those who, because of race, income, language or cultural barriers, may have severely limited access to health care services. Faced with severe budget constraints, these centers provide creative public health strategies to help people who are otherwise excluded from our health care system. As such, there are unique opportunities to utilize community and migrant health centers for various public health research objectives. What percentage of the NIH budget is directed towards research that incorporates the experiences of community and migrant health centers? How can NIH, and NIEHS in particular, expand research protocols that include these centers?

*Answer.* The NIH values the unique perspectives that community and migrant health centers provide in health research. We continue to build partnerships with these centers. In fiscal year 1996, approximately 2 percent of the NIH extramural budget was directed toward research involving these centers. Research involving community and migrant health centers would be part of the support for clinical research, approximately 36 percent of the extramural budget.

The NIH will develop strategies to assist researchers in their outreach to communities as a step toward building partnerships and increasing collaborative participation in research. The NIH has already identified a number of successful approaches for involving communities and migrant health centers in research. For example, through the National Black Leadership Initiative on Cancer, the NIH has reached out to minorities on cancer treatment in the Minority-Based Community Cancer Oncology Program. Additional examples include a community-based, public health oriented program to increase physical activity of older adults and community programs for clinical research on AIDS.

NIEHS has a number of specific programs that utilize community and migrant health centers in accomplishing their research objectives. Within the NIEHS Centers program, Centers located at the University of Iowa and the University of California, Davis, specifically target environmental health problems of migrant farmworkers and interact with local health centers to help alleviate adverse health impacts. NIEHS-supported Developmental Centers at Columbia, Tulane, and the University of Louisville also utilize the resources of local health centers to address environmental health problems of socioeconomically disadvantaged and medically underserved populations in their vicinity.

In addition, NIEHS supports a grant program in Community-Based Prevention/Intervention Research that has the specific aim of developing culturally appropriate intervention strategies based on a partnership among scientists, health care providers, and community members. Two of these projects focus on pesticide-related health problems among migrant farmworkers in North Carolina and Oregon. Others address lead poisoning and outdoor/indoor air pollution and asthma in both children and adults in urban as well as rural settings. All of these projects are community-based and therefore collaborate extensively with local health centers and clinics.

Through its Environmental Justice grant program, NIEHS supports additional projects involving partnerships among researchers, clinicians, and residents. These projects seek to increase the community's awareness about environmental health issues and to enhance their input into the decision-making process that develops future research and intervention approaches to address their concerns. One project concentrates on migrant farmworker health problems on the Texas-Mexico border. Others deal with a diverse array of hazardous exposures and underserved populations, including Native, African, Asian, and Hispanic Americans. Again, because of the specific community-based nature of this initiative, the twelve grants within this program all make significant use of local health centers and clinics.

*Question.* Does the Administration support extending the ban on federal funding for human embryo research in the fiscal year 1998 Labor, HHS and Education Appropriations bill?

*Answer.* As indicated in the President's fiscal year 1998 budget, the Administration does not believe it is necessary to address this issue in legislation and does not support doing so. In December 1994 the President took administrative action to ban the use of federal funds to create embryos for research purposes, stating, "I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research."

#### CONCLUSION OF HEARINGS

Senator SPECTER. Thank you all for being here and that concludes our hearings, the subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 4:05 p.m., Wednesday, June 11, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]



## Material Submitted Subsequent to Conclusion of Hearing

[CLERK'S NOTE.—The following statements were received subsequent to conclusion of the hearing. The statements will be inserted into the record at this point.]

PREPARED STATEMENT OF DR. ENOCH GORDIS, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM [NIAAA]

I am pleased to be here with you today to discuss the many scientific advances and research opportunities at the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The NIAAA is the foremost Federal agency supporting biomedical and behavioral research directed towards improving the prevention and treatment of alcohol abuse and alcoholism and reducing associated health, economic, and social consequences. NIAAA funds 90 percent of all alcohol research in the United States and provides leadership in the country's effort to combat these problems by developing new knowledge that will decrease the incidence and prevalence of alcohol abuse and alcoholism, and its associated morbidity and mortality.

Alcoholism research has the potential to impact on the lives of approximately 14 million alcoholics, alcohol abusers and their families—an estimated 98 million Americans. Although a dollar figure cannot adequately reflect the social and human devastation caused by these illnesses, it is estimated that the economic and health care costs to society from alcoholism and alcohol abuse approach \$100 billion annually<sup>1</sup>. Research findings that improve the prevention or treatment of alcohol abuse and alcoholism have tremendous potential for affecting the quality of life of nearly every American and can influence thinking in other areas of medicine.

Among the areas where alcoholism research has made significant strides is the demonstration that a significant amount of the vulnerability to alcoholism is inherited. Previous twin and adoption studies laid the foundation for current genetics work, much by individual NIAAA intramural scientists but most extensively in the Collaborative Study on the Genetics of Alcoholism (COGA) supported by NIAAA. COGA is a multi-site collaborative, tightly controlled study of large families who have alcoholism multiply represented among their members. COGA involves six extramural research study centers in which investigators are searching the entire human genome for genetic markers linked with alcoholism.

COGA scientists developed accurate, valid, reliable, and specific comprehensive interviewing tools, the Semi-Structured Assessment for the Genetics of Alcoholism (SSAGA) and its companion version for children (C-SSAGA-C) and adolescents (C-SSAGA-A). These new interviewing tools represent a major advance in currently available interviewing techniques, and are in use internationally. Resources subsequently developed by COGA include diagnostic and pedigree data on 3,000 individuals belonging to about 300 families with alcoholism, along with corresponding biochemical, genetic, and neurophysiological data. Also developed is a collection of DNA samples and immortalized cell lines derived from these individuals and maintained in a Cell Repository. COGA resources will thus provide a wealth of data available to the scientific community for further investigation.

We are very pleased to report that initial COGA findings have identified promising chromosomal locations relating to alcoholism, and colloquially referred to as "hot spots." Distinct from this research is the finding of chromosomal locations for a specific brain wave pattern, P3, found in persons at high risk for alcoholism. Each chromosomal location contains many genes and the next task is to identify the precise genes. The payoff for this research is the development of new medications, targeted prevention programs, and a precise understanding of both the genetic and environmental influences on the development of alcoholism.

<sup>1</sup>Rice, Dorothy, P. The Economic Cost of Alcohol Abuse and Alcohol Dependence: 1990. Alcohol Health and Research World 17(1):10-11, 1993

Another area where alcohol research has advanced is in the use of animal models for studying complex behavior, such as, alcohol consumption. Molecular biology techniques are being used to identify quantitative trait loci (QTL) which give investigators the ability to define the contribution of single genes, any of which together create the quantitative trait. We are pleased to report that an NIAAA-sponsored investigator has located two sex-specific genes influencing alcohol consumption in mice. One QTL (Alcp1) is active only in males; the other (Alcp2) is active only in females, and only when inherited through the maternal lineage. Because of similarities between the mouse and human genes, this work promises to accelerate locating human genes that contribute to alcoholism.

Earlier work led to the conclusion that the neurotransmitter, serotonin, is involved in alcohol consumption. Recently, a study identified one precise serotonin receptor subtype, 5-HT1B, that is involved in regulating the consumption of alcohol in mice. This was accomplished by genetically removing the serotonin receptor, 5-HT1B, and observing increases in alcohol consumption. Stimulation of the 5-HT1A serotonin receptor subtype, however, reduces consumption. Other investigators showed that clinically realistic doses of alcohol affect several neurotransmitters including, NMDA subtype of glutamate receptor, the GABAA receptor, and other serotonin receptors. The effect of alcohol on these receptors varies among brain locations in single animals and between strains raised to demonstrate major differences in alcohol related behaviors.

Advances are also being made in understanding the mechanism of alcohol-induced tissue damage (toxicology). These findings include: the fact that alcohol can influence the expression of cytokine-regulated genes in the liver; that clinical management of alcohol-induced liver injury might be improved by reducing the number of gram-negative bacteria producing endotoxin in the intestine; and that the pathogenesis of fibrosis in alcoholic liver damage may involve the direct deposition of collagen induced by acetaldehyde, the first product of alcohol metabolism.

Advances are also beginning to unravel the mechanisms of alcohol's effects on human fetal development leading to the manifestations of fetal alcohol syndrome (FAS). Two findings suggest reasonable mechanisms for alcohol's effects on the fetus. One finding is that alcohol induces excessive cell death through the formation of free radicals in pre-migratory neural crest cells resulting in subsequent malformation. The addition of a free-radical scavenger can ameliorate alcohol-induced cell death. The second finding is that at clinically relevant levels, alcohol completely inhibits the activity of the L1 cell adhesion molecule which helps guide newly forming neural cells to their proper location.

Research on effective medications is built upon findings such as those previously mentioned. Naltrexone, nalmefene, and acamprosate are among the most promising medications. The use of naltrexone which was recently approved by the FDA for the treatment of alcoholism is based on clinical and basic science observations. NIAAA-sponsored clinical trials are now determining which groups of patients are most responsive to this medication and the benefits and side effects of long-term use. Nalmefene, another opioid antagonist, also appears promising and has several potential advantages over naltrexone including a longer half-life, enhanced bioavailability, less liver toxicity, and more complete blockage of opioid receptors. Acamprosate, now under an FDA investigational new drug protocol, has been tested in clinical studies throughout Europe with promising results. It appears to act on NMDA and GABA receptors. NIAAA is providing consultation on methodology and trial design to pharmaceutical companies planning clinical trials on acamprosate.

In addition to medications development, other aspects of treatment research are also advancing rapidly. We are ready to begin advanced clinical trials built upon data obtained from both medication studies and from the recently completed multi-site treatment trial, called Project MATCH. This study compared the effects of different treatment types when matched to specific patient characteristics and was the largest, most complex randomized clinical trial ever undertaken in alcoholism treatment. A number of alternative treatments for alcohol problems are available. They range from brief, motivational interventions to "broad spectrum" treatments, such as social skills training, and the 12-step "Minnesota model." Frequently two or more treatment types are combined in one therapeutic approach.

Based upon the literature and previous small studies, the hypothesis was advanced that matching patient characteristics to specific treatment modalities would be the most efficacious. Patients were randomly assigned to well-specified treatment strategies. Subsequently the relationship between treatment outcome, patient characteristics, and treatment type were assessed. A total of 1728 patients were recruited from nine states, with ample representation of women (25 percent) and minorities (20 percent). Three specific, well-defined, and well-controlled treatment ap-

proaches were tested. The findings from MATCH, however, did not confirm this expectation.

Instead, the three treatments achieved comparable outcomes and the data indicate that each treatment type resulted in substantial reductions in drinking. Furthermore, this reduction in drinking was generally sustained for 12 months. With the exception of patients with serious psychiatric problems, it appears that matching patient characteristics to a specific treatment type did not improve outcome. This study demonstrates that well-designed treatments, in combination with good training of therapists, contribute to excellent retention rates in treatment. Furthermore, these findings run counter to the belief that treatment gains are inconsequential and short-lived.

The next major step is to build upon the findings from Project MATCH and the randomized trials for medication, such as those previously reported for naltrexone. The major goal is to combine MATCH with new insights gained from medications research. Follow-up clinical trials will include new pharmacotherapies, such as naltrexone, nalmefene, and acamprosate, combined with standardized behavioral strategies. In sum, we expect findings from genetics research, neuroscience, and medications development to inform the development of increasingly improved treatment strategies.

Prevention research is also a priority at NIAAA, the goal of which is to obtain scientifically objective and measurable effects attributable to specific interventions. To ensure the acquisition of meaningful results, these studies employ rigorously defined scientific methodologies including random selection and control communities. One excellent example is a recent study nearing completion which may provide a model alcohol use prevention program that can be implemented in communities around the country. The Northland study used a multi-component, multi-year, community trial to delay, prevent, and reduce the prevalence of alcohol use and alcohol-related problems among a group of adolescents from 22 school districts in northeastern Minnesota. The project targets the Class of 1998 and has been ongoing for five years, beginning with students in the sixth grade and following them through grade 10. Interim results look quite hopeful. At the end of three years of program (grade 8) the rates of alcohol use were significantly lower among students in the program school districts compared to the reference districts. When compared to reference districts, 19 percent fewer students who received the program used alcohol in the past month, and past week use was 29 percent lower. Of great significance is the fact that overall fewer students initiated alcohol use. For instance, past month alcohol use by 8th graders who did not drink in grade 6 was 28 percent lower in program communities than in reference communities.

In addition, NIAAA is taking a leading role in educating the public and physicians about alcoholism. Our Alcohol, Health and Research World is an award winning journal and information about nearly all of NIAAA's activities are available on our web site, including grant and funding information. This past year we published and disseminated 75,000 copies of The Physicians' Guide to Helping Patients with Alcohol Problems. At the request of the Office of National Drug Control Policy (ONDCP), an additional 165,000 copies were printed for distribution by ONDCP. DuPont Pharma is also significantly aiding in this effort at their own expense by printing and distributing through their field representatives an additional 60,000 copies to primary care physicians nationwide.

In conclusion, alcohol research is progressing rapidly and the scientific advances and opportunities in our field are very encouraging. Mr. Chairman, the fiscal year 1998 President's budget request for the National Institute on Alcohol Abuse and Alcoholism is \$208,112,000. Thank you. I will be happy to answer any questions the committee may have.

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#### BIOGRAPHICAL SKETCH OF DR. ENOCH GORDIS

Enoch Gordis, M.D., became the Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in October 1986. Prior to this, he was Professor of Clinical Medicine at Mt. Sinai School of Medicine, New York City, and a staff member of the Elmhurst Hospital in Elmhurst, N.Y., where he founded and directed the hospital's alcoholism program from 1971 until his appointment to NIAAA. This large comprehensive program, with both inpatient and outpatient components, served some 15,000 patients during his tenure.

The NIAAA, a part of the U.S. Department of Health and Human Services' (HHS) National Institutes of Health (NIH), is the principal Federal agency for research on the causes, consequences, treatment, and prevention, of alcohol-related problems. Through an intramural scientific program, which includes a 14-bed clinical research



facility on the National Institutes of Health (NIH) Bethesda, Maryland Campus, and through an extensive array of extramural research grants and contracts, NIAAA supports studies in a variety of biological and behavioral areas such as, neurosciences, pharmacology, epidemiology, genetics, molecular biology, and prevention and treatment. The Institute also supports research training and health professions development programs, and research on alcohol-related public policies that provide HHS and other Federal, State, and local government decisionmakers with state-of-the-art analyses of the relationships between public policies and alcohol-related problems. The current NIAAA budget is \$212 million.

Dr. Gordis trained in internal medicine at the Mount Sinai Hospital in New York. During this period, he also was a research fellow in Dr. Solomon Berson's laboratory at the Bronx Veterans Administration hospital. Following his residency, Dr. Gordis spent 10 years at New York City's Rockefeller University in the laboratory of Dr. Vincent Dole, conducting research in the areas of lipid metabolism, toxicology of carbon tetrachloride, analytical biochemistry of drug stereoisomers, the metabolism of alcohol and alcohol withdrawal. He has published on the clinical evaluation of alcoholism treatment, biological markers of drinking, disulfiram therapy, and the relationship between science and social policy.

As NIAAA Director, Dr. Gordis' principal goal is to continue support for activities designed to give maximum visibility to the Institute's role as a leader in alcohol-related research and the integral part of that role in preventing and treating alcohol abuse and alcoholism. This will include continued support for NIAAA's extramural and intramural research programs; support for a continuing Institute role in health professional education; increased attention to public policy research; and enhanced data collection and dissemination activities.

A member of Phi Beta Kappa, Dr. Gordis received his B.A. degree from Columbia University in 1950 and M.D. degree from the Columbia College of Physicians and Surgeons in 1954. He is a member of the American Physiological Society, the American Federation for Clinical Research, Sigma Xi, the American Gastroenterological Association, the American Society of Addiction.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH [NINR]

Mr. Chairman, it is a pleasure to be here today to describe for you NINR-supported research that demonstrates the relevance and rich variety of our research endeavors. I also look forward to discussing our current and planned activities for fiscal year 1998. The Nation's investment in health research has resulted in improved health for our citizens. However, many more questions remain to be answered. This is particularly true when we look at the implications of changing demographic trends on the health of our Nation. The Nation's population is shifting to the upper decades of life. With longer lives, we can expect an increase in chronic illnesses, which will require longer and more costly health care. The demand for innovation through nursing research discoveries has never been greater.

Nursing research is an emerging science that adds a vital and necessary perspective to the conduct of research. Although the search for cures continues, research on improved care is a parallel necessity. Nursing research focuses on the patient in the pursuit of answers. This, in turn, can lead to basic laboratory studies or clinical research, as well as to research on prevention of disease and promotion of healthy life choices.

To demonstrate the contributions of nursing research, I would like to begin my discussion of research funded by the Institute by highlighting a health concern that we have all felt—pain. Pain generates nearly 40 million visits to health care providers, can prolong hospital stays, and may impede recovery. Pain research is complicated, because while we all share a basic common physiology, we do not react to pain the same way.

Recent findings from an NINR-supported study on pain have generated national, scientific and media attention. In addressing the influence on pain of a variety of factors, such as age and ethnicity, NINR-supported researchers focused on the role of gender—the first such study—to determine if women and men respond differently to painkillers. When completed, the study showed that women could obtain pain relief, with fewer side effects, from commercially available but seldom used painkillers known as kappa-opioids, such as nalbuphine or butorphanol. Men, however, were not so fortunate. They received little benefit from the drugs. Kappa-opioids were tested on young men and women who had their wisdom teeth removed which, as many of us know, produces moderate to severe pain. Although kappa-opioids are in use to ease women's labor pains, they are not generally in use for other pain reduc-

tion. Earlier clinical testing, primarily on men, found these same painkillers ineffective. Consequently, morphine-like opioids are typically used because they are effective in both men and women. However, they can have the undesirable side effects of nausea and disorientation. The recent findings present further questions about effective management of pain. For example, we need to understand better the role of hormones on the perception of pain. How do estrogen or testosterone mediate pain? Do women have more kappa receptors on certain nerve cells than men, thus enabling kappa-opioids to block pain better? Another question is are there gender differences in the way the brain regulates pain relief? Clearly, this continues to be an important area of research, with many yet unanswered questions about better pain management for everyone.

With regard to another health problem, one that affects 10 to 15 percent of Americans and two or three times more women than men, nursing researchers have made important advances in understanding the mysteriously caused, unpleasant gastrointestinal symptoms known as irritable bowel syndrome, or IBS. This disorder accounts for more than two million medical prescriptions, 3.5 million physician visits, and 34,000 hospitalizations each year. Existing research suggests IBS may result from heightened arousal of the sympathetic nervous system, which governs the involuntary activities of internal organs, including the intestines. With the goal of preventing and treating IBS, NINR-supported investigators studied three neuroendocrine markers—norepinephrine, epinephrine, and cortisol—which indicate levels of sympathetic nervous system activity. Three groups of women were studied, including a group of patients diagnosed with IBS. Scientists found this group to have significantly higher norepinephrine levels in the evening and morning, and higher epinephrine and cortisol levels generally. Not unexpectedly, the patient group reported higher levels of stress, the only consistent variable that accounted for higher arousal of the sympathetic nervous system. As a next step, researchers will be designing screening programs to distinguish between behavioral and physiological causes of IBS. The results of this research will also have important implications for cost effective therapies. Currently, IBS is diagnosed very indirectly—through a process of eliminating other causes. How many doctors visits could be avoided, with what savings to the health care system, if a positive diagnosis were possible based on scientific methods?

Although cardiovascular disease is decreasing, it is still the number one killer of more than 950,000 Americans each year, and accounts for at least \$2 billion in Medicare expenditures. Those who live with the disease may undergo invasive therapeutic procedures, such as angioplasty or bypass operations. Extensive lifestyle changes are usually required to preserve health. The roots of cardiovascular disease often go back to childhood, and risks intensify as age increases. Interventions early in life are key to achieving a healthy adulthood. Nursing investigators have designed and tested an 8-week intervention to reduce cardiovascular risk factors in more than 2,200 third and fourth grade school youngsters in rural and urban areas, almost 20 percent of whom were African-American. By the study's end, students showed reductions in total cholesterol levels, body mass index, and body fat. The children also showed increased physical endurance. This intervention is being expanded to 1,600 middle school students, 26 percent of whom are African-American. The focus of this study will be on those living in rural areas.

Threaded throughout NINR's research portfolio is a responsiveness to ethnic and cultural diversity. As we learned from important findings on the effect of gender in pain, health care models need to address the requirements of diverse populations to be effective and ensure improved health outcomes. From the research perspective, questionnaires and health assessments written only in English exclude many non-English-speaking subjects from health research. Consequently, ethnically and culturally diverse groups miss the opportunity to participate in protocols, and research findings will not adequately address their health needs. To deal with this issue, NINR-supported researchers adapted an English language Arthritis Self-Management Program for Hispanic patients with arthritis. Hispanics represent about 9 percent of the U.S. population. About 20 percent are unable to speak English well, and about 11 percent are affected with arthritis and other rheumatic conditions. Seven health assessment scales were translated into Spanish and incorporated into questionnaires answered by Hispanic subjects about various aspects of their health. Findings indicate that the reliability and validity of the scales were not compromised in the translation process, and were appropriate for a variety of Spanish speakers of different national origins and regions.

The research I have briefly described today is but a sample of NINR's research portfolio. The vitality of research, however, stems from the many questions that still remain to be answered. Therefore, I would like to discuss briefly several research emphases for the fiscal year ahead: symptom management for chronic neurological

conditions; managing traumatic brain injury; improving quality of life for transplantation patients; and attending to end-of-life care issues.

Two out of three Americans seek treatment in any given year for problems involving the brain or nervous system at tremendous cost to the health care system. The NINR will continue to support research dealing with symptoms typically associated with such neurological disorders as stroke, epilepsy, Parkinson's disease, and spinal cord injury. Symptoms include problems with mobility, pain, sleep and depression. We also seek to identify factors related to successful family caregiving, both from patient and caregiver perspectives. Collaborations addressing these issues will be sought with other NIH institutes and the Veteran's Administration.

Another neurological issue, managing traumatic brain injury, also involves nursing researchers. Traumatic brain injury alone accounts for the hospitalization of 500,000 people each year. Two-thirds survive with impaired brain function, and another 5,000 develop epilepsy. Much of the damage that results from traumatic brain injury is caused not by the initial injury but by the cascade of biochemical events triggered by the injury. If untreated, brain tissue and cells are deprived of sufficient oxygen, leading to the formation of metabolic toxins that contribute to the progressive deterioration of the brain. NINR, in collaboration with a number of other NIH Institutes and Centers, is supporting the development of promising antiacidosis therapies to prevent this progression and its destructive sequelae. Last year, NINR reported success in neutralizing metabolic toxins using an antioxidant, deferoxamine, in an animal model. NINR will continue to investigate the role of antiacidosis therapies in protecting viable brain tissue as a treatment for head trauma. In order to focus attention on the prevention, treatment, and rehabilitative needs of children, NINR is cosponsoring an NIH consensus development conference on managing traumatic brain injury. A program announcement regarding research directions identified by this conference will be issued in fiscal year 1998.

Thanks to health research, twelve thousand Americans benefit from an organ transplant each year. Many of these patients, the majority of whom have received kidney transplants, have survived into their 50s and 60s, and are following long-term drug regimens, including steroid and immunosuppressive therapies. These regimens are not without side effects, such as osteoporosis, cancer, neurologic impairment, cardiac dysfunction and atherosclerosis. In seeking answers about management or prevention of these complications, the NINR is a partner with other institutes on an interdisciplinary NIH workgroup that will explore research opportunities aimed at improving the quality of life of long-term transplantation survivors.

Complex issues associated with the end of life have been receiving considerable national attention. NINR funds studies of bioethical, biological and behavioral issues directly related to the end of life. For example, its research portfolio includes management of pain; family decisionmaking for patients who are incapacitated; and surveys of end of life medical and supportive practices. This year a workshop will be cosponsored by NINR and other NIH institutes to identify research needs in palliative care. NINR will also collaborate in issuing a program announcement in 1998 on end-of-life care, which will address four critical issues: 1) managing the transition to palliative care, 2) understanding and managing pain and other symptoms, such as nausea and depression, at the end of life, 3) measuring results, such as relief of symptoms, and 4) documenting costs for patients and family caregiving during end-stage illness.

As NINR begins its second decade at the NIH, current and emerging research and societal issues intensify the need for the perspectives of nursing research. Clinically-based, patient-oriented nursing research is well positioned to make important contributions to improving health and quality of life for our citizens.

Mr. Chairman, the fiscal year 1998 request for NINR is \$55,692,000. I will be pleased to answer any questions you might have.

#### BIOGRAPHICAL SKETCH OF PATRICIA A. GRADY

Dr. Patricia A. Grady was appointed Director, NINR, on April 3, 1995. She earned her undergraduate degree in nursing from Georgetown University in Washington, DC. She pursued her graduate education at the University of Maryland, receiving a master's degree from the School of Nursing and a doctorate in physiology from the School of Medicine.

An internationally recognized stroke researcher, Dr. Grady's scientific focus has primarily been in stroke, with emphasis on arterial stenosis and cerebral ischemia. She is a member of several scientific organizations, including the Society for Neuroscience, the American Academy of Neurology, and The American Neurological Association. She is also a fellow of the American Heart Association Stroke Council.

In 1988, Dr. Grady joined the NIH as an extramural research program administrator in the National Institute of Neurological Diseases and Stroke (NINDS) in the areas of stroke and brain imaging. Two years later, she served on the NIH Task Force for Medical Rehabilitation Research, which established the first long-range research agenda for the field of medical rehabilitation research. In 1992, she assumed the responsibilities of NINDS Assistant Director. From 1993 to 1995, she was Deputy Director and Acting Director of NINDS. Recently Dr. Grady was appointed to the NIH Warren Grant Magnuson Clinical Center Board of Governors.

Before coming to NIH, Dr. Grady held several academic positions and served concurrently on the faculties of the University of Maryland School of Nursing and School of Medicine.

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PREPARED STATEMENT OF DR. JUDITH L. VAITUKAITIS, DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES [NCRR]

Mr. Chairman and Members of the Committee: It is a pleasure to appear before you today to discuss the activities and accomplishments of the National Center for Research Resources. NCRR has a unique responsibility for biomedical research infrastructure at the National Institutes of Health. That infrastructure can be compared to a great locomotive that transports passengers—in this case scientists who explore disease and its remedies—toward ever-changing destinations. Investigators depend on NCRR to create, develop, and provide the “engine” or infrastructure of modern science to keep science moving forward.

Infrastructure takes many forms—from sophisticated instrumentation and technologies, clinical research environments, and animal research models of human disease, to construction and human resource-building activities. Most of NCRR’s budget supports center grants that underwrite research infrastructure at academic medical centers and universities throughout the nation. Those centers provide specially adapted facilities, instrumentation, and expertise to biomedical investigators on a local, regional or national basis. NCRR-supported research facilities and repositories serve more than 10,000 investigators nationwide.

Recent findings at NCRR-funded biomedical technology centers have great dollar-saving potential. For example, the first magnetic resonance images using hyperpolarized gas in living systems have been developed. This technology produces a signal 100 to 10,000 times more powerful than traditional MRI, with no added cost to the MRI system and only a moderate cost for polarized gas.

NCRR is a key player in new drug discovery, design, development, and testing as well. For example, cytomegalovirus (CMV) infects up to 70 percent of the U.S. population and can cause life-threatening infections in immunosuppressed individuals. Scientists using an NCRR-funded biomedical technology resource at Cornell University have succeeded in visualizing the 3-D structure of cytomegalovirus’ protease enzyme required for CMV replication, thereby providing a new target for antiviral drug design.

In another study, scientists recently synthesized a peptide from the sea snail *Conus magnus* for use as a potential pain-reducing drug for cancer and AIDS patients. NCRR-supported Shared Instrumentation Grants played a prominent role in analyzing the toxins and an NCRR-supported mass spectrometry resource in San Diego characterized the structures of conotoxins. Clinical trials are underway at General Clinical Research Centers to assess the effectiveness of these potential pain-reducing drugs. With more than 500 species of sea snails, the *Conus* family has enormous potential for drug discovery.

Clinical investigations at NCRR-supported General Clinical Research Centers and through the Clinical Research Initiative at several minority medical schools advance our knowledge of how to prevent, diagnose and treat serious health problems. For example, investigators at a Yale University GCRC used a noninvasive imaging technique, known as single photon emission computerized tomography, to provide additional proof that increased transmission of the neurotransmitter dopamine causes the symptoms of schizophrenia.

Investigators at the University of Utah GCRC recently identified a gene that, with others, controls the regularity of a person’s heartbeat. By detecting individuals who have a mutated form of this gene, physicians can prescribe medications that protect against cardiac arrhythmias, which cause a staggering death toll each year, even among young, apparently healthy people.

A step toward better treatment of a deadly disease took place at a GCRC at the University of Connecticut. There, melanoma patients were immunized with cytolytic T lymphocytes (CTLs), an approach known to attack melanoma cells at the vaccina-

tion and distant tumor sites. In this study, investigators induced a peptide-specific CTL response against the melanoma.

In fiscal year 1996, the network of GCRCs hosted 7,835 investigators who carried out 5,604 research projects—both numbers are the greatest in the program's history. Many GCRC sites, where managed care has heavily penetrated, have become oases for patient-oriented research. For the same reason, several academic medical centers which currently do not have GCRCs are actively pursuing competing for a center for their faculty to conduct patient-oriented research.

To address the health issues which disproportionately affect under served populations, NCRR launched the Clinical Research Initiative (CRI) within selected Research Centers in Minority Institutions (RCMI)-supported institutions to enhance their clinical research infrastructure. The RCMI program enhances the capacity of minority colleges and universities that offer doctorates in health or health-related sciences to conduct health-related research. The CRI provides the resources for patient-oriented research so that investigators at the RCMI sites can more effectively compete for NIH clinical research funding.

Whether investigating cancer or an emerging infectious disease, researchers also need a wide range of animal and other models. Almost half of all NIH-funded

grants include animal-based research. Often research is most effectively advanced by a combination of model systems rather than by reliance on only a few. Successful new research models include a rhesus monkey model for Lyme disease, as well as colonies of aged monkeys for investigations of the neurobiology and physiology of aging and Alzheimer's disease.

Centralized shared resources for genetically-altered animals and other organisms are of great interest to the scientific community because they provide unique models with specific genetic defects with which to determine gene function. An economical research model is the zebrafish. This tiny creature will allow study of genetic defects that are comparable to genetic defects in humans. Best of all, this model is economical—the cost of supporting 1,700 zebrafish equals that of supporting 17 mice! NCRR supports a host of other genetic stock centers, including those for the fruit fly, yeast, and round worm as well as for induced mutant resources for mice.

NCRR also supports human resource development through two science education programs. The Science Education Partnership Award (SEPA) program encourages scientists to work with educators and other organizations to improve student and public understanding of science and promote interest in scientific careers. For example, BrainLink, a SEPA project at Baylor College of Medicine, communicates the fun and excitement of “doing” science and promotes healthy behaviors for youngsters in elementary and middle schools. NCRR also supports a Minority Initiative for K–12 Teachers and High School Students. That program's purpose is to ensure that an adequate supply of under-represented groups enters the career pipeline for biomedical research and the health professions.

A primary NCRR objective has been to promote accessibility to novel and essential research tools and to support cutting-edge technologies. Breakthroughs in basic engineering and physics can provide the research tools for health-based research. NCRR programs will continue to foster that transition in fiscal year 1998. For example, the NCRR will develop and coordinate a new initiative that will focus on understanding the structure and function of the brain and its dynamic changes with time, the fourth dimension. To attain these goals, further development of new imaging modalities as well as new tools for neurosimulation and modeling are needed. Studies of the brain microvasculature, mechanisms of cell death and studies to map concentrations of specific neurotransmitters in the brain will lead to improved knowledge about neurodegenerative diseases such as Parkinson's and Alzheimer's diseases.

Another initiative will encourage development of innovative software, algorithms, and techniques for use with high performance computers and telecommunication facilities to increase the number of biomedical technology resources and their applications that can be remotely accessed by investigators across the country over the next generation of the Internet, which will be 1,000 times faster than the current Internet. Magnetic resonance imaging resources and other modeling resources, essential for structural biology, are candidates for this approach.

Another initiative will extend development of gene vectors for human diseases through the National Gene Vector Laboratories. Gene vectors will be generated for a variety of diseases, including rheumatoid arthritis, immunologic disorders, vascular diseases, AIDS, metabolic diseases and cancers. The Regional Primate Research Centers (RPRCs) and the network of GCRCs will host studies designed to define innovative approaches to human gene therapy. In addition, both the GCRCs and RPRCs will host studies to define the molecular basis for disease.

In conjunction with the regional primate research centers, investigators will focus on the development of novel vaccines for AIDS. Studies that may pave the way for developing vaccines against HIV in humans were recently reported by scientists at the NCCR-supported New England Regional Primate Research Center. Investigations with rhesus monkeys showed that vaccine protection against intravenous challenge with simian immunodeficiency virus (SIV), similar to its human counterpart, could be attained with live attenuated vaccine from which certain viral genes had been deleted. These and other related efforts will be extended to help identify an effective vaccine for HIV.

In the future, as in the past, it is important for NCCR to set priorities and to anticipate investigators' needs to assure that appropriate research facilities and resources are in place when investigators need them. Accordingly, this year NCCR will update its strategic plan, first developed in 1994, and will again seek input from its many constituencies in the scientific community. Nearly all the actions recommended in the 1994 plan have been implemented.

Continued improvement of research "engines"—from technologies to clinical environments, research models, construction, and human resource development—will allow NCCR to pull many "cars" and ensure a cost-effective biomedical research enterprise that can meet both scientific and economic demands.

Mr. Chairman, the fiscal year 1998 President's Budget Request for NCCR is \$333,868,000. I would be pleased to answer any questions you may have.

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PREPARED STATEMENT OF DR. PHILIP E. SCHAMBRA, DIRECTOR, JOHN E. FOGARTY  
INTERNATIONAL CENTER [FIC] for Advanced Study in the Health Sciences

Mr. Chairman, it is my privilege to present the programs and accomplishments of the Fogarty International Center (FIC). Our namesake, John E. Fogarty, who served as Chairman of this subcommittee, is one of a continuing lineage of Congressional Representatives who have enabled NIH to become an international leader, not only in the quality of its research, but through cooperation with over 100 nations.

FIC was established to improve health through international scientific cooperation. As we look toward a new century, health concerns are increasingly global in scope. Unexpected diseases have surfaced due to altered patterns of land use, the adaptability of disease pathogens, and other factors. With the ease and frequency of international travel, disease outbreaks in foreign countries can rapidly cross U.S. borders. This includes infectious diseases such as the Ebola virus, new variants of the AIDS virus, and dengue fever. Pollutants in the atmosphere, water, and food chain pose equally insidious risks, contributing to a host of chronic diseases and developmental disorders. The persistence of population growth in resource-poor nations threatens to undermine health gains by impeding economic growth. It is estimated that in the next 25 years, nearly three billion people will be added to the world's population. Ninety-five percent of this growth will occur in developing countries, where high birth rates already force subsistence farmers onto marginal land, into crowded urban areas, or across national borders. Such global demographic changes will lead to the emergence of new infectious diseases and increased human exposure to pollutants.

Biomedical research is the foremost means of reversing these disturbing health trends through new medical technologies and prevention strategies. Through prevention research, it is conceivable that the developing world may be spared the burden of disability and death from diabetes, coronary heart disease, and hypertension that has plagued industrialized, urban societies. But these challenges cannot be met through research that is confined within our borders. What is urgently required are international partnerships that enable American scientists to train foreign colleagues and to work cooperatively in affected regions of the world. This is how the United States helped to eradicate smallpox globally, and virtually eliminate polio in this hemisphere. Ultimately, such cooperation will become the most effective armament against the new epidemics of infectious and chronic disease.

FIC builds these partnerships through research training programs, small grants, individual fellowships and institutional alliances. Technical skills and knowledge are shared with scientists worldwide in such fields as epidemiology, immunology, microbiology, endocrinology, cell and molecular biology, toxicology, biochemistry and biostatistics. Cooperative studies are supported in regions of the world that, due to disease burdens or environmental conditions, provide unique opportunities to devise methods of treatment and prevention. For example, the development of certain vaccines may depend on international field trials. These include vaccines for HIV/AIDS,

respiratory infections caused by pneumococcus, and diarrheal diseases caused by shigella and cholera.

FIC's international partnerships are planned and conducted in cooperation with our sister institutes at NIH. In addition, FIC undertakes concerted efforts to bring new resources and scientific perspectives to global health through cooperation with other agencies of the Public Health Service and Federal Government. Almost sixty percent of the funds managed by FIC (including AIDS funding sanctioned by the OAR) come from other NIH or Federal components, who view FIC as a means of advancing their international goals. These intra- and interagency alliances also reduce administrative costs and streamline management requirements.

The model for FIC's global health efforts is its AIDS International Training and Research Program, established by Congress in 1988 to provide training for scientists and health professionals from developing countries where HIV is a critical health concern. Since its inception, over 1000 scientists from over 80 countries have received training in the United States and now assist the U.S. in international prevention efforts. This past year, the program documented a substantial decrease in the prevalence of HIV in the population of one foreign country as a result of a systematic prevention strategy. Our long-range objective is to create these same partnerships to meet the challenge of emerging infectious diseases, environmental health and population growth. This would demonstrate a compelling leadership role for the United States in international health. The geopolitical, as well as scientific benefits of these linkages are significant. Many FIC trainees represent the future scientific leadership of their countries.

During the past fiscal year, FIC launched the International Research and Training Program on New and Emerging Infectious Diseases. The purpose is to support cooperative research and training in regions of the world that are the potential origin of new epidemics, employing new molecular and analytic tools in their study. New knowledge is needed to develop a global research surveillance system capable of detecting and containing future epidemics. The program represents a partnership with the National Institute of Allergy and Infectious Diseases and The Centers for Disease Control and Prevention (CDC) in support of a Presidential Decision Directive and recommendations of the President's National Science and Technology Council. The useful role of this program already has been demonstrated in the case of the deadly Ebola virus. In early 1996, a scientist from Gabon received research training on this infectious agent at Yale University. Upon return to Gabon, he traced the origin of an

Ebola-infected patient to a lumber camp. Because of his special training, he was able to perform the required laboratory studies in collaboration with CDC. As a consequence, Gabon was able to confirm the Ebola outbreak, take appropriate treatment and prevention measures, and undertake a research program to identify the natural history of the virus.

This new program builds on current research conducted under the Fogarty International Research Collaborative Award (FIRCA), a small supplemental grant to NIH-supported investigators to increase scientific cooperation in this hemisphere and with the new democracies of Eastern Europe and the former Soviet Union. Since its initiation by Congress in the wake of the fall of communism, the FIRCA has supported 64 projects with the former Soviet Union and 45 projects with Latin America in scientific areas of mutual priority. Under the FIRCA, scientists at the Academy of Medical Sciences in Moscow are collaborating with the New England Medical Center to determine the extent of Lyme disease in Russia and the precise identification of the specific microbe isolated from Russian patients. Such information is needed as work progresses on the development of a vaccine that can be used worldwide. Collaborative research between scientists at the University of Oklahoma and the Russian Academy of Sciences in St. Petersburg are identifying the distinguishing genetic characteristics of Group A streptococci, commonly known as "flesh eating" bacteria. Because microbes are so readily transmitted across international borders, the Russian streptococci might be imported and cause disease in the United States. If this were to occur, knowledge about Russian streptococci would be key to diagnostic and treatment strategies.

The International Training and Research Program in Population and Health, now in its second year, supports research to improve reproductive and neonatal health care and demographic capabilities. The goal is to create a broad range of safe, reversible and acceptable contraceptive methods and to decrease maternal mortality and morbidity from infections, nutritional deficiencies, toxemia, high blood pressure and other conditions. The program was launched in partnership with the National Institute of Child Health and Human Development. The International Training and Research Program in Environmental and Occupational Health, also in its second year, enables the U.S. to work cooperatively with regions of the world with high lev-

els of contaminants in the environment and workplace. With the application of new scientific methods, the effects of environmental agents on human health will be examined and interventions devised to reduce health risks. It is notable that the American public was alerted to the carcinogenic properties of agents such as dioxin through international studies. This program was launched in cooperation with the National Institute of Environmental Health Sciences and CDC's National Institute for Occupational Safety and Health.

The health consequences of environmental degradation also include the potential loss of valuable medicinal products derived from nature. For centuries, plants have been the source of medicines such as digitalis for heart disease and quinine for malaria. Yet only a small fraction of the world's biological wealth has been studied for potential therapeutic benefit. The International Cooperative Biodiversity Groups Program, supported and administered by FIC, is designed to discover new drugs from the earth's biological diversity. In addition, strategies are pursued to preserve natural ecosystems and promote economic growth through drug discovery and development. This pioneering program has influenced resource management policies in several participating countries, and has served as a case-study in international treaty discussions. In its first two years, over 3,000 species of plants and insects have been examined for their potential therapeutic properties. Bioactive samples are now being tested as candidate drugs against certain cancers and viral diseases, malaria and degenerative neurological disorders. The program is supported by several NIH components, the National Science Foundation, the U.S. Agency for International Development, and U.S. industries. It demonstrates the potential of pooling expertise and resources across the public and private sectors.

Mr. Chairman, the political basis for public investment in biomedical research emerged from our nation's critical needs during World War II. Today, the pursuit of health through research again is integral to our nation's security. Scientific solutions to global health threats require a coordinated global response. Dr. John Evans, a Canadian who served as chairman of the independent Commission on Health Research for Development, aptly remarks "that with increased awareness of global interdependence in health, self-interest should reinforce humanitarian concerns" in our efforts to improve global health. With the support of Congress, FIC will continue to advance this important mission through international cooperation.

Thank you Mr. Chairman. Our fiscal year 1998 budget request is \$16,755,000. I will be pleased to answer any questions.

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PREPARED STATEMENT OF DR. DONALD A.B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE [NLM]

Mr. Chairman, thank you for the opportunity to appear before you today. The last 12 months have been especially eventful at the National Library of Medicine. I believe it is safe to say that whatever preconceived notions one has about what a medical library is and does, the NLM shatters them. Previous support by the Congress is resulting in remarkable new information products that are finding widespread acceptance not only within the medical and science communities but, increasingly, with the public. I can also report that the Administration's "Reinventing Government" initiative has taken root at the National Library of Medicine. It is providing us with the latitude and efficiency to develop new products (such as the Internet Grateful Med described below) and to plan for major changes in how we will deliver information services in the future.

To demonstrate what has happened over the past year, I want to present a sampling from NLM's broad portfolio of information services: imaging databases that save lives, World Wide Web access to the world's largest computer resource of medical knowledge, a "human gene map" now available to all via the Internet, progress in reaching a full text retrieval for medical information seekers, and diagnosing and treating patients via "telemedicine." Let me explain.

The Visible Humans: I reported to the committee last year about two very large datasets the Library commissioned based on the imaging of cadavers—a Visible Male and Visible Female. Last month's LIFE magazine features on its cover and throughout the issue a series of stories based on this project. One particularly poignant story is of a 12-year-old Rhode Island boy with a tumor on his brain stem that, unless it is removed, would kill him in a few years. The surgeon preplans the operation using 3-dimensional holograms, based on a practice method introduced with the Visible Male. The 6-hour operation is a success and the tumor is excised without disturbing healthy tissue. "Spelunking through the body" is the way scientists at the Mayo Clinic have described putting data from real patients into applications that



were developed using the Visible Humans, and then using the computer to traverse through the anatomical structures to find and visualize the problem.

Last fall the Library held a meeting of some of the researchers who are using the Visible Human datasets in a variety of ways. There are more than 700 projects using the data, but a few will give you an idea of their range: non-invasive colon cancer screening, visualizing in advance the results of plastic surgery, rehearsing prostate cancer surgery, training students to do spinal taps with a needle simulator and, of course, teaching anatomy. Although we didn't hear directly from them, Hollywood animation experts are even using the Visible Human dataset to create a movie character.

**Access to MEDLINE:** Last year when I testified before you, we had just introduced the Internet Grateful Med. You may remember that this system affords anyone with access to the World Wide Web the ability to register with the Library and to search the immense MEDLINE database. The system is easy to use and no other software is required. Now MEDLINE may be searched not only by medical librarians, scientists, and health care providers—the audience for which it was originally intended—but members of the general public are now discovering its benefits. MEDLINE, as you will recall, is the Library's largest and most-consulted database containing more than 8 million references and abstracts to medical journal articles.

The instant appeal of Internet Grateful Med has resulted in a dramatic increase in the number of persons using the Library's online network—there are now about 150,000—and online computer usage statistics are repeatedly hitting all-time highs. Internet Grateful Med received another boost in popularity when Ann Landers printed a letter from Dr. Michael E. DeBaakey, a member of our Board of Regents, praising the new system. We have already improved the system by adding NLM's AIDS and health services research databases to its searching capabilities, and more databases will be added in the future.

**Genetic Medicine:** Scientists at NLM's National Center for Biotechnology Information, working with colleagues at NIH and leading genome centers around the world, have put up on the World Wide Web "human gene map" that contains the computerized sequences of more than 16,000 human genes. This is roughly one-fifth of the estimated total number of genes in the human genome; as scientists unravel more they will be added to the map. Now, for the first time, scientists seeking to locate the gene for a specific disease have a 1 in 5 chance that it has already been described. Among the set of research tools provided through the human gene map are the ability to do text searches, sequence searches, and to download files containing DNA mapping information. We expect the availability of this information to researchers around the world to reduce substantially the time between identifying the gene culprit for a specific disease and developing an appropriate diagnostic test and treatment.

Equally noteworthy about the human gene map is that it will provide the public with a running update on scientific progress toward specifying the complete human genome. In addition to the tools for scientists, the map graphically displays each of the 23 pieces of chromosomes and provides consumer-friendly descriptions of many genes associated with specific disorders, for example, Alzheimer's disease, breast cancer, and cystic fibrosis. For each, there are links to pertinent foundations, voluntary organizations, and other government agencies. Some 6,000 visitors come to the site each day, ranging from high school students to commercial and academic researchers. The human gene map takes a complex subject out of the laboratory and makes it understandable in the classrooms and in the home. Such a widely accessible means of informing the public about genetics and the role of genes in disease is essential if American citizens are to benefit fully from genetic research.

The amount of molecular sequence (DNA) information coming out of our laboratories continues to increase. NLM's GenBank is equal to the task of storing this information; sophisticated computer systems developed at the Library allow the data to be analyzed, retrieved, and applied by scientists. The GenBank database is growing rapidly both in size (it contains 1,114,000 sequences, up 80 percent in one year) and in use (there are now more than 40,000 GenBank queries every day from scientists around the world).

**The "Holy Grail" Information Retrieval:** For more than a century, the National Library of Medicine has been viewed on as the touchstone of published knowledge in the health sciences. In the 1800s the Library "revolutionized the field" by publishing indexes to the medical literature. In the early 1960s we first used large computers to process reference data. In the 1990s the Library is making its databases widely available over the Internet. All this activity was centered on references to the literature helping scientists and health professionals locate what they really want—the article itself. Today, the World Wide Web offers the potential for providing ac-

cess to complete texts of articles, and the NLM has taken the lead in developing a system that will do this. The system is called PubMed.

PubMed is an experimental system that links online MEDLINE users from an NLM-created reference and abstract to the corresponding full-text of a journal article provided directly by the publisher. The route of this transaction is the World Wide Web. Because of its role as a public biomedical information provider, NLM is uniquely positioned to create linkages from the publishers—articles not only to MEDLINE references, but also to gene sequences, protein structures, disease descriptions, and clinical practice guidelines. The National Center for Biotechnology Information, which is NLM's lead agency in this project, has demonstrated the feasibility of the concept by linking a subset of MEDLINE in the area of molecular biology to several online journals. We are talking to major medical publishers around the world and, soon, it may be possible for a scientist or doctor to call up on an office computer the full article—photographs, x-rays and all—from MEDLINE citations. We will have reached the Holy Grail.

Telemedicine: As communications technology continues to advance at a rapid pace, so too does the promise that it can play an important role in delivering health care. Last year we noted that the Library had funded several projects in telemedicine. We have made an even greater commitment this year: In the fall of 1996 the Department of Health and Human Services announced the funding by NLM of 19 new telemedicine projects. In making the announcement, Secretary Shalala said that "telemedicine offers us some of our best and most cost-effective opportunities for improving quality and access to health care." The 19 multi-year projects, located in 13 states and the District of Columbia, total some \$42 million.

Among the studies to be conducted are those providing care to center city elderly (California), linking health care providers with rural patients (West Virginia, Washington, Missouri, and Alaska), linking ambulances to trauma centers (Maryland), managing patients in home settings (New York), and specialist consultation for diagnosis and treatment (Oregon, California). At about the same time these awards were being announced, the National Academy of Sciences released a study funded by the NLM on criteria for evaluating telemedicine. These criteria will be applied to the new projects, as will the recommendations from an Academy report (again funded by NLM), to be released in March 1997, on best practices for ensuring the confidentiality of electronic health data. We hope the 19 telemedicine projects will serve as models for both evaluation and confidentiality.

Outreach: We continue our efforts to bring the Library's information services to the attention of all American health professionals. The outreach program received a shot in the arm this year from the publicity attendant on the announcements concerning Internet Grateful Med, the Visible Human Project, the Human Gene Map, and the telemedicine awards. They all received considerable attention in the print and electronic media. Although usage of the Library's services continues to climb, outreach remains one of our highest priorities. We know that there are many more who could benefit from MEDLINE and other NLM information resources.

Of inestimable help in the Library's outreach program is the National Network of Libraries of Medicine. The mission of the Network, since its formation in the 1960s, has always been to make biomedical information readily accessible to U.S. health professionals irrespective of their geographic location. The eight Regional Medical Libraries that form the backbone of the Network are supported by contracts from the NLM. To continue their successful programs, the NLM recently awarded new contracts totaling \$34 million over the next five years to the eight institutions that are serving as Regional Medical Libraries for the national network. Today there are some 4,500 institutional members of the Network providing a wide range of services to American scientists, educators, practitioners, and the public. They conduct many outreach activities, including exhibits, hands-on workshops, and training. One emphasis in the new contracts is to make even greater use of the National Information Infrastructure, and especially the World Wide Web, in providing information services to health professionals.

One highly successful outreach tool is the World Wide Web site maintained by the NLM at <http://www.nlm.nih.gov>. Not only is MEDLINE accessible there (through Internet Grateful Med), but extensive information files in health services research, molecular biology information (such as the Human Gene Map), patient guidelines, image databases, and much more. These information resources, although provided over the Web, are in many cases grounded in the basic medical library services that the NLM has built up over the past century and a half.

NLM also has an Extramural Program for providing grant assistance to further the Library's objectives. Several of these are outreach-related, including support to connect medical institutions to the Internet. Other extramural programs support improving library resources within the National Network of Libraries of Medicine, re-

search and development into health science communications, and research training in medical informatics and the related subfields that deal with biotechnology and molecular biology.

Mr. Chairman, for fiscal year 1998 the President has requested a total of \$152,689,000 for the Library. I would be pleased to answer any questions you have.

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PREPARED STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH [NIH]

Mr. Chairman, Members of the Committee, we are pleased to be here today to discuss the fiscal year 1998 budget request for the Office of the Director (OD). As you know, the OD provides leadership, coordination and policy direction for the overall extramural and intramural research and research training programs of the various Institutes and Centers (ICs), as well as the special offices within the OD. The office also provides management leadership and centralized support activities essential to the operations of the entire NIH.

The NIH Institutes and Centers (ICs) conduct medical research programs to foster scientific discovery and to disseminate advances in scientific and medical applications to NIH's stakeholders—health care providers and their patients, and the general public. Furthermore, the ICs support initiatives within the research community to accomplish these two objectives through their infrastructure programs related to research training and facilities. The OD facilitates and encourages the attainment of these objectives through its program direction and central support offices. This is accomplished by a trans-NIH focus that emphasizes IC-wide cooperation in special programs to improve the health of women, minorities, and the medically underserved; to support research in the social and behavioral sciences; and to encourage research on rare diseases, dietary supplements and alternative and complementary medicine. These coordinated efforts are focused in the OD and are the responsibility of specially designated offices and programs. With such cooperation, we hope to continue to improve the health of the Nation and decrease the burden of disease and disability through research. I will describe in further detail the offices that carry out these functions in the OD.

OFFICE OF RESEARCH ON WOMEN'S HEALTH (ORWH)

The ORWH budget request will allow this office to continue its role as the focal point for research in health and disease areas that appear to affect women. Funding will enable ORWH to assess compliance with revised policies regarding the inclusion of women and minorities in research studies, continue activities to assure that all NIH research studies include women and minorities as subjects, and continue programs to increase the number of women in biomedical research careers.

THE OFFICE OF RESEARCH ON MINORITY HEALTH

The budget request for the Office of Research on Minority Health (ORMH) and the Minority Health Initiative (MHI) provides continued funding for a series of multi-year research studies aimed at improving the health of minority populations and continuing existing programs to prepare minority scientists for careers in biomedical sciences.

Current minority health priorities include increasing the number of minorities who participate in clinical research studies; conducting research studies that address the highest priority health needs of minority populations, such as infant mortality, low birth weight, asthma, and lead exposure in childhood; and increasing the number, and scientific skills, of minority scientists engaged in research.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH (OBSSR)

It is clear that behavioral patterns and social status are risk factors in an array of health problems. The budget request for the OBSSR will enable the office to stimulate research in the behavioral and social sciences and to disseminate findings from this research to the public. Such efforts will include a trans-NIH initiative for research on the four leading health risk factors in the U.S.—physical inactivity, smoking, diet, and alcohol abuse. OBSSR is joined in this initiative by the National Center for Research Resources, the National Institute on Drug Abuse, the National Institute of Nursing Research, and the National Institute of Dental Research.

## THE OFFICE OF DISEASE PREVENTION

Maintenance of health and prevention of disease are critical to the length and quality of life. All of the NIH institutes and centers have programs in prevention research which are coordinated by the Office of Disease Prevention (ODP), as follows:

## THE WOMEN'S HEALTH INITIATIVE

The Women's Health Initiative (WHI), a \$628 million, 15-year project involving 164,500 women, aged 50–79, is a trans-NIH activity which focuses on strategies for preventing heart disease, breast and colorectal cancer, and osteoporosis in older women. The 1998 budget request of \$54.719 million reflects a planned decrease from last year's level, since it is based on completion of the recruitment phase of the study in May 1998. As such, the Initiative continues to be on budget and on schedule. In addition, we expect to reach our goal of 20 percent participation in the study by minority women. As of December 31, 1996 over 16 percent of the 91,000 women recruited were from minorities, probably the largest number of minority women ever studied in the United States.

## THE OFFICE OF ALTERNATIVE MEDICINE

Alternative medicine is becoming increasingly popular, and it is expected that research in this area will help to identify new and effective practices. The Office of Alternative Medicine (OAM) has been established to investigate and validate alternative medical therapies, and to recommend a research program to fully test the most promising of these practices. Alternative medical practices include the use of herbal medications, homeopathy, and acupuncture. The budget request for the OAM includes funds to support collaborative research and training efforts in complementary and alternative medical practices in areas such as cancer, addictions, asthma and in the study of pain. In fiscal year 1998 we also plan to award and continue support of a yet to be selected Congressionally mandated chiropractic center to foster chiropractic-related research.

Another part of the disease prevention activities concerns rare diseases—those diseases having a prevalence of 200,000 or fewer cases per year in the U.S. The ODP's, Office of Rare Diseases Research (ORDR) provides information on rare diseases and conditions, and links investigators with research activities on those diseases. The budget request will enable ORDR to continue to stimulate research endeavors that provide criteria for diagnosing and monitoring these rare conditions and disorders.

The Office of Dietary Supplements (ODS) was established in fiscal year 1996 to support research related to the use of dietary supplements, their health benefits and their role in disease prevention. The ODS budget request for fiscal year 1998 will enable the office to stimulate research on the use of dietary supplements through grants, conferences and workshops, and to conduct a study to determine what type of information is needed to respond to public questions regarding the use of dietary supplements.

## OTHER OD ACTIVITIES

As noted before, other OD entities such as the Office of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Science Policy (OSP), and the Office of Management, provide leadership in regard to the overall extramural, intramural, and management activities of NIH, setting policies and defining goals that enable ICs to effectively and efficiently fulfill their missions.

In addition, the OER coordinates the Academic Research Enhancement Award (AREA) program that provides grants to those institutions that award degrees in health sciences but are not major recipients of NIH grant funds.

The OIR coordinates NIH's loan repayment and scholarship programs. This year the request includes funds to initiate a new Clinical Research Loan Repayment Program to repay the educational loans of clinical investigators conducting research in extramural programs supported by NIH. Fifteen awards will be made under this new program, in addition to those made currently. The OIR also manages the Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds. This program provides scholarships of up to \$20,000 per year, in return for which the students agree to participate in 10 weeks summer employment at the NIH and a year of service after graduation for each year of scholarship. There are currently 13 individuals enrolled, all of whom are under-represented minorities. OIR also oversees the care and use of research animals, and is responsible for the high stand-

ards in this area that have led to AALAC accreditation of the animal facilities within NIH.

The Office of Science Policy (OSP) coordinates all phases of science policy and science education, and addresses issues in areas in which science interfaces with society at-large, such as the privacy of medical and genetic information collected during clinical trials or in the performance of human genetic therapy protocols. The OSP also coordinates a number of science education activities that benefit both students and teachers.

Other OD offices provide the public with science-based health information, advise the Director on legislative issues, and provide policy direction to assure that NIH personnel have equal employment opportunities. In this respect, I am happy to report continuing progress in maintaining a diverse workforce within OD with increases in each minority group and in the placement of minorities in all grade levels including senior level employment. In addition, OD has introduced alternate dispute resolution techniques to resolve employee issues and this program achieved a resolution rate of 98 percent last year.

Continuing NIH's efforts to improve management, at the request of Chairman Porter, the NIH has initiated a comprehensive review of its administrative structure and associated costs to document the effectiveness of current practices and to identify areas for future improvements. The effort is intended to cover Research Management and Support costs and those administrative costs financed by the intramural research program. The review is being led by a Project Director who is managing an outside contract effort aimed at further conceptualizing and formally conducting the review itself. The Project Director serves as chair of an Advisory Committee that is assisting in overseeing the contractors' efforts, and in reviewing recommendations for enhancing administrative efficiency that emerge from the review. This arrangement will bring together the objectivity of an independent contractor with the knowledge and expertise of NIH managers. It is expected that the study will identify best practices for a range of administrative functions that could be adapted across the agency.

The fiscal year 1998 budget request for the Office of the Director is \$234.2 million. I will be pleased to answer questions.

**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 1998**

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U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

**RELATED AGENCIES**

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on related agencies, but the statements of those submitting written testimony are as follows:]

**PROSPECTIVE PAYMENT ASSESSMENT COMMISSION**

PREPARED STATEMENT OF JOSEPH P. NEWHOUSE, PH.D., CHAIRMAN

I am pleased to submit this testimony for the record presenting the appropriation request for the Prospective Payment Assessment Commission (ProPAC) for fiscal year 1998.

**COMMISSION RESPONSIBILITIES**

The Commission was created in 1983 to serve the analytic and information needs of the Congress and to provide objective recommendations from a knowledgeable group of citizens. The Commission is composed of physicians, nurses, and other individuals with expertise in hospital and other health care facility management, third-party payment (including managed care), health care economics, and health services research. The membership of the Commission also reflects a broad geographic representation, including urban and rural areas.

Initially, our responsibilities were limited to the Medicare hospital prospective payment system (PPS). Over the years, however, the Congress has expanded our mandate to include all Medicare inpatient and outpatient hospital services, as well as skilled nursing facility, home health, and ESRD dialysis services. In addition, we perform analyses and make recommendations concerning Medicare's risk contracting option.

**CURRENT WORK**

We submitted our annual Report and Recommendations to the Congress on March 1, 1997, and our annual report on Medicare and the American Health Care System on June 1, 1997. Our work, including the reports we submit to Congress, is determined by statute and by requests from committees.

In addition to our reports, we frequently testify before Congress concerning Medicare's payment policies. We testified at eight committee hearings this Spring to assist Congress in developing the Medicare legislation it is now considering. We also meet regularly with the staff and members of various committees to provide information on proposals they are developing. In the past year, we prepared numerous briefing papers and background documents for committee members and staff in support of legislation to reform and improve the Medicare program. Many of the Commission's recommendations have been incorporated into these legislative proposals, and in numerous cases data and information the Commission provided were a critical contribution to the development of policies.

## FISCAL YEAR 1998 APPROPRIATION REQUEST

For fiscal year 1998, ProPAC is requesting an appropriation of \$3,579,000, an increase of \$316,000 from our 1997 amount (see Chart 1). Our appropriation was reduced 30 percent for fiscal year 1996. In 1997, it was essentially frozen. Consequently, our request for fiscal year 1998 is less than our appropriation ten years ago. In terms of available funds, this is comparable to a funding freeze for 10 years, despite inflation and major expansions of our responsibilities over that time. The 30 percent reduction and subsequent freeze has required us to reduce the number of staff by 30 percent, to curtail the number of analyses that we are able to perform, and to reduce the number of Commission meetings.

A major reason for our funding reduction for fiscal year 1996, as well as that of the Physician Payment Review Commission (PPRC), was the anticipated merger of ProPAC and PPRC that was included as part of the Medicare legislation that was vetoed by the President. Current Medicare legislative proposals again provide for a merger of the two commissions. This merger, however, would result in only modest administrative savings, which are far less than the funding reductions. Moreover, the legislation under consideration provides for sweeping changes to the Medicare program and added responsibilities to the mandate of the merged commission above and beyond those currently required of each of the Commissions individually. Our appropriation request provides for a modest increase to enable us to analyze these changes to the Medicare program and to make appropriate recommendations, whether or not a merger occurs.

*The impact of a continuing appropriation freeze*

Mr. Chairman, you asked us to address what impact a continuing freeze of our appropriation level from fiscal year 1997 through 2002 would have on the function of the Commission. Such a freeze would result in an appropriation in fiscal year 2002 that is less than our appropriation in fiscal year 1987, 15 years earlier. Simply put, a freeze that would effectively extend over 15 years would significantly reduce the number and extent of the analyses that we could undertake and the support that we could provide to the Congress at a time of fundamental changes to the Medicare program. We believe such a scenario would lessen the ability of the Congress to continue to reform the Medicare program based on data and information regarding policy options and their effects on Medicare spending and the care furnished to beneficiaries.

If Medicare legislation is enacted this year, many interest groups will turn their efforts to presenting data that will bolster their position on the law's impact and their desire for favorable changes. It will be extremely important for Congress to have objective analyses as you consider additional modifications to the Medicare program. Many of these modifications are called for in the legislation currently under consideration and others will be necessary. Consequently, a sufficient level of resources will be more important than ever for the Commission to provide needed advice and analysis to the Congress.

Since 1996, we have reduced our staffing levels by 30 percent and severely curtailed extramural data gathering and analysis. This extramural work is especially necessary to evaluate and recommend improvements to Medicare's capitation program since the kinds of cost and utilization information available for the fee-for-service program is not available for this program. A continuing freeze at our current appropriation level will require continued reductions in the number of staff as inflation escalates our fixed costs. Consequently, the number of analyses, background, and briefing papers we will be able to produce for the Congress will also decline.

*Investments in automation*

You also asked, Mr. Chairman, whether investments in automation had improved the efficiency of our organization. Personal computers are an essential component of our work. The overwhelming amount of our data is in very large files which require the use of the mainframe computer. We have, however, developed the capacity to create smaller files for use on our personal computers. In the past month, as the House and Senate have been developing their Medicare proposals, we have had dozens of requests from Members of Congress and committee staffs for specific analyses that we were generally able to complete within 48 hours because we anticipated this need and had the computer tools set up to respond.

This past year, we installed a local area computer network and established a connection to the Internet. In the past few weeks, we have used our electronic mail capability to answer questions from Congressional staff virtually instantly and to provide briefing papers and talking points for staff and members. Some staff also have been able to access our Internet service provider from home to respond to urgent requests for information from Committee staff on nights and weekends. The

network has also allowed us to easily share data and information among our staff, reduce the paper duplication of materials, and communicate more quickly and effectively both within and outside the ProPAC staff.

Although there is no doubt this automation has improved our efficiency, it has also increased our work load as the Congress has increasingly used this expanded capability to request additional information and assistance.

#### *Staffing*

The major item in our budget is staff salaries and benefits. By statute, the Commission can employ an Executive Director and up to 25 full-time equivalent staff. Until 1995, we operated at this level. As a result of the 30 percent reduction in our fiscal year 1996 appropriation, and the uncertainties regarding future funding, we have operated over the past two years with between 16 and 18 staff.

The Commission's staff is responsible for completing the complex analytic studies that form the basis for the Commission's recommendations, reports, and testimony. The staff also prepares background and briefing materials for Congressional committees, regularly consults with committee staff, and at times briefs individual members. This substantial reduction in the number of staff has limited our ability to undertake a number of important analyses and to provide comprehensive information on important topics to Congress. Our budget request for fiscal year 1998 would allow us to increase the number of staff to 20.

#### *Computer and analytic support*

The other large budget item is for computer programming and the use of the mainframe computer. We use the computer resources of the U.S. House of Representatives (HIR). We are requesting \$940,000 for these activities, an increase of \$40,000 for computer time and \$40,000 for programming. Our spending in this area increased dramatically when the Congress expanded our responsibilities. The analyses we undertake, such as those necessary to examine and recommend methods to curtail the rapid growth in Medicare spending for post-acute care, are very complex and require very large data bases. The findings from these analyses, however, were instrumental in the develop of payment reforms to slow Medicare spending growth.

We are also requesting an increase of \$50,000 in our extramural research budget. We use this budget item to obtain data and information that is not otherwise available. For example, the work we have reported to you over the years on the levels of hospital uncompensated care and the effects of Medicare, Medicaid, and private sector payments on hospitals was funded through this budget item. While we have continued this project, in the past two years funding limitations led us to greatly curtail other important data gathering activities. Such extramural studies, for example, are necessary to obtain information on the services furnished to Medicare beneficiaries enrolled in the risk contracting program.

#### *Other budget items*

The remaining portions of our budget include the funding necessary for payment of Commissioners for travel and time spent on Commission business; for facilities, supplies, equipment, and travel; for communications with the public, including maintenance of mailing lists, publication of reports, expenses required by open meetings of the Commission, and for other administrative expenses associated with facilitating the work of the Commission. The General Services Administration (GSA), under contract to ProPAC, provides personnel, payroll, and accounting services. GSA also arranges on our behalf for office space, telecommunications services, and travel services at government contract rates.

In the past several years, the number of requests for our reports has grown rapidly putting pressure on our printing budget. Costs for Commissioner travel, meeting space, supplies, computer upgrades, and the other items we have purchase have continued to increase. As I noted, as long as our appropriation level is frozen, these added costs can be covered only by continuing to reduce staff or data gathering and analytic activities.

#### *Conclusion*

Mr. Chairman, I know that Congress and this Subcommittee are committed to eliminating this nation's annual deficit and improving the operation of the Federal government. These activities attract a lot of attention and require data and information to balance many competing claims. The Department of Health and Human Services has strong research and analytic capabilities to bolster their proposals. Many interest groups also have the funds to develop and present information to Congress to support their views. To enact the Medicare policies necessary to slow spending growth, ensure the solvency of the Medicare Part A trust fund, and con-



tinue to provide access to quality care for Medicare beneficiaries, the Congress must also have timely and useful information.

For 13 years, ProPAC has provided Congress with the information it needs to evaluate and choose among Medicare policy options. In making your difficult decisions among budget requests from competing programs, I hope you will consider the importance of our work to the Congress and the consequences of what in fiscal year 1997 is comparable to a 10 year freeze in our appropriation level.

#### PROSPECTIVE PAYMENT ASSESSMENT COMMISSION

[Budget authority by object class in thousands of dollars]

Object classification	Fiscal year—		Change	Fiscal year 1998 request
	1996 actual	1997 estimate		
<b>Salaries:</b>				
Full-time staff .....	\$1,136	\$1,221	+ \$128	\$1,349
Commissioners .....	84	96	.....	96
<b>Total .....</b>	<b>1,220</b>	<b>1,317</b>	<b>+ 128</b>	<b>1,445</b>
<b>Benefits .....</b>	<b>309</b>	<b>340</b>	<b>+ 33</b>	<b>373</b>
<b>Travel:</b>				
Staff .....	14	18	.....	18
Commissioners .....	64	79	+ 7	86
<b>Total .....</b>	<b>78</b>	<b>97</b>	<b>+ 7</b>	<b>104</b>
Standard level user charges .....	256	256	.....	256
Mainframe computer .....	492	400	+ 40	440
Telephone .....	13	30	.....	30
Postage .....	15	22	.....	22
<b>Total .....</b>	<b>520</b>	<b>452</b>	<b>+ 40</b>	<b>492</b>
Printing and reproduction .....	73	98	- 3	95
Computer programming .....	565	460	+ 40	500
Research contracts .....	24	100	+ 50	150
Commercial contracts .....	94	70	+ 5	75
Government contracts .....	.....	1	- 1	.....
GSA support .....	34	35	+ 3	38
<b>Total .....</b>	<b>717</b>	<b>666</b>	<b>+ 97</b>	<b>763</b>
Supplies .....	22	17	+ 3	20
Publications .....	11	10	+ 1	11
<b>Total .....</b>	<b>33</b>	<b>27</b>	<b>+ 4</b>	<b>31</b>
Equipment and furnishings .....	20	10	+ 10	20
Lapsing .....	41	.....	.....	.....
<b>Total .....</b>	<b>3,267</b>	<b>3,263</b>	<b>+ 316</b>	<b>3,579</b>

Note: Numbers may not add to totals because of rounding.

#### PHYSICIAN PAYMENT REVIEW COMMISSION

PREPARED STATEMENT OF GAIL R. WILENSKY, CHAIR

Mr. Chairman, I am pleased to report on the activities and work plan of the Physician Payment Review Commission. For more than a decade, the Commission has enjoyed a strong working relationship with the Congress. That is no more apparent than in the past few years in which the Commission has worked closely with Mem-

bers and congressional staff to develop options for restructuring the Medicare program. Congressional requests for assistance have been at an unprecedented level, and the Commission has responded despite a 30 percent reduction in its budget in fiscal year 1996. In the short term, the Commission has been able to maintain its level of effectiveness under current budget constraints, but it expects this to become more difficult without the increase in resources it requests for fiscal year 1998.

The Commission was established in 1986 to advise the Congress on Medicare physician payment reform. With the expertise of its 13 Commissioners and a strong analytical staff, it has established a track record of providing useful and timely advice to the Congress. Its work has been strengthened by a tradition of consensus in shaping recommendations on difficult issues.

The Commission's recommendations formed the basis for the Medicare physician payment reforms enacted in 1989. Subsequently, the Congress expanded the Commission's mandate to:

- Monitor the impact of physician payment reform and advise the Congress on setting standards for expenditure growth and updating fees in the Medicare Fee Schedule; and
- Consider policies related to financing graduate medical education, reforming the medical liability system, ensuring quality of care, improving access in underserved areas and for Medicaid beneficiaries, and controlling health costs faced by employers.

#### COMMISSION ACCOMPLISHMENTS

This past year the Commission focused on providing advice to the Congress on the restructuring of Medicare, while continuing to monitor the effects of physician payment policy. It kept the Congress informed of its progress through reports, informal briefings, and testimony.

##### *Annual report*

The Commission's Annual Report to Congress 1997 responded to congressional interest in Medicare's managed-care program by evaluating key policy issues such as improving Medicare's policies for determining capitation payments to managed-care plans, improving Medicare's methods of risk adjustment, and including provider-sponsored organizations as an option for Medicare beneficiaries. Other managed-care issues considered include access to care in Medicare risk plans, access for vulnerable populations, use of quality and performance measures, program data needs and health plan data capabilities, and consumer protection issues.

The report also examined the impact of the 1989 payment reform on physicians and beneficiaries. It proposed recommendations for addressing issues related to the design of that reform or its implementation. Its analyses provided a foundation for current congressional deliberations on options to both improve the Volume Performance Standard system and respond to issues related to the development and implementation of resource-based practice expense relative values in the Medicare Fee Schedule.

The Commission's report included several issues with implications beyond Medicare such as the role of secondary insurance, the impact of changes in the health care market place on the physician labor market and on academic medical centers, the effects of reform on dual eligibles (people covered by both Medicare and Medicaid), and the growth of Medicaid managed care. The implications of moving Medicare to a competitive premium contribution model were also considered.

##### *Mandated reports*

More recently, the Commission also submitted mandated reports on Volume Performance Standards (VPS), access to care for Medicare beneficiaries, and beneficiary financial liability. The VPS report made recommendations for setting performance standards and conversion factor updates. The access report showed that access remained good for most beneficiaries, but some vulnerable groups continued to experience problems. The report on beneficiary financial liability documented increases in physician participation and assignment rates and decreases in balance billing. New analyses were presented describing beneficiaries' liability for out-of-pocket costs beyond those attributable to the use of physicians' services.

##### *External studies*

While the Commission's reduced appropriation for last year precluded funding external studies, we were able to publish two additional reports on studies funded previously. One, which we presented in testimony before this subcommittee, described the results of a Commission-sponsored survey on access in Medicare managed-care plans. This is the first national survey of Medicare beneficiaries who are enrolled

in or disenrolled from managed-care plans. The second report focused on managed-care products, delivery systems, and arrangements with providers.

*Updates and basics*

The Commission recognizes the vital importance of providing information to the Congress in a concise and timely manner. Based on input from congressional staff, the Commission launched a new Update series, which briefly highlights Commission work on specific issues. We have issued 19 Updates so far on such topics as risk selection, access in Medicare managed care, expenditure growth in Medicare, resource-base practice expense payments, and the physician labor market.

The Commission also has prepared chart books for Members and staff on Medicare managed care and on graduate medical education. In addition, it has designed a new Medicare Basics series that describes the essential elements of Medicare managed-care and fee-for-service policies. We have received very favorable comments from congressional staff on the usefulness of these new publications which provide a concise explanation of key issues being considered in current deliberations on Medicare.

*Ongoing advice to Congress*

This past year, Commission staff spent considerable time responding to requests from congressional staff for information and technical advice. They have been in daily contact with committee staff considering different policy options, participated in drafting sessions, and provided information to health staff throughout the Congress. Staff have also conducted briefings for Members and congressional staff on Medicare capitation payments, payment issues for rural areas, and restructuring Medicare. These activities have accelerated in recent months as staff and Members have worked to develop a new Medicare package. For example, Commission staff have played a central role in simulating the impact of alternative policies to change Medicare capitation payment rates during the recent congressional deliberations.

*Testimony and briefings*

In addition to the ongoing analytical support and advice provided to congressional staff during the past year, the Commission presented formal testimony at numerous committee hearings. It testified before each of the committees with jurisdiction over Medicare policy as well as the Senate Special Committee on Aging. As you know, it also testified before this subcommittee concerning the Commission's survey on access in Medicare managed care. Since January, Commissioners and staff have participated in more than seven hearings and 19 briefings. Given the continued importance of Medicare on the congressional agenda, the Commission anticipates a very active year working with the Congress.

*Commission work plan*

The Commission's appropriation request submitted to the Committee on Appropriations in February presented the details of our work plan for fiscal year 1998. It is not possible in this brief statement to touch on all the issues we will take up. Instead, I would like to begin by telling you how we approach our work and the broad issue areas we will address. Then I will highlight work on some issues of immediate interest to the Congress.

After developing an initial work plan, we revise it and set priorities in consultation with committee staff and Members of Congress. We believe that the Congress is best served by this process of consultation and expect that specifics of our work plan will evolve in the coming months because of it. Moreover, the precise nature of the work we do, in part, depends on congressional actions taken between now and the coming fiscal year. If legislation is enacted, our focus on some topics will shift from policy design to issues of implementation, monitoring the effects of reform, and policy refinements requiring congressional action.

The Commission's plans include work on issues specifically related to Medicare fee for service and managed care as well issues that affect the entire program. Medicaid policy issues and issues raised by changes in the broader health care market will also be addressed.

*Expanding options for medicare beneficiaries*

As the Congress considers restructuring the Medicare program, the Commission's work will continue to inform deliberations on key elements of a policy to expand options for Medicare beneficiaries and constrain spending growth. If legislation is enacted later this year, the focus of our work will shift to monitor the law's implementation, assess its impact, and identify areas for further attention. In either case, our analytic agenda will focus on several pivotal issues.

First, revising the current method used to pay health plans is critical. Without that change, the program will perpetuate wide geographic variation in payments, create barriers to access for beneficiaries with high-cost medical problems, and risk spending more than necessary for beneficiaries who enroll in managed-care plans. The Commission sees its assessments of both new payment methods and strategies to implement improved risk adjustment as top priorities in advising the Congress.

As new types of health plans are offered to beneficiaries, questions about standards for participation, the enrollment process, measures to facilitate informed choice by beneficiaries, and consumer protections must all be examined. Moreover, current strategies for monitoring both quality and access must be revised because of the differences in service delivery and availability of data between fee for service and managed care. These are all issues that the Commission will continue to address in the coming year.

#### *Federal premium contribution*

Proposals to restructure Medicare address many of the limitations identified with the current program. Some policy experts caution, however, that these changes may lead to distortions in local health care markets and that further measures will be necessary to control program expenditures. They propose replacing Medicare's current defined set of benefits with a federal contribution for beneficiaries to use in purchasing coverage from a variety of approved health plans. Because this would represent a significant departure from the current Medicare program, the Commission has begun to set out the issues and implications of such a change to allow for a more informed discussion of such proposals.

#### *Volume performance standard and practice expense*

While the policy debate in the past few years has focused on Medicare managed care, some important issues in Medicare fee for service remain of concern to the Congress. Two of the most pressing are the correction of flaws in the Volume Performance Standard system that is used to update payments under the Medicare Fee Schedule and implementation of resource-based practice expense relative values in the fee schedule.

Both the Congress and the Administration have proposed a revision of the VPS system, called the sustainable growth rate system, which would incorporate many of the Commission's previous recommendations to correct the limitations of the VPS. The Commission will continue to work with the Congress on the specific design of the policy, and will comment on its implementation as part of its mandated responsibilities to advise the Congress each year on setting targets for spending on physician services and updating fees.

The immediate concern with practice expense relative values is what steps must be taken to refine the proposed values released by the Health Care Financing Administration (HCFA) earlier this month. Although current law calls for implementation in January 1998, it is anticipated that this will be delayed for a year, and a multiyear transition will be put in place. The Commission is now analyzing HCFA's proposed rule to advise the Congress on the new relative values and the process HCFA plans to use in refining them. Having conducted pioneering work that led to the legislation mandating HCFA to develop resource-based practice expense relative values, the Commission is in a unique position to continue to monitor their development and implementation.

#### *Improving the traditional Medicare Program*

The Commission's work on fee for service extends to consideration of how the traditional Medicare program will fare under policies to expand the range of health plan options for Medicare beneficiaries. Two issues of particular importance are how to improve the efficiency of the fee-for-service program and how to constrain expenditures across all sectors of the traditional program.

The Commission will build on work begun last year to examine the potential for Medicare's greater use of care-management techniques adapted from private indemnity insurers. It will also assess the feasibility of incorporating a preferred provider option into the traditional fee-for-service Medicare program.

#### *Graduate medical education*

Concerns about federal health care spending coupled with questions about the supply and specialty distribution of physicians have focused attention on Medicare funding of graduate medical education (GME). The Commission monitors changes in the markets for both practicing physicians and residents to provide a context for considering policy change. This information would not be available to the Congress without the Commission's analysis. Our work plan is intended to inform decisions

about the rationale for continued federal support for residency training as well as the design of funding mechanisms.

*Appropriation request for fiscal year 1998*

The Commission requests \$3,577,646 for fiscal year 1998, an increase of \$314,646 above our 1997 appropriation. Even with this increase, the Commission's budget for next year will be nearly 20 percent below its fiscal year 1993 appropriation. The Commission's budget was reduced by 30 percent in fiscal year 1996 in anticipation of a merger with the Prospective Payment Assessment Commission (ProPAC) which did not occur. This came on top of Commission efforts to streamline its operations, which had already allowed it to reduce its appropriation requests by 8 percent in the three years prior to fiscal year 1996.

At a time when the demand for the Commission's analyses and advice has never been higher, its resources to respond have been significantly reduced. Nonetheless, the Commission has made every effort to fulfill its congressional mandates and respond to congressional requests. It has also taken further steps to restrain costs. With the experience of adjusting its operations for its lower appropriation level, the Commission believes that it could maintain its essential activities with the modest increase requested for fiscal year 1998. This funding level, however, will still require the Commission to make trade offs between short-term analyses responding to congressional requests and longer-term policy analysis and data development that provide the foundation for its work.

Once again, there is pending legislation to merge the Commission with ProPAC. Our budget request has taken into account that possible merger. While there are likely some administrative savings associated with such a merger, those savings were already realized in the 30 percent reduction in each commission's appropriation in fiscal year 1996. Moreover, there will be some additional initial costs associated with a merger (such as moving costs), which come from combining two organizations into a single, functioning entity.

The increase proposed by the Commission for fiscal year 1998 would be distributed among three main budget items: staffing, computer services, and outside contracts. The appropriation requested would maintain the Commission staff who are critical to producing the analytical work that supports both the Commission's recommendations and its ongoing assistance to the Congress. During the past two years, the Commission has placed a high priority on retaining its highly trained and productive staff, even when faced with its recent significant budget reductions. The Commission proposes a 4.9 percent increase in funding for salaries and accompanying benefits. We have been reluctant to recruit staff in recent years because of the uncertainty regarding the Commission's funding. This modest increase would provide the opportunity to add one staff position to keep up with the increase in congressional demand for analysis and policy advice.

Much of the analysis conducted for the Congress involves the use of large data bases, such as the Medicare physician claims files and data on enrollment, plan participation, and payment rates for the Medicare risk-contracting program. Given the nature of the issues before the Congress and the data bases that can be used to study these issues, a major proportion of the Commission's budget supports quantitative analysis.

By introducing measures to increase the efficiency of its computer work, the Commission was successful in reducing its computer services budget by over 40 percent between fiscal year 1993 and fiscal year 1996. With the reductions in the Commission's appropriation last year, the funds available to support quantitative work dropped by an additional 36 percent. At this level of funding, the Commission has had to curtail or delay certain analyses. In the short term, its work may not suffer substantially from these constraints. The Commission believes, however, that the analytic support expected by the Congress (particularly with the high priority placed on Medicare restructuring) cannot be sustained without an increase in the funds for computer services. It therefore proposes an increase of \$125,000 over its current funding level for this budget category.

Funds to support outside contracts for policy analysis and data development allow the Commission to expand its access to needed data and to make use of specialized analytic resources available in the private sector. Projects supported by these funds have ranged from fairly large contracts for surveys to quite small projects, such as preparation of expert background papers.

Due to reductions in its appropriation, the Commission was not able to support any new studies and had to halt some of its ongoing analyses, because it could not purchase the necessary data. The lack of funds for contracted studies was not so apparent in the past year, because the Commission was able to publish new data

on access from its survey of Medicare beneficiaries enrolled in managed-care plans. This survey, however, was funded out of fiscal year 1995 monies.

Without an increase in the budget, the Commission will no longer be able to bring such timely information to the Congress. At its current funding level, it has only limited ability to collect necessary data, support complementary policy analyses, or consult with relevant experts. It is for this reason that the Commission is requesting an increase of roughly \$100,000 for this budget category. Even with this level of funding for outside contracts, difficult choices will have to be made among the potential studies and data collection efforts that were described in the Commission's appropriation request submitted to the Committee on Appropriations in February.

The Commission's proposed budget for fiscal year 1998 reflects its effort to restrain costs while ensuring adequate funding to carry out an ambitious work plan. Given the importance that the Congress has placed on reforms in Medicare and Medicaid, and the degree to which Members and congressional staff turn to the Commission for analysis and advice, the Commission looks forward to a very productive year.

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#### ADDITIONAL COMMITTEE QUESTIONS

*Question.* I would appreciate information on the potential impact of a freeze at the fiscal year 1997 level through the year 2002 on your agency's mission as well as staffing levels and any other relevant details you can provide.

*Answer.* As noted in my statement, the Commission's work has already been constrained significantly by the 30 percent reduction in our fiscal year 1996 budget. We responded to this cut by streamlining operations but primarily by eliminating all funding for outside research contracts.

This action has permitted us to continue meeting the immediate needs of the Congress for advice in the development of legislative options and the evaluation of alternative policies. But it has meant that we can no longer develop new sources of data or invest in longer-term analyses that provide the foundation for our work. Such investment in data and analytical work in years prior to our major funding reduction in fiscal year 1996 put us in a strong position to advise the Congress during current deliberations on restructuring Medicare. A five-year freeze at our current funding level would compromise the future availability of information that the Commission and the Congress have come to rely on in reshaping Medicare policy. Let me provide two examples of how the Commission's work would be affected.

The Commission has had a tradition of investing in studies on key issues of interest to the Congress that could elevate the debate from a discussion of anecdotes to a more systematic examination of an issue. The most recent example is the Commission's survey of Medicare beneficiaries' access to care in Medicare managed-care plans, the only existing national survey on this question. In discussing the results of the Commission's survey at a hearing last November, members of this subcommittee expressed interest in how access differs between Medicare beneficiaries in fee for service and those in managed care. Unfortunately, there is currently little reliable information to make those comparisons. This information could be obtained by surveying beneficiaries about access and outcomes. Such a project would be a high priority for the Commission if funding were available. The additional cost of such a survey, however, would be around \$600,000.

The inability of the Commission to purchase private sector data provides another example of how further funding constraints will jeopardize Commission work. As the Congress considers ways to restructure Medicare to take advantage of innovations in the private sector, it becomes increasingly important to evaluate systematically what is occurring in the private sector, how it varies in different markets, what lessons are relevant to Medicare, and what the implications of various changes will mean for the Medicare program, its beneficiaries, and taxpayers. An example of the type of data needed for this purpose is data to compare Medicare payments with those of private payers. Prior to our reduced appropriation in fiscal year 1996, the Commission was able to purchase private sector data. It had conducted analyses each year that tracked payment changes in the private sector, as well as in the Medicare program. This work contributed to our understanding of how changes in the health care market were affecting Medicare. Without the modest increase requested for the Commission's fiscal year 1998 appropriation, we will face a third year in which we cannot purchase those, or other market-related, data. A five-year freeze would only exacerbate this problem.

The impact of a freeze through fiscal year 2002 is shown in Figure 1. In 1987 dollars, our current funding level is already the lowest for any year in which the Commission was fully operational (the 1987 appropriation of \$1 million was the start-

up budget for the Commission's first year). Under a freeze, our appropriation would continue to fall in real terms, so that by 2002, it would be nearly 12 percent below our current level and fully 42 percent below our peak funding level in fiscal year 1992.

FIGURE 1.—*Appropriation for the Physician Payment Review Commission in 1987 dollars, fiscal year 1987–2002*

	<i>Thousands</i>
Actual appropriations:	
1988 .....	\$2,886
1989 .....	2,669
1990 .....	3,361
1991 .....	3,209
1992 .....	3,631
1993 .....	3,352
1994 .....	3,269
1995 .....	3,187
1996 .....	2,174
Projected appropriations under a freeze:	
1997 .....	2,367
1998 .....	2,310
1999 .....	2,254
2000 .....	2,199
2001 .....	2,145
2002 .....	2,090

Note: Values are adjusted for inflation using the gross domestic product deflator. Projected values for fiscal year 1998–2002 assume a freeze at the fiscal year 1997 level.

A 5-year freeze would not only eliminate our capacity to gather or purchase new data; it would further constrain Commission resources for computer analysis and likely lead to staffing reductions at a time when congressional requests for assistance are at an all-time high. I am particularly concerned about losing the highly skilled professional staff whose analytical work make it possible for the Commission to provide timely advice to the Congress and its staff. A freeze of this length would both lead to some reduction in staff through attrition and make it more difficult to recruit if there was a position available because of salary constraints. It also would diminish our ability to appropriately reward staff for good performance, which is a key to retaining a strong staff.

*Question.* I would be interested to learn whether investment in automation has improved the efficiency of your agency and any steps you have taken, or plan to take, to address future automation needs.

*Answer.* The Commission has made several investments in automation over the past few years. Most recently, it upgraded its internal computer network and obtained access to the Internet. The Internet has proved to be a valuable tool for staff in obtaining data from other government agencies and private sector organizations, as well as for the Commission to reach others. We launched a website ([www.pprc.gov](http://www.pprc.gov)) that allows the public to download certain publications, view transcripts from Commission meetings, and order publications on-line. This innovation saves both postage and printing costs while making Commission materials more immediately accessible to the public.

Given the Commission's modest size and the nature of its work, it appears unlikely that future investments in automation will substantially change our already efficient operation.

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#### UNITED STATES INSTITUTE OF PEACE

PREPARED STATEMENT OF DR. RICHARD H. SOLOMON, PRESIDENT

Mr. Chairman, members of the Committee, I appreciate this opportunity to review the fiscal year 1998 budget request of \$11,160,000 for the United States Institute of Peace. Although the Institute could responsibly utilize an appropriation larger than it is requesting, we are mindful of the goal of federal deficit reduction. Thus, we seek only the same level of support for the Institute approved by the Congress for the current fiscal year. Our objective is to maintain stability in (the scale of) the Institute's programs, which I believe are a vital and unique component of our national efforts to meet the complex challenges of realizing our national interests and foreign-policy goals in the post-Cold War world.

## THE INTERNATIONAL SECURITY ENVIRONMENT

Today we are six years into a disorderly and often confusing era still defined by the fact that it is not the Cold War. Conflict among the major powers is in abeyance, although considerable uncertainty remains about the future of both Russia and China, which are in historic transitions. Our Cold War-era preoccupation with the global balance of nuclear terror has been replaced by concern with dozens of smaller conflicts and humanitarian crises and episodes of chaos, conflict and human suffering, from Bosnia to Burundi. These conflicts, often driven by ethnic and religious violence, offends our values and sometimes puts our national interests, or those of our allies and friends, at risk. Yet even as such problems mount, many governments—including our own—face fiscal constraints and preoccupations with domestic concerns. We seek to minimize the risks and resources committed to involvement in crises and conflicts around the world.

Yet our own national interests demand that we remain engaged in global affairs. Our security may not be directly affected by national rivalries in Central Asia, a sarin gas attack in the Tokyo subway system, or the difficult transition to democracy in the former Yugoslavia, yet the cumulative effect of such sources of conflict abroad is to highlight the need for new approaches to managing international disorder. The human and material toll mounts daily, as measured by refugee flows, disease, starvation, and ethnic/religious strife, its savagery magnified in our consciousness by global television and other mass media and its destructiveness enhanced by easy access to modern weaponry.

The international community has yet to fashion new organizational mechanisms and rules of engagement for managing political turmoil and humanitarian crises produced by failing nation states and ethno-religious conflict. Traditional diplomacy and the institutions which served us well during the Cold War have frequently proven ill-suited to meeting many of these contemporary challenges to order and security. The old approaches of negotiation, military balances-of-power, economic aid and disaster assistance may be less important to mediators today than a grasp of cultural history and dynamics for effective response to ethnically or religiously driven conflict. Scholars and statesmen alike seek new insights and tools to make conflict resolution and peacekeeping more effective and to understand the meaning of the worldwide revolution in information technologies for the conduct of international affairs. The next generation of American leadership, now at secondary and college levels of education, must be better equipped to meet the new and complex challenges of managing conflict in the 21st century.

## THE NEW CHALLENGES OF MANAGING CONFLICT

This all underscores the importance of the Institute's mandate to strengthen our national capabilities for resolving international conflicts without resort to violence. Today, we are all searching for new instruments and means to adapt to new realities. And if we have learned anything about international affairs in the years since the Cold War ended, it is that American leadership remains essential to global stability—not to say the protection of our own national interests abroad. The Institute's unique mission is to bridge the world of academia and that of public affairs in order to provide policymakers with a broader spectrum of choices between the extremes of doing nothing or pulling the trigger of U.S. military intervention. Success in preventive diplomacy, in ameliorating conflicts, and in conflict resolution means not only saving countless lives, but also saving U.S. taxpayer dollars. It makes good policy sense to place an emphasis on developing capacities to prevent conflicts from occurring, to mitigate conflicts and their consequences once they occur, and to devise ways of assuring the effective implementation of peace accords once negotiated.

## HEIGHTENED RELEVANCE OF INSTITUTE PROGRAMS

The United States Institute of Peace is making a difference in expanding these relevant yet underdeveloped national capacities. With each passing year since the end of the Cold War, we have found growing interest in the Institute's programs, publications and inventive approaches to diplomacy and conflict management from Congress and such Executive Branch agencies as the Department of State, the National Security Council, and the U.S. military as well as the international research community. The Institute is a cost-effective national center of innovation that is helping our country translate such concepts as "preventive diplomacy" and "international conflict resolution" into an operational reality. The watchwords that give focus to our five program areas are: (1) innovation of new policy approaches; (2) application of new theories and approaches of conflict resolution through professional training programs and policy support work, and (3) education of the coming genera-



tions and the general public about the rapidly evolving changes in the nature of international affairs.

*A special example of our relevancy—"Virtual Diplomacy"*

As an example of the relevance of our work, I want to highlight the Institute's most recent effort to help the government explore the changing realities of international relations. On April 1092, the Institute convened a major international conference on the theme of "Virtual Diplomacy: The Global Communications Revolution and International Conflict Management." This two-day forum brought together diverse private and public sector communities to explore the ways new telecommunications technologies are reshaping international relations, concepts of state sovereignty, opportunities for more effectively managing our foreign policy, and new possibilities for the prevention, management and resolution of international conflict. "Virtual Diplomacy" sought to identify how to improve government effectiveness in managing crises and emergency humanitarian operations and explored how public and private sector crisis management groups can better cooperate and coordinate their efforts. More broadly, we seek to catalyze new thinking about ways in which the Internet and other communications instruments of the age of the information revolution can be utilized to more effectively project our leadership abroad in the service of minimizing international conflict and realizing our interests in an increasingly interdependent world.

The Institute's varied programs are at the forefront of analysis, education, and action in the field of international conflict management. Let me briefly outline the five integrated program areas through which we fulfill our congressionally chartered mission to assist the U.S. and the international community:

- Policy assessment and development. The Institute's in-house array of experts, grant and research programs, and its ability to mobilize prominent specialists both nationally and internationally, forms an unmatched intellectual network that provides both real-time policy support and long-term perspectives to decision makers. The Institute acts as a bridge between the world of analysis and that of policy practitioners, applying geographic and topical expertise to policy-relevant issues, providing insights that give early warning about potential conflicts and crises, and facilitating efforts at preventive diplomacy.
- Training foreign affairs professionals. The Institute's training programs continue to develop new approaches for training foreign affairs practitioners. Working with U.S. diplomatic and military personnel such as the National Defense University and the Peacekeeping Institute at the Army War College, we are helping these programs expand their negotiation and mediation skills and our armed forces adapt to new peacekeeping roles. Institute workshops are unique in bringing together foreign policy, military, international and non-governmental organizations who increasingly need to work together in managing crises and conflicts.
- Education. Institute programs systematically educate both teachers and students at the secondary, undergraduate and post-graduate levels about the changing character of international conflict and the new fields of conflict prevention, management and resolution through seminars and public outreach programs.
- Outreach. Through the use of print publications, radio, the Internet and other electronic means, the Institute is broadening public understanding of the nature of international conflicts and new ways of managing and resolving them.
- Facilitation and dialogue. The Institute has been active in facilitating "Track II" dialogues (informal meetings) among parties to current or emerging disputes, or between private experts and officials in unofficial capacities to explore issues with the hope of laying the groundwork for "Track I" or governmental negotiations.

#### HIGHLIGHTS OF THE INSTITUTE'S CURRENT PROGRAMS

I want to accent the current relevance of our work by illustrating some of our practical activities in the areas I have just outlined. We have focused our modest resources on issues where we sense urgency and special national interest either in preventing conflicts or building peace in post-conflict situations. I will touch on Bosnia, East Asia, and Central Africa, as well as several other important new ventures.

*Reconciliation in post-conflict Bosnia*

I particularly want to highlight our efforts to support the U.S. government in building peace in Bosnia. To this end, the Institute has developed a range of activities that apply techniques and research developed over the past decade to the work

of stabilizing the Bosnian peace processes and facilitating reconstruction of that society.

At the heart of reconciliation efforts in Bosnia is the need to deal with the legacy of war crimes. Building on the Institute's previous landmark work on transitional justice, we are working with local authorities in Bosnia and the international community to help develop options to heighten the accountability of those guilty of war crimes. This accountability is essential to stabilizing the peace process. As part of our larger efforts in the area of Rule of Law, the Institute plans to convene this summer a roundtable on justice and reconciliation in Bosnia that will involve the ministers of justice and the interior of both the Federation and the Republika Srpska. That forum will make available to political leaders the Institute's work in this area and will also convene an international group of experts to help the Bosnians consider how to address, in a constructive manner, the thousands of war crimes cases that will not be dealt with by the international tribunal at the Hague.

The Institute has also launched in Washington a Bosnia working group including both administration and non-administration representatives to discuss policy considerations that go beyond immediate operational issues. In its brief history, this working group has served to coordinate the development of policies by disparate groups and to keep key decision makers informed in an efficient and effective manner.

In addition, the Institute's grant and fellowship programs are focusing on Bosnia and Balkan-related issues. Several prominent senior fellows are now doing research projects on such topics as community peace building efforts in ethnically divided communities, questions of reconstruction, and the impact of the "Albanian question" on stability in the Balkans.

Institute training, outreach and education efforts have also focused on Bosnia. Our International Conflict Resolution Training Program (ICREST) has held two training sessions on the Balkans, and Institute staff have conducted four additional training sessions on the ground in Bosnia. Institute grants to promote reconciliation in Bosnia have involved training in conflict resolution skills for teenagers in Bosnia, Croatia, and Serbia, and in mixed Croat and Muslim communities, and the training of representatives of religious communities in approaches to more effectively resolve conflict. In order to avoid duplication of effort and promote collaboration among international organizations, the Institute has supported the development of an Internet-based electronic clearinghouse of information about activities in the region and a database of organizations pursuing conflict resolution in Bosnia.

Finally, our Religion, Ethics and Human Rights program has been working with religious leaders in Bosnia to identify areas of cooperation and to initiate programs that will address the inflammatory language which religious groups use in describing each other and which militates against a culture of tolerance.

#### *Managing and preventing conflict in East Asia*

The Institute also has been active on key problem areas in the Western Pacific which hold the potential to erupt into major conflict: the Korean Peninsula, the South China Sea, and the China-Taiwan dispute. The Institute's ongoing working group on Korea has provided support to the administration since 1993, and to the Korean Energy Development Organization (KEDO), in efforts to design and implement the October 1994 Agreed Framework which froze North Korea's nuclear weapons program. A working group "Special Report" issued in 1994 played an important role in the policy debate leading to the nuclear accord; two subsequent reports have also contributed significantly to the policy community's understanding of this complex situation. In addition, periodic meetings of the working group with senior administration officials and also with KEDO officials—most recently, just last month—have supported their efforts to realize the nuclear accord and craft approaches to reducing the risk of conflict and fostering reconciliation between North and South on the Korean Peninsula. The Institute has also concentrated on the security implications of the agricultural crisis in North Korea, and is now seeking to identify confidence-building measures that may lead to a reduction in the massive conventional military forces deployed on both sides of the Demilitarized Zone. We also are exploring the development of a "Track II" dialogue with North Korea on approaches to arms control and reduction.

The Institute has also focused on other potential Asian flash points. The unresolved territorial disputes in the South China Sea over the Spratly Islands have been the subject of an Institute working group, research efforts, and a "Special Report." In addition, festering territorial disputes and sovereignty questions, particularly the China-Taiwan question and territorial issues in the East China Sea and Sea of Japan, pose serious threats to regional stability and to U.S. interests. In response to concern in the policy community, the Institute is expanding its focus on

these disputes and their implications for U.S. interests in the Asia-Pacific, and is seeking to craft new political approaches which could ameliorate these problems.

*Ongoing ethnic conflict Central Africa*

The Institute has also concentrated efforts on the horrendous ethnic conflict in the Great Lakes region of Central Africa (e.g. Rwanda, Burundi, and Zaire/Congo) in the areas of transitional justice and in assessing the impact of the current turmoil in Zaire/Congo on its nine neighbors in the region.

In regard to Zaire/Congo, earlier this year the Institute, together with the State Department, organized a day-long symposium on the situation facing that country in the transition to a post-Mobutu government. That session provided an opportunity for U.S. government officials to hold a dialogue with international scholars and analysts and policymakers from Europe and Africa. In addition, that forum was followed by more detailed policy discussions at the State Department aimed at building international consensus on how to manage the transition in Zaire/Congo.

As part of our Rule of Law Initiative, the Institute has been involved in Rwanda and Burundi with the key issue of transitional justice, i.e., how societies emerging from repression or civil war deal with the legacy of past war crimes and other human rights abuses. Shortly after the 1994 genocide in Rwanda, the Institute assembled fifty U.S. and UN officials, leading scholars, experts on war crimes and international law, the Rwandan Prime Minister (by phone) and the chief prosecutor for the UN war crimes tribunal for the former Yugoslavia for a major conference on ways of dealing with the legacy of violence in Rwanda. Subsequently, an Institute Senior Scholar worked with the Rwandan President to devise a plan for accountability after the genocide (including the drafting and enactment of the genocide legislation), and recently the Institute, with concurrence from the State Department, assumed an expanded role in assessing and advising on the implementation of the genocide legislation in Rwanda and in coordinating external assistance to that country.

The Institute has also been involved in Burundi. In September 1996, the Institute co-sponsored a day-long conference with the State Department to help assess policy options to avert the kind of genocide experienced in Rwanda, and it has provided funding for the Burundi Open Forum, a preventive diplomacy effort designed to avoid a repeat of the violence that wracked Rwanda.

*Other new institute initiatives*

**European/Russian Security:** The Institute has convened a working group to examine in depth the consequences of NATO expansion. Former National Security Advisor Brzezinski initiated the first session of this group on Capitol Hill with a presentation about the Russian dimensions of this issue. Subsequent sessions have focused on the NATO-Russia Charter and the prospects for NATO expansion after this summer's first round. Future sessions will focus on Central Europe, the Baltic Republics, the Ukraine and NATO itself. This working group is chaired by Ambassador Max Kampelman, vice chairman of the Institute's Board of Directors.

**Afghanistan:** Having done extensive work on conflict resolution processes in other conflicts, including Cambodia, Somalia, Angola and Lebanon, the Institute organized a small working group to consider whether any of the lessons from these conflicts would be applicable to the current situation in Afghanistan. With the ultimate objective of making a determination as to whether a negotiated settlement to the Afghan conflict is possible at this time (as opposed to a victory on the battlefield), the Institute has convened two groups of experts: some of the more prominent Afghan experts in the United States, and specialists on the four conflicts mentioned above. Four sessions have been held in 1997.

**Central Asia:** The five states of Central Asia represent a serious source of potential regional instability, both concerning their internal relationships and also concerning their relationship with the former Soviet Union. To look at possible flash points in Central Asia, with the objective of generating recommendations for defusing or resolving them, the Institute convened a seminar in May.

*Training professionals in conflict management skills*

Finally, I want to highlight the Institute's critical work on conflict resolution and negotiation skills training for foreign affairs professionals. This activity continues to be our fastest growing area and draws heavily on our substantive policy work. The combination of substantive work and training is one of the Institute's distinctive characteristics.

To respond effectively to the new requirements of peace operations and diverse international negotiating opportunities, effective policymaking and planning must be supported by inventive diplomatic methods. Increasingly, there is a need for supplemental efforts beyond traditional diplomatic instruments. A whole new strata of

non-governmental actors is playing a larger role in international affairs, while some traditional actors and institutions, particularly the military, are finding themselves in non-traditional roles such as managing peacekeeping operations, as in Somalia, Haiti and post-Dayton Bosnia. The Institute's training programs are in growing demand to help the military adapt to new missions and to help governments and non-government actors cope with new realities. I have already touched on some of our efforts to train these new actors in Bosnia.

I particularly want to highlight the Institute's collaboration on training and other areas with the U.S. Army's Peacekeeping Institute (PKI). The Institute of Peace was called on to assist in writing the negotiation and mediation section of the 1995 Joint Commanders Field Handbook. Subsequently, the Institute has expanded its collaboration with the PKI, holding three annual ICREST training seminars on managing conflict in peace operations. Military staff colleges are using the Institute's materials on peacekeeping operations, and the Institute has also begun to work with foreign militaries. The Institute has also designed and conducted three training seminars for senior officers from Latin American countries at the request of the Inter-American Defense College, with whom we are planning additional programs.

In fulfillment of its mandate, the Institute has reached out beyond professionals to educate the next generation through our teacher training and student enrichment programs. Over the past four years, 120 secondary school teachers from over 40 states participated in Institute summer training seminars, while undergraduate faculty seminars have attracted more than 75 professors from 25 states in the past three years. And the Institute's National Peace Essay Contest has involved upwards of 7,000 secondary school students annually in grappling with the complexities of decision making on matters of war and peace in international affairs today.

#### CONCLUSION

Mr. Chairman and Members of the Committee, in closing I want to stress that the Institute deeply appreciates congressional support for its work, and understands full well the imperative of fiscal prudence. We have devised our budget submission with that objective in mind, just as we are managing the Institute so as to gain the maximum programmatic impact from our modest annual appropriation.

As the committee deliberates on our budget request, I would again stress the Institute's real-time efforts to prevent, ameliorate, or resolve conflict such as those in Bosnia, Korea and Central Africa which I have outlined. It is evident that it is much less costly and risky for our nation to help prevent or mitigate the effects of conflict than to contend with the devastating and unpredictable consequences of a raging crisis. As Father Ted Hesburgh, a member of our Board of Directors, stressed to you several years ago, "If the Institute of Peace helps prevent just one war or helps resolve one humanitarian crisis peacefully, it will justify its mandate and its financial support many times over."

I believe the United States Institute of Peace has grown to be a highly valuable, cost-effective center for action as well as research, training and policy support for practitioners in the conduct of America's international relations in a world still burdened with conflict. We have organized ourselves to make maximum use of our capabilities, to draw effectively on the expertise and resources of others where appropriate, and to distribute widely the results of our work. It is fulfilling the promise that Congress entrusted in us when it established the Institute in 1984.

#### ADDITIONAL COMMITTEE QUESTIONS

##### NEGATIVE IMPACT OF A FUNDING FREEZE THROUGH FISCAL YEAR 2002

*Question.* Please provide information about the potential impact of a freeze at the fiscal year 1997 level through the year 2002 on your agency's mission as well as staffing levels and any other relevant details you can provide.

*Answer.* A freeze of our appropriation at the fiscal year 1997 level through fiscal year 2002 would seriously impair the Institute's ability to fulfill its Congressionally-mandated mission. Such a freeze would (1) eliminate any opportunity for development of Institute programs beyond current levels; and (2) reduce current program activities because of the need to absorb the effects of inflation over the next 5 years.

Level funding for past six fiscal years: From fiscal year 1992 through fiscal year 1997 the Institute's appropriations have been limited almost to the same degree as if a freeze had been in force. Any consideration of a future freeze through fiscal year 2002 should, therefore, take into account the fact that the total cumulative period of freeze-like effects would cover a total of 11 fiscal years—from fiscal year 1992 through fiscal year 2002.

Since fiscal year 1992, the Institute's level of appropriations has varied slightly between \$11 million and \$11.5 million. The Institute's one-time increase to \$11.5 million (about a 5-percent adjustment) in fiscal year 1995 was awarded to fund only part of a proposed expansion of the Institute's Education and Training Program. Consequently, appropriations during the past five annual cycles have neither (i) included any adjustments for inflation nor (ii) allowed for any additional program development beyond that supported by the \$11.5 million appropriation.

The Institute has accepted these limitations to demonstrate its voluntary support for the objective of federal budget deficit reduction. Yet, during that time period, Institute services have been called upon at an increasing rate. The market for its programs has grown in proportion to the growth in its reputation for (i) prompt and effective steps on urgent issues related to resolution of international conflicts, and (ii) its educational work supporting teaching about world conflict to American students and the provision of training to foreign affairs professionals about approaches to managing international conflicts.

National need for more development of Institute programs: In attempting to meet the domestic and international demand for Institute services, Institute programs have continued to grow and mature during these six years of basically level funding. During this period the Institute has maintained, in its annual budget submissions to Congress, that it can use larger appropriations effectively and responsibly to enhance American interests in peace and security throughout the world.

Having been constrained for the past six years, the Institute now can address the period through fiscal year 2002 and state more strongly than ever that it could utilize more funding to even greater benefit in pursuit of its legislated mission. The Institute estimates that modest increases in funding of about three percent per year beyond the rate of inflation would enable it to realize its national mission more fully at a time when the world continues to be plagued by newly developing violent conflicts in places like Zaire (Congo) and old settlements that are at best shaky (as in Bosnia) or are in danger of falling apart (as in Cambodia).

Additional funds would be used for such activities as a significant expansion in the rule of law initiative dealing with accountability for war crimes and transitional justice in places like Bosnia and Rwanda; further expansion of the education and training program along the lines proposed to Congress in fiscal year 1995; greater efforts at Track II conflict-resolution dialogues and facilitations; restoration of grant and fellowship programs to prior levels; and expansion in public outreach through the use of radio, the World Wide Web, and other electronic media.

Significant program erosion from inflation: A five-year freeze holding the Institute's appropriation to the \$11,160,000 level appropriated for fiscal year 1997 could seriously limit the Institute's capacity to carry forward its Congressional mandate. If inflation during this period is assumed to average 3 percent annually, the total cumulative reduction in the Institute's purchasing power across-the-board for this period would be about 16 percent.

Damaging as would be a budget reduction of one-sixth, the impact of inflation would be compounded even further if one differentiates between the effects on (i) the Institute's fixed non-discretionary costs (such as personnel and rent) and (ii) its variable discretionary costs (such as travel, service contracts, equipment, grants, fellowships, scholarships, etc.). The Institute's first response to continuing budget erosion from cost increases would be to maintain the level of personnel and other non-discretionary expenditures (the rationale being to preserve its institutional infrastructure and work for a restoration of funding at some future point). It would accordingly be forced to reduce expenditures for the discretionary items listed above. If the full impact of a cumulative inflation of 16 percent were allocated to discretionary costs alone, the available purchasing power for such expenses would be reduced by one-quarter to one-third.

Faced with such a dramatic impact, the Institute would need to contract a number of its programs as well as consider reductions in personnel. The precise nature of such cuts would depend on further review and consultation with the Institute's board of directors. In this process the Institute would conduct an assessment of personnel needs and could be forced to reduce its FTE level by from 10 to 15 percent from the level of 59-60 it judges to be the minimum needed to operate the Institute effectively down to the range of 50 to 53—a step that would significantly restrict Institute operations and force cutbacks in Institute programs.

Apart from considering possible program contraction as described in the preceding section, the most basic feature of the Institute's current program planning is its objective of seeking to maintain a stable base of funding and program activity for its operations during the coming five years:

—Program stability is important so that the Institute can sustain the initiatives and maintain the degree of flexibility and innovation that it has developed in

recent years (e.g. our work on North Korea, Kashmir, Sudan, and Bosnia). Marginal budgetary reductions over time will gradually reduce the Institute's ability to respond to new challenges in international conflicts with policy assessment activities and Track II facilitation dialogues in support of administration and Congressional needs.

- Further development and refinement of the Institute's education and training activities requires a firm base of funding from which to respond to the interests of its Congressional sponsors and administration collaborators, and to strengthen our educational enrichment activities addressing questions of international conflict management from high school through graduate and professional training—activities that support President Clinton's stated goals of giving education a central role in federal programs.
- The transfer to the Institute in late 1996 of jurisdiction over a tract of federal land on which to build a permanent headquarters further underscores the need for program continuity.

#### CONSTRAINTS ON THE FEDERAL BUDGET

The Institute is mindful and supportive of the goal of federal budget deficit reduction. It has sought to develop annual budget requests that are fully consistent with this goal and has crafted its programs to ensure the efficient use of resources and a focused and disciplined setting of priorities.

In considering the Institute's appropriation request, we hope that you will consider the fact that our effectiveness in fulfilling our Congressional mandate can produce significant cost savings for the nation—including smaller expenditures for military interventions, lower risks of combat casualties, and reduced conflict-related humanitarian assistance. As Institute board member Father Theodore Hesburgh has noted, when testifying before the House Appropriations Subcommittee for Labor, Health and Human Services, Education and Related Agencies, "If the Institute prevents just one war or helps resolve one humanitarian crisis peacefully, it will justify its budget many times over."

In this context, the Institute could responsibly utilize more than the amount it is requesting, but at a minimum it seeks to maintain a stable level of funding in order to continue to serve its policy support and professional training purposes.

To maintain a stable level of operations it is necessary to take into account the effects of inflation. Even a low rate of inflation reduces overall capability if enough time is allowed to pass without appropriate compensatory measures being taken. Yet the Institute has not requested any recognition of inflation in its budget requests since its current level of funding was established about five years ago and hence has seen its funding erode in real terms from year to year.

Consequently, the Institute proposed in the fall of 1996 that the President's budget request include \$11,495,000 for our programs, an amount that would have represented an increase of 3 percent above the Institute's appropriation for fiscal year 1997 and within a few thousand dollars of the amount appropriated for fiscal year 1996.

Since the President's budget request does not include this increase for inflation, the Institute has set its own request at the \$11,160,000 level, as described above, in order to be consistent with the President's level. At the same time, the Institute believes that the degree of program stability that the Institute needs cannot be assured over time without some allowance for inflation. A single year, by itself, is unlikely to present a serious problem; but the cumulative effects over several years of level funding can be considerable. As described above, the effect in fiscal year 1998 will be a slow down in the growth of the Institute's education and training activities and a reduction in grants and fellowships and other research activities that will significantly constrain the Institute's capacity to respond to the changing world situation.

On behalf of the board of directors of the United States Institute of Peace, I want to thank you for OMB's Passback Guidance allocating \$11,160,000 to the Institute and for OMB's support for Institute programs. As you know, this allowance maintains the Institute at the fiscal year 1997 enacted level but is \$335,000 less than the \$11,495,000 that the Institute included in its submission to OMB. The Institute's higher figure was designed to cover some of the increases in Institute costs due to inflation.

None of OMB's allocations of budget authority to the Institute during the last six fiscal years have directly recognized the effects of inflation; none, in fact, have exceeded the prior year's appropriation. Yet cost increases during this period have included, for example, (1) salary adjustments for cost of living and locality increases totaling over 17 percent, and (2) increases in printing costs of about 7 to 8 percent

per year (in fiscal year 1995 alone, the costs of paper for our publications increased by 30 percent).

For these reasons we have seriously considered submitting a formal appeal to the Institute's fiscal year passback, but after further review, we have decided not to press a matter that for 1 year would amount to \$335,000. We did, however, wish to call to your attention the cumulative effect of a straight-line budget and lay the basis for a continuing dialogue on this matter.

#### IMPROVED EFFICIENCY THROUGH INVESTMENT IN AUTOMATION

*Question.* Has investment in automation improved the efficiency of the Institute? What steps has the Institute taken or does it plan to take to address future automation needs?

*Answer.* The Institute has been a leader among federal agencies in automating the management and operation of its various analytical, educational, training, and administrative activities. In order to assure that public funds are used as efficiently as possible, and to make our limited appropriation work most effectively in fulfilling our mission, the Institute's policy is to promote automation of as much of its work as feasible.

In its fiscal year 1998 budget request to Congress the Institute described how it is using information services technology and related automation efforts both to improve the efficiency of its internal operations and to explore how automation can strengthen the Institute's outreach to its various audiences in the U.S. and abroad. We believe that our efforts in this area could serve as a model for other publicly funded organizations.

Overview of automation efforts—1991 through 2002: Since 1991 the Institute has made a series of well planned and steady investments in office automation. A plan adopted in 1991 set the goal of supporting every staff member, fellow and research assistant with the computer tools needed to:

- communicate internally and with the world at large;
- create materials for publication of books and reports as well as distribute such materials electronically to targeted lists of interested individuals and organizations;
- use electronically-maintained client lists to build new working groups and communities interested in supporting the Institute's mission;
- plan, execute and track events and program participants (including grant, fellowship and essay contest participants);
- track expenditures through the various Institute programs and departments; and
- make available to the public the Institute's publications and its collection of library reference materials and other resources on international conflict management.

In this process the Institute has sought to (1) identify tasks or activities that would benefit from automation, (2) set objective goals, and (3) use standard commercially-available off-the-shelf hardware and software whenever possible. The Institute's policy is to purchase products or services that have a track record for ease-of-use, reliability, and long-term economy. Outsider observers of our work frequently remark on the high quality information systems we have established at a modest investment of our resources.

The information system goals set in 1991 were met by early 1995. In 1996 the Institute began to evaluate the results of these efforts in order to produce a new information systems plan by the end of fiscal year 1997. This new plan will guide system development, acquisition, maintenance, and training priorities through fiscal year 2002. It will also contribute significantly to the Institute's development of a new permanent headquarters building next to the Mall in Washington, D.C.—a building which the Institute intends to build and equip in a way that will take maximum advantage of the ongoing technological revolution in telecommunications, information, and other automated systems in fulfillment of our legislated mandate for public and professional education, training and research support.

*Accomplishments to date:* The move to increased automation has affected all areas of the Institute's operations:

Communicating within and outside the Institute—e-mail: By early 1992, the Institute had installed an e-mail network linking all of its offices, and file and database servers to assist in the creation and exchange of electronic information and Internet-accessible electronic mail applications on all computers used by staff, research assistants, and fellows.

Publishing Institute products: Investment in automation has substantially improved the efficiency of the Institute's publications. Recognizing that the publishing

world of 1997 is primarily digital in nature, the Institute maintains an in-house, digital desktop publishing operation. Use of digital technology allows the Institute to create and produce high quality publications in a timely, efficient, and cost-effective manner. Primary vendors—printers, typesetters, and designers—also work in the digital world. Our in-house capability facilitates faster turnaround of projects and flexibility in creating new and appropriate products that publicize the Institute's work. The Institute also uses the Internet/Web as described below, to disseminate its publications.

In terms of sales, all Institute distribution centers are fully automated. Customer service and book order information is maintained on an automated system that provides us with a great deal of information about our varied audiences and their interests.

For direct mail, the use of computers has improved efficiency in several ways:

- Work is performed faster.
- More work can be done in-house rather than contracted out.
- Tracking publications and recalling information is much more efficient.

Reaching special audiences—the Institute's Client List: The Institute's Client List database is the heart of the Institute's operations. To save money on mailing costs and to manage information about Institute clients, the Institute brought its mailing list in-house in 1992. After consultations about applicable categories for identifying and grouping contacts, the mailing list became a Client List, which now offers a variety of ways to cross check and determine client interest and history of participation in Institute events as well as receipt of our publications. By electronically manipulating this list, the Institute can customize groupings of people interested in Institute work and target them through a variety of media including print, fax, and electronic mail.

The short-term result of bringing the mailing list in-house was to reduce redundant mailings by two-thirds. The long-term result of developing a more substantive client profile database from the mailing list is that all of the Institute's program work has been strengthened by a greater capacity to:

- identify experts in the field of conflict resolution, in quick response to requests from other federal agencies, the media, academics, and the general public seeking expert advice in a broad range of categories.
- assemble working groups of qualified experts to advise policy officials of alternative approaches to managing changing events.
- profile the Institute's audiences to aid in the design of programs and publications that better serve their interests.

Scheduling events—the Institute calendar: The Institute is able to organize high-quality meetings of diverse communities with minimal lead time. Its automated information systems provide the means for a small staff with limited resources to respond to a growing need for Institute services, particularly for policy relevant meetings. The Institute's primary automation vehicles are its Client List, Calendar, and its participant handling databases. These applications generate an automatic series of tasks, deadlines and forms that must be completed in order to comply with federal purchasing regulations and at the same time organize the events that comprise much of the Institute's work. Procedures and forms that took weeks and months of training to understand and process, now take minutes. The electronic Calendar has saved the Institute months of man-hours and helped improve the quality of Institute events.

In 1994, in response to the growing number of Institute-sponsored events, the Institute began developing an automated event planning application to improve efficiency, circulate pertinent information, and track costs. This unique software application was designed, programmed and implemented by Institute staff. It was installed on an Institute server and was in general use by 1995. The participant handling database works in conjunction with the event planning features of the Calendar to arrange for participant travel and honoraria and other logistical arrangements. The Client list insures the delivery timely and targeted notices informing interested groups of upcoming events. Staff use of the Calendar, participant handling database, and Client List has helped the Institute make more efficient use of limited staff, reduce emergency spending, and consequently the number of Institute-sponsored meetings has nearly doubled since 1994.

In addition the calendar also provides the automated means to prepare administratively for the arrival and orientation of new employees. The Institute also manages various competitive programs (e.g., fellowships, grants and essay contest) by using database applications that have been customized by Institute staff.

Tracking expenditures: Since most of the Institute's non-personnel expenses are related to events and products, the Institute Calendar is used to automate purchase requisitions and work-orders.



By following steps automatically prompted by the Calendar, any item or work that results in a purchase is entered, justified, and processed either as an internal work order or as a purchase request that goes through standard government purchasing procedures. In this way individual programs and departments can track, in real time, all of their requests for purchases or work against their annual budget and work plans and thereby save days of record keeping and more accurately budget future activities and events.

The Institute uses a variety of automated accounting systems to develop Institute budgets, to manage its endowment accounts, and to interface with GSA for the accounts which it maintains.

Expanding media outreach: To fulfill its mission, the Institute must attract audiences willing to listen, participate, and advance the Institute's work. The Client List provides the Institute's principal outreach vehicle for building bridges to diverse communities. Although much work remains, its development has provided a focal point for the Institute's effectiveness in supplying client services.

Even so, the Client list is only the starting point of our community development efforts. Since 1992, the Institute has experimented with various forms of outreach other than publications to reach its target audiences. These include radio and TV broadcast, video production, fax lists, e-mail lists and web site development. The Institute's recent conference on "Virtual Diplomacy" demonstrated the effectiveness of online electronic tools in attracting the attention of a broader domestic and international audience to the Institute's work.

The Institute is beginning to gain the experience needed to assess the most efficient and effective manner in which to disseminate its work through radio broadcasts, electronic mailing lists, fax and e-mail on demand, and documents and databases accessible through the Institute's web site ([www.usip.org](http://www.usip.org)). Our long-term goal is to have the means to produce broadcast or online programs that draw simultaneously from a diverse community of experts and interested parties, synthesize associated ideas, and disseminate in real time to audiences who are most affected by and interested in a particular issue.

Automating the library: In 1995, the library initiated plans to replace its outdated hardware and software as funding became available. It was guided by a need to take advantage of new computer tools and networks to better facilitate and support the effective provision of information services and efficient operations.

The goals of the library's information systems plan were to:

- expand public access to information resources in international conflict management;
- facilitate communication and delivery of services to Institute staff and fellows at the desktop via the Institute's network resources; and,
- integrate library automation plans, to the extent possible, into the Institute-wide information system.

In early 1995, the library began to upload to the Institute's Internet site files (i) containing new titles added to the Institute's book collection; (ii) describing library operations and services; and (iii) providing links to World Wide Web resources. The library uses these tools to support Institute-wide programs and to promote knowledge about peacemaking and conflict resolution to a "virtual" audience of practitioners, researchers, and citizens at home and abroad, and encourages them to direct their research inquiries to the Institute's staff.

The library staff maintains and develops the Library & Links pages (<http://www.usip.org/library.html>) on the Institute's web server. The library will continue to focus a substantial amount of its effort on developing innovative services and access to resources in international conflict management via the Internet.

To further automate operations in late 1995, the library acquired a Macintosh-based client/server integrated library system (ILS) composed of five core modules: acquisitions, serials management, cataloging, circulation, and the online public access catalog. The implementation of this system is scheduled to be completed by the end of the 1997.

Over the last few years, the library has been subscribing to an increasing number of electronic information services, resulting in a growing need for server space on the Institute-wide network. To alleviate this situation, Institute staff will install a network server in mid-1997 for the ILS and the library archive of electronic documents.

By February 1996, the hardware and software upgrade in library staff offices, and basic training in Macintosh for library staff was completed.

In March 1996, the library switched to a new Internet service provider which offered a low cost dial up connection with technical support for unlimited access to the Internet. At the same time, the library acquired new software for navigating the Internet via a graphical browser. These changes significantly simplified and en-

hanced the library staff's access to external electronic resources in support of Institute-wide information needs.

In early 1997, a new Macintosh computer for Institute-wide use was configured to provide quick and easy access to the Internet, enhancing navigation and facilitating the use of the Internet for the research and information needs of Institute staff and fellows. Prior to the installation of this public use computer, Institute staff were using one of the office Macintoshes in the library for accessing the World Wide Web. The availability of the Internet in the library has exposed Institute staff and fellows to the World Wide Web, and enhanced the information sources available to them at the Institute.

Also in early 1997, library staff oversaw the installation of a jukebox with CD-ROM drives, and handled the installation of various bibliographic and full-text databases in CD-ROM format. The number of CD-ROM products increased significantly in 1997, thus helping to avoid the need for costly searches on commercial databases. The library also continues to subscribe to and utilize commercial databases such as Lexis/Nexis and Dialog to initiate and fulfill interlibrary loan requests among participating libraries. This service is of importance to the Institute and to other libraries with limited funds for collection development, recognizing that access is becoming more important than ownership in meeting the information needs of many library users.

Training staff for automation: Neither sensible hardware and software acquisition nor creative design and program implementation can insure that Institute investments in automation will produce the desired results. Working with and training staff is key to maintaining efficient and effective systems. Recognizing this need since 1993 the Institute has gradually implemented a formal computer training program to ensure that its technological investments translate into productive staff work skills. Each year the Institute teaches new staff, fellows, research assistants and interns how to use its information services. Since the start of the Institute's formal training programs, the amount of time spent on technical assistance problems with new staff has dropped more than 50 percent.

In mid-1996, the Institute's library designed and began to offer a one-hour hands-on individual training session on "Doing Research on the Web Using Netscape" tailored to the work of the Institute. The goals of the training session were to introduce the World Wide Web as a research tool to retrieve information in subject areas of interest to Institute staff and fellows, and to provide hands-on experience in navigating the Web, retrieving information, and searching for Web resources relevant to the work of the Institute.

Increasing overall efficiency: In summary, the adoption and use of new information technologies to automate Institute procedures as described above has improved the Institute's efficiency by helping it to:

- arrange events in a way that avoids time conflicts and duplication;
- better manage its finances;
- better manage its library resources;
- rapidly develop and produce new publications;
- build bridges among policymakers, academics, NGOs, the business community, philanthropic organizations, and the general public—through use of the client list to better target communications;
- communicate the results of our work to increasingly larger and more influential and international audiences—through publications of books and reports and material available on the Institute's web page;
- more rapidly marshal expertise among Institute clients in response to the needs of American policymakers and diplomats; and
- assess and promote new opportunities to resolve international conflict through non-violent means.

Addressing future automation needs: In the future the Institute expects to continue developing the role of automation in the same vigorous manner as described above. In so doing, during the next five years through fiscal year 2002 it will pursue two parallel lines of activity:

- developing an information systems plan to address its future needs for information systems infrastructure, information management procedures and acquisitions of hardware and software.
- planning the construction of a new permanent headquarters building next to the Mall in Washington, D.C. that will incorporate many elements of the revolution in information and telecommunications technology.

The planning for information systems will feed into the planning for the headquarters building and help define the technological features that will best serve the Institute's future needs.

Information systems planning: The planning goals will be to (i) provide a blueprint for the Institute's electronic infrastructure, (ii) outline Institute policies regarding acquisition, maintenance, and disposal of software and equipment, and (iii) establish user skill requirements. The plan will simultaneously support each program's needs in light of the Institute's mission and prepare the Institute to integrate and to exploit increasingly powerful automation tools. The Institute believes that keeping up with the state of the art in automation will be a necessity if the Institute is to maintain its current work pace at roughly its present funding and staffing levels.

As currently projected, the first step in the planning process will be an audit in four areas:

- A review of personnel that will cover intended and actual job duties, job performance objectives, reporting relationships, and use of Institute resources and procedures.
- An examination of processes that will focus on the mechanics of how work and information flows through the Institute, how interaction takes place with those outside the Institute, and what procedures and resources are used to facilitate both of these processes.
- A comprehensive inventory of hardware and software that will include the Institute's existing computer and networking infrastructure, the kind of capabilities they provide, and the capabilities still needed.
- An identification of data involving where, in what form, and by whom information is stored and referenced at the Institute. An attempt will also be made to determine where information stored in different forms or places overlaps as a way of identifying where gains in efficiency and effectiveness might be achieved.

After the audit is completed, more detailed planning will be pursued regarding continuing development of the Institute's program for automation and related implementation measures.

Building a permanent headquarters for the Institute: In 1996 Congress and the President enacted legislation transferring to the Institute a parcel of land located at 23rd Street and Constitution Avenue in Washington. The U.S. Navy has since transferred jurisdiction of this site to the Institute, and the Institute is now beginning a fundraising campaign to finance the cost of constructing its permanent headquarters building on this site.

The Institute intends that its permanent headquarters will serve as a model of high tech outreach, including video/conference facilities with global satellite linkups, state-of-the-art World Wide Web connections, and automated communication through computer and other displays with the American public who will visit the headquarters while spending time in the Mall area.

Physical planning for the headquarters will be based on an architectural competition which is certain to involve computer-assisted design techniques. This physical planning in turn will draw upon the Institute's information systems planning with the goal of making the Institute's operations even more effective and efficient.

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## CORPORATION FOR PUBLIC BROADCASTING

PREPARED STATEMENT OF ROBERT COONROD, EXECUTIVE VICE PRESIDENT AND CHIEF  
OPERATING OFFICER

### CPB'S FUNDING REQUEST

CPB requests a regular appropriation of \$325 million for fiscal year 2000—the equivalent of just 2.7 percent more than the level of funding public broadcasting received in fiscal year 1990, adjusted for inflation. The Administration's fiscal year 1998 budget assumes a funding level of \$325 million for CPB's regular fiscal year 2000 appropriation.

Both stations and producers are working within the constraints of repeated cuts and rescissions, but they cannot do so indefinitely. Eighty-nine percent of the increase we are seeking will go directly to public television and radio stations around the country, and to grants for program producers to help maintain high quality programming and station services into the future. Our limited discretionary funds will be used to pursue initiatives in which Congress has expressed interest, such as expanding our activities to meet emerging technologies, like the internet; drawing minorities to careers in public broadcasting at all levels of employment; developing educational outreach programs and projects; and funding systemic reform through a new grant program known as The Future Fund.

Given the effects of 10 years of inflation, \$325 million in 2000 is only a \$6 million increase in buying power over our fiscal year 1990 appropriation of \$229 million. Using the same analysis, CPB's already enacted appropriation for fiscal year 1999—\$250 million—provides 18 percent less buying power than did our fiscal year 1990 appropriation.

To further illustrate this point, the graph on the next page charts CPB appropriations between fiscal years 1990 and 2000, comparing our year-to-year appropriations as passed by Congress, to our year-to-year appropriations converted to 1990 constant dollars. The difference between the two lines is the effect of inflation since 1990.

#### *The importance of the federal dollar*

Federal support is essential to the continuation of this system. It is the foundation upon which state support, local support, university support and viewer support rests. It is not the icing on the cake; it is the batter that binds the system together.

Stations serving rural areas and poor populations would likely not be served by public broadcasting without federal backing, because those stations have fewer alternative resources. Elimination of funding to larger stations would jeopardize our best source of premier programming, and would hurt small stations indirectly. Large stations subsidize small stations in a variety of ways—PBS dues, for example.

The 15 percent federal investment is an example of a successful public/private partnership. Congress provides just enough seed money to draw additional funds from a variety of sources. Independent surveys show that the average American thinks this is a good use of federal funds—that the per-person cost of a year's worth of public TV and radio is a bargain. They appreciate having a tangible and valuable service in return for their tax dollar.

Because federal funds do not require costly pledge drives, mailings or phone campaigns, the federal dollar is the most efficient dollar.

#### *How funding increases will be used*

Seventy-one percent of our appropriation is distributed to the more than 1,000 public radio and television stations that benefit from CPB grants. Each station has its own management team and Board of Directors, so the federal investment has varied uses. Approximately, 87 radio and 61 TV grant recipients rely on federal grant money for 25 percent or more of their budgets. These stations are at the greatest risk of financial insolvency should federal support continue to drop. These stations would, in turn, benefit most from a return to the equivalent of 1990 funding levels.

Eighteen percent of our federal support is distributed to program producers through a variety of program development grant funds. After subtracting our contributions to ITVS, the Minority Consortia, and PBS, the remaining grant money for programming is distributed through CPB's Television Program Fund and Radio Program Fund. Based on the number of new television and radio programs funded this year, and not factoring in reduced buying power due to inflation, we could fund roughly 17 additional television programs and 5 additional radio programs.

System Support funds would increase by \$4.5 million over fiscal year 1997 levels, with the possibility of savings from administrative belt-tightening adding to this total. In fiscal year 1997, \$10 million of System Support funds went to meet statutorily required expenses (interconnection fees, music royalties, ITVS administration, Minority Consortia administration, and the archives). If those costs did not increase, \$9.5 million would remain to be used at CPB's discretion for minority initiatives, computer based grant programs, public broadcasting research, partial financing of the Future Fund, international activities, handicap services, dissemination of information to the system, education projects, and new priorities that arise over the course of the intervening years.

#### *Additional future funding needs*

Our funding request is designed to address the costs involved in carrying out our regular activities, such as providing grants to stations, and distributing grants for program development. However, the future holds at least two additional challenges for public broadcasting that will involve significant costs that the regular appropriation does not address. We are not requesting funds for these future needs at this time, but we want to make you aware of these approaching concerns.

First, the broadcasting industry is getting ready for a dramatic technological change: digital broadcasting. All broadcasters, including public broadcasters, face the need to pay for new broadcast equipment, new production equipment, new channel structures, and new programming options. Under the current plan, all broadcasters must convert to digital broadcasting as early as seven years from now, or eventually go out of business when television sets are no longer manufactured to

pick up analog signals. Unlike commercial broadcasters, non-profit public broadcasting stations cannot finance the enormous capital costs of conversion to digital broadcasting and production equipment from profits or equity financing. We must have the support of the Administration and Congress to help us cross the threshold to this new technology. We want to work with the Administration and Congress in the coming year to calculate the costs that transition to digital broadcasting will involve.

Second, public broadcasting must prepare to replace its satellite distribution systems by as early as 2004. The premature failure this January of public television's satellite, Telstar 401, makes the need for a new system more pressing. We have not requested funding for a new system, in part because we have not yet determined what the next generation of program distribution technology and equipment will be. We want to work closely with Congress to plan for these necessary changes.

#### *The need for reauthorization*

Our request this year follows two years of intense Congressional interest in public broadcasting funding that manifested itself in lengthy Congressional hearings and questionnaires, extensive negotiations over draft reauthorization bills, and several critical votes. One of our disappointments of the last Congress was that a reauthorization bill was not passed. In fact, legislation didn't even make it as far as subcommittee mark-up in either the House or Senate. It is our hope that a reauthorization bill will be considered and passed this Congress.

#### REFORMS INITIATED BY CPB

I am pleased to report that during my tenure at CPB, management has been able to work with the board to institute some of the most sweeping changes to our grant programs in years—changes designed to create a more efficient system.

#### *Radio program grant improvements*

We set new minimal audience standards that every radio station must meet in order to continue to qualify for a Community Service Grant. Basically, we laid down a marker: if almost no one listens to your programs and almost no one in your community provides financial support, you are not serving your community well and we can no longer support you with a grant. More than 95 percent of public radio stations meet these basic standards and CPB is offering professional and financial assistance to those that do not. Stations have had 18 months advance warning about the new standards, which will take effect at the beginning of fiscal year 1998.

#### *TV signal overlap reform*

We are addressing the problem of TV signal overlap. For the first time, signal overlap is a factor taken into account when determining the level of financial support for which a station qualifies. Two years from now (at the end of a three-year phase-in), we will provide only one base grant per market in 16 overlap markets. The base grant in 1997 amounts to \$286,000. Eventually, the funds not going to base grants will be distributed throughout the system as a whole to help offset the effect of overall federal cuts. All stations will continue to qualify for Non-Federal Financial Support matching funds.

#### *Administrative cuts*

We have cut CPB's staff, and devoted the money we saved to system reform. Total CPB positions, some of which were unfilled, were cut by 25 percent in 1996. That money, along with funds from additional administrative savings, went into a competitive grant program (The Future Fund) we created to help public broadcasters implement systemic reforms.

The Future Fund has two parts, radio and television, each funded at a level of \$4.6 million in 1997. Half of the funds come from CPB discretionary funds, half come from station grant funds.

The Radio Future Fund has already awarded grants for several promising projects:

- Public Radio International and 12 radio stations are working to turn a \$361,000 grant into \$1.3 million in additional underwriting through collaboration and an improved marketing approach;
- With the assistance of a \$50,000 grant, 13 jazz-oriented public radio stations are joining forces to conduct research about music, financing options, and audience preferences, then engage in joint strategic planning based on the findings; and
- State-of-the-art audience survey methods will be taught to public radio stations through development of a Member Survey Toolkit by Market Trends Research of Oviedo, FL. Properly conducted surveys can provide valuable information to

public radio stations about their listening audience, and how that audience, and memberships, can be increased. The Member Survey Toolkit will provide expert advice on inexpensive ways to conduct scientifically accurate surveys.

The TV Future Fund has committed \$3 million to 17 projects, so far. In Florida, CPB is committing about \$1 million to match \$2.5 million being put up by Florida stations to put together a new model for regional or state-based public broadcasting organizations. Already, one programming office now does the work that was previously done by six programming offices. Eventually, all Florida programming will be done centrally, with the possibility of expansion across state lines. For the first time, underwriting credits are being made available on a statewide basis, rather than simply station to station. One preliminary step to accomplishing a statewide system was to establish uniform underwriting guidelines for all Florida stations. Also, all back office operations related to membership drives are being consolidated. Computerized data bases, telemarketing, and direct mail initiatives all will be handled jointly, freeing staff to develop new sources of funding. It is expected that these changes will generate as much as \$20 million in additional, sustainable income by the third to fifth year of implementation. Illinois, Texas and several New England states already are copying the Florida model.

Another project brings together major producing stations and PBS to "crossmarket" national public television programs in order to maximize the development of national underwriters. Stations are sharing information about which potential underwriters have been contacted and forming a common strategy to expand national support. For the first time, an individual station seeking underwriting for its own in-house productions, will also share information with potential underwriters about programs produced by other stations, or PBS, that need sponsorship. Our \$300,000 investment is expected to increase PBS program funds by 10 percent (\$10 million) per year.

A third project involves 12 to 15 stations teaming up with an audience research firm specializing in public television programming to develop software to analyze, in real time, audience reaction to pledge drives. Already, two pledge cycles have been subjected to this analysis. After strengths and weaknesses are assessed, a fund raising model will be developed that, hopefully, will be more effective while requiring fewer on-air hours devoted to pledge drives.

Public broadcasting has never subjected itself to such intense self-analysis and, sometimes, painful changes as it has over the past two years. These changes will lead to better, more efficient operations.

#### MINORITY PROGRAMMING AND TRAINING

Last year, this subcommittee praised CPB's improved relationship with minority producers and directed CPB to be prepared to testify about further steps we have taken to strengthen and enhance minority programming, and the career development of minority media professionals.<sup>1</sup>

During my tenure at CPB, I have made the development of minority programming and minority talent a priority. We will continue to fund several important programs despite the reduction to our federal funds.

A common misconception about CPB is that we have vast amounts of discretionary funds to distribute to stations, producers, or particular causes that we value. The reality is that less than 10 percent of our appropriation is available for discretionary distribution. This includes all program development funds under our control as well as station support funds not dedicated to meeting Congressional mandates. Over the past several years, we have managed to add a little to that total by cutting back on administrative costs, but the fact remains that most of the funding we receive either is distributed to stations and other organizations in accordance with statutory requirements, or goes to support other mandated purposes.

Of that relatively small amount of discretionary money (small compared to common expectations), a high percentage, 20 percent, went directly to fund minority programs in both fiscal year 1996 and fiscal year 1997. Of course, further cuts to our appropriation and the effect of inflation mean that less money will be available in the future to stations, producers, and special concerns like minority programming and employee development.

<sup>1</sup>The Committee is encouraged by the improving relationship between CPB and minority program producers. The Committee directs the CPB President to be prepared to testify during the hearing on the fiscal year 2000 appropriation for CPB regarding steps CPB has taken during fiscal years 1996 and 1997 to strengthen and enhance African-American, Asian-American, and other minority programming and to support career development of African-American, Asian American and other minority media professionals. (House Report 104-659)

The good news is that, even with shrinking dollars, we are making effective investments in minority-interest and minority-produced programming, and in the professional development of people of diverse backgrounds within the industry's employee talent pool.

We are not starting from scratch. Since 1989, we have provided annual reports to Congress about our efforts to expand diversity both in terms of what public broadcasting stations air and whom they employ. We have a track record of progress. A 1995 independent survey reported that 65 percent of individuals asked believe public television performs better than other television networks in creating realistic, non-stereotypical characterizations of people from various backgrounds. We are proud of that statistic, but not satisfied. As of January 1996, between 18 percent and 19 percent of all full-time employees at public radio and television stations were minorities. More than 17 percent of station officials and managers were from diverse backgrounds. Again, we are proud of progress in this area, but we intend to improve.

#### PROGRAMMING

##### *Minority consortia*

Through our support of the five Minority Consortia<sup>2</sup>, we have made significant investments in human and capital resources with the goal of creating an infrastructure of minority producers and public broadcasting executives that will eventually achieve independence from CPB. The Consortia function as developers, producers, and distributors of radio and television programming that not only appeals to diverse audiences, but also harnesses the creative talents of minority communities. In 1996 and 1997 combined, CPB will provide \$9.7 million for programming and administrative support for the five Consortia.

The Consortia are becoming valued sources of innovative programming. Congress should be recognized for its role in supporting these organizations through funds directed to CPB. Mr. Bill Pearce, a Native American, who recently retired after 26 years as president of public radio station WXXI-AM in Rochester, NY, made the following observations in *The Vision Maker*, the newsletter of Native American Public Telecommunications:

CPB has carried out its mission to democratize a national radio and TV system so that all facets of our national community are represented—and it has done this despite reduced appropriation and staff cutbacks. NAAPT and all its constituencies are deeply appreciative of CPB's continued dedication to a primary goal, that of reaching diverse audiences with programming from diverse sources.

CPB's coming 30th birthday deserves a salute from all Americans for inspiring outstanding programming for all radio and television audiences that never would have resulted otherwise.

The funding history of the consortia is one of steady increase from an initial funding of \$840,000 in 1978 through a total of \$5 million in 1995 and 1996. Despite an overall funding cut of \$44 million, or 15 percent, between passage of our fiscal year 1995 appropriation and payment of our fiscal year 1996 appropriation, we protected the Consortia from any funding cuts in our fiscal year 1996 budget. Our overall fiscal year 1997 appropriation was hit with a rescission of 17 percent. Minority Consortia funding for fiscal year 1997 will be reduced by 5 percent from the previous year.

Also in 1995, as CPB began emphasizing the need for stations to move toward self-sufficiency, the five Consortia sought help in moving toward self-sufficiency, too. In response, in 1996, CPB hired the Teller Group, a strategic consulting firm with substantial experience in ethnic and media market analysis, to design a business plan for the Minority Consortia. The Teller Group is working with the Consortia to ensure effective fund raising and program development, and suggest improvements where appropriate.

##### *CPB-controlled programming dollars*

In addition to the support supplied to the Minority Consortia, CPB's radio and television program funds make grants to minority producers and to producers of projects of interest to minority communities.

<sup>2</sup>The five Minority Consortia are: the National Asian American Telecommunications Association, the National Black Programming Consortium, the National Latino Communications Center, Native American Public Telecommunications, and Pacific Islanders in Communication.

### A. Radio

Of the funds set aside for radio stations and radio programming, 7 percent are reserved for CPB's Radio Program Fund. In 1997, that \$4.4 million fund will support 22 projects. Eight of those projects, funded at a cumulative level of \$2.2 million, are projects that are either produced by, or are of interest to, minorities.

For example:

- Through the University of Texas, Austin, Center for Mexican American Studies, we are funding a weekly, English language, half hour news and cultural arts journal dedicated to coverage of the Hispanic community;
- The voices of former slaves in America, recorded in the 1930's, will be rebroadcast in a program entitled Slaves No More; and
- Native America Calling and American Indian Radio on Satellite provide programming of interest to Native Americans.

Over the last several years, CPB has devoted significant funding to American Indian Radio on Satellite (AIROS). Prior to funding AIROS, CPB funded the Downlink Assistance Project from 1991 to 1995. Fifty stations, 16 of which were Native American Stations, became interconnected to the Public Radio Satellite System and, therefore, able to broadcast AIROS programming.

### B. Television

In 1996, CPB supported:

- An ambitious six-part series that will explore the natural history and cultural development of the African continent, to be titled Africa: Land of the Sun;
- Family Name, in which filmmaker Macky Alston traces her roots through her black and white ancestors from North Carolina as a way of examining the legacy of slavery in America;
- Watts Side Story examines a unique after-school program known as Colors United, which is claiming a 100 percent success rate of helping at-risk students complete high school; and
- Puzzle Place, where multicultural puppets help children learn to appreciate the differences between people and the ties that bind them together.

First round grants from the 1997 Program Fund have been awarded, and, again, many of the winners are projects either produced by minorities or that deal with issues that highlight other cultures and minority interests. For example, the abusive relationship between Japanese Imperial soldiers in World War II and Korean women will be examined in a one-hour documentary, and 350 years of Jewish community life will be examined in *They Came for Good, A History of Jews in America*.

#### *Television program funds not controlled by CPB*

By contract, and in accordance with our statute, CPB provides \$22.5 million to PBS for development of its National Program Service. Historically, CPB's contribution to the National Program Service amounts to roughly 20 percent of the total, though PBS determines which projects are to be funded. Many programs funded by PBS are by minorities or of interest to minorities, but it is not possible to trace CPB programming dollars to those specific projects.

Similarly, CPB provides \$7 million in programming funds to the Independent Television Service (ITVS). ITVS, in turn, determines which projects it will fund. When ITVS develops a project produced by a minority or of interest to minorities, the effect is that CPB money is supporting that project, as Congress intended.

#### *Local programming by or of interest to minorities*

CPB's radio and television program funds are reserved for the development of projects intended for a national audience. Individual television and radio stations, however, use their resources to produce and air local programming to local audiences. These programs often are produced by minorities or are about topics of interest to minorities. Over 200 examples of programs produced and aired locally are listed in our most recent report on Public Broadcasting's Services to Minorities and Other Groups, July 1, 1996.

For example, Native Americans are one of the fastest growing radio audiences. Since 1992, CPB has approved four new stations for grants, bringing the total number of Native-run stations supported by CPB grants to 28. A staple of every one of these stations is local programming for the local Native American population, often in the local Native American language. Though CPB does not directly fund these local programs, we provide overall support to the stations that originate the programs.



## MINORITY EMPLOYMENT AND TRAINING PROGRAMS

*College internships*

In 1993, CPB developed The Jump Start Support Program, a matching grant program designed to increase diversity in the workplaces of public broadcasting stations. In 1995, The National Scholars Program, under the umbrella of Jump Start, provided 30 college students the opportunity to work at local stations and regional organizations to expose them to the world of broadcasting, and public broadcasting in particular.

The National Scholars Program was continued in a slightly different form in 1996 through a \$95,000 grant to the Pacific Mountain Network and is now known under the name New Media Fellows.

Here are some of the students involved in the 1996 program, as they described themselves to us on their applications:

- Chris Burnside, a film and TV major at Montana State University whose native tongue is Navajo, and who considers English to be his second language.
- Blanca Torres, a communications major from Stanford University who says of herself, “I am a dynamic, dedicated Latina woman who is determined to educate those around her and fight the ignorance that plagues the beliefs our society holds. This desire drives my life and molds me into a person who is dedicated to making a difference, however slight it may seem.”
- Gladys Knight, a communications major from the University of Puget Sound, listed some of her activities. “As an officer and member of the Black Student Union, I presented talks about our culture. I became the first black woman to become a Passages Leader (camp counselor) during a week-long Orientation Program for incoming freshmen. As a Passages Leader, I presented BaFa BaFa, a cultural game and African Storytelling and Dance, and led an excursion to the Snohomish and Skokomish Indian Reservations.”

Thirty-five other equally interesting and impressive young people participated in the program. Better yet, as of our last check, 11 of those individuals have been hired by the stations where they interned.

*Next generation*

Next Generation is a public radio leadership program that matches seasoned public radio leaders with younger professionals and managers of diverse backgrounds. The goal is to help provide the tools, experienced advice, and important contacts that will help these young professionals advance in their careers. It is hoped that this next generation of industry leaders, in turn, will help to develop the subsequent generation of leaders. The program helped ten participants and ten mentors in 1994–1996.

The success of the first Next Generation program has led us to initiate a second round. This project will be a joint undertaking with National Public Radio, which has contributed \$20,000 to the effort.

*Koahnic Broadcast Corporation Training Center*

Formerly known as the Indigenous Broadcast Center, the Koahnic Broadcast Corporation Training Center is the only national institution dedicated to training Native Americans and Alaskan Natives in public radio. It serves as the operating headquarters for radio training of Native American public broadcasters in Alaska, Hawaii, and the lower 48 states. It is a place for Native Americans to learn production skills, broadcast engineering, reporting, and station development.

*The Affordable Career Development Project*

This program underwrites the costs of attendance at seminars organized by the National Press Foundation’s Washington Journalism Center and the Poynter Institute for Media Studies in St. Petersburg, FL. Public broadcasting journalists, particularly women and minorities, receive assistance in their career development.

*Employment Outreach Project*

The Corporation established a nationwide applicant referral project as a service to public TV and radio stations. The Employment Outreach Project solicits and receives resumes from individuals interested in career opportunities in public broadcasting. Those resumes are referred to stations for possible consideration for job openings. Minorities and women are particularly sought.

## OUTREACH

*Networking among multicultural producers*

CPB provides financial assistance for qualifying producers and directors to attend the Multicultural Producers Forum at the annual Public Radio Conference, and the Producers of Culturally Diverse Programming Forum at the yearly Public Television Meeting. The assistance includes meeting fees, reimbursement for reasonable lodging costs and partial reimbursement of transportation expenses.

*Outreach at minority media fairs*

CPB provides financial support to minority radio projects at the annual meetings of the National Black Journalists Association, the Asian American Journalists Association, the National Press Foundation's Washington Journalism Center and the Poynter Institute for Media Studies.

*Research*

CPB's research department investigates the listening and viewing interests of minority groups, and assesses how well public broadcasting programming matches those interests. Information gathered from this research is distributed throughout CPB and the public broadcasting industry to provide factual guidance on how best to serve diverse audiences.

## SUMMARY OF MINORITY SUPPORT IN 1996 AND 1997

CPB has aggressively established programs that recruit new talent from minority pools, promote existing talented minorities working in public broadcasting, and promote diversity in public radio and television workplaces all over the country. Our support for internship programs like the New Media Fellows will continue in 1997. We will select a new group of potential leaders to match with mentors through the Next Generation program. Support for the Koahnic Broadcast Corporation Training Center will be maintained at 1996 levels (\$165,000). And we will continue to fund the Affordable Career Development Project.

Although programming for minority audiences will remain a priority, reduced federal appropriations will affect our efforts. In 1997, we are continuing to fund the administrative and program development costs of the Minority Consortia on a priority basis by limiting funding reductions to 5 percent, despite a \$55 million rescission. However, total funding for our radio and television program funds will be reduced in proportion to our appropriation. We intend to maintain our track record of using a high proportion of those funds to support projects by minorities or of interest to minorities.

We plan to continue our efforts to bring minority producers together for networking and information sharing at national conferences through the Multicultural Producers Forum and the Producers of Culturally Diverse Programming Forum. We will visit more minority media fairs than before, and will continue, where necessary, to use research dollars to identify the needs of minority audiences and work to meet them.

Overall funding for these programs will likely decrease as our very limited discretionary funds decrease. We are continuing, however, to spend roughly 20 percent of our discretionary funds on these programs in 1997.

## EDUCATION

Education is at the heart of what public broadcasting does. Public broadcasting reaches almost every home, school, and business in America to make important learning resources available to all. CPB is dedicated to helping—and inspiring—learners of all ages in schools, at colleges and universities, at work, and at home. We are particularly proud of our reputation for excellence in children's programming, and we are building on that strength through new program development, the Ready to Learn Program, and a variety of teacher training programs.

*Nonviolent children's programming*

Our commitment to children is as old as public broadcasting itself. Mister Rogers' Neighborhood and Sesame Street are among the longest running series offered through the Public Broadcasting Service. These pioneering programs have been joined by award-winning series such as Barney and Friends, Lamb Chop's Play Along, Wishbone, 'Kratz's' Creatures, and Where in the World Is Carmen Sandiego?, among others. Child development and education experts often cite these carefully created series as examples of how television can benefit children. Their educational value has been confirmed by a number of academic studies.

Public television stations air nearly 1,900 hours of children's programming, or more than 3,300 programs, every year. Nearly 50 percent of the children's programming aired nationally is funded directly by CPB. The average public television station airs more than six hours of quality, non-commercial children's programming every day.

#### *Ready to learn*

The Ready To Learn (RTL) initiative is designed to help all children enter school ready to learn by the year 2000. In 1997, CPB is administering a \$7 million grant from the Department of Education for Ready to Learn initiatives. From 10 stations in 1994, the Ready to Learn program has grown to 95 stations in 1997. These stations reach 76.5 percent of U.S. television households, or more than 73 million American homes, and more than 29 million children ages 2–11.

Participating public television stations work with local partners to provide a variety of services to children, their parents, and caregivers. These services include excellent children's programming, publications, caregiver workshops, and free book distribution.

Specifically:

- RTL stations agree to air at least 6.5 hours of nonviolent, educational children's television programming daily.
- 800,000 copies of PTV Families/Para La Familia are distributed bimonthly through stations to families across the country. The magazine is designed to help adults become more involved in the learning process by featuring learning activities for parents and children.
- Parents, teachers, and caregivers may attend "person-to-person" training provided by professionals working with their local public television station to link the lessons in the programming with related reading and learning activities.
- In cooperation with First Book, a national nonprofit organization, CPB distributes half a million books to participating public television stations that then provide the books, free-of-charge, to children in their communities.

#### *Public television in the classroom*

Inexpensive VCRs have made the use of television programming in the classroom more convenient and widespread than ever. Public broadcasters help teachers use these television programs effectively. System-wide, public broadcasting invests about \$60 million in formal instructional television services every year.

According to CPB's "Study of School Uses of Television and Video":

- Almost four out of every five teachers used television in their classroom during the 1990–1991 school year, serving close to 24 million students; and
- three of the five most used programs cited by teachers—and six of the top 10—were originally broadcast by public television.

With funds from CPB and other sources, PBS's National Program Service recently bought extended rights for classroom teachers to use more than a dozen prime-time programs, such as NOVA and The American Experience.

#### *Helping teachers teach*

CPB sponsors training programs that give teachers access to information about education reforms and technological advances.

- The National Teacher Training Institute—CPB and Texaco have teamed up to provide funding assistance for this program created by Thirteen/WNET in New York City to help educators use public television's wealth of instructional programming and telecommunications resources effectively and creatively.
- The Ernest L. Boyer Technology Summits for Educators—CPB and the National Council for the Accreditation of Teacher Education are holding four regional summits (named in honor of the late president of the Carnegie Foundation for the Advancement of Teaching) that will engage teams comprised of high school teachers, university professors, and librarians in serious discussion about technology and how it can best be used to help students master academic content. In a nine month follow-up period, each team will work to create a finished curriculum project that employs technology in the teaching of content subjects.
- The Annenberg/CPB Math and Science Project—For five years, the Math and Science Project has funded more than 40 educational technology endeavors. Funded projects capitalize on existing reform efforts, creating a coordinated communications system of human and electronic networks, video and print resources and major media campaigns.
- The 1996 NII Awards—For the second year running, CPB is a proud sponsor of the National Information Infrastructure (NII) awards which pay tribute to the best of the best on the Information Highway. From electronic commerce, Intranets and telemedicine to community networks, educational Web sites and

broadband, the NII Awards go to projects that show the world the power and potential of networked, interactive communications.

#### NEW TECHNOLOGY

Using a portion of our very limited Station Support funds, CPB is investing in a number of initiatives designed to create a presence for public broadcasting in emerging communications fields like the Internet.

##### *Civic networking grants*

CPB is providing grants to four civic networking organizations and public broadcasters for the development of community focused online services and activities. Grant recipients in Davis, CA; Hampton Bays, NY; Chicago, IL; St. Louis, MO; and Spokane, WA, will team with local libraries, public broadcasters, schools, and other community institutions to consolidate their strengths and give local character to their services.

Civic networking provides better ways to find, create, and exchange information within communities.

##### *CWEIS: Community-Wide Education and Information Services*

The CWEIS initiative is designed to develop and encourage free public access to education and information online services where they do not already exist, using local public radio and television stations as a nucleus. Our goal is to have each new network bring together a wide range of institutions, including area public broadcasting entities, local educational, cultural and community organizations, as well as members of the telecommunications and computer industries. Together, they will build a community-based telecommunications infrastructure that will provide free access to essential services on the information superhighway.

For example:

—WNIN Online is a dial-up bulletin board that links existing community wide education and information services in Evansville, IN, and creates new public access points to break down barriers to the information highway faced by low income residents. Service for Evansville and nearby communities in Illinois and Kentucky include internet electronic mail, newspaper supplements, interactive forums on community issues, educational and outreach materials related to WNIN, broadcast programming access to local public university libraries, public school bulletin boards, and social service agency information.

##### *The K-12 internet testbed*

In this program, local public broadcasters, schools, universities, and numerous community organizations team up to develop a wide range of curricular programs and provide K-12 students and teachers with electronic publishing capabilities.

So far, CPB has funded 15 educational technology projects across the country as part of this grant effort.

For example:

—With Yugtun Qanemcit (“People Talking”), KYUK brings direct internet access for the first time to the students of the Yukon-Kuskokwim Delta in southwest Alaska, a remote region about the size of Ohio. The student population of Bethel Regional High School, largely made up of Yup’ik Eskimo and Athabaskan Indians, will focus on World Wide Web publishing and long-distance information exchange projects with other schools. So far, students plan to develop web pages to coincide with the Iditarod Sled Dog Race, which would be covered by student reporters; engage in on-line collaboration with the school district’s sister school in Jerusalem; and explore a variety of cultural literacy events which focus on native lifestyles and traditions.

##### *Multimedia/multichannel educational projects*

A \$2.5 million grant has been made available for eight interactive educational networking projects that provide teachers, parents, and children free access to information and online computer resources for learning.

For example:

—The Soundprint Media Center, Inc., of Washington, D.C., has received a grant of \$750,000 from CPB in addition to funding from the United States Department of Education to create the Education Connection, a community, school and business partnership. In addition to CPB funding, public broadcasting stations in Philadelphia, Los Angeles, Mississippi, and Louisiana are providing resources such as educational materials, broadcast programs, infrastructure assistance and electronic delivery systems to help school systems create an interactive K-12 curriculum in math, science, social studies, geography and the fine arts.

*Public broadcasting stations and the Internet*

A survey of public broadcasting stations reflecting station activities in 1995 shows that stations—each of which is managed independently—are quickly moving to provide services on the Internet. Out of approximately 200 television and radio stations responding, 190 had Internet access, 63 had established bulletin boards on the internet, 93 had e-mail capabilities, 83 had links to other online resources, and 63 used the Internet to provide forms for audience and membership feedback. Eighty-two had established home pages on the World Wide Web.

More and more stations are using their Internet access to provide services to schools and the general public. Forty-three stations provide electronic mail to schools or the public, 15 provide access to UseNet news groups, 15 provide an online newsletter, and 19 provide access to the Gopher server. In addition, 79 stations make locally created content available to schools and the general public.

## THE IMPACT OF A FREEZE AT THE FISCAL YEAR 1998 LEVEL THROUGH FISCAL YEAR 2002

Having described our funding request and the programs CPB supports, I will close by specifically addressing two issues of interest to the Subcommittee: the potential impact of a freeze from fiscal years 1998 through 2002 at the fiscal year 1998 level; and an analysis of the impact of automation on efficiency.

Congress has already passed CPB's fiscal year 1998 and fiscal year 1999 appropriation. Funding for fiscal year 1998 will be \$10 million below the fiscal year 1997 level of \$260 million. Funding for fiscal year 1999 is frozen at the fiscal year 1998 level of \$250 million, the lowest federal support for CPB in a decade, when factoring in the effect of inflation. In addition, CPB experienced rescissions (adding up to almost \$100 million) in each of the three years leading up to fiscal year 1998.

In light of this history of real cuts and loss of buying power due to inflation (see the chart on page two), a freeze at the \$250 million level through fiscal year 2002 would have a potentially devastating impact on the system. Seventy-one percent of funds appropriated to CPB go directly to radio and television stations in the form of grants. Each radio and TV station that receives our funds has its own budget and its own sources of funding to maintain operations. Should federal support be frozen at \$250 million through fiscal year 2002, each station will find itself in a different position depending on the availability of other funding sources, such as affiliations with other stations through state networks. For example, approximately 87 radio and 61 TV grant recipients rely on CPB funds for 25 percent or more of their budgets. These stations are at the greatest risk of financial insolvency should federal support be frozen at \$250 million through fiscal year 2002.

Eighteen percent of our funds support the production of quality television and radio programming—the most important service we deliver. A freeze for another three years at our lowest funding level in recent history would almost guarantee that the quality and scope of new programming will suffer. Because quality programming is the most important service we deliver, we would be unable to afford to provide a product that meets the high standards the public has come to expect from public broadcasting. If the excellence of our programming erodes, underwriters, viewers, and donors will begin to turn away and the system will begin to unravel.

We identify our core mission in four parts: education, localism, universal service, and non-commercial broadcasting. A funding freeze carried out to 2002 would compromise each of these core goals.

Education is carried out through programming and special station outreach programs. Program development funds support not only new programs, but also new episodes of existing shows. When program development funds fail even to keep pace with inflation, every educational program is affected. As public broadcasting has grown to encompass more than traditional broadcast services, our community outreach programs will also suffer. Few stations would be able to continue to afford educational outreach programs if federal support is frozen at the current low level for another four years.

Localism—local news, local programming, and community involvement—is one of the main benefits derived from having a variety of stations within a state. We encourage stations to maintain these crucial local identities while spreading the word that duplicative buildings, equipment, and staff are not necessarily needed to accomplish this important goal. Nevertheless, four years of cuts followed by a four-year hard freeze would force many states to stop funding local stations in favor of repeating the “big city” signal to every community. In some extremely isolated situations, there is no “big city” signal available to retransmit, and the only alternative to the local station is no station at all. If a station ceases operations, without another public station available to provide service, the threat to localism also becomes a threat to our goal of universal access.

CPB believes public broadcasting stations have the potential to be more entrepreneurial—in fact, we created a new grant program to fund these types of activities (the Future Fund). We do not, however, advocate compromising our noncommercial nature—an essential part of our character and identity. In addition to being an integral part of our mission, noncommercialism is mandated by the FCC regulations that govern public broadcasters and provisions in the CPB authorizing statute. If stations find themselves in a position in which they must double or triple outside fund raising in order to maintain operations in the face of continued low levels of federal support, many will ultimately be forced to discontinue broadcasting. Others will no longer be able to afford to air the excellent national programming that people associate with public broadcasting: shows distributed by National Public Radio, the Public Broadcasting Service, Public Radio International and other national program sources.

#### SAVINGS THROUGH AUTOMATION

As mentioned on page five of this testimony, CPB has reduced its own staff by about 25 percent since 1995. These reductions were not generally the result of increased dependence on automation. Unlike large federal agencies, individual departments at CPB tend to be small, 5 to 10 people (total employees number fewer than 80). Automation tends not to show dramatic savings at the small scale at which CPB operates. We found that the best way to reduce costs was simply to shrink the total staff and, to the extent possible, carry out our duties with fewer employees.

Public broadcasting as a whole is, by its nature, already a highly automated business. People provide creative direction of projects and administrative oversight, but much of the remainder of the work involves operating, maintaining, and repairing sophisticated equipment. In some cases, the jobs done by people can be carried out by computers in a more cost-effective manner. Sometimes a more effective way to save time and money is to eliminate the human and machine redundancy that currently exists within many states and markets. CPB's Future Fund is designed to enable stations to seek out these sorts of inefficiencies and eliminate them.

#### CONCLUSION

What I have described to you is an organization that is:

- actively reforming itself to increase self-sufficiency and efficiency;
- progressively developing programming by and of interest to minorities;
- aggressively working to further diversify our employee talent pool;
- setting the standard in the broadcasting of children's educational programming;
- and
- creatively looking to future technologies and new avenues of public service.

We are carrying out these initiatives to the best of our ability, despite a string of rescissions and funding cuts. Our request does not, and is not intended to, reverse all cuts and rescissions since 1995. For fiscal year 2000, we are asking to be funded at a level that is roughly equivalent to what we received 10 years ago. We believe the programs and services we provide merit this continued investment.

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#### FEDERAL MEDIATION AND CONCILIATION SERVICE

##### PREPARED STATEMENT OF JOHN CALHOUN WELLS, DIRECTOR

Mr. Chairman and Members of the Subcommittee, it is my pleasure to present to you the fiscal year 1998 appropriation request for the Federal Mediation and Conciliation Service (FMCS). I would like to describe our recent accomplishments, outline our objectives, and provide information on the resources needed to achieve them.

In 1997, FMCS celebrates its 50th anniversary. Created as an independent agency by the 1947 Taft-Hartley Act, FMCS was directed to provide mediation, conciliation and arbitration services to labor and management. Since then, FMCS's charter has been expanded by a variety of subsequent statutory enactments, making it our nation's premier body for resolution of labor-management disputes and the key public source of alternative dispute resolution (ADR) assistance to other governmental agencies. Today, FMCS provides, on a strictly voluntary basis, mediation, arbitration and ADR services and awards grants to promote labor-management cooperation.

## RECENT ACCOMPLISHMENTS—FMCS REINVENTION EFFORTS

As we approach our historic 50 year landmark, FMCS is being challenged to adjust to profound and persistent change. We are responding to the same social and economic forces which are transforming the work lives of labor and management. The American workplace, both private and public, is facing dramatic challenges posed by new technologies, heightened competition, both domestic and international, deregulation of major industries, and growing workforce diversity. These profound changes compelled us to rigorously review our own mission, services, performance, and structure.

For the last three years, FMCS has been engaged in a comprehensive and systemic organizational change effort for the purpose of improved mediation performance and customer satisfaction with our services. Today, FMCS "reinvention" initiatives are substantially underway. The Agency has experienced very significant change. This has not been easy, and not everyone among our ranks has agreed with the direction taken. However, almost without exception, our customers from business and industry and organized labor have been supportive of our reinvention efforts. Our mediators and our entire workforce are deeply committed to the work of this Agency and to strengthening its performance so that it can continue to successfully contribute to our nation in this challenging era. I am personally very grateful for their efforts over the last three years and for the tremendous progress we have made together.

We have taken a private sector approach to our own reinvention. Critical to this entrepreneurial approach is a focus on customers and their needs, improving the quality of our services, and strengthening our performance. Our Strategic Action Plan 1995–97, based on the recommendations of The Mediator Task Force on the Future of FMCS, is a series of mutually reinforcing, sequential steps to institutionally position us to continuously respond to changing external demands with high quality performance. The change process underway has entailed an organizational restructuring; redefining leadership roles and responsibilities; evaluating hiring criteria and expectations of performance; creating a learning environment; closing technology gaps; setting evaluation criteria to reward and encourage improved performance; and, institutionalizing a customer focus to ensure ongoing monitoring and reassessment—the pursuit of continuous improvement.

FMCS is striving to be a full service mediation agency with "360 degree mediators" able to deliver the full array of services which our customers seek—from traditional mediation of adversarial or acrimonious labor disputes to assisting management and labor in the creation of new partnering processes for workplace improvement, from alternative dispute resolution assistance in complex regulatory negotiations to providing assistance to emerging nations seeking to create industrial relations systems and conflict resolution capabilities.

To support our strategic redirection, in fiscal year 1997 FMCS sought and Congress appropriated funds for a customer survey, for education and training of our workforce, and to modernize the agency's technology. We are proud of our progress in each of these initiatives.

## CUSTOMER SURVEY

During 1997 we will be examining the results of the first-ever FMCS nationwide customer survey. Designed by a senior professor and research professionals from MIT's Sloan School of Management, the survey will let us hear from our labor and management customers about the value and quality of our services and how we can improve. We expect to receive the report and analysis of the survey data within the next few months and will immediately provide a copy to this Committee. About 1600 labor and management representatives, or 74 percent of the scientifically-representative sample of customers and potential customers, responded to the survey, conducted by telephone interviews. This survey will provide a baseline of information against which to measure the Agency's future performance and progress over time. It will thereby be a benchmark against which to measure performance and customer satisfaction.

## EMPLOYEE EDUCATION AND TRAINING

Over the past two years, education and training of our entire workforce has been a top priority. With a newly appointed training and education coordinator, we began by surveying skills and interests of each employee and creating individual development plans. In 1996, an ambitious education and training plan included a national seminar, regional seminars, a three-part training course for newly hired mediators, and extensive technology training. Mediators attended courses at the Harvard Uni-

versity Program on Negotiation and other courses on high performance workplace strategies. These efforts continue in 1997, including a national educational seminar to be offered in conjunction with the Agency's 50th anniversary.

A major curriculum design initiative is underway which will give mediators high quality tools enabling them to diffuse "best practices" in mediation and training in their work with the parties. In 1997 regional seminars will focus on educating mediators on the newly developed curriculum and information and communication technology.

In our headquarters, we provided courses relating to the Agency's mission, necessary job skills, and partnership skills such as team work and problem solving. In connection with our reengineering efforts, we have taught work redesign concepts and processes. This year we will explore cross training possibilities arising from our reengineering.

Following our organizational restructuring last year, education was provided to the new leadership team in organizational change, team leadership, performance measurement and learning organization concepts. In February 1997, agency leadership participated in a challenging and rewarding one-week executive leadership development program offered by the Center for Creative Leadership.

In 1998, we will continue to upgrade skills to keep pace with rapid workplace changes, maintaining and fine tuning existing training plans. We will use customer survey data to assess whether our training approaches have been appropriate. A major goal, however, will be to broaden our fairly traditional learning approach geared at upgrading skills and acquiring new ones to create a systemic learning organization environment, or one in which we are constantly learning from each other. With the basic foundation in place, we will strive to progress to a more expansive level of continuous improvement and innovation.

#### TECHNOLOGY MODERNIZATION

Three years ago, less than 25 percent of our mediators had access to computers, only a third of our 78 field offices were equipped with fax machines, there was limited internal communications linkage, and there was no E-mail. Reports were being completed by hand or on typewriters, and files and reports were transmitted by mail. Following the issuance of the Mediator Task Force Report, a commitment was made to upgrade the agency's information and communications technology.

Today, we have already transformed our information technology (IT) capabilities. Our strategic information plan encompassed system architecture, hardware and system software requirements, application software, and training. Fundamental to our IT plan is a commitment to implement no new technology without comprehensive training to assure effective usage and increase proficiency. In 1996 our priority was to equip mediators with the tools necessary to do their jobs more efficiently. A substantial portion of the 1996 technology appropriation was dedicated to hardware and software purchases for the field.

On April 1, 1997, we introduced an Intranet system. This will provide a fully integrated information system throughout the Agency and its field offices. It will enhance agency communications, broaden access to educational resources, contribute to more effective and efficient operations, reduce reliance on traditional clerical support, and enable us to perform better. It will allow electronic filing of travel vouchers and itineraries, and provide capability to send and receive E-mail and faxes. It will also provide access to our growing resource clearinghouse containing books, articles, training materials, videos and other information on collective bargaining, labor management relations and partnerships, conflict resolution, negotiated rule-making and resolution of EEO disputes. Training in the system will continue intensively during the year. By October 1, we will complete the switch to a fully electronic case management system, covering assignment, reporting and tracking of all mediation activity.

Also, on April 1, we went on-line with an FMCS home page at [www.fmcs.gov](http://www.fmcs.gov). In conjunction with ongoing reengineering in our arbitration and notice processing offices, we are planning to introduce, hopefully, within the next year, electronic access for our labor and management customers to file required notices of contract expiration and requests for arbitration services. A design for such a system has been completed.

Our information technology investment strategy has been linked to improving mission performance, supporting work processes that are being redesigned to reduce costs and improve effectiveness, and fulfilling agency streamlining goals. Given unceasing innovation, we understand that technology modernization never ends. Our Fiscal year 1998 goals are to maintain our integrated information system, system-



atically replace hardware as it reaches the end of its useful life, and keep pace with innovation.

We are proud of our progress in achieving our reinvention goals. We recognize, however, that this work will never be completed. Through our efforts, we hope to create the internal capacity to continue to adapt and grow in the face of the certain change which lies ahead.

#### FMCS PROGRAMS

FMCS programs are designed to improve the country's collective bargaining, labor-management relations, and conflict resolution systems, in an effort to improve workplace relations and performance and thereby enhance our Nation's ability to compete in the international marketplace.

#### DISPUTE MEDIATION

Mediators assist labor and management in the negotiation of collective bargaining agreements, thereby helping them to settle their disputes and avert or minimize work stoppages. Federal mediators have been active in negotiations throughout the United States, conducting 17,870 dispute mediation meetings in 5,285 active cases in fiscal year 1996.

Notable cases this past year include our work to help resolve a 94-day strike against McDonnell Douglas Corporation by the International Association of Machinists, with marathon bargaining sessions. In another case involving UNO-VEN, a joint venture between a U.S. oil company and the Venezuelan State oil company, and the Oil, Chemical, and Atomic Workers Local 7-517, after numerous mediation sessions, a strike was avoided and a five-year agreement was reached.

Over the last five years, 85 percent of the negotiations in which mediators were actively involved have resulted in agreements. By contrast, agreements were reached in only 69 percent of those negotiations without FMCS mediation. The positive contribution of our mediators is evident, especially since mediation is usually sought only when negotiations are difficult.

In fiscal year 1998, contracts will expire and negotiations occur in many industries, including trucking, communications and information, utilities, retail food, construction, health care, tire manufacturing, hotels, amusements and entertainment, and paper manufacturing, as well as in public schools. Livelihoods of thousands of American working people are at stake in many of these negotiations. FMCS mediators will be actively involved in about 5,300 of these cases, where they will be instrumental, if not critical, to the peaceful resolution of these disputes.

#### PREVENTIVE MEDIATION

Mediators also assist labor and management in learning to minimize conflict, improve their relationships, and move from antagonism to partnerships. Through this work mediators help the parties to create profitable and economically secure enterprises, thereby improving economic performance, employment security, and organizational effectiveness. FMCS mediators provide a variety of programs which introduce the parties to more effective techniques and skills in bargaining, communications, joint problem-solving and innovative conflict resolution. Preventive mediation is a growing portion of our workload. In fiscal year 1996, FMCS mediators were involved in 2,537 preventive mediation cases.

Significant preventive mediation work last year involved Bechtel Corporation and the Southern Nevada Labor Alliance. Mediators provided facilitation and training for continuous improvement committees established to improve productivity, quality and work methods. This is the first time a Nevada Test Site prime contractor and its unions have engaged in cooperative processes and, in fact, the first private sector activity of this type in the State of Nevada.

Also, mediators assisted the Amoco Texas City, Texas, refinery and the Oil, Chemical & Atomic Workers Local 4-449 in a Relationship By Objectives process to establish goals and build a more constructive relationship and trained them in interest based bargaining. In the words of the Amoco Senior Vice President, the mediators helped the parties usher in a "new era of a labor relations partnership" that will give them "a competitive advantage in the refining industry."

As the date for transition of the Panama Canal approaches, FMCS mediators are playing a major role in the development of constructive, collaborative relationships between the Panama Canal Commission and unions representing 8,000 employees. This work is viewed as critical to the smooth transition of the Canal in 1999 and will likely increase over the next two years.

In fiscal year 1998, mediators will be actively involved in about 2,600 preventive mediation cases.

#### ARBITRATION

Arbitration is used almost universally by management and labor to resolve disputes which arise under their collective bargaining agreements. This reduces the incidence of both strikes and litigation. FMCS maintains a roster of 1,700 private, professional arbitrators. Upon request from the parties, FMCS furnishes a list of names from which they can choose an arbitrator to hear their case and make a final and binding decision. Through this work, FMCS fosters improved contract administration. In fiscal year 1996, FMCS issued 30,066 panels of arbitrators to the parties.

In accordance with the National Performance Review, FMCS is examining its arbitration operations. Over the last year, we have been engaged in a reengineering process. Our goal is to improve the efficiency and effectiveness of our service, streamline processes and lower costs. This initiative has had the full participation of employees in the arbitration office. Upcoming technology improvements should provide improved assistance for arbitrators and the labor-management community, including electronic access to our services.

For the first time since 1979, FMCS arbitration rules and regulations will be thoroughly reviewed. Proposed changes will be published for comment and final, revised regulations will be issued. In March we conducted a customer focus group comprised of arbitrators and representatives of both labor and management. We sought and received valuable input on the proposed rule changes and how we might improve our services.

As authorized by Congress last year, we are preparing to provide our arbitration services on a modest fee-for-service basis, with the revenue generated to be retained by the Agency and dedicated solely to the education and professional development of our workforce. In fiscal year 1998, we expect to issue 29,500 panels of arbitrators.

#### LABOR-MANAGEMENT COOPERATION PROGRAM

The Labor Management Cooperation Act of 1978 expanded our charter by authorizing FMCS to encourage and support joint labor-management cooperative activities designed "to improve labor-management relationships, job security and organizational effectiveness." Congress authorized FMCS to award grants to establish or expand labor-management committees. Through these grants, we seek to encourage joint, innovative approaches to collaborative labor-management relationships and problem-solving. Last year, for example, grants were awarded to establish a comprehensive Oklahoma City-wide public school labor-management cooperative effort, a statewide Connecticut construction industry labor-management council, and a nation-wide labor-management committee which will promote the high performance work organization concept with major corporations and the International Association of Machinists.

Since 1981, FMCS has awarded almost \$15,000,000 to 239 labor-management committees. There have been 1,031 applications requesting nearly \$75,000,000 during the same period. In fiscal year 1998, FMCS is requesting \$1,741,000 for the Labor-Management Cooperation Program. With these funds, we hope to award 18 new grants and nine extensions. Customer panels will be used for the third time to review applications.

#### ALTERNATIVE DISPUTE RESOLUTION

Mediators assist governmental agencies in using mediation and other forms of conflict resolution as an alternative to litigation and to improve government. Our alternative dispute resolution (ADR) services include systems design and evaluation, education, training, and mentoring, and "train the trainer" programs. We also mediate disputes within agencies (e.g., age discrimination and other fair employment complaints, whistle blower complaints) and between agencies and their regulated public (e.g., environmental disputes). A major ADR project in 1997 is with the Equal Employment Opportunity Commission. In this pilot program designed to reduce the EEOC's large case backlog, we will mediate private sector discrimination complaints.

We continue to conduct regulatory or public policy negotiations involving other governmental agencies. One, with the Departments of Agriculture and Interior, involves contentious and longstanding public land use disputes in the northern Minnesota Voyageurs National Park and Boundary Waters Canoe Area Wilderness. Any agreement reached by the participants to this dialogue will be forwarded to the Minnesota congressional delegation for possible legislative action. Also, in 1996, medi-

ators successfully concluded the largest regulatory negotiations process ever held involving the Departments of Interior and Health and Human Services and 48 Native American Tribal Councils working to develop regulations implementing the Indian Self-Determination and Education Assistance Act.

In fiscal year 1998, we expect to be involved in 75 alternative dispute resolution projects. There is growing demand for our ADR services. Since funds have never been appropriated, FMCS performs this ADR work through interagency reimbursable agreements.

#### OBJECTIVES FOR FISCAL YEAR 1998

We intend to continue working to improve our services and strengthen performance through customer outreach and feedback, education and training of our workforce, technology modernization, development of new preventive mediation programs, and performance measurement.

As required by the Government Performance and Results Act of 1993, FMCS will strive to set and achieve outcome-related goals and objectives for this agency and to measure our performance in terms of results. We believe that the services we provide to the American people have tremendous value and that, with the progress we have made over the last three years in strengthening our organization, we are well positioned to meet future challenges. Our goals for fiscal year 1998 can be summarized simply:

- Continuing implementation of our Strategic Action Plan; re-evaluating and fine-tuning;
- Continuing implementation of the FMCS Strategic Information Plan; maintaining our technology and keeping pace with innovation;
- Continuous improvement of the professional skills and abilities of our workforce through education and training; creating a learning environment;
- Improved responsiveness to customer needs and interests through the use and analysis of customer surveys; and
- Striving to achieve outcome-related goals and measure performance in terms of results.

#### RESOURCES REQUIRED

To prepare itself for the future, and to remain the premier conflict resolution agency, FMCS must hire, train, and retain the most qualified workforce possible. Staff must be given the resources needed to carry out our important statutory mandates and mission. We will continue to do our part, through the programs outlined in this submission and through our reinvention efforts, to resolve disputes and improve relations between labor and management in the organized sector of the economy, to enhance the Nation's economic performance and competitive position, and to promote the use of constructive, peaceful methods of conflict resolution. To meet the challenges facing us, FMCS seeks a full-time equivalent level of 290 and an appropriation of \$33,481,000 for fiscal year 1998.

Mr. Chairman, I am deeply grateful to you and this Subcommittee for the support you have given FMCS by providing the requisite monies to enable us to transform this government agency. Without this crucial support, we could not have undertaken the improvement and innovation of the past three years. And, we could not have responded as well as we have to our customers needs—both business and industry, and labor.

I will be pleased to respond to any questions you or other Members of the Subcommittee may have.

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#### ADDITIONAL COMMITTEE QUESTIONS

*Question.* What would be the potential impact of a freeze at the fiscal year 1997 level through the year 2002 on your agency's mission as well as staffing levels? Please provide any other relevant details.

*Answer.* The impact of a freeze at the fiscal year 1997 base level of \$32,579,000, would result in financial difficulties for FMCS. Yearly pay raises and cost increases of approximately three percent would have to be absorbed. FMCS would be forced to steadily decrease funding for programs, including mediator hiring and spending plans associated with the programs, and to examine each for possible reductions, delays or elimination. In addition, funds for three new preventive mediation programs would not be available.

The current hiring effort has been chiefly directed at filling mediator vacancies created by a large number of retirements. In the near future we hope to be able

to actually increase the number of mediators to perform the vital services which, based on the initial results of our nationwide customer survey, highly satisfy our current customers. In an effort to continue to meet and exceed customer expectations, FMCS has begun to raise the level of awareness of the mediation and other services that we provide and to expand the number of customers to whom we provide them. To deliver these services requires FMCS to focus on increasing the ratio of mediators (including mediator managers)—who directly deliver services to the labor-management community—to the total workforce. As administrative and support staff have retired or resigned, FMCS has generally not replaced them. As of June 1997, the ratio of mediators to the total workforce is 72 percent. In September of 1995 that ratio was 68 percent, and in September 1992 it was 67 percent. Remaining at the fiscal year 1997 level, FMCS would be forced to leave unfilled approximately one-half of all mediator vacancies. The current staffing level of 290 FTE would drop by at least six to eight FTE a year. Such a reduced level would result in at least three to five field stations without mediators and an even greater number with drastically reduced mediators to handle caseload activity.

Vital necessities for caseload activity: travel, rent, communications, replacement equipment and contractual services and support would be greatly reduced. With limited travel funds, moving mediators back and forth to areas of critical need would no longer be an option.

The Labor Management Cooperation Program currently has a funding level of \$1,500,000 for grants. Some or all of these grant funds could perhaps be redirected to cover some of the other spending items but this has never been done and would not be desirable as the vital work of this program would thereby be curtailed or eliminated.

Three new programs to be developed and implemented would not be delivered:

—*School yard mediation.*—A program to teach meditation skills to teachers, so that they in turn can institutionalize the program and make conflict resolution techniques, problem solving skills, as well as diversity issues, all part of the school curriculum.

—*Conflict resolution and cultural diversity.*—The demographics of the American work force have been changing rapidly and these changes will continue in the future. The most rapidly increasing groups coming into the labor movement today are immigrants, women, and minorities. Initial results from our customer survey show that workforce demographics raise critical issues in negotiations and workplace relationships. This preventive mediation program is designed to build skills to enable better management of conflict stemming from diversities of cultures in workplaces and to maximize the opportunities for enrichment and enhanced organizational performance coming from diversity.

—*Putting it back together.*—The threat or actual use of strikes as an effective tool during negotiations has diminished, and the number of strikes has fallen significantly; however, those that have occurred have tended to be protracted and bitter. Even when a dispute is successfully mediated and a contract is reached, the relationship between the company's management and its unionized employees is strained, at best. The relationship can also suffer without a strike. Excessive grievances or use of arbitration and serious breakdown in communication between employer and employee concerning workplace conditions can be just as damaging. FMCS customers have identified a need for this program which provides structured intervention to rebuild positive labor-management relations.

If FMCS were to receive the fiscal year 1997 funding level for the next five years, in some parts of the country our work would cease or be reduced to an intolerable level. Progress made in recent years on strengthening performance, on developing and offering new preventive mediation programs, and on "reinvention" efforts would be stymied. FMCS ability to respond to increasingly demanding customer requests for our services would be greatly curtailed by our reduced workforce, and time and effort directed at finding sufficient funding for salaries and related expenses would drain attention away from our many worthwhile projects and activities.

*Question.* Has investment in automation improved the efficiency of your agency and what steps have you taken, or do you plan to take, to address future automation needs?

*Answer.* Investment in automation has already significantly contributed to improved agency efficiency and will continue to do so. FMCS has pursued the adoption of modern information technology as an integral part of our effort to create a government that works better and costs less. Our Agency Strategic Plan 1995–97 envisions "effective, strategic use of information technology to improve Agency mission performance and delivery of high quality services." Three years ago, less than 25 percent of our mediators had access to computers, only a third of the Agency's field offices were equipped with fax machines, and there was limited internal communica-

tions linkage. Reports were being completed on typewriters, and many casework files and reports were being transmitted by mail. Following the issuance of the Report of the Mediator Task Force on the Future of FMCS in July 1994, a commitment was made by top leadership to upgrade the Agency's information and communications technology.

In fiscal years 1996 and 1997, funding was provided by Congress to complete our technology modernization within two years, fully integrate the information system throughout the Agency and its field offices, and reduce the field offices' reliance on traditional clerical support.

Over the last 18 months we have transformed our information technology capabilities. As of today, all mediators are now equipped with computers—either desk top or lap top. Our e-mail system is operational and has tremendously improved our internal communications. Field offices have now been equipped with fax machines. Effective April 1, 1997, we introduced an intranet system, providing a fully integrated information system throughout the Agency and its field offices. This will enhance agency communications, broaden access to educational resources, contribute to more effective and efficient operations, reduce reliance on traditional clerical support, and enable us to perform better. It will allow electronic filing of travel vouchers and itineraries, and provide capability to send and receive e-mail and faxes. It will also provide access to our growing resource clearinghouse containing training program curricula, books, articles, training materials, videos and other information on collective bargaining, labor management relations and partnerships, conflict resolution, negotiated rulemaking and resolution of EEO disputes. Training in the system will continue intensively during the year. By October 1, we will complete the switch to a fully electronic—paperless case management system, covering assignments, reporting and tracking of all mediation case activity. On April 1, 1997, FMCS also went on-line with an Internet home page at—[www.fmcs.gov](http://www.fmcs.gov)—which provides the labor-management community and others with information on our services and activities.

Automation has allowed us to reduce the number of field clerical staff from 18 (two in each of the nine prior district offices) to 14 (on average 2.8 in each of the five current regions). As stated, as of April 1, 1977, all of our mediator staff now have computers. For many, this is a new experience. They will be receiving intensive training in the technology over the summer and, by October 1, all will be required to conduct all case administration activity electronically. Field clerical staff will be critical during this transition in providing instruction to mediators struggling to learn the new technology. It is anticipated that once all of our mediator staff become adept at using their new computers the need for field support staff may decrease further.

For the last 14 months, FMCS has been proceeding with “reinvention,” or re-engineering, efforts in its headquarters, concentrating on those offices which are highly labor-intensive and technology dependent, e.g., budget and finance, arbitration, and notice processing. We plan to introduce new technologies to broaden means of access to our services. We have conducted a very informal survey to determine the current ability and interest among the parties in taking advantage of electronic filing options. We are studying ways to provide the capability to labor and management parties to electronically file with FMCS the statutorily required notice of contract expiration and the request for arbitration services. This would both ease filing requirements for the parties and also decrease the time spent by staff in inputting data from written forms submitted today by the parties. These efforts should definitely result in greater efficiencies as well as better service.

Our goal in fiscal year 1998, is for our Arbitration Services to have the capability for arbitrators to interact with FMCS electronically when submitting roster applications or when updating biographical information. Likewise parties will be able to access the FMCS home page to request a panel of arbitrators. In addition, arbitrators can update and post information to the FMCS web page regarding the status of a case, and the parties will be able to access that information. Notices to arbitrators and parties will be automatically generated when requirements have not been met.

We are currently developing a strategy for upgrading and integrating the remaining FMCS systems such as procurement and property management with our core financial system. Fundamental to our information technology plan is a commitment to implement no new technology without comprehensive training to assure effective usage and to maintain and increase proficiency.

FMCS has already dramatically transformed its information technology (IT) capabilities. Our future plans include staying current with and adapting to innovation so that we may continue to enhance Agency communications, broaden awareness of and access to educational resources, provide more effective and efficient operations,

and deliver high quality services. We plan to incorporate IT outcome measurement into our Government Performance and Results Act (GPRA) reporting.



**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 1998**

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U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
Washington, DC.

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses, the statements and letters of those submitting written testimony are as follows:]

DEPARTMENT OF LABOR

PREPARED STATEMENT OF THE ASSOCIATION OF OUTPLACEMENT CONSULTING FIRMS  
INTERNATIONAL (AOCFI)

The Association of Outplacement Consulting Firms International (AOCFI) is pleased to submit this testimony to the Labor, HHS, and Education, and Related Agencies Subcommittee on the funding and operations of the Department of Labor's Dislocated Worker Assistance program and the provision of job search assistance through the workforce development system.

The outplacement industry can help this Committee, this Congress, and the workforce development system save the American taxpayer hard-earned tax dollars and at the same time provide the American worker with the best available job search assistance. This can be accomplished by the outsourcing of job search assistance from public sector programs to private outplacement firms. For every dollar spent per worker through Dislocated Worker Assistance, U.S. outplacement firms charge at least 50 cents less. For every 100 workers placed through Dislocated Worker Assistance, U.S. outplacement firms place from 25 to 50 workers more. Combining the lower cost and higher placement rate in the private sector, this represents a 200 to 300 percent improvement that has not been taken advantage of by the Department and the workforce development system.

No one doubts the benefits of professional outplacement services. Outplacement assistance has the obvious economic benefit of putting workers back into productive activities and helps keep down the public and social costs associated with unemployment. There is, however, a reluctance on the part of the public sector to fully utilize private, for-profit firms. AOCFI urges this Committee to direct the Department of Labor to take the necessary leadership role with the workforce development system to achieve this public-to-private outsourcing. Private sector service providers can offer dislocated workers services second to none and are ready, willing and able to serve those workers who require assistance through publicly-funded programs.

*The outplacement industry provides job search assistance to the American worker at no cost to the American taxpayer*

The private, for-profit outplacement industry has served the American worker for the past three decades, and since 1992 has helped place over one million workers each year into new jobs within an average of 6 weeks after entering our programs. The average cost for placing all of these workers was \$700 per individual at a placement rate of 90-plus percent. All of this is done at no cost to the American taxpayer. Compare this to the Department's own estimates of \$2,000 to \$4,300 per worker



with a placement rate of between 40 to 70 percent for workers served through Dislocated Worker Assistance.

Private outplacement firms are hired by corporate employers and serve dislocated workers by providing job search assistance that can range from help in identifying job openings, to classes on resume writing and interviewing skills, to individual counseling. We serve all workers, from management to the shop floor; in fact, we offer job search assistance to as many hourly wage earners as we do salaried workers.

We are a very competitive industry, and each of our member firms work hard at delivering a service that will earn them new business in the future. Our performance has contributed to an increased willingness among employers to use outplacement services as a way to help workers when lay-offs must occur. In fact, outplacement is an important component of corporate responsibility at the time of downsizing, and it is a responsibility the employer has shown an ability to pay for.

Increasingly, the public sector, from the Department of Labor to local workforce development programs are aggressively marketing their services, including outplacement services, to corporate employers as “no cost” options to the private sector. The real cost, however, is borne by the American taxpayer. An additional cost is borne by the unemployed worker who is required to take second best in job search assistance. There is no legitimate public policy reason to shift the burden of providing outplacement services and job search assistance from corporate employers to the American taxpayer. Nor is there any legitimate reason to support a public program that attempts to duplicate services available in the private sector. This increases the burden on public programs, creates pressures for larger funding levels, and takes the focus of public programs away from the truly needy—those hard core unemployed workers in need of a variety of social services and intense skills development.

AOCFI believes that new priorities and commitments relating to the provision of outplacement assistance will create real opportunities to reduce current funding levels and at the same time offer job search assistance that will place more Americans into new jobs sooner.

—*Government Programs Should Focus on the Hard Core Unemployed.*—During the current period of record employment levels, with unemployment at an all time low, and as part of our efforts to balance the federal budget, this Committee should reduce the level of funding for job search assistance available through Dislocated Worker Assistance and direct an appropriately reduced level of taxpayer dollars to the hardcore unemployed.

—*Private Outplacement Firms Should be Utilized for Offering Outplacement and Job Search Assistance.*—For employable workers who may need publicly-funded assistance to find new employment, local workforce development systems should be required to outsource their needs to private outplacement firms. This Committee should direct the Department of Labor to take the leadership role necessary to achieve this public-to-private outsourcing. Private outplacement firms can place more workers at less cost than in-house public sector programs.

—*Utilizing the Private Sector Results in Greater Flexibility and Reduced Budget Commitments.*—Congress should not fund programs and activities that duplicate resources and capabilities that exist in the private sector. This is an inappropriate use of taxpayer dollars and government programs simply do not match the effectiveness of our industry. Requiring public programs to outsource to the private sector allows this Committee to respond with appropriate levels of support for the unemployed in need of job search assistance. It also avoids the creation of a permanent bureaucracy that will require long-term commitments and impose increasing demands for federal funding.

*The dislocated worker should not be forced to settle for Second Best*

Unless this Committee believes that a government-run, in-house program can outperform the private service sector in quality of services and price, it has a responsibility to require the workforce development system to utilize the services of private outplacement firms through Dislocated Worker Assistance. The goal of the program is to provide services to the American worker, not to create and preserve public sector programs.

There should be no hesitation to save money for the American taxpayer and provide the best outplacement service possible to the American job seeker.

—The Department and local workforce development programs should have no qualms in partnering with private, for-profit firms.

—The Department should take a leadership role in realizing savings and providing the best service possible.

—The expertise and capabilities already exist in the private sector, and outsourcing to private, for-profit firms is the most cost-effective way to provide job search assistance to the dislocated worker.

*As more corporations send their workers to one stops and other state and local programs, the American taxpayer will be required to carry an increasing burden of serving dislocated workers*

As the public sector markets its programs as alternatives to private sector offerings and more corporate employers choose to send their workers to state and local programs and take advantage of “no-fee”, publicly-funded job search assistance, the American taxpayer will be required to support services that are far too costly and inefficient.

Greater reliance on public programs like Displaced Worker Assistance will not solve any problems; rather, it will create a bureaucracy that has proven itself unable to deliver services that workers deserve and should have access to through the private sector. The natural result of this will be the creation of a public works program with a mandate it cannot achieve.

There is no valid public policy reason to reproduce the services offered by the private sector. It misses the ready opportunity to realize significant savings by partnering with private firms. It also cheats the American worker by denying the very best re-employment assistance we as a country have to offer.

The Department should concentrate its efforts on improving the performance of those programs that are intended to benefit the hard-core unemployed. Building a first-class program for this group is challenge enough for the workforce development system.

*The taxpayer will realize significant cost savings if this committee requires the workforce development system to partner with the private, for-profit sector in the provision of job search and outplacement assistance to dislocated workers*

The private outplacement industry can help the Department of Labor realize significant savings and offer the American worker quality job search assistance. At a time when the public is calling for a balanced budget and less government, it is most appropriate to save tax dollars, reduce costs, and improve services.

By outsourcing to the private sector, programs supported by the Dislocated Worker Assistance program will be able to focus their internal competencies on the hard core unemployable. This would allow the use of the private sector as and when needed, providing through public-to-private outsourcing “just in time” outplacement services to dislocated workers. During times of high unemployment, more outsourcing will be necessary. During times of low unemployment and downsizings, less outsourcing will be required. This represents a flexibility and efficiency that both this Committee and the Department of Labor should work towards. Funding levels for job search assistance will match actual needs and the public-to-private outsourcing structure will avoid the long-term and irreversible commitment required to sustain permanent bureaucracies.

This Committee should direct the Department of Labor to stop duplicating the job search assistance already available in the private sector and to outsource services to outplacement firms. Duplication of what the private sector does is a loss to the American taxpayer and the dislocated worker. Partnering with the private sector is a win-win situation for everyone involved.

*AOCFI has received a grant from the Department of Labor that will support workshops between the public and private sectors in six major labor market areas*

AOCFI has been awarded a grant to undertake six workshops that will bring together public sector officials and private outplacement firms. These will be conducted in major labor market areas to explore effective practices that will enable the public sector to outsource to private sector firms. AOCFI believes that much of the resistance to outsourcing in the workforce development system derives from a lack of leadership from the Department of Labor, a lack of focus by the public sector on its core competencies of addressing the needs of the hard core unemployed, and a lack of understanding regarding the availability and capabilities of private outplacement firms to deliver outplacement assistance to dislocated workers who are forced to turn to publicly-funded programs.

To overcome this systemic resistance, workshop participants will introduce their respective sectors, identifying their respective core competencies as service providers to dislocated workers. Case studies of effective public-to-private outsourcing, based on recent and current work between the public and private sectors, will also be presented at the workshops by local private sector practitioners and public sector administrators. In order for these to be truly effective, the Department of Labor must take a clear and unambiguous position of supporting the goal of outsourcing job

search needs to private outplacement firms. Equally important will be the commitment of this Committee to involve the private sector in the provision of services through publicly-funded programs.

It is hoped that these workshops will demonstrate the value in outsourcing outplacement needs to the private sector. In order to accomplish the goal of lasting communication between the sectors and meaningful levels of outsourcing, these workshops must be duplicated in additional labor market areas. AOCFI urges this Committee to support the funding of additional workshops and the other related activities as an investment that will result in achieving maximum efficiencies in program expenditures and the delivery of quality service to dislocated workers.

#### *Conclusion*

AOCFI urges this Committee to take aggressive steps in identifying ways to reduce unnecessary expenditures and to spend taxpayer dollars more effectively.

- The workforce development system should focus its attention on and the Appropriations Committee should direct program funding to the hardcore unemployed. These are the people who need the basic skills-building that will make them employable, and these are the programs not otherwise supported in the marketplace.
  - Private outplacement firms are available to provide the job search services that the employable American worker requires and deserves, but right now private outplacement firms are not given the opportunity to provide these services. Additional workshops between the public and private sectors, along with unambiguous leadership from the Department of Labor, will help achieve the public-to-private outsourcing necessary to allow private sector outplacement firms to assist dislocated workers.
  - Partnering with the private sector is a cost-effective way for the workforce development system to offer the best available job search assistance and outplacement services to dislocated workers. The outplacement industry was built upon a tradition of serving the American worker with the highest quality job search assistance and utilization of our services will save the American taxpayer money and provide better job search services to the American worker.
- There is no comparison between the quality or costs of services offered; the outplacement industry has an accomplished track record of worker placement, and private outplacement firms provide services second to none. These skills and efficiencies should be made available to the American worker.

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#### PREPARED STATEMENT OF JAMES B. HUBBARD, DIRECTOR, NATIONAL ECONOMICS COMMISSION, THE AMERICAN LEGION

Mr. Chairman and Members of the Subcommittee: The American Legion appreciates the opportunity to present its views on the Administration's proposed budget for the Veterans Employment and Training Service for fiscal year 1998. In addition, The American Legion would like to express its views regarding the President's significant spending increases for higher education programs.

Regarding the overall fiscal year 1998 budget, The American Legion is deeply disappointed that the President would make proposed increases for higher education programs and not include increases in veterans educational benefits. Mr. Chairman, to be eligible for the Montgomery GI Bill, all first term service members must agree to an eight year military obligation, relinquish personnel rights and freedoms and subject themselves to the Uniformed Code of Military Justice. In addition, service members must maintain certain physical and professional military educational standards and face the reality of frequent deployments in often hostile environments. Active duty members must contribute a \$1,200 cash contribution to receive benefits and National Guard and reserve members receive less benefits but make no cash contribution.

The American Legion believes if any group of young Americans should receive an increase in educational spending, it should be veterans. Mr. Chairman and Members of this Subcommittee, veterans have earned their educational benefits through time, sweat equity and sometimes blood and bodily injury. I hope this Subcommittee and Congress will consider these points regarding education spending as the debate on the President's fiscal year 1998 budget proposal moves forward.

Mr. Chairman, an apparently little known government law enacted by Congress has proven a point made by some of us over a long period of time. The Veterans' Employment and Training Service (VETS) is an agency which works. It works for veterans and it works for employers. The Government Performance and Results Act (GPRA) has required agencies to document the money they spend and the results

they achieve. By any standard, VETS has performed admirably. For fiscal year 1996, the money appropriated for Local Veterans Employment Representatives and Disabled Veterans Outreach Program specialists, has placed well over 327,000 veterans into careers.

The American Legion supports funding for the Veterans' Employment and Training Service in the following amounts:

- Local Veterans Employment Representatives are the people charged with representing veterans to employers. Their job becomes larger as the agency shifts some emphasis to marketing. The American Legion supports an appropriation of \$77.1 million, which will place 152,000 veterans into jobs
- Disabled Veterans Outreach Program Specialists are those who seek out disabled veterans and attempt to match their skills and training with available positions. If the skills do not match, training is scheduled to provide skills which can be useful. The American Legion seeks \$80.1 million for this program, which will place 156,000 veterans into jobs.
- The Homeless Veterans Reintegration Project was canceled last year due to a funding rescission. It was reauthorized in 1996 by Public Law 104-275. The purpose of this legislation is to locate homeless veterans, and provide them with the type of care and guidance so as to find them shelter, and get them job ready and placed in employment. The American Legion recommends this program be funded at \$2.5 million, which will serve 4,000 veterans with 2,000 being placed in employment.
- The Job Training Partnership Act Veterans Programs are designed to provide the necessary training opportunities for veterans so as to get them into career positions. This money is usually spent in the form of competitive grants to the states, with some held by the agency for special projects. The American Legion supports an appropriation of \$7.3 million for this important work.
- Federal Administration requirements for this agency will not change much from the FTE authorization of the previous year. It should be recognized that a new mission of this agency's federal staff is the investigation of cases under the Uniformed Services Employment and Reemployment Rights Act. These investigations are carried out by federal staff. The act helps members of the National Guard and armed forces reserves who are victims of employment discrimination. The American Legion supports funding for federal staff of \$22.9 million which will support 245 employees.
- The National Veterans Training Institute is the glue which holds this whole veterans' employment system together. Because of the standardized training provided by NVTI, a veteran in Pennsylvania gets the same quality of service that a veteran in Florida or West Virginia receives. The President has requested \$2.0 million for fiscal year 1998. The American Legion recommends \$3.0 in order to institute the marketing courses necessary to begin the new strategic plan. This effort is critical to easing the transition of people with good skills from the military into civilian society.

The American Legion would like to make you aware of one other issue of concern to this Subcommittee. By way of background, the armed forces of the United States are releasing about 250,000 people from active duty each year and will continue to do so for the foreseeable future. Historically, these veterans have become some of the more productive members of our society, provided they are given the right opportunities. They are stable, with over 50 percent married. They know about leadership. They have an excellent work ethic. They show initiative and are very familiar with teamwork. They are certifiably drug free. In short, they are a national resource. The problem is, unfortunately, that in too many cases the American workforce is not able to take advantage of their skills.

These veterans have attended some of the finest technical and professional training schools in the world. They are graduates with experience in health care, police and investigative work, electronics, computers, engineering, drafting, air traffic control, nuclear power plant operation, mechanics, carpentry, and many other fields. Many of their skills require some type of license or certificate to find a career in the civilian workforce. Often, this license or certificate requires schooling which has already been completed by attendance at an armed forces training institution. Unfortunately, in all too many cases, the agencies which issue the license or certificate do not recognize the training or experience already completed. As an example, a medic who treated gunshot wounds in Operation Desert Storm is qualified as a medic, but will not be certified as an emergency medical technician in our nation's cities without additional, redundant schooling.

Another example is that of a former member of the U.S. Air Force trained at Keesler Air Force Base as an air traffic controller. In 1983 he was pulled from his controller duty at an Air Force airfield tower and sent to a civilian airfield tower

to perform the same duty. During his time at the civilian airfield he was recruited by a supervisor from the Federal Aviation Administration (FAA) to join the FAA as a controller when he left the Air Force. He did so, but only after attending an FAA school, for which he was forced to use his VA educational benefits. His studies at the FAA school duplicated the Air Force training he received. The FAA did not recognize the air traffic control training provided by the Air Force, despite the fact that he performed duties with the FAA while serving in the military.

The American Legion has reason to believe that this problem is large and widespread. In order to determine its size, we have requested the United States Department of Labor to undertake a study to determine what skills, for which the Department of Defense provides training, are directly applicable to a civilian career and for which a license or certificate is required. This study, which will examine two areas of skills licensing to determine the extent of the problem, is well underway. Once this information is obtained, it will be relatively easy to approach the agencies and professional organizations and perhaps the Congress with proposals to relieve these previously trained and experienced people of the burden of redundant schooling. When the results are available in about six months, we would be pleased to share them with you.

The lack of recognition of skills learned in the armed forces by civilian licensing authorities results in recently separated veterans, particularly those who are 20 to 34 years of age, suffering the highest unemployment rates of all veterans. The unemployment rate for this group is in the two digit range, as it has been for years (currently 11.8 percent). VETS labors to help these young, recently separated veterans with a multitude of integrated services, to prevent their unemployment and ease their transition to careers in the civilian labor market.

Congress should be concerned for several reasons. In the first place, if your mission is to standardize training across government, here is a clear case of skills taught to a set of standards recognized by one segment of the workforce (military), which standards and maybe even some of the skills are not recognized by another segment (civilian). This is clearly not fair to the people who were trained by the military. Nor is it fair to either the businesses who hire these people and then pay for redundant training or the taxpayers who pay for redundant training either through GI Bill benefits or through additional federal civilian schooling such as those run under the supervision of the Federal Aviation Administration.

In the second place, the men and women who leave the armed forces, as has been mentioned, are enormously productive. Placing artificial barriers to employment in front of them The American Legion views as a drag on the economy. They need a clear path into the workplace where they can become productive, taxpaying members of our society.

Mr. Chairman, The American Legion is concerned that the important work funded and accomplished by the Veterans' Employment and Training Service is not recognized by those who have an important influence on the future of veterans in American society. Prior to the creation of VETS, veterans suffered higher unemployment rates than their civilian counterparts. Before 1983, veterans' employment assistance programs were administered through block grants to the states. Because states failed to provide proper employment assistance to veterans, the Office of the Assistant Secretary for the Veterans Employment and Training Service was created within the Department of Labor. The American Legion believes that veterans have special needs and face unique problems when searching for employment, VETS meets these special needs.

Mr. Chairman, that concludes our statement.

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#### PREPARED STATEMENT OF THE NATIONAL JOB CORPS COALITION

Mr. Chairman, it is an honor to submit to you and the members of the Subcommittee our testimony and request for full funding of Job Corps in fiscal year 1998. The National Job Corps Coalition is aware of the challenges confronting you and the members of the committee given the diminishing resources available for discretionary programs. Your support for full funding of Job Corps is testimony to your commitment to reach the hardest to serve population in this country—the economically disadvantaged young people with multiple barriers to employment who are eligible for Job Corps. Last year alone, your support helped 68,540 young men and women become productive members of society through their participation in Job Corps. Your leadership has allowed these young people to turn their lives around. For that you have our gratitude and utmost admiration.

Mr. Chairman and members of the Subcommittee, with diminishing resources available to fund education and training programs and within the context of efforts

to balance the federal budget, Congress must focus its investment on programs that work. Job Corps is a cost-effective, time-tested means of addressing our nation's growing need to educate and train economically disadvantaged youth. For 33 years, Job Corps has consistently demonstrated its ability to achieve positive results working with America's most difficult to serve youth. During the past year, Program Year 1995 (July 1995–June 1996), 75 percent of all Job Corps participants got jobs, enlisted in the military, or enrolled in higher education. When one considers the cost to our society of the lifetimes of crime, unemployment, or welfare that these young people might otherwise have led, it becomes apparent that Job Corps is a sound investment that merits continued support.

The Job Corps 50/50 Plan for fiscal year 1998 requests \$1.268 billion in funding for Job Corps. This includes \$1.115 billion for base level operations at 118 Job Corps centers. This will ensure that Job Corps can provide its comprehensive, residential education to approximately 69,700 disadvantaged youth each year. With this level of operational funding, the Committee will allow all of the new Job Corps centers that have been funded during the last four years to begin operating by the end of 1998.

Historically, Job Corps centers have been located in previously used facilities such as former hotels, military bases, orphanages, and seminaries. More than 50 percent of Job Corps facilities are more than 30 years old. As a result, many Job Corps facilities require intensive maintenance on a regular basis to keep them functioning to minimum standards, as well as to stave off further deterioration.

During the 1970s and 1980s, Job Corps' facility repair and rehabilitation needs were inadequately funded. Dormitories, classrooms, and other buildings, many of which were old when Job Corps acquired them, often remained in service beyond their useful lives. The failure to sufficiently fund Job Corps facility needs has led to the current \$306 million backlog of necessary facility improvements. This has adversely affected program performance at some Job Corps centers. The fiscal year 1998 50/50 Plan request of \$90,991,000 for facility construction and rehabilitation will help to prevent continued deterioration of older Job Corps facilities and allow inroads to be made into the current backlog of unmet facility needs.

The Atlanta, Cleveland, Cincinnati, Jacksonville, and Little Rock Job Corps centers need to be relocated because they are housed in cramped facilities on small sites where needed modifications cannot be accomplished. In the long term, the relocation of these centers will remove impediments that their current facilities present to higher performance. This will also result in reduced maintenance costs. The \$20 million requested for fiscal year 1998 will allow the relocation of the Cleveland Job Corps Center to be completed. Any funds remaining from this project will be used to begin the relocation of one of the remaining four centers.

Job Corps needs to prepare its students for high growth occupations and to meet industry skill standards. In order to professionalize Job Corps' vocational offerings for the 21st century and to better equip students for the transition from school to work, Job Corps must identify and offer emerging high technology and high wage occupations that will allow its students greater placement opportunities.

At too many Job Corps centers vocational training is conducted with outdated or obsolete tools, equipment, and materials that impede the ability of students to meet the demands of today's job market. By upgrading Job Corps' vocational offerings and modernizing its equipment and classrooms, the Committee will enable the program to widely improve its vocational training. These improvements will generate more stable, better paying jobs for growing numbers of Job Corps students well into the 21st century. They will also result in training that better meets the needs of employers.

The \$15 million that Congress invests in modernizing Job Corps' vocational training will enable Job Corps to intensify its existing efforts to review, update and modernize its vocational offerings, equipment and programs over a five year period. It is estimated that this process will lead to the conversion of approximately half of all vocational classes, facilities and equipment in Job Corps to new or substantially updated occupations.

Most Job Corps centers have been in operation since the late 1960's and early 1970's. The replacement of equipment and furnishings used in classrooms and dormitories has consistently received low budgetary priority during the intervening years. As a consequence, many centers are badly in need of funds to replace worn out furnishings and equipment. The Job Corps program is successful in training students because it attempts to simulate a workplace environment in its classrooms and shops.

In order to create such an environment, serviceable equipment and furnishings must be available, including computers, printers, tables, chairs, desks, and file cabinets. Replacement of worn furniture in dormitories is necessary to ensure that Job

Corps students feel comfortable and safe in their living environment. An investment of \$5 million in equipment and furnishings in Job Corps' classrooms and dormitories will enhance vocational training. It will also help Job Corps centers to retain even more students who will tend to experience better outcomes in terms of learning gains, GED attainment, and quality job placement.

As more and more Americans strive to make the transition from welfare to work, cost-effective education and training programs will be vital to their success. Job Corps is a national education and training program with a long history of results that justify its cost. Presently, Job Corps is unable to meet the tremendous need for its comprehensive services. Under welfare reform, this need will become even more acute.

By providing \$12 million in targeted funds to expand training slots at existing high performing Job Corps centers, the Committee will be making a cost-effective investment. For the one time cost of rehabilitating a building, constructing a dormitory, or developing a satellite center, the Committee will allow a few of the most successful, best managed Job Corps centers to provide their highly effective residential education and training services to even more youths each year. This approach fulfills Congressional intent, as stated in House Report 104-659, "to examine low-cost options for serving more at-risk youth through Job Corps, such as expanding slots at existing high performing centers or constructing satellite centers in proximity to existing high performing centers." This approach is also more economical and will take substantially less time to implement than would constructing new Job Corps centers.

More and more Job Corps students are single parents who cannot enroll in the program unless provisions for their children are made. Under welfare reform, the number of single parents who could benefit from Job Corps' residential services will grow. Without additional child care facilities to serve the children of potential enrollees, the needs of this population may go unmet.

A one-time infusion of \$10 million in construction funds will allow Job Corps to build 10 new child care facilities on Job Corps campuses. By expanding its collaboration with Head Start to operate these new facilities, Job Corps will be able to cost-effectively serve more single parents.

In the past, the Committee has urged the Department of Labor to continue to crack down on poor-performing Job Corps centers. The National Job Corps Coalition supports the many steps that the Department has taken in recent years to respond to this concern including:

- Providing intensive on-site technical assistance by teams of program experts.
- Changing the operators of 9 Job Corps centers since July 1, 1995.
- Awarding contracts for the operation of 11 Job Corps centers to six companies that never before operated Job Corps centers
- Revising the procurement system for center contractors to place increased weight on past performance
- Contracting out the operation of the Iroquois Job Corps center, formerly operated by the Department of Interior.
- In partnership with the National Park Service, closing the Gateway Job Corps Civilian Conservation Center in June 1997.

In addition, Job Corps has worked with the Office of the Inspector General to identify best practices of successful Job Corps centers. The OIG report issued in 1996 was shared with every Job Corps center. Job Corps is currently undertaking a best practices review of placement contractors in cooperation with the OIG. The resulting report will be disseminated to the Job Corps community

The National Job Corps Coalition is also very pleased that two Job Corps centers—Hubert H. Humphrey in St. Paul, Minnesota, and Denison in Iowa—were recognized along with 16 other exemplary youth programs by the Promising and Effective Practices Network (PEPNet) last year for their effective practice in youth employment and development. Job Corps will continue to disseminate best practices as an important tool in continuously improving performance among its centers.

Job Corps is currently able to serve only a small portion of its target population. By funding the Job Corps 50/50 Plan for fiscal year 1998 at \$1.268 billion, the Committee will help to reduce the number of Americans who depend on public assistance by breaking the cycle of poverty and welfare dependence. This will help provide a proven education and training program that capitalizes on public-private partnerships, quality programs, and fiscal integrity to benefit the youth of our nation. Moreover, this will help to keep America competitive by educating and training populations of youth who will comprise a significant portion of the nation's future work force.

Mr. Chairman, Job Corps needs your continued support, as do the more than 68,000 young people each year whom it serves. Without your leadership and support

for Job Corps, thousands of young people would be deprived of the means to pull themselves away from the obstacles of crime, welfare dependency, and chronic unemployment. You have been steadfast and unwavering in ensuring that these young men and women are provided with the assistance they need in Job Corps to lead independent lives. Thank you once again for this opportunity to submit testimony on behalf of Job Corps. You are a true Job Corps champion.

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PREPARED STATEMENT OF W. RON ALLEN, PRESIDENT, NATIONAL CONGRESS OF AMERICAN INDIANS

INTRODUCTION

Chairman Specter, Senator Harkin and distinguished members of the Appropriations Subcommittee on Labor, Health and Human Services, and Education. Thank you for the opportunity to submit testimony regarding the President's fiscal year 1998 budget request for the Departments of Labor, Health and Human Services, and Education. My name is W. Ron Allen. I am President of the National Congress of American Indians (NCAI), the oldest, largest and most representative Indian organization in the nation, and Chairman of the Jamestown S'Klallam Tribe located in Washington State. NCAI was organized in 1944 in response to termination and assimilation policies and legislation promulgated by the federal government which proved to be devastating to Indian Nations and Indian people throughout the country. NCAI remains dedicated to advocating aggressively on behalf of the interests of our 230 member Tribes on a myriad of issues including the critical issue of adequate funding for Indian programs.

BACKGROUND INFORMATION

Mr. Chairman, unfortunately it has been a rare occasion indeed, if ever, that programs serving the American Indian and Alaska Native population have received the federal funding required to fulfill even the most basic needs of Tribal members. Historically, funding for Indian programs has lagged far behind the funding of many non-Indian programs and this gap only continues to grow. Compared to all other sectors of the American populace, American Indians and Alaska Natives most often rank at or near the bottom or top of most social and economic indicators, whichever is worse. Of the 557 federally-recognized Indian Tribes, a great majority of their populations are characterized by severe unemployment, high poverty rates, ill-health, poor nutrition and sub-standards housing. In 1989, the average unemployment rate in Indian country was 52 percent, and by 1990 the rate had jumped to 56 percent.<sup>1</sup> The 1990 Census shows the percentage of Indian people living below the poverty line is 31.6 percent, or three times the national average.

In the 104th Congress, Tribes faced extraordinary challenges throughout the appropriations process resulting in unprecedented reductions in federal Indian program funding that left many Tribes facing extreme circumstances. Non-funding "riders" attached to Interior Appropriations bills reached well past the scope of the appropriations process and were interpreted by Indian Country as an attempt to diminish Tribal sovereignty and change the basic fabric of the federal-Tribal relationship. While we appreciate the commitment to balance the federal budget, we maintain that such a laudable initiative does not and should not preclude the federal government from fulfilling its trust responsibilities to Indian Tribes throughout this great nation. In short Mr. Chairman, extraordinary budget reductions in federal Indian programs throughout the past two funding cycles have created a state of emergency for many Tribal governments. It should also be noted that more recently, Congress' conversion of welfare entitlement funds into state discretionary funding has added to the urgency felt throughout Indian Country.

Local empowerment, the theme of the 104th Congress' federal downsizing and budget balancing initiative, was initially met with optimism by Tribes who believed related measures would enhance economic opportunities throughout Indian Country, thereby advancing tribal self-determination and self-sufficiency. Unfortunately, the result was quite the opposite. While the Administration's fiscal year 1996 and fiscal year 1997 budget request sought to empower Tribal governments with more program and service responsibilities, the Congress drastically reduced funding levels for those same programs and services.

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<sup>1</sup>See generally "1990 Census of Population—Characteristics of American Indians by Tribe and Language", U.S. Department of Commerce, Economic and Statistics Administration, Bureau of Census.



As Congress begins to shape the fiscal year 1998 budget, NCAI urges the reversal of the downward direction the annual appropriations process has taken on Indian programs. We believe that the President's fiscal year 1998 budget request has taken a very positive step in that direction.

THE PRESIDENT'S FISCAL YEAR 1998 BUDGET REQUEST

*Department of Labor*

*Employment and Training Administration.*—The Job Training Partnership Act (JTPA) authorizes Section 401 Native American Program and a two percent set-aside for Native Americans in the Title II-B Summer Youth Employment program. These two provisions are the main source of support for employment and training services for Indians, Alaska Native and Native Hawaiian workers—the most disadvantaged segment of the American work force. The President's fiscal year 1998 funding request for Section 410 Indian JTPA program is \$52.5 million, the same level provided in fiscal year 1997. NCAI supports this request but recommends that funding be increased to \$65 million in fiscal year 1998. NCAI also supports the fiscal year 1998 request of \$871 million for the Summer Youth Employment Program, the same level provided for in fiscal year 1997. Like last year, the Indian set-aside in fiscal year 1998 would be approximately \$15.8 million. On most Indian reservations, this program provides the only source of employing Indian youths.

*Department of Health and Human Services*

*The Administration for Native Americans.*—NCAI supports the President's fiscal year 1998 request of \$34.9 million for Administration for Native Americans (ANA) operations, but would urge Congress to increase this funding level given the success of ANA programs and their strong support from Tribal leaders. Although the ANA budget is small compared to the total HHS budget or other agencies that deal with Indian economic and social development, the budget allocation for the ANA is important because of the types of programs it funds, rather than its total dollar amount.

The principle that underlies ANA funding policy is to assist Indian Tribes and Native American organizations implement their own strategies for growth and development. This policy is the main reason for ANA's success and the rationale for NCAI's strong support for the ANA as a catalyst for change in Indian Country. By remaining committed to these core factors the ANA has been singularly successful in Indian Country since its inception. In addition to the large number of communities served by this agency, the ANA distinguishes itself by encouraging long-term strategies for tribal independence and economic development. Unlike other federal programs that originate in and are administered from Washington, D.C., ANA stands apart because its programmatic priorities are set locally, with appropriate deference to local Tribal authorities. While there are considerable pressures on the Congress to reduce spending, current and future spending decisions must be made with an eye to ensuring that local governments and local populations are in a better position to build local capacity and become increasingly self-reliant. By recognizing that the tactics that will most likely be successful in the long-run are those which maximize local needs and stress the primacy of local responsibility, the ANA is a model program the federal government would be advised to mimic in other realms.

*Administration for Children and Families.*—The newly formed Tribal Services Division of the Office of Community Services, a division under the Department of Health and Human Services (HHS)—Administration for Children and Families (ACF), is the Administration's foresight into what is necessary at the federal level to ensure fair and just treatment of Tribal governments under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193), the welfare reform law. However, this Division currently has no direct funding source of its own and must borrow scarce resources from other agency programs in order to provide any services to Tribal governments. HHS Secretary Shalala and the Assistant Secretary for the ACF have tried to provide the necessary funding to carry-out the welfare reform implementation process in Indian Country, but it has been obvious from the beginning that unless Congress authorizes a direct funding source for the Tribal Services Division, Indian Tribes will literally be left out in the cold in regards to full and complete participation in many state welfare plans.

Funding for the Tribal Services Division is especially critical because with the enactment of the welfare reform law comes a myriad of unique issues that are of concern to Indian Tribes. Of these, the most critical is the ability of Tribes to enjoy equal treatment under the law as sovereign governments (similar to states), which will in turn nurture meaningful Tribal participation in welfare reform throughout Indian Country. Empowerment of Tribal governments only works if federal funding

levels are there to ensure such transition of powers. Unfortunately, the President's fiscal year 1998 budget does not list any new discretionary funding sources which would allow for such transitions. Taking an entitlement program such as welfare assistance and converting it into discretionary block grants to the states creates two dilemmas which must be addressed. First, this approach ignores the government-to-government relationship that exists between Tribes and the federal government. This relationship is built upon pillars of trust responsibilities owed to Indian Tribes which include health, education and welfare. Unfortunately, the welfare pillar has been block-granted to the states with no enforcement provisions that protects the federal trust responsibility from state encroachment and diminishment. Second, many Tribal communities suffer from the lack of adequate infrastructure, economic development and other community development factors which would allow for the successful conversion of federal welfare programs to the Tribal level. In order for Tribes to reach the level of community development necessary to afford the capability to administer welfare and other social service programs under the law, they must have adequate funding for technical assistance, data collection, construction, job training, child care, and Tribal enforcement plans.

Lastly, NCAI has developed a set of Indian amendments to the welfare reform law which have been forwarded to Congress. Not only do we hope that the recommendations put forth will be considered by Congress, but more importantly, that Tribes are given the assurance by Congress that necessary funding will be provided to begin the Tribal implementation process.

*Administration on Aging.*—Within the Older Americans Act (Public Law 89-73), there are four provisions that are of special importance to Native American elders. The first provision is Title VI: Grants to Native Americans. The purpose of this program is to promote the delivery of supportive services, including nutrition services to American Indians, Alaska Natives, and Native Hawaiians. In fiscal year 1997, \$16 million was appropriated to aging grants for Indian Tribes and Native Hawaiian organizations. NCAI requests that the authorized level of \$30 million be appropriated in fiscal year 1998. This title provides key "front-line" services for 229 programs serving Indian elders residing on reservations, including communal and home-delivered meals, transportation, and chore services. On almost every Indian reservation, there are no alternate providers.

The second provision is Title V: Community Service Employment for Older Americans. This program provides funds to ten national sponsors, including the National Indian Council on Aging (NICOA), to train low income elders in community service programs. The program encourages timely placement of enrollees into unsubsidized employment. In fiscal year 1997, \$463 million was appropriated to Title V from which \$5.4 million was allotted to NICOA. This is an especially important program for Indian Country because unemployment rates on reservations are extremely high. NCAI supports the President's fiscal year 1998 request of \$463 million.

The third provision is Title IV: Training, Research, and Discretionary Programs. Activities supported under Title IV have helped NICOA design and test innovative services, gather information about the problems and needs of Indian elders, and train a workforce to meet the needs of this rapidly-increasing population. The President's fiscal year 1998 request is \$4 million. NCAI supports an increase in Title IV funding. Additionally, we request a set-aside of \$130,000 for the training of Title VI Directors. Title IV provides the sole source of training funds for Title VI program directors in Indian Country.

The fourth and final provision is Title VII: Allotments for Vulnerable Elder Rights Protection Activities, Subtitle B: Native American Organization Provisions. This title is intended to assist in prioritizing elder rights issues and carrying out elder rights protection activities. State programs currently received \$4.5 million for ombudsman services and \$4.7 million for prevention of elder abuse programs; however, no funds have ever been provided for Indian programs, despite an authorization level of \$5 million. With the abuse of Indian elders on the rise due largely to deteriorating economic and social conditions found in much of Indian Country, prevention programs for Tribes throughout the country are desperately needed. We request that the full \$5 million be appropriated for Tribal programs.

*Health Resources and Services Administration.*—Under the Ryan White CARE Act Amendments of 1996 (Public Law 104-146), up to 3 percent of the amounts appropriated for Titles I, II, III, and IV, not to exceed \$25 million, is authorized to Title V, the Special Projects of National Significance (SPNS) Program. Title V funds are used to address the needs of special populations, including the development and evaluation of case management programs for Native Americans. The Centers for Disease Control and Prevention have reported that as of June 1996 there are 1,434 reported and verified diagnosed cases of AIDS among Native Americans, an increase of 191 cases for 1995. The report also showed that the growth in Native American

AIDS cases between 1992 and 1993 was larger than any other ethnic group. In fiscal year 1997, the total amount of funds available to Native American communities was \$1 million, which funded 3 grants. For fiscal year 1998, the President has requested \$25 million for the SPNS Program. NCAI is concerned that Native American communities are not being funded to the extent that the increase in the overall Title would lead us to expect. We request that a set-aside under Ryan White Title V is established that equals no less than \$3 million to provide AIDS care for Native Americans.

*Department of Education*

*Office of Indian Education (OIE).*—For fiscal year 1998, \$59.75 has been requested to fund formula grants to Local Education Agencies (LEA's) and \$2.9 million for program administration for OIE. For the last two years, no funding has been appropriated to fund OIE's discretionary grant programs and fellowship program, and the National Advisory Council on Indian Education (NACIE). NCAI supports full funding of \$83 million which would reinstate funding of these programs. These programs have proven successful in helping American Indian and Alaska Native students in continuing their education beyond high school. Also, although NCAI supports the President's request of \$200,000 to fund the Presidential Executive Order on Tribal-Controlled Community College which has been designated to come out of OIE funding we would like to see the funding level increased to \$400,000 with the entire amount covered by a non-OIE funding source.

*Other DOE Indian Education Related Programs.*—NCAI supports the funding recommendations of the National Indian Education Association (NIEA) for other Indian education-related programs in the Department of Education, including Goals 2000, School-to-Work Opportunities, Title I, Impact Aid, Education for Homeless Children and Youth, Bilingual Education, State Special Education Grants, State Special Education for Infants and Families Grants, Technology Literacy Challenge Fund, Vocational Rehabilitation State Grants, and Vocational Education.

*Proposed National School Construction Initiative.*—NCAI supports the recommendation of Interior Secretary Bruce Babbitt to the Office of Management and Budget to include a 10 percent set-aside for schools funded by the Bureau of Indian Affairs (BIA) rather than the one percent set-aside included in S. 12, the Education for the 21st Century Act. Under this bill, \$5 billion is authorized over the next four years for nationwide school construction and renovation. This funding would help pay for up to half the interest that local school districts incur on school construction bonds, or for other forms of assistance that will spur new state and local infrastructure investment. The recommended 10 percent set-aside would allow the BIA to address its backlog of \$475 million in school repair projects, including school replacements.

CONCLUSION

Mr. Chairman, we urge the Congress to fulfill its fiduciary duty to American Indians and Alaska Native people and to uphold the trust responsibility as well as preserve the Government-to-Government relationship, which includes the fulfillment of health, education and welfare needs of all Indian Tribes in the United States. This responsibility should never be compromised or diminished because of any Congressional agenda or party platform. Tribes throughout the nation relinquished their lands as well as their rights to liberty and property in exchange for this trust responsibility. The President's fiscal year 1998 budget acknowledges the fiduciary duty owed to Tribes. We ask that the Congress consider the funding levels in the President's budget as the minimum funding levels required by Congress to maintain the federal trust responsibility and by Indian Country to continue on our journey toward self-sufficiency. This concludes my statement. Thank you for allowing me to present for the record, on behalf of our member Tribes, the National Congress of American Indians' comments regarding the President's fiscal year 1998 budget.

PREPARED STATEMENT OF SARA S. ELLISON, DIRECTOR, COMMUNITY RELATIONS,  
NORTHEAST UTILITIES SYSTEM

I am Sara S. Ellison, Director, Community Relations, Northeast Utilities, an electric company serving Connecticut, western Massachusetts and New Hampshire.

Senator Specter and members of the Subcommittee, I am pleased to have the opportunity to submit testimony about the significant value of the Low Income Home Energy Assistance Program (LIHEAP), how we at Northeast Utilities partner with LIHEAP in the conduct of programs to benefit low-income and working poor households; and, LIHEAP's increased importance in the future.

Northeast Utilities serves some 1.6 million customers in 407 communities in Connecticut, western Massachusetts and New Hampshire. We estimate that about 15 percent of our residential customers are income eligible for LIHEAP energy assistance. Like everyone, these low-income customers need access to electricity; but they often have difficulty paying for needed energy services. We target a series of programs—partnered with LIHEAP—to help these families maintain access to electricity, use energy safely and wisely, conserve energy, budget and use available resources to help pay their bills.

In brief, I'll document how the Low Income Home Energy Assistance Program supports healthy functioning and self sufficiency for families with children, the elderly, disabled and working poor: promotes the health of recipients directly by aiding the purchase of winter heating fuels and indirectly by enabling households with very low incomes to avoid the "heat or eat" problem; helps prevent illness, undernutrition, homelessness and even death; helps people cover basic home energy costs, make affordable payment arrangements and/or qualify for arrearage credit programs; helps companies work proactively and preventively with these customers; and helps people who need this assistance at the time of their need.

Recent reductions in LIHEAP funding have hurt. It's estimated that more than a million fewer LIHEAP eligible households received assistance in fiscal year 1996 due to funding reductions from fiscal year 1995.

Note that in the New England states we serve, a third to three quarters of LIHEAP participants use LIHEAP to purchase deliverable fuels. At all times, a payment or payment guarantee is needed.

Cite some important strengths of the current LIHEAP: Governor's design their LIHEAP programs for their states' needs. While it's primarily a heating assistance program, states can and do use it for cooling assistance and some weatherization, and heating assistance can be defined to cover home energy more broadly. A clearly targeted block grant, it's carefully administered. The provision of LIHEAP advance funding helps states plan more effectively. In turn it helps agencies and consumers plan better.

I'll describe our series of programs which partner with LIHEAP and leverage the benefits for these households. We know that they make life better for families and communities. And, that many other electric and gas companies have similar beneficial partnerships. Lastly, I'd like to tell you why we think that LIHEAP will be even more important in the future: LIHEAP's importance as a support to the working poor and families children who are going to work through welfare reform; the aging of our population—with more elderly living in the community; the heavy use of deliverable fuels in the Northeast; and deregulation in the gas and electric industries. Most importantly, the value of continuing a program which has effectively helped millions of families each year stay healthy, maintain access to essential home energy. In fiscal year 1995, it helped some 5.2 million stay warm in their own homes, in winter, and 400,000 stay cool in summer's heat. It has value in helping families maintain service year-round. I'll ask you to join us in supporting continuation of this effective, valuable program with full funding for fiscal year 1998, provision for emergency funding and advance funding for fiscal year 1999.

In Connecticut, Massachusetts and New Hampshire, LIHEAP is primarily a heating assistance program. In fiscal year 1996, a quarter to almost a third (30 percent) of the income eligible population received LIHEAP funded energy assistance. Some 10 to 17 percent of the recipients used it to help pay electric bills. A majority of them were elderly customers.

LIHEAP importantly helps with the full range of fuels. For example, it's used to purchase deliverable fuels—primarily oil and propane—by almost a third of Connecticut and Massachusetts recipients (Connecticut 32 percent; Massachusetts 31 percent) and three-quarters (73 percent) of New Hampshire recipients. Deliverable fuels are not covered by a winter moratorium. Immediate payment or a payment guarantee is usually required.

About half the LIHEAP recipients in Connecticut and Massachusetts, 17 percent in New Hampshire, use it for natural gas (Connecticut 44 percent; Massachusetts 52 percent). In Connecticut, the gas companies match, dollar for dollar, the LIHEAP funds that they receive as part of their arrearage credit program. This is a great benefit to these customers.

I have administered Northeast Utilities' programs for low-income and special needs customers in Connecticut and Massachusetts for more than 15 years. Northeast Utilities takes very seriously our public service obligation to all our customers. As a matter of corporate policy we work to improve the social and economic conditions in the communities we serve. I have seen that the availability of LIHEAP funds: promotes the health of recipients directly by aiding the purchase of winter heating fuels and indirectly by enabling households with very low incomes to avoid

the “heat or eat” problem; helps prevent illness, undernutrition, homelessness and even death; helps people cover basic home energy costs, make affordable payment arrangements and/or qualify for arrearage credit programs; helps the Company identify and work proactively and preventively with these customers; and assists people at the time of their need.

LIHEAP is a clearly targeted block grant which helps people with a basic necessity. It is carefully and accurately administered in our states.

The provision of advance funding importantly helps the states do necessary program planning; it helps agencies and consumers plan better.

To document the vital preventive impact of LIHEAP, regarding the healthy development of children under the age of three; and, the problem of undernutrition and what is termed the “heat or eat” phenomenon, I have attached to my testimony, and cite below, reports of two epidemiological studies of children under the age of three who were seen at Boston City Hospital’s Pediatric Emergency Department:

“Seasonal Variation in Weight-for-Age in a Pediatric Emergency Room,” Dr. Deborah A. Frank, lead investigator, Public Health Reports: Volume III, July/August 1996 found that: “\* \* \* the percentage of children visiting the emergency room with weight-for-age below the fifth percentile was significantly higher for the three months following the coldest months than for the remaining months of the year; \* \* \* gastrointestinal illness was correlated with both season of measurement and weight-for-age, but the seasonal effect remained for the entire sample after controlling for dehydration. \* \* \* The questionnaire data suggested a relationship between economic stress and food insecurity that might help explain the seasonal effect. Families who were without heat or who were threatened with utility turnover in the previous winter were twice as likely as other families to report that their children were hungry or at risk for hunger.”

“Housing Subsidies and Pediatric Undernutrition,” Alan Meyers, MD, PHD the lead investigator, Archives of Pediatrics and Adolescent Medicine: Volume 149, October 1995. Copyright 1995, American Medical Association. found that: “\* \* \* The risk of a child’s having low growth parameters was 21.6 percent for children whose families were on the waiting list for housing assistance compared to 3.3 percent for those whose families received subsidies \* \* \* Receiving a housing subsidy is associated with improved growth in low-income children, an effect which is consistent with housing subsidies’ having a protective effect against childhood undernutrition.”

LIHEAP is not a housing subsidy, but LIHEAP helps pay for an essential component of shelter. Protecting the healthy development of young children reduces later remedial costs such as special education. As you know, most rental property requires tenants to pay for their home energy costs. Also various studies have shown that children who (because of housing moves) move from school to school have difficulty succeeding in school.

In regard to LIHEAP’s value to the elderly and working poor, a statement from the Connecticut Association for Community Action which represents the fourteen community action agencies in Connecticut who administer the LIHEAP funded energy assistance program says, with regard to the working poor and households with elderly and disabled members, who accounted for almost 60 percent of recipients during their 1995/1996 program year:

“We have seen, for the working poor, that this critical help allows them to manage winter heat in addition to necessities like winter clothing for children, day care or medical expenses as well as cover emergency car repairs \* \* \*”

“The struggle to survive is evident in our elderly population, those who should never be without heat. Our clients state that they can not survive on Social Security alone—They have to make the unacceptable choices between food and fuel—A choice no one should have to make!”

Let me briefly describe some of the effective partnership programs that we operate in conjunction with LIHEAP funded energy assistance:

Winter service protection. Both Connecticut and Massachusetts have laws requiring a moratorium on shutoffs of electric and gas service for “hardship” customers during the winter months (November 1–April 15 in Connecticut; November 15–March 15 in Massachusetts). The income guideline for “hardship” is the same as for LIHEAP funded assistance. When a household is accepted for energy/fuel assistance—for any fuel—the Company is notified and we code the customer household for “winter service protection.” It’s our most effective means of identifying such households.

“Hardship” coded customers get our Help-Line newsletter with information on conservation, company programs including payment arrangements, assistance resources, employment, health and safety. A D.E.C. Research survey (Summer 1995) documents that these customers act on our information.

We use our "hardship customer" lists to recruit participants for our WRAP weatherization program in Connecticut. It's a fuel blind weatherization program which provided weatherization services to some 4,100 housing units during 1996.

—In WRAP we partner our conservation dollars with those of the gas companies in our service territory and with federal Weatherization Assistance Program dollars to jointly provide a cost effective program.

—The community action agency staff provide or arrange the services and provide conservation education to participants as well.

—Many participants are LIHEAP clients—The Weatherization Assistance Program funds are targeted to serving LIHEAP's "vulnerable" households (households with a child under the age of six or a member who is elderly or disabled).

We use utility conservation dollars to help weatherize those homes; but we also use utility funds to weatherize units occupied by the "non-vulnerable."

Low-income customers who are seriously delinquent (owe more than \$100 which is 60 days delinquent) and who have used energy assistance to help pay their electric bill are eligible to participate in our NU START payment incentive program. NU START gives them a credit on their arrears, each month, when they pay their monthly bill. Over a three year period, most customers can eliminate their back bill for electricity.

We ask NU START applicants to participate in our "Choices" workshops on conservation and budget management before joining the program. The budget counseling program is seen as being so effective that the State of Connecticut has made participation in "Choices: Your Money" mandatory for all applicants for the State's Unemployment Compensation program.

The "Choices" workshops are offered to other "hardship" customers as well, as part of our proactive, preventive approach.

Other partnership efforts include annual fall meetings with representatives of more than 500 agencies to advise them about energy assistance and discuss our separate and joint efforts to work with or help low-income and special needs customers; publications in Spanish, and mailings of the Earned Income Tax Credit form to all hardship coded customers with a letter encouraging participation by eligible households.

Despite the fact that, in Connecticut, we must offer unlimited electric service to all low income "hardship" eligible customers for 5½ months a year regardless of any payment (from November 1 to April 15) and must reconnect any disconnected customer each November, most of the electric bills of identified "hardship" customers are paid, these households try hard to cover their bills, but the situation is deteriorating.

—In fiscal year 1996, in Connecticut 36,900 hardship coded customers paid 89 percent of their bills (billings were \$31.8 million; some 8,100 received \$2.4 million in energy assistance). In addition, there were \$4.1 million in write-offs for 6,800 customers, and we carry millions in delinquent bills year-round.

—The equivalent figures for Massachusetts are 20,400 customers paid 90 percent of their bills (billings were \$11.7 million (A \$3.6 million, 30 percent rate discount is provided; \$600,000 in LIHEAP funds was received.) There was \$1.3 million in write-offs for 3,000 customers and millions in delinquencies are carried year-round.

We are very concerned about recent reductions in LIHEAP and the impossibility of the households' or the private sector's picking up the slack. The drop in LIHEAP funds for fiscal year 1996 versus fiscal year 1995 is reflected, not only in the drop in percentage of bill payment from 94 percent to 89 percent for Connecticut and 93 percent to 90 percent for Massachusetts, but most seriously in the health affects cited by health and social services agencies as families try to fill the gap. In other states the programs have been closed early due to lack of funds, denying people any needed assistance. I am told that other companies are seeing more serious problems with their customers.

Let me turn briefly to the future and explain why we think that LIHEAP will be even more important.

The heavy use of deliverable fuels in the Northeast, combined with our cold weather and the aging of our population makes access to assistance with winter heat a necessity that's going to be needed by more people.

Nationwide, deregulation of the gas industry means that they operate in a more competitive marketplace. Residential rates have not gone down. The new gas turbine electro-technologies will mean, in the near future, an expansion in market pressures for gas—it is unlikely that increased demand for gas will lead to a reduction in price. Thus, the millions of low income households who depend on gas for heat can be expected to face higher prices. Partnerships, as I have described for Connecticut, related to LIHEAP will become more important.

We are in the midst of electricity restructuring. We know that the same market pressures will exist. LIHEAP funds will be needed to help some of these households pay for electricity or the cost for "default service" will rise and hurt all "default service" users. What are we seeing locally?

- In Connecticut, the draft restructuring bill provides for low income conservation and "hardship" protection (the winter moratorium on service shutoffs applies to electric suppliers as well as the distribution company). There is supposed to be a 10 percent rate cut from July 1999 until 2002. But once the competitive market supplies the electricity, the price will respond to the cost to serve.
- In Massachusetts, continuation of current "hardship" protections, the 30 percent rate discount and low income conservation programs are included in the restructuring proposals.
- In New Hampshire there is a commitment to maintaining affordable access to electricity. A new percent-of-income program is proposed. It will certainly help these households. However, given that 73 percent of New Hampshire's LIHEAP recipients use LIHEAP for deliverable fuels during the winter, it's not the answer.

Nationwide, welfare reform means that more families with young children will be working. As Joanne Balaschak from the Connecticut Association for Community Action puts it: "With the impending changes to the welfare system, the Energy Assistance Program becomes even more significant. Along with welfare reform, the Energy Assistance Program will provide this new working group a much needed boost to self sufficiency."

The aging of our population means that there will be more households with limited incomes living in the community. Currently about one third of LIHEAP participant households have an elderly member. Maintaining their health and helping them remain outside of institutions is cost saving and humane.

The NCLC study of the "Energy Affordability Crisis of Older Americans" p. 5 says "Approximately 50 percent of all cases recorded by the Federal Centers for Disease Control and Prevention as hypothermia-related deaths were of persons over 64 years of age."

The LIHEAP program annually helps millions (more than 5.2 million households in fiscal year 1995) stay warm in the winter, in their own homes. It helps thousands of families (almost 400,000 in fiscal year 1995) stay cool in the heat of summer and prevents life threatening heat stress. It promotes health. The funds often help families make arrangements with utility companies so that they avoid shutoffs. LIHEAP may only account for a small share of total energy spending, but it is critically needed assistance. It is often the linchpin that makes the difference. Electric and gas companies and community agencies operate many constructive partnership programs built in conjunction with LIHEAP. Millions of families benefit as do the communities in which they live. Please join us in supporting an effective, vitally needed, fully funded LIHEAP program. Please support funding for fiscal year 1998 of at least the 1995 fiscal year level, \$1.319 billion, provide for emergency funding and for advance funding for fiscal year 1999 at at least that level.

Thank you again for the opportunity to testify.

#### PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) is the service organization representing the interests of the more than 2,000 municipal and other state and locally owned utilities throughout the United States. Collectively, public power utilities deliver electric energy to one of every seven U.S. electric consumers (about 35 million people) serving some of the nation's largest cities. The majority of APPA's member systems are located in small and medium-sized communities in every state except Hawaii. APPA member systems appreciate the opportunity to submit this statement in support of fiscal year 1998 appropriations for the Low Income Home Energy Assistance Program (LIHEAP).

We fully support the Administration's fiscal year 1998 budget request of \$1 billion for LIHEAP. APPA also supports the request for \$300 million in emergency funds in fiscal year 1998 and \$1 billion in advanced funding for fiscal year 1999. Because the majority of LIHEAP monies is needed during a short period of time in the winter months, advanced funding for LIHEAP is critical in enabling states to effectively plan for and administer the program.

Funding cuts since LIHEAP's last reauthorization have forced a tightening of eligibility standards and, in some cases, significant reductions in benefit levels. According to the National Energy Assistance Directors' Association (NEADA), the primary educational and policy organization for state LIHEAP directors, the number

of recipients has been cut by over one million households during the recent past and average benefits have declined by about 10 percent. Prior to the dramatic reduction in LIHEAP funding in fiscal year 1995, the program was serving 20 percent of the eligible population, with one-half of the recipients elderly or disabled Americans living on fixed incomes. Without the assistance provided by LIHEAP, many would be forced to choose between paying their home energy bill or purchasing other necessities of life, such as food.

As the debate over restructuring of the electric utility industry and the issue of providing and funding "public benefits" programs continues, some in Congress have stated their belief that electric utilities should assume the entire burden of energy assistance for low income customers as a cost of doing business. As these restructuring efforts take place at both the federal and state levels, the risks become greater that bills for residential customers, especially those with low incomes, will increase if retail markets are opened to competition. An ever larger number of households may be unable to obtain any electricity at all. The need for full funding of LIHEAP remains critical in ensuring that all those in need of energy assistance receive help. APPA believes that any public benefits programs should not replace or supersede existing programs, such as LIHEAP, that are funded by federal appropriations.

As evidence of commitment to low income assistance, public power systems across the country support a variety of programs providing help to low and fixed income customers. A recent survey conducted by the National Fuel Funds Network (NFFN) shows that publicly-owned utilities raised 14 to 26 cents more per customer than other utilities in their efforts to assist low income and needy customers in paying their bills. Many public power systems provide special rates for low income households and some have residential conservation and demand side management programs designed to reduce energy consumption.

In addition, the impact of welfare reform on energy assistance is just beginning to be felt and LIHEAP is likely to play an important role in the transition. Persons who will be leaving the public assistance rolls likely will be entering lower paying jobs and still will be confronted with large energy bills. These families remain at risk.

LIHEAP is one of the outstanding examples of a successful state-operated program. The requirements imposed by the federal government are minimal and most important decisions are left to grantees.

APPA urges this Subcommittee's favorable consideration of the Administration's fiscal year 1998 budget request for LIHEAP. Again, thank you for this opportunity to present our views.

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PREPARED STATEMENT OF KATHLEEN WALGREN, CHAIRPERSON, NATIONAL FUEL FUNDS NETWORK

I want to thank Chairman Specter and the members of the subcommittee for the opportunity to submit this testimony. The National Fuel Funds Network (NFFN), which I represent as Chairperson, supports adequate funding for the Low Income Home Energy Assistance Program (LIHEAP) at no less than \$1.3 billion for fiscal year 1998.

The NFFN is a membership organization comprised of over 200 dues paying representatives of private fuel and energy assistance funds, community action agencies, social service organizations, utility companies, trade associations and private citizens. Our member organizations are located in 44 states and the District of Columbia. The NFFN is concerned with the ongoing energy crisis being experienced by the poor of America.

Since our first steering committee meeting in 1984, the NFFN and its member organizations have put into action a commitment to help the poor of America meet their basic energy needs.

Our member fuel funds are organizations that raise private contributions in their local communities to help low-income households pay their home energy bills. Fuel funds range from small church groups which distribute hundreds of dollars in a single neighborhood to large independent organizations which distribute millions of dollars across a state. Fuel funds may be a division of a large, social service agency or they may be operated by a local utility or energy company.

Whatever their form, they all raise and distribute private sector monies and they all, inevitably, discover that the resources they manage and the resources provided by LIHEAP, are inadequate. As a consequence, fuel funds become involved in attempting to increase the resources available to help the poor meet their energy needs.



NFFN has identified nearly 300 fuel and energy assistance funds which have developed since the late 1970's to raise private energy assistance dollars at the local level to provide a safety net for households who have exhausted all avenues of public energy assistance. The families served by fuel funds rank among the "poorest of the poor" in America; the majority have annual household incomes of less than \$10,000. Nationally, fuel funds make heating and cooling bill assistance payments of over \$72 million dollars each year on behalf of over 500,000 families. These payments, while vitally needed, are quite small in comparison to the \$1 billion in fiscal year 1997 LIHEAP funding.

As a result of the decline in LIHEAP funding over the years, other sources of payment assistance, such as private fuel and energy assistance funds, have taken on increased importance. When state programs are forced to close prior to winter's end because of inadequate federal funding, many needy families must look to other sources of energy assistance. Fuel funds are unable to fill the gap between the need for assistance and available federal funds. Many fuel funds themselves are under greater pressure and struggling to maintain current funding and levels of service.

In my home state of Michigan, most LIHEAP funds are allocated to Home Heating Credits, which are applied to the heating bills of low-income households. In 1995, the average grant was \$188. Last year it was \$114—a forty percent decrease because of the reduction in LIHEAP funds. Private fuel funds, such as The Heat and Warmth (THAW) Fund which I administer, were sought out for assistance earlier than in previous years and were the only resources available. THAW is an independent non-profit organization that raises and distributes \$1.5 million annually for energy assistance in Southeastern Michigan. THAW's funds were exhausted in the City of Detroit a month earlier than in the past. Our community agencies reported that they turned away 390 applicants a day in March. Many other privately funded energy assistance programs found their funds exhausted before the winter moratorium on utility shut-offs expired leaving many vulnerable families unable to find heating assistance throughout a very cold spring.

As the director of a fuel fund, I am often asked to describe the typical recipient. The only common denominator I can define is that they are poor. In my program, THAW, three quarters are well below the federal poverty guidelines. They often pay as much as 25-30 percent of their already inadequate income to heat and light their homes. Ladies and gentlemen, think of your own income and "remove" one quarter of it. That certainly narrows your choices for discretionary spending. For low income families, too often less discretionary money means less food or less medicine. Their dilemma is which necessities to do without.

This fall I received a call from an eighty year old woman who lived in a small town. She asked if there was a possibility THAW could help her. She said she keeps her heat so low during the day that she wears a coat in the house. She turns the heat off at night. She described turning only one light on and said she goes to bed when it gets dark. I asked the local community agency to check on her. They found she had been hospitalized with pneumonia. The elderly are especially vulnerable to hypothermia and require adequate nutrition to maintain their health during the cold months. Is this woman "typical?" For our elderly recipients, I'm afraid she is.

Often applicants are unemployed. The loss of a job, especially a low wage job, throws a family already struggling to make ends meet into immediate crisis. There is no savings with which to pay utility bills.

Often our applicants are single parents, many of whom are working at low wage jobs. Helping them means that the children will stay in warm homes.

Other recipients are disabled and struggling to pay monthly expenses. A winter such as we have just experienced, where gas and fuel prices increased 30 percent, finds them unable to keep up with utility bills and seeking fuel fund help.

It is important to remember that when we talk about "the poor" we are making huge generalizations. Families and individuals move in and out of that category due to the circumstances of their lives. A death in the family, divorce, a plant closing, loss of a job, extended illness or any number of situations can create a crisis. These are the people that fuel funds, emergency assistance programs, seek to help.

Reductions in LIHEAP are bringing more and more families to the doors of fuel funds around the country. As skilled as we are in raising charitable contributions from private donors, we are inadequate to compensate for the loss of federal support. Most fuel funds do not distribute LIHEAP. Most are last resort programs which require that applicants have sought all other resources including LIHEAP, before receiving help. When that assistance is inadequate or insufficient, they turn to private resources. Detroit's United Way information and referral service reports that seventy-five percent of calls during the winter are from people seeking energy assistance, some 1,800 per month. Local churches report the similar percentages.

The impact of welfare reform on energy assistance is just beginning to be felt. People who are leaving public assistance will enter low paying jobs and will still be confronted with large energy bills. These families are at risk. Furthermore, roughly half of the LIHEAP funded Home Heating Credits in Michigan go to the elderly and disabled populations that are not expected to move into the workforce. LIHEAP will play an increasing role in the welfare reform transition.

Some may suggest that private fuel funds and other charitable contributions will make up the deficit resulting from further cuts in LIHEAP funding. Others will point to fuel funds as an example of the kinds of help that could potentially take the place of LIHEAP. Fuel funds raise only about 5 percent of what is available through LIHEAP. When LIHEAP suffers a 25 percent cut, as it did last year, fuel funds cannot close the gap. As thankful as we are for the continued generous response from private donors across the country, we are painfully aware that our efforts still fall far short of the need. Privately raised energy assistance dollars can only supplement LIHEAP dollars to a small degree, and can never take the place of federal energy assistance funds.

Without LIHEAP funding during periods of prolonged and extreme winter weather, approximately 2.8 million families with children would be left virtually "out in the cold." In 1994, of the 5.6 million households who received assistance from LIHEAP, fifty percent included a child under the age of eighteen. One in five have a disabled person. About 33 percent of households have elderly residents. For those states with extremely hot weather, the number of elderly households is more than 40 percent. Further cuts to an already underfunded program would have a devastating effect on our most vulnerable citizens.

The receipt of assistance to pay utility bills can mean the difference between a child remaining safe and warm in their home, or suffering deadly consequences. When some of the families who had experienced a periodic loss of their heating utility were asked what they did for heat when they had a heat interruption, 54 percent of the households said they were not able to heat their homes. Thirty-nine percent reported that they heated one or two rooms with another heat source such as a fireplace or cooking stove to keep warm—clearly a fire hazard.

There have been a number of tragic events from using dangerous alternatives. House fires disproportionately take the lives of children and the elderly. Recognizing the relationship between loss of utility service and the risk of injury and death from fires, the NFFN has formed a relationship with fire marshal's in Philadelphia, Washington, D.C., Detroit and other communities, to educate families about the risk of fire and to put in place prevention measures.

More often than not, the receipt of assistance to pay utility bills can also make a difference in the quality of life for low-income children. In recent years, increasing national attention has been focused on education, yet low-income children are still less likely to receive a good education. A study entitled "A Road Often Taken: Unaffordable Home Energy Bills, Forced Mobility and Childhood Education in Missouri" explored the interconnection between two seemingly unrelated problems in rural Missouri households: unaffordable home energy bills and poor educational attainment. Findings conclude that a substantial portion of the low-income population is "frequently mobile" over a five year period; that one primary cause of this frequent mobility is the unaffordability of home energy bills, including home heating and electricity; and that the frequent mobility creates problems for both the students in these mobile households and for the teachers and schools who seek to educate those transient students.

Another study done in Philadelphia reports that a utility shut-off notice is the clearest indicator of potential homelessness. When families are unable to maintain essential services they may be forced to move. The result is abandoned properties, and the economic decline of neighborhoods. Intervention, in the form of energy assistance, helps stabilize those families.

While we who daily serve the energy needs of low-income families understand the difficult task of setting national priorities that is before Congress, we respectfully, but urgently request you, as you consider funding for fiscal year 1998, to keep in mind the important role that LIHEAP plays as a safety net for millions of our nation's most vulnerable citizens. It is a broad based, effective and efficient program. The need is very real. Your deliberations today can potentially assist those who daily struggle to protect themselves and their families from extremes of weather.

Thank you for your careful consideration of this testimony.

## PREPARED STATEMENT OF THE PENNSYLVANIA ELECTRIC ASSOCIATION

The Low Income Energy Assistance Program (LIHEAP) is an important safety-net for Pennsylvania's poor and elderly residents. The LIHEAP helps pay the energy bills of hundreds of thousands of low income families throughout the Commonwealth. Pennsylvania's investor owned electric utilities urge the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education to maintain a funding level of at least \$1.0 billion for fiscal year 1998.

Federal funding for the LIHEAP has decreased dramatically over the years: from \$2.1 billion in fiscal year 1986 to \$1.0 billion in fiscal year 1997. Similarly, the LIHEAP allocation for Pennsylvania over this time period has fallen from \$141 million to \$67—a drop of 52.5 percent. The LIHEAP benefits for electric utility customers in Pennsylvania fell from \$19.6 million in fiscal year 1995 to \$9.5 million in fiscal year 1997.

The U. S. Department of Health and Human Services (HHS) may allocate supplementary LIHEAP funds to states that have acquired non-federal leveraged resources for low-income households. The leveraged resources request submitted by Pennsylvania to HHS was one of the highest in the nation, and the Commonwealth has received significant leveraging awards from the Department. Last year Pennsylvania's regulated electric and gas utilities accounted for \$52.7 million in leveraging funds. This total also includes \$5 million that the state's electric and gas utilities helped to raise for private fuel funds.

Some federal and state policy-makers mistakenly believe that the energy crisis is over for poor Americans; however, experience in the Commonwealth shows otherwise. In Pennsylvania, the percentage of income needed to cover typical annual energy bills exceeds 20 percent for the average low-income families and 5 percent for higher income families. The average LIHEAP cash grant in 1986-87 covered 27 percent of the average annual electric heating bill. In 1995-96 the average LIHEAP cash grant covered only 15 percent of the average annual electric heating bill, even though prices for electricity have remained fairly constant.

The Pennsylvania Department of Public Welfare (DPW) estimates that only one-third of LIHEAP eligible households receive energy assistance because of limited funding. In 1991-92, for example, the LIHEAP served 520,600 low income households in Pennsylvania; that number is expected to drop to 280,000 in 1996-97. Less funding for the LIHEAP has forced DPW to tighten income guidelines, to restrict eligibility, and to shorten the program year. As a result, thousands of working poor families have been excluded from receiving LIHEAP benefits.

The LIHEAP is a critical program that helps sustain a basic need for low income families. Its recipients are the elderly, the working poor, and the disabled. One-third of LIHEAP recipients are over 60 years of age and 13 percent are disabled. Nearly 7 out of 10 recipients have annual household incomes under \$8,000. Many low income Pennsylvanians face difficult situations, and further reductions in the LIHEAP could turn hardship into tragedy.

The LIHEAP is an effective block grant program. In Pennsylvania, for instance, LIHEAP grants are not distributed merely on the basis of income; rather, they are targeted according to household income, family size, energy costs, and weather regions. The program has the type of built-in flexibility that many states are looking for in federal-state partnerships.

We urge your continued support of this most important program.

## PREPARED STATEMENT OF UNITED DISTRIBUTION COMPANIES (UDC)

Mr. Chairman and members of the Subcommittee: United Distribution Companies (UDC) is a group of natural gas companies serving customers chiefly in the Midwest and Northeast. UDC member companies are deeply committed to meeting the energy needs of all our customers, in particular, those of low and fixed-income. Our companies are a vital part of the communities we serve.

Mr. Chairman, once again, this past winter certain regions of the country experienced record cold weather coupled with record levels of snowfall. In particular, some Midwestern areas suffered through brutal weather well below zero for extended periods of time that forced certain states to virtually shut-down. To compound the severity of the problem, as the weather began to turn bitter, prices for fuel oil, propane gas, and in some states natural gas rose dramatically in the autumn and early winter over previous levels. On March 4, 1997, The Wall Street Journal reported that oil prices reached an 11-year high during the second half of 1996 (excluding the 1990 price fly-up during the Gulf War) and propane prices doubled and tripled in some areas of the country.

These conditions challenged and stressed the “average” American household, but to millions of low-income elderly, disabled and working poor families this confluence of factors became overwhelming. The choices many were forced to make were untenable; however, we should add that the situation that many low-income families face in trying to meet their home energy needs is difficult even under “normal” circumstances.

While most of us can take the comfort of a warm home in the winter or a cool home in the summer for granted, try to imagine what it would be like if you did not have the means to secure these basic necessities. For millions of seniors, disabled, working-poor families, and others across this country, LIHEAP is more than economic assistance, it is a lifeline for health and safety. This winter, northern-tier states faced multiple days of sub-zero weather. No one can go without heat in those conditions.

Mr. Chairman, in the coming weeks you and your colleagues will work to craft necessary budget and spending measures for fiscal year 1998 that will set the fiscal spending priorities for the next year, as well as to chart the course for the government to meet “balance” in five years. As you chart the course to continue to protect our nation’s fundamental health, education and social services priorities, we ask you to provide critical funding for home energy assistance for low-income Americans.

#### LIHEAP FUNDING RECOMMENDATION

Mr. Chairman, on behalf of all of our residential customers—especially the low-income customers who live in our communities—we urge you to restore critical funding for LIHEAP. We ask for your continued support for the Low Income Home Energy Assistance Program, and urge that this Subcommittee and the Congress adopt the following in the fiscal year 1998 Labor, HHS and Education Appropriations Bill: Provide an appropriation of at least \$1.319 billion for the fiscal year 1998 LIHEAP; provide an “advance appropriation” of at least \$1.319 billion for the fiscal year 1999 LIHEAP; and ensure that any leveraging monies will not “supplant” regular LIHEAP appropriations for meeting low-income households’ basic energy needs.

In addition, UDC also endorses the continuation of the “Emergency Contingency Fund,” consistent with LIHEAP’s authorization statute, which authorized \$600 million. In our view, the emergency funds should not be used in lieu of regularly appropriated funds for LIHEAP.

UDC is urging a restoration of LIHEAP funding to at least the \$1.319 billion level of funding after a careful review of the facts. In recent years, LIHEAP funding has been slashed; between fiscal year 1995 and fiscal year 1996 alone cuts totalled 30 percent. Last year, the National Energy Assistance Directors’ Association (NEADA) reported that 1.4 million needy households—many of them elderly or disabled—lost necessary aid. Fourteen states, including Louisiana, Pennsylvania and Florida reported in excess of a 30 percent drop in elderly served due to insufficient funds.

Other families losing benefits included many working poor households that face a day-to-day struggle attempting to remain self-sufficient and stay off welfare. We believe that the \$1.319 billion in regular appropriations—the fiscal year 1995 LIHEAP funding level—is the bare minimum amount necessary to enable restoration of critical assistance to these vulnerable households.

Mr. Chairman, we applaud you for recognizing the pivotal role that advance appropriations plays in the implementation of LIHEAP by the states, and we urge you and your colleagues to continue to give the states the necessary tools to plan the next year’s program prior to the next heating season. Last year’s piecemeal funding had a disruptive effect on the states’ abilities to plan and implement their LIHEAP Programs. An advance appropriation of \$1.319 billion for fiscal year 1999 is central to the effective administration of the program.

UDC shares the views of the representatives of the states and local agencies that testified earlier this month on LIHEAP before the House Committee on Education and the Workforce’s Subcommittee on Early Childhood, Youth and Families. They stated that the Leveraging Incentive Program should not be expanded at the expense of the core LIHEAP program. Unfortunately, LIHEAP has not been funded at the levels the Congress intended when the Leveraging Program was designed. The legislative history makes clear that the Congress intended that these leveraging grants be supplemental to the full authorized amount of LIHEAP.

Congress ought not to penalize low-income seniors and families living in states without mandated programs for low-income households, or casino revenues for lifeline programs dedicated to vulnerable citizens. There is no “level playing field” in the states when it comes to leveraging. Also, recent changes in the federal rules on leveraging marginalize the benefit of states’ leveraging efforts. The paperwork burden on leveraging is disproportionate to the size of the program. It is interesting

to note that there appears to be more of pages in the Federal Register on the leveraging program than on the entire LIHEAP block grant program. We question the value of continuing the effort at LIHEAP's current funding. Such constraints also make the Residential Energy Assistance Challenge (R.E.A.Ch.) Program unrealistic.

#### BROAD SUPPORT FOR LIHEAP

During the 104th Congress, you, Senator Harkin and many of your colleagues worked hard to restore critical funding for LIHEAP. More recently, Mr. Chairman, in addition to your letter, we know that you are aware of the numerous congressional letters urging the rejection of any cuts to LIHEAP in the fiscal year 1998 Budget, and asking for the full release of emergency contingency funds for fiscal year 1997. These efforts have enjoyed broad bi-partisan support.

In addition, the National Governors' Association (NGA) supports maintaining adequate federal funding for LIHEAP. The NGA has endorsed LIHEAP as a targeted block grant that provides the states with the necessary flexibility to best assist the elderly, disabled, and working-poor households in meeting their home energy needs. The Governors have also urged the Congress to continue to provide advance appropriations for LIHEAP to avoid unnecessary disruption in the program.

Another long-standing supporter of LIHEAP, the National Association of Regulatory Utility Commissioners (NARUC)—representing the state regulatory bodies responsible for regulating the rates and services of electric and gas utilities throughout the United States—has also adopted a resolution rejecting any further cuts or rescissions to LIHEAP. NARUC has urged the Congress to provide at least \$1.3 billion for fiscal year 1998 and to continue to provide advance appropriations. LIHEAP is the foundation for many low-income programs authorized/mandated by the state public utility commissions.

#### THE NEED: LIHEAP HELPS SENIORS AND THE DISABLED

Let us examine the households that actually receive LIHEAP. Of the 6.0 million households which received LIHEAP assistance in fiscal year 1994, approximately 70 percent of these families had annual incomes of less than \$8,000. In fact, 78 percent of LIHEAP-recipient households in Illinois earned less than \$8,000. Yet despite this low income, the majority of recipient households are not receiving public assistance. In Illinois, 70 percent of LIHEAP-recipient households are not on welfare.

On average, one-third of LIHEAP households are elderly. States, such as Michigan, Maine, Nevada, Georgia, Tennessee, South Carolina, and Arkansas find more than 40 percent of their LIHEAP recipient households include an elderly person. According to the latest available data, nearly 60 percent of the assisted households in Mississippi included an elderly person. Due to federal cuts this year, many of these households may have lost assistance. For example, in Illinois, 17 percent of seniors that received LIHEAP in fiscal year 1995 lost all benefits in fiscal year 1996 due to cuts. Finally, nationwide, over 20 percent of the households served include a disabled member. LIHEAP-recipient households in 11 states, such as, Georgia, South Carolina, North Carolina, Tennessee, Arkansas, Kentucky, and California have in excess of 30 percent with a disabled member; while in Illinois, 39 percent of the households include a disabled person.

#### ASSISTANCE CRITICAL TO POOR MAKING TRANSITION OUT OF WELFARE/WORKING POOR

One of the primary goals of the 104th Congress was to secure a comprehensive reform of our nation's welfare system. A key underlying principle of the legislation is to assist low-income families and individuals become/remain self-sufficient. LIHEAP is such a program; LIHEAP is the antithesis of welfare. LIHEAP is designed to address the needs of low-income families in meeting their annual energy expenses. LIHEAP promotes self-sufficiency; it protects these families on the edge of poverty from falling deeper into debt, and allows them to have more control over their lives and their resources. LIHEAP will become all the more important as more welfare recipients make the transition to employment.

Working-poor households account for approximately one-third of the LIHEAP-recipient population. Changing dynamics in the work place, including inadequate and stagnating wages, part-time employment, and fewer benefits are swelling the ranks of the working poor. Some of these households have learned that a job does not necessarily get you out of poverty. To illustrate, on December 19, 1996, Catholic Charities USA released the results of its 1995 survey—the most comprehensive report available of private social services and activities. It reported that increasingly, working people have been coming to them in crisis. This organization provided emergency food and shelter to almost 7.2 million people in 1995. Over half of those as-

sisted were not on welfare. The families and individuals in this survey needed help with grocery or utility bills to make it to the next paycheck. For many, the choices continue to be between heat and food, rent, medicine for a child, or bus fare to work.

Low-income families struggle to stay together. With resources stretched thin, a meaningful LIHEAP benefit helps families face daily challenges to pay for basic necessities. If you take away or reduce their energy assistance, that is one more push toward dependence. These families are worth the investment of a LIHEAP benefit to keep them independent. LIHEAP fosters independence rather than dependence. It helps low-income people stay off welfare.

#### HEALTH AND SAFETY CONCERNS

In attempting to argue that LIHEAP is no longer needed, program critics have misrepresented “shut-off” moratoria as a “safety-net” in protecting low-income families. In those states in which moratoria exist, the moratoria may provide some protection for low-income consumers, but no long-term protection. Moreover, moratoria do not exist in all states (including cold weather states). In fact, the NARUC survey on “uncollectibles” catalogues the states policies on “shut-offs,” and illustrates that the states’ policies vary greatly. In addition, moratoria do not govern unregulated fuels—such as propane, fuel oil, or wood; often do not govern emergency situations; and do not relieve low-income families of the ultimate obligation to pay for their home energy costs when the moratoria end. In addition, HHS reports that one-third of LIHEAP-recipient households use bulk fuels; thus, are unprotected. In states such as Wisconsin, Minnesota and New Hampshire between 30 to 40 percent of their low-income households use unregulated fuels.

With higher payments for home heating fuel, low-income families face tough choices: heat-or-eat; go further into debt which will jeopardize their ability in the future to become self-sufficient; or use potentially unsafe alternative methods to heat which could result in tragedies. Elderly households might use single room space heaters and turn their thermostats down; these actions will increase the risk of hypothermia for these customers. Yet other low-income customers will move households together to make ends meet. Tragically, overcrowded substandard housing, and the improper use of space heaters have proven to have disastrous consequences in our communities.

#### TARGETED LIHEAP BLOCK GRANT WORKS

Mr. Chairman, LIHEAP works! As designed by the Congress, LIHEAP is a block grant that is targeted to assist low-income households with the costs of home energy. While there are broad federal guidelines for LIHEAP, the states are encouraged to tailor their programs to best meet their individual needs. The Governors determined what agencies should administer the program, what eligibility standards will be used, how benefits will be structured, the guidelines for the crisis program, and the range of assistance to be rendered.

In addition to program flexibility, the administrative costs of the program are minimal—in the range of seven to eight percent. This ensures that the majority of LIHEAP dollars (generally 92 to 93 percent) are directed to energy assistance benefits for the low-income families that it was intended to help. Carry-over funds are minimal and typically run about 3 percent in most years. Late funding decisions by the Congress have unfortunately forced some states to further restrict eligibility and to reserve additional start-up funding for September.

#### LIHEAP IS THE CENTERPIECE OF PRIVATE AND UTILITY EFFORTS

The burden of low-income household needs does not rest solely on the Federal Government. Our member companies are involved in and concerned about the well-being of our communities—both in economic and human terms. The states and the private sector recognize their responsibility to contribute to the needs of these consumers.

UDC member companies have developed a host of innovative and effective programs to assist their low-income consumers; these include: operating and/or contributing to fuel funds; providing discounts and credits to low-income customers; providing partial or full waivers of home energy connection and reconnection fees, and late payment charges; partial or full waiver of home energy security deposits; and partial forgiveness of home energy arrears. Moreover, many of our companies are involved in various energy conservation/management activities. Overall, millions of dollars each year are dedicated to assisting the low income with their fuel bills. However, these efforts and most other private efforts are built around LIHEAP as their cornerstone. Private charitable efforts alone cannot take up the slack for reduced federal funding.

## CHANGING ENERGY POLICIES &amp; UTILITY RESTRUCTURING CREATE UNCERTAINTY

More than 50 percent of low-income households in this country heat their homes with natural gas. Federal and state policies favoring greater competition in both the electric and natural gas industries have shifted significant costs away from industrial customers, and other users with energy alternatives, to residential customers. These households are now paying a higher share of the costs of purchasing and transporting natural gas today than they did in 1980, when LIHEAP was first created. Thus, low-income households continue to face increasing energy burdens.

According to a 1994 report by Oak Ridge National Laboratory, many low-income households' expenditure for residential energy (their energy burden) exceeds 30 percent of income. The report also states that all the low-income households which are federally eligible for LIHEAP spend over \$1,000 per year or 10 percent of income on energy. Typically, low-income households pay four times the percentage of monthly income for energy costs than an average household in America pays. In Illinois, the average family pays 5.9 percent of its income on home energy in winter, while the average low-income family pays between 20–37 percent of income for these energy bills.

In recent testimony before the House Subcommittee on Early Childhood, Youth and Families, Joel Eisenberg, Senior Analyst for Public Policy at Oak Ridge testified on the potential impact of the restructuring of the electric industry on low-income households. He stated that there is "substantial uncertainty as to whether residential consumers in general, and low-income consumers in particular, will benefit from these changes to a significant degree. In some places there is concern that residential rates may actually increase." Eisenberg noted that momentous change in the electric and gas industry is in process. He cited recent data for the natural gas industry from the Energy Information Agency (EIA) which indicate that between 1985 and 1995, savings for residential consumers have been relatively small so far—in the range of 1 percent (EIA Monthly Energy Review, February 1997).

Deregulation and increasing competition create intense financial pressures on gas and electric utilities. As a result, these companies cannot afford to shoulder the burden associated with serving low-income households without government support in the form of continued LIHEAP funding. Since its inception, LIHEAP has been a strong and successful public-private partnership that has worked to address the problem. If government pulls out of this partnership, a serious financial hardship will be created for our low-income citizens. LIHEAP maximizes the opportunities for success in helping our low-income customers.

## CONCLUSION

Mr. Chairman, the House Subcommittee on Early Childhood, Youth and Families held a hearing examining the LIHEAP Program on April 8th. Witnesses included Members of Congress, as well as representatives from the states, and the private and public sectors. The panel included a representative from a local agency and a former LIHEAP-recipient.

The witnesses strongly endorsed LIHEAP, and cited the need for more adequate funding. The stories about low-income households that have benefited from the program were compelling. The Maryland LIHEAP-recipient described her situation as the primary wage earner with a family of four children. Behind in her utility payments, this divorced mother was scheduled to be disconnected. Qualifying for LIHEAP was the linchpin to securing continued utility service and working out a long-term repayment schedule.

The witness representing a local agency recounted information about numerous beneficiaries of the program, including a divorced mother in her thirties with three young children. Recently diagnosed with cancer, this mother had to quit her job in January when she developed side effects to the chemotherapy. This forced her to go onto AFDC and file for disability. Her income dropped from \$1,600 to \$406 per month; consequently, she fell behind in her utility bills. LIHEAP helped bridge the gap during this crisis. As the House witness cited, "This is an example of the kind of situation that can plunge a self-sufficient working family into poverty."

Mr. Chairman, the changes in the welfare system adopted in the last Congress will have profound implications. As families move from dependence towards independence, they will need targeted supplemental assistance. Families in transition normally start at, or near, minimum wage levels. In order for them to continue working and gaining employment experience, so that they can be eligible for better jobs in the future, they need help to maintain a basic standard of living from programs such as LIHEAP.

As the winter ends, problems for the poor do not! The spring brings collections pressures on unpaid heating bills. Without the safety-net afforded through LIHEAP

low-income households could lose gas and electric service. The truth is simple. LIHEAP is a public-private partnership program that works for low-income households and helps to make energy service available and more affordable to them.

Mr. Chairman, we commend you for your leadership on this issue. We look forward to working with you and providing any supporting facts and information that might be helpful to you in your efforts to secure at least \$1.319 billion in regular funding for LIHEAP in fiscal year 1998, and an advance appropriation for fiscal year 1999 at that same level.

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PREPARED STATEMENT OF ANNE D. STUBBS, EXECUTIVE DIRECTOR, COALITION OF  
NORTHEASTERN GOVERNORS

The CONEG Governors are pleased to provide testimony for the record to the Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies as it considers fiscal year 1999 advance appropriations for the Low-Income Home Energy Assistance Program (LIHEAP). The CONEG Governors appreciate the support provided by the Committee in maintaining this important program, and urge the Committee to provide advance funding at the current appropriations level of \$1 billion for fiscal year 1999. In addition, we are requesting that additional funding authority be provided to allow for the release of emergency funds in the event of continued volatility in energy markets, colder than normal winters, and other potential emergencies.

During the current fiscal year, almost 1.5 million very low income households in the Northeast states will receive LIHEAP assistance. About 40 percent of these households are disabled or elderly, and many live on fixed incomes. The majority of the region's recipients are very poor with annual incomes of less than \$8,000 per year. For many of these recipient households, annual income is not sufficient to pay high winter heating bills.

The retail price of heating oil, propane and natural gas increased significantly this past heating season. Price increases in heating oil pose a particular problem in the Northeast because the region accounts for close to 75 percent of all heating oil consumed in the country due to the rapid volatility in energy prices. Therefore, regular LIHEAP funding this year was not adequate to meet the heating assistance needs of program recipients. The release of emergency funds in February helped to offset the impact of the last year's price increases and eased the financial burden on low-income Americans in the Northeast as well as in other parts of the country.

The availability of advance funding for fiscal year 1998, approved as part of the Fiscal Year 1997 Labor, Health and Human Services, Education and Related Agencies Appropriations Act, will play a significant role in helping states plan their programs prior to the start of the winter heating season. In the Northeast, the winter heating season often begins before the completion of the annual appropriations process. By providing advance funding, states can plan the orderly allocation of funds, thereby reducing administrative costs. It also allows states to coordinate outreach and prioritize program goals and components more efficiently.

LIHEAP funds play a major role in helping to make home energy more affordable for low-income households in the Northeast. Program funds are targeted to those with high energy burdens, averaging 15 percent of household income, approximately four times the rate for all households. The program has been very successful in helping low-income households pay their energy bills, thereby preventing fuel supply shut-offs.

States have established programs throughout the Northeast to leverage additional funds from the private sector. These programs include requiring margin-over-rack and oil bid programs to provide the lowest possible prices for heating oil; initiating partnerships with utilities to provide discounts and avoid shutoffs; and exploring options for purchasing natural gas through cooperative arrangements with local governments. States are also establishing closer links between energy conservation services and LIHEAP, thereby helping to reduce long-term energy bills.

As a result of the increasing volatility in energy prices, states are also exploring the use of summer fill programs to purchase oil during the summer months when prices are low, thereby increasing the purchasing power of program funds. Last summer for example, New Hampshire purchased close to \$1 million in heating oil, thereby protecting low-income households in their state against last year's rapid price increases.

States have also adopted various administrative strategies designed to minimize the amount of program dollars that are used to operate the program, thereby allowing more funds to be used for assistance. LIHEAP administrative costs are among



the lowest of human service programs. States pay less than \$25 per household for program administration.

Specific examples of innovative administrative strategies include the development of uniform application forms to determine program eligibility, establishment of a one-stop shopping approach for the delivery of LIHEAP and related program services, and the use of mail recertification. For example, the state of Maine has recently developed a streamlined delivery system which includes an abbreviated application, a prioritized interview form, and a computerized model of household fuel usage. This approach has significantly shortened the time period for processing and distributing fuel assistance benefits.

As another example, Pennsylvania has established a project combining weatherization and LIHEAP emergency services into one agency in order to better serve program clients with life or health-threatening situations. Services are provided for clients who need weatherization-type emergency service. Households can be eligible for a number of energy systems repair and replacement programs in addition to direct fuel assistance.

Electric utility industry restructuring is also expected to highlight the continued need for LIHEAP assistance. As the region begins to open electricity markets to competition and traditional pricing mechanisms change, supplemental LIHEAP assistance currently provided by utilities could be eliminated as competition becomes an increasingly important factor in pricing. Utilities will be less able to support programs providing discounted services unless these services are required of all energy providers. As a result, LIHEAP is likely to remain, for the foreseeable future, the primary source of energy assistance for low-income households.

CONEG is pleased to have had the opportunity to share its views with the Subcommittee, and stands ready to provide any additional information about the importance of LIHEAP in meeting the home heating needs of low-income, disabled and elderly residents of the Northeast.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### PREPARED STATEMENT OF MICHAEL ALDEN, SOUTHWEST TEXAS STATE UNIVERSITY

Mr. Chairman and Members of the Subcommittee, my name is Michael Alden and I am the chairman of the National Youth Sports Program (NYSP) Committee of the National Collegiate Athletic Association. I am also an athletics director at Southwest Texas State University, located in San Marcos, Texas. I appreciate this opportunity to testify in support of a fiscal year 1998 appropriation for the NYSP.

As your Subcommittee takes stock of the hundreds of programs under its jurisdiction this appropriations season, it is my hope that you will give careful consideration to the merits of the NYSP. I understand the constraints you are under to allocate federal dollars carefully and am sympathetic to the challenges you face in selecting which programs will continue to receive federal funds. I ask you to consider that the NYSP is a successful public/private partnership that utilizes the best resources our nation's colleges and universities have to offer to help build healthy, drug-free communities by allowing young people from disadvantaged backgrounds to participate in summer sports, academic enrichment, and fitness education programs coupled with free medical and dental exams.

The NYSP partnership enlists the support of the federal government, represented by the U.S. Department of Health and Human Services, the nation's colleges and universities and the National Collegiate Athletic Association (NCAA), to offer youth who come from low-income families aged 10-16 with five weeks of sports, physical fitness and educational instruction during the summer months. The NCAA's resources help provide administrative support so that all the federal dollars can be used to support the local community programs. Thanks to this team effort, the NYSP has developed into a program that has grown from two institutions in its first year to 172 today.

The NYSP generates \$3 for every federal dollar allocated, provides an exceptional athletic and academic opportunity to nearly 70,000 students from disadvantaged backgrounds in forty-seven states at a cost of less than \$7 per day per child, and all of the program's administrative costs are borne by a private foundation.

Young boys and girls of all economic backgrounds enjoy sports. Unfortunately, the privileges of good coaching and education about the long-term benefits of physical fitness are inadequately extended to low income families. The need for quality athletics opportunities, both organized and self developing, among low-income children is widely recognized. For 28 years the NYSP has addressed this need. Through the NYSP, the federal government invests a modest amount of federal funds to reap tre-

mendous rewards that benefit tens of thousands of children, positively influence our communities and contribute toward shaping our nation's future.

One distinguishing feature of NYSP is its location on college and university campuses. Utilizing the personnel and facilities of higher education introduces students to a different environment, one comprised of high quality resources and free from the threats and dangers of many of their communities. Participants have the opportunity to see the institution from the inside; to walk the halls and engage in activities in the classrooms. They are also surrounded by college students and faculty who have worked to be there and value the opportunity to be part of the college community. This glimpse of the world of postsecondary education is part of the NYSP strategy to encourage youth to aspire beyond their current school life. The NYSP motto is "NYSP helps youngsters walk tall—talk tall—stand tall." And after a summer with us—they do.

Each NYSP program is led by a full time employee of the university, who supervises an administrative, instructional, and support staff. The program employs a local staff of instructors and support people to maintain an instructional participant-to-staff ratio between 15 and 20 to 1. NYSP sites are carefully selected by a review panel and once an institution joins the NYSP, it must maintain rigorous criteria to remain a designated NYSP site.

The NYSP also works closely with many of sports' National Governing Bodies (NOB) such as U.S. Swimming, U.S. Tennis Association, U.S. Soccer, U.S. Volleyball and U.S. Softball. The NGB's provide qualified instructors who administer innovative developmental programming that encourages youth to participate in sports. Every NYSP project offers at least three of the following sports: badminton, basketball, dance, football, gymnastics, physical fitness, soccer, softball, swimming, tennis, track and field, volleyball, and wrestling. Other sports of local interest also can be included. Appropriate supplies, including athletic equipment, swim attire and staff apparel are provided by the NCAA. The NYSP programs' goals reach beyond sports instruction to broader goals of wellness and physical fitness.

In addition, since 1991, the NYSP educational program has featured classes in math and sciences. These programs have been combined with ongoing activities in alcohol and other drug prevention, nutrition, disease prevention and personal health. In addition, each program has a component that addresses career opportunities, higher education and job responsibilities. Borrowing the teaching model used in the sports component, the education sessions consist of interactive activities for all participants.

The goals of NYSP regarding alcohol and substance abuses are also important national goals. A number of recent studies have indicated that an increased number of American youth use tobacco and alcohol. For example, the Nation Institute on Drug Abuse's 1995 "Monitoring the Future", study reported that the percentage of 8th, 10th and 12th graders who smoke cigarettes daily, increased for 1991 to 1995. NYSP has devoted a special education focus on helping youth understand the consequences of using alcohol and tobacco. Such efforts to dissuade our nation's youth are indeed valuable. Not only does the NYSP provide an environment that encourages a healthy life-style but it also teaches respect for self and others through team activities, educational programs, and interaction with community role models.

Healthy individuals contribute to healthy communities. Both are essential to a healthy and productive economy and to the pursuit of happiness so important since the time of our founding fathers and mothers. With help from the local medical community, each of the programs' participants (minimum of 250 boys and girls at each campus) receives a free medical examination before the program session commences. In 1996, over 69,000 medical examinations were administered. If a health problem is found, the child is referred for adequate follow-up treatment. Over 15,900 participants were referred to physicians for follow-up medical attention last year. If children are injured or become ill during NYSP activities, they are covered by health insurance and treated by a certified medical professional. Additionally, the NYSP provides at least one hot United States Department of Agriculture-approved meal each day of the program.

The NYSP ensures the effectiveness of its programs by involving local community leaders through its advisory committee and by working closely with the mayor or city manager. At all participating institutions, an advisory committee is comprised of representatives from the local agencies such as the Housing Authority, private industry, state government and the public schools. In addition, projects collaborate with the local community action agency to help identify the eligible youth.

In fiscal year 1997, Congress appropriated \$12 million for the NYSP. As the committee can probably understand, the demands for the NYSP in rural and urban settings have never been greater. The NYSP is under constant pressure to expand its programs, yet we are aware of the budget problems in Washington, D.C. and under-

stand that all programs must shoulder the burden. On behalf of the 172 NYSP programs and 70,000 young people who annually participate in the program, we respectfully request \$15 million for fiscal year 1998. This slight increase will enable over 44,000 youth to participate in math and science education programs; serve 25 additional communities with a program thereby reaching 9,250 additional youth, extend the programming year-round for 8,000 participants and provide technical training to personnel to enable them to meet the needs of participants youth and communities.

A child needs direction to develop into a productive adult, especially when facing the challenges of growing up in an economically disadvantaged environment. In communities across the nation, parents are eager for their children to be part of a NYSP summer sports camp. They apply early and the waiting lists grow longer each year. They know the NYSP is more than fun and games. The NYSP provides a positive, nurturing environment where young people from disadvantaged backgrounds are given an opportunity to benefit from athletics participation, team play, group self-esteem building activities, a medical physical exam, hot nutritious meals, and educational programs on a college campus at no cost to the student or his parents.

I encourage each member of this Subcommittee to visit a NYSP site in your home district to see first-hand what a life-changing opportunity the program is for the young people who participate. A list of each participating institution is attached to this statement and I assure you the children, their parents, NYSP staff and campus officials would warmly welcome you.

Thank you again for allowing me to present this message on behalf of this worthwhile program. I would be pleased to answer any questions members of the Committee may have regarding NYSP.

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PREPARED STATEMENT OF DENIS MURSTEIN, ADMINISTRATIVE DIRECTOR, ILLINOIS  
COLLABORATION ON YOUTH

Mr. Chairman and Members of the Subcommittee: On behalf of the Illinois Collaboration on Youth (ICOY) and all the young people, families and communities who benefit from the work of the nearly one hundred community-based youth serving agencies that we represent, I want to thank you for providing us the opportunity to present our views before this body.

I write to urge you to continue to ensure that young people develop into healthy and productive adults. Since 1974, Congress has successfully challenged local communities to allocate their resources toward this end. The Runaway and Homeless Youth Act (RHYA), Title III of the Juvenile Justice and Delinquency Prevention Act, has been the foundation of support for sheltering millions of youth who are in need of temporary services and, most importantly, reuniting hundreds of thousands of families in crisis.

The RHYA, with its three major programs—Basic Center (BC), Transitional Living Grants Program (TLP) for homeless youth, and Street Outreach (SO)—is integral to the safety and positive development of young people who run or are homeless. It is crucial that Congress fund these cost-effective programs at the highest levels.

In my nearly twenty years of experience in working with and on behalf of young people and their families, I have experienced the greatest amount of pride in being associated with the many fine people who have dedicated their lives to reaching out to youth in high-risk situations. Groups such as the National Network for Youth, based in Washington, DC, have worked tirelessly to develop and disseminate best practices that help BC, TLP, SO, and other youth programs build capable youth, strong families and responsible communities.

Sometimes, for example, a young person may run away or be forced from their home due to an untenable situation, such as physical or sexual abuse. Feeling frightened, they may not think of what is available in their own neighborhood—they just go. To that young person at that point in time, it's a matter of survival. In situations like this—and there are literally hundreds occurring every day throughout the U.S.—I am truly grateful that the federal government has taken leadership in providing and directly funding a system of intervention for youth in crisis—many of whom cross state lines—that does not burden law enforcement and juvenile justice authorities.

As an active and concerned member of my community, and as a parent, I am comforted to know that there exist safe places which are accessible to all young people in need. I also value the national communications system, funded through the Basic Center Program, operated by the National Runaway Switchboard in Chicago.

Through a toll-free number, young people in crisis can reconnect to their families and be referred to services that will help them.

While communities differ and their responses to problems are congruent with their unique needs, the challenges confronting our nation's young people on their path to adulthood cut across racial, ethnic and economic boundaries. Several years ago, I was privileged to serve as director of a shelter for girls located in the north suburban Chicago area. The program was of modest budget by any standard, but incredibly effective.

With only eleven beds available at any time, more than two hundred and fifty girls were provided temporary shelter in any given year. Ninety-five percent were reunited with their families, with continued counseling support. I am certain that without the availability of that program, ninety-five percent of those girls would have had no other place to go than to the state's child welfare system. But, this is not the exception. This is merely typical of the miracles performed by the programs you have funded under the Runaway and Homeless Youth Act.

What is even more incredible is that prior to 1974, the year the Juvenile Justice and Delinquency Prevention Act (JJDP) was first authorized, those same girls, under the same circumstances, would have been locked up in jail. More than twenty years later, it's difficult to even imagine a time when young people in this country were locked up, for lack of an alternative, after having undergone the trauma of abuse. Perhaps more than any other benefit, I am most grateful for the conversion from wasted human potential to maximized human capital that has been realized due to the existence of these programs. It reinforces one of the basic tenets of the Act: Young people who run away or have been forced to leave their homes, but who have not committed crimes, should not be locked up in jails, detention or other facilities.

From an appropriations standpoint, I cannot overestimate the dividends which are realized from the state and local levels as a result of a relatively modest federal investment. In fiscal year 1996, the appropriation for the Basic Center program was \$40.458 million. Illinois' formula share of that was \$1.621 million. These funds were distributed to seventeen programs throughout the state—from Omni Youth Services in the northern Cook and Lake County suburbs of Chicago and Aunt Martha's Youth Service Center in Chicago's far south suburbs, to McHenry County Youth Service Bureau up near the Wisconsin border and Franklin-Williamson Human Services at the southern tip of the state extending to the Kentucky border.

I am appreciative of the opportunity to present to this body and even briefly convey to you the remarkable story of these wonderful programs. While I am most familiar with Illinois, whenever I come into contact with colleagues from other parts of the country—Texas, Oklahoma, Florida, California, our neighbors up in Wisconsin and Ohio—I know that they are similarly committed to serving young people and their families in their respective communities. You have been supportive and I hope that some day you will help us expand RHYA as a community-based system of opportunities, services, skills and experiences for youth, so that all young people have the chance to become the kind of parents, workers, neighbors and citizens we value.

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#### PREPARED STATEMENT OF THE NETWORK OF UNIVERSITY AFFILIATED PROGRAMS

Mr. Chairman and Members of the Committee:

In July 1996, the U.S. Congress agreed, by unanimous consent, to reauthorize the Developmental Disabilities Assistance and Bill of Rights Act (Public Law 104-183) for three more years. The overwhelming support for reauthorization of this important law showed that Congress places a high value on recognizing the rights of people with developmental disabilities and their families to live independent, productive lives with in the community.

Under Public Law 104-183, the University Affiliated Programs (UAP's) have been making a difference in the lives of persons with developmental disabilities for over 35 years. UAP's were designed to respond to the needs of individuals and families by training professionals for leadership positions in the field of disabilities; working with community services to ensure that people with developmental disabilities do not fall between the cracks in the service delivery system; conducting research and validating state-of-the-art practices in the field of developmental disabilities; and disseminating research findings to individuals with disabilities, family members, professionals, and policy-makers.

Today, there are over 60 UAPs, with at least one in every state and territory in this nation. UAPs serve as a bridge between University training and research and the provision of direct services in the community. Core funding for UAP's is provided by the Administration on Developmental Disabilities (ADD) in the Depart-

ment of Health and Human Services. In addition, the Maternal and Child Health Bureau (MCHB) provides funding for highly specialized training to ensure that the State Title V programs will be able to meet the needs of mothers and children with special health care needs.

*Preparing Personnel for the Future*

Virtually all individuals with developmental disabilities wish to live independent and productive lives in their own communities. To do so requires access to appropriately trained support personnel. Unfortunately, there continue to be critical shortages of well-trained professionals, including occupational and physical therapists, speech-language pathologists, nutritionist educators, physicians, and nurses. Furthermore, well-trained personnel are needed to support the implementation of federal disability policy and legislation in such areas as health and related agencies (MCHB), early intervention and related services (IDEA), and Assistive Technology (The Technology-Related Assistance Act)

UAP's have a unique ability to work in a coordinated fashion to address the needs of people with developmental disabilities and are the only university-based program that addresses issues that are (1) lifespan appropriate, (2) interdisciplinary, and (3) cross service systems through training. ADD support allows UAP's to maintain this unique infrastructure within the university system and establishes a mechanism by which UAP's can garner additional support for the actual implementation of training programs.

Example: UAP's, with federal assistance from the Maternal and Child Health Bureau, support 34 projects prepare professionals for leadership roles in health and related professions that care for infants, children and adolescents with, or at risk for, neurodevelopmental and related disabilities. The principal purpose of the LEND projects is to support the Maternal and Child Health Services Block Grant (State Title V programs) by providing technical assistance and trained leaders in health professions to meet new and emerging needs of children with disabilities.

*Improving the System Through Direct Services and Supports Using Community Training and Technical Assistance*

UAP's provide family and individual support services, as well as personal assistance, clinical, health, prevention, education, vocational, and other services. This support could include training staff to provide direct services providing family support and diagnostic services to children and adults with developmental disabilities.

Example: The UAP in Illinois developed assessment tools that have been used to facilitate the transfer of 80 persons with developmental disabilities who were inappropriately placed in nursing homes, to more appropriate community settings. To support this process, the UAP also operates one of the largest family support and diagnostic clinical programs in the Midwest.

Over the past few years, technical assistance provided by the UAPs has had a significant impact on the provision of technical assistance and community training. For many UAPs, it is the technical assistance activities, as opposed to the provision of direct services, that has had the greatest impact on ensuring that existing state and local service delivery systems can adequately respond to the needs of people with developmental disabilities. In this regard, UAPs do not duplicate existing services; rather, they work to ensure that existing services are equipped to serve people with developmental disabilities. The faculty and staff expertise located at UAPs is brought to bear in an effort to respond to the changing needs of individuals with disabilities.

Example: In 1992, the UAP at Temple University in Philadelphia began implementing Pennsylvania's Initiative on Assistive Technology (PIAT). This initiative established a statewide system to provide needed assistive technology services and equipment, through a direct loan program, to all citizens with disabilities in the Commonwealth.

RESEARCH AND DISSEMINATION OF INFORMATION

University-based programs engage in research and evaluation activities to address the needs of the developmental disability system. Information from UAP research is used to better understand and guide policy and practice in the field.

Example: Congress has supported the national commitment to collect information and measure outcomes on our Nation's success at providing care for our citizens with developmental disabilities through the Projects of National Significance longitudinal data sets. The data collected provide meaningful guidance for Governors and State Legislators to evaluate, plan and implement policy in order to achieve desired outcomes. Through the Projects of National Significance (PNS), data is available on where people with developmental disabilities live and work. The State of the States

in Developmental Disabilities, authored by the UAP at the University of Illinois in Chicago, provides information to governors and state legislators on how state dollars are spent for care and services for persons with developmental disabilities.

UAPs also use cutting edge technology to provide individuals with disabilities and their families access to existing information.

Example: The Family Village project at the Waisman Center in Wisconsin is an Internet system designed to help families with disabilities network with other families around the world. In addition, the system provides families with organized listings of existing health and community services that are available.

#### LEADING THROUGH COLLABORATION

UAPs are expected to provide leadership to the field of developmental disabilities, to initiate new service models, to evaluate current efforts, to determine their efficiency, and to address new initiatives and changes as the developmental disabilities field advances. Some of these advances have included programs in the areas of supported work, early intervention services, assistive technology, health care and AIDS research. Much of the training material for new initiatives such as these has been developed in the UAPs and have been made available at the national level for service agencies to use.

Collaboration happens at multiple levels. UAPs work both locally and nationally with sister developmental disabilities programs to ensure that people and families have access to a full continuum of rights and care. UAPs also collaborate with other federal agencies to bring developmental disabilities expertise to their ongoing work.

Example: UAPs are working with the Administration on Children and Families/Children's Bureau to impact special needs adoption. With the appropriate training for adoption personnel and potential parents, more children with special needs will be adopted by loving families rather than living in foster homes. In Pennsylvania, Project Star is working closely with parents who give birth to a child with a developmental disability, providing supports and services for the family in an effort to help families feel comfortable in keeping their child.

#### FUNDING FOR THE UAPS

Although the UAP network receives a very minimal level of federal funds through appropriations to the developmental disabilities program, this support is extremely powerful. UAPs are state-federal partnerships. More than 29 percent of the money that funds UAPs comes from the states. Most of the federal money is in short-term research, demonstration, and training projects that benefit the state as well as the nation in developing new cutting-edge approaches to address the needs of persons with disabilities in our nation. The ADD is a small source of fiscal support to UAPs, but it is the most critical funding in that it gives them their identity and focus. Without such funding, UAPs would break apart into fragmented projects, each engaged in its own activities, and the focused approach to the needs of people with disabilities in state service agencies and in the national agenda towards independence and efficiency would therefore be lost.

While the federal investment in UAPs through ADD is very minimal, a significant impact is achieved by bringing to bear the resources of the university and other funding sources at the state and national levels to address developmental disability problems. With federal support, UAPs can continue not only to provide leadership on cutting-edge issues such as supported work, early intervention, assistive technology and AIDS research, but to resolve complex challenges in understanding and serving people with severe cognitive and behavioral problems and to develop innovative and effective ways to support these individuals to achieve greater independence and productive lives. The results of these developments contribute not only to the growth and development of each person, but also to a much more cost effective support system that emancipates people from dependency upon public supports.

As the nation moves further in the direction of state/local decision-making, UAPs will be more important than ever as existing community programs depend on UAPs to supply them with well-trained professionals and to ensure that the service meets the needs of the 3 million people nationwide who have a developmental disability. Because of changes to the nation's welfare system, it is estimated that over 135,000 children with special health care needs/disabilities will lose their Supplemental Security Income (SSI) payments. Up to 50,000 of these children are expected to also lose their Medicaid eligibility. The families of these children will turn to care provided at UAPs, hospitals and clinics supported by Administration on Developmental Disabilities (ADD) funds and Maternal and Child Health Block Grant (MCH) funds. This new demand on services will put a further strain on already limited ADD and MCH dollars. UAP and LEND Project staff are already working on the state level

to provide evaluation services and training for state disability determination officers to ensure that families of children currently receiving SSI will be properly evaluated under the new law.

In addition, there is an ever increasing need for well-trained professionals to work in the field of developmental disabilities because of societal increases in violence, drug abuse, teen pregnancy and poverty which are putting more children at risk each day of being born with a developmental disability. States and local communities will have to deal with the complex needs of these children and can rely on the guidance and expertise of the University Affiliated Programs to help them cope with the responsibility of caring for this new generation of children with special needs, but only if funding is available to keep the programs running. Lack of funding for training of professionals, advice for state policy makers, and services that keep families together will result in a disintegration of coordinated services for people with developmental disabilities.

While Congress is working to streamline the budget, UAPs are working to bring together various fragmented federal and state programs in an effort to provide coordinated care for the nation's most vulnerable population. UAPs are part of the ideal vehicle by which this objective can be realized in the disability field. Support for the innovative work of the UAPs, which foster independence and quality of life for all Americans, saves money by helping people to live and work within their own community, and provides a coordinated system of protection and care that is critically needed. This is a goal that can be accomplished only with substantial federal support.

The American Association of University Affiliated Programs for Persons with Developmental Disabilities (AAUAP) therefore recommends that \$20 million be provided for the UAP system for fiscal year 1998. This number represents level funding based on fiscal year 1995 with a CPI increase built in for inflation. AAUAP also recommends that \$6.1 million be provided for Projects of National Significance. Additionally, the AAUAP recommends that \$705 million be provided for the Maternal and Child Health Block Grant.

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PREPARED STATEMENT OF MERLE BOYD, ACTING PRINCIPAL CHIEF, SAC AND FOX NATION

INTRODUCTION

Honorable Chairman Arlen Specter, Senator Tom Harkin and distinguished Members of the Committee, I am Merle Boyd, Acting Principal Chief of the Sac and Fox Nation, located in the State of Oklahoma. I thank the Committee for this opportunity to present written testimony on the fiscal year 1998 fiscal year budget for the Department of Health and Human Services.

APPROPRIATION REQUESTS

Provide Federal subsidy to Tribes for States who opt not to include State matching funds in a Tribal TANF Plan;

Provide \$50,000 to each Tribe administering TANF to purchase computers and software for record automation, complete training and obtain technical assistance for tracking requirements under the Personal Responsibility and Work Opportunity Reconciliation Act;

Provide additional funds to Tribes which cannot produce employment opportunities for families residing in Indian Country in order to prevent complete loss of essential benefits for a needy household; and,

Provide direct funding to Tribal courts and law enforcement officers to enforce juvenile provisions in Indian country.

IMPACT ON INDIAN COUNTRY—PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996

The primary purpose of our statement to the Committee is to once again address the concerns of Indian Country regarding the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and the respective fiscal year 1998 appropriations that will be made to support the new Law. Welfare Reform as we know it today, encompasses each Federal Department under the jurisdiction of this Committee. Many of our federally funded programs are vital to the well-being of our Tribal members. As Congress and the Administration undertake activities affecting Native American tribal rights, trust resources, and essential human services, such activities should be implemented in a knowledgeable manner that is sensitive to our tribal

sovereignty. This has NOT occurred under the new welfare reform law in all states, inclusive of Oklahoma.

TECHNICAL AMENDMENTS (H.R. 1048)

The technical amendments developed thus far for the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (H.R. 1048), do not adequately address our service responsibilities or appropriation needs. The Sac and Fox Nation has appeared before House and Senate Committees since the U.S. House of Representatives first began consideration of H.R. 4 in the 104th Congress. We have addressed our concerns for the record, but to no avail. Unfortunately for Indian Country, our early predictions and estimates of potential harmful impact have come to fruition.

NARRATIVE JUSTIFICATION ON APPROPRIATION REQUESTS

Provide Federal subsidy to Tribes for States which choose not to include State matching funds in a Tribal TANF Plan. Regretfully, I cannot ascertain the amount of appropriations needed for the Sac and Fox Nation or adequately project the appropriation needs for other Tribes, regionally or nationally. To date, the State of Oklahoma is unable to provide accurate figures to Tribes for the anticipated caseload demands if TANF is to be transferred from the State. However, the Act only mandates that states provide the federal share of funding to a Tribal government that opts to administer its own TANF. Without the use of state funds that will otherwise be made available to needy families participating in a state TANF program, Tribes cannot sustain equitable services to Indian households in Indian Country. Indian citizens will essentially be denied equal protection and equal access under this law. Therefore, we ask the Committee to subsidize Tribal TANF's with funds that will not otherwise be made available by a state that chooses not to apportion matching funds to a Tribe administering a TANF program.

Provide \$50,000 to each Tribe administering TANF to purchase computers and software for record automation, complete training and obtain technical assistance for tracking requirements under the Personal Responsibility and Work Opportunity Reconciliation Act. The Act does not provide funds to Tribes to purchase tracking equipment such as computers and software for or record automation. Yet, Tribes who desire to administer TANF must implement administrative data collection and reporting requirements, manage records, and implement an automated tracking system, locally, regionally, nationally and on an inter-national basis. States have had 60 years to develop, demonstrate and implement a complete infrastructure for this purpose. Further, States have received appropriations over the years to fulfill this requirement under AFDC and related programs. States have the necessary infrastructure in place and will be able to meet the requirements of the Act. The Tribes cannot, reasonably be expected to be successful without ANY appropriations to establish these system requirements and for authorized access to State data tracking programs, unless appropriations are made for this purpose.

Provide additional funds to Tribes which cannot produce employment opportunities for families residing in Indian Country in order to prevent complete loss of essential benefits for a needy household. The Act provides that families residing on reservations will be dropped from the welfare rolls when their time limit is up even if they have not secured a job. The reality in Indian country is that jobs are not plentiful as in other non-reservation areas. Under the current language of the Act, states can place time limits on how long a family receives TANF benefits. The time limit however, cannot exceed 60 months or 5 years. No more than 20 percent of a state's caseload can be exempted from the time limit for hardship reasons. Although proposed technical amendments under H.R. 1048 are intended to lift the ceiling on the 1,000 population limit, the unemployment source data that would be acceptable is not defined in the Act itself. Additionally, Oklahoma tribal jurisdictions are not considered reservations per se, and do not meet the requirement as set forth in the Act. Congress must uphold its trust responsibility and provide sufficient financial resources to assist Tribes in developing viable economic opportunities and infrastructure needs to support employment prospects in Indian country. Without full cooperation between Congress, States and Tribal governments, Welfare Reform in Indian country will become a dismal failure. Tribes do not have sufficient financial resources to support the intent of the Act.

Provide direct funding to Tribal courts and law enforcement officers to enforce juvenile provisions under the Act in Indian country. The Personal Responsibility and Work Opportunity Reconciliation Act provides for Tribes to establish child care standards, determine paternity, develop child support enforcement requirements, and work with States to pursue and collect child support for children. However, the infrastructure needs, development of standards and essential Tribal law enforce-



ment authority has not been provided for under the Act to fulfill this obligation. Tribal courts will require additional personnel to oversee child support hearings on orders, to coordinate with State agencies on the same, to develop child care standards and ordinances, and to staff their law enforcement departments to pursue negligent parents within and across Indian Country borders. Appropriations are needed to increase the budgets of Tribal courts and law enforcement departments throughout Indian Country. Additionally, such funding should be provided directly to a Tribe.

In conclusion, I urge this Committee as well as all other authorizing Committees to give careful consideration to the appropriation needs of Indian Tribes for the implementation of the Personal Responsibility and Work Opportunity Reconciliation Act. As Congress continues to work out the problems States have encountered in implementing Welfare Reform, i.e., restoring benefits to adult food stamp households, extending benefits to legal aliens, etc., we ask that you do not forget to correct the grave oversight on the part of Indian Country's needs.

The Sac and Fox Nation appreciates this opportunity to present our concerns to the Committee regarding the fiscal year 1998 appropriations needed for us to implement the Personal Responsibility and Work Opportunity Reconciliation Act. I am available to the Committee to respond to any additional questions or comments you may have regarding our testimony.

Thank you.

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NATIONAL INSTITUTES OF HEALTH

PREPARED STATEMENT OF AMERICAN FEDERATION FOR MEDICAL RESEARCH

The American Federation for Medical Research (AFMR) appreciates the opportunity to present our views about the challenges confronting our nation's clinical research effort. The AFMR is a national organization of 7,000 physician scientists—primarily medical school faculty members—engaged in basic, clinical, and health services research.

The AFMR is most grateful for this Subcommittee's strong support for the National Institutes of Health. We also applaud your acceptance of the NIH proposal for additional funds to construct a new clinical research center on the NIH campus. However, we are concerned that increased appropriations have not been provided for much needed initiatives to strengthen clinical research in the extramural community. Legislation will be introduced this year in both the House and Senate to address this issue. Unfortunately, while we await enactment of this legislation, American clinical research continues its decline. The AFMR urges this Subcommittee to move forward this year and propose additional NIH funding to revitalize our nation's clinical research effort.

*The Problems Confronting Clinical Research*

First, what is clinical research? A definition of clinical research could extend from fundamental experiments of nature using human subjects or tissues, to clinical trials, to technology assessment, to health services research. This testimony will focus on the area of clinical research that should be of particular concern to the NIH: the earliest stage of clinical research through which a basic science discovery is applied to the study of human physiology, to research on a disease or condition, or to the initial study of a potential therapeutic intervention. This phase of clinical research, sometimes referred to as "translational" or "integrative" research, is the pathway that links basic science to human health. Basic science and clinical research are mutually dependent: basic science discoveries are the foundation of clinical research, but without clinical research, basic science offers little to mankind. Accordingly, threats to clinical research jeopardize our ability to reap the rewards of the NIH investment in basic science.

Should NIH play a role in supporting clinical research? Absolutely. There is significant industry support for clinical research and clinical trials aimed at the development of new products. However, for clinical research that may not offer a product "pay off," funding is extremely limited. For early-stage translational research that may have little or no commercial product potential, NIH funding is critically important. Examples of such research include: small-scale human studies of techniques or compounds that have shown promise in animals; research on nutrition, prevention, transplantation, or behavioral interventions; investigator-initiated studies to test clinical hypotheses, such as the research that identified a bacterial cause for peptic ulcer disease; and small-scale studies of off-label uses of approved drugs, such as research on the use of Ibuprofen for Cystic Fibrosis patients.

Because there is literally no industry interest in this type of research, it requires investment by NIH. In addition, of course, NIH funding is critically important for the training and career development of clinical investigators.

The difficulties confronting clinical researchers and their patients have received much attention but little action over recent decades. In 1979, former NIH Director James Wyngaarden gave his seminal presentation characterizing the clinical investigator as an “endangered species.” In September of 1994, the Institute of Medicine of the National Academy of Sciences published a report on the opportunities and challenges confronting clinical research. The IOM recommendations are the foundation of the clinical research legislation to be introduced shortly. In late 1995, the journal *Nature Medicine* published a report documenting a slowing of medical discovery in the United States over the last several decades.

Specific challenges to clinical research include the following:

- First is the issue of tuition debt. A low-paying research fellowship is not an option for the indebted medical school graduate. The average debt of the 1981 medical school graduate was \$20,000. By the mid-1990s, that amount has tripled to \$63,000. A research fellowship paying \$28–30 thousand is a financial impossibility for most individuals with such high tuition debt.
- Second, young physicians are further alienated from careers in research when they see their mentors struggling or abandoning their research careers. The AMA reports that between 1985 and 1993, the number of physicians reporting research as a major professional activity fell from 23,268 to 14,716—this occurring while the total number of physicians grew dramatically. This poses problems for the NIH extramural program as well. In 1970, physicians made up 43 percent of all principal investigators on funded grants. By 1987, this had dropped to 30 percent. Applications for NIH grants have grown dramatically in the past fifteen years, but most of the growth has been among PhDs. Without a dramatic increase in the overall success rate for NIH grant applications, there has been an inevitable squeeze on the physician investigator.
- The third problem: NIH peer review. A special outside committee of the Division of Research Grants concluded that clinical research proposals are inadequately reviewed by study sections that evaluate only a minimal number of clinical research grants. In other words, in many study sections, physician scientists have a greater chance of securing NIH funding with basic science studies than clinical proposals. Accordingly, most physicians applying for NIH funds confine themselves to the same scientific questions and projects being pursued by PhDs instead of bringing their clinical expertise and understanding of the human body and disease to the translation of basic science from the bench to the patient’s bedside.
- A fourth problem confronting clinical research is the severe financial pressure on the academic medical centers. Competition in the health care marketplace has forced academic institutions to: demand that physician faculty spend more time generating revenue from patient care activities, diverting them from research projects; and eliminate the “profit margin,” if you will, from clinical services that was used in the past to subsidize clinical research and clinical research training.

Five years ago, one could walk into a teaching hospital patient ward and find substantial numbers of research patients mixed in with those receiving non-investigational treatment. Today’s wards lack the additional resources and staff necessary for complicated clinical research protocols. Researchers and their patients seek safe haven from health care competition in the General Clinical Research Centers (GCRCs), which are underfunded for the task. In fact, to our distress, the fiscal year 1998 President’s request for the GCRCs would hold them to a subinflationary increase of less than 1—percent effectively, a programmatic cut.

#### *The Implications of the Clinical Research Crisis*

What is the impact of a weakened clinical research effort? Why should this Subcommittee provide additional funding to address the problems confronting clinical research?

- First, improvements in patient care and the prevention of disease depend on clinical research that brings basic scientific discoveries to the benefit of human beings. Any obstacles to clinical research slow progress in medicine. Patients out there waiting for “the cure” must wait longer, and the NIH investment in basic science can not pay off.
- Second, the fruits of clinical research are often taken by industry and developed into new drugs, vaccines, or health care products. These new products boost our economy and create jobs.

- Third, while not all medical discoveries reduce health care costs, many do, as documented in NIH reports on the cost-savings resulting from new therapies. Certainly, it is less expensive to vaccinate against polio and hepatitis than it is to treat these diseases and the chronic disability resulting from them.
- Finally, the international implications of allowing clinical research to falter are enormous. We are beginning to see signs that other nations are picking up the clinical research banner that America is dropping. The discovery of the cure for peptic ulcer disease—one of the greatest medical scientific breakthroughs since the polio vaccine—was made in Australia.

*Solutions to the Problems Confronting Clinical Research*

The AFMR believes that this Subcommittee must take action to provide additional funding for extramural clinical research just as it has wisely invested in a new clinical research center on the NIH campus. First, the Subcommittee should take steps to increase substantially funding for the NIH-sponsored General Clinical Research Centers across the country. As noted above, these “safe havens” for clinical research are vitally important. Funding for the GCRCs has not kept pace with NIH-wide budget growth in recent years. For fiscal year 1998, the AFMR recommends an increase of \$20.5 million (17 percent) for the GCRCs. Of this increase: \$13 million would partially bridge the average 25 percent cut below Advisory Council approved budgets for the GCRCs; \$5 million would fund three additional centers; \$2 million would expand the Clinical Associate Physician and Minority Clinical Associate Physician training programs in the GCRCs; and \$500,000 would expand the GCRC clinical scholars program.

Second, we recommend that the Subcommittee provide an additional \$59.5 million—a mere half of a percent of the NIH budget—to fund the initiatives to be proposed in the clinical research legislation. This would include: \$1 million to expand the existing NIH loan repayment program for intramural scientists to the extramural community; \$3 million for the creation of a 5-year career development award for clinical researchers; \$52.5 million to establish an “innovative medical science awards” program; and \$3 million to create a grant program for Masters and Ph.D. degree training in clinical investigation.

We recognize and applaud this Subcommittee’s resistance to “disease of the month” earmarking for the NIH budget. As you consider our proposal for specified additional funding for clinical research initiatives, please keep in mind that such funds would not be directed to particular diseases or investigators. These funds would go to peer reviewed proposals to translate basic scientific discovery to the study of any disease. Rather than special interest set-asides, these initiatives are more comparable to the Subcommittee’s directives to fund the extramural facilities construction program and the new clinical research center on the NIH campus. They will advance the goals of the NIH as a whole, will benefit all NIH Institutes and Centers, and will boost existing NIH efforts focussed on women’s health, minority health, and prevention.

In closing, the AFMR would suggest that if this Subcommittee fails to fund NIH initiatives to address the clinical research crisis, we will continue to see a slowing of medical discovery. You will continue to hear exciting reports of the identification of specific disease genes or the discovery of molecular mechanisms of disease but will wonder why these findings do not result in cures or vaccines. If this Subcommittee fails to act in 1997, by the year 2000 you will be directing the NIH to implement a crash program to replenish the nation’s corps of clinical investigators only to be told that such an effort will take 10–12 years. Disease research breakthroughs will occur, but an increasing number will come from other countries that are applying the fruits of NIH-sponsored basic research to the development of new therapies. Please do not delay further. Construction of the new clinical research center in Bethesda has begun. Please move forward this year with funding to rebuild the extramural clinical research capacity of the NIH.

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PREPARED STATEMENT OF PETER E. SCHWARTZ, M.D., PRESIDENT, SOCIETY OF  
GYNECOLOGIC ONCOLOGISTS

I. INTRODUCTION

Chairman Specter, Senator Harkin, other Members of the Subcommittee, I am Peter E. Schwartz, M.D. I am here today in my capacity as President of the Society of Gynecologic Oncologists (SGO). The SGO is the only national medical specialty devoted to the study and treatment of female reproductive organ cancers. These malignancies include cancers of the cervix, uterus, and ovary. The SGO has more than 750 members who specialize in providing comprehensive care for women with

gynecologic cancers, including prevention, diagnosis, surgery, and all subsequent therapy required during the course of her disease. To qualify as a member, physicians must complete a four year obstetrics and gynecology residency, complete a 3- or 4-year fellowship in gynecologic oncology, and pass the written and oral examinations for a Certificate of Special Competence in Gynecologic Oncology and Board certification in Obstetrics and Gynecology. The SGO maintains strict educational requirements to ensure that women with cancer receive the best and most up-to-date, "state-of-the-art" care.

I am extremely grateful for the opportunity to provide public witness testimony on behalf of the SGO in support of increased funding for the National Institutes of Health, and particularly the National Cancer Institute, which provides the majority of the funding for gynecologic cancer research

#### THE INCIDENCE OF GYNECOLOGIC CANCERS

There are three main gynecologic cancers: (1) Cervical; (2) Uterine; and (3) Ovarian. The incidence of each these cancers and the women developing these diseases are different, reflecting the unique biologic characteristics of these diseases.

*Cervical cancer.*—Both the incidence and mortality for invasive cervical cancer have declined steadily in this country over the last three decades. Although only 14,500 women will develop cervical cancer in 1997, one-third of them will die from this preventable disease. African-American women continue to experience an incidence rate that is nearly two times higher than the incidence rate for white women, and African-American women have a 56-percent 5-year-survival rate as compared with a 70-percent survival rate for white women.

Higher rates of cervical cancer are found in the American South as compared to other parts of the U.S. This reflects the tendency of the disease to disproportionately affect women in rural areas and women in lower socioeconomic classes. Cancer of the cervix is a preventable disease if women are regularly screened using the Pap Smear.

Women with invasive cervical cancer are most often over the age of 50, while women with carcinoma in situ, a precancerous condition, are most often between the ages of 25 to 34 years old. However, there has recently been an increase in the incidence of cervical cancer among young white women in the U.S.

*Uterine cancer.*—Cancer of the uterine corpus or endometrium is the fourth most common cancer among U.S. women and is the most common invasive gynecologic cancer. An estimated 34,900 women will be diagnosed with uterine cancer in 1997. Fortunately, this cancer causes a limited number of deaths, as evidenced by a 5-year survival rate of 83 percent.

Uterine or endometrial cancer is uncommon before the age of 45, but the risk of being diagnosed with endometrial cancer rises sharply among women in their late 40's to mid 60's. Endometrial cancer rates are highest in North America and northern Europe. In the U.S., incidence rates for white women are nearly twice as high as the incidence rates for black women. Also, a number of clinical trials have recently indicated an increased risk of endometrial cancer among tamoxifen treated breast cancer patients.

*Ovarian cancer.*—In 1997, the American Cancer Society estimates 26,800 new cases of ovarian cancer will be diagnosed in this country and 14,100 women will die from ovarian cancer this year. The 1987–91 age-adjusted incidence was 14.8 cases per 100,000 women; the incidence increases with age until age 75 when the rate declines.

A relative survival rate of 90 percent can be achieved if ovarian cancer is diagnosed early, but unfortunately, 70 percent of women with ovarian cancer are not detected until the cancer has reached an advanced stage, which has an 80 percent fatality rate. Ovarian cancer ranks fourth as a cause of death among cancers in females. White women in the U.S. are twice as likely as black women to be diagnosed with ovarian cancer. The risk of a women developing ovarian cancer is three to five times greater, if her mother or her sisters had or have ovarian cancer. Women who have been diagnosed with breast cancer are 70 percent more likely to develop ovarian cancer, than the general population.

#### EXAMPLES OF CURRENT CLINICAL RESEARCH INTO THE CAUSES OF AND CURES FOR GYNECOLOGIC CANCERS

In the area of cervical cancer research, the Food and Drug Administration has recently approved the use of a Lipopeptide vaccine for investigation at the NCI. This clinical initiative targets the Human Papilloma Virus (HPV), which has been associated with over 90 percent of cervical cancers. The development of a therapeutic vaccine to treat advanced cervical cancer represents a novel and attractive alternative

to current therapies. This will be a phase I protocol clinical trial that is open to patients with recurrent or refractory cervical cancer who have an expected survival of at least three months. Also underway is the development of a prophylactic HPV vaccine with the potential to prevent the transmission of the HPV virus, and thus prevent cervical cancer.

Recently, in the area of ovarian cancer, protocol 111 of the Gynecologic Oncology Group, one of the NCI Cooperative Groups, demonstrated a 50-percent increase in median survival time among women with advanced ovarian cancer who were treated with the combination of paclitaxel and cisplatin compared with the standard approach of cisplatin with cyclophosphamide. This helped to confirm that paclitaxel has important anti-tumor activity in patients with ovarian and breast cancer.

#### AREAS FOR EMPHASIS: PRIORITIES TO SUCCEED IN GYNECOLOGIC CANCER RESEARCH

The SGO is very supportive of a doubling of the NIH budget over the next five years, as called for in Senate Resolution 15 and House Resolution 83. As a way to begin to achieve this goal, the SGO would ask that this Subcommittee approve an increase of at least 9 percent for the NIH and that this increase be uniformly distributed to each Institute in an equitable manner, thus the NCI would receive an increase of 9 percent as well.

We would like to share with the Subcommittee some areas that need attention and hold great scientific promise, if appropriate funding and research efforts are directed towards these issues.

#### I. GYNECOLOGIC ONCOLOGISTS AS PRIMARY INVESTIGATORS IN INDEPENDENT LABS ON THE NCI CAMPUS

The issue of gynecologic oncologists as principal investigators in the intramural program is quite timely, with the building of the new clinical center and the emphasis on research during the fellowship training of a gynecologic oncologist. The SGO advocates a greater physical presence of gynecologic oncologists at the NIH and particularly at the NCI. The multi discipline training received by gynecologic oncologists during their fellowship programs facilitates the optimal delivery of care to women with gynecologic cancer. Increasing the number of principal investigators should increase the enrollment in screening and treatment trials in gynecologic cancer at the NIH clinical center. There is currently only one fully trained and board eligible gynecologic oncologist with an independent lab on the NCI campus.

The SGO would urge this Subcommittee to work with Dr. Klausner, as we are, to ensure that at a minimum, three independent labs are established and supported in the new clinical center, where the primary investigators are fully trained gynecologic oncologists.

#### II. INCREASED EMPHASIS ON EARLY DETECTION OF AND PREVENTION OF OVARIAN CANCER

As already noted in my remarks, there is quite a difference in the survival rates of women who are diagnosed with cervical cancer and women who are diagnosed with ovarian cancer. The reason for this is that we have a very good method for diagnosing cervical cancer, the Pap Smear. We do not have a test such as this for the detection of ovarian cancer. Today, we have ultrasound and CA 125 as the methods for detection of ovarian cancer. Unfortunately, more than 66 percent of the ovarian cancer in this country is diagnosed in the operating room, after the cancer has spread to other internal organs.

Currently, there is the clinical PLCO study, which is being supported by the NIH, that is testing the effectiveness of CA 125 and sonogram for ovarian cancer screening. However, given the difference in survival rates for women whose ovarian cancer is detected and then diagnosed early and for those women who are diagnosed with advanced ovarian cancer, the SGO is advocating that additional federal resources be directed towards increasing clinical trials for ovarian cancer prevention and detection.

#### III. A SPECIALIZED PROGRAM OF RESEARCH EXCELLENCE (SPORE) FOR OVARIAN CANCER

Last year the full Appropriations Committee encouraged the NCI to providing funding for a SPORE that was targeted at ovarian cancer research. A SPORE is a competitive grant mechanism to conduct translational research, where cancer centers are the applicants. SPORE's, with the exception that they are for translational research only, are similar to investigator initiated program project grants, commonly known as PO1's. Currently, there is a PO1 grant for ovarian cancer research at Memorial Sloan-Kettering Cancer Center.

The SGO would like to thank the Committee for its efforts in this area. Unfortunately, we have yet to see a request for application (RFA) be announced for a SPORE specifically for ovarian cancer, but we hope that after the cancer center evaluations are finished and released, this will occur. The SGO has heard from our members, who are at cancer centers, that the SPORE, as a grant mechanism, works well for increased coordination within the cancer center. We ask that this Subcommittee continue to monitor this situation until a SPORE, targeted for ovarian cancer, is funded by the NCI.

#### IV. THE NEED TO TRAIN MORE GYN SCIENTISTS

The SGO would like to suggest to the Subcommittee that they consider directing the NIH Office on Women's Health to take on a greater role in encouraging research directed at cancers of the reproductive system. One way to do this is to have the Office on Women's Health dedicate a small portion of their fiscal year 1998 budget, to administer a young investigator program in gynecologic oncology research. This could be done in collaboration with the NCI. Numerous grant mechanisms, like the RO3's, and the Clinical Associate Physician (CAP) program, already exist for the Office on Women's Health to use as a model. Applicants to this program would have as their goal to become independent clinical investigators in gynecologic oncology research.

The SGO, through its foundation, the Gynecologic Cancer Foundation, has already partnered with the NCI to provide funding for one young investigator. In the next few months, the SGO will be engaged in discussions with the NCI on how to expand this program, as well.

#### CONCLUSION: A SUCCESS STORY

Chairman Specter, Senator Harkin, and Members of this Subcommittee, I greatly appreciate your time and attention to the need for additional resources for research being conducted to find the causes and subsequently the cures for ovarian cancer. I would like to close today with a success story. I would like to share with you the story of the first patient I treated at Yale University Medical Center with chemotherapy, a success that happened because of past research in the area of gynecologic cancer.

Peggy was 18 years old when diagnosed with a pelvic mass, thought to be a twisted ovarian cyst. She had surgery, where a big, ugly tumor was removed. A frozen section was done and an endodermal sinus tumor, a rare ovarian cancer, was diagnosed. The prognosis was grim. In 1975, 50 percent of the women diagnosed with this cancer were dead within 6 months, and almost all of the rest died within 1 year. I went to the head of my division, as I had just come to Yale, having completed my gynecologic oncology fellowship at M.D. Anderson in Houston, TX, to discuss her treatment. At that time, radiation was the treatment of choice. I wanted to try an experimental chemotherapy program, that had recently been successful at the M.D. Anderson Cancer Center in the treatment of a few similar patients. Peggy was treated with 18 months of that chemotherapy. She was then re-operated and no evidence of cancer was found. Peggy went on to become the mother of two healthy children and remains alive and well today, 22 years following her original diagnosis.

This patient was the first of well over 100 women treated at our medical center with these rare cancers who are alive today, with 66 percent having had their fertility preserved, because of successful medical research. It is this sort of outcome that drives my colleagues and me to seek new ways to prevent, to diagnosis, and to treat women at risk for, or who have gynecologic cancers.

I and the SGO look forward to working with each of you in the years ahead on behalf of the women of this country and their reproductive health. I would be happy to answer your questions, at this time.

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PREPARED STATEMENT OF FRANCES M. VISCO, PRESIDENT, NATIONAL BREAST CANCER COALITION

Thank you, Mr. Chairman and members of the Committee for all your previous hard work and leadership in working together with the National Breast Cancer Coalition to create support for the battle to eradicate breast cancer. I am Fran Visco, President of the National Breast Cancer Coalition and a wife, mother, lawyer and a breast cancer survivor.

As you know, breast cancer is the most common form of cancer in women; every three minutes another woman is diagnosed and every 11 minutes another woman

dies of breast cancer. We still do not know the cause or have a cure for this dread disease.

As a result, the National Breast Cancer Coalition, a grassroots advocacy effort dedicated to the eradication of breast cancer, was conceived in January 1991. The Coalition now numbers over 400 member organizations, and more than 40,000 individual women, their families and friends.

Breast cancer costs this country untold dollars in medical costs, lost resources, lost productivity, and in lost lives. The war against breast cancer, the search for answers to what causes the disease, how we can prevent it, how we can cure it—these are immense issues, requiring a concerted, coordinated effort on the national level. Spending money now on biomedical research is fiscally responsible. We are investing in a healthful, more productive future.

Mr. Chairman, you and your Committee are certainly aware of the need for increased breast cancer research funding as a result of your hearing in February, on mammography screening guidelines. During the hearing, Mr. Chairman, you demonstrated your commitment to our fight by asking me how much money is needed for breast cancer research. I have thought about it in-depth and realize that to meet the NBCC goal of \$2.6 billion for breast cancer research between now and the year 2000 to create real progress in the battle against breast cancer, \$590 million must be appropriated to NIH this year. The immediate need for increased resources for breast cancer research could not be better illustrated than by the recent mammography debate. The data available on breast cancer is not enough for the scientific community to even come to a consensus on how to best detect this disease, let alone to prevent it or cure it. We desperately need more answers about this disease.

Therefore, it is important to send a clear message to both NIH and NCI, about our high level of commitment to eradicating breast cancer. The National Breast Cancer Coalition is calling on Congress to appropriate \$590 million to NIH for peer-reviewed breast cancer research in fiscal year 1998 and we strongly support Senator Snowe's bill, S.67 (Breast Cancer Research Extension Act of 1997) which authorizes the appropriation of \$590 million for breast cancer research for NIH in fiscal year 1998. It is essential to ensure that NCI makes breast cancer research a top priority and that the increased resources appropriated to NIH are used for peer-reviewed breast cancer research.

In the six short years that the National Breast Cancer Coalition has been in existence, crucial strides have been made. In 1991, less than \$100 million dollars was spent on breast cancer research; a disease that afflicted 180,000 women per year. But thanks to the work of the Coalition and your leadership, in fiscal year 1997, the NIH appropriation received a 6.9 percent increase, which should result in approximately \$430 million for breast cancer research. These increases have already had a positive impact on the challenge to eradicate this dread disease.

The increased funding for breast cancer research has revitalized the scientific community. There is a level of excitement, an energy, among scientists that had been lacking for some time. Scientists, consumers and policy-makers have come together around this issue and have forged a new partnership that can only bring us to our goal that much faster.

Young scientists are choosing the field of breast cancer research for their careers, and experienced, prestigious scientists have shifted their focus and are now engaged in the challenge to find the cause and ultimately the cure. The breast cancer gene, BRCA1, was identified in 1994—a major breakthrough for breast cancer research. And even though the discovery has raised as many questions as it has answered, this progress begins to chip away at the fundamental questions about breast cancer that are so essential to unraveling the mysteries of this killer. In addition, over the past few years, there have been incredible discoveries at a very rapid rate that offer fascinating insights into the biology of breast cancer, including discoveries about the basic mechanisms of cancer cells. These discoveries have brought into sharp focus the areas of research that hold promise and will build on the knowledge and investment we have made.

However, we still have a long way to go. As you know, this disease is complex and there is much work to be done before our goal can be achieved. The research simply needs to continue so that answers to the questions around breast cancer can be found. The women who are living with this disease and those who live in fear of this disease, deserve information they can depend on and answers that come one step closer to saving their lives. If the funding levels for breast cancer research are not increased, the forward progress we have begun to make in these past years will be lost.

I cannot emphasize enough the importance of biomedical research in our fight. The National Cancer Institute has the infrastructure, and unparalleled expertise in pursuing and funding the basic and clinical research that continues to be essential

in the quest to find the answers to the mystery of breast and all cancers. Our federal government must not waiver in its commitment to such high quality research with the potential to save billions of dollars and millions of lives.

Now is the ideal time to make a significant commitment to eradicating breast cancer by substantially increasing breast cancer research funding. The one consensus about breast cancer in the medical, advocacy, policy and political communities is that more data is needed. Following the leadership of this Committee, many other Congressional Members have begun to introduce various legislation this year toward the fight against breast cancer. The interest and commitment to eradicating breast cancer is more apparent this year than ever before—making this year the best time to create real progress in the breast cancer battle and propel research forward with a significant increase in the amount of money appropriated to NIH for peer-reviewed breast cancer research.

The progress that has been made in the past six years has been a result of your Committee's previous leadership, as well as the dedicated hard work of the members of the National Breast Cancer Coalition. In the past six years, thousands upon thousands of breast cancer survivors, their families and friends have worked tirelessly to advance the cause of eradicating breast cancer.

Our members are continuing to work towards our goal of the eradication of breast cancer. In May of 1996, the NBCC launched its third petition drive, Campaign 2.6. The goal was to collect 2.6 million signatures on petitions calling on the President and the U.S. Congress to spend 2.6 billion on breast cancer research between now and the year 2000. On May 6, we will present a petition which has gained over 2.6 million signatures for \$2.6 billion for breast cancer research by the year 2000, to the Congressional leaders on the steps of the Capitol. Women and their families across the country have worked hard to gain these signatures. Funding for peer-reviewed breast cancer research at the NIH is an essential component of reaching the \$2.6 billion goal that so many women and families have worked to gain.

We realize, however, that while increased funding is a critical element to finding the cause and cure for breast cancer, funding alone is not enough. That is why we have worked to create a national strategy. Toward this end, in 1993, the Coalition presented a petition to President Clinton with 2.6 million signatures. The Petition requested that he move to develop a national plan of action to achieve the goal of the eradication of breast cancer. In response, a summit was convened in December 1993, at the National Institutes of Health. It was a historic gathering of over 150 scientists, leaders from the corporate world, consumer activists, and public policy-makers. The scientists and consumers work together in a unique and unprecedented partnership. I co-chair the continuing National Action Plan on Breast Cancer and am intimately involved in its thoughtful and thorough implementation.

We have also worked extensively with Congress. As you know, we have deluged Congress with letters, telegrams, phone calls and visits. Once again, we are prepared to bring our message to Congress. In early May, many of the women and family members who supported the campaign to gain the 2.6 million signatures will be at our Annual Advocacy Training Conference in Washington, D.C. We expect 600—700 breast cancer activists from around the country to join us in continuing to mobilize behind the efforts to eradicate breast cancer. The overwhelming interest and dedication to eradicate this disease continues to be evident as people are not only signing petitions, but are willing to come all the way to Washington, D.C. to deliver their message about the importance of our commitment.

Largely because of the work of the National Breast Cancer Coalition, there has been a revolution in the way breast cancer research is pursued. Unprecedented partnerships have been forged between scientists and consumers, activists and corporate leaders. As a result, the research has the benefit of the wisdom of each of these important perspectives, ensuring the value of investment in breast cancer research and ultimately the success of its endeavor: to make breast cancer a thing of the past.

I truly believe that breast cancer research remains an important responsibility of the federal government. In the last five years, breast cancer advocates and the 2.6 million American women with breast cancer have been heartened by our government's response to their cries for the long needed increase in breast cancer research funding, and thanks to that investment, real progress is being made.

We ask this Committee to do whatever it can to find the funds to continue to make breast cancer research a priority and appropriate \$590 million for peer-reviewed breast cancer research at NIH. The 2.6 million women who now have breast cancer deserve no less. Thank you for your consideration and we look forward to continuing to work with you in the future.



## PREPARED STATEMENT OF ROBERT G. LUKE, M.D., PRESIDENT, AMERICAN SOCIETY OF NEPHROLOGY

## INTRODUCTION

Chairman Specter, Mr. Harkin, and other Members of the Subcommittee—my name is Robert G. Luke, M.D., and I am the President of the American Society of Nephrology (ASN), the national organization representing physicians and researchers who are committed to finding cures for kidney disease. I am also one of the ASN representatives to the Council of American Kidney Societies (CAKS). CAKS was founded in 1996 to serve as a representative body of scientific and professional nephrology practice organizations engaged in the promotion, support, and influence of the policies that affect the broad field of kidney diseases. I am extremely grateful for the opportunity to provide public witness testimony on behalf of ASN's 6,500 members and CAKS in support of the National Institutes of Health and particularly the National Institute of Diabetes, Digestive, and Kidney Diseases, which provides funding for most of the kidney disease research in the United States.

## THE INCIDENCE AND PREVALENCE OF KIDNEY DISEASE

The number of patients in this country with end stage renal disease, that is total kidney failure, now exceeds 300,000, and this number was increasing by about 10 percent every year. However, recent trends show that the rate may have decreased to 7–8 percent. In the next few months, this new rate will be validated. If it is determined that the rate has actually decreased, it will be because of NIDDK sponsored research.

The incidence rate of 210 patients with end stage renal disease (ESRD) per million population in the United States is the highest in the world. In your state alone, Mr. Specter, the number of people undergoing therapy for ESRD has increased from 4,988 as of December 31, 1984 to 10,749 as of December 31, 1993, or over 115 percent. In your state, Mr. Harkin, the number of patients undergoing treatment for end stage renal disease increased from 927 to 2,055 during the same time period, an increase of over 121 percent. Attached to my statement are tables that show for each state the dramatic rate of increase of people receiving therapy for end stage renal disease.

The highest percentage, 37.4 percent, of ESRD patients covered by Medicare are between the ages of 45–64 years old. The next largest group at 28.5 percent, is between the ages of 20–44 years old. ESRD is four times more likely in African Americans than in whites, and approximately 54 percent of those living with ESRD are male.

As I will discuss more fully in another section of my statement, the possibility of early death for those with end stage renal disease is with us every day. I am saddened to share with this Committee that since the ASN was here last year, Dr. Elziena Dawson from Chicago, who accompanied Dr. Bill Couser for last year's testimony and who was with us in Chicago when we presented Mr. Porter with our ASN Congressional Award, died earlier this year from post-operative complications following a kidney transplant. Dr. Dawson is one of 40,000 Americans who will die from kidney failure or its complications this year.

## WHAT CAUSES ESRD

The main causes of ESRD are diabetes (27 percent), hypertension (24 percent), glomerulonephritis (18 percent), and polycystic kidney disease (5 percent). Hypertension and diabetes affect minorities disproportionately, accounting for the higher incidence of ESRD in the minority population. Diabetes is the most common cause of kidney failure in Native Americans, and it leads to kidney failure more often in women than in men.

## DIRECT COSTS OF ESRD TO THE NATION

As the committee is well aware, over 90 percent of patients with ESRD and patients receiving kidney transplants are covered by Medicare, and kidney disease represents the single largest disease expenditure in the Medicare program. Over a four year period, 1991 through 1994, Medicare paid \$25.57 billion in claims for ESRD patients. And in just one year, 1994, the total estimated direct medical payments for ESRD by public and private sources was \$11.13 billion.

If we were to assume that the cost to the Medicare program for covering the health care services needed by patients with ESRD increases at a rate of 5 percent a year, then the cost to the Medicare program in 1997 would be approximately \$9.63 billion to cover dialysis and transplantation patients. This increase in cost would

occur despite the fact that payments for dialysis treatments in constant dollars have actually decreased since 1972, a truly remarkable example of federal cost containment.

The total funding at NIH for kidney disease research will be approximately \$202.6 million this year or just a little more than 2 percent of this country's direct cost to treat ESRD. The majority of this funding is at NIDDK, where the fiscal year 1997 appropriation is \$127.1 million. This is a very small percentage, yet it is my view and the view of the members of the American Society of Nephrology that an investment in research is the only real opportunity we have to reduce the enormous Medicare costs and human suffering imposed by ESRD.

#### WHAT ARE THE EFFECTS OF ESRD ON QUALITY OF LIFE

Medical research, made possible largely through Congressional support, has given the men, women, and children who suffer from chronic renal failure hope. Thirty-five years ago, ESRD patients died. Dialysis technology was in its infancy, available only for patients with acute rather than total renal failure. Kidney transplants were only a dream.

Since then, millions of Americans, have benefitted from dialysis or kidney transplants. However, while treatment often prolongs life, ESRD remains a serious medical condition. There is a misconception that the dialysis patient is able to live a full, active life. Sadly, that is not the case. Dialysis does not simply mean being hooked up to a machine three hours a day, three times a week. Dialysis patients commonly suffer bouts of anemia, nausea, fatigue, low blood pressure, chills, and itching (due to impurities in the blood). The body has difficulty adjusting to the frequent changes in toxicity levels, as toxins are removed and then build back up prior to the next dialysis. Many patients suffer depression, due to feelings of vulnerability and illness.

Children with chronic renal diseases present medical challenges not usually seen in adults. Children undergo continued somatic, mental and psychological maturation even in the face of ESRD. Therefore, an understanding of how these issues of normal development interact with chronic renal disease in the production of abnormal growth and development is the highest priority. This may be examined in the mechanism of disease progression, including identification of early markers of diabetic nephropathy in the child and the adolescent.

Despite the progress we have made and the possibilities on the horizon, the mortality rate for ESRD patients is still very high. Approximately 50 percent of dialysis patients die within a few years after they begin treatment. The life expectancy of a 49 year old ESRD patient is less than seven years, compared to 30 years for a healthy 49 year old American.

#### WHAT CAN RESEARCH OFFER TO PATIENTS WITH KIDNEY DISEASE

Nephrology research is addressing many issues that affect patients with kidney disease. We are defining the best dialysis regimens in patients with ESRD. In experimental animals, we are exploring treatments to prevent or shorten the course of acute renal failure. We have recently cloned the gene responsible for polycystic kidney disease and are now studying the protein to determine how it causes this disease. Hopefully, this discovery will lead to new treatments or preventions for this disease.

Research is also addressing the mechanisms by which glomerulonephritis is induced, with the hope that this will lead to strategies for prevention. A good example of this is the ANCA test, which is now available to help in the diagnosis of vasculitis.

Basic animal research led to clinical studies that have now established that the progression of chronic renal disease can be substantially slowed by: treatment of blood pressure to normal levels; use of specific types of anti-hypertensive drugs, that have kidney-protecting effects in addition to their action to lower blood pressure; and dietary protein restriction. These approaches may well be responsible for the recently noted slowing in the rate of growth of ESRD in the U.S.

Fifteen years of NIH-supported research established the role of increased blood pressure in the kidney itself as an important cause of the loss of kidney function. These findings stimulated a recent clinical trial that demonstrated that captopril, a drug that lowers blood pressure in the kidney, could also reduce the progression of diabetic kidney disease by about 50 percent, a finding that will save the Medicare program an estimated \$2.6 billion over the next ten years.

Additionally, decreasing the anemia that accompanies chronic renal failure by the use of erythropoietin has been shown to reduce the incidence of heart failure in dialysis patients. Heart disease is the main cause of death in such patients.

The ASN is hopeful that a doubling of the NIH budget over the next five years as called for by S. Res 15 and H. Res 83, can be achieved, and the ASN looks forward to working with each member of this Subcommittee and its Senate counterpart to accomplish this goal. ASN requests that this Subcommittee approve the increase of nine percent, as requested by the NIH professional judgement budget, as the first step towards a doubling of the NIH budget by 2002.

More specifically, for NIDDK and kidney research, it is our understanding that the President requested an increase of 2.2 percent over the 1996 level. This increase would place NIDDK in 16th place in relation to the increases the President has requested for other Institutes. Given the cost to human life and to the federal government caused by ESRD specifically, and of all the diseases for which research dollars are provided by the NIDDK, we urge this Subcommittee to provide a 9-percent increase to NIDDK, as well.

Mr. Chairman, that concludes our statements and we are prepared to answer your questions.

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PREPARED STATEMENT OF CHRISTINE STEVENS, SECRETARY, SOCIETY FOR ANIMAL  
PROTECTIVE LEGISLATION

Last year I submitted testimony to this Committee concerning the mistreatment of chimpanzees by The Coulston Foundation (TCF) of Alamogordo, New Mexico.

The most recent example of destructive incompetence at The Coulston Foundation concerned a chimpanzee from the Laboratory for Experimental Medicine and Surgery in Primates (LEMSIP) where he had lived for many years. His name was Jello. Defying all normal protocol for anesthetization, the animals were first fed, then anesthetized. According to the whistle blower, Jello choked on his own vomit. According to Coulston, the death was caused by an even more astounding violation of proper procedure for anesthetization, by anesthetizing several animals in the same enclosure simultaneously with Ketamine. Jello collapsed before the last chimpanzee went down and, staggering like a drunken individual, this chimp put his foot on Jello's throat. He could not be revived.

It appears that the turnover in veterinarians is such that proper procedures for handling of chimpanzees have been abandoned. The DHHS site visitors referred to in my last year's testimony expressed high praise for the head veterinarian, Dr. Pat Frost, for her management under difficult circumstances without adequate supporting staff. This January, Dr. Frost left The Coulston Foundation, and the bungled attempt to anesthetize three chimps in one go is likely to be followed by further egregious harm to other members of the huge colony.

According to a press release by In Defense of Animals: "Dr. Fred Coulston reportedly demoted Dr. Frost after she questioned conditions at the facility and then appointed himself as head of veterinary services. This brazen move by the controversial toxicologist, who has no formal veterinary training, shows TCF's total disregard for federal animal welfare laws and policies \* \* \* In June 1996, TCF agreed to settle the [USDA] charges by paying a \$40,000 fine, the second-largest ever levied against a research institution for violations of animal welfare laws."

Dr. Frederick Coulston has evidently been coached to avoid hostile comments about the hundreds of chimpanzees whose misfortune it is to remain under his tight-fisted control. He recently appeared on national television answering questions by Tom Brokaw and telling listeners that chimpanzees are too valuable to be retired (see his earlier sarcastic comments on retirement in attached testimony). He also misinformed the public by stating that chimpanzees do not get cancer.

On April 21st, New York University students and alumni demanded a federal investigation of the NYU chimpanzee transfer to Fred Coulston. Student Olga Boshard said: "NYU seems to have plenty of money to construct new secret animal laboratories here at the Washington Square campus, but we can't retire these poor chimpanzees. There was \$700,000 for chimp retirement that has literally been given away, and the retirement NYU promised is off forever."

NYU biology graduate James Hansen said, "This chimpanzee situation is out of hand, and the fact that this new lab construction is a secret speaks volumes for the case overall." His charge of secrecy is based on a confidential e-mail message to New York University faculty from the Dean for the Faculty of Arts and Sciences, which reads:

"I want to alert you to the fact that there is a resurgence of activity among animal rights groups focusing on NYU. Although their arguments are principally with the Medical Center, the protests occur here because of our more central and visible location and the presence of large numbers of students. It has been quiet for over a

year, but recent news stories that are only peripherally related to NYU have rekindled the situation and brought it back into public view. One of the organizations (Students for Education and Animal Liberation—SEAL) is attempting to directly recruit students and will be holding meetings and protests on campus from time to time. First, we keep a very low profile—there is little to no awareness of the presence of animals at Washington Square and we want to try to keep it this way. Even the construction on the roof is intended to be just another ‘biology laboratory.’ If any students approach you regarding this issue, the response is that we do everything that is legally and morally required to assure the health and well-being of any animals. If there is any organized approach including student newspaper writers, you should refer the group to the Press Office, Mr. John Beckman. If you notice any unidentifiable or suspicious individuals in or around our laboratories, especially the tenth floor of Brown, please notify our department office or security. Above all please try to be discrete and take care to keep the profile of animal usage as low as possible.”

Further shocking abuse of taxpayer funds, which went through NIH to Dr. Ron Wood of NYU, is documented by the U.S. Department of Agriculture in the course of its enforcement of the Animal Welfare Act: “\* \* \* the respondent significantly departed from the protocol by depriving nonhuman primates of water, in violation of section 2.3 1(a) of the regulations \* \* \* the respondent used deprivation of water to handle animals without IACUC [Institutional Animal Care and Use Committee] approval \* \* \* ” The complaint documents improper surgery and infection which resulted. The unfortunate monkeys, besides being repeatedly deprived of water, were receiving a drug toxic to the liver. When they died because of botched surgery, the autopsy showed an enlarged liver.

In spite of a record of 378 violations of the federal Animal Welfare Act, Dr. Wood remained at NYU until he took a leave of absence and, with a grant from NIH, moved to the University of Rochester. According to the *Campus Times*, November 21, 1996: “Wood’s research is funded by a 10-year National Institutes of Health grant, of which there are two years remaining. The grant, in the amount of \$417,266 per year, was originally awarded to Wood for his research at NYU \* \* \* Following the expiration of his original grant, Wood took an indefinite leave of absence from NYU and joined UR a year later. Wood’s grant was then reissued for use at the [University of Rochester] Medical Center.”

We strongly object to continued government funding of the Coulston Foundation and of Dr. Ron Wood’s crack cocaine experiments on macaques.

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PREPARED STATEMENT OF JOSEPH W. KEMNITZ, PH.D., INTERIM DIRECTOR, WISCONSIN REGIONAL PRIMATE RESEARCH CENTER, UNIVERSITY OF WISCONSIN—MADISON

Chairman Specter and Members of the Subcommittee: I am Dr. Joseph Kemnitz, Interim Director of the Wisconsin Regional Primate Research Center and Senior Scientist in the Department of Medicine at the University of Wisconsin School of Medicine. I am here to represent the seven Regional Primate Research Centers which are located at distinguished universities in the states of California, Georgia, Louisiana, Massachusetts, Oregon, Washington and Wisconsin. They receive support as part of the Comparative Medicine Program of the National Center for Research Resources of the National Institutes of Health (NCR—NIH). I am proud to have served the Wisconsin Regional Primate Research Center for 20 years, and I welcome the opportunity to come before this Committee and talk about the accomplishments and current needs of the primate centers.

Congress acted with great wisdom and foresight in 1960 to establish the national Primate Center Program by appropriating funds to build the seven centers we have today. In the nearly forty years since their establishment, it is increasingly clear that this was an excellent investment. These centers provide specialized and unique scientific capabilities not available through any other program within the Department of Health and Human Services. For a variety of reasons, including the ever-increasing complexity and sophistication of research questions and methodologies, the Primate Center Program is even more important today than when the centers were established. Well over 1,000 investigators depend on the Regional Primate Research Centers to conduct research supported by the National Institutes of Health as well as other governmental and private-sector sources. These investigators are not only those based at the primate centers, but also include regional, national and international scientists who rely on resources and expertise at primate centers to conduct their research.

The importance of nonhuman primates to progress in biomedical research cannot be overestimated. These animals are the closest surrogates for our own species,

sharing more than 90 percent of the genetic makeup with humans. This close genetic similarity results in marked similarities in anatomy, physiology and behavior that make these animals outstanding models, in some cases the only appropriate choice, for understanding human health and disease processes. Nonhuman primates are often the vital link between basic research and human application. Examples of significant accomplishments resulting from primate research abound in the fields of neuroscience, reproduction and developmental biology, and infectious diseases, among others.

Recent advances at Regional Primate Research Centers include increased understanding of the pathobiology of AIDS and the development of vaccines for protection against the disease. Indeed, the most prevalent model of AIDS, simian immunodeficiency virus, was established at Primate Centers. Our Center and others are now also engaged in research to prevent the AIDS virus from being transmitted from HIV-infected mothers to their babies.

Other advances include better understanding of fertilization and early prenatal development, another example of a research area where the nonhuman primate offers unique benefits because of similarities to humans and differences from other laboratory species. Nonhuman primate research is also leading to enhanced knowledge of the genetic basis of disease and immunity, of development of obesity and its complications such as diabetes and hypertension, and of specific women's health issues such as endometriosis, polycystic ovary syndrome, and of changes during and after menopause.

Very significant advances have also been made in the area of primate neuroscience. As Congress recognized in declaring this the "Decade of the Brain", neuroscience is now a highly productive and exciting research frontier, fueled by rapidly developing technologies. Primate center research has made significant strides in elucidating the neural mechanisms controlling voluntary movement, emotional behavior, and higher cognitive brain functions.

Older people represent the fastest growing segment of our population. People are living longer and there is a need to improve the quality of life of older individuals. Efforts are underway at our Primate Center and elsewhere to uncover the basic processes of aging in primates and to develop new approaches to postpone the development of age-related infirmities, such as cancer, osteoporosis, loss of muscle mass, impaired vision and neurological problems. We have promising preliminary evidence to suggest that diet can reduce the incidence, delay the onset and lessen the severity of some metabolic diseases associated with aging. New hypotheses regarding the mechanism of these beneficial effects of reduced caloric intake are now being tested.

In spite of their productivity the infrastructure at the Regional Primate Research Centers has had to cope with static base operating budgets. At one time the support for primate centers covered operating costs and research projects conducted at the centers. Today those base grants cover only a portion of the operating expenses and little or none of the research costs. The research projects themselves are now primarily funded through a rigorous system of peer review at NIH. The sum of these competitively awarded grants exceeds the size of the base grant by more than five-fold at some centers and requires resources exceeding those available in terms of animals, laboratories and support functions. We need additional operating funds in order to meet expeditiously the operational needs of the biomedical research community now.

The use of primates in research represents less than 1 percent of laboratory animal use overall, but the demand for primate research is increasing because of the unique insights these animals can provide to human health issues. It is noteworthy that nearly half of academic primate research is conducted at the Regional Primate Research Centers, where there is multidisciplinary focus on questions of basic biological and medical interest. Greater numbers of external investigators are requesting access to primate center resources for projects that require the nonhuman primate model. The increasing concentration of primate research at the Primate Centers reflects the need for special facilities for these complex animals and special expertise for their husbandry, veterinary care and psychological well-being that is available at these sites. The centers are cost-effective because of their already established expertise and also because of economies of scale. It is very important that the primate centers continue to provide continuity of research context in which to address new questions and challenges as they arise. Life-long care of these animals in a laboratory setting has also greatly extended their life-expectancy enabling initiatives in the study of aging.

The centers attempt to maintain self-sustaining colonies of the most commonly utilized species (for example, rhesus monkeys), which greatly reduces the need for removing animals from their natural environments and also provides better research subjects. For example, offspring of generations of laboratory-raised monkeys

have completely known histories and pedigrees, which are essential for better understanding of the genetic basis of disease susceptibility.

The Regional Primate Research Centers are nearly 40 years old and some renovation and replacement of facilities is becoming urgent, while expanded facilities are also required to catalyze the scientific opportunities into the next century. This is especially necessary for AIDS research and investigation of other infectious diseases which require special biocontainment capability. NCCR obtained construction authority from Congress in 1993 for the first time since 1969, and we are grateful for this support during the past few years. We are very concerned, however, that the President's budget request for next year's construction funding to NCCR is only \$4M, which is 20 percent of the award for last year. We request that every effort be made to restore the NCCR budget allocation to at least last year's level and that a portion of this be specifically targeted for the Regional Primate Research Centers, so that we can maintain state-of-the-art, competitive facilities and equipment.

In summary, the seven Regional Primate Research Centers have made substantial contributions in the realm of biomedical research and they will continue to do so. In order to accelerate progress, we ask that the base operating budgets for the primate centers be increased and that additional funding be allocated to renovation and new construction at these centers.

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PREPARED STATEMENT OF DAN LARSON, PRESIDENT AND CEO, POLYCYSTIC KIDNEY RESEARCH FOUNDATION

Dear Members of the Subcommittee:

I have the good fortune of serving as the President & CEO of the Polycystic Kidney Research Foundation, the only organization worldwide solely devoted to programs of biomedical research and patient information for polycystic kidney disease.

On April 24, 1997, I had the opportunity to provide personal testimony before the U.S. House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies. It just so happened that April 24th was also my 46th birthday!

Though one might think including this personal reference to be self-serving, it is not. I share this to make the point that though birthdays are a cheerful experience for people like me, for countless American's with polycystic kidney disease (commonly referred to as PKD), reaching such a milestone might well be a fearful occurrence. I am blessed with good health, I look forward to each new year, and I don't at all mind turning 46!

However, for 600,000 Americans and 12.5 million people worldwide who are afflicted with PKD, age 46 is the usual time when severe and life-threatening symptoms are occurring. Commonly, PKD causes patients at this age to experience high blood pressure, chronic fatigue and debilitating flank pain, recurrent urinary and kidney infections, enlarged heart and weakened valves, inguinal and abdominal hernias, diverticuli of the colon, pancreatic and hepatic cysts, life-threatening brain aneurysms and ultimately total loss of kidney function. PKD definitely has some very "sharp edges."

If I had PKD, by age 46 the picture on the front of this report would likely be what my "insides" would look like. Each of my kidneys, which normally should be the size of my fist (pictured on the right), could easily be the size of a football (or larger) and weigh as much as 38 lbs EACH (like the one pictured on the left).

If I had PKD, my kidneys would likely be shutting down by now, and by age 50 I would probably experience End Stage Renal Disease, commonly called "kidney failure." According to the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), PKD accounts for 10 percent of ESRD in America, making it the 3rd leading cause of kidney failure in the U.S.

Were I one of the 600,000 PKD patients in the United States, I would have the dubious distinction of having the most prevalent life-threatening genetic disease. Though not well known, PKD affects more individuals than the combined number of those with cystic fibrosis, hemophilia, sickle-cell anemia, muscular dystrophy and Down's syndrome!! PKD is two times more common than multiple sclerosis and twenty times more common than Huntington's disease \* \* \* and there is no treatment or cure.

PKD is not selective; it strikes children at birth, which is usually fatal, as well as adults in the prime of life. PKD is a dominantly inherited disease, equally affecting men and women, regardless of age, race or ethnic origin and it does not skip a generation. If I were a PKD patient, my children would have a fifty percent chance of inheriting it. In most cases, PKD produces kidney failure, requiring dialysis or a kidney transplant to survive. Although it is true that these therapies are

lifesaving, they certainly are not curative, and many patients receiving these treatments suffer from resultant life-threatening complications.

Since the Federal Government picks up most of the cost of dialysis and kidney transplantation, it is clear that an effective treatment for PKD (not to mention a cure) would yield more than a billion dollars annually in savings for the taxpayer.

Due to numerous recent major research breakthroughs, including the discovery of the two principal PKD genes and their protein products, polycystin 1 and 2, scientific momentum is clearly evident and provides the basis for greatly expanding PKD research. In fact, in recent years this committee as well as the Senate Appropriations Committee, have singled out PKD research progress in your reports, asking NIDDK to commit substantially more effort and resources into PKD research. The time is now for this fertile area of investigation to catch up.

Extraordinary scientific progress in PKD research is increasingly and widely hailed as noteworthy within the scientific community. In recent statements before this Subcommittee, NIH Director Harold Varmus, M.D., and NIDDK Director, Phil Gordon, M.D., have singled out advances in PKD research as gratifying examples of significant progress in understanding major genetic diseases. Additionally, Human Genome Project Director, Francis Collins, M.D., recently stated that, "though we know more about cystic fibrosis than we do about PKD, I believe that PKD research is likely to catch up fairly soon."

With all of this excitement about PKD research, it would surely not be amiss for this Committee to support a "step increase" of 50 percent in the overall PKD research allocation at NIDDK, from the current \$7 million to a modest \$10.5 million. This would greatly increase the likelihood of discovering a treatment or cure for polycystic kidney disease. This would be an excellent investment in future savings of countless lives, and tens of billions of dollars to the federal government. I urge the Committee to take advantage of this extraordinary opportunity for intervention by funding this effort accordingly.

I thank this Committee for its past support in winning the war on PKD.

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#### PORTRAIT OF A SILENT KILLER

This lethal disease is silently stalking more than 600,000 American's at this very moment. If you think it is frightening to look at, just imagine how its victims must feel. This genetically inherited abnormality can strike children at birth (generally fatal) or adults in the prime of life without preference to race or gender. It develops slowly, forming fluid-filled cysts which ultimately destroy otherwise healthy kidneys, vital life-supporting organs. There is no known cure or efficacious treatment.

Although over one billion dollars are spent annually through Medicare and Medicaid for dialysis, transplantation, and related treatments, there are surprisingly few dollars spent on PKD research. Occurring 2 times more often than MS, 10 times more often than Sickle Cell Anemia, and 20 times more often than Cystic Fibrosis or Huntington's Disease, PKD affects more than 12.5 million people worldwide. As the largest segment of our population, America's "boomer generation" reaches middle-age, adult PKD could reach colossal proportions. Skyrocketing healthcare costs will only be outweighed by needless suffering and loss.

The quickest, most "user friendly" method of conveying the nature of our mission is contained in the following five "word pictures", a laymen's description of our battle with polycystic kidney disease (PKD).

##### *"Water Balloons and Crabgrass"*

This is what we are up against. PKD, the most common life threatening genetic disease, causes water balloon type cysts to grow in the kidneys. Though innocently looking, over time a cyst can grow to the size of an egg (or a baseball) and together with hundreds of likesize cysts, enlarge a kidney to be the size of a football or larger. As they grow, cysts crowd out kidney function, and ultimately cause the kidney to fail.

Treating PKD is similar to treating a lawn for crabgrass; a person can dig it out, spray it, or pre-emerge a chemical to prevent it. With PKD, some surgeons have been able to surgically drain cysts, the equivalent of trying to "dig" it out. However, this procedure has not been highly effective and has many risks.

Recently studies on laboratory animals at UCLA have shown some success treating PKD mice with taxol, the equivalent of a "spray" to stop PKD. This is a promising area of potential intervention, but much more must be done.

Finally, since the two genes for PKD have now been identified and their protein products (polycystin 1 and 2) have been discovered, scientists strongly believe that

in the not-too-distant future a gene therapy can be developed to be “pre-emerged” to correct the genetic defect and prevent PKD from being expressed.

*“D-Day”*

In June of 1944, D-Day marked the “beginning of the end” of World War II. In June 1994, the war with PKD had its D-Day when the gene that causes 90 percent of PKD was identified. Researchers truly call this the beginning of the end. Now they can much better understand the proteins expressed by the PKD genes and develop methods of treating and curing this disease.

As in 1944, once a beach head was established on D-Day, what won the day (and eventually the war) was the Allies ability to re-supply more arms and men than the Third Reich could destroy. However, in our struggle with PKD, the “beach head” has been established but there are limited resources currently available to mount successful attacks on PKD through biomedical research. The National Institutes of Health (NIH) can only fund a small percentage of the cutting edge scientific projects it receives.

Current and future generations of PKD families need the assurance that PKD can and will be conquered, and sooner \* \* \* not later. But without cultivating new resources, victory may be too late for many.

*“Underdogs”*

The PKR Foundation is fifteen years old but still too few people know about PKD and the PKR Foundation. This in spite of the fact that there are 600,000 Americans with this life-threatening disease. A comparison might be helpful.

Multiple Sclerosis affects about 300,000 Americans, half of that of PKD. However, the MS Society has been around since 1946, it has 90 Chapters, 55 Branches, multiple hundreds of staff, and an income budget of \$110 million per year.

In contrast, the PKR Foundation represents twice the disease prevalence of MS. However, we have no Chapters or Branches, we have a total of 7.5 staff (full-time employees) and a budget of \$1.5 million. Interestingly, we are the only organization worldwide solely devoted to programs of biomedical research and patient information for polycystic kidney disease.

In 1997, according to the National Journal, the following is the amount of money that the federal government is spending on research on some well known diseases:

[Dollars in Millions]

	1997 Spending <sup>1</sup>	Afflicted in U.S.	Amount Spent Per Affected Person
AIDS .....	\$1,500	205,102	\$7,313
Heart Disease .....	923	13,500,000	68
Breast Cancer .....	509	2,600,000	196
Diabetes .....	313	16,000,000	20
Parkinson's .....	78	1,000,000	78
This year, total spent on research for PKD is .....	7	6000,000	12

<sup>1</sup> Source: National Institute of Health estimate.

It's easy to see that we are fighting an uphill battle.

*“Conversions”*

Though not evangelists, we are wholeheartedly committed to conversions. We convert ignorance into knowledge through our professional and public education programs. We convert despair into hope through our patient education seminars and communications. We convert isolation into community through our Friends Program \* \* \* volunteer groups around the U.S. who reach out to PKD patients and their families. We convert ideas into reality through the research we fund and we convert small dollars into large dollars by funding starter grants and by working with congress to intensify funding for the National Institutes of Health, in support of PKD research.

*“Shoe Leather”*

The PKR Foundation offers interested individuals the opportunity to be a part of the PKD solution. They can transfer their interest into action in a number of ways. People can organize a Friends Group, helping the Foundation gain awareness and promote patient education, support and membership. They can lobby congress \* \* \* write, call or visit their congressional representatives about the importance



of PKD research. They can become a Member and financially support the PKRF mission. They can help us get the word out by encouraging media contacts they know to help convey our mission. Or they can help us by providing linkage to a potential source of research or educational funding.

We are collectively committed to conquering this disease and have found our efforts to be more successful when pooling our time, talents and resources.

#### PREPARED STATEMENT OF NEW YORK UNIVERSITY MEDICAL CENTER

On behalf of the New York University Medical Center (NYUMC), I would like to express our gratitude for the opportunity to submit this statement for consideration by the Subcommittee.

New York University (NYU) was founded in 1831 and is the largest private university in the United States, with an enrollment of 50,200 full time and part time students. The NYUMC, an integral component of NYU, encompasses one health care philosophy with three key priorities: education of future physicians, exemplary patient care, and innovative scientific research. NYUMC is recognized as one of the nation's leading biomedical resources, combining excellence in patient care, research and medical education.

The NYUMC complex is comprised of the NYU School of Medicine and Post-Graduate Medical School, Tisch Hospital, the Rusk Institute of Rehabilitation Medicine, the Hospital for Joint Diseases and the New York Downtown Hospital.

Approximately 29,000 patients are admitted to NYUMC's Tisch Hospital annually. In addition, NYUMC faculty serve as the attending physicians at Bellevue Hospital, which is New York City's largest municipal hospital where over 400,000 patients are treated each year. The NYU/Bellevue campus provides care to the largest AIDS and TB patient populations in New York City, NYU physicians also staff the Goldwater Memorial Hospital—the city's largest chronic care facility. The facilities of the NYUMC complex support basic and clinical research in a wide variety of serious and debilitating diseases such as Acquired Immunodeficiency Syndrome (AIDS), Tuberculosis (TB), breast and prostate cancer, diabetes and other important endocrine abnormalities, cardiovascular diseases, neurological diseases (including Alzheimer's) and genetic and developmental abnormalities.

I would like to thank you, Chairman Specter, and members of the Subcommittee, for your leadership in the field of biomedical research. Over the years, you have clearly demonstrated that you recognize that today's investments may be tomorrow's cures. As the Federal government continues to invest more in research and technology, we are advancing our knowledge about the prevention and treatment of disease. In the past few years, we have witnessed astonishing advances in biomedical research. As both this Subcommittee and the National Institutes of Health (NIH) have shown, basic research drives the continuing success in medical discoveries that may prevent, or even cure, some of the most complicated and dreaded diseases.

I am pleased that the President's fiscal year 1998 budget includes \$13.3 billion for university-based research which represents an increase of \$289 million over 1997. With continued strong Federal support of medical research, our researchers will be able to capitalize on many of the opportunities that exist in basic and clinical research and will help the United States maintain its world-renowned leadership in biomedical research. NYUMC urges Congress to support the recommendation of the Ad Hoc Group for Biomedical Research which advocates a 9 percent increase for the NIH in fiscal year 1998.

However, NYUMC is concerned with the recommendation in the President's budget to drastically reduce funding for health professions education and area health education centers. I urge the Subcommittee to review the enormous success of these programs and to consider funding levels consistent with past years.

In addition to supporting basic biomedical research, I would also like to thank you and the members of your Subcommittee for recognizing that the Federal government has an important role to play in the development of our nation's technology infrastructure. The rapid development of communications and information technology presents enormous opportunities for transforming the health care delivery system and increasing access to quality health care for traditionally unserved and underserved groups. Telemedicine has applications in patient care, education, and research. NYUMC has a number of exciting technology initiatives underway and under development in these areas.

One proposed initiative would develop a provider network to facilitate access to family-based HIV/AIDS primary and specialty care linked to community, mental health, and substance abuse services for HIV-affected, women, children, and adolescents. This initiative recognizes that HIV-infected women with children face a num-

ber of barriers to care. Certain services, such as mental health and substance abuse services, are particularly difficult to assess and are limited in availability to this population. The proposal offers the prospect of understanding current service delivery patterns, which are dictated in large part by funding streams rather than family need, and of identifying opportunities for more efficient service delivery.

Another project underway at NYUMC is the development of a high speed data communications network which will enable NYUMC and its affiliated hospital organizations to share selected business, clinical, and research information, and to develop and share advanced information systems as partners in an integrated health care delivery system. The utilization of such information, some of which would be in the public domain via internet access, would allow for enhanced communication of clinical and research information to the general public and to professionals.

The National Library of Medicine (NLM) has played an important role in improving health care information sharing among researchers, clinicians and educators through the implementation of the national information infrastructure and the internet. In addition, NLM has supported projects to evaluate the cost effectiveness, quality, and potential to increase access, of telemedicine networks. NYUMC supports these efforts, and is pleased that the President's budget recommends an increase for NLM over fiscal year 1998.

Technology has important applications in the area of education as well as health care. I am pleased that the President's fiscal year 1998 budget increases funding for a number of advanced computing and telecommunications initiatives. NYUMC shares the President's belief that in our efforts to develop our information infrastructure, we must ensure that it does not bypass our classrooms. The fiscal year 1998 budget includes \$500 million in fiscal year 1998 for two important technology programs—the Technology Literacy Challenge Fund and the Technology Innovation Challenge Grant program. This is the second installment of the President's \$2 billion Technology Literacy Challenge Fund to encourage states and communities, in conjunction with private partners, to develop and implement plans for fully integrating educational technology into their school curriculum.

NYUMC believes that the twenty-first century education and work environment can only be achieved through the integration of the computer and modern communications technologies. The Hippocrates Project, established in 1987, is an example of why the NYUMC is considered to be one of the nation's leaders in applying computers to medical education. Hippocrates is a multi-disciplinary effort that explores the ways that information technology can augment the learning process. NYUMC faculty are also using the latest technological advances, such as the use of virtual reality for clinical training and new educational technologies to abbreviate the time students now spend in the classroom. Such computer based information systems and internet access of selected information will play an important role in the transmission of information relating to basic and clinical research as well as the latest approaches in treating disease.

The Department of Education funds a number of important programs that seek to address problems and encourage improvement in postsecondary education by funding innovative projects. One such example is the Fund for the Improvement of Postsecondary Education (FIPSE). We encourage Congress to continue to support FIPSE in fiscal year 1998. The Office of Educational Research and Improvement also funds programs that seek to promote excellence in teaching through professional development programs, as well as through the development and implementation of educational technology.

All of the initiatives underway and under development at NYUMC described above offer the promise of ensuring that we continue to train high quality physicians, deliver health care services more efficiently and effectively as well as to increase access to the medically underserved. All of these initiatives depend upon having the Federal government as a partner to achieve these ambitious goals. NYUMC looks forward to continuing to work with members of this Subcommittee to ensure that we deliver the benefits that these initiatives promise to millions of individuals.

Thank you, Mr. Chairman and members of the Subcommittee, for allowing me this opportunity to submit testimony on behalf of NYUMC.

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#### PREPARED STATEMENT OF THE SOCIETY OF TOXICOLOGY

The Society of Toxicology (SOT) is pleased to have this opportunity to submit written testimony in support of fiscal year 1998 funding for the National Institutes of Health (NIH), and specifically for the National Institute of Environmental Health Sciences (NIEHS).

The Society of Toxicology (SOT) is a professional organization that brings together over 4,000 toxicologists in academia, industry, and government. A major goal of SOT is to promote the use of good science in regulatory decisions. With scientific data as our guide, we can use sound judgment in addressing numerous environmental issues. In particular, we work closely with the National Institute of Environmental Health Sciences (NIEHS) in addressing research related to environmental risk.

One program we would like to highlight is the Superfund Basic Research Program. This program is administered by NIEHS although it is funded through a pass through from the Environmental Protection Agency (EPA) to NIEHS. SOT is interested in Superfund because the cleanup of hazardous waste is an enormous undertaking which can be greatly facilitated through toxicology research. The Superfund Basic Research Program is the only scientific research program focused on health and cleanup issues for Superfund hazardous waste sites.

The Superfund Hazardous Substances Basic Research Program supports university and medical school research to understand the public health consequences of local hazardous waste sites, as well as to develop better methods for remediation. Currently, there are 18 programs at 70 universities involving more than 1,000 scientists.

The primary purpose of SBRP is to provide the scientific basis needed to make accurate assessments of the human health risks at hazardous waste sites. In addition, research data is used to determine which contaminated sites must be cleaned up first, to what extent clean up is needed, and how best to clean up contaminated sites in the most cost-effective manner. This is accomplished by developing more rapid and cost-effective strategies for measuring the existence and movement of chemicals in and around waste sites, placing major emphasis on technology to detect these chemicals in humans and to analyze their effects. Collaboration between engineers and physical chemists is encouraged to better understand how chemicals are physically trapped in soils so that improved clean-up strategies may be devised. In addition, basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances are developed.

Research projects include basic research on the potential chemical effects on cancers, such as breast and prostate, birth defects, and other environmental health-related diseases. The interaction, common goals, and exchange of knowledge that result from this research program are among the most highly developed in the United States public health, environmental sciences and engineering communities. Moreover, it is important to note that this is the only university-based research program that brings together biomedical and engineering scientists to provide the science base needed for making accurate assessments of human health risks and developing cost-effective cleanup technologies.

Much progress has been made as a result of research conducted under the auspices of the SBRP. This includes discoveries about the neurotoxicity and estrogenicity of PCB's, advancements in mechanisms to assess the risks to human health of hazardous waste exposure, toxic mixtures, and arsenic in drinking water, and developments in remediation technologies which ensure timely and cost-efficient cleanups.

We believe the Superfund Basic Research Program is critical to the success of the Superfund hazardous waste cleanup program and much of this success is due to the tremendous effort NIEHS has done in administering the program. Funding for SBRP represents a tiny percentage of the total funding provided for hazardous waste cleanup. Unfortunately, every year we fight a battle with the President and EPA to continue funding this research. Once again, in his budget, the President has requested a 21 percent decrease in funding for SBRP. Last year the President requested a 60 percent funding cut. We have testified before the House Appropriations Subcommittee on Veterans Affairs, Housing and Urban Development and Independent Agencies, and have urged them to reject the President's request and fund this program at \$37 million, the level recommended in the pending Superfund reauthorization legislation.

Communities near hazardous waste sites want to know if hazardous chemicals are reaching their water or air supplies. They want to know if low levels of these contaminants affect their health and their children's health. They want it cleaned up. Our universities are responding with technology driven research efforts which are results-oriented and economically feasible, and are scientifically credible with the public. This is only possible because of the research effort funded through the Superfund Basic Research Program.

Members of the Society of Toxicology strongly believe that our investment in medical research is well worth it. We are appreciative of the efforts of NIEHS and are supportive of the research priorities identified by NIEHS Director Dr. Kenneth

Olden. NIEHS has been very effective in raising public awareness about the linkages between the environment and human health.

Research supported by the NIH and NIEHS is helping us to understand how our environment affects our health. Research is being conducted to study the effects of air pollution such as ozone, particulate matter, and acid aerosols on our respiratory health. NIEHS supported research has shown the health effects of lead, leading to the reduction of many sources of environmental lead. Researchers are now expanding their efforts to better understand why some people are more susceptible to environmental exposures than others. The new Environmental Genome Project will further explore these questions. Finally, NIEHS under the auspices of the National Toxicology Program are developing new mouse models to more efficiently test the toxicity of chemicals. This increased efficiency will allow for more chemicals to be tested.

Therefore, we urge you to double funding for the NIH over five years as recommended in S. Res. 15. This would require a 15 percent increase in NIH funding for fiscal year 1998. In addition, we urge you to increase funding for NIEHS by \$40 million over last year's level for a total of \$348 million. This would bring NIEHS' funded grant level to the NIH average. NIEHS currently funds only 21 percent of all grant applications.

Thank you for considering our request. We look forward to working with you in the future as you determine the Committee's funding priorities.

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PREPARED STATEMENT OF RAYMOND FONSECA, DEAN AND PROFESSOR OF ORAL MAXOFACIAL SURGERY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF DENTAL MEDICINE

Thank you, Chairman Specter, for inviting me to submit testimony for inclusion in your Subcommittee's fiscal year 1998 hearing record. I am Raymond Fonseca, Dean and Professor of Oral Maxofacial Surgery at the University of Pennsylvania School of Dental Medicine (UPSDM). On behalf of UPSDM, I would like to express support for the National Institute of Dental Research (NIDR), the National Library of Medicine (NLM), and the National Center for Research Resources (NCRR).

Penn's School of Dental Medicine was established in 1878, and is one of the oldest university-affiliated dental institutions in the nation. Over its one hundred and nineteen year history, Penn has remained at the forefront in teaching and implementing the newest and best diagnostic, prophylactic, and curative techniques.

*National Institute of Dental Research*

UPSDM has a longstanding tradition of excellence in oral health research, and I am proud to note that our faculty have had great success in obtaining funding from NIDR.

During fiscal year 1998, the National Institute of Dental Research (NIDR) plans to enhance research in the areas of oral cancer, opportunistic infections associated with immunodeficiency, chronic pain, biomimetics and drug development. NIDR is also playing a significant role in several trans-NIH special initiatives in fiscal year 1998, including: the biology of brain disorders, therapeutics/drug development, and the genetics of medicine.

To ensure that NIDR will be able to continue to expand research to address the full range of basic, translational, clinical, and demonstration research with regard to craniofacial health and disease, it is critical to increase funding in fiscal year 1998 for the National Institutes of Health. Penn supports the professional judgment budget and the recommendation of the Ad Hoc Group for Biomedical Research of a 9 percent increase for NIH in fiscal year 1998.

*National Library of Medicine*

UPSDM has made one of its highest priorities the development of new technologies to enhance our educational, research, and service missions. In fact, UPSDM was one of the first dental schools in the nation to establish a computer program for dental students. Besides being introduced to usual business applications, such as word processing, database management, and electronic spreadsheets, they are also shown the various ways in which information technology is and can be used in dental care delivery, i.e., dental practice management programs, clinical charting programs, national dental networks, and clinical patient management programs.

The National Library of Medicine (NLM) has been a leader in implementing the national information infrastructure, which is an effort to develop a structure to share information among researchers, clinicians, and educators. This information infrastructure has important applications in the area of health care, and NLM continues to fund innovative projects that attempt to: design telemedicine networks; meas-

ure the effectiveness of networks; develop mechanisms to ensure the privacy of medical records, and other important issues. These projects will provide us with important information about telemedicine and its applicability to broader populations and geographic areas. I am pleased that the President's budget includes an increase for NLM in fiscal year 1998.

*National Center for Research Resources*

The National Center for Research Resources (NCRR) at NIH plays an critical role in improving and maintaining our nation's biomedical research infrastructure. By supporting the construction and renovation of research facilities, NCRR fosters the growth of biomedical research and ensures that we will be able to maintain our leadership in this area. A 9 percent funding increase for NIH will enable NCRR to continue to meet its ambitious mission of serving as a catalyst for discovery for NIH-supported research throughout the nation.

UPSDM was the first and only dental school to receive a general clinical research grant from NCRR, and I am hopeful that NCRR will continue to support research for oral health care.

Thank you again, Mr. Chairman, for allowing me to submit this testimony for consideration by your Subcommittee.

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PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the 30,000 children and young adults with cystic fibrosis (CF), the Cystic Fibrosis Foundation (CFF) is pleased to submit public witness testimony to support fiscal year 1998 appropriations for the National Institutes of Health (NIH). Specifically, we request your continued support of research activities sponsored by the National Institute on Diabetes, Digestive and Kidney Diseases (NIDDK) and the National Heart, Lung and Blood Institute (NHLBI). Your past vote of confidence in the NIH has made the future of individuals with CF much more promising. This important investment in the NIH has led to pioneering gene therapy experiments in patients, and has paved the way for developing other new approaches to successfully manage and eventually cure CF.

Before we discuss our request for fiscal year 1998, we would like to thank this Committee for its past support of the NIH. We are acutely aware of how difficult the decision making process is in such a restrictive fiscal environment. The Foundation applauds the Committee for the specific CF language included in the fiscal year 1997 Appropriations bill. As you are aware, this played an important role in the internal allocation decisions made at the NIH last year.

Because of your support of the NIDDK and the NHLBI, nearly 30 innovative new projects were initiated last year as a result of a special request for applications. In addition, the Foundation, through its innovative program which funds "meritorious" grants that are unfunded by the NIH, was able to fund an additional 59 projects. Together, we can confidently say, that all scientifically meritorious grants submitted in response to the announcement are now underway. This clearly exemplifies a dynamic partnership between a Foundation, the Congress, and the Federal research community.

The NIH and the CFF continue to work together, providing a base for leadership in this country that is unparalleled. This leadership is critical to continue the programs that will one day find a cure for this deadly disease. Already we have achieved a wonderful pipeline of new scientific discoveries that will be translated into lifesaving treatments for thousands of individuals with CF. Much of the progress in CF research has been made possible because of this Committee's continued support and vision to nurture and expand biomedical research in our nation.

Despite all of this, individuals with CF remain in an environment of uncertainty, cautiously optimistic as they wonder how CF research will continue to move forward. This year, you will hear testimony punctuating the need for increased federal funding for many entities, including medical research. It is our hope, however, that one day there is not going to be a need for extensive deliberation—not because an infinite pool of resources has suddenly become available to draw from, but because a portion of the need has been eliminated. For individuals suffering the death sentence of cystic fibrosis, the need will be eradicated the day researchers correct CF cells permanently. This will be the ultimate victory for patients who have fought a courageous, yet exhaustive fight against this disease for so long.

When we are young, we believe we are invincible. For individuals with cystic fibrosis, that gleaming ray of youthful arrogance is clouded by the shadow of a merciless chronic disease—a disease that introduces a chilling reality into the minds of these patients early on, that the road of life is a finite one.

You have the ability to give back the carefree outlook robbed away from children and young adults with CF. The Foundation once again asks for your help as we set forth, together, to write the final chapter of our success story.

Gene therapy research holds tremendous promise for individuals with CF. Gene therapy trials, involving more than 100 patients with CF, are taking place throughout the country. Nine research centers jointly funded by the CFF and the NIH are evaluating gene therapy technology and developing new vectors. The CFF/NIH Gene Therapy Centers are located at: the University of California at San Francisco; Johns Hopkins University; Cornell University; the University of Iowa; the University of Pennsylvania; the University of North Carolina at Chapel Hill; the University of Cincinnati; the University of Washington at Seattle; and Baylor College of Medicine. We strongly encourage you to recommend continued support of these gene therapy centers of excellence, as well as other center-based programs aimed at further understanding the pathogenesis of CF. Through the continued support of programs supported by the NIDDK and the NHLBI, we are optimistic that new therapies will continue to be forthcoming and have a positive impact in the lives of individuals with CF.

The unique synergy between the NIH and the emerging biotechnology community must continue to be finessed. The infusion of research dollars into the NIH will assure viability of the evolving biotechnology industry. An increase in NIH funding ensures that future scientists and clinicians will be trained to keep the United States on the cutting edge of biomedical technology. Pulmozyme, the first new drug developed specifically for CF in 30 years, is a product of the U.S. biotech industry. The CFF works aggressively to see that new therapeutic interventions move quickly from the test tube to the bedside.

More than a dozen new CF drugs are charted to begin clinical trial investigations. Phase III clinical trials have already been completed for the drug TOBI. This reformulated antibiotic, now an aerosol, successfully manages chronic *Pseudomonas aeruginosa* infections in many individuals with CF. Phase I clinical trials of aerosolized uridine triphosphate (UTP), DMP-777, and CPX are underway as well. UTP helps to liquefy CF mucus by stimulating chloride secretion. DMP-777 may interrupt the viscous cycle of CF inflammation by inhibiting the over-production of destructive enzymes released by excess white blood cells. CPX is an innovative synthetic compound that binds to the defective CFTR protein inherent in CF cells, and repairs it.

To facilitate the initiation of clinical trials, leading Foundation researchers are developing a centralized clinical trial network. This new innovative network equipped with standardized tools, laboratories, and techniques, will facilitate Phase I and II drug development. We ask that this Committee direct the NIDDK, NHLBI, and the National Center for Research Resources to develop key mechanisms to assure rapid translation of basic research into new therapeutic interventions. While we applaud the acquisition of new knowledge through current programs at the NIH, a mechanism must be created to nurture clinical research. Creative development of an institutional infrastructure, similar to that already in existence to support basic research in teaching institutions, should be created to support and monitor ongoing clinical trial investigations.

The Foundation understands current funding constraints and that federal programs—regardless of their merit—have been placed in competitive positions. Stable, long-term funding will not be possible without a dedicated funding source. Thus, the CFF enthusiastically supports S. 441, the “National Fund for Health Research Act,” proposed by Senators Specter and Harkin, which would provide a supplemental funding source for the NIH through a one percent surcharge on health insurance premiums. However, we urge Congress to seriously consider our request to double NIH appropriations over five years, requiring a 15 percent increase in funding for fiscal year 1998. At the very least, we support the recommendation of the Ad Hoc Group for Biomedical Research for a minimum of a 9 percent increase, so that the institution may grow to take advantage of the specific opportunities that abound.

The futures of many young individuals hang in the balance now. Please do not keep them waiting.

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PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

The non-profit American Heart Association, powered by 4.2 million volunteers in virtually every community throughout the nation, is alarmed that federal government, through its National Institutes of Health and the Centers for Disease Control and Prevention, is not devoting sufficient resources for medical research and preven-

tion of our nation's number one killer—heart disease—and to our country's number three killer and most disabling disease—stroke.

Some 57 million Americans of all ages suffer from heart disease, stroke and other cardiovascular diseases. The absolute number of Americans with heart disease is expected to increase dramatically with the aging of the “baby boomer” generation. While heart disease and stroke occur at all ages, they are most common in people over 65—an age group that is now about 13 percent of the U.S. population and will be 20 percent by year 2030. Heart attack, stroke and other cardiovascular diseases do not begin late in life. They often begin in childhood and progress through mid-life. Thus, our research and educational efforts must be targeted at populations of all ages.

Thanks to advances that already have occurred in defining and countering the risk factors for heart disease and stroke and in the treatment of these and other cardiovascular diseases, more people are surviving heart attack and “brain attack” (stroke), and in many cases, are developing these diseases at later ages than did their parents or grandparents. Due to these accomplishments made possible by previous investment of funds for research and education by the federal government as well as the American Heart Association, heart disease and stroke have evolved into chronic—or long-term—health problems much like diabetes and arthritis. No longer does a heart attack or stroke necessarily mean immediate death. But, they usually can mean long-term disability, requiring costly medical attention, and loss of productivity and quality of life. Over the last 20 years there has been a dramatic increase in the indicators of prevalence of heart disease and stroke. This situation will worsen in the 21st century.

Cardiovascular diseases already are a staggering burden to our nation's health care system, consuming about 1 out of 6 health care dollars, with a price tag in medical expense and lost productivity of \$260 billion per year. No other disease costs this nation so much money, and that amount is expected to increase dramatically with the growth of the senior citizen population and as a consequence of the relatively recent trends, in all ages of our population—but particularly in the young—of smoking, obesity and physical inactivity, which are among the several risk factors for heart disease and stroke.

The American Heart Association challenges our government to invest additional funds in cardiovascular disease research. Our government's response to this challenge will help define the health and well-being of citizens in the next century. We have a choice between: a nation of physically and mentally healthy citizens, capable of enjoying an active, productive life, living as independently as they wish late into their lives; or a population of frail elderly individuals, disabled by stroke and congestive heart failure, the latter too often the end-result of heart disease.

*Federal support for heart disease and stroke research and education:*

The AHA remains a strong advocate of increased overall funding for NIH and CDC, since the programs of both agencies contribute to the health and well-being of our nation's citizens. NIH research maintains America's status as the world leader in biotechnology and pharmaceuticals. As a member of Research!America, AHA subscribes to their call, based on state poll results, to double the medical research budget by year 2002. AHA supports measures in Congress to reach this goal for NIH.

However, the AHA believes it must exhibit the self-interest appropriate to a non-profit organization dedicated to reducing death and disability from diseases that rank as our population's number one and three killers. Therefore, speaking for the 57 million Americans who today suffer from cardiovascular diseases and millions who are now healthy but who are susceptible to developing these diseases, the AHA must demand that the historical pattern of federal government underfunding of heart disease and stroke research and education be reversed, and that research on these diseases be funded at a level that reflects the tremendous impact of these disorders on the population and the exciting research opportunities that exist in cardiovascular science.

Therefore, the AHA asks the U.S. Congress to insure that the NHLBI's heart research and NINDS' stroke research programs be doubled in absolute dollars by year 2002. These funds would help insure that existing programs be funded at an adequate level and that investments are made in new initiatives, identified later in this document.

For reasons that are unclear, many people have labored under the misperception (based perhaps on several recent successes in treatment) that cardiovascular diseases are solved problems, and as a result the seriousness of public health messages about healthy lifestyle have been undermined, and there has been devastating underfunding of NIH research on heart disease and stroke. Now is the time to cap-

italize on progress in understanding heart attack, stroke and other cardiovascular diseases when promising, cost effective breakthroughs are on the horizon. These research advances could pave the way to disease prevention and even a cure.

However, if adequate funding of heart disease and stroke research exists the following could occur:

- We will examine how heart disease and stroke begin at the most basic level (inside the cells lining the blood vessels to the heart and brain) and the genetic factors that influence each individual's risk for developing the disease and his/her response to medical treatment. Armed with this knowledge, researchers will be better equipped to design prevention and treatments that will bring heart disease and stroke down from their current ranks as the number one and number three killers, respectively.
- Talented physicians and scientists dedicated to the prevention and treatment of heart disease and stroke will be nurtured by NIH grants designated for scientists under the age of 40.
- Pharmaceutical and biotechnology companies will be able to develop many more effective drugs and other treatments because they have lacked new knowledge that traditionally has emerged from NIH supported basic research on such exciting topics as the interplay of cells, fat particles in the blood and inflammation inside the blood vessel in causing the obstructions that cause heart attack and stroke.

The following outlines the American Heart Association's recommendations for funding levels at NHLBI, NINDS, CDC and various other agencies.

*National Heart Lung and Blood Institute:*

A serious shortfall has occurred in NHLBI's funding of its extramural Heart Program. In constant dollars from fiscal year 1986 to fiscal year 1996, the overall NIH budget increased 35.9 percent—while funding for the Heart Program decreased 5.5 percent. If the mission of reducing cardiovascular diseases had been pursued with the vigor that these diseases deserve, considering their impact on society, there would have been an additional \$303 million dollars in the Heart Program's research budget in 1996.

This situation must be corrected. The AHA recommends that NHLBI's budget be doubled by the year 2002. To reach this funding goal, AHA recommends a fiscal year 1998 NHLBI appropriation of \$1.65 billion, including \$834 million for the Heart Program. Of the latter amount, AHA requests that \$790 million be dedicated to supporting existing programs and \$44 million be invested in the following promising research initiatives:

*Origins of atherosclerosis.*—A heart attack is the end result of a disease process called atherosclerosis, in which a blood vessel to the heart becomes obstructed by deposits of cholesterol and other material. If the origins of these blockages were understood, many heart attacks possibly could be prevented. Scientists know that blockages begin when the inside wall of a blood vessel is injured by too-high levels of "bad" cholesterol in the blood, high blood pressure and other factors (possibly including defective genes) that are not yet understood. The injury ignites an inflammatory process that over time creates scar tissue in the vessel wall. Ultimately, the scar tissue can rupture, creating the blood clot that can obstruct blood flow to the heart and cause a heart attack. More research is needed to understand the nature of the blood vessel wall, the role of genes in influencing the reaction of the blood vessel to cholesterol and how the vessel's inflammatory response to injury can be controlled.

*Congestive heart failure.*—Five million Americans suffer from congestive heart failure, the single most frequent cause of hospitalization for those age 65 and older. In the past 16 years, the number of hospitalizations for congestive heart failure has more than doubled. More research is needed to understand how and why the disease occurs and how it can best be treated and prevented. Among the several promising treatments that the AHA believes deserve to be evaluated include: surgical techniques to remove dilated and non-functioning heart muscle; left ventricular assist devices, regarded as possible bridges to and even substitutes for a transplanted heart; and use of animal hearts for transplant. Another exciting treatment needing additional study would transplant healthy heart cells from a donor onto the failing heart of the person with congestive heart failure.

*Heart disease in infants and youth.*—Prevention and treatment of heart diseases present at birth depend on improving scientific knowledge about how the heart develops from the embryonic stage. Many different types of cells must work together if the heart is to develop normally. The heart diseases that afflict infants and young children occur when these different cells do not work together. Scientists believe that this occurs because the hereditary material—the genes—of these cells are de-



fective. Researchers have already identified the sites on human chromosomes related to certain heart defects. They are also trying to pinpoint the genes responsible for the defects. However, much research is needed to understand these chromosome sites and to locate other sites responsible for other heart diseases. After specific genes involved in congenital heart defects are identified, more effective prevention and treatment of this nation's most common birth defect should be possible.

*A healthy lifestyle.*—Most Americans know that smoking, physical inactivity and being overweight are unhealthy. Why then are more teenagers smoking cigarettes, more people overweight, and less than 25 percent of the population physically active? The answer is that awareness of healthy—or unhealthy—behaviors such as smoking does not always translate into healthy actions. Research is needed on behavioral modification and long-term compliance if we are to have effective educational and public health approaches that change people's behavior. Also needed is more research about the role of nutrition in preventing heart attack, stroke and other cardiovascular diseases. There are many unanswered questions about the heart-healthy benefits of a diet that is high in fish oils, polyunsaturated fat, or dietary antioxidants such as vitamins E and C and low in trans fatty acids. Because a healthy diet is an anti-heart disease and anti-stroke diet, findings from this research will affect the entire population.

*National Institute of Neurological Disorders and Stroke:*

Stroke is the main cause of permanent disability in this country and America's number three killer. Death rates from stroke have declined for many decades, but a 10 percent increase in stroke deaths occurred in a recent three-year period (from 1992 to 1995). This news comes at a time when opportunities to improve the treatment of stroke—to reduce death and disability of stroke—have never been greater. Thus, the AHA recommends doubling of the NINDS stroke research budget by the year 2002. A fiscal year 1998 appropriation of \$93 million for stroke, the first increment toward this goal, will allow NINDS to make more rapid progress toward the "Decade of the Brain" goal of "prevention of 80 percent of strokes and protection of the brain during acute stroke" by expanding and initiating programs to:

- develop functional neuroimaging capabilities to allow non-invasive diagnosis, treatment assessment and prediction of functional recovery following stroke;
- investigate mechanisms responsible for the death of cells during a stroke and evaluate the safety and effectiveness of agents to protect brain tissue from damage during a stroke;
- explore whether stroke can be prevented by reducing blood levels of cholesterol, through drugs and/or diet;
- study the interactions of various brain cells and the molecules on the cells during reduced blood flow to a brain area, which occurs during stroke, and when blood flow has been restored as a result of treatment. Information from such research would contribute to the development of treatments to protect brain tissue from damage and to improve survival;
- promote research on the molecular mechanisms of the natural barrier in the brain that separates brain tissue from the blood supply, in order to gain better understanding of how areas of the brain affected by stroke interact with the nutrients and cellular elements as well as therapeutic agents;
- identify brain-specific mechanisms that may predispose an individual to a stroke or lessen, or increase, the impact of risk factors on susceptibility to stroke;
- create programs combining epidemiology, long-term prevention and clinical trials to decrease stroke impact;
- continue identifying and evaluating promising treatments to prevent or treat stroke and develop strategies and systems to promote clinical testing of these experimental treatments in a wide range of medical settings in which they may be used;
- advance basic research on mechanisms in acute strokes, based on results from clinical studies and trials; and,
- develop programs for more effective diagnosis and treatment of dementia caused by stroke.

*Other NIH institutes and centers of interest*

National Center for Research Resources help institutions and researchers obtain and provide humane care for animals. An fiscal year 1998 appropriation of \$477.4 million will fortify animal research, correct deficiencies in research animal resources and fortify nationwide Clinical Research Area Centers and Biomedical Technology and Infrastructure Areas.

National Institute on Aging research defines mechanisms by which aging processes contribute to cardiovascular diseases, a main cause of disability and number one killer of older Americans. An fiscal year 1998 appropriation of \$33.35 million for NIA cardiovascular research will allow continuation of on-going studies and expansion into innovative, promising areas.

National Institute of Diabetes and Digestive and Kidney Diseases research helps reduce death and disability from cardiovascular diseases. A very high percentage of diabetes and kidney disease sufferers develop or die from heart or blood vessel diseases. The AHA advocates an fiscal year 1998 appropriation of \$938 million for NIDDK.

National Institute of Nursing Research studies play an instrumental role in biobehavioral aspects of health. Interventions to promote self-care and patient education are a large part of the portfolio. NINR-supported research is critical to primary and secondary prevention of heart attack, stroke and other cardiovascular diseases. The AHA advocates an fiscal year 1998 appropriation of \$68.7 million for NINR research.

*Centers for Disease Control and Prevention*

The AHA supports a fiscal year 1998 appropriation of \$3 billion for CDC as a whole. CDC programs are essential to reducing risk factors for heart disease, stroke and other diseases. A proposed CDC activity, about which the AHA is enthusiastic, is a national cardiovascular disease prevention program that would assist the states in implementing innovative strategies promoting heart-healthy behaviors with special emphasis on populations that are undeserved and are at high risk. AHA recommends \$10 million for this program.

Particularly because of the increase in obesity and physical inactivity among Americans, the AHA applauds the CDC's proposal to build a comprehensive program of physical activity and nutrition promotion to reach children, adolescence and adults throughout the country. AHA recommends \$15 million for this program.

In the preventive health and health services block grant, established to meet the nation's objectives for Healthy People 2000 for health education and risk reduction, the AHA recommends that increased funds be provided to insure that states that receive the grants obtain maximum return on the dollars. Additional moneys will enable states to target several of the health goals cited in Healthy People 2000. AHA recommends \$210.5 million for this program.

The tobacco use program is administered by the CDC's Office on Smoking and Health, a national leader in the nation's efforts to prevent and reduce the use of tobacco and to protect nonsmokers. In conjunction with the FDA, National Cancer Institute and nonprofit organizations such as AHA, this office plans to develop a national public education campaign to reduce access to and appeal of tobacco products among young people—a very worthwhile program since daily about 3,000 young Americans become regular smokers, creating about one million new smokers a year. At least one in three of these new smokers will die later in life as a result of tobacco use. CDC also proposes to develop a smoking and volatiles lab to analyze cigarette ingredients, tar and nicotine and the presence of tobacco attributed carcinogens in humans. AHA recommends \$36 million for this program.

The adolescent health program currently funded 13 states to implement a comprehensive school health education program to provide youth with the information and skills needed to avoid risk behaviors. AHA wants more states to be funded with the necessary resources to battle tobacco use, poor nutrition and physical activity. AHA recognizes this as a worthy investment since every one dollar spent on health education saves 14 dollars in health care costs. AHA recommends \$25 million for this program.

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PREPARED STATEMENT OF DR. RODNEY MEAD, PROFESSOR OF ZOOLOGY, DIRECTOR OF NIH IDEA PROGRAM, UNIVERSITY OF IDAHO

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit this testimony regarding the National Institutes of Health's Institutional Development Award (IDeA) program. Allow me to express our deep appreciation for the support Senator Larry Craig has given to the NIH IDeA program, and the other EPSCoR programs that are so important to our state. Senator Craig has worked tirelessly for the state of Idaho, and we thank him for his efforts.

Let me first give the subcommittee some background information. IDeA allows researchers and institutions in participating states to improve the quality of their research so they can compete for non-EPSCoR research funds. IDeA was authorized in the NIH Revitalization Act (Public Law 103-43) of 1993, which directed NIH to

establish a program to enhance the competitiveness of biomedical researchers in states with historically low success rates.

The IDeA program funds merit-based, peer reviewed research and works to enhance the competitiveness of research institutions. It increases the probability of long-term growth of regular NIH competitive funding in the NIH IDeA states. States that participate in IDeA include: Alaska, Arkansas, Delaware, Idaho, Kansas, Kentucky, Mississippi, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, West Virginia, and Wyoming.

#### *The IDeA Program in Idaho*

The NIH IDeA program is designed to enhance the biomedical research capabilities of states that have not had a long history of NIH funding. Idaho has received two IDeA awards totaling \$500,000, all of which has been matched dollar for dollar by the state of Idaho. The federal funding has been equally divided between the University of Idaho (UI) and Idaho State University (ISU), and has been used to upgrade the biomedical research infrastructure at both institutions.

Money from the first award was used by both universities to create, equip and staff core molecular biology research laboratories. These core laboratories are designed to provide technical support, training and access to multi-user equipment that was not formerly available. These services are made available to all biomedical researchers on both campuses. At UI, the core molecular biology laboratory is staffed by a full time Ph.D., whose position is now permanently funded by state funds.

The second award has been used to purchase a state of the art phosphoimaging system at UI. Money in years two and three of this award will be used to upgrade the core confocal microscope laboratory, thereby expanding the utility of this important multi-user instrument, and meeting the ever-changing needs of the research community. For example, this upgrade will permit UI faculty member Dr. Bruce Miller for the first time to use the new UV laser capabilities of this instrument in his studies of the molecular genetic mechanisms that integrate developmentally regulated, cell-specific gene expression with cell cycle regulation. WAMI faculty member Dr. Michael Laskowski also relies upon this instrument in his NIH funded studies of the growth and regeneration of mammalian nerves.

Purchase of highly specialized animal cage units which permit the rearing of animals in a germ free environment will also expand the research capabilities of UI biomedical researchers. For example, acquisition of these cage units will allow UI faculty member Dr. Steven Austad to rear mice, used in his NIH funded aging studies, in a germ free environment and thus more adequately distinguish between disease and age-related declines in physical fitness that are associated with aging.

These core research facilities are currently being used by biomedical researchers in the Departments of Biological Sciences, Animal Science, Food Science and Toxicology, Microbiology, Molecular Biology and Biochemistry, and by the Washington, Alaska, Montana, Idaho (WAMI) medical faculty at the University of Idaho. The core molecular biology laboratory at ISU is principally being used by biomedical researchers in the Department of Biological Sciences and the College of Pharmacy.

The creation and enhancement of these research facilities have led to at least six important results. They have:

- provided access and training in the proper use of expensive multi-user equipment that was not previously available. Use of this equipment has significantly reduced the amount of time required to acquire, analyze, graphically display data, and obtain publication quality images. This has increased the productivity of Idaho's biomedical research community such as Dr. Holly Wichman, who is making extensive use of the imaging system in obtaining preliminary data to be included in an NIH research grant regarding the evolution of viruses;
- expanded the research capabilities of faculty and students by providing training in new and rapidly changing molecular biology technologies used in biomedical research. This has allowed faculty, students, and post-doctoral trainees to undertake research projects that were previously impossible due to inexperience with the new techniques required to investigate the complex biomedical problems that remain to be solved;
- reduced the time required to establish these new techniques in investigators' laboratories and provided unlimited access to methodological trouble-shooting expertise that was formerly not available without impinging upon other researchers' time and goodwill;
- enhanced the chances of Idaho's biomedical researchers of obtaining NIH research grants by providing them with increased technical capabilities and the opportunity to demonstrate their ability to use these new techniques by collecting preliminary data which are so vital in convincing grant reviewers that they

- have the facilities, technical expertise and actual ability to do what is proposed. For example, I obtained preliminary data which ultimately convinced an NIH panel to approve funding of a grant to investigate factors necessary for promoting changes in the uterine environment that may be essential for successful implantation of mammalian embryos;
- enhanced the ability of UI and ISU faculty to provide state of the art training to future biomedical researchers. For example, one of our graduate students, Mr. John Eisses, obtained training and used equipment in the molecular biology laboratory extensively to complete his thesis dealing with molecular genetics; and,
  - resulted in Idaho universities being better able to compete for the brightest young biomedical researchers. For example, UI has just hired Dr. Deborah Stenkamp, who studies the developmental and molecular biology of color vision. She has just submitted an NIH grant application to continue her work in this area. Access to the confocal microscope and core molecular biology labs was an important factor in her decision to accept this position at UI.

#### *Conclusion*

As this subcommittee considers its priorities for fiscal year 1998, I encourage you to consider the importance of making sure all parts of the country are able to contribute to the important research mission of the NIH. I encourage the subcommittee to fund the IDeA program at the level of \$12.6 million—\$10 million over the budget request.

Overall NIH funding grew by \$2.4 billion from fiscal year 1993 through fiscal year 1997. Funding for the National Center for Research Resources (NCRR) alone increased by nearly \$103 million. As a strong supporter of biomedical research, I applaud these efforts, and I encourage this subcommittee to provide \$12.6 million of these funds for the IDeA program.

I would like to thank the subcommittee for the opportunity to submit this testimony for the record.

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#### PREPARED STATEMENT OF REED V. TUCKSON, M.D., PRESIDENT, CHARLES R. DREW UNIVERSITY, ON BEHALF OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit the views of the Association of Minority Health Professions Schools (AMHPS). I am Dr. Reed V. Tuckson, President of Charles R. Drew University of Medicine and Science, and president of the Association of Minority Health Professions Schools (AMHPS).

AMHPS is an organization which represents twelve (12) historically black health professions schools in the country. Combined, our institutions have graduated 60 percent of all the nation's African-American pharmacists, 50 percent of African-American physicians and dentists, and 75 percent of the African-American veterinarians. Our twelve schools are becoming even more ethnically and culturally diverse in terms of Hispanic students and Native American students, and most of these students and graduates matriculate from and are working in the nation's underserved rural and inner-city communities.

While African-Americans represent approximately 12 percent of the U.S. population, only 2–3 percent of the nation's health professions workforce is African-American. Studies have demonstrated that when African-Americans and other minorities are trained in the health professions, they are much more likely to serve in medically underserved areas, more likely to take care of other minorities and more likely to accept patients who are medicaid recipients or otherwise poor. For this reason, it is imperative that the federal commitment to training African-Americans and other minorities in the health professions be strong. Clearly, institutions which train disproportionately high numbers of minorities address a national need.

In spite of our proven success in training minority health professionals, our institutions endure a financial struggle that is inherent in our missions to train disadvantaged individuals to serve in underserved areas. The financial plight of the majority of our students has affected our schools in numerous ways, such that we are not able to depend on tuition as a means by which to respond to the discontinuation of funding or other forms of federal support for health professionals education. Additionally, due to the fact that the patient populations served by the AMHPS institutions have historically been poor, our institutions have not earned money from the process of patient care at the time when the average medical school gets 40–50 percent of its revenue from patient care.

As a nation, we must address the shocking and disturbing disparities in our health care system. In addition to a higher prevalence of violence and drug use, minority communities have a higher rate of infant mortality, cancer, emphysema, stroke, heart disease, aids, and other diseases. Many of the programs supported by your Subcommittee help our institutions meet these challenges head on. We are committed to face these issues, and your commitment to providing resources will be a vital component to our success.

#### SPECIFIC KEY PROGRAMS SUPPORTED BY AMHPS

##### *Health Professions/Disadvantaged Minority Training*

There have been several reports recently, including reports by the Pew Foundation, the Institute of Medicine, and the Council on Graduate Education, that predict a general over-supply of physicians and other health care providers. This is not the case among all health care providers—in fact the opposite is true. This nation needs many more minority physicians, dentists, pharmacists, veterinarians, and allied health professionals.

The health professions programs supported by your Subcommittee are the only federal initiatives that are designed to deal with acknowledged shortages among diverse populations and in geographic areas.

The Minority Centers of Excellence Initiative, the Health Career Opportunity Program and other health professions programs recognize and support the institutions that have a track record and existing mission and commitment to addressing those shortages. The support provided for the Centers of Excellence program, represents, very frankly, the difference between keeping the doors open or closed at several historically minority health professions schools. AMHPS is disappointed that the president's budget recommendation severely cuts health professions training. We urge the Subcommittee to restore fiscal year 1998 funding to the current level of funding of \$292 million. A funding level of \$302 million would allow a modest increase for inflation.

##### *National Institutes of Health*

The historically minority institutions which I represent today are committed to narrowing the health status gap among minorities when compared to the general population. Our institutions can achieve this national goal by improving our research capabilities through continued development of our research labs, faculty improvement, and other learning resources.

Almost every health professions training and research institution in this country was built and developed with a significant contribution from federal sources. At this stage in our development, we are prepared to accept this same kind of support.

Three programs specifically address developing the research infrastructure at our institutions:

The Research Centers at Minority Institutions program at the National Center for Research Resources (NCRR) is helping us develop the research capability to solve health problems disproportionately impacting minorities. Funding for this program should grow at the same rate as NIH overall.

Secondly, the Extramural Facility Construction program at NCRR can help our schools catch up to our non-minority counterpart institutions by providing us the resources to build adequate research facilities. The subcommittee is urged to provide \$30 million for fiscal year 1998 for this program. We remain concerned about the administration of the program. The statute designates 25 percent of the funding for this program to "Institutions of Emerging Excellence", yet heretofore NCRR has not designated these funds properly.

Third, the Minority Health Initiative and the Office of Research on Minority Health at NIH each support critical specific disease related research initiatives through the various NIH institutes. We recommend a combined funding level of \$80 million for these programs in fiscal year 1998.

##### *Centers for Disease Control*

Mr. Chairman, minority populations of all ethnic backgrounds are at significantly increased risk of infectious disease, low birth weight, Hepatitis B, sexually transmitted diseases, tuberculosis, and other chronic disorders.

The Centers for Disease Control has taken a leadership role in combating these problems by supporting initiatives to control infectious and chronic diseases among disadvantaged minority populations through CDC's plan, "Addressing Emerging Infectious Disease Threats: A Preventative Strategy for the United States". With additional resources, CDC could begin to support community-based infectious disease prevention programs in each state.

Because of the proximity of minority health professions institutions to disadvantaged, medically underserved communities, CDC can and does play a leadership role in supporting disease prevention and public health education activities in partnerships with our institutions.

Our overall funding recommendation for CDC for fiscal year 1998 is \$2.75 billion.

*Strengthening Historically Black Graduate Institutions/Higher Education*

The Strengthening Historically Black Graduate Institutions, Title III, Part B, Section 326 is a program of extreme importance to the AMHPS institutions. This program allows historically black graduate institutions, including those represented by AMHPS to participate in the part B programs for strengthening our schools. The funding from this program is utilized by our institutions to establish and strengthen development offices, to begin endowment development campaigns (a definite need of all HBCUs), and to enhance our educational capabilities on the graduate level.

The Higher Education Act Reauthorization added eleven Historically Black Graduate and Professional Schools to Section 326 of Title III, making sixteen schools eligible for this funding. In order to accommodate these new schools at the minimum funding level and continue the progress being made at existing schools, increased funding is a necessity in the fiscal year 1998 appropriation for this program. A funding level of at least \$20 million is necessary to accommodate each of the existing and the 11 new schools added during the reauthorization.

In Closing: Mr. Chairman, please allow me to offer our sincere appreciation to you and the members of this subcommittee for the support they have provided for our institutions and their students. With congressionally funded programs for minority health and health professions education, we can overcome the disparity in health care in this country. We must be careful not to eliminate, paralyze or strangle the programs that have proven to work. There are success stories, but not enough of them. The lack of participation by minorities in medicine and the sciences is characteristic of a long-term, complex, multi-faceted set of variables which will require a sustained, vigorous, and visionary commitment from our high schools, colleges, medical schools, and support organizations—and from this Subcommittee and the entire Congress.

For the record I am submitting: a set of funding recommendations for programs under the Subcommittee's jurisdiction; and a report from the 12 AMHPS schools on progress made by each institution with funding from the health professions programs.

Once again, thank you for allowing our association the opportunity to submit our views.

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PREPARED STATEMENT OF DAVID WHITE, M.D., PRESIDENT, AND BARBARA PHILLIPS, M.D., CHAIRPERSON, GOVERNMENT AFFAIRS AND PUBLIC POLICY, AMERICAN SLEEP DISORDERS ASSOCIATION

We are pleased to have the opportunity to submit testimony on behalf of the American Sleep Disorders Association (ASDA). A medical and scientific society, the ADA represents more than 2,800 physicians and researchers. Part of the ASDA's mission is to foster research in the field of sleep medicine and to educate both the public and health care professionals about sleep disorders. The ASDA appreciates this opportunity to present its comments on funding for sleep disorder's research and education within the National Institutes of Health (NIH) for fiscal year 1998.

First of all, we would like to commend Chairman Specter and the Subcommittee for their leadership in working to support funding for the NIH for fiscal year 1997 at a substantial increase over the President's budget proposal.

Thanks to the leadership of dedicated policy makers, the National Center for Sleep Disorders Research (NCSDR) was established in the 1993 NIH Revitalization Act. The Center was the cornerstone recommendation of the National Commission on Sleep Disorders Research which was established in 1988 to address the growing concern over sleep disorders and their effect on our society. The Center is now part of the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health. During its first three years the development of the Center has progressed admirably due to Dr. Lenfant's leadership of the NHLBI. The ASDA continues to firmly support the National Center and believes, that with adequate support, the widespread consequences of untreated sleep disorders will be markedly reduced.

A strong and fully funded National Center for Sleep Disorders Research is crucial to the health of our nation, as patients with sleep disorders suffer many accidents which often have dire consequences. Forty million American adults suffer from chronic sleep disorders, such as insomnia and sleep apnea; and another 20–30 mil-

lion have intermittent sleep problems; millions more at any given time have not obtained sufficient sleep. The consequences of these sleep disorders and common sleep deprivation are not trivial. They include reduced productivity, lower performance in school, an increased likelihood of accidents (behind the wheel, on the job, and at home), increased cardiovascular disease, a higher mortality risk and decreased quality of life.

More specifically, sleep-related motor vehicle accidents continue to take the lives of our citizens—young and old alike. These accidents come at great emotional and financial cost. The Appropriations Transportation Subcommittee recognized this problem and in its fiscal year 1996 and fiscal year 1997 budgets appropriated \$1 million each year to the National Highway Traffic Safety Administration to conduct research, data collection and public awareness activities in collaboration with the National Center. It is not by chance that the number of alcohol-related motor vehicle accidents has declined over recent years; this change has occurred in conjunction with proactive measures to educate the public about the consequences of driving while intoxicated. The same must now be done about the hazards of driving while drowsy.

The National Center has progressed measurably in its first three years. The Center's scientific advisory board was established and has held regular meetings. The Board includes representatives from various NIH Institutes and other federal government agencies including the Department of Transportation. The Education Subcommittee of the Advisory Board has developed a national public awareness and mass media campaign which is progressing adequately and includes print advertisements, radio and television public service announcements and patient and professional education materials.

During the next fiscal year the ASDA hopes to have the support and collaboration of the National Heart, Lung and Blood Institute and the National Center, to establish "High School 2000". This program will educate our nation's youth about sleep disorders and the importance of sleep as part of a healthy life. The goals of the program are: to ensure that education on sleep and its disorders is a part of the health curriculum in all high schools in the United States; and to have sleep and its disorders described in all drivers' education manuals in all states. To implement the program, a national task force would be created. We hope to start a pilot program in two or three states in 1997 and would then progress nationally based on the experience in the initial three states. It is important to note that designated funding would be needed to administer and carry out this program.

The Research Subcommittee has developed the National Sleep Disorders Research Plan, which has been approved by NIH Director, Dr. Harold Varmus and has been endorsed by major organizations including the American Academy of Neurology, the American College of Cardiology, the American Thoracic Society, the Society for Neuroscience, the Alliance for Aging Research, the American Sleep Apnea Association and the Narcolepsy Network. The purpose of the plan is to map out opportunities and challenges that exist in sleep disorder's research and training. One objective of the plan is to formulate recommendations on how these challenges and opportunities can be pursued by the scientific field and by the NIH. Continued strong funding of NIH is needed to accomplish this agenda.

In its first year the Center initiated a request for applications for a research project on the cardiopulmonary consequences of sleep apnea. In addition the Center introduced a cooperative multi-institute request for applications in general sleep research. Most recently, the Center introduced several sleep academic awards for fiscal year 1996/97. The objective of the awards is to "encourage the development and/or improvement of the quality of medical curricula, physician/patient and community education, and clinical practice for the prevention, management, and control of sleep disorders."

A recent finding as a result of an NHLBI supported sleep research study indicate that sleep apnea, or periodic cessation of breathing during sleep, increases a driver's risk of automobile accidents. These results suggest that a significant fraction of motor vehicle accidents could be preventable through recognition and treatment of this common disorder.

In its early stages one of the Center's main challenges, aside from funding, was the lack of opportunities to develop collaborative efforts with other NIH Institutes involved in sleep research. The legislation that established the Center authorized the Center to collaborate with the national Institutes of Neurology, Aging, Mental Health and Child Health. Due to the leadership of the Center, this collaboration is now taking place regularly with several Institutes and will continue to be a priority of the National Center.

A more recent challenge facing the National Center lies in its public education efforts. As you know, the National Heart, Lung and Blood Institute, more than any

other at NIH, supports well known and successful public education campaigns such as those for asthma, high blood pressure and hypertension. It is this same office that is carrying out the national sleep disorder's public awareness campaign. Due to Congress' efforts to reduce administrative costs and its freeze of the Research, Management and Support (RMS) budgets of the Institutes, the NHLBI has had to seriously curtail its public education efforts. The funds for these efforts come from the RMS budget line. This is an issue that must be addressed in order for the NHLBI to be able to carry on with its important public education work relative to sleep.

The ASDA recommends funding for the National Institutes of Health for fiscal year 1998 at \$13.89 billion and the National Heart, Lung and Blood Institute at \$1.56 billion, a 9 percent increase for each. Notwithstanding this specific recommendation, it is very critical that NHLBI receives a funding increase that is at least proportionate to the overall increase for NIH.

The ASDA commends the National Heart, Lung and Blood Institute for its leadership and the National Center on Sleep Disorders Research on its progress and thanks the Chairman of this subcommittee for his dedication and leadership by insuring the establishment and funding of the National Center.

We appreciate the opportunity to submit testimony, and more important, for your continued commitment to helping the millions of Americans who suffer from sleep disorders and the millions more who have been or may be the victims of sleep-related accidents.

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PREPARED STATEMENT OF SUZANNE ROSENTHAL, PRESIDENT EMERITUS, AND NANCY NORTON, CHAIRMAN, OF THE DIGESTIVE DISEASE NATIONAL COALITION

Mr. Chairman and members of the subcommittee, thank you for the opportunity to discuss the federal government's support of digestive disease research and education programs conducted through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Centers for Disease Control and Prevention (CDC).

The Digestive Disease National Coalition (DDNC) is comprised of 22 voluntary and professional organizations concerned with the many diseases of the digestive tract. Founded in 1978, the DDNC has as its goal a desire to improve the health and quality of life for millions of Americans suffering from both acute and chronic digestive diseases. Digestive diseases include such disorders as inflammatory bowel disease, irritable bowel syndrome, ulcers, colorectal cancer, and hepatitis.

The social and economic impact of digestive diseases is enormous. Twenty million Americans are treated for a chronic digestive disease each year and disorders of the digestive system consistently rank among the leading causes of hospitalization, surgery, and disability in the U.S. In addition, an estimated 200,000 people miss work each day because of digestive problems, resulting in costs of approximately \$70 billion a year in lost wages, reduced productivity, health care expenditures, and disability payments.

Mr. Chairman, we have two major points that we hope to convey to the subcommittee on behalf of the digestive disease community:

Millions of Americans around the country who suffer from a variety of digestive disorders are pinning their hopes for a better life—or even life itself—on medical advances made through research supported by the National Institute of Diabetes and Digestive and Kidney Diseases. For that reason, the DDNC recommends a 9 percent increase in NIDDK's budget for fiscal year 1998 (an increase of \$73 million over fiscal year 1997), bringing NIDDK's total appropriation to \$889,420,380.

The DDNC strongly believes that if patients suffering from digestive diseases are to receive the highest quality care available then NIDDK must practice and emphasize a balanced approach to biomedical research. Specifically, the DDNC endorses a research approach that aims to both unmask the mysteries of digestive diseases at the cellular and molecular level and transfer those discoveries to the bedside of digestive disease patients in the form of improved treatment and care.

One group of patients who would benefit from a more balanced research approach are those suffering from viral hepatitis. More than 5 million Americans are infected with chronic hepatitis B or chronic hepatitis C and overall 165,000 new cases are reported each year. Because chronic infections can result in severe liver impairment/cirrhosis, liver transplantation (at a cost of approximately \$250,000 per patient) often becomes the only treatment option available for many individuals. Already, chronic hepatitis C accounts for nearly one third of all liver transplants being performed in the United States. It is estimated that there are up to 8,000 deaths annu-



ally due to hepatitis C and the CDC projects that this number may more than triple by the year 2010.

The DDNC believes that research efforts should be directed toward gaining an understanding of the natural history of hepatitis and defining the pathogenetic mechanisms of hepatic viral infections. Currently, treatment of chronic hepatitis B provides a sustained response in about 30 percent of patients compared with 15 percent of patients with chronic hepatitis C. Although significant research is occurring in the area of anti-viral therapy, we believe more emphasis needs to be placed on developing effective vaccines and treatment therapies.

A second group of patients who would benefit from more targeted research are those suffering from Inflammatory Bowel Disease (IBD). IBD represents two diseases—distinct yet quite similar in clinical presentation and symptoms—ulcerative colitis and Crohn's disease. Combined these disorders represent the major cause of morbidity from chronic intestinal illness. While the exact pathogenesis of IBD is poorly understood, scientific evidence has shown that interactions between the immune system, genetic susceptibility and the environment are strongly implicated.

In recent years, unprecedented developments in molecular biology have permitted the creation of a new class of rodent models that more closely resemble IBD in humans. These techniques now make it possible to over express or delete selected genes in rodents. Applications of these genetically engineered rodents may provide clues to a better understanding of the pathways which control the chronic inflammation that occurs in IBD. Further studies are needed in these animal models to determine how current pharmacologic agents are used to treat IBD. In addition, these rodents may prove to be useful in applying novel immunologic treatment approaches such as gene therapy.

In addition to viral hepatitis and Inflammatory Bowel Disease, the DDNC has long focused on the importance of research related to functional gastrointestinal disorders. These disorders include such conditions as Irritable Bowel Syndrome (IBS) and fecal incontinence.

Irritable Bowel Syndrome is a chronic complex of disorders that malign the digestive system affecting 10–15 percent of the general population annually. These disorders strike people from all walks of life and result in a significant toll of human suffering and disability. IBS is one of the most common GI disorders yet people are very isolated by their condition. In a recent U.S. Householder Survey of Functional Gastrointestinal Disorders, Prevalence, Sociodemography and Health Impact, Irritable Bowel Syndrome accounted for 10 percent of the total gastrointestinal disorders population, 46 percent of which required the supervision of a gastroenterologist. This care alone results in millions of dollars in health care costs every year. In addition, individuals who suffer from IBS will miss 13.4 days of work annually as opposed to the 4.9 national average, further contributing to higher health care costs and loss of productivity. IBS alone has recently been called a multi-billion dollar problem by the gastrointestinal community. Much more can be done and should be done to address the needs of the millions of Americans suffering from IBS.

Mr. Chairman, besides being strong advocates for research, the Digestive Disease National Coalition is also very active in supporting public education activities with respect to digestive disorders. We are currently working very closely with the Centers for Disease Control and Prevention to help implement CDC's new colorectal cancer screening public education initiative. Colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States and the second leading cause of cancer related deaths. Although survival rates are greatly enhanced when the cancer is treated at an early stage, recent studies have shown a tremendous need to: inform the public about the availability and advisability of screening; and educate health care providers with respect to colorectal cancer screening guidelines. CDC's education and awareness program has begun to address these needs by coordinating with national partners like the DDNC to develop an information program emphasizing the value of early detection. We encourage the subcommittee to provide CDC with \$5 million in fiscal year 1998 (an increase of \$2.5 million over fiscal year 1997) for this vital campaign.

Once again, Mr. Chairman, thank you very much for allowing us to present the views of the Digestive Disease National Coalition. If you have any questions regarding our testimony or the research/education priorities of the digestive disease community please do not hesitate to contact us.

PREPARED STATEMENT OF ROSALIE LEWIS, VICE PRESIDENT OF DEVELOPMENT, AND DANIEL LEWIS, DYSTONIA MEDICAL RESEARCH FOUNDATION

I am Rosalie Lewis, Vice President of Development of the Dystonia Medical Research Foundation. It is my pleasure to submit testimony to the Subcommittee on behalf of the Foundation.

First and foremost I would like to thank this subcommittee for its generous funding of the National Institutes of Health in its fiscal year 1997 appropriations bill. The Foundation is aware of the tremendous fiscal constraints under which you were working and we are extremely appreciative of your continued commitment and support of biomedical research.

I have been formally involved with the Foundation since 1989, but on a more personal level I have been dealing with dystonia since 1985 when the first of the three of our four children with dystonia was diagnosed. In fact, I had hoped that my 19 year-old son Benjamin could have joined me today in speaking with you about dystonia. However, dystonia has not only robbed him of the ability to walk unaided, or to use his hands for any fine motor coordination like writing, but now has made speaking most difficult. Like Benjy, my son Dan—now 16—also first exhibited symptoms of this disorder at age 7. Dan can tell you about dystonia first hand—what it is like to live a life filled with frustrations and unanticipated change. In fact, the only thing predictable about dystonia is its unpredictability.

Daniel and I would like to tell you a little something about dystonia and why we, and the estimated 300,000 other children and adults, need your help so urgently.

Dystonia is a neurological disorder characterized by severe involuntary muscle contractions and sustained postures. There are several different types of dystonia, such as: generalized dystonia which afflicts many parts of the body and usually begin in childhood (my sons Benjamin and Daniel have generalized dystonia); focal dystonias affecting one specific part of the body such as the eyelids, vocal cords, neck, arms, hands or feet (my son Aaron has a focal dystonia of the hand); and secondary dystonia which is secondary to injury or other brain illness.

There is no definitive test for dystonia and many primary care doctors have never seen a case of it. This fact coupled with its varied presentations make it difficult to correctly diagnose. It is estimated that 85 percent of those suffering from dystonia are not diagnosed or have been misdiagnosed.

In primary, uncomplicated dystonia, there is no alteration of consciousness, sensation, or intellectual function. Treatment for dystonia has met with limited and variable success with drug therapy, botulinum toxin injections, and several types of surgery. My children with generalized dystonia take huge doses of drugs which makes cognition difficult. But with a choice between walking and not walking, one may choose to tolerate drug side effects. Ben receives injections of botulinum toxin (botox) into the abductor muscles of his vocal cords, and he is experiencing moderate improvement.

I am proud to be involved with the Dystonia Medical Research Foundation, founded just 21 years ago and since 1993 a membership-driven organization.

The goals of the Foundation have remained the same: to advance research into the causes of and treatments for dystonia; to build awareness of dystonia in the medical and the lay communities; and to sponsor patient and family support groups and programs.

*To Advance Research*

Since 1977 the Foundation has awarded over 275 medical research grants totaling over \$14 million dollars. Among the most significant results of this research was the discovery in 1989 of a genetic marker for dystonia and in 1995 of the gene for the dopa-responsive form of dystonia. We expect to have another gene announcement this June. In addition, several drug therapies have been developed including the use of Botulinum Toxin, Baclofen, and Artane.

In 1981 the Foundation established three centers for dystonia research in New York, Vancouver, and London and still finances its “flagship” center at Columbia Presbyterian Medical Center in New York.

*To Build Awareness*

It is the goal of the Foundation to educate the lay and medical audiences about dystonia so that people afflicted with the confusing symptoms need not go undiagnosed or misdiagnosed as is so common.

The New York dystonia research center, which I mentioned earlier, is designed as a teaching center as well as a research and treatment institution. Thereby, residents and fellows have the unique opportunity to learn about both the clinical and research aspects of dystonia.

The Foundation conducts medical workshops and regional symposiums during which comprehensive medical and research data on dystonia is presented, discussed, and then disseminated. In October, 1996 the National Institutes of Health (NIH) was one of our co-sponsors for an international medical symposium with 60 papers on dystonia and 125 representatives from 24 countries.

Over 3,000 medical videos have been distributed since 1995 to hospitals and medical and nursing schools and at medical conventions. In addition, media awareness is conducted throughout the year but most especially during Dystonia Awareness Week observed nationwide this year from October 12th through the 18th.

*To Sponsor Patient and Family Support Groups*

The Foundation has more than 200 chapters, support groups and area contacts across the United States and Canada. We have eight regional coordinators and leaders in each region representing awareness, children's advocacy, extension, medical education, development, and symposiums.

Patient symposiums are held regionally in order to provide the latest information to dystonia patients or others who are interested in the disease. In fact, in 1995 we held nine regional symposiums to attract, educate and inform more people about dystonia. Attending were over one thousand people, more than 35 doctors and nine grant holders who were speakers on dystonia. In 1997 we are conducting at least five more. Our most recent international patient symposium was held on May 24-26, 1996 in New York City, and was a tremendous success with 350 in attendance.

*The National Institutes of Health and Dystonia*

As mentioned, In October of 1996 we conducted a major medical symposium with support of the National Institute of Neurological Disorders and Stroke (NINDS) and we expect to conduct one on genetics in 1997. In February 1993 the Dystonia Foundation co-sponsored with the National Institute on Neurological Disorders and Stroke an international workshop to bring together basic and clinical investigators. The purpose of the workshop was to identify advances. Some conclusions reached as a result of the workshop according to the workshop summary were that "a greater interaction is needed among researchers from different scientific disciplines; carefully collected epidemiological information on the dystonia subtypes would provide a greater recognition not only of the prevalence of the dystonias but may promote an understanding of the environmental factors that result in clinical expression; and that it should be possible in the near future to further refine the classification of dystonias based on genetic patterns and clinical patterns correlated with age of onset and anatomical sites of involvement. NINDS encourages these ongoing research efforts towards the elucidation, treatment and eventual prevention of the various subtypes within the clinical spectrum of dystonia."

As you probably are aware, it can be extremely difficult for young scientists to break into the NIH grant system. The Dystonia Foundation believes that NINDS should focus even more on extramural dystonia research and would like to encourage creative collaborative efforts.

The Dystonia Medical Research Foundation recommends that the National Institutes of Health, the National Institute on Neurological Disorders and Stroke, and the National Institute on Deafness and other Communication Disorders be funded for fiscal year 1998 at a 9 percent increase over fiscal year 1997. Because dystonia affects Americans six times more than most other better known disorders such as Huntington's, Muscular Dystrophy, and ALS, we ask that NINDS fund dystonia-specific extramural research at the same level it supports research in those other neurological diseases.

With the proper dedication of resources, we believe that more treatments and a cure can be developed that will help my three boys—Aaron, Benjamin, and Daniel, and thousands of others.

I would like to emphasize that we are clearly at a point of understanding the genetic causes of this disorder. We believe with increased NIH funding of research by NINDS and with the Foundation grants, we will celebrate together the discoveries.

Thank you for the opportunity to submit testimony to the Subcommittee on behalf of the Dystonia Medical Research Foundation.

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PREPARED STATEMENT OF CAROL ANN DEMARET, BOARD MEMBER, IMMUNE DEFICIENCY FOUNDATION

Mr. Chairman and members of the subcommittee, as a part of this process, you will be receiving declarations from experts who will define how close we are to medical breakthroughs in correcting faulty immune systems—and how much it will cost to reach this wellborn goal.

I can't speak with their authority and precision on these matters. But I can speak of the wrenching human needs, and hopes, and failures and successes.

I was told you need to know—and feel—these details, too.

You may have heard of my beloved son, David. The world knew him as “The Bubble Boy,” because he was born into a bubble to shield him against the airborne sea of germs and viruses that most of us can counteract, most of the time, with the natural system of self-defense called the immune system. Because of a genetic defect, David was born without any sort of an immune system, not even a weak one.

The problem is called Severe Combined Immune Deficiency, and bears the fearsome acronym pronounced SCID. It comes in many intensities, for many reasons.

David lived, and flourished, in a bubble, at home, while the doctors and scientists labored in their laboratories to find ways by which they might cause him to develop an immune system.

If they could help David, scientists knew, they could help the thousands of people with deficient systems who live so precariously in our world, those who always seem to be ill from something, and the children who otherwise would be doomed to death within a few months.

Science is, after all, the organization of facts—and before David's long survival there were precious few facts to work with.

We lived quietly, as normally as possible. I fed my baby in that bubble, handling him through a glove system designed for moon rocks, and changed his diapers, and hugged him, and felt his warmth through the soft plastic walls, and helped him learn to walk, and talk, and learn, and grow, and have a spiritual sense. And he did all those things, my cheerful, gallant son with the black hair and dark eyes that seemed to see things beyond the reach of the rest of us. For many years I yearned to kiss him, and feel his skin without the heavy plastic and thick black gloves, and hear his voice without the muffling barrier that had to be between us.

He waited patiently, with dignity, mostly without complaint, and looked out his window at the stars, and hoped someday to learn what it would feel like to walk barefoot in the grass.

When he was twelve years old, David and his caregivers decided that there was a very good chance that enough had been learned to treat him and free him from his bubbles. But something went amiss. It didn't work. The story didn't end as everyone had prayed. My David died.

A few hours before he went away, he was freed from the bubble, and I did get to kiss and hold him and hear him speak so lovingly of so many.

Every parent who has lost a child prays that their short lives must meant something to the world. And they do.

In world-affecting ways my manchild has continued to live on—in spirit and silent research.

Of greatest and most far-reaching importance, we are told, is that through his valiant life and death my son David has enabled science to learn enough to help thousands of other children, and adults. As progress continues to be made on the guidance he bravely helped form, understanding the immune system, and how to manipulate it, will help to lead to many cures, of many ills. AIDS, for instance, acquired immune deficiency, is estimated to affect 40 million people in the world by the year 2000. And no more children will ever go into bubbles. From what was learned from my son immune systems can now be stirred into more vigorous action, even created within the womb before the child is born.

A few days ago I was profoundly touched by meeting scores of parents and children who had gathered in Bethesda at the behest of the National Institutes of Health to share their problems and methods of coping, and success stories. They came from all over the nation. I even met people from Norway, who wanted to pass along their gratitude to my son, and to this nation.

Wide applications of what was learned, however, has only begun. More must be learned and applied. It takes money, and I appeal to you to grant everything that can be sensibly spent in this valorous effort.

My kiss to David was a private, mother's gesture of love, and grief, and farewell.

But in a very real sense—you are empowered to bestow the kiss of life. Mr. Chairman, the Immune Deficiency Foundation recommends a 9 percent increase for the National Institute of Allergy and Infectious Diseases in fiscal year 1998.

PREPARED STATEMENT OF ROGER GUARD, DIRECTOR, ACADEMIC INFORMATION TECHNOLOGY AND LIBRARIES, UNIVERSITY OF CINCINNATI MEDICAL CENTER, ON BEHALF OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

Mr. Chairman and members of the subcommittee, I am Roger Guard, Director of Academic Information Technology and Libraries at the University of Cincinnati Medical Center. I am pleased to submit testimony on behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) in support of increased fiscal year 1998 funding for the National Library of Medicine (NLM) with particular emphasis on funding for NLM's basic services/personnel, and outreach activities.

MLA is a professional organization representing over 4,000 individuals and 1,200 institutions involved in the management and dissemination of biomedical information to support patient care, education and research. AAHSL is composed of the directors of libraries of 142 accredited U.S. and Canadian medical schools belonging to the Association of American Medical Colleges. Together, MLA and AAHSL address health information issues and legislative matters of importance to both organizations and the NLM. The common goal of our organizations is to ensure that biomedical information is made available to health sciences libraries and is accessible to health care professionals, scientists, students and patients throughout the nation.

Mr. Chairman, members of the MLA/AAHSL Legislative Task Force were present on March 5th when Dr. Donald Lindberg, director of the National Library of Medicine, testified before Congressman Porter's L-HHS House subcommittee. To a person, we were impressed with Dr. Lindberg's remarks on the tremendous progress NLM has made in the areas of information communications, the Visible Human Project, and telemedicine. MLA and AAHSL fully support these important initiatives and hope to work with NLM to enhance these programs as we enter the next century. In the interest of time Mr. Chairman, I will not restate the many successes of the Library over the past year as detailed by Dr. Lindberg. However, I would like to touch on a few areas of particular interest to the medical library community.

*NLM Basic Services & Personnel*

Basic library services must still be the foundation for NLM's long term success as a service agency. However, the lack of sufficient staff to perform these services is a major problem. The demand for basic NLM services is increasing at a rate of 10 to 15 percent per year. Maintaining the current standard of acquisitions, indexing, cataloging, database searching, and lending will become more and more difficult, if not impossible, if NLM staffing levels and fiscal resources continue to decline. In addition, NLM's resources have been stretched in recent years by the establishment of two major new congressionally mandated programs—the National Center for Biotechnology Information and the National Information Center on Health Services Research and Health Care Technology. As a result, we urge the subcommittee to consider reinstating staff level positions, and the necessary financial support for them, so that NLM can meet its increasing service needs and insure that the quality of its programs and information services is not compromised.

One of NLM's basic programs that has proven to be extremely beneficial to health care providers and patients is MEDLINE. Simply stated, MEDLINE is the world's premier biomedical information resource. In southern Ohio, northern Kentucky and southeastern Indiana, the University of Cincinnati Medical Center and over 35 public and private partners provide consumer access to high quality health information via the World Wide Web. Although this demonstration project, called NetWellness, was seeded by a U.S. Department of Commerce matching grant, NLM's MEDLINE remains the core information resources desired by NetWellness users. We have learned that MEDLINE is nearly as important to consumers as it is to health professionals.

*Outreach Programs*

NLM's Outreach programs are of particular interest to our organizations. These activities, designed to bring the most current medical information to a variety of health professionals, have proven to be very successful in improving the quality of our nation's health care. In 1991, a major medical journal published an article in which physicians reported positive changes in their diagnosis, choice of tests and drugs, length of hospital stay and advice given to patients as a result of information provided by medical librarians [Robert J. Joynt, Joanne G. Marshall, Lucretia McClure. "Financial Threats to Hospital Libraries." JAMA. Sept.4, 1991 226 (9):1219-20]. In addition to these changes, physicians reported a reduction in mortality, hospital admissions, surgery, and hospital-acquired infections, due to data obtained from medical libraries.

In the five years between 1989 and 1994, NLM has undertaken and supported close to 275 outreach projects, involving over 500 institutions across the country. In conjunction with the eight Regional Medical Libraries and the members of the National Network of Libraries of Medicine, over 20,000 health professionals across the country have learned more about accessing the medical information resources that NLM provides. Outreach programs have been geared toward individual health professionals practicing in under served geographic regions, unaffiliated health professionals, health professionals serving minority populations, and care givers and patients who need vital HIV/AIDS information.

Clearly, NLM has been able to accomplish a great deal through its outreach activities. However, there are still far too many health care professionals throughout the country who are not aware that NLM and the NN/LM exist and work together to provide access to the most up-to-date medical information. Mr. Chairman, outreach will not be complete until every health professional in this country is familiar with NLM and the information resources it provides. Similarly, the nation's medical library community believes with the advent of the World Wide Web there is now a greater opportunity to not only reach out to health care professionals but to the U.S. citizenry at large through greater access to NLM's data bases.

#### *High Performance Computing and Communications*

The dissemination of information and the quality of NLM's outreach programs have been greatly enhanced by the High Performance Computing and Communications (HPCC) program. The NLM, the National Science Foundation (NSF) and other agencies are working together to connect hospitals and other biomedical institutions to the Internet. The High Performance Computing and Communications Act passed by the 102nd Congress legislated the establishment of a national information highway designed to provide health care practitioners and patients with greater access to the world's medical literature. As a result, health professionals with access to the Internet, can from their offices, homes, or bedsides access information such as recently published literature, current clinical trials, toxicologic data, and consumer health information. In addition, HPCC technology is providing researchers with the high speed computing power necessary to create complex biomedical models and allowing scientists in different areas of the country to work together on intricate research projects.

Mr. Chairman and members of the subcommittee, the information age is well underway. The National Library of Medicine, through its High Performance Computing and Communications efforts and its expertise in providing medical information on the Internet, is the critical investment agency for improving access to health care information in medically under served areas. We in the health sciences library community applaud the Congress for having the foresight to provide NLM with the resources to support telemedicine and test bed network projects. There is no question that these technologies will have a profound influence on future health care in this country. It is critical that Congress provide adequate funding to NLM for the HPCC program and the Next Generation Internet initiative in fiscal year 1998 in order to capitalize on numerous opportunities which hold great promise for improving the delivery of health care to millions of Americans.

#### *Fiscal Year 1998 Recommendation*

The landmark 1989 NLM Outreach Panel study chaired by Dr. Michael DeBakey recommended a doubling of the National Library of Medicine's budget to take full advantage of outreach and HPCC opportunities. The Medical Library Association and the Association of Academic Health Sciences Libraries strongly believe that the National Library of Medicine should, at a minimum, receive an increase that insures basic Library services will be maintained and HPCC and outreach activities will be able to expand significantly. Therefore, Mr. Chairman, we recommend a 9 percent increase in funding for NLM in fiscal year 1998, bringing the Library's total fiscal year 1998 appropriation to \$164.7 million.

Mr. Chairman, thank you very much for the opportunity to present our views.

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#### PREPARED STATEMENT OF LORI DICKEY, SUDDEN INFANT DEATH SYNDROME ALLIANCE, AND JOHN AND DENISE ANDERSON, CJ FOUNDATION FOR SIDS

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit testimony to you regarding the federal government's response to and funding of Sudden Infant Death Syndrome (SIDS).

As the parents of children who have died from SIDS, we have come together from opposite coasts of the United States to remind you that SIDS is a frightening disease that knows no geographic, economic or cultural boundaries. It can strike any

infant, even if the parents do everything “right”. In the typical, but always tragic SIDS case, an apparently healthy child is put to bed without any indication that something is wrong. Sometime later, the infant is found dead. The infant’s prior medical history, a complete postmortem examination, and a thorough investigation of the death scene provide no explanation for the cause of death.

Although cases of the syndrome have been noted since biblical times, organized scientific research into the cause of SIDS is recent, dating to the mid-1970’s. After decades of scientific study, we are just beginning to make real progress in reducing the number of babies dying of SIDS and are starting to unravel the mystery. The U.S. “Back to Sleep” campaign has heightened awareness about SIDS and offered parents an opportunity to reduce their infant’s risk for SIDS. Initial results from this campaign indicate that SIDS rates have been reduced by 30 percent, the highest reduction in infant mortality rates in 20 years! We have also learned that some infants who die of SIDS have an abnormality in a region of the brain thought to play a role in heart and lung control. This defect may hamper normal respiratory activity, and though not the sole cause of SIDS, it may contribute to a larger respiratory impairment leading to the baby’s death. Whereas healthy babies’ nervous systems detect breathing difficulties and arouse them, it is believed that SIDS babies may not be able to detect reduced levels of oxygen or elevated levels of carbon dioxide. Therefore they do not respond by gasping for breath, crying, or turning their heads like a non-impaired infant, leaving them more vulnerable to SIDS.

These are important breakthroughs, expanding our understanding about SIDS and offering renewed hope that with further research we will be able to identify babies that are most vulnerable and ultimately prevent all SIDS deaths. However, our work is far from over. In this country approximately 4,000–5,000 infants die each year as a result of SIDS—nearly one baby every hour, every day. SIDS is the number one cause of death for infants one month to one year of age. It is a major component of the high rate of infant mortality in the United States, yet we still do not know what causes SIDS nor how to prevent it from claiming so many young lives.

The primary federal agency responsible for conducting research into SIDS is the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH). In addition to federal funding of SIDS research, there are other agencies involved in SIDS efforts. Since 1975, the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) has supported specific programs for SIDS family counseling and for public and professional education about SIDS. Currently, MCHB is implementing SIDS initiatives recommended by the federally funded “Nationwide Survey of Sudden Infant Death Syndrome Service”, including issuing a grant request for a new SIDS Services Center. The Centers for Disease Control and Prevention (CDC) have established a standardized death scene investigation protocol for SIDS incidents. An Interagency Panel on SIDS, which includes the NIH, HRSA, CDC, Indian Health Services, Food and Drug Administration, Substance Abuse and Mental Health Service Administration, US Consumer Product Safety Commission, Department of Defense, Administration for Children and Families, and the Department of Justice help coordinate SIDS activities between government agencies.

*National Institute of Child Health and Human Development*

Mr. Chairman, thanks to the funding which has been provided by this Subcommittee, researchers supported by the NICHD SIDS Program have been making real progress in the fight against SIDS. In 1988, at the request of Congress, the NICHD assembled a group of scientists to examine the current state of knowledge about SIDS and articulate future SIDS research needs. The result of this effort was the SIDS Five Year Research Plan. The Five Year Plan was so successful and productive that a second SIDS Five Year Plan was initiated in fiscal year 1995. Through research projects sponsored by NICHD, scientists have expanded our base knowledge of SIDS and our understanding of the causes and underlying mechanisms of the syndrome. Research objectives have focused on: identifying infants at risk for becoming victims of SIDS including developing markers to detect which babies are most vulnerable; clarifying the relationship between high-risk pregnancy, high-risk infancy, and SIDS; investigating factors which place babies at higher risk and stresses that may trigger a SIDS occurrence; and exploring mechanisms and interventions that may prevent SIDS deaths.

Provided below are a few highlights of the accomplishments achieved through your support of the SIDS Five Year Research Plans, as well as some indications of the direction of future research concentrations outlined in the current year of the second SIDS Five Year Research Plan.

NICHD funded the establishment of a repository for brain and tissue specimens from infants and children with various neurodevelopmental disorders. Greatly en-

hancing the resources available for SIDS investigation, the accessibility of brain and tissue samples have lead to an important understanding of the causes of SIDS and the abnormalities of SIDS infants. One picture that has emerged is that SIDS infants may be born with a brain deficit that makes them vulnerable because they do not respond appropriately to decreased oxygen or increased carbon dioxide during sleep.

Another study focused on the effectiveness of apnea monitors in identifying and describing life threatening events. The hope is that information gained from this research will aid in the development of home monitoring systems that will be simpler, more specific, and have greater potential to identify infants poised to have life-threatening episode in time to save the infant. In a follow-up study, NICHD established a clinical network of investigators to conduct a standard protocol for high risk infants and develop centralized data collection and analysis. In addition to assisting the development of new monitoring technology, this study has added to our understanding about the maturation of heart and respiratory functions in sleeping infants. The ultimate goal is to establish specific variables (such as an infant's cry, cardiorespiration and sleep characteristics) which may be used to predict life threatening events in high risk infants.

NICHD carried out a multi-disciplinary project on the maturation of sleep states in the infant and the maturation of life sustaining mechanisms during sleep. It is hypothesized that the rapid developmental changes in these mechanisms and their interactions may make an infant vulnerable to sudden death during a sleep period.

In cooperation with the Indian Health Service and the Centers for Disease Control and Prevention, NICHD conducted a study that investigated the causes of and risk factors for the high rate of SIDS incidents in the Native American population in the Aberdeen area. A case controlled study of sudden unexpected infant deaths in Chicago, Illinois, was also initiated in collaboration with CDC to identify possible behavioral, social and environmental risk factors for SIDS in an inner city, predominantly black population. The incidence of SIDS is 3 times higher for Blacks than Whites, and 5 times higher for Native Americans.

In May 1994, the NICHD and other members of the U.S. Public Health Service, along with the American Academy of Pediatrics, the SIDS Alliance, and the Association of SIDS Program Professionals launched the "Back to Sleep" campaign in the U.S. to encourage parents to put healthy babies to sleep on their backs or sides. This campaign was based on reports from overseas indicating a substantial increase in the incidence of SIDS when infants were put to sleep in the prone (stomach-down) position. NICHD has actively monitored the change in infant sleep practices subsequent to the campaign. Most recently, research has indicated that back sleeping is most preferable. An impressive 30 percent decline in SIDS rates have occurred since the campaign began; the goal of the NICHD is to reduce SIDS deaths by 50 percent and increase back sleeping to 85 percent by the year 2000.

Beginning in fiscal year 1995, thanks to the funding generously provided by this Subcommittee, the second SIDS Five Year Research Plan was initiated, enabling NICHD to continue to support its active research into the etiology, pathogenesis and prevention of SIDS. Existing programs were extended and expanded during fiscal year 1995 and fiscal year 1996, including the high risk infant monitoring study, the Chicago infant mortality study, and the "Back to Sleep" campaign. At the request of the Government of the Russian Federation, NICHD led a delegation of scientists and health professionals at a conference on Perinatal Pathology to discuss the problem of SIDS in Russian and plan areas of collaboration.

Beginning in fiscal year 1998 NICHD plans to work with the Office of Research on Minority Health to establish community based centers in areas with a substantial under-represented minority population to develop common biomedical research protocols; and to train minority researchers. If adequate funds are allocated in fiscal year 1998, NICHD plans to extend the prospective "Infant Care Practices Study" which is evaluating care-taking practices from birth through one year of age, documenting infant sleep position and other risk factors, correlating factors with sociodemographic characteristics and examining the reasons for and predictors of changes in behaviors. Funds will also be used to improve and expand the distribution of the "Back to Sleep" campaign. A prospective study to validate potential predictive biologic tests for SIDS risk and studies to increase our knowledge of the molecular, cellular, organ system and behavioral aspects of arousal in developing organisms are new efforts to be initiated this year.

The SIDS Alliance is grateful to the Subcommittee's past support. We urge you to again provide full funding in the amount of \$17,355,000 for the fourth year of the second Five Year SIDS Research Plan so that NICHD can complete critical initiatives. Further research is essential to find the reasons for, and means of preventing the tragedy of Sudden Infant Death Syndrome.



#### *Centers for Disease Control*

Due to inconsistencies from state to state at the scene of an unexplained infant death, in 1993 Congress recommended that a standard death scene protocol be established. The hope was that the death scene protocol would be adopted by states to assist in developing a better statistical grasp on SIDS cases, and would help to avoid awkward and sometimes emotionally charged misunderstandings at the scene. In July 1993, the Centers for Disease Control and Prevention and the National Institute of Child Health and Human Development held a workshop on "Guidelines for Scene Investigation of Sudden Unexplained Infant Deaths". The proceedings of the workshop were published in the *American Journal of Forensic Sciences* in 1995. The actual protocol was published in the *Mortality Morbidity Weekly Report* last summer. The long term goal of the SIDS Alliance is to work with and encourage each state's adoption of the guidelines.

#### *Maternal and Child Health Bureau*

The MCHB supports a number of SIDS related services and issues, including the National SIDS Resource Center, a major source of current information about SIDS. The Center maintains a national database of approximately 5,000 books, reports, and articles on SIDS and bereavement, and publishes information for national distribution. The National SIDS Resource Center has played a significant role in the "Back to Sleep" campaign, staffing the 800 hotline number and processing the more than 4 million pieces of campaign materials.

MCH Service Block Grant funds are used by MCH State Directors, either alone or in combination with non-federal funds, to provide a range of services to SIDS families in each state. Block grant funds support activities such as contact with families immediately after death; discussion of the autopsy results with the family; and family support through the first year of bereavement. Unfortunately, in many jurisdictions across the country, funds for these services have decreased or even been eliminated because of budgetary difficulties.

At the direction of Congress, MCHB funded the "Nationwide Survey of Sudden Infant Death Syndrome Services" in 1992. In response to needs identified through the Survey, MCHB contracted the development and field testing of a curriculum to train health care providers in the case management of families who have experienced an infant death, as recommended by the Survey. To date, 100 health professionals have participated in the training program. MCHB is also supporting the development of model programs to meet the needs of families—particularly the underserved and minorities—who experience an infant death, as recommended by the Survey. Four demonstration grants in California, Massachusetts, Missouri and New York have been initiated to target services for specific populations.

Currently, the MCHB is in the progress of establishing a national SIDS program support center to address SIDS service issues at the federal level on an ongoing basis. They have issued a request for applications and hope to have the center up and running in the next fiscal year. The center was another recommendation of the SIDS Survey.

#### *Fourth SIDS International Conference*

The SIDS Alliance, in conjunction with SIDS International and in cooperation with NICHD, MCHB and CDC hosted the Fourth SIDS International Conference on June 23–26, 1996 in Bethesda, Maryland. Over 700 registrants and 300 guests participated in this unique event. The partnership of countries provided by the International Conference has resulted in a heightened awareness of SIDS throughout the world, as well as a vital link allowing the rapid exchange of high quality international research, prevention, and service data. The global focus of efforts facilitates scientific breakthroughs and enables the development of innovative public health strategies to combat SIDS and assist families. Collaborative efforts such as the Fourth SIDS International Conference are crucial in moving forward with all aspects of activities relating to SIDS including research, death scene protocol and local SIDS services.

We are all too painfully aware, Sudden Infant Death Syndrome has historically been a mystery, leaving in its wake devastated families and bewildered physicians. In the past there have been no answers to why a baby dies of SIDS. For new and expectant parents there have been no answers on how to prevent SIDS from claiming their child. But today, we are beginning to find some of the answers such as factors that increase the risk for SIDS and actions parents can take to reduce the risks. Recent research has provided us with an unprecedented opportunity to decrease the number of SIDS deaths by alerting new parents about a few simple steps that they can take. It is important to realize however, that while following the recommendations presented may help to prevent some SIDS deaths, it will not save

all babies; we still do not know what causes SIDS nor do we know how to predict which babies are vulnerable.

There is still a great deal more that needs to be done in the fight against SIDS. It would truly be a tragedy if research efforts were halted or delayed at the point when so much progress is being made. Research capability and technology are available to conduct additional studies that will advance our abilities to eliminate SIDS. Now is the time for us to do something about SIDS and prevent babies from dying of SIDS in the future.

As SIDS parents, we are active in private organizations such as the SIDS Alliance and the CJ Foundation for SIDS that provide support to newly bereaved families, educate the public about SIDS and reducing the risks for SIDS, and fund SIDS research; but these organizations cannot do it alone. We need your help, your commitment, and your support. Moving towards the 21st Century, the political and fiscal realities of the world require that the public and private sectors work together to solve societal problems.

We urge the subcommittee to support SIDS research and education by funding the NICHD at a level of \$690,000,000, a 9.3 percent increase over the fiscal year 1997 budget. Designating \$17,355,000 for SIDS research in fiscal year 1998 is a critical factor in our continued progress. We also request that Congress continue to encourage MCHB and CDC to move forward with their initiatives to help SIDS families by expanding the availability of services and promoting standardized, thorough and compassionate death scene investigations.

On behalf of the thousands of families who have been devastated by the loss of a baby to SIDS, and the millions of concerned and frightened new parents each year, we thank you for your past leadership and support, and for enabling the Sudden Infant Death Syndrome Alliance and the CJ Foundation for SIDS to provide this testimony. If you have any questions, please do not hesitate to contact us.

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PREPARED STATEMENT OF DAVID JOHNSON, PH.D., EXECUTIVE DIRECTOR,  
FEDERATION OF BEHAVIORAL, PSYCHOLOGICAL AND COGNITIVE SCIENCES

Mr. Chairman, members of the Subcommittee, my name is David Johnson. I am Executive Director of the Federation of Behavioral, Psychological and Cognitive Sciences, a coalition of 16 scientific societies and 150 university graduate departments. The scientists of the Federation conduct behavioral research. Support for their work comes, among other sources, from the Office of Educational Research and Improvement at the Department of Education and the National Institutes of Health. My testimony will, therefore, be directed toward the fiscal year 1998 appropriation requests for these two agencies.

OFFICE OF EDUCATIONAL RESEARCH AND IMPROVEMENT

Let me first take up the request for the Office of Educational Research and Improvement. Any discussion of OERI funding properly begins with a look back at OERI's 1995 reauthorization. That legislation was carefully crafted over the course of five years, and its aim was to make OERI one of the government's premier supporters of research and research applications. A major impediment to building a solid scientific knowledge base for educational improvement has been that OERI and its predecessor, the National Institute of Education were buffeted by the political winds and by passing fads regarding educational interventions. NIE and OERI found themselves having to change gears to fit the current desires of those in power. That is not the right way to build a research knowledge base. The right way to do this is to look at the real problems in education and to develop research agendas to address those problems, much as the National Institutes of Health does with diseases. And so it is no happenstance that when OERI was reauthorized, it was organized into a series of research institutes, each focusing on a major problem area in education. It is also not a happenstance that an outside oversight board similar to the National Science Board of NSF or the advisory committees of the NIH was created to keep OERI on a steady course rather than to allow its programs to be whipsawed by each passing educational fad.

OERI has engaged in a strategic planning procedure to assure that the elements of the reauthorization accomplish their intended purposes. The result is that today we have an OERI that is taking substantial strides toward becoming a strong research and research applications agency for education. The process is by no means complete, but all indications are that the reinvention of OERI is going very well. The Congress deserves to take pride in its handiwork with respect to the reauthorization because the reauthorization has at last established a strong framework for the support of educational research and its applications.

Now it is time to see that adequate resources are placed within that framework to bring the promise represented by the reauthorization to fruition. Last year the appropriations committees and the Congress showed their support for education improvement with a good appropriation for OERI. This year, the Administration is asking for an appropriation of \$510.7 million for OERI. This represents a healthy, real increase over fiscal year 1997. The Federation supports the Administration request.

We had long argued that OERI needed to establish a better balance between research funded in centers and labs and field-initiated research. The reauthorization contained language to bring the three approaches to research into better balance. And the fiscal year 1998 request makes an incremental step toward achieving that balance by designating \$19 million for field initiated research, \$32.1 million for research centers and \$53.5 million for the regional labs. Each of these mechanisms offers a particular strength to overall educational research. Field initiated research is the source of new ideas and is a means to devote research to areas of concern that are not covered by the labs and centers. The research centers are in a good position to take findings from basic research and to develop them into workable applications. And the regional labs are both a point of dissemination for new, scientifically developed applications and for refining interventions to fit the particular needs of schools and school districts within the service range of the lab. Taken together, these three elements of the educational research enterprise represent a potential powerhouse for educational improvement. We urge the Subcommittee to fully support the Administration's request for OERI.

#### NATIONAL INSTITUTES OF HEALTH

Let me turn now to the appropriation request for the National Institutes of Health. The Administration is requesting a 2.6 percent increase from \$12.7 billion to \$13.1 billion. The Federation is joining with many other scientific organizations and with a number of key members of Congress in asking the Subcommittee to recommend an increase of 7.5 percent for NIH. This would bring the fiscal year 1998 appropriation to \$13.65 billion. We base our request for this increase on two observations. The first is that the pace of discovery in the full spectrum of the health sciences is accelerating, and the country needs to keep that momentum going. The second is that health care costs are at crisis proportions in this country, and one of the most important ways to control those costs is to find better ways to keep people healthy. The ultimate purpose of health research, including health research in the behavioral and social sciences, is to make the citizens of this country healthier throughout their lifespan.

One of the most significant developments in science in recent years has been the emergence of cross-disciplinary collaboration as a method for carrying out research. It has been important because it has become one of the means for accelerating the pace of discovery. Across the NIH-supported sciences, the growing tendency for scientists from many disciplines to come together to solve research problems has shown significant results. AIDS has not been cured, but research has shown how a mixture of treatments can ward off the worst effects of AIDS for many years. These treatments involve the use of a variety of drugs in combination and they involve a demanding level of discipline on the part of the patient to see that the medications are taken properly, a discipline that can be trained by application of techniques developed through behavioral research.

Similarly, it has been shown that many health problems of the elderly stem not from their infirmities, but from their misuse of medication. A host of sciences has contributed to the development of effective pharmaceuticals for use with elderly patients. Behavioral science has contributed interventions to help assure that patients take the right medications at the right time.

Congress recognized the significance of behavioral and social sciences research when it established just a few years ago, the Office of Behavioral and Social Sciences Research (OBSSR) under the purview of the Director of NIH. This office leads the coordination efforts of all the institutes and centers in marshalling their individual resources to collaborate on behavioral and social sciences research. A recent example of this is OBSSR, in conjunction with the National Center of Research Resources, has announced a new request for applications (RFA) focusing on "Educational Workshops in Interdisciplinary Research." This RFA fosters the development of cross-disciplinary communication and research collaboration among various behavioral and social sciences or between the behavioral and social sciences and biomedical sciences. As technological advances are developed it is imperative that parallel behavioral interventions are also developed.

Another application of behavioral intervention in concert with the use of medicines has to do with deadly diseases that are reemerging after decades of dormancy in this country. Tuberculosis is the example that comes most readily to mind. A serious challenge is faced with respect to these diseases. When medications are misused, the result is not only that the patient's disease fails to be controlled, but also the bacterium that causes the disease is able to develop resistance to medication making the disease much more difficult to treat. These diseases are cropping up in indigent populations such as the homeless—among the hardest groups in our society to treat.

Frankly, research is still underway to determine what behavioral interventions can best assure that such patients will carry their treatments through to conclusion. But behavioral and social scientists are working in concert with other scientists and with health providers to find answers to the problem. Our experience with collaboration to date leaves every reason to believe that even in this very difficult area, solutions can be found if support is maintained for the research teams that seek the answers.

NIH funding has permitted us to use researchers wisely, that is, in the combinations that will be most efficient in reaching solutions to typically multifaceted problems. If solid support continues to sustain the pace of discovery, then the variety of ways we have to assure the health of our population will increase. The largest per-person expenditures for health care occur near the end of life. Thus one goal of research has become to understand what interventions through the lifespan will have the greatest promise of assuring that the period of great illness before the end of life is minimized.

Behavioral research has a large role to play here since controllable choices and behaviors in life have a heavy impact on the quality of life of those who are aged. Obviously such behavioral choices as whether or not to smoke and what foods and quantities of food to consume are among the most important choices we make in determining our health. But each of us knows how difficult it is to do the right thing.

Behavioral researchers in cooperation with nutritional researchers, neuroscientists, epidemiologists and a host of other specialists are working to find ways to make it easier for people to make the right choices about their health. The payoff for finding solutions to these problems will be not only a healthier population, but also the ability of the country to bring health care costs back to a manageable size without sacrificing the well-being of the country's citizens. Through research, it is becoming possible to maintain good health and keep health care costs low at the same time.

We urge the Subcommittee to recommend a 7.5 percent increase for NIH because the investment in knowledge will result in health care cost savings that far exceed the research investment. And by the same token, slighting research will assure that rising health care costs will remain among our most serious national crises.

I thank the Subcommittee for this opportunity to present our views.

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#### PREPARED STATEMENT OF THE LUPUS FOUNDATION OF AMERICA

By way of introduction, my name is Jack Lavery, and while my full-time job is that of Senior Vice President of Merrill Lynch & Company, I am here today representing the Lupus Foundation of America as its Chairman of the Board. I am also representing the nearly 1.4 to 2 million Americans living with lupus. One of those people is my daughter.

The Lupus Foundation of America is a national advocacy organization dedicated to finding the cause and cure for systemic lupus erythematosus, a chronic, inflammatory disease in which the body's immune system fails to serve its normal protective functions and instead forms antibodies that attack healthy tissues and organs. In layman's terms, it is the body turning against itself. Lupus is incurable and extremely difficult to diagnose because, generally, no two people with systemic lupus have exactly the same symptoms. Moreover, it is a devastating illness. Thousands of Americans die each year from lupus-related complications. For those living with the illness, the disease wreaks havoc on their quality of life, with the side-effects for current treatments of lupus-related problems often causing worse problems than the disease itself.

Lupus is often called a "woman's disease" because 90 percent of lupus patients are women. The relative incidence of lupus is even greater among African American females, Asian American females, and Hispanic females than among Caucasian females. A market research study conducted by the Lupus Foundation of America in 1994 showed that as many as 1 out of every 102 women, and as many as 1 out of

every 62 women of color, may have lupus. Lupus is truly a diversity issue in 1997, and I must stress this to both the corporate sector and to the Federal government as well.

I want to thank you, as does the Lupus Foundation of America, Mr. Chairman, and the members of this committee for your leadership role in ensuring the continuation of research on the immune system at the National Institutes of Health and, in particular, the National Institute for Arthritis, Musculoskeletal and Skin Diseases (NIAMS). We want the Subcommittee to understand how important such high quality research on immune dysfunction is to those with lupus. I therefore urge the members of this committee to support funding for the NIAMS at the \$280 million dollar level recommended by the Coalition of Patient Advocates for Skin Disease Research, of which the Lupus Foundation of America is a member. This level of funding is crucial for three reasons.

First, it is a pivotal time for lupus research. The outlook for lupus patients has significantly improved over the last two decades. Better diagnostic techniques and evaluation methods have given physicians the tools to manage lupus symptoms and complications more effectively. However, a cure is still not within our reach. While scientists believe there is a genetic predisposition to the disease, environmental factors—such as infections, ultraviolet light, the sun, stress, and certain drugs—are also thought to play an important role in triggering lupus. We must know what causes lupus before we can develop a cure, and this is where research plays a critical role.

Recently, researchers at the University of California at Los Angeles, with funding from NIAMS, the NIH Office of Research on Women's Health, and the Lupus Foundation of America, have identified the location of a gene that predisposes people to systemic lupus across ethnic groups. This discovery and others like it provide important new insights on why people get the disease and may help researchers develop new treatments. It is a significant and positive step toward finding a cause for lupus—a breakthrough where additional research is still critical.

Second, I believe lupus is the prototype for autoimmune diseases, as well as for the management of chronic disease more generally. Research on lupus, therefore, has far-reaching consequences. Any insight we can gain from high quality research on immune dysfunction could provide important information on other autoimmune diseases and could potentially reveal new and different ways to control other chronic diseases.

Finally, LFA research indicates that as many as 2 million Americans report having been diagnosed with lupus. This year, we estimate that many thousands of people will call our organization's hotline. Most of the callers are individuals recently diagnosed with lupus or their family members who seek answers to questions about this disease. Only through further research will we find ways to improve both the prognosis and the quality of life of the many people living with lupus, including my own daughter, Dena.

Dena developed lupus at the age of 13, although it was initially incorrectly diagnosed as juvenile rheumatoid arthritis and then as vasculitis, a non-specific inflammation of the blood vessels. At 19, she was finally correctly diagnosed with systemic lupus. She is 28 now. She has been close to death at least twice and has permanently lost her vision in one eye as a result of lupus-related optic neuritis.

The side effects of treatments for lupus are often as devastating as the disease itself. As in my daughter's case, protracted use of steroids can cause osteonecrosis, i.e. bone death. She also has had to undergo multiple core decompressions in an attempt to recreate blood vessel growth. These involved individual operations drilling her left and right knees, left and right hips, and left elbow. Though at an age when most of her peers do not even have to think about such operations, my daughter has now also had surgery for a bilateral hip replacement, i.e. two prosthetic hips. Lupus is active in her kidneys, and her treatment involves the toxic chemotherapy drug cytoxan. The side effects of this drug grow cumulatively with protracted use and can include sterility, bladder cancer, and lymphoma.

I am proud to say that, despite these setbacks, my daughter has moved forward with her life like a true fighter and is currently a high school English teacher. She is an example of the courage of the many Americans who fight lupus everyday.

Last year, members of the Lupus Foundation of America donated nearly 400,000 volunteer hours to raising funds which are used to fund our own research, education, and support programs. However, the amount of funds lupus patients and their families can raise on their own is limited and relatively small compared to what is needed. Federal support of medical research in general is critical if we are to find a cause and a cure for lupus and other autoimmune diseases.

The Lupus Foundation is committed to developing and maintaining a partnership between the private and public sectors on lupus research. Only through such a col-

laboration can we ensure that the highest-quality research is conducted and leads to a cure for this devastating disease.

In summary, funding of lupus research is critical because we are at a pivotal time in lupus research; research on lupus could benefit those suffering from other autoimmune and chronic illnesses; and, finally, many thousands of Americans suffer a decreased quality of life due to the devastating nature of this disease. The Lupus Foundation of America is committed to push for federally supported research dollars which will yield answers to this mysterious disease. I cannot stress enough the importance of your support so that research on autoimmune dysfunction continues without interruption. Thank you for your attention, and my daughter also thanks you, as I'm sure all lupus patients and their families do.

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PREPARED STATEMENT OF DR. RAYMOND E. BYE, JR., ASSOCIATE VICE PRESIDENT  
FOR RESEARCH, FLORIDA STATE UNIVERSITY

Mr. Chairman, thank you and the Members of the Subcommittee for this opportunity to present testimony. I would like to take a moment to acquaint you with Florida State University. Located in the state capitol of Tallahassee, we have been a university since 1950; prior to that, we had a long and proud history as a seminary, a college, and a women's college. While widely-known for our athletics teams, we have a rapidly-emerging reputation as one of the Nation's top public universities. Having been designated as a Carnegie Research I University several years ago, Florida State University currently exceeds \$100 million per year in research expenditures. With no agricultural nor medical school, few institutions can boast of that kind of success. We are strong in both the sciences and the arts. We have high quality students; we rank in the top 25 among U. S. colleges and universities in attracting National Merit Scholars. Our scientists and engineers do excellent research, and they work closely with industry to commercialize those results. Florida State ranks seventh this year among all U. S. universities in royalties collected from its patents and licenses. In short, Florida State University is an exciting and rapidly-changing institution.

Mr. Chairman, last year, Florida State University (FSU) and the University of Miami (UM), jointly submitted two collaborative NIH projects to this Subcommittee seeking your support. As background, in June 1996, the Presidents of FSU and UM signed a unique research and education partnership. Two of the areas identified for collaboration were risk assessment activities and structural biology and magnetic resonance technologies. Last year, this project received strong supportive language from your Subcommittee. We greatly appreciate the past support for this joint venture and look forward to your continued support for our efforts in fiscal year 1998. Let me briefly describe these two collaborative projects.

The FSU/UM Risk Assessment and Intervention Consortium is dedicated to reducing the medical and social costs of health care through the development of cost efficient, behaviorally effective interventions. The Consortium is currently focusing its efforts on two specific activities. First, the Consortium is developing strategies to assess the access, medication compliance, and transmission risk implication of the new antiretroviral protease inhibitor therapies for various HIV infected populations. These new therapies represent a major step forward in efforts to reduce the onset of AIDS and the incidence of AIDS-related mortality. These medications have been effective in reducing and regulating viral load in HIV-infected patients to the point where many can lead more productive lives. While the advantages of these therapies are clear, they also have constraints. First, to be effective, patients must adhere to strict and complex treatment regimens. Second, although the protease inhibitor therapies are effective treatments to prevent the onset of AIDS and reduce and control viral load, they do not prevent HIV-infected persons from transmitting the virus. The characteristics of many HIV-infected persons suggest a difficulty in maintaining compliance. Thus, as health is restored, behaviors that could put the individual and others at risk must be examined.

The projects proposed are divided into two phases. The primary objectives of phase one are to identify the factors that contribute to non-compliance of medication regimens, and to investigate the types and frequencies of risk and risk reduction behaviors engaged in by HIV-infected persons. The accomplishment of phase one objectives will allow our team to move toward the development and testing of further medical compliance and risk reductions models in our second phase of this project.

The second area of focus for the Consortium is adolescent substance use. Substance use among adolescents is frequently associated with other health risk behaviors and has costly long-term implications. Data from two recently-released national surveys show that substance use is increasing among adolescents, that the age of

first use has become younger, and that adolescents are increasingly viewing substance use as an acceptable behavior. These patterns of behavior and attitude prevail across all categories of drugs, and arose after the Drug Abuse Resistance Education (DARE) program had been introduced across the country. Current trends—coupled with several independent evaluations of the DARE program and its lack of theoretical grounding—clearly indicate that the DARE program is not an effective intervention program. A proposal is being developed which will allow the Consortium to develop and test alternative interventions for adolescent substance use and associated risk behaviors.

Funding is being sought for the Risk Assessment and Intervention Consortium at the \$4 million level for fiscal year 1998 through the Department of Health and Human Services.

Our second SSU-UM collaborative effort involves structural biology and magnetic resonance technologies. With this collaboration, the universities, along with the National High Magnetic Field Laboratory (NHMFL), will initiate a major research and instrumentation effort that is built around macromolecular structure and functions—research key to drug development, delivery, and aspects of molecular function and binding—all of which are critical to many medical areas.

The FSU/UM collaboration, working closely with the NHMFL, and, with the aid of NMR instrumentation, will maximize the vast potential for biomedical research, training, and clinical utilization of magnetic resonance imaging (MRI), cellular and structural biology, and a broad range of other exciting research initiatives. Further, it is our long-term intent to establish a national network, where universities throughout the United States can benefit.

To help facilitate a nationwide program, the collaborators will first create a State-wide demonstration project, directed at the establishment of a high speed data network to support the use of shared instrumentation and human resources. This network will provide an opportunity to develop and test required human and hardware interfaces and protocols critical to the successful implementation such a concept. This initiative will serve as a demonstration for a larger network linking most universities in the United States to the NHMFL and the establishment of a national “collaboratorium” for shared instrumentation and resources.

Funding is being sought for this Magnetic Resonance network from the National Institutes of Health at the \$4 million level for fiscal year 1998.

Having concluded the discussion regarding the FSU/UM collaborations, I would like to discuss, FSU’s proposed, Rosa Parks Institute in Civil Liberties. The purpose of the Institute is to develop, produce, and disseminate programs and materials that not only highlight diversity but forge positive change in the work and school environments. Consistent with the life and works of Mrs. Parks, the Institutes’ ultimate objective is to assist individuals in realizing and achieving their highest potential.

The Institute will incorporate various projects including the following: A leadership development activity that will utilize individuals at mid-career who have dedicated their lives to actualizing the ideals of positive values at home, school, and the workplace. These individuals will become mentors and role models in this effort. Next, a university and community collaboration will include working with various partners such as civic organizations, educational institutions, business, and industry in order to promote educational dialogue concerning human rights, organizational, and societal change, and the importance of volunteerism. Thirdly, an oral history activity will focus on gathering direct personal perspectives from several leaders in the civil rights movement on their assessments of our past, present, and future with regard to racial diversity. Finally, a distance education technology program which will promote cultural diversity programs that can be utilized in education and employment settings.

The Institute will present a broad range of programs comprised of short courses and lectures which will be delivered both at the Institute and at remote sites around the Nation. New technologies will be crucial in the delivery and assessment of the programs. A Website Clearinghouse will be established for individuals, schools and businesses, around the country, to disseminate information provided by the Institute. Further, the Institute will obtain feedback, via the website, from participants to evaluate the effectiveness of the programs that are offered.

Funding for the Rosa Parks Institute in Civil Liberties is being sought from the U.S. Department of Labor at the \$1 million level.

Mr. Chairman, these activities discussed will make important contributions to solving some key problems and concerns we face today. Your support would be appreciated. And, again, thank you for the opportunity to present these views for your consideration.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING, ON  
BEHALF OF THE NATIONAL INSTITUTE OF NURSING RESEARCH

The American Association of Colleges of Nursing (AACN) submits this statement in support of funding for the National Institute of Nursing Research (NINR) at the National Institutes of Health and the Nurse Education Act. AACN represents over 510 baccalaureate, master's and doctoral nursing education programs in senior colleges and universities across the United States. We very much appreciate the past strong support this subcommittee, the Congress and the Administration have shown for NIH and for nursing education, and appreciate the opportunity to be heard on this important matter.

Federal funds are very important to schools of nursing, nursing students and society. In fiscal year 1996, 57 AACN member institutions received research funding from NINR and 13 received training funds. Further, a number of AACN member schools receive funds from other NIH Institutes and Centers and from other federal programs such as the Nurse Education Act and Scholarships for Disadvantaged Students, as well as Higher Education Act programs.

While being sensitive to the need for deficit reduction, overall, AACN respectfully recommends increasing NINR funding 9 percent, from \$59.743 million in fiscal year 1997 to \$65.120 million for fiscal year 1998. Because high quality professional nursing education is vital to research as it is to practice and teaching, AACN also stresses the importance of maintaining sound funding for the Nurse Education Act and other federal programs that help nursing schools and students. AACN supports the funding levels recommended by the Health Professions and Nursing Education Coalition of \$302 million for PHSA Titles VII and VIII.

*Nursing Practice Benefits from Scientific Inquiry*

Nurses, the largest group of health care professionals, are the backbone of patient care, not just in hospitals but in ambulatory clinics, public health departments, long term care facilities, skilled care nursing homes, schools, and hospices, as well as in corporations and private employ. They assess and monitor patients, evaluate the progress of treatment, carefully watch for adverse effects or conditions, and help prepare the patient and his or her family for re-entry into the everyday world. Nurses service all phases of illness and provide care to the most vulnerable, the very old, the very young and women. Nursing's presence in all domains of health care makes nursing research imperative to improve patient care and outcomes, with a recognition of the need to be cost effective. Nurses help patients and their families to manage difficult symptoms and disabilities, such as pain, incontinence, or paralysis; and to resume self-sufficiency when illness is most debilitating or threatening; even the transition from life to death. Nurses are the ones who assist people to resume functional status, mentally and physically, when medical interventions, however well meant and professionally done, have rendered them unable to do so for themselves. Nursing's issues of care span the spectrum of human concerns and are real and immediate; therefore, so is our research agenda. As a result NINR's broad research perspective links human health science to patient recovery and the promotion of health. Health promotion and disease prevention, a long time, elemental role of nursing practice and research, can reduce health costs and improve the quality of life.

*Nursing Research Emphasizes People, Not Just a Disease or Injury*

Nurses frequently help patients manage pain. Through NINR, research is being done on how to assess, control and manage pain, a major source of health care visits, hospital complications and lost work productivity. Recent nursing research studies have shown that poor pain control following surgery is linked to enhanced tumor growth in animals and that a particular type of pain reliever works better for women than men. And nursing research has refuted the myth that infant pain following surgery is minimal.

While research associated with life-threatening diseases such as heart disease, AIDS and cancer has high visibility, the possibility of having to live with a chronic condition is a more likely prospect for many Americans. With the "graying of America," we can only expect this to increase. The frailties of aging and chronic illness are high on the agenda of nursing researchers because it is most often nurses who are coordinating or giving the direct care to affected individuals. For example, about 4 million Americans suffer from Alzheimer's disease, many living 8 to 20 years before dying, after requiring either expensive facility care or major caregiving commitments from their families. The NINR is supporting research to discover how to limit disruptive behaviors such as wandering and loud vocalizations and to promote normal resting patterns by testing light therapy and behavioral modifications. Solutions to these issues can help a family care for patients at home and avoid costly



institutionalization. An estimated 250,000 hip fractures occur in people over 65 years of age at a cost of \$7 billion per year in the United States. Older adults in good physical condition are less likely to fall and break hips or other major bones, leading to hospitalization, and possibly custodial care and death. NINR research has sought ways for older people to keep fit and to test the effects of hip pads to prevent fractures in a fall.

*Nursing Research to Promote Health and Prevent Disease*

Until recently, America had a disease and illness system rather than a health care system. Plenty of information suggests that the root of many health care problems are food, drink and substance abuse, inadequate stress management, along with exercise, sleep, social, and educational deprivations or abuse. Major health problems such as heart disease, some cancers, diabetes, rheumatic disease, and ulcers have multiple contributing factors, in large measure due to unhealthy lifestyles. These disease-contributing factors largely are behaviors, which if modified prior to the development of disease consequences, could save much money. Teaching people how to treat or prevent illness and promote health will reduce the cost of health care, an idea emphasized in nursing for a long time. NINR's research agenda recognizes the concept that nutrition, sleep and exercise and other behaviors have enormous impacts on health status.

One NINR funded project is studying women with fibromyalgia (FM), a mysterious, invisible chronic illness (no known pathology) that affects upwards of 10 million Americans, five times more women than men. Almost all report overwhelming fatigue and poor sleep, awakening with muscle pain and discomfort. This study is designed to link separate pieces of evidence that a sleep disturbance is fundamental and that a hormone disturbance is evident. Why is this important? Chronically disturbed sleep obviously can lead to a decline in health status. Poor sleep impairs daytime performance, results in injury accidents (estimated to cost society upwards of 15 billion dollars a year), and retards tissue healing, alters immune function, and may herald early onset of psychiatric illness. This study will generate a basis for defining which treatments to test, be they sleep therapies, hormone augmentation, or some combination. Better treatments could reduce health care costs by reducing health care visits, since FM accounts for 15 to 40 percent of referrals to rheumatologists.

Understanding contributing factors to domestic violence against women is a focus for nursing researchers to gather knowledge for prevention of health problems. One NINR project involves examining the effects of battering during pregnancy on the victim and subsequently on her baby. Battering can lead to increased likelihood of delivering low birthweight infants that need costly tertiary care, increased child abuse, as well as increased smoking, substance abuse, depression, and other health risk factors in mothers. Outcomes from this study will inform us on identification of those at risk and guide the testing of primary and secondary prevention strategies.

Another NINR project funded a prenatal training program for expectant mothers that reduced the incidence of low birthweight babies. Tertiary care costs were sharply reduced (38 percent for diabetic mothers and their babies; 29 percent for cesarean section mothers and their babies) by a carefully planned early discharge based on from hospital program that includes a home visit follow up with mother and child by advanced practice nurses.

NINR supported research is being done to improve the health of school children, particularly African-American at risk for cardiovascular disease, through interventions focused on education, diet and exercise. This North Carolina project demonstrated favorable effects on reducing child body fat, fitness and cholesterol levels. Healthy behavior patterns instilled in these youngsters hopefully will produce adults with lower incidence of cardiovascular and other disease.

*NINR: Strong Stewardship of Resources*

Funds appropriated to the NINR represent only a little less than a half percent of the \$12.7 billion total NIH appropriation. But this relatively small amount of money makes a meaningful difference for nurse researchers to develop knowledge to better the health of Americans. NINR not only funds institutional and individual researchers, but also supports the training of nurse scientists at several career levels. NINR provides funds for the preparation of highly skilled nurse researchers through pre-and post-doctoral fellowships awarded to leading research universities and to deserving individuals, and it offers senior fellowships that encourage experienced researchers to pursue new research initiatives. Most major universities are desperately in need of skilled researchers for faculty since nursing is a relatively new health science and must grow to increase the critical mass of nurse researchers

and amplify the synergy of discovery. The National Research Council has recommended that training positions for nurse researchers are increased to 500 in 1996–99. But NINR's fiscal year 1997 financial resources of \$4.6 million will support an estimated 113 individual awards and 95 institutional awards. We can and should do better.

NINR stretches its dollars by collaborating with other NIH entities on scientific issues of shared interest; NINR will spend \$1.2 million in fiscal year 1997 on new intramural research projects. NINR also supports 6 specialized research centers, serving as cores for interdisciplinary health science work by established investigators. The foci are Prevention and Management of Chronic Illness in Vulnerable People (University of North Carolina at Chapel Hill), Chronic Illness and Disability (University of Pittsburgh), Symptom Management (University of California at San Francisco), Women' Health (University of Washington), Serious Illness and Cancer (University of Pennsylvania), and Gerontology (University of Iowa). In fiscal year 1997, NINR expects to commit \$1.87 million to the centers program. All will advance human science knowledge.

#### *NINR Initiatives for Fiscal Year 1998*

NINR's initiatives for fiscal year 1998 will be symptom management for chronic neurological conditions (stroke, epilepsy, Parkinson's disease), managing traumatic brain injury, improving quality of life for transplantation patients, and end of life issues. In order to leverage our resources and maximize our health research dollars, the NINR co-sponsors research opportunities with other NIH institutes to foster multidisciplinary work. For example, an NINR project in collaboration with the National Institute on Aging will assess and train caregivers from a variety of ethnic groups who care for Alzheimer's disease patients.

#### *Nursing Education: A Sound Foundation for Nursing Research and Practice*

Given the vast influence of nurses on health care delivery and the commitment of the profession to research addressing the immediate issues of human health science, the education of nurses has been and is central to our capacity to deliver cost-effective, high performance health care delivery. Nursing education is, as NINR Director Patricia Grady put it a few weeks ago when she appeared before the House Appropriations Subcommittee, "a pipeline issue" for nursing research. Quality educational preparation is central to competence in nursing practice and research. For that reason, AACN also requests funding for federal nursing education programs.

#### *The Nurse Education Act*

Recognizing the importance of nursing education programs, Congress appropriated \$65.4 million for the Nurse Education Act (Public Health Service Act Title VIII) for fiscal year 1997. The NEA supports the programs for nursing students who will give direct care, and who will become the researchers, nursing faculty, and advanced practice nurses (APNs) of tomorrow. Many nurses provide cost effective health care to people who would otherwise have no health care. For example, it is estimated that about 70 percent of the anesthesia in the United States are given by nurse anesthetists. Nurse practitioners, midwives and other nursing professionals are in great demand in a decentralized, community based health system becoming more oriented toward wellness, health promotion, and primary care. Nurses are often willing to work in an underserved community. NEA funds mean direct financial support to disadvantaged students, which increases the number of potential minority faculty and researchers. The NEA has provided seed money for 28 nurse-managed health centers that, as part of the clinical teaching process, deliver primary care to high risk and vulnerable populations. AACN respectfully requests maintaining the fiscal year 1997 level of funding of \$65.4 million for the NEA.

#### *Other Education Programs*

AACN recommends funding at the fiscal year 1997 level for the following Public Health Service Act education programs important to nursing: Scholarships for Disadvantaged Students, National Health Service Corps scholarship and loan repayment, Rural Health Outreach Grants, and Interdisciplinary Training for Rural Health. AACN supports a total figure of \$302 million for PHSA Titles VII and VIII. Adequate federal funds also should be committed to the gathering of data about nursing practice, demand, and supply.

We need to know what works and what don't so that NEA and other funds can be intelligently allocated. This means adequate federal support for the Agency for Health Care Policy and Research for assessment of the outcomes of health services and medical procedures in general. Lastly, AACN urges the subcommittee to fund Higher Education Act programs used by nursing students including Pell Grants,

Perkins Loans, Harris Scholarships, Federal Work Study, GANN, and TRIO programs. Each in its own way helps students and ultimately our society.

*Conclusion*

AACN believes that a sound approach to the health of the public in America is based on linking adequate support for human health research such as that sponsored by NINR to the education of nurses and other health professionals to meet America's health care research and population care needs.

PREPARED STATEMENT OF DR. ROBERT J. GUMNIT, PRESIDENT, NATIONAL ASSOCIATION OF EPILEPSY CENTERS

Mr. Chairman and Members of the Subcommittee, I am Dr. Robert J. Gumnit, President of MINCEP Epilepsy Care, a comprehensive epilepsy center in Minneapolis, Minnesota and Clinical Professor of Neurology, Neurosurgery and Pharmacy at the University of Minnesota. I am here today in my capacity as the President of the National Association of Epilepsy Centers (NAEC), an organization representing 60 specialized epilepsy centers in the U.S.

Approximately 2.5 million people in the United States have epilepsy—a chronic neurological condition defined as the occurrence of more than one seizure on more than one occasion. Epilepsy primarily affects children and young adults. Each year about 100,000 people are diagnosed with epilepsy. More than two-thirds of them are below the age of 25.

Timely entry into the medical care system, making the correct diagnosis, and early and appropriate treatment of the medical, psychological and social conditions of people with epilepsy have been major goals of the National Association of Epilepsy Centers. These goals are particularly important because the initial diagnosis of epilepsy is most frequently made by primary care physicians who treat a very limited number of persons with epilepsy. With the increased use of managed care and a greater dependence on primary care practitioners for managing patients with chronic diseases such as epilepsy, it is increasingly important that new information be widely disseminated on accurate diagnosis and treatment options available to achieve seizure control. Chronic disease tends to be slighted under managed care. Epilepsy is a very treatable chronic disease, and this disability is often reversible.

For these reasons NAEC has explored avenues within the Centers for Disease Control and Prevention (CDC) to educate health care practitioners and people with epilepsy and their families about the benefits of early intervention. This Subcommittee was instrumental in initiating funding for an epilepsy program at CDC. For 1998, NAEC seeks an extension of the CDC program at the originally requested level of \$1 million.

*CDC—Educational Efforts to Promote Early Intervention*

As directed by Congress in 1993, the CDC launched its epilepsy program within the National Center for Chronic Disease Prevention and Health Promotion. Focusing on early detection and effective treatment of epilepsy and enhancing the overall quality of life for persons with epilepsy and their families, the epilepsy program targets its outreach and education efforts on consumers, health professionals, and health systems including managed care plans and Medicaid. The NAEC, the Epilepsy Foundation of America (EFA) and the American Epilepsy Society (AES) have been active participants in a working group with the CDC in planning the future course of the epilepsy program.

We are currently working with CDC on plans for a conference scheduled for September to set objectives for improving the health of persons with epilepsy and seizure disorders. The conference will bring experts in the field of epilepsy treatment and research together with patients and families affected by epilepsy and seizure disorders as well as public health and managed care professionals and primary care providers. Experts in the field will present data and findings from existing scientific literature to show that timely recognition of seizures and effective treatment can reduce the risk of subsequent brain damage, as well as disability and mortality from injuries incurred during a seizure and from reoccurring seizures. We also plan to discuss strategies for overcoming barriers to optimal health and functioning for persons with epilepsy and seizures.

The intent of the CDC epilepsy initiative is not only to improve the care of people with epilepsy and seizure disorders, thus helping them live more active and productive lives, but also, to contribute to the development of model strategies of care for people with other chronic diseases. While treating epilepsy and seizure disorders requires specific expertise among providers, the core health care services and system elements needed to provide optimal care for people with epilepsy is remarkably

similar to those needed by people with diabetes, asthma and Parkinson's disease, as well as other chronic diseases. Through this model epilepsy program and anticipated follow-up activities, we hope to develop effective prevention, early recognition, appropriate care and treatment strategies leading to improved health and reduced disabilities for people with epilepsy and seizures which can be extended to individuals with other chronic diseases.

Funding for the epilepsy program has remained at just over \$700,000 since fiscal year 1994. NAEC recommends that the program be provided a modest increase of \$300,000 in order to begin implementation of the recommendations from the September conference next year.

*HCFA—Research, Demonstration and Evaluation*

Though Medicare and Medicaid were both created to provide coverage for the episodic acute care needs of beneficiaries, greater emphasis is now being given to prevention and the management of chronic disease including key quality of life issues. While the incidence of epilepsy among Medicare beneficiaries is not as common as other disorders, the prevalence of this disease in the Medicaid population is significant. Studies to determine how health care systems can be organized to best care for and support people with epilepsy and other chronic diseases could yield information that provides better treatment for individuals and over the long term, substantially reduce the high costs of unnecessary acute care often paid for by these programs.

Consider the following:

- Chronic diseases require close and repeated contact with numerous health care providers to diagnose the condition and stabilize the treatment regimen.
- Because chronic diseases, by their nature, are rarely cured, their care requires a focus on helping people to remain active, productive members of society, as well as on arresting the progression of the disease and preventing complications.
- Chronic diseases require repeated health care visits and active monitoring throughout the patient's lifetime.
- And chronic diseases generally place a considerable burden on the patient and family; while the physician can provide prescriptions, advice, information, and warnings of the dire consequences of non-compliance, the day-to-day care for most chronic condition falls on the shoulders of the patient and his or her family.

NAEC seeks the support of this Subcommittee in encouraging HCFA to expand its research and demonstration activities to help determine the unique elements of effectively managing the care individuals with chronic disease. Epilepsy is an excellent model for determining chronic disease treatment plans that is oriented toward improved health and functioning, and empowers patients to live long and productive lives.

*NINDS—Enhance Research In Epilepsy*

I want to commend the Subcommittee for its support of the National Institutes of Health and the increase in research funding provided for fiscal year 1997. On behalf of the epilepsy community, I urge the Subcommittee to build upon last year's increase and provide for a continued high level of support for NIH and the National Institute of Neurological Disorders and Stroke (NINDS). Medical research has greatly improved the quality of life for persons with epilepsy and their families. The development of anti-seizure medications over the past few decades, as well as the more recent advent of improved surgical techniques, has enabled many people with the condition to lead independent and productive lives.

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PREPARED STATEMENT OF THE PUBLIC POLICY COUNCIL, ON BEHALF OF THE SOCIETY FOR PEDIATRIC RESEARCH, THE AMERICAN PEDIATRIC SOCIETY, AND THE ASSOCIATION OF MEDICAL SCHOOL PEDIATRIC DEPARTMENT CHAIRMEN

This statement is submitted on behalf of the Public Policy Council which represents the Society for Pediatric Research, the American Pediatric Society and the Association of Medical School Pediatric Department Chairmen. These organizations represent thousands of pediatric researchers involved in basic, clinical and health services research with the goal of improving the quality of life for all of America's children. These scientists come from medical schools, children's hospitals and other research facilities. They are the driving force behind advances in science that benefit children and also are the mentors for training our next generation of pediatric scientists.

In addition to the specific recommendations which are attached, we also support the fiscal year 1998 National Institutes for Health (NIH) recommendation presented by the Ad Hoc Group for Medical Research Funding, the Friends of NICHD Coalition's recommendation for the National Institute of Child Health and Human Development and the overall health spending recommendations of the Coalition for Health Funding.

There are four main points to our statement: First, greater emphasis must be given to pediatric clinical research; second, clinical studies offer the best hope for reducing the cost of medical care while improving the health of our children, and indeed, all of our citizens; third, all that benefit from clinical studies need to share their cost, this includes insurance companies and managed care organizations; and fourth, children need more opportunities to participate in clinical trials.

*Clinical Research:*

We are in an age of great technological innovation that has allowed for a better understanding of the pathogenesis of disease, enhancing diagnostic capabilities and improving the treatment of patients. However, the actual practice of medicine is too often based on empiricism rather than evidence derived from well-controlled clinical trials. Clinical trials when done well can establish the usefulness of a particular test or treatment and examine their cost effectiveness compared to current practice. Unfortunately, only 10—20 percent of medical practices are based on data from well-controlled studies according to the Government Accounting Office. Thus, when your child or grandchild is being treated for an illness today there is only about a one in five chance that the therapy is based on solid evidence that it will be helpful.

Last year, this committee put a down payment on our children's future by funding the Pediatric Research Initiative at \$5 million to increase the pediatric biomedical and behavioral research at NIH. Through the leadership of Senator Mike DeWine, the Pediatric Research Initiative has been reintroduced this year, and it is our hope that this Committee will maintain its commitment to improving the quantity and quality of pediatric research at NIH, its sister agencies and throughout the country.

*Clinical Studies and Cost-Benefit:*

In the current era of constricting federal dollars for health care and research, most of our colleagues believe that U.S. medical research is currently in a crisis. We recognize that the NIH received a substantial increase in funding this year and applaud the high priority Congress and this subcommittee in particular has given to health care research. However, we remain concerned that the percentage of grants being funded continues to decrease. There is also growing concern that the focus of academic institutions, where most of the nation's pediatric research occurs, is shifting away from the traditional triple role of patient care, teaching and research to one concerned predominately with clinical care. In the long run such a shift in focus will be detrimental to the health of our children and very costly. This change in emphasis will impair the quality of the training of future generations of pediatric medical scientists. Furthermore, a decreased emphasis on research will lessen our ability to prevent disease in children and eventually lead to an increase in the number of adults who are medically ill and therefore less productive. Certainly members of this subcommittee remember the crippling effects the polio virus had on people, both during their childhood and later on when they became adults. The development of two polio vaccines proved not only to be a very cost-effective means for preventing this disease in the United States, but will likely, in the near future, bring about the elimination throughout the world.

It is our belief that this current crisis also allows us an opportunity to utilize research as the primary tool to overcome the constraints of a constricting budget. We must use research not only to manage or cure disease, but also to decide how we can most effectively spend our health care dollars. It is no longer enough to ask if a treatment works. The question is also whether the therapy is a cost-effective use of our resources. If we have the foresight to put a significant portion of these cost savings back into additional research endeavors, we believe we can achieve two important but seemingly opposing goals; i.e., better health for our citizens at a lower cost.

In pediatrics we have some spectacular examples of how well-controlled multi-center trials can improve the health of our children in a cost effective manner. For example research supported by NIH led to the development of surfactant treatment for Respiratory Distress Syndrome (RDS). Surfactant can be administered into the lungs of premature infants and has resulted in fewer deaths of infants from Respiratory Distress Syndrome (RDS). This has saved an estimated \$90 million a year in hospital costs.

Another example is the finding that vitamin supplements containing folic acid prevent common and disabling birth defects, such as spina bifida and anencephaly. These birth defects are the leading cause of disabling conditions in children, which cost families and our government billions of dollars each year. Research discovered that if American women of childbearing age consumed an adequate daily supply of folic acid, 2,000–3,000 cases of birth defects could be prevented each year, saving nearly \$245 million.

Unfortunately, many excellent clinical studies that are proposed to examine these types of clinical issues are delayed or canceled. Numerous examples can be cited. One case that occurred involves a neonatologist who submitted a study to the Agency for Health Care Policy and Research (AHCPR) to examine cost-effective approaches for discharge and follow-up of premature infants with chronic respiratory disease. Despite receiving an outstanding priority score at the 3.6 percentile the funding to do this study remains uncertain.

*Cost Sharing:*

The monies to do these clinical studies should not come at the expense of basic or translational research, for these provide the foundation upon which clinical studies are based. Therefore, we must find additional funding to do well-controlled clinical studies. The pediatric academic societies have long recognized the need to increase the amount of clinical research in children and recently have established a program designed to help initiate multi-center clinical trials in children.

Other means to enhance our clinical research capabilities must also be explored. We believe that insurance companies and managed care organizations must share equally in funding clinical research, since their viability is predicated on delivering high quality, cost-effective health care. Congress should encourage and explore incentives to persuade companies that benefit from clinical research to provide substantial funding for these endeavors.

Other health care companies, such as those in the pharmaceutical industry should also be encouraged to contribute more resources to research. In our opinion, increased funding in research is a long-term investment as opposed to a short-term view based on bottom line profitability. The results of a 1997 Research!America Harris poll in Ohio showed that 77 percent of those surveyed urged Congress to support legislation that will encourage private industry to conduct medical research.

*Inclusion of Children in Clinical Trials:*

Finally, in the past the tendency has been to exclude children from many relevant clinical trials. This was done under the guise that new procedures and treatments should first be tested in adults. Multiple studies, such as those involving HIV-infected children, show that children can benefit greatly from inclusion in well designed clinical trials, some of which can be conducted while similar studies are ongoing in adults. The pediatric academic societies believe that this issue needs to be addressed.

This Committee has also shared similar concerns as evidenced by the fiscal year 1996 Committee Report language which included the following:

The Committee strongly encourages the NIH to strengthen its portfolio of basic, behavioral and clinical research conducted and supported by all of its relevant Institutes to establish priorities for pediatric research, and to ensure the adequacy of translational research from the laboratory to the clinical setting. The Committee encourages the NIH to establish guidelines to include children in clinical research trials conducted and supported by NIH.

Last June, the NIH convened a workshop on the "Inclusion of Children in Clinical Research." The workshop examined the participation of children in clinical research, including clinical trials, sponsored by all Institutes, Centers and Divisions of the NIH. As a direct result of that workshop, in January 1997 the NIH issued a notice recommending "that when there is sound scientific rationale for including children in research, investigators should be expected to do so unless there is a strong overriding reason that justifies their exclusion from the studies." The policy states that "although this is the same scientific rationale that is the basis for the policy requiring the inclusion of women and minorities in clinical research, this policy does not mandate the inclusion of children in all clinical research. Because the issues and sensitivities surrounding children's participation in research are significantly different from those regarding women and minorities, such a mandate would be inappropriate." The NIH did stress, however, that "even though the inclusion of children is not an absolute requirement, applicants for NIH funding will be expected to address this issue in their proposals." The pediatric academic societies are committed to working with NIH to monitor its progress on this important matter.

We would further hope that other agencies with a research agenda, such as the FDA and the CDC also further examine this important issue.  
Thank you for the opportunity to submit this statement.

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PREPARED STATEMENT OF THE AMERICAN ACADEMY OF NURSE PRACTITIONERS

The American Academy of Nurse Practitioners represents over 17,000 nurse practitioners of all specialties throughout the United States. This testimony has been submitted to speak to the need for continued and increased federal funding for nurse practitioner and nurse mid-wife educational programs and traineeships for the coming fiscal year.

Nurse practitioners and nurse midwives constitute an effective body of primary care providers that may be utilized at a cost savings in both fee for service and managed care programs in this country. Savings to the federal government of greater than \$55,000,000 in the Medicare program are estimated with All utilization of nurse practitioners in the system. Likewise, managed care data is becoming available that demonstrates an aggregate patient per month cost savings of over 50 percent among patients seen by nurse practitioners when compared to similar patients being cared for by physicians.

Other cost savings that can be realized by the government when nurse practitioners and nurse midwives are appropriately utilized, include savings due to reductions in emergency room visits and hospitalizations and savings associated with the treatment of illness in its early stages. Multiple studies in both fee for service and, now, managed care have been conducted that demonstrate cost savings in diagnostic testing, prescribing and hospitalizations and emergency room use when these two groups of providers are utilized to provide primary care to populations of all ages.

As this committee knows, nurse practitioners and nurse midwives are highly qualified primary care providers who have demonstrated their ability and interest in providing primary medical care to individuals and families in both rural and urban settings, regardless of age, occupation or income. The quality of their care has been well documented over the years. With their advanced preparation, they are able to manage the medical and health problems seen in the primary care and acute care settings in which they work.

Nurse practitioner specialties include family, adult, pediatric, women's health and gerontologic care. Their services include obtaining medical histories, performing physical examinations, ordering, performing and interpreting diagnostic tests, diagnosing and treating acute episodic and chronic illnesses including the prescription of medications and other nonpharmacologic treatments, and appropriate referral to other sources of care. In addition, they are skilled in the areas of health promotion and disease prevention which include health education, screening and counseling for patients of all ages.

Nurse practitioners and nurse midwives provide care in both rural and urban settings, in community health centers, public health clinics, hospitals and hospital outpatient clinics, Indian Health Service and National Health Service Corps sites as well as in private primary care offices and other freestanding primary care settings. According to data collected by the American Academy of Nurse Practitioners, 82 percent of nurse practitioners are employed in primary care settings and over 50 percent of their patients have family incomes in the poverty range.

In order to guarantee the proper preparation of nurse practitioners and nurse mid-wives, assistance in the development of high quality programs continues to be needed across the country. The funding for such programs has always been limited, and should always be more, but the value and worth of such funding continues to be undisputable.

Two years ago only 14 new programs out of 127 applicants were able to be funded for a three year period at the amount of approximately \$200,000 per program. Last year, new applicants were not even solicited as the Division of Nursing sought to fund the approved applicants unable to be funded the previous year. Out of that pool another 21 programs were able to be funded. This year, 88 programs from 35 states have applied for assistance, and again, only a small number will be able to be funded at these modest amounts. While the sums of money described here are but a drop in the bucket compared to investments made by the federal government to underwrite the cost of preparing other medical professionals, the loss of this funding would create significant problems and erect additional barriers to the effective utilization of the most cost effective primary care providers in our health care system.

Likewise, traineeship monies are being utilized by students in all 50 states and the District of Columbia. These monies are of particular importance in the recruit-

ment of nurse practitioners and nurse midwives in underserved communities. Again, while the funds fall far short of the mark for assisting in the preparation of these important, cost effective health care providers in the system, the amounts appropriated in the past have helped to reduce barriers for many students desiring to become nurse practitioners and nurse midwives. Surveys of nurse practitioners and nurse midwives have shown this investment to be a good one in terms of assisting students who otherwise might not be able to return to school, and in terms of adding providers who care for the rural and urban underserved in this country.

In addition, the need for funding for special projects to evaluate the worth, quality and cost effectiveness of nurse managed centers and other creative applications of primary care services by nurse practitioners and nurse midwives, and the need for continued data collection in this realm can only reinforce the fact that the appropriations should not only not be cut (as has been proposed in this years budget by the administration), but that they should be substantially increased if the government is truly seeking methods to provide quality, cost effective care to all populations, especially to the underserved, as it says.

While we once again recognize the difficult decisions that must be made regarding HHS appropriations for the coming year, it seems logical that continued appropriations for nurse practitioner/nurse mid-wife educational programs, traineeships and program exploration would still be a wise investment.

We thank the members of the Appropriations Committee for their efforts in behalf of nurse practitioners and nurse mid-wives and the patients they serve. We know you recognize the value of our services and the need for utilizing us in the provision of quality, cost effective medical care. It is obvious that we can be part of the solution to the current fiscal problems surrounding the provision of medical care in this country, and we are asking for your help to facilitate the process. If there is anything we can do to provide further information or assistance regarding this issue, please feel free to call on us.

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PREPARED STATEMENT OF RENEE MCLEOD, MSN, RN, CS, CPNP, PRESIDENT,  
NATIONAL ASSOCIATION OF PEDIATRIC NURSE ASSOCIATES AND PRACTITIONERS, INC.

On behalf of the 5,200 members of the National Association of Pediatric Nurse Associates and Practitioners, I submit this statement for the hearing record to express our views and concerns about the proposed consolidation and funding of nurse education programs, funding for the National Institute of Nursing Research and the immunization programs. We thank the committee for its commitment to funding these programs, particularly its strong support for Nurse Practitioners (NP) education.

Pediatric Nurse Practitioners (PNPs) are front line, primary care providers specializing in pediatrics who deliver a broad range of health care services to children from birth to age 21. PNPs perform physical examinations, treat common childhood illnesses, coordinate care of chronic illnesses in children, and help families meet other important health care needs. In summary, NAPNAP seeks your favorable consideration to fund the following programs: Nurse Practitioner/Midwife Education of at least \$17.588 million; National Institute of Nursing Research (NINR) at \$65.2 million; and, Immunization Programs at least \$467.9 million.

What follows are more extensive remarks providing our views and concerns about the above.

#### *Consolidation of Nursing Education*

In an effort "to provide comprehensive, flexible, and effective authority" for Federal support of the nursing workforce, the Administration's fiscal year 1998 budget proposal includes a provision to consolidate Title VIII nurse education authorities. This clustering would replace the following nursing programs currently in the Public Health Service Act: Advanced Nurse Education (Section 821); Nurse Practitioner/Nurse Midwife Training (Section 822), Professional Nurse Traineeships (Section 830) and Nurse Anesthetist Training (Section 831).

NAPNAP is particularly dismayed that the Administration's proposal also reflects a reduction of fiscal year 1997 appropriations by \$55,488,000, basing their decision on "market forces already reconfiguring the nursing workforce." Similarly, the congressional authorizing committees are also considering consolidating these programs. While the stated goals appear laudable, we are very concerned that severely limiting funding while clustering these programs under one heading, "Advanced Practice Nurses," is not based on accurate data, would do little to serve these goals, and would have the unintended effect of diminishing access to health care providers in underserved areas and to disadvantaged students.



PNPs are particularly concerned that the reduction in and consolidation of funding under the Administration's 1998 budget proposal as well as other proposals to cluster or consolidate such programs, would have the following unintended, detrimental consequences:

Consolidation fails to recognize valid distinctions between the various advanced practice nursing roles and would decrease accountability of funding dollars.

—While we understand the desire to streamline programs, consolidation should not occur at the expense of proven, established programs that meet distinct health care needs. For example, the Administration's proposal would add case management, nursing informatics, and nursing management/administration to items funded under this title. These items have not traditionally been part of the nurse practitioner education programs and for good reason—NPs specialize in delivering primary care.

—Giving authority to the Health Resource Services Administration without empirical data on the numbers of, and need for certain specialties will result in arbitrary decisions at best, and at worst, less politically-powerful groups at risk of losing all funding. In addition, assessing outcomes would become more difficult under a cluster scheme because groups would not be directly accountable for their programs.

A decrease in funding arising from consolidation would inhibit the PNP workforce from meeting the primary care needs of our nation's children.

—While, the health care marketplace has been making strides in recent years in promoting the goals of primary care, more needs to be done particularly in underserved areas where, without the support of government, market demand simply does not elicit provider supply.

—Recently, the Institute of Medicine (IOM) called for fundamental changes to improve and expand primary health care in the U.S. in order to address the many challenges facing the Nation's health care system (IOM Report, "Primary Care: America's Health In a New Era", 1997). The IOM highlighted the important need to coordinate efforts that would promote and enhance primary care.

—There are about 10 million children, nearly 14 percent of all children between the ages 1 and 18, who have no health insurance ("Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 1996 Current Populations Survey. EBRI Issue Brief. No. 179, November 1996.) Congress is now deliberating on ways to provide health insurance and access to care for these children. If the efforts are successful, the need for PNPs will be even greater.

—Primary health care is in great demand but is often overlooked by the nation's specialists as it does not generate the highest salaries. Since PNPs specialize in primary care, much caution should be taken to preserve funding directly to PNPs who fulfill a distinct public need.

A decrease in funding for PNPs would impede them from serving in health care shortage areas where the need for primary care and prevention is often the greatest.

—While the numbers of PNPs have increased over the years, they are still in great demand in rural and underserved areas. If funding is consolidated and therefore reduced, fewer PNPs will be educated and choosing to practice in disadvantaged areas, resulting in decreased access to health care in these areas. Underserved areas are, by their very definition, areas which lack even the most basic of services including primary care and prevention, needs successfully met by PNPs.

—The recent Council on Graduate Medical Education (COGME) draft report notes that NPs and physician assistants may be utilized to increase the number of primary care providers in Health Professional Shortage Areas (HPSAs). Overall, COGME recommends supporting NPs (as well as physicians and physician assistants) in order to improve geographic distribution in rural and underserved areas.

—The COGME draft report also provides an update on the work of the Joint Workgroup on Primary Care Workforce Projections. According to the report, six scenarios were developed to project integrated requirements to the year 2005. The model projected increased needs for NPs in the range of 12–24 percent.

Consolidation would result in heightened battles among advanced practice specialties over funding as well as serious inefficiency and inequity in funding decisions.

—The proposal would result in heated battles over APN education monies. Since there is yet no empirical data available to assess the need or importance of the individual advanced practice disciplines, the battles between APN groups would be won by the most politically-powerful, not necessarily those who can best meet the nation's health care needs. Under this scenario, we are certain that federal support for nurse practitioners or PNP education could be virtually eliminated.

- Our experience to date has been that despite the significant demand for PNPs within the health care system, few PNP education programs have competed successfully for these dollars because of the biases that exist within the current funding mechanisms. For example, there appears to be a recent trend to fund family nurse practitioner programs over PNP education programs because of the mistaken belief that a generalist can meet a family's entire needs and therefore pediatric specialists are unnecessary. This is obviously a concern for us and our pediatric clients.
- The proposal also raises more concerns than it addresses—Who will determine the distribution of dollars within the APN groups? Will there be separate pools of funds within the cluster for each of the various groups? Who will establish the criteria for eligibility? How will funding for APN programs be coordinated with other health professional disciplines? What began as consolidation for administrative simplicity, will turn into a more complex and time consuming system.
- In addition, NAPNAP has promoted the need for the federal government to perform integrated, workforce projections accounting for both physicians, PNPs/NPs and physician assistants. We strongly believe that this work will assist us in projecting which and what number of professions can best serve the nation's health care needs. Without that information, a reconfiguration of funding for these specialty areas is premature and not good public policy.

In conclusion, NAPNAP asks that the committee oppose the proposed consolidation of nursing programs in the Public Health Service Act with respect to funding NP education programs. Such consolidation fails to recognize important distinctions in specialties, thereby, inhibiting PNPs' ability to meet the primary care needs of our nation's children particularly in underserved areas. Further, consolidation would engender inefficiencies, inequities, and poor public policy in nursing education. NAPNAP appreciates the Committee's past support and recognition of the important contributions nurse practitioners make to our society. NAPNAP requests that the committee fund the NP/Midwife education program to last year's funding level of \$17.588 million.

#### *National Institute of Nursing Research (NINR)*

NAPNAP supports the National Institute of Nursing Research (NINR), a particularly dynamic and vital arm of the National Institutes of Health (NIH). NINR is essential in promoting those values that we nurse practitioners hold so dearly—prevention, wellness, the holistic approach to patient care, and scholarly nursing research which seeks to improve patient outcomes and the quality of life. In its research efforts, NINR targets vulnerable populations including minorities, children, and adolescents to develop health education models that lead to successful prevention, intervention, and early diagnosis and treatment. NINR is also at the forefront of developing and testing strategies to reach those at risk for contracting the AIDS virus.

As such, NAPNAP supports an increase of 9 percent in fiscal year 1998 over last year's \$59,743,000 NINR appropriation, for a total of approximately \$65,200,000. We support this figure as NINR's purpose and track record are of solid nursing research which leads to strategies that not only improve the profession, but also vastly improve public health.

#### *Immunization*

NAPNAP is also greatly concerned about the immunization of our nation's children as vaccinations protect children from deadly diseases such as measles, whooping cough, and rubella, while dramatically reducing overall health care costs. While significant progress has been made over the past 10 years alone with immunization levels at their highest level ever recorded (a total of 76 percent), more than one million children aged 19–35 months are not immunized. We have only three short years to reach the Year 2000 goal of immunizing 90 percent of infants by the age of 2.

Of utmost importance are the benefits and breakthroughs in vaccination. This year alone, a new schedule using both Inactivated Polio Vaccine (IPV) and Oral Polio Vaccine (OPV) which is even safer than the previous use of only OPV is being recommended. Also, the recently approved use of the diphtheria/tetanus/acellular pertussis (DTaP) vaccine for infants is being lauded for its lower incidence of adverse events. As such, support for such efforts and in reaching our Year 2000 goals are crucial to NAPNAP. NAPNAP recommends funding immunizations at \$467,900,000, the same level as in fiscal year 1997, and opposes the \$41 million reduction in the President's proposal considering there is no legislative proposal that would engender the projected savings and such tinkering might threaten the stability of the immunization program.

Thank you for the opportunity to provide written testimony to your Subcommittee. NAPNAP is mindful that this year is one in which there is even more pressure to cut programs. However, these three priorities—support of nurse practitioner education and training, NINR funding, and immunizations—combine into a vital investment towards protecting our nation's most vulnerable citizens, our children.

PREPARED STATEMENT OF THE AMERICAN DENTAL ASSOCIATION

Mr. Chairman and Members of the Subcommittee: The American Dental Association is submitting this testimony on behalf of its 140,000 members. The ADA thanks the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for this opportunity to submit testimony on federal dental programs.

The Association would like to publicly thank this Committee and especially Senator Kit Bond for his steadfast support last year for the restoration of the Division of Oral Health (DOH) within the Centers for Disease Control and Prevention (CDC). As Sen. Bond knows, the DOH plays a pivotal and unique role in many programs designed to educate the nation about oral health diseases and helps communities undertake prevention measures. Two areas where support for DOH will make an immediate difference—the development of statistics and research necessary to help fight the rise of oral cancer in this country, and support for expansion and upkeep of public water system fluoride programs—are very necessary components of efforts to enhance the oral health of the American public and may only take place if the agency is adequately funded for fiscal year 1998.

The ADA would also like to thank the committee for its support of the Maternal and Child Health program. We are very pleased to note that the Department of Health and Human Services responded favorably to the committee's directive in last year's report language asking that more money be made available to the seven states with public water system fluoridation rates below 25 percent. We hope to do more this year.

DENTAL EDUCATION

*General Dentistry Program:*

The Association thanks the Committee for supporting the Health Professions Programs. Included in these programs is the General Dentistry program which is a win-win proposition. Dentists gain clinical experience in a training program that is analogous to that experienced by primary care physicians in their residencies, and the care is provided to underserved populations and communities. In fact, the General Dentistry program has been successful in meeting the federal goal of increasing access to primary care not only because it serves as a dental care "safety net" for the elderly, disabled, and medically compromised; but also because most graduates of the program remain in primary care, many establishing practices in underserved areas.

The ADA recommends that \$6 million be appropriated for fiscal year 1998 for the General Dentistry Program.

*Loan Repayment Program:*

Historically, dentistry has not received a proportionate share of the National Health Service Corps (NHSC) positions. Limiting this option could close the door to a career in dentistry for those who are often most willing to commit to a lifetime of service in underserved areas. And many dentists are willing to stay to serve a population that still does not receive regular dental care. This is vitally important because oral health problems are reported as the number one health concern in migrant programs.

The Association is willing to work with the Department of Health and Human Services to assist in the identification of dental needs in communities and populations seeking designation as a Health Professional Shortage Area. We ask that the subcommittee support the ADA's efforts to increase the number of loan repayment positions awarded to dentists.

*Ryan White HIV/AIDS Dental Reimbursement Program:*

The Ryan White HIV/AIDS Dental Reimbursement program makes available vitally needed oral health care to people living with HIV/AIDS, while providing dental students and residents with extensive experience in caring for patients with special dental needs. In fiscal year 1996, 102 institutions participated, serving over 70,000 patients.

Because of their impaired immune systems, people living with HIV/AIDS suffer a high incidence of oral disease, which if untreated, can lead to significant pain, oral

infections, and fevers; difficulty in eating, speaking or taking medication; and medically dangerous weight loss. Receiving a prompt diagnosis and appropriate treatment for these oral conditions is often difficult for uninsured individuals because virtually all dental services are not reimbursed under Medicare and are seldom covered by Medicaid. By covering the costs of providing quality care to people living with HIV/AIDS, this program can prevent much more serious and expensive health complications.

The Association requests \$9 million for the HIV/AIDS Dental Reimbursement program.

*Minority and Disadvantaged Assistance Programs:*

The ADA recommends increased funding for the Disadvantaged Assistance program (Health Careers Opportunity Program/Federal Assistance for Disadvantaged Health Professions Students), and the Exceptional Financial Need Scholarships (EFN) and Scholarship for Disadvantaged Students (SDS) programs. These funds help recruit and retain minority and disadvantaged students.

The Association believes that increased funding levels are important to foster diversity in the student population. Assisting low-income families and minority students is necessary as current dental education costs often exceed \$67,000 for a four-year period. The ADA recommends \$35 million for the Disadvantaged Assistance program, \$15 million for the EFN, and \$20 million for the SDS programs.

DENTAL RESEARCH

The National Institute of Dental Research (NIDR) supports research concerning disorders, diseases, and normal development that affect tissues of the craniofacial-oral-dental complex. The scope of NIDR research includes oral cancers, infectious diseases (e.g. AIDS), and chronic and disabling disorders such as bone and joint diseases.

These diseases and disorders cause untold pain and suffering for those afflicted, but they also adversely affect our society as a whole, reflected in increased health care costs and loss of productivity. For example—one in every 33 babies born in 1995 had at least one anatomical birth defect, three-fourths of which affected the head, face, and neck. The most common craniofacial defect is cleft lip, affecting one in 500 births. Lifetime costs for the repair of clefts and treatment for associated speech, hearing and other problems are estimated to be \$100,000 per patient. In addition—oral, pharyngeal and laryngeal cancers affect 42,000 Americans annually, resulting in 9,000 deaths every year.

On the other hand, improvements in oral health, attributable at least in part to dental care research, save \$4 billion in dental care costs annually. Future savings must necessarily depend to some degree on continued research. For example—in fiscal year 1996, NIDR funded four new Oral Cancer Research Centers with plans to develop “smart” therapies, such as treatments designed to reactivate tumor-suppressor genes, or causing cancerous cells to self-destruct. NIDR has also long been a leader in pain research. In fact, the NIDR Director has established a trans-NIH Pain Research Consortium to encourage information sharing and collaborative research efforts within NIH. Some diseases or disease treatments cause chronic pain at an estimated cost of \$100 billion a year according to pain specialists, so the benefits emanating from the agency’s efforts in this arena should reach far beyond oral health care concerns.

Certainly, the continued adequate funding of NIDR is necessary and cost-effective, as it helps ensure continued advances in oral care treatment and research into disorders and diseases that are very costly to society. The ADA requests that the subcommittee appropriate \$212.5 million in funding for NIDR in fiscal year 1998.

DISEASE PREVENTION

The Division of Oral Health (DOH), Centers for Disease Control and Prevention (CDC), is the federal agency with primary responsibility for community-based programs aimed at preventing oral disease and promoting oral health, and for applied research to enhance oral disease prevention within the community. The DOH continues to serve as the federal agency responsible for developing infection control recommendations for dentistry. For example, the ADA has collaborated with the Division in developing infection control guidelines for hepatitis B, AIDS and tuberculosis.

Preventing oral cancer is one of the Division’s major areas of concern. Each year, there are more than 30,000 new cases of oral and pharyngeal cancer. And each year, these diseases kill more people than does cervical cancer, malignant melanoma, Hodgkin’s disease and other well known cancers (about 8,000 lives lost). In addition,

the survival rate for these cancers is one of the lowest—only about 50 percent, early detection has demonstrated to increase the survival rate (approximately 75 percent).

Funding is essential for the DOH to work with the states to develop state-specific plans for preventing and controlling oral and pharyngeal cancers in high risk populations. With additional resources the DOH, working with states, could enhance public and provider education, develop and evaluate early detection and screening protocols, and build capacity with voluntary partners that will extend support for prevention and early detection capabilities.

Severe tooth decay (caries) is another major priority for the Division. Despite the fact that with the effective application of currently available prevention strategies, caries is almost entirely preventable, 53 percent of children ages 6–8 and 78 percent of 15-year-olds have experienced no dental caries. Further, the highest burden of disease is in the underprivileged children in our society. More than 100 million Americans lack the benefits of fluoridated water despite its proven effectiveness in fighting dental decay. For 20 years, the CDC has provided leadership in improving the quality of community water fluoridation, assessing the risks and benefits of fluoride, and extending this population-based preventive measure to new communities. Current efforts include examining the role of water fluoridation in ensuring appropriate fluoride exposure, as well as implementing the Public Health Service National Fluoride Plan. Dental sealants, another proven preventive strategy, is grossly underutilized in U.S. children (<20 percent).

The CDC works closely with state and local governments to develop and implement prevention and control efforts including community water fluoridation and dental sealant initiatives. However, much remains to be done. Increased technical support and oral health grants to state and local health departments would have very positive effects on the nation's oral health and produce substantial cost savings nationwide.

The Association recommends an additional \$2 million above the current funding level for the DOH.

#### AGENCY FOR HEALTH CARE POLICY AND RESEARCH

The Agency for Health Care Policy and Research (AHCPR) can facilitate the introduction of advances in biomedical research into the dental practice setting, improving the quality and cost-effectiveness of oral health care. In the current health care marketplace, forces are at work producing dramatic changes and pressures on patients and providers, and the effects on quality of care and patient well-being is of concern. The dental profession, public, and policy makers do not have the information needed to assess or predict the impact these changes will have on cost, quality and access.

It is important to provide sufficient funds for continuation of the Medical Expenditure Panel Survey (MEPS), which began in 1997. In assessing information gained from the most recent (1987) AHCPR expenditure survey, the Association noted that the survey provided much less comprehensive or reliable information about dental care than was provided about other health care. The Association supports the budget necessary to field this survey, but recommends that the dental care component of this survey be improved, so as to provide more accurate estimates of utilization patterns, composition of services, and costs of care and how these are influenced by characteristics of patients, providers, and insurance plans.

The findings from research supported by NIH and AHCPR are openly shared within the scientific and professional communities to maximize the benefits to the public of this investment. There must be support for a continuum of research—from basic, biomedical (bench), and clinical research, through controlled clinical trials, outcomes research, and cost-effectiveness trials. We must understand not only what causes diseases and how they can be prevented or treated, but also what works in dental practice and how much it costs. Research supported by AHCPR will assist dental practitioners by providing the evidence base for selecting among alternative dental treatments. AHCPR's research is also needed to improve the system providing health care, so that the fruits of biomedical research are readily available to all citizens.

The Association supports the expansion of AHCPR's outcomes and effectiveness research program, which has the potential to improve the evidence base for selecting among alternative diagnostic and dental treatments. Advances in this program, for example, would enable AHCPR to improve the treatment of musculoskeletal disorders, including temporomandibular disorders (TMD), improving the science base for both medical and dental practitioners and providing information needed to establish reimbursement policies that would enable patients to receive the treatment

most appropriate for their needs. An increase would also enable AHCPR to improve the quality and cost-effectiveness of care for children and adolescents.

The Association recommends a fiscal year 1998 funding level of \$160 million.

The Association thanks the Committee, for its thoughtful consideration of the ADA's recommendations.

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PREPARED STATEMENT OF ROBERT C. YOUNG, M.D., PRESIDENT, FOX CHASE CANCER CENTER

Albert Einstein once said, "Things should be made as simple as possible, but no simpler." This is the crux of the problem with mammography for women 40–50 years of age. For women above 50, the message is clear and unequivocal. Regular mammography reduces breast cancer mortality by 30 percent. Simply put, mammography saves lives.

For women in the 40–50 year age group, the scientific data are less clear. The results of the studies done to date have been at best murky. Several of the smaller studies show little benefit; others show none at all. The most positive results, derived from a large Swedish study, demonstrate a 12 percent reduction in mortality for women in this age group who were screened every two years. That mortality reduction did not become apparent until eight years after the randomized trial began. Prior to that, screened and unscreened women had identical breast cancer death rates.

No one wants it to be this murky, but neither should anyone be surprised. The risk of breast cancer increases steadily with age. For women under age 40, without other risk factors, the risk is quite low and there is no convincing argument for mammography screening at all. For women over 50, the case for screening is open and shut. It is inevitable, however, when dealing with a rising increase in risk, that at some point there will be a gray area, an intersection at which the convergence of various factors make it difficult to arrive at clear cut, unambiguous conclusions. For mammography screening, that gray zone occurs between the ages of 40 and 50. The factors which contribute to the confusion are lower incidence of breast cancer in women of this age, difficulty in detecting the disease because of the nature of the breast tissue, and differences in the biology of the tumors themselves. Because of these compounding factors, small or short-term studies yield equivocal and even misleading results. Much larger, long-term trials are required to demonstrate the smaller effect anticipated in this age group. In that regard, it is noteworthy that the largest and longest trials show the most positive result.

We should not, however, allow ourselves to be paralyzed or to become equivocal because not all of the trials demonstrate that mammography reduces mortality in women age 40–50. Nor do I think it is adequate for the medical profession to throw the issue back at women and tell them to make their own decisions. A number of very well designed, large studies, most notably those done in Sweden, have shown a small, but definite improvement in survival. They even suggest that the more aggressive nature of breast cancer in younger women might require annual rather than biannual screening in order to be most effective in extending lives. To my mind that is sufficient justification for not only continuing screening for women in this age group, but also for encouraging them to be screened regularly.

The reality is that public health guidelines cannot and should not ever be based exclusively on the existence of unequivocal scientific data. Guidelines are just that—guidelines. Even when reasonable people disagree, as they frequently do in science, the purpose of guidelines is to give people the best advice, not the purest. Guidelines must be clear and understandable and not weighed down by the conditional statements and conflicting conclusions. But prudent guidelines should always balance benefit with risk. In the particular instance of mammography in 40–50 year olds, while the benefit is small, the risks appear to be minuscule. There is little or no evidence that screening inflicts any physical harm on the women who undergo it. The argument against mammography screening then becomes largely economic—the dollars spent for mammograms and follow-up examinations to detect a relatively small number of breast cancer cases. From this perspective, most women and their doctors would opt for the small, but well defined benefit. And as a society, I believe that we have already made the choice to invest in mammography as a means of saving the lives of our wives, mothers, sisters and daughters. I believe this investment should include those women 40 to 50.

There are other investments we need to make as well. We need to continue to improve mammography technology to make it a more sensitive and valuable tool than it already is. But even the best applications of mammography will not solve the breast cancer problem, and it will not save the women whose disease cannot be

picked up by mammography. For these women with breast cancer, we need new tools and better understanding of the basic biology of breast cancer so that we can identify those individuals who are truly at risk and develop better screening, prevention and treatment techniques. The answers to the questions posed here today about the efficacy of mammography screening in women 40–49 are not likely to come from more of the same studies. Ultimately, the solutions will be found in research that addresses the more fundamental questions and leads to new ways to prevent or eliminate this terrible killer of women.

Thank you for your time and attention.

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PREPARED STATEMENT OF ERIN BOSCH AND KATE KLUGMAN, NATIONAL COALITION FOR HEART AND STROKE RESEARCH

The National Coalition for Heart and Stroke Research is a group of organizations with missions related to heart disease and/or stroke. The purpose of the coalition is to increase public awareness about heart disease and stroke research, and to impact the process by which funding levels for heart disease and stroke research are determined, in favor of increased allocations.

This coalition includes the following organizations: the American Academy of Neurology, the American, the Academy of Physical Medicine and Rehabilitation, the American Association of Neurological Surgeons, the American College of Cardiology, the American Heart Association, the Americans for Medical Progress, the Congress of Neurological Surgeons, the American Neurological Association, the Association of Black Cardiologists, Citizens for Public Action on Blood Pressure and Cholesterol, Inc., Mended Hearts, Inc., the National Stroke Association, the North American Society of Pacing and Electrophysiology, the Society of Cardiovascular and Interventional Radiology, and The Stroke Connection, Inc.

The honorary celebrity committee of the coalition includes Red Auerbach, NBA Manager; Robby Benson, Actor; Sid Caesar, Actor; Jack Carter, Actor/Comedian; Mike Ditka, Former NFL Coach; James Garner, Actor; Bob Keeshan, “Captain Kangaroo”; Larry King, Talk Show Host; Walter Koenig, Actor; Patricia Neal, Actress; Bill Parcells, NFL Coach; Regis Philbin, Talk Show Host; Dan Reeves, NFL Coach; Rod Steiger, Actor; and Joe Torre, Manager, New York Yankees.

Hello. My name is Erin Bosch. I am here on behalf of the National Coalition for Heart and Stroke Research. Six months ago tomorrow I was in Minnesota having open heart surgery at the Mayo clinic. I have a genetic disease called hypertrophic cardiomyopathy. It causes the muscle below my aorta to balloon out and partially blocks the flow of blood. This disease causes high risk for heart attack and sudden death from dangerous heart rhythms. The surgery I had is designed to lessen the obstruction by shaving away some of the muscle. This procedure was originally pioneered at the National Institutes of Health. My surgery was our last resort aside from transplanting. Before this surgery NIH had implanted a therapeutic pacemaker in me because they had been shown to reduce the obstruction caused by the extra heart muscle. Without adequate funding for research these options would not have been possible for me. Most people think heart disease is a problem that only affects older people. But, I am living proof they are wrong. According to recent studies, 36 percent of young athletes who die suddenly have Hypertrophic Cardiomyopathy. Congenital heart disease is still the number 1 birth defect of children. Your child or grandchild could be born with heart disease. Thank you for the opportunity to speak to you today. I am hopeful that you will not forget about young people like me who depend on you for adequate funding for heart research so that we can live long productive lives.

Mr. Chairman, honorable members of the Committee, it is a privilege to speak to you today. My name is Kate Klugman. I am here on behalf of the National Coalition for Heart and Stroke Research, I am representing over 5 million volunteer, and most importantly, I am a mother, and a wife. I know many people feel skeptical about Congress. Many people believe that government can do no good and that everything in Washington is all about the all mighty dollar. I am here to say that THEY are wrong. You as a body have done great things for those unfortunate people, who through no fault of their own, are sick and in real need of real help. The American’s with disabilities act, and the help you have given to research, to prevent cure, and lessen the effects of stroke and heart disease, are some of the finest things to ever come out of any government.

I know you face hard challenges in today’s world, what you spend here, you can not spend there. You are faced with very, very difficult choices. But, the true measure of a society, is how it treats the least of its members, how it cares for the sick, and the needy.

I am only 34 years old, and before my devastating stroke in June, of 1995, I was a mother, a wife, an athlete and person vitally interested in my community. Now, after suffering a double brain stem stroke, which left me totally paralyzed, unable to even blink, after a miraculous recovery, I am still a mother, a wife, and someone vitally interested in a broader community. Only now, I am all these things without the use of the left side of my body.

Without the funding, you have already given to fight stroke and heart disease; I would be none of these things. After my stroke, I suffered from locked in syndrome. I spent 50 days in the ICU. During those 50 days, I was conscience, I could feel everything, I could feel pain, but I could not move any part of my body. I was totally trapped in my body. Fed by a tube surgically placed in my stomach, breathing only by using a tube surgically placed in my throat. I could not speak, could not eat, could not drink, and could not move, from the ridged death like position my body had assumed.

There was little hope for me to even live through the night, and frankly, my doctor hoped I would not live, since my future appeared so bleak. I am a very lucky woman. I lived, and more than that I overcame the locked in syndrome.

My miracle did not come about without much prayer, and much knowledge, and great skill on the part my doctors. The knowledge and skill my doctor's possessed is something that this Government, acting at it's best, helped make possible. Without years of research and many dollars provided by men and women like you. I would not be here to talk to you today.

Of course, the story does not end with my leaving ICU; it only begins there. I have been through countless hours of therapy. Physical therapy has been developed to its present stage with the help of the funds provided in part by this government.

I have seen my own life come to a point where I could do nothing for myself. I found myself at 33 wearing a diaper unable to control my own bodily functions. I saw myself unable to talk for months, all the communication I had with the outside world, was limited to my blinking, yes and no. I will not mention the physical pain for it was transitory.

The tears of my daughters 18-month-old Rachel and 3-year-old Stephanie would be enough if you saw them, to convince you to fund research as one of your top priorities. If you could see what this has done to my husband and other friends you would realize that Stroke and heart disease is not just a problem that strikes one person, it strikes families, and whole communities.

Every Minute in the United States someone suffers a stroke. Annually stroke strikes more people than cigarette smoking kills. Each year over 500,000 people have a stroke, nearly a third will die with in a few months. Almost all of the survivors will be disabled for the rest of their lives. Heart disease and stroke will cost this nation over 259 billion dollars in medical expenses and lost productivity in 1997. If we hope to save Medicare, which is one of this Congress's top priorities we must learn to spend medical dollars wisely. With research we can prevent and cure stroke thus saving billions of dollars and in the bargain saving innocent people from a living death.

There is no greater good that you as a Congress could possible do than to help the dedicated men and women who fight daily to prevent and to cure stroke and heart disease. I pray you will generously help us. I will close by asking you to be just a little selfish for if I can stand here today, when yesterday I was the picture of health, so can you stand here tomorrow also the victim of Stroke. I pray it will not happen to you, but the truth is within the next 10 years it will happen to some of you, and it may happen to all of you. So, please help, for in helping any of us, you help all of us.

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PREPARED STATEMENT OF RITCHIE L. GEISEL, PRESIDENT, RECORDING FOR THE  
BLIND AND DYSLIXIC

Mr. Chairman, Senator Harkin, Members of the Subcommittee: Recording for the Blind and Dyslexic (RFB&D) is pleased to submit this statement and accompanying fact sheet in support of our request for continued federal support of our mission as the nation's primary producer of recorded textbooks for people of all ages who cannot use standard print because of a visual, perceptual or physical disability. We also welcome this opportunity to thank the members of the subcommittee for the continuous support which you have shown for RFB&D since our first federal assistance began in 1975. With this support, as well as the support we receive through private philanthropy, our organization this last year circulated more than 225,000 textbooks, free of charge, to more than 40,000 disabled students.



RFB&D, founded in 1948 as a service for returning blind veterans of World War II, has grown into a national, private, volunteer-based organization which serves as the national education library for people who cannot read standard print because of a disability. Located in Princeton, New Jersey, with volunteer readers spread throughout the United States, RFB&D distributes textbooks and other educational materials in accessible audio and digital formats. Our tape and digital library includes more than 75,000 titles and is constantly updated to meet the needs of our student and professional users.

Our request to the subcommittee for fiscal year 1998, our 50th anniversary year, is for an appropriation of \$5,500,000, an increase of \$1,000,000 over the amount provided by the Congress last year. This federal subsidy, approximately 25 percent of our total operating budget, will be used for two principle purposes. First, our principle need is for increased resources to meet the demand of a growing user population, particularly a rapidly expanding population of students with severe dyslexia. By the year 2000, only three years from now, RFB&D expects the number of borrowers to increase by almost 90 percent, with more than 75,000 students dependent on us for their textbooks. Since these students are entitled by both the Americans with Disabilities Act (ADA), and the Individuals with Disabilities Education Act (IDEA), to appropriate educational materials, RFB&D believes that our federal appropriation represents an appropriate contribution towards this cost. Because our highly trained readers are volunteers, RFB&D is able to meet this need at a fraction of what it would cost government, whether local or federal, if it were required to produce these textbooks on their own.

The second purpose for the increase that we are requesting this year, is to begin a multi-year effort to convert our existing analog system of recordings to a new generation of digital technology. This new technology will be the basis for our service in the 21st century. The advantages of digital technology, which was demonstrated to this and other committees by our research staff in January, will be two-fold. First, it will allow our students to search and move around within a textbook in the same "random" way as sighted students do within their textbooks. Currently, RFB&D students must scroll through tapes longitudinally in an awkward and slow process. In addition to providing this "searchability", use of digital technology will eventually permit books to be circulated on CD-ROM and electronically through the Internet, eliminating the need for expensive reproduction of cassettes, their packaging and shipping.

Mr. Chairman, RFB&D and its student users are grateful for the support the Committee has provided in the past, and are hopeful that you will be able to approve our request for \$5,500,000 for fiscal year 1998. This level of support will assist RFB&D to continue our joint efforts to serve the educational needs of disabled students throughout the United States.

FACT SHEET RECORDING FOR THE BLIND AND DYSLEXIC (RFB&D) SPECIAL  
EDUCATION, MEDIA AND CAPTIONING SERVICES

Fiscal Year	Base	Technology	Total
1997 Appropriation .....	\$4,500,000	.....	\$4,500,000
1998 President .....	4,500,000	.....	4,500,000
1998 RFB&D Request .....	5,000,000	\$500,000	5,500,000

Recording for the Blind and Dyslexic (RFB&D) is the nation's primary producer of recorded textbooks for people of all ages who cannot use standard print because of a visual, perceptual or other physical disability. Books from its master tape library are loaned, free of charge, to users throughout the United States. In 1995, over 200,000 books were sent to more than 37,000 users. The number of RFB&D books produced for, and circulated to, students has grown substantially in recent years and is expected to continue to grow in the future (see box). RFB&D is supported principally through private, charitable giving and volunteer labor, but has received support from the Department of Education continuously since 1975.

RECORDING FOR THE BLIND AND DYSLEXIC

	1990	1995	2000 (est)
Students .....	23,287	37,176	75,000

	1990	1995	2000 (est)
Books Loaned .....	143,020	214,621	400,000

In January of this year RFB&D supplied to the Appropriations Committees, at their request, a report on its long range, financial plan for support of its activities. This report outlines the increased level of support required to finance the growing needs of the student community that it serves. In this report RFB&D assumes that the majority of the growth in its operating budget will continue to be financed by the private sector, but it also requests that Federal support grow in tandem with private funding. The additional \$500,000 in RFB&D's fiscal year 1998 request to the Congress for operations will permit it to continue to meet the growing need for its services to blind, severely dyslexic and physically disabled students.

In addition to the increase for its normal operations, RFB&D is requesting \$500,000 in fiscal year 1998 to begin a three-year project to convert its operations from an analog tape system of recording to new digital technology. This change will have two principal advantages. First, it will allow visually-impaired students to search and move around within a textbook in the same "random" way that sighted students search their print books. Currently, RFB&D students must scroll through tapes longitudinally in an awkward and slow process. In addition to providing this "searchability", use of digital technology will eventually permit textbooks to be circulated on CD-ROM and electronically through the Internet, eliminating the need for expensive reproduction of cassettes, their packaging and shipping.

PREPARED STATEMENT OF JOHN W. SUTTIE, PH.D., PRESIDENT, FEDERATION OF  
AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

Mr. Chairman, Mr. Harkin, Members of the Subcommittee: I am John Suttie, professor of biochemistry and nutritional sciences at the University of Wisconsin. I also serve this year as the President of the Federation of American Societies for Experimental Biology, usually referred to as FASEB. It is as President of the Federation that I submit this statement in support of adequate funding for the National Institutes of Health, a cause for which the Chairmen and members of this subcommittee have strongly supported and championed on a bi-partisan basis.

FASEB, for those of you who are not familiar with the organization, is a coalition of 14 societies with a combined membership of more than 43,000 individual scientists who work in the life sciences. The Federation was created in 1912 to provide an organization which could represent the views of the basic scientist in the science policy debates of its day. This remains more than 80 years later the fundamental purpose for the existence of our Federation.

FASEB has joined with nearly 200 organizations who are advocates for biomedical research in asking this Subcommittee to continue its strong leadership on behalf of biomedical research, and approve an increase in funding for the NIH for fiscal year 1998 of 9 percent. As you are aware, this is the level the NIH has identified through its professional judgment process as the amount it believes can be effectively used next year.

Our partnership with the Ad Hoc Group for Medical Research Funding, and other members of the health research advocacy community, goes much deeper than endorsement of a common advocacy goal. While each sector of the research establishment brings its own different perspective to this debate, all are involved in one overarching goal—progress against the diseases and disabilities that continue to afflict our people and, indeed, the people of the world.

Among those presenting testimony to this subcommittee, whether families fighting juvenile diabetes, Parkinson's caregivers, victims of breast cancer or AIDS, or young adults suffering from Cooley's Anemia or Muscular Dystrophy, are groups representing the causes that the biomedical science community is committed to. While we are practitioners of molecular biology, biochemistry, anatomy, and other basic sciences, our cause is to apply our science to the reduction of human suffering caused by disease.

The basic message of these patient advocates and the scientists whom I represent is, therefore, the same. Investment in biomedical research is the first and critical step in prevention, treatment and control of disease, which, in turn will lead to longer, healthier and more active lives. Without adequate funding of the NIH, progress will be slowed and suffering will be prolonged.

As this subcommittee reviews our request for a 9 percent increase in funding for next year, we believe you should do so in the context of the remarkable accomplishments that past investments in the NIH have produced. FASEB has described a

number of these in detail in the written materials previously distributed to the subcommittee, as have other witnesses.

I believe that one example is typical of the opportunity created by this country's biomedical research investment. This example relates to skin cancer, the most common form of cancer affecting more than 750,000 Americans each year. In recent research, with enormous implication for all of oncology, mutations in a recently isolated human "patched" gene have been linked to development of many forms of skin cancer. As a basic scientist, I have chosen this case study to discuss because the findings, related to a particular human disease, followed from the discovery of a similar gene in fruit flies. This is an excellent example of the importance of basic research, which at its onset would not have been identified as of special interest to cancer research. Further understanding of this gene's role in cancer development will be a critical factor in cancer diagnosis, prevention and treatment. Other recent examples of how basic, untargeted research provides benefits for biomedical applications include drugs for treating AIDS and a test for screening blood for HIV. I believe these examples are typical of the quality of science that you can expect from continued investment in the NIH.

Mr. Chairman, in our role as spokesmen for working scientists, we at FASEB write not only as advocates for biomedical research funding, but also to express our views on the approaches we, as scientists, believe will lead to the most productive science in the public interest. It is for this reason that our recommendations focus not only on the budget, but also on the methods for allocating funds among programs and diseases—the so-called system of "prioritization" of NIH funding. This issue recently has been the subject of hearings before the Senate Labor and Human Resources Committee, and has also been discussed widely by members of other committees.

While I will not address the issue in detail here, I would be remiss if I did not take this opportunity to encourage the subcommittee, as it reviews this important question, to defer to the NIH itself the basic responsibility for allocating appropriations among different diseases and program areas.

As this subcommittee well understands, the decision to allocate funding to one area inevitably results in less to another—whether another disease or another avenue of basic science. Yet, I believe that most of us also understand that these decisions cannot be made using simple mathematical models, comparisons, or other purely quantitative measures. While these factors provide useful benchmarks of relative effort, allocation decisions are fundamentally matters of "judgment". As scientists who understand the complexity of the process of discovery, FASEB believes this "judgment" must not be dominated by the emotion and politics that inevitably present themselves to the Congress when it looks at the human suffering associated with various diseases. It is our belief, therefore, that the leadership at the NIH, in consultation with the Congress and with the public, is in the best position to make these Solomon-like choices. As a member said earlier this year, let "the science call the shots"—not science in a vacuum but science managed by the most broadly informed science managers with a constant goal of improving human health.

Mr. Chairman, we have previously distributed to the subcommittee other recommendations of the Federation in several areas under your jurisdiction. In the interest of space, I will not cover all of these in my statement at this time.

There is, however, one other issue which I want to touch on briefly. This is our concern regarding the use of animals in research. The role of animals remains critical to understanding the fundamental processes of life and to developing treatments for injury and disease. Compassionate, humane treatment of animals is also important. The members of FASEB recognize that Americans want both the benefits of medical research using animals and the assurance that such research is being conducted according to the highest scientific and ethical standards. While FASEB urges that Congress impose no undue restrictions on the use of animals in research, at the same time we support rigorous enforcement of existing animal welfare laws. We believe this is the best way to ensure the proper balance in the protection of animals and the needed advancement in human research that is possible only with responsible use of animals by the biomedical research community.

In conclusion Mr. Chairman, we at FASEB believe that the continuum of scientific discovery now makes possible real breakthroughs in many areas of human health. But continued robust support is necessary if this potential is to be realized. We at FASEB know you and this subcommittee share our commitment to this cause and will make every effort to provide to the NIH the resources that are needed.

Our detailed recommendations are included in the written report previously submitted to the committee. Mr. Chairman, this concludes my statement.

PREPARED STATEMENT OF THE HEALTH PROFESSIONS AND NURSING EDUCATION  
COALITION

The Health Professions and Nursing Education Coalition (HPNEC) is pleased to have this opportunity to comment on the fiscal year 1998 funding for the health professions and nursing education programs authorized under Titles VII and VIII of the Public Health Service Act. HPNEC is an informal alliance of nearly 40 national organizations (list attached) comprising a variety of schools, programs, and individuals dedicated to educating professional health personnel. HPNEC's goal is to ensure adequate and continued support for the health professions and nursing education programs. The members of HPNEC are united in their belief that these programs, which are essential to the development and training of health professionals, also are critical to our nation's efforts to provide health services to underserved and minority communities.

The members of HPNEC thank the Chairman and the members of the Subcommittee for recognizing the importance of health professions and nursing education programs and for restoring funding for these programs in fiscal year 1997 to their fiscal year 1995 pre-rescission levels.

The members of HPNEC are extremely concerned that if the Administration's fiscal year 1998 budget for the Titles VII and VIII programs is enacted, this nation will not have sufficient numbers of health professionals and nurses to meet future public health and primary care needs. In particular, the Administration proposes the virtual elimination of critically important programs in primary care and nursing education and a more than 50 percent reduction in funding for programs that provide community-based training of public health and primary care providers to serve rural or inner-city medically underserved communities.

The Administration cites "the huge increases in the number of health professionals over the past few decades leading to an oversupply in some disciplines." However, the Administration fails to account for the continuing undersupply of primary care physicians, advanced practice nurses, physician assistants, dentists, and other health professionals in many parts of the United States. HPNEC believes that these drastic cuts proposed by the Administration will have significantly adverse health consequences for underserved populations.

Since 1986, the number of federally designated primary care health professional shortage areas has increased from 1,949 to 2,492, but the number of primary care physicians needed to eliminate these shortages has not kept up—despite an increase in the overall number of physicians. The Council on Graduate Medical Education's (COGME) Fourth Report—entitled "Recommendations to Improve Access to Health Care Through Physician Workforce Reform"—noted continued shortages in the field of preventive medicine and recommended increasing the percentage of physicians trained and certified in preventive medicine as a national goal.

Moreover, these programs are necessary for an increasingly complex health care system that must care for a population that includes growing numbers of serious pediatric conditions as well as serve an aging population with more chronic illness and major demographic changes. The Administration's cuts would cripple the federal mission to increase the number and to target the distribution of much needed health professionals and nurses.

As our nation's health care system undergoes rapid change, with an increasing emphasis on managed health care, an appropriate supply and distribution of health professionals has never been more essential to the public health. In 1995, the Pew Health Professions Commission reported that managed care will increase the need for public health professionals. COGME's Seventh Report to Congress states the need for more generalist physicians trained in community-based, managed care settings due to the rapid growth and interest in managed health care. The report recommends providing incentives for generalist training including residencies in family practice, general internal medicine, general pediatrics, medicine-pediatrics, and preventive medicine training, and increased training in non-hospital settings. Titles VII and VIII health professions education programs continue to assist health professions institutions in responding to the changing demands of the health care marketplace and in ensuring that all Americans have access to appropriate and timely health services.

The members of HPNEC urge the Congress to reject the Administration's efforts to reduce the funding for these programs. Instead, we recommend that the Subcommittee provide a combined appropriation of \$302 million for Titles VII and VIII in fiscal year 1998. This recommendation represents a 3 percent inflationary increase over the amount appropriated for these programs in fiscal year 1997. While acknowledging that the Congress has placed a high priority on balancing the federal

budget, HPNEC emphasizes that a \$302 million appropriation is necessary to maintain current efforts to address our nation's rapidly changing health care system.

Many of the Title VII and VIII programs underwent major changes as a result of the Health Professions Education Extension Amendments of 1992, Public Law 102-408. These amendments provided new and expanded areas of emphasis, including minority representation, allied health, rural areas, and HIV/AIDS, along with a continued strong focus on primary care, nursing, and network programs. These programs have been restructured to respond to the following national health professions goals: increase the number of underrepresented minorities graduating; increase the proportion of graduates selecting generalist careers; and increase the number of graduates practicing in underserved areas.

As a result of the reauthorization, the Title VII and VIII programs promote several important themes, including generalism and primary care in education and training, linkages between service and education, community-based education, multidisciplinary education, and workforce diversity.

In closing, Titles VII and VIII of the Public Health Service Act meet the nation's need for an expanded supply of primary health care providers and public health professionals. For both institutions and students, the educational process is not a faucet that can be turned on and off without serious consequences. It is a carefully planned and carried out undertaking that depends upon stability of financial support. Federal funds are a vital part of this effort because they focus on innovative approaches to changes in the health care delivery system and help to prepare those who deliver basic care to underserved people. Drastic cuts in health professions education needlessly put at risk the public's future health. The solution is to protect Titles VII and VIII from the proposed reductions and to fund in accordance with the need. In this rapidly changing health care environment, it is crucial Title VII and Title VIII programs receive an appropriation of at least \$302 million for fiscal year 1998 to meet their missions.

The members of HPNEC appreciate the opportunity to comment on these vital programs and look forward to working with the Subcommittee in support of them.

List of HPNEC Members Endorsing This Statement: Ambulatory Pediatric Association; American Academy of Pediatrics; American Academy of Physicians Assistants; American Association of Colleges of Nursing; American Association of Colleges of Osteopathic Medicine; American Association of Colleges of Pharmacy; American Association of Dental Schools; American Association of Nurse Anesthetists; American College of Preventive Medicine; American Dental Association; American Geriatrics Society; American Pediatric Society; American Psychiatric Nurses Association; American Psychological Association; American Society for Clinical Laboratory Science; Association of American Medical Colleges; Association of American Veterinary Medical Colleges; Association of Medical School Pediatric Department Chairmen; Association of Minority Health Professions Schools; Association of Professors of Medicine; Association of Schools of Allied Health Professions; Association of Schools of Public Health; Association of Teachers of Preventive Medicine; Clerkship Directors in Internal Medicine; National Association of County and City Health Officials; National Association of Geriatric Education Centers; National Association of Social Workers; National Organization of AHEC Program Directors; National Rural Health Association; Society of General Internal Medicine; and Society for Pediatric Research.

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#### PREPARED STATEMENT OF THE AD HOC GROUP FOR MEDICAL RESEARCH FUNDING

The Ad Hoc Group for Medical Research Funding appreciates this opportunity to submit written testimony to the Senate Labor, HHS and Education Appropriations Subcommittee.<sup>1</sup>

The Ad Hoc Group for Medical Research Funding is a diverse coalition of nearly 200 organizations representing patient and voluntary health groups, medical and scientific societies, academic and research organizations and industry. The Ad Hoc Group advocates for an increased federal investment in medical research through the National Institutes of Health (NIH) to build upon past scientific achievements, address present medical needs and anticipate future health challenges.

The patients, scientists, and research institutions represented by the Ad Hoc Group acknowledge the difficult choices this subcommittee has made in the past few years that have enabled the extraordinary funding increases for the NIH. We thank the subcommittee for making the NIH one of its very highest priorities. We have confidence that the subcommittee will continue to ensure that the NIH budget is

<sup>1</sup>The Ad Hoc Group for Medical Research Funding receives no Federal funding.

sufficient to sustain the brisk pace of research and discovery this nation has come to expect from the biomedical and behavioral sciences. We are especially grateful to the Chairman for his recent statements expressing his commitment to advancing this nation's biomedical research efforts through the NIH.

To ensure that NIH funding levels are consistent with currently available research opportunities, the Ad Hoc Group relies on the professional judgement of scientific leaders, including the NIH leadership. For fiscal year 1998 the Ad Hoc Group supports the nine percent increase identified by Dr. Varmus in his professional judgement budget. The Ad Hoc Group believes that this judgement is the best and most reliable estimate of the minimum level of funding necessary to sustain the high level of scientific excellence attained by the NIH.

A nine percent increase will boost the number of competing research grants to over 8,000. This would allow the NIH to exploit the opportunities now present in medical science, as well as increase the size of these grants to keep pace with inflation. Moreover, a nine percent increase will allow the expansion of the research centers program, the focus of clinical science, along with research training and the intramural program.

NIH research manifests itself in the everyday lives of Americans as patients, consumers and employees. The benefits of biomedical and behavioral research are realized on several levels—improved diagnosis, treatment and prevention of disease and disability; enhanced the quality of life through increases in functional capacity and reductions in pain and suffering; and contributions to a stronger economy through decreased health care costs, increased productivity and the development of a thriving biotechnology industry.

As patients, the millions of Americans afflicted with acute or chronic diseases and disabilities and the families and other loved ones who care for them know all too well the painful health challenges that face us. They must endure the physical and emotional distress and the economic costs associated with disease and disability. While an array of diseases, like cancer, asthma and heart disease, have caused an untold amount of human suffering over time, threats from new and emerging infectious diseases demonstrate our continuing vulnerability to the forces of nature. NIH plays a central role in mitigating the effects of both new and old diseases.

Since the late 1960s there has been a sharp decline in heart disease mortality for both men and women, blacks and whites alike. A decreased fatality rate, measured as the proportion of patients who die shortly after suffering a heart attack, appears to be responsible for the reduction in overall heart disease mortality. While medical research has been successful in the effort to save the lives of heart attack victims, a cure for heart disease still eludes researchers. Consequently, an increasing number of individuals living with heart disease are susceptible to heart failure—the inability to pump blood through the heart. The heart failure rate has tripled over the past 30 years, causing 45,000 deaths annually.

A National Heart, Lung and Blood Institute-sponsored clinical trial showed that the use of an angiotensin converting enzyme (ACE) improved the survival rate among heart failure patients and may retard the loss of heart pumping capacity. The study indicates that the ACE inhibitor reduced deaths and hospitalizations of heart failure victims by 16 percent and 26 percent, respectively. Routine use of an ACE inhibitor to treat heart failure could prevent 10,000 to 20,000 deaths and 100,000 hospitalizations annually.

Another NIH clinical trial demonstrated the value of tissue plasminogen activator (t-PA), a clot-busting drug, as a useful treatment for ischemic stroke, which is caused by a blockage in a major artery leading to the brain. This finding is particularly noteworthy because previously physicians could only offer stroke patients a diagnosis and a prognosis of permanent disability. When given within three hours of the initial stroke symptoms, t-PA can dislodge the clot, thereby restoring blood circulation to the brain. t-PA increases the chances for complete recovery for stroke victims by at least 30 percent. Further, upwards of 40,000 patients may experience functional recovery from stroke following the use of t-PA.

Clearly, NIH basic and clinical research facilitates the development of many new treatment modalities allowing patients to survive serious health conditions. But the highest form of success against disease and disability is attained through the prevention of disease. Fortunately, NIH-funded researchers have prevailed in the development of new vaccines and screening techniques that allow individuals to live healthy lives uninterrupted by certain diseases. The development of new tools to prevent the onset of disease also poses important implications for health care costs. As consumers, Americans observe the reduced health care expenditures for certain diseases that once exacted a significant toll on human life and health spending, but now may be eliminated or dramatically reduced.

Prevention activities achieve the highest yield in younger Americans, especially children. Consequently, the National Institute of Child Health and Human Development (NICHD) places high priority on pioneering the development of conjugate vaccines to prevent infections in children. One of NICHD's major successes in this effort was the development of the vaccine against the *H. Influenzae* type b (Hib) bacterium. Prior to the introduction of the Hib vaccine, Hib meningitis was the leading cause of mental retardation in the U.S. The routine use of the Hib vaccine in children is credited with eliminating 10,000 to 15,000 cases of Hib meningitis each year. The estimated cost savings associated with the Hib vaccine is \$400 million each year in health care dollars that would have been spent for treatment and rehabilitation of children with this type of meningitis.

Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) recently designed a screening device to permit early detection of chlamydial infections, the most common bacterial sexually transmitted disease in the U.S. Untreated chlamydial infections frequently lead to pelvic inflammatory disease (PID), which causes long-term complications such as infertility and tubal pregnancy. As many as 70 percent of women with chlamydial infections have no symptoms and do not seek treatment. Studies show that the pervasive use of this new screening device for detection and treatment of asymptomatic chlamydial infections may lead to a 60 percent lower incidence of PID in women. This finding has important cost implications since the cost of treating PID and its complications exceeds \$7 billion annually.

In addition to causing pain and suffering and driving up health care costs, disease and disability places a burden on an individual's ability to perform in the workplace and live independently. Premature death and disability remove productive individuals from the workforce, resulting in significant productivity losses. Fortunately, the NIH sponsors research in medical rehabilitation of individuals suffering from disease and disability with the intent to enable them to return to work and live independently. As employees, Americans realize the need to utilize the energy and talents of all members of society to compete effectively in the global economy.

Alcoholism poses a significant impact on society affecting the approximately 14 million alcoholics, alcohol abusers and their families. In terms of economic and health care costs, alcoholism and alcohol abuse is estimated to cost society nearly \$99 billion annually, in addition to the social and human devastation caused by the illness. Over 70 percent of this \$99 billion is related to losses in productivity, excess illness and early death as a direct consequence of alcohol misuse.

With the hopes of designing new drugs to treat alcohol abuse and alcoholism, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) sponsors basic research to inform our understanding of the biological bases for alcoholism and the craving phenomenon. Such research led to the discovery of naltrexone, the first medication approved for alcoholism in 40 years. In combination with counseling, naltrexone lengthens the periods of sobriety and reduces the number of "slips" that become full relapses into alcohol abuse. Clearly, this drug holds the promise of returning many alcoholics and alcohol abusers to healthy and productive life styles at home and in the work place.

Not only does NIH research make Americans more productive employees through reductions in disability and disease, the NIH also bolsters the biomedical research industry. NIH research fuels the overall economy vis a vis employment in the budding biotechnology industry. Many Americans sustain their livelihood in industries directly or indirectly related to medical research. NIH supported research propagated the development of the biotechnology industry, which increased sales last year by 16 percent to \$10.8 billion and supported 118,000 high tech jobs in the national economy. Furthermore, NIH basic research leverages the pharmaceutical and agricultural research efforts.

The member organizations of the Ad Hoc Group for Medical Research Funding vigorously urge you to appropriate a nine percent increase for the NIH for fiscal year 1998 to allow it to continue its research efforts that permit Americans to overcome serious illness, prevent the onset of disease and prepare individuals suffering from disabilities to return to work and live independently. However, the struggle against disease is never-ending. Many Americans face life-threatening health problems and new medical challenges constantly arise. For most of these conditions, research offers the best, and in many cases, the only hope. Our national investment in the NIH over the past 40 years has produced a wealth of opportunities in basic and clinical science that will ultimately alleviate and eliminate many of these conditions. This year as you make the difficult resource allocations, we encourage you to keep in mind the Ad Hoc Group maxim that medical research "saves lives, saves dollars and stops human suffering."

## PREPARED STATEMENT OF AMY S. LANGER, EXECUTIVE DIRECTOR, NABCO

Good morning, Mr. Chairman, and distinguished members. As a 12-year breast cancer survivor leading a national breast cancer organization, it is my privilege to appear before you with these expert colleagues, and to introduce Toni Shaheen, a fellow breast cancer survivor who is here to speak from the heart. Usually my role is limited to breast cancer issues, but today those issues form one part of a larger problem that you have tools to repair.

The many mysteries yet to be unraveled about how cancer works and how it chooses its enemies are exemplified by breast cancer, a single disease among hundreds of cancers, but the most common form of cancer in women in this country. Because of America's familiarity with—and fear of—this disease, when women become breast cancer patients, they are astonished that many vast questions remain unanswered. Among them:

- How soon will we know how to prevent breast cancer? So far, prevention research is still in progress, stalled, undernourished or the source of conflicting information;
- When will we have true early detection? We cannot yet diagnose breast cancer cells gone wrong until they cluster in billions, forming masses big enough to image, but also to spread and kill;
- When can we design the right treatment for each patient? As good as many breast cancer treatments are, we still cannot predict which patients should receive what treatments, or how much of them, so that thousands of women are routinely over treated with drugs they do not need and others live unprotected, their cancers ready to reassume control; and,
- Can we ever promise a certain cure? Although an increasing portion of breast cancer survivors remain cancer free, physicians cannot honestly reassure us that we can take a deep breath, have our families, make our plans, smell the roses—without the constant counterpoint of cancer that could return.

We need a shift in national values, a reaffirmation and an unwavering commitment to bring resources to the fight against cancer. We need increased funding for basic and clinical research, and a plan to prioritize translational activities that will have immediate impact on prevention and treatment. We need a scientific environment that attracts the best minds and nurtures their explorations. We need science to be responsive to priorities of cancer patients and survivors—their needs, perceptions, hopes and fears.

Ms. Shaheen captures this paradox—a strong and admirable woman who is cancer-free because of advances in treatment, but not worry-free, because research has not advanced enough. It is my honor to introduce Toni Shaheen.

## PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

## INTRODUCTION

The Humane Society of the United States (HSUS) is the nation's largest animal protection organization, with over 4.7 million members and constituents. We submit this testimony on behalf of The HSUS, as well as the American Humane Association, the Doris Day Animal League, the American Humane Association, the Massachusetts Society for the Prevention of Cruelty to Animals, and the Industrial In Vitro Toxicology Group. The latter is an organization of industrial toxicologists who work with in vitro (i.e., non-animal) methods. We appreciate this opportunity to submit testimony on the fiscal year 1998 appropriation for the National Institute of Environmental Health Sciences, or NIEHS, which is one of the components of the National Institutes of Health (NIH).

The organizations we represent are part of a unusual coalition that includes animal protection societies, consumer product companies, and a university. Our goal is to improve the welfare of animals used in the field of product safety testing. We seek to achieve this goal by encouraging the federal government to help industry modernize its testing methods. What unites the coalition is our conviction that we can both improve consumer safety and reduce our reliance on animals in safety assessment, through the application of good science.

In this regard, we applaud the federal government for establishing the Inter-agency Coordinating Committee for the Validation of Alternative Methods, or ICCVAM, a multi-agency effort spearheaded by the NIEHS. We are testifying to urge this committee to support the work of the NIEHS/ICCVAM.



## BACKGROUND

Numerous federal agencies regulate the product safety testing practices of industry. Historically, these agencies have played a relatively minor role in helping industry move away from its reliance on traditional animal tests. They have provided little or conflicting guidance to industry on how to gain regulatory approval of new methods. In particular, companies sought guidance on how to conduct evaluations of new test methods, an expensive and complex process known as "validation."

Industry's attempts to move away from traditional animal tests reflect its desire to respond to public concerns about animal welfare and to take advantage of the latest technology applicable to safety testing. Understandably, companies are hesitant to pursue "alternative" test methods without the involvement and imprimatur of the regulatory agencies. It became imperative, therefore, that the federal government assume a more active and high profile role in alternative test development.

The NIEHS seemed to be the most suitable agency to coordinate the government's expanded participation in the development of new and more humane test methods. It has the requisite technical expertise and the experience of running the National Toxicology Program, an interagency program charged with developing new test methods.

In 1993, our coalition worked with the Congress to expand the NIEHS's mandate to include coordinating the government's work on alternative methods. In legislation reauthorizing the NIH (the 1993 NIH Revitalization Act), Congress directed the NIEHS to: develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing; and, establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use (Title XIII, § 1301).

As the term is used in this legislation and in the field of laboratory animal welfare, "alternatives" fall into three categories, collectively known as the Three Rs. They are methods that completely replace the use of animals in specific tests. When replacement is not feasible, alternatives may be developed that reduce animal use in a test or refine the test to minimize animal suffering. Examples of each of the Three Rs are numerous. The chemical-based kits of modern pregnancy testing have replaced the use of animals. The routine use of six or more rabbits in the Draize Eye-Irritancy Test has been reduced to three, without any meaningful loss in information, thanks in part to a statistical analysis conducted by the Food and Drug Administration. The LD50 Test, in which animals are dosed to determine the concentration that kills half of them, has been refined in several ways, including euthanizing moribund animals.

Although alternative methods are defined with reference to animal welfare, the Three Rs approach to safety testing is embraced by industry and regulatory agencies, given its potential to provide methods that are quicker, less expensive, and more informative than traditional procedures.<sup>1</sup>

We commend the NIEHS for its ongoing work in implementing the alternatives provisions in the NIH Revitalization Act. The NIEHS initiated a modest but important funding program (\$1.5 million) to support studies of alternative methods. These studies, now in the second year of a three-year program, base the development of new methods on an understanding of the actual mechanisms of toxicity.

In 1994, in a more far-reaching initiative, the NIEHS established the ad hoc Interagency Coordinating Committee for the Validation of Alternative Methods, known as ICCVAM, which includes representatives from all relevant federal regulatory agencies.<sup>2</sup> In October, 1995, ICCVAM issued a draft guidance document on "Validation and Regulatory Acceptance of Toxicological Test Methods." Two months later, ICCVAM held a workshop to solicit comments on its draft report from all interested parties, including wide representation from industry, academia, and public interest groups, as well as from officials of ICCVAM's European counterpart, the

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<sup>1</sup>NIEHS Interagency Center for the Evaluation of Alternative Toxicological Methods, NIEHS draft proposal dated March 6, 1997.

<sup>2</sup>These include the Consumer Product Safety Commission, the Environmental Protection Agency, the Departments of Agriculture, Defense, Energy, Interior, Labor, and Transportation, as well as the Department of Health and Human Services (through the Food and Drug Administration, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, and parts of the National Institutes of Health).

European Center for the Validation of Alternative Methods (ECVAM).<sup>3</sup> ICCVAM integrated these comments into its final report, which it issued earlier this year.<sup>4</sup>

The publication of this report is a landmark event in the process of modernizing toxicological methods and decreasing reliance on traditional animal tests. The report provides the federal government's collective advice on how to validate new test methods and it encourages industry to involve appropriate government representatives in validation programs from the earliest stages.

The report also outlines the process that the government will use in assessing the regulatory acceptability of proposed new methods, as well as the principles that will govern that assessment. ICCVAM will coordinate the review of proposed methods with other federal agencies that may find the method useful. It will focus on testing issues that are common to multiple agencies without impinging on considerations unique to individual programs and agencies. It will forward recommendations regarding the scientific validity and potential acceptability of test methods to agencies for consideration. Each federal agency will then determine the regulatory acceptability of the method, according to its regulatory mandates.

#### CURRENT SITUATION

The NIEHS is moving swiftly to translate the ICCVAM report into action. It is changing ICCVAM's status from an ad hoc committee to a standing body. Moreover, the NIEHS plans to establish a Center for the Evaluation of Alternative Toxicological Methods with a small staff to handle the day-to-day work of ICCVAM, such as organizing workshops and peer reviews of proposed new methods (the members of ICCVAM itself are agency representatives with full-time responsibilities at their home agencies).

Since its inception in 1994, ICCVAM has become a major player in promoting the development, validation, and regulatory acceptance of alternative methods in the United States. ICCVAM has also been active internationally, not only on these issues but on the critical trade issue of harmonizing testing requirements across countries. It has garnered widespread support from private industry and the animal protection community, and news of its activities has appeared in prestigious scientific journals such as *Science*.<sup>5</sup>

Thanks to Congress' foresight in passing the NIH Revitalization Act, and to the NIEHS's leadership in implementing it, the formation of ICCVAM is allowing the various federal agencies involved in safety assessment to speak with one voice when addressing industry's efforts to substitute new alternative methods for current animal tests.

#### CONCLUSION

We recognize that the NIEHS's 1998 budget request of \$319 million reflects the agency's budgetary constraints and competing priorities. However, the NIEHS's monetary investment in advancing alternative methods, though too small to constitute a line item in the agency budget, will nonetheless have a considerable impact in facilitating the private sector's adoption of more sophisticated and humane methods of safety testing. Moreover, federal agencies themselves will incorporate the newer methods into their own safety assessment programs. The NIEHS's modest investment in new technology now will be quickly recouped given the cost-efficiency of alternative methods.

We therefore request that this committee express its support of the NIEHS's important work in advancing new, alternative methods of safety testing, in its report language on the 1998 Labor HHS appropriation.

#### PREPARED STATEMENT OF THE CONSORTIUM OF SOCIAL SCIENCE ASSOCIATIONS

The Consortium of Social Science Associations (COSSA) appreciates this opportunity to comment on the fiscal year 1998 appropriations for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). COSSA represents nearly 100 professional associations, scientific societies, universities and research institutes concerned with the promotion of and funding for research in the

<sup>3</sup> Final Report: NTP Workshop on Validation and Regulatory Acceptance of Alternative Toxicological Test Methods, December 11-12, 1995, Arlington, VA. NTP, Research Triangle Park, NC, 1996.

<sup>4</sup> Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIEHS, Research Triangle Park, NC, 1997 (NIH Publ. Number 97-3081).

<sup>5</sup> "Panel Backs Animal Testing Alternatives," *Science*, 12 Jan. 1996, p. 135.

social and behavioral sciences. A list of COSSA's Members, Affiliates, and Contributors is attached.

First, Mr. Chairman, COSSA would like to thank you and the subcommittee for your efforts on behalf of the NIH and the CDC during last year's budget proceedings. We recognize the difficult decisions which you and the members of the subcommittee were confronted. COSSA would also like to thank the Subcommittee for its sustained support of behavioral research at NIH, especially that which falls under the rubric of "health and behavior" research. Your recognition that our nation's health problems have multiple determinants—social, behavioral and biomedical—is essential for ensuring efficient, effective solutions to the complex health challenges we face now and in the future. A sustained investment in the NIH and the CDC is critical to the health of America.

#### THE NATIONAL INSTITUTES OF HEALTH

For more than a decade, COSSA has strongly advocated for increased social and behavioral research at the NIH. Critical health issues including adolescent pregnancy, infant mortality, substance abuse, cardiovascular disease, cancer and AIDS have significant behavioral and social factors that must be addressed in order to prevent and treat them.

It is well known that individual behavior is important to health, however, it must not be the only focus of our efforts to solve these complex problems. Social and economic factors that contribute to the quality of life among the ill, or affect their adherence to treatment regimens, are equally important aspects of the health experience. These factors include racial/ethnic status, gender, age, income, education, community, cultural orientation, and religion. It is COSSA's position that federal disease prevention and health promotion activities cannot be effective without recognizing the role of these social and economic factors.

*For fiscal year 1998 COSSA supports a 9 percent increase in funding for the National Institutes of Health, the level of funding needed to maintain the high standard of scientific achievement represented by the NIH*

While the potential that social and behavioral research possesses has not been fully recognized by the NIH, there are institutes that support significant programs in social and behavioral research: the National Institute on Aging (NIA), the National Institute on Child Health and Human Development (NICHD), the National Institute of Nursing Research (NINR), the National Institute of Mental Health (NIMH), the National Institute of Alcohol Abuse and Alcoholism (NIAAA), and the National Institute on Drug Abuse (NIDA).

*The Office of Behavioral and Social Sciences Research.*—The bipartisan creation of the Office of Behavioral and Social Sciences Research (OBSSR) is a recognition by the Congress of the substantial influence of behavior and social factors on health. COSSA is extremely pleased with the progress that has been made by the OBSSR and its director, Dr. Norman Anderson. Despite having only been in operation since July 1995, the OBSSR has many activities underway, and have completed several others, including a working definition of behavioral and social sciences research and a strategic plan.

*National Institute on Aging.*—Because it is currently estimated that the number of Americans age 65 and over is expected to double by 2030 to nearly 68 million, it becomes increasingly vital to the health of our entire society that we age well. As the baby boom generation ages, the demands on our human and fiscal resources will increase exponentially.

NIA is examining ways to stimulate additional research that looks at the social and behavioral factors in initiating and maintaining healthy behaviors. It is well documented that many of the problems that accompany aging are the result of behaviors that place individuals at a greater risk for negative outcomes such as poor health and depression. It is imperative that as Americans age there are approaches to prevent and delay disease and disability. Recent research supported by the NIA has shown the benefits of adopting healthy lifestyle practices: physical activity and nutrition, as well as discontinuing unhealthy habits such as smoking. Nevertheless, regardless of the well-publicized benefits of these lifestyle changes, surveys report that older people are not motivated to change their behavior.

NIA is also examining ways to translate social and behavioral findings into strategies to improve the lives of older people and their families. As we age, one of the most commonly reported problems by Americans is difficulty in remembering. NIA, in collaboration with NINR, has begun a multi-site cooperative field trial of a cognitive intervention to improve independent functioning or postpone decline in different groups of older persons, who vary in racial, ethnic, gender, socioeconomic, and cognitive characteristics.

Finally, the work of NIA's Office of Demography in Aging and its Health and Retirement Survey, a 12-year study following nearly 13,000 individuals, is critical to analyzing the economic well-being and health among older households as people age, especially as we seek to cope with key policy questions concerning Social Security, Medicare and pensions. The Survey will provide the first up-to-date picture of work and retirement and the relations of these factors to health and midlife family roles in the 1990s.

*National Institute of Child Health and Human Development.*—NICHD has long served as a strong example of an institute that looks not only to the physiological factors affecting health, but recognizes the importance of behavioral, social, environmental and genetic factors to health outcomes. The institute's research agenda is driven both by basic scientific questions and by issues of current societal concern. However, among the NIH institutes, NICHD historically has had one of the lowest funding rates, whether measured by award rate or success rate.

While the quality of research being conducted at all of the branches of NICHD is well known and appreciated by Congress, COSSA would like to underscore the Demographic and Behavioral Sciences Branch (DBSB). Its scientists recognize the importance of multidisciplinary research. At DBSB scientists from a wide variety of disciplines including demography, sociology, economics, psychology, anthropology, epidemiology, biology and public health all contribute, often with interdisciplinary approaches, to understanding population issues.

In fiscal year 1998 nonmarital childbearing and fatherhood will continue to be targeted by NICHD as high priority scientific areas. The institute has launched a set of research projects to improve our understanding of the determinants of adolescent pregnancy. Thus far, the research supported by DBSB has yielded important information on the reasons behind the increase in nonmarital childbearing. The branch is also at the forefront of a government-wide effort to improve our understanding of the contributions men make in their children's lives and their own development.

*As a member of the Friends of NICHD Coalition, COSSA supports the Friends' recommendation that NICHD receive \$690 million in funding, a 9.3 percent increase for fiscal year 1998.*

*National Institute of Nursing Research.*—COSSA is very pleased to serve as an advocate for NINR. Although one of the youngest and smallest of the NIH institutes, it directs a major portion of its funding to research and research training in areas of health promotion and behavior related to disease. Like NIA and NICHD, NINR recognizes the importance of the relationship of social and behavioral and biological phenomena.

While the other institutes carry on the vital research necessary to eliminate maladies, NINR helps to find ways for patients to live more comfortably in the meantime. NINR is addressing some of our most pressing health problems including: controlling pain, understanding the interactions among physical environments, individual lifestyles, and genetic makeup; how care givers and patients make health related decisions and; postponing the physical and psychological degeneration associated with Alzheimer's and other chronic diseases. The NINR's programs are broad in scope and include all age groups, multiple disease categories and participants from a large spectrum of the population. The Institute is a vital part of the biomedical and behavior research at NIH. *National Institute of Mental Health.*—NIMH has made tremendous progress in understanding, treating, and preventing mental disorders, as well as helping the American public overcome the stigma of mental illness. Its multidisciplinary research programs lead the Federal efforts to identify the causes of and the most effective treatment for mental illnesses, which afflict more than one in five Americans.

Studying mental disorders in children and adolescents is a top research priority for the NIMH in fiscal year 1998. It is during childhood or adolescence that mental and behavioral problems may first appear and have life-long consequences. NIMH investigators are giving renewed attention to the first onset of childhood mental illness as an opportunity to prevent progression of these disorders.

Additionally, NIMH's research includes developing new approaches to diagnosis, treatment and prevention through its research efforts, including research on manic-depressive illness, autism and obsessive compulsive disorder. The NIMH is also focusing research efforts on racially and ethnically defined populations to understand the cultural differences in the expression of symptoms, resulting in misdiagnoses and inappropriate treatment. COSSA commends NIMH for its support of behavioral science investigators at the beginning stages of their career through its B-START (Behavioral Science Track Award for Rapid Transition) program.

*National Institute of Alcohol Abuse and Alcoholism.*—The abuse and misuse of alcohol is responsible for more economic and social damage than almost any other

health problem. It is estimated that the costs to society from alcoholism and alcohol abuse exceed \$100 billion annually. Approximately ten percent of adult Americans are affected by alcohol abuse and alcohol dependence. More importantly, more than 6.6 million children under the age of 18 live in households with at least one alcoholic parent, putting them at risk for physical, sexual, and/or emotional abuse which in turn places them at risk for a range of emotional and behavioral problems. These problems include conduct disorders, anxiety and depression.

NIAAA places a priority on research that looks at psychological treatment and prevention of alcoholism and alcohol-related problems. The institute recently completed one of the largest and most complex randomized clinical trials (Project MATCH) ever taken in alcoholism treatment. The program compared the effects of different treatment styles when matched to specific patient characteristics, demonstrating that well-designed treatments, in combination with good training of therapists, have a positive effect on retention rates in treatment. The Institute is planning a follow up study on the Project MATCH findings to evaluate the combination of various medication combined with behavioral treatments.

*National Institute on Drug Abuse.*—NIDA supports a comprehensive research portfolio of behavioral and psychosocial research to improve the prevention and treatment of drug abuse, dependence and addiction. It is well known that use of drugs is detrimental to health, family life, the economy and public safety. The abuse of drugs is currently the fastest growing vector for the spread of HIV in the U.S. and injection drug users (IDU) are at high risk for exposure and transmittal of HIV/AIDS as well as for other drug-health related problems.

From survey monitoring tools, such as the 1996 Monitoring the Future Survey, as well as from other research-based instruments, we know that drug use among the young continues at unacceptable levels. NIDA is to be commended for the recent release of the first science-based guide to preventing young people from using drugs. The guide summarizes knowledge produced by 20 years of NIDA-supported research and recommends how to apply the knowledge to successfully prevent drug use among America's youth.

COSSA supports the institute's decision to emphasize three general areas to target in fiscal year 1998 for more specific research including: (1) research on therapies for adolescent drug abuse; (2) research that addresses drug addiction treatment and HIV risk reduction (3) research to determine the transportability of behavioral therapies to the community.

*The Office of AIDS Research.*—Since first being identified more than 15 years ago, AIDS has become the number one killer of young adults in the U.S. In addition, rates of increases in AIDS cases are now greatest for adolescents, minorities, women, injecting drug users, and persons infected through heterosexual contact.

COSSA supports a consolidated appropriation for the Office of AIDS Research (OAR) to coordinate behavioral and biomedical HIV/AIDS research at the NIH. The OAR with a consolidated budget is essential to achieving our ultimate goal of preventing and curing AIDS. Created to plan, coordinate and evaluate the NIH AIDS research efforts are essential to minimizing inefficiency and duplication.

COSSA commends the OAR for the completion of its comprehensive evaluation of the NIH AIDS research portfolio which resulted in the Report of the NIH AIDS Research Program Evaluation Task Force. In fiscal year 1998, the NIH AIDS research program plan and budget is based on the recommendations made in the report, including placing an emphasis on prevention science research (enhanced studies of risk-taking behavior and the development of strategies to avert infection). As HIV is spread primarily through risk behavior, a better understanding of human behavior and behavior change is necessary. Even if a cure for HIV/AIDS was found tomorrow, changes in behavior would be necessary for eradication of the disease.

#### CENTERS FOR DISEASE CONTROL AND PREVENTION

COSSA urges you to be as generous as you can in the fiscal year 1998 appropriation for CDC. The CDC makes significant and critical contributions to the health of the American public, leading to longer, healthier lives. CDC's public health programs effectively promote health and quality of life by preventing disease, disability, and injury.

COSSA commends Dr. David Satcher, for his acknowledgment that as human behavior and demographics create new public health challenges, the expertise that the social and behavioral sciences have will be critical in keeping the American public healthy. These behavioral risk factors: tobacco use, poor diet, physical inactivity, sexual behavior and illicit drug use are, according to the CDC, "the underlying cause for nearly half of all deaths in the U.S."

Again, Mr. Chairman and members of the Subcommittee, thank you for the opportunity to present COSSA's views on the invaluable and behavioral research being conducted at the National Institutes of Health and the Centers for Disease Control and Prevention. Your continued support for these programs is vital to the U.S. and maintaining America's status as the world's premier biomedical and behavioral research leader.

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PREPARED STATEMENT OF ROTARY INTERNATIONAL

The Rotary Foundation of Rotary International is grateful for this opportunity to submit written testimony in support of the President's fiscal year 1998 request for the polio eradication activities of the U. S. Centers for Disease Control and Prevention.

Rotary International is a global association of 28,000 Rotary clubs, with a membership of 1.2 million business and professional leaders in 155 countries. We are the world's first service club, having been established in Chicago in 1905. In the United States today there are more than 7,400 Rotary clubs with some 400,000 members. All of our clubs work to promote humanitarian service, high ethical standards in all vocations and international understanding.

Rotary is submitting this testimony on behalf of a broad coalition of child health advocates, including the American Academy of Pediatrics, the Task Force for Child Survival and Development, the March of Dimes Birth Defects Foundation and the U.S. Committee for UNICEF, to seek your support for the global program to eradicate polio.

Rotary and our coalition would first like to express our sincere gratitude. A year ago we made the case for increased funding for the Polio Eradication Initiative. You responded enthusiastically, recommending that \$47.2 million be allocated for laboratory support, technical expertise, and polio vaccine purchase and delivery, through the U.S. Centers for Disease Control and Prevention.

*Progress in the Global Program to Eradicate Polio*

We would like to use this opportunity to inform you about the extraordinary progress toward eradicating polio that has been achieved during the past twelve months:

- Some seventy-five countries conducted National Immunization Days in 1996, taking extra measures to protect over 450 million children against polio—more than one half of the world's children under the age of five.
- Preliminary indications are that reported polio cases for 1996 will be only half that of 1995—from 7000 to approximately 3,500. This dramatic one-year decline is due to the tremendous success of National Immunization Days (NIDs) in South Asia and Africa.
- During its second year of NIDs, India was able to immunize 113 million children on one day in December 1996, and over 123 million on January 18, 1997—the largest single public health event in history. India's tremendous success provides more evidence that "Target 2000" is a reachable goal. Pakistan and Bangladesh coordinated their NIDs with India's to achieve the maximum effect over the entire region.
- Twenty-eight sub-Saharan African countries conducted National or Sub-National Immunization Days during 1996 and the first months of 1997, as part of the continent-wide "Kick Polio Out of Africa" campaign, reaching nearly 70 million children. Forty-nine African countries have agreed to undertake NIDs in 1997–98.
- The third year of the "Operation MECACAR" immunization campaign is currently underway. This three-year campaign is designed to virtually eliminate polio from 19 contiguous countries stretching from the Middle East to Russia.
- As a result of three years of successful NIDs, China reported no laboratory-confirmed indigenous polio cases in 1995. Reported polio cases in the Western Pacific are confined to the Mekong Delta and the region of China bordering Myanmar. The entire region has started on the process of certifying polio eradication.

*The Role of the U.S. Centers for Disease Control and Prevention*

In fiscal year 1997, Congress appropriated \$47.2 million for the polio eradication activities of the Centers for Disease Control, meeting the President's request. In its report, the Appropriations Committee commended the CDC for its active leadership in this effort, and recognized the possibility of eradicating polio by the year 2000. As a result of these funds, in 1997 the CDC is:

- Supporting the international assignment of 32 long-term epidemiologists, technical officers, virologists, and data managers to assist WHO and polio-endemic countries to implement polio eradication strategies.
- Providing \$30 million to UNICEF for polio vaccine and operational costs for NIDs in more than 50 countries worldwide. Many of these NIDs would not take place without the assurance of CDC's support.
- Providing \$5.5 million to WHO for surveillance and National Immunization Days (NIDs) operational costs, primarily in Africa. As successful NIDs take place, surveillance is emerging as a critical need, to determine where polio cases are continuing to occur. Good surveillance can save resources by eliminating the need for extensive immunization campaigns if it is determined that polio circulation is limited to a specific locale.
- Training virologists from all over the world in advanced poliovirus research. The CDC's laboratories serve as an international reference center and training facility.
- Helping to persuade countries such as Afghanistan and Sudan to plan and conduct NIDs despite ongoing civil conflict. Warring factions have agreed to "days of tranquillity" in order to allow immunization campaigns to occur, fully aware that polio and other diseases make no political distinctions.
- Some 75 countries in Asia, Eastern Europe, the Middle East and Africa have already or are expected to benefit from CDC funding for vaccine and technical expertise for fiscal year 1997. The CDC sets funding priorities based on the global plan to eradicate polio agreed upon by all of our partners.

*Eradicating Polio Will Save the United States at Least \$230 Million Annually*

Even though there has not been a case of endemic poliomyelitis in the United States since 1979, we cannot be complacent. Our children are not protected from polio unless the entire world is free of polio. If we succeed in eradicating polio by the target year 2005, no child will have to be immunized against polio ever again. The United States currently spends at least \$230 million annually to immunize its newborns against polio, a disease no longer occurring naturally anywhere in the Western hemisphere. This figure is expected to rise as the U.S. switches from an immunization program using inexpensive oral polio vaccine (OPV—Sabin vaccine) to one based on the higher-priced inactivated polio vaccine (IPV—Salk vaccine). Globally, over 1.5 billion US dollars are spent annually to immunize children against polio. This figure does not even include the cost of treatment and rehabilitation of polio victims, nor the immeasurable toll in human suffering which polio exacts from its victims and their families. Once polio is eradicated, tremendous resources will be unfettered to focus on other diseases.

Humankind is on the brink of a historic opportunity. Poliomyelitis is the second major disease in history that is close to eradication. The case to invest in polio eradication is compelling. We celebrated the eradication of smallpox in 1979. No child in the United States or in the world will ever suffer from smallpox again. The annual global savings of nearly \$1 billion per year in smallpox disease and control costs far exceeds the approximately \$300 million that was spent over ten years to eradicate smallpox. The United States was a major force behind the successful eradication of the smallpox virus, and has recouped its entire investment in smallpox eradication every 2½ months since 1971.

In 1988 and again in 1993, the member nations of the World Health Assembly, including the United States, affirmed their commitment to eradicate polio by the year 2000 and to achieve certification of eradication by the year 2005. But even with these great intentions and with the tremendous reduction of polio cases being achieved in many countries, there is concern that other more pressing demands will divert attention and funding from this program. If we hesitate in our commitment to eradication, we will lose momentum and risk substantial setbacks in the fight against the polio virus, including the risk of re-introducing the wild polio virus into North or South America. The risk of virus importation remains high, particularly when routine immunization levels are allowed to fall below acceptable levels.

*Eradicating Polio Will Help Develop the Infrastructure Needed to Fight Other Diseases*

Investing in polio eradication means helping countries to develop the public health and disease surveillance systems necessary to effectively implement the WHO-recommended polio eradication strategies. Not only does a strong surveillance system help eradicate polio, but it helps to control the spread of other infectious diseases. Already, much of Latin America is free of measles, due in part to improvements in the public health infrastructure implemented during the war on polio. The campaign to eliminate polio from communities has also led to increased public

awareness of the benefits of immunization, creating a “culture of immunization” and resulting in higher immunization rates for other vaccines.

*Resources Needed to Finish the Job of Polio Eradication*

Although most of the costs of polio eradication efforts are borne by the governments of polio-endemic countries themselves, the World Health Organization estimates that at least \$140 million in special contributions per year, for the next four years, is needed to help polio-endemic countries carry out the polio eradication strategy. We are asking that the United States continue to take the leadership role in meeting this shortfall.

The United States’ commitment to polio eradication is stimulating other countries to increase their support as well. We are not requesting an increase in US funding for polio eradication this year because we strongly believe that as the developed nations of the world will gain the greatest financial benefits of polio eradication, so must they share its costs. The U.S. commitment to meet over fifty percent of the global shortfall is sending a strong message that America cares about the health of the world’s children, and is challenging other countries to follow its lead. Belgium, Canada, Finland, France, Italy, Norway, Sweden and Switzerland are among those countries which have followed America’s lead and have recently announced grants for polio eradication campaigns in Africa, Eastern Europe, and South Asia. Japan and Australia have been and will continue to be major donors in Southeast Asia and the Western Pacific. And both Denmark and the United Kingdom have recently made major grants that will virtually guarantee that India eradicates polio by the target year 2000.

Rotary International has been working for more than a decade to help eradicate polio from the world, and the end is in sight. This has been one of the largest private/public sector initiatives ever organized. By the time polio has been eradicated, Rotary International will have expended nearly \$400 million on the effort, making it the largest private contribution to a public health initiative ever. Of this, \$277 million has already been allocated for polio vaccine, operational costs, laboratory surveillance, cold chain, training and social mobilization in 118 countries. More importantly, we have mobilized tens of thousands of Rotarians to work together with their national ministries of health, UNICEF and the World Health Organization, and with health providers at the grassroots level in thousands of communities. Together with our partners, we have achieved some remarkable successes. The reported number of cases worldwide has decreased from over 38,000 cases in 1985 to an estimated 3,500 cases for 1996—a decline of over ninety percent! The attached chart depicts this dramatic progress.

*Fiscal Year 1998 Budget Request*

For fiscal year 1998, we are again requesting that at least \$47.2 million be channeled through the U.S. Centers for Disease Control and Prevention for targeted polio eradication efforts—primarily polio vaccine purchase and delivery, as well as technical support for National Immunization Days. This would maintain funding at the fiscal year 1997 level, and ensure that the USA remains the decisive factor in the success of the global initiative. This \$47.2 million for fiscal year 1998 is essential to reaching the goal of global polio eradication by the year 2000.

Polio eradication is an investment, but few investments are as risk-free or can guarantee such an immense return. The world will begin to “break even” on its investment in polio eradication only two years after the virus has been vanquished. And the financial and humanitarian benefits of polio eradication will accrue forever. This will be our gift to the children of the twenty-first century.

Thank you for this opportunity to submit testimony.

*Report global incidence of poliomyelitis, 1981–96*

	<i>Reported cases of polio<sup>1</sup></i>
1981 .....	66,052
1982 .....	51,900
1983 .....	40,219
1984 .....	35,345
1985 .....	38,637
1986 .....	33,038
1987 .....	39,866
1988 .....	35,251
1989 .....	26,207
1990 .....	23,484
1991 .....	13,484



*Report global incidence of poliomyelitis, 1981-96—Continued*

	<i>Reported cases of polio<sup>1</sup></i>
1992 .....	14,777
1993 .....	10,503
1994 .....	8,635
1995 .....	7,028
1996 Estimated .....	3,500

<sup>1</sup>Number of polio cases reflects only those cases reported to the surveillance network.

Source: World Health Organization Actual polio cases occurring may be as many as ten times greater.

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PREPARED STATEMENT OF SHARON TERRY, PRESIDENT, PXE INTERNATIONAL, INC.

Mr. Chairman, and members of the subcommittee: My name is Sharon Terry, and I am the President of PXE International Inc. We wish to express our sincere thanks to you for this opportunity to submit a written testimony regarding the budget of the National Institutes of Health (NIH).

I would like to thank Chairman Specter and members of the Subcommittee for your continued and unflagging support of biomedical research and the NIH.

Pseudoxanthoma elasticum (PXE) is an inherited connective tissue disorder. It causes calcification of connective tissue including: skin, eyes, cardiovascular and gastrointestinal systems. Most of the time it causes legal blindness, and many times it causes heart disease and gastrointestinal bleeding. PXE is estimated to affect about 1 in 50,000 Americans, but recent studies suggest that it may be more prevalent.

People affected with PXE experience blindness associated with retinal bleeding. Thus, at a time when they are most productive, in their 40s and 50s, they are unable to continue to work, they cannot drive, or read and the life they once knew is changed. Early heart attack and gastrointestinal bleeding can be life threatening and debilitating. Clearly we need to advance research for PXE, so little is known that there is at present no treatment.

My two children have PXE. They are very young and thus time is on their side if basic biomedical research can continue to be funded adequately. As parents we hope and pray. As the founders and chief officers of PXE International we care deeply for the many people who have come to us for help, and we work hard for their interests.

At the present time, grants funded by the NIH have led to some exciting discoveries for PXE. These breakthroughs continue to help us move closer to cures for PXE. An international symposium in Bethesda, in late 1997, is partially supported by the NIH. In addition, adequate funding of clinical research is necessary to translate these remarkable findings into better treatment therapies. We feel very strongly that an investment in NIH research is a healthy investment in our future.

But it is not only for PXE that we testify. PXE International is a member of several alliances and coalitions. Working with these other patient advocacy groups has helped us become aware of exciting advances in basic science, that will lead to cures and better treatments for all disease sufferers. One of the coalitions that we are members of is the National Institute of Arthritis and Musculoskeletal and Skin Diseases Coalition. This organization represents 50 other skin disorders. We have seen basic medical research result in advances in a better understanding of Alopecia Areata, Epidermolysis Bullosa, and Ichthyosis.

We respectfully urge Congress to continue to invest in conquering these common, costly, and crippling diseases by providing \$280 million annual appropriations for the NIH fiscal year 1998. This would be a 9 percent increase over the current fiscal year. This increase would allow more allocation of funds to support more approved research grants. It would also provide more research training and career development for future investigators, conduct urgently needed new clinical trials, and expand the intramural research program currently underway.

We represent hundreds of Americans suffering the effects of pseudoxanthoma elasticum, and further, we represent ordinary Americans, all affected by medical issues each day. We offer our thanks to the Committee and to Congress for its continued support of biomedical research. Without this support, we could not hope to provide a cure or to ameliorate the pain and disability caused by this disorder, or any other.

## PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

The American Society of Clinical Oncology (ASCO) represents 11,000 oncologists who care for people with cancer and conduct clinical research. Our members commend Congress for recognizing the continued need to support biomedical research at the National Institutes of Health (NIH) in the face of efforts to balance the federal budget. But, as Mr. Specter and others have recognized, we must be relentless in maintaining NIH funding as a high priority.

Research has fortunately moved us forward toward increased survival rates and improved quality of life for many people diagnosed with cancer. The pace of discovery in science is affected by many factors. But, clearly, a primary limitation is insufficient resources to support research, infrastructure, and personnel. Right now, the opportunities in cancer research justify at least a doubling of the budget of the NIH over five years. This proposal has broad bipartisan support in both the House and Senate. The National Cancer Institute (NCI) specifically should receive its fair share of this increase to ensure that scientists are able to take advantage of current knowledge by expanding our understanding of the fundamental nature of cancer and translating basic research into clinical practice.

The scientific challenges we face are too numerous to detail here, but include some of the most promising areas of investment:

- Translate basic research in immunology and molecular biology into the design of vaccines that target the prevention (e.g., Papilloma type cervical cancer) or treatment (e.g., melanoma) of specific cancers;
- Support research on immunologically directed therapies that use antibody-radioisotopes to identify tumor-specific antigens that bind the isotope to the tumor cell for the purpose of killing it;
- Develop agents to block angiogenesis, the formation and creation of blood vessels that facilitate tumor cell dissemination or metastasis;
- Improve our ability to induce cell differentiation, the lack of which characterizes cancer cells, through such agents as Vitamin A analogues;
- Utilize the information from the human genome project to improve cancer predisposition testing and to individually tailor therapies, for example, through cancer suppressor genes; and,
- Identify and test agents to interfere with the initiation and promotion of cancer cell growth.

To accomplish this agenda, the country must be willing to make more of an investment in cancer research. Several surveys have demonstrated that the American people support this goal; now, we must find the political will to reach it.

Increased NIH funding should be used to support a balanced research portfolio that includes basic, translational, and patient-oriented research. ASCO, as a voice for physicians and their patients, has a particular interest in patient-oriented research. In 1995, ASCO reported that NCI had invested only 1 percent of its funds in investigator-initiated research with clinical application. As a result of this astonishing finding, NCI altered its review procedures such that clinical applications have begun to receive more favorable ratings. Last year, the Senate report acknowledged the need for this program, which we concur should continue. Nonetheless, more permanent steps need to be taken.

How should we address the underlying problem? While no one can answer this question with certainty, there are two areas where we believe NIH can improve the viability of clinical cancer research: (1) establishment of a study section dedicated to the review of clinical grants; and (2) development of a granting mechanism for mentors of young clinical investigators.

The lack of an appropriate study section to review patient-oriented research project grants is a major barrier to the support of clinical cancer research. Because research involving people with or at risk for serious disease involves variables and outcome measures that are difficult to control, these proposals are at a significant disadvantage when directly compared in a study section with relatively straightforward laboratory science grants. Numerous reports from such groups as the National Cancer Advisory Board and the congressionally mandated Subcommittee on the Evaluation of the National Cancer Program (SENCAP) have urged adoption of a dedicated study section as a remedy to this problem.

Without a balanced approach to the distribution of scarce research dollars, the clinical research infrastructure will not be prepared to rapidly translate the promising developments in basic research. The establishment of a clinical research study section with a primary focus on patient-oriented research is an important step that could have a tremendous impact on clinical research with minimal new outlays. Congress should urge NIH to take this step at the earliest possible time.

In addition to improving grant review procedures, we must also recognize that becoming a good clinical investigator requires more than course-driven knowledge or even hands-on experience. A well-trained clinical investigator must also understand the art of clinical grantsmanship, appreciate academic values as they relate to scientific integrity and patient care, and recognize resources available for continued educational and scientific experiences. These refined skills, unfortunately, are not readily taught or learned. They develop over time and are best acquired from a mentor—an experienced individual who takes specific interest in the development of the career of a young trainee.

The changing health care environment with its increased focus on generating clinical revenues has made this so-called “socialization” process more difficult. Senior staff have less time and fewer resources to devote to the mentoring process, despite the fact it is well accepted that individuals working with mentors are more successful and more satisfied in their professional life. While data are limited, studies of women and minorities are consistent in their findings that these populations of trainees perform particularly well when working in conjunction with mentors.

ASCO proposes the establishment of a new NIH award program for “clinical research mentors.” By establishing a new grant mechanism specific to mentorship, we will send our senior scientists the message that this is an important and rewarded activity in which they should participate.

What would a mentor do with grant funds? The monies would be utilized primarily as direct compensation for the time and resources required to nurture a young trainee, and to better define what constitutes a successful mentorship program. Particular attention would be placed on teaching the young trainee how to develop an investigator-initiated research grant proposal that is both innovative and scientifically sound enough to attract the attention of study section reviewers.

In closing, we can only take advantage of the opportunities to advance knowledge and improve cancer care by putting the necessary resources into our research and training budget. The national goal of containing costs is laudable, but inadequately funding biomedical research with its long-term potential to save money and lives is shortsighted. With the necessary resources, we can look forward to a day when the devastating impact of cancer is minimized. Simply speaking, we need much more funding, as well as an improved system to support clinical investigators who are in the vital position of translating the exciting work of basic scientists into improved bedside care.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) thanks you for the opportunity to provide a written statement for the record in support of the fiscal year 1998 appropriation for the Centers for Disease Control and Prevention (CDC). The ASM is the largest single life science society in the world with a membership of over 42,000 individuals who are engaged in basic and applied research and diagnostics and work in clinical, public health, and industrial laboratories, as well as in academia and government. The ASM recognizes the difficult budget constraints the Committee on Appropriations faces in determining the fiscal priorities for the nation, and would like to thank you for your past support for the CDC, especially for infectious disease funding. The CDC has been recognized for its efforts to combat the continuing threats of new and reemerging infectious diseases, and the ASM recommends that Congress continue its support and adopt the Administration’s request for new and reemerging infectious diseases.

The Administration’s request for CDC’s infectious disease program includes an increase of \$15 million for new and reemerging infectious diseases and \$10 million for its role in foodborne disease prevention as outlined in the Presidential Food Safety Initiative. The ASM supports the Administration’s request for an additional \$25 million to combat new and reemerging infectious diseases, including foodborne diseases. This request represents the minimum level of resources needed by the CDC to improve the nation’s public health capacity to combat infectious diseases. New and reemerging infectious diseases continue to proliferate and many chronic diseases and conditions have now been proven to have infectious origins (ulcers, cervical cancer, chronic liver disease). The ASM also recommends that Congress adopt the fiscal year 1998 budget proposal developed by the CDC Coalition. The CDC Coalition members, over 100 in number, are committed to improving the public’s health through cost effective prevention and control strategies. For fiscal year 1998, the CDC Coalition recommends Congress appropriate \$3 billion for the CDC.

### *Infectious Diseases*

Our nation continues to be faced with new, reemerging and drug resistant infections. To what extent these infectious diseases are rising is still unknown due to the lack of a comprehensive needs assessment and evaluation of the nation's surveillance capabilities. Infectious diseases remain the world's leading cause of death, accounting for over half of the 50 million deaths annually. In the United States, the death rate from infectious diseases rose 58 percent between 1980 and 1992, claiming approximately 166,000 lives annually. At a cost of \$120 billion each year, recognized infectious diseases account for one out of every six health care dollars and a quarter of all physician office visits. However, these are only estimates due to the lack of information and data on the actual national, state and local surveillance capabilities, the total infectious disease burden, and the economic and social costs of infectious diseases to the nation. There are a number of known and many still unknown reasons for increasing rates of infectious and multi-drug resistant diseases. Some examples and reasons for emergence include but are not limited to:

*Social Factors-Child Care Facilities.*—Infectious diseases are the leading cause of pediatric visits. Children in child care facilities are 2–3 times more at risk of infectious diseases compared to children cared for at home. It is predicted that by the year 2000, 75 percent of mothers with children under 6 will work outside the home. Incidences of some child care associated infections (otitis media, giardia) have been rapidly increasing as well as related incidences of antimicrobial resistance. In spite of these trends, CDC does not have the resources to support routine surveillance of pediatric practices.

*Environmental Factors.*—Ecological changes such as the development and deforestation of former woodlands, farms, and fields into housing developments and shopping centers have led to the emergence of new infectious diseases previously unknown to cause disease in humans. Humans, because of their recent assessability due to parts of rural America becoming suburban, have become the “new” hosts for many tick borne diseases. Although Lyme disease accounts for the majority of known tick borne diseases, the CDC has recently detected the emergence of a new tick borne disease, Ehrlichiosis, which can cause life threatening illness and sometimes death if not treated properly and quickly.

*Chronic Diseases and Infectious Diseases.*—Many chronic diseases, and diseases once thought to be noninfectious, have been proven to be of infectious origin. The most well known example is peptic ulcer disease which was accepted for years by the medical community as a chronic condition which required constant medication. It has now been associated with helicobacter pylori, a bacterium found in the stomach and is treated much more effectively by a course of antibiotics.

Most recently, the CDC has identified a fungus that thrives in waterlogged basements and may account for a percentage of infant deaths that had been previously attributed to sudden infant death syndrome (SIDS). CDC scientists have shown a link between exposure to this fungus, *Stachybotrus atra*, and to the death of six infants in the Cleveland area, and the hospitalization of twenty four other infants. This fungus had been previously known to cause severe gastrointestinal bleeding in livestock in Europe but had not been suggested as affecting human beings in this country. SIDS is listed as the cause of 6,000 infant deaths a year and is the leading cause of death in babies 1 month and older. CDC is now conducting a retrospective investigation of 172 infants who were considered SIDS babies to determine the prevalence of this fungus.

Hepatitis C is now considered the leading cause of chronic liver disease and the leading indicator for liver transplant. There are an estimated 8,000–10,000 number of persons who die as a result of chronic liver disease, and approximately 35,000 new infections occur each year. There are now an estimated 3.9 million chronically infected Americans. The consequences of Hepatitis C infection often occur years after infection. The medical, economic and social impacts of 3.9 million individuals infected with Hepatitis C are only slowly being realized. The numbers of Americans who will eventually get chronic liver disease and require treatment, including liver transplants, may overwhelm the health care system in the next century.

Another example of the increasing numbers of chronic diseases which are now, in many cases, considered infectious in origin, is infertility and certain cancers which occur years after the initial onset of infection. The leading cause of infertility in this country is chlamydia infection. This is just one of the twenty-five or more infectious organisms (STD's) that are transmitted through sexual activity. In many women, chlamydia causes pelvic inflammatory disease which is one of the major causes of infertility in this country.

Sexually transmitted pathogens also cause certain types of cancer. For example, the human papilloma virus (HPV) has been shown to cause nearly 80 percent of invasive cervical cancer cases. Women with HPV infection of the cervix are 10 times

more likely to develop invasive cervical cancer than are women without such an infection. In addition, it has been demonstrated that the Hepatitis B virus causes many cases of liver cancer.

#### *Antibiotic Resistance*

New, resistant strains of bacteria continue to threaten the effectiveness of antibiotics. Antibiotics are the second most commonly prescribed category of drugs in the U.S. Children under the age of 15 are being prescribed antibiotics 3 times more than adults. Although, antibiotic resistance is not yet measured on a national scale due to a lack of resources and the absence of a national surveillance system, select studies strongly indicate a rapidly growing problem with resistant strains of bacteria. Treatment costs are escalating, and run into the billions, due to ineffective therapeutic treatments, and longer hospital stays which are required to fight resistant organisms.

As the CDC continues to expand its surveillance, investigational and research activities, it will gain knowledge of the growing toll of infectious diseases. However, once this knowledge is gained, the CDC will utilize this information to design effective prevention and control strategies to help prevent and eliminate the spread of infectious diseases.

#### *CDC Infectious Diseases Program*

Surveillance is the primary public health tool used to combat the outbreak of infectious diseases. Without adequate surveillance, disease outbreaks flourish without abatement, causing unnecessary illness and death and contributing to the spiraling health care costs in this country. Surveillance involves people monitoring the incidences of disease, figuring out how to stop the spread of infectious diseases, and replicating proven strategies throughout the nation's communities. Prevention of infectious diseases is a national responsibility due to transmission of microorganisms across local, state, and international borders. The CDC conducts infectious disease surveillance working in cooperation with state and local health departments and private health care providers.

The Administration's request for an additional \$15 million to continue implementation of the CDC plan to address new and reemerging infectious diseases is essential. The CDC emerging infectious disease plan is focused on four goals: strengthening the surveillance of and response to emerging infectious diseases; implementing an applied research extramural program to address important research questions related to emerging diseases (including research to develop new or improved diagnostic tests); developing and implementing prevention and health communication activities and strengthening the infrastructure of CDC and state/local health departments, including laboratories, to address new and reemerging diseases.

With increased resources, the CDC will be able to expand its Emerging Infections Programs (EIP) from seven states to eight in fiscal year 1998. The EIP states are conducting "early warning" surveillance activities and investigations to monitor more accurately and respond to infectious disease outbreaks, illnesses and death. These surveillance sites are the backbone of the national surveillance system for new and reemerging pathogens. At these sites, applied epidemiological and laboratory research are conducted to help identify known microbial agents responsible for infectious diseases and also discover new pathogens which have emerged to create a new niche for microbial proliferation in humans.

The proposed new funds for new and reemerging infectious diseases will also allow CDC to expand its Epidemiology and Laboratory Capacity (ELC) program which provides states with financial and technical support towards modernizing the public health laboratory's facilities and abilities to combat new and reemerging pathogens. To prevent the public health infrastructure and laboratories from further deterioration, these additional resources will provide specific states with upgraded information systems, enhanced laboratory technology, and trained staff to strengthen the capacity for public health surveillance and disease outbreak response. A portion of these resources will also be devoted to implementing health communication strategies for the general public to prevent the spread of new and reemerging infectious diseases and developing and implementing educational programs to improve antimicrobial drug use practices among health care providers and consumers.

#### *Foodborne Diseases*

There are more than 250 foodborne diseases which have been diagnosed and recognized. Many different bacteria (such as *Campylobacter*, *Salmonella* and *Escherichia coli* 0157:H7) viruses, and parasites (such as *Giardia*) cause foodborne disease and microbiological contamination. Estimates for incidences of foodborne disease vary widely from 6 million to more than 33 million cases per year due to incomplete data and sporadic surveillance. Impacts of foodborne illnesses range from

mild to severe cramps and diarrhea which can cause a range of mild to severe illness, paralysis and sometimes death.

As part of the Presidential Food Safety Initiative, CDC is a partner with the United States Department of Agriculture and the Food and Drug Administration to combat infectious foodborne hazards. Collaboratively, these agencies have established FoodNet, the foodborne disease component of the CDC Emerging Infections Program. FoodNet provides a network for responding to new and emerging foodborne disease of national importance, monitoring the burden of foodborne diseases, and defining the source of specific foodborne diseases so that proper action and prevention measures can be taken. The major components of FoodNet are active laboratory based surveillance, surveying clinical laboratories and physicians for cases of foodborne illnesses, surveying the population and conducting case-control studies using patient samples including antibiotic resistance testing. FoodNet was established in 1995 at five sites in Minnesota, Oregon, Georgia, California and Maryland. 14.7 million people or 6 percent of the U.S. population are "covered" by this foodborne disease surveillance system. The ASM supports the additional \$10 million the Administration has requested to expand the FoodNet program to 8 states which will lead to a more effective early warning system which will detect outbreaks earlier and should lead to the prevention of illness and death from foodborne pathogens.

#### *Conclusion*

The CDC is the primary federal agency responsible for guarding the public's health, including, among other activities, safeguarding the food and water supply and investigating outbreaks of potentially life threatening infectious diseases. The CDC has developed a strategic plan to address emerging infectious diseases and was able to begin implementation of this plan three years ago. The strategic plan, "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States," emphasizes surveillance and targeted research and prevention activities to maintain a strong defense against infectious diseases that threaten the public's health. The ASM supports the Administration's fiscal year 1998 CDC budget request which includes a total of \$112 million for infectious diseases. The additional \$25 million proposed for fiscal year 1998 (\$15 million for infectious disease, \$10 million for foodborne diseases) would allow the CDC to continue implementation of the emerging disease plan by expanding the five networked domestic surveillance sites to seven sites. These sites are linked electronically and allow for a more rapid dissemination of information and increased ability to detect pathogens and antimicrobial resistance. These funds would also increase the number of states receiving additional critical and technical resources to investigate infectious disease outbreaks.

The ASM would like to thank you for your continued support for CDC funding and recognition of its unique role in combating infectious diseases. There have been a proliferation and increase in the numbers and types of infectious diseases being identified and diagnosed both here in the United States and abroad. Infectious diseases remain the single most prevalent cause of death worldwide, and are the third ranked cause of mortality of Americans of all ages. The extraordinary resilience of infectious microbes which have a remarkable ability to evolve, adapt, and develop resistance to drugs requires the nation's attention and resources to prevent unnecessary human suffering.

Thank you for considering our request and recommendations for the CDC. We would be pleased to provide further information and to assist the Subcommittee as the appropriations bill for Labor, HHS, and Education moves forward.

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#### PREPARED STATEMENT OF MARK L. BATSHAW, M.D., ON BEHALF OF THE MENTAL RETARDATION AND DEVELOPMENTAL DISABILITIES RESEARCH CENTERS

Mr. Chairman and Members of the Committee: I am Mark Batshaw and I am the Physician in Chief of the Children's Seashore House at the University of Pennsylvania's School of Medicine. It is my pleasure to submit the record this testimony on behalf of the Mental Retardation and Developmental Disabilities Research Centers. There are currently fourteen such centers that support the work of the National Institutes of Health—with a special focus on the National Institute of Child Health and Human Development (NICHD).

NICHD devotes its research to ensuring the birth of healthy babies and the opportunity for each infant to reach adulthood and achieve full potential, unimpaired by physical or mental disabilities. This is clearly a mission that deserves our support. In order to accomplish this goal, we need to continue to invest in this important research institute and in the Mental Retardation and Developmental Disabilities

Research Centers. We therefore recommend that the NICHD receive \$690 million in funding for fiscal year 1998. We also recommend an increase of 9 percent overall for the National Institutes of Health.

In order to accomplish its broad mission, NICHD is structured by an intramural program, which largely targets basic research related to human development, and an extramural program which includes the Center for Population Research, the Center for Research for Mothers and Children, and the National Center for Medical Rehabilitation Research. In addition, the NICHD has long served as a strong example of an institute that looks not only to the physiological factors affecting health, but recognizes the importance of behavioral, social, environmental and genetic factors to health outcomes as well. The fourteen Mental Retardation and Developmental Disabilities Research Centers pursue biomedical and behavioral research that will lead to understanding the causes of mental retardation and other developmental disabilities.

NICHD and MRDD Research Center research has made major contributions toward preventing mental retardation and other developmental disabilities. The most celebrated screening program is the one for PKU, a metabolic disorder that causes mental retardation. Research on PKU led to the finding that a special diet could prevent a newborn with PKU from becoming mentally retarded. MRDD Research Center research also established the dangers of maternal alcohol consumption. In addition, MRDDRC research identified lead as a major cause of mental retardation—even at levels that previously were considered safe.

It is evident that research conducted at the Mental Retardation and Developmental Disabilities Research Centers, with support and funding from the NICHD, demonstrates considerable cost savings as well as making a real difference in people's lives.

Exciting New MRDD Research Center Research:

#### *Early Intervention*

Recent work on brain development strongly suggests that early educational and language instruction actually re-wires the brain of the developing child.

Research designed to better understand the processes underlying neuroplasticity may make it possible to increase this window of opportunity for early intervention which is so critically important for children with disabilities. The NICHD has just launched a major autism research program based at Yale University, UCLA, University of Chicago, University of Pittsburgh, and the University of Washington. The research study is designed to provide a better understanding of ways to prevent and treat autism, and to provide a better understanding of ways to provide more targeted educational services to youngsters with autism spectrum disorders. It appears that many children in the early stages of autism spectrum disorders can be spared from developing the most seriously debilitating symptoms through intensive early language and social intervention.

#### *Genetic Research*

Advances in genetics research methods have now made it possible to explore the relation between genetic errors and specific behavioral and psychological consequences of those defects. Projects on Fragile X Syndrome, Rett Syndrome, Down Syndrome and other genetic disorders have made substantial strides in recent years. Research sponsored by NICHD at Baylor, Yale, UCLA, Harvard, and Vanderbilt Universities have linked specific errors on human Chromosome 15 to highly specific behavioral disorders of major health importance. Research has shown that most people with Prader Willi Syndrome, a genetic disorder which also causes life threatening obesity, also have Obsessive Compulsive Disorder (OCD), a psychiatric disorder affecting 5 million Americans. Researchers are homing in on the critical region of Chromosome 15 to identify which genes in this region are responsible for specific aspects of this condition. Once the gene product is identified, the search for a more effective treatment, or even a cure is possible.

#### *Mental Retardation and Language*

One of the most important aspects of children's early language learning is the ability to understand the concept of categories. This is a specific skill deficit for many children with mental retardation. If a child is unable to understand the idea that each category of things has properties in common that differentiate them from other categories of things, they are at an enormous disadvantage.

Research at the Eunice Kennedy Shriver Center (an NICHD-funded MRDDRC) in Waltham, Massachusetts and at the University of Kansas MRDDRC, has led the way in clarifying exactly how children or older individuals with disability learn such relationships. Techniques developed at these two MRDDRCs have made it possible

to teach such relationships to people with severe disabilities which previously was thought to be impossible.

Work Continues:

*Self-Injurious Behavior*

Successful treatments have been developed to reduce self-injurious behavior in some individuals with mental retardation. Many people with mental retardation are forced into restrictive living settings, not because of their mental retardation, but because of their tendency to harm themselves. MRDDRC researchers have found changes in brain chemistry that cause self-injurious behavior, as well as medications that correct them. Combined with positive behavior management techniques, many of these individuals with experience a marked reduction in their self-injurious behavior.

*Anomalous Genes*

MRDDRCs are making extraordinary progress in identifying anomalous genes that cause a variety of developmental disabilities, including Duchenne Muscular Dystrophy, Fragile X syndrome, Myotonic Dystrophy, and several enzyme deficiencies that cause mental retardation (e.g., glycerol kinase and glutaric acidemia).

*Muscular Dystrophy*

Significant research involving gene therapy for Duchenne Muscular Dystrophy (DMD) suggests that the muscle deterioration responsible for the disability and premature death of young males can be halted. This effective intervention has the potential of changing the lives of the 13,200 children that currently have DMD, and those 600 children who are born with it each year. Annually, it could also save our economy \$60 million in health and related services costs.

*Research on Cytomegalovirus (CMV) continues*

This common virus is now the most common cause of acquired mental retardation—affecting over 5,000 infants each year. Tests to confirm current and previous CMV exposure are more readily available. While neither a preventive vaccine nor a cure currently exists, additional research support could lead to these significant achievements in the next few years.

Research conducted by NICHD has contributed substantially to the knowledge base regarding physical and behavioral aspects of maternal and child health, human reproduction and the prevention and amelioration of cognitive and physical disabilities. It has saved billions of dollars in related health, education and institutionalization costs. The current cost of institutional care of people with mental retardation is approximately \$100,000 per person per year.

Because estimates show that nearly half of all Americans have some type of disability, and new disabilities are still emerging, adequate funding for NICHD research remains critical. In many arenas, we sit poised on the threshold of major new discoveries and advances. In other areas, the work is only beginning. With these needs in mind, Mr. Chairman, I urge you to provide \$690 million in funding for the NICHD for fiscal year 1998. Each dollar spent on research and prevention of disease and disability is the ultimate cost savings for the future.

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PREPARED STATEMENT OF ANNIE V. SAYLOR, PH.D., PRESIDENT, NATIONAL ALLIANCE FOR THE MENTALLY ILL

Mr. Chairman and Members of the Subcommittee, my name is Annie Saylor, President of the National Alliance for the Mentally Ill (NAMI). I am sincerely appreciative for the opportunity to offer NAMI's position on funding for the National Institutes of Health, with specific focus on the National Institute for Mental Health (NIMH), and the Center for Mental Health Services (CMHS). In addition to representing the views of hundreds of thousands of families across the country, I testify as a sibling of an individual with a brain disorder—my sister was diagnosed with schizophrenia in 1985. Through advances in research and the development of new, state of the art medications, these individuals are able to live fuller and more productive lives.

NAMI is the nation's largest grassroots organization dedicated to improving the lives of persons with severe mental illnesses, including schizophrenia, bipolar disorder (manic-depressive illness), major depression, and anxiety disorders. NAMI's membership includes more than 140,000 people with brain disorders and their families, and 1,100 state and local affiliates in all 50 states, the District of Columbia, Puerto Rico, and Canada. NAMI's efforts focus on advocacy for nondiscriminatory and equitable federal and state policies, research into the causes, symptoms and



treatments for severe mental illnesses and education to eliminate the pervasive stigma toward those who suffer from these serious brain disorders.

Mr. Chairman, on behalf of all people with severe mental illnesses and their families, I would like to thank you for supporting increases in research funding these past two years. Without funds for the basic medical research to understand the brain, scientists would not have the fantastic new understanding of the brain that they now have, and continue to discover. Neuroimaging techniques, as an example, such as magnetic resonance imaging (MRI) and positron emission tomography (PET) have opened new windows into the terrain of the brain. These techniques have permitted scientists to identify mechanisms producing various malfunctions, eventually offering the hope that drugs can be developed that will target these brain areas. For these reasons, we believe that it is imperative to fund NIMH at a level of \$764.1 million for fiscal year 1998.

For too long, severe mental illness has been shrouded in stigma and discrimination. These illnesses have been misunderstood, feared, hidden, and often ignored by science. Only in the last few decades have we seen the first real hope for people with severe mental illnesses through pioneering research that has uncovered both a biological basis for these brain disorders and treatments that work.

Research has proven that brain disorders are treatable. The current success rate for treating schizophrenia is 60 percent. The success rate for bipolar disorder has risen in recent years and now approaches 65 percent. For major depression, the rate has climbed to nearly 80 percent. These recent advances would not have been possible without substantial investment in biomedical research directed to the most complex organ in the human body, the brain.

The treatment of schizophrenia and schizoaffective disorder is undergoing rapid change, with the introduction of second-generation antipsychotic drugs. By 1998, clinicians will need to know which of many first- and second-generation drugs to try with what type of patient. NIMH is currently proposing clinical trials to reform clinical guidelines and clinical practice. This initiative would explore the use of these new drugs for patients with various types of schizophrenia, including first-break, chronic, treatment-resistant, with comorbid substance abuse, and with associated depression. There is a similar need to assess the efficacy and patient characteristics of new anticonvulsant drugs being used for the treatment of bipolar disorder.

Advances in the development of molecular models of disease, including the creation of genetically manipulated mice (transgenic) which mimic a specific disease, have created new and exciting opportunities to understand brain development and function. Genetic technologies have progressed rapidly. The increasing ability of scientists to manipulate the mouse genome has created remarkable new scientific opportunities to understand the development of the brain, brain function, and the genetics of behavior.

One of the most important advances that resulted in the past decade has been in treatment for schizophrenia. The introduction of clozapine has helped thousands of patients with schizophrenia to leave mental hospitals, and in some cases, to return to school, hold a job, and live independently. NIMH research on the basic biology of clozapine's action has built the foundation for understanding how this drug works in the brain.

Clozapine saves an average of \$23,000 per patient annually. This translates into a total savings of approximately \$1.4 billion each year; the savings are realized primarily through the reduction in the need for hospitalization. The annual costs of a new drug to treat schizophrenia is \$4,500; annual hospital costs for persons with schizophrenia average \$73,403. Thus, widespread use of drug therapy could save approximately \$69,000 per patient annually.

NIMH sponsored research findings support proposals to reduce the frequency of blood monitoring in clozapine-treated patients, particularly after the first six months of treatment. Reducing the blood monitoring from weekly to monthly (as is now done in Europe) would save 75 percent of the cost of safety monitoring, approximately \$5,000 per year per patient, resulting in cumulative savings of \$225 million per year in the United States based upon the 60,000 patients currently receiving clozapine. This reduced blood monitoring also would increase the number of potential patients using the drug, some of whom currently avoid the treatment due to the weekly drawing of blood.

NIMH supported research is also offering new hope to people who suffer bipolar disorder. For some people with bipolar, also known as manic-depressive illness, lithium treatment does not work at all. For others, lithium may lose its effectiveness due to the development of tolerance or treatment interruptions. Recent NIMH clinical research have shown that two other drugs that were originally developed as anticonvulsants, carbamazepine and valproate, are effective for some manic-depressive patients who do not respond well to lithium. NIMH research aims to increase

the treatment options for manic depressive illness and to learn how to target different drug therapies to the needs of individual patients.

Mr. Chairman, through your leadership in supporting increases for research at NIH and NIMH we have been able to see this rapid progress continue. As your Subcommittee was told last year by a panel of Nobel laureates, brain research offers the most tremendous potential for advances in basic science and clinical treatment. These investments will certainly prove critical in improving public health and extending life expectancy for decades to come.

According to a study by the World Health Organization, diseases such as major depression, schizophrenia, and bipolar illness currently make up about 40 percent of the total loss of health life due to noncommunicable disease. This figure is expected to climb to 60 percent by the year 2020. It is important to note that while unipolar major depression is ranked as the fourth highest costly disease in 1990, the study projects that it will become the second highest ranking disease by 2020, outranking road-traffic accidents, cancer, and infectious diseases. In addition, bipolar disorder, schizophrenia, and obsessive-compulsive disorder are all expected to climb into the top 25 diseases, making continued research on serious brain disorders a top priority.

In the U.S., severe mental illnesses account each year for more than \$148 billion in direct health care costs, and indirect costs, such as lost work days for patients and care givers. In a given year, these disorders account for 25 percent of all federal disability payments (Social Security Insurance and Social Security Disability Insurance).

Mr. Chairman, in addition to urging the Subcommittee to support increased funding for brain research, I would also like to make note of the importance of federally funded mental illness services through the Center for Mental Health Services (CMHS). Federal support for community-based care is a critical resource for people with the most severe mental illnesses. With many states reducing their inpatient hospital beds and a growing number moving toward managed care systems, the federal investment in community-based care continues to grow in importance. For example, funding for the Mental Health Performance Partnership now constitutes nearly 40 percent of all non-institutional services spending in many states.

Services such as case management, crisis intervention and psychosocial rehabilitation are critical in enabling people with the most severe mental illnesses to live productive lives in the community. As you know, many programs within the CMHS budget have not received increases to account for inflation in nearly five years. Moreover, recent changes in federal law such as welfare reform and restrictions on eligibility for SSI and SSDI for people whose disability is based in part on drug abuse or alcoholism are now placing tremendous pressure on local treatment and support systems.

These programs, particularly the Mental Health Performance Partnership, PATH, Children's Mental Health and Knowledge Development and Application Demonstrations, are critical to our nation's public mental health system. Increasing funds for these programs is vital, in order to keep pace with higher demand for services and the absence of inflation adjustments over the past five years.

In summary, NAMI urges you to support a funding level of \$764.1 million for fiscal year 1998 for funding of the National Institute of Mental Health. This is not only what our families want—it's what they need.

Mr. Chairman, thank you for the opportunity to offer my views on fiscal year 1998 funding for programs of critical importance to people with serious brain disorders. We look forward to working with you in the coming months to educate both the general public and your colleagues in Congress on the critical importance of investment in biomedical research.

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PREPARED STATEMENT OF THE NATIONAL COALITION FOR CANCER RESEARCH

The National Coalition for Cancer Research appreciates the opportunity to submit testimony for the written record.

The Coalition is comprised of 18 not-for-profit lay and professional organizations devoted to the pursuit of cancer research. Today I represent these organizations which consist of 55,000 cancer researchers, nurses, physicians, and health care workers; tens of thousands of cancer survivors and their families; 40,000 children with cancer and their families; 82 cancer hospitals and cancer centers across the country; and more than 2 million volunteers.

The National Coalition of Cancer Research commends the Chairman and the Subcommittee Members for their past commitment to cancer research. The Coalition recognizes that the Subcommittee is pressed with providing funding for programs

that train our workforce, educate our children, and strengthen the health of the nation. We further realize that a myriad of issues surround the many aspects of cancer alone, especially since it is a major social and economic burden to our society. Within this complex mix, the Subcommittee has made biomedical research a priority. The Coalition commends the Subcommittee's attention to the need for adequate funding for biomedical research because, without doubt, research is the gateway to progress against cancer.

Cancer is a complex of many diseases. The origins of these cancers are multifactorial—an interplay between genetics and the environment. During recent years, molecular geneticists have been unraveling the mysteries of carcinogenesis and providing new hope for better means of controlling the disorder. However, despite the declining death rates of the past few years, in the United States, men have a 1 in 2 lifetime risk of developing cancer, and women have a 1 in 3 risk. Cancer is still the second leading cause of death and is expected to be the leading cause of death by the turn of the century. The direct costs of health care services to cancer patients is currently estimated at \$100 billion annually and is increasing each year.

It is the Coalition's central conviction that the solution to the complex problems surrounding cancer—the reduction in morbidity, mortality, and the high costs of medical care—will come in a stepwise manner from the generation of new knowledge through research. The prospects for meaningful progress are good.

As a national priority, our investment in cancer research has paid tremendous human and economic dividends. The contributions of cancer researchers in government, industry and academia have been pivotal in saving lives and in shaping a global preeminence in medical research for the United States.

During the past 25 to 30 years, more has been learned about the workings of the human body and the abnormalities caused by disease than throughout all prior centuries. With respect to cancers, increasing knowledge of the molecular events involved in cause and progression should lead to increasingly effective means of protection and treatment. At the end of March, NIH supported researchers at M.D. Anderson Cancer Center discovered a gene involved in fatal brain tumors. The finding and capturing of the gene was characterized as one of the biggest breakthroughs in brain tumor research in over 20 years. Just last week it was announced that NCI supported researchers at the University Hospitals and Case Western Reserve in Cleveland, have discovered that a component found in artichokes can prevent skin cancers caused by repeated exposure to ultraviolet rays. Realizing breakthrough treatments begins with research discovering these findings.

The discoveries referenced above are due to the Subcommittee's past support of research. Last year the Committee provided almost \$12.8 billion to the National Institutes of Health; of which \$2.2 was allocated to the National Cancer Institute. The President has requested an increase of \$61 million, or 2.8 percent, in fiscal year 1998 for the NCI. We feel that the current appropriation and the fiscal year 1998 request for cancer research are too low. This is especially true when one considers the fact that basic research fuels a large commercial enterprise that is important to the U.S. economy. In fact, in several States, such as New York and California, the health care industries are one of the top two employers.

The Coalition is concerned that because our annual investment in cancer research is merely: 2.3 percent of the total cost of cancer in the U.S.; .0004 percent of our GDP, equivalent to an investment of \$10.40 per person—a little more than the price of one movie ticket a year!

Health care costs for cancer exceed \$104 billion annually and over half of the medical costs of cancer are due to the treatment of breast, lung and prostate cancers. However, we only invest about 2 percent of cancer's health care costs in research to find effective prevention measures, treatments and cures for cancer. There is no company in America that can keep the doors open if they only invest 2 percent in developing innovative products.

The Coalition supports the Congressional leadership, demonstrated in S. Res. 15 and S. 124, which set the course to double the budget of the National Institutes of Health, including the National Cancer Institute. We strongly recommend that the fiscal year 1998 appropriation for the National Cancer Institute be an increase of 15 percent as the first step toward doubling the appropriation for the NCI within five years.

How could a doubling of the NCI's budget be effectively used? A doubling of the budget for the NCI is a sound investment which will enable the following:

- fund a greater proportion of fully approved investigator initiated research applications;
- support of the priorities identified in the By Pass Budget, including cancer genetics, preclinical models of cancer, detection technologies; developmental diagnostics;

- strengthened efforts in translational research to more rapidly translate research progress from the bench to the bedside;
- initiatives to incentivize the research collaboration and establish a strong partnership between the government, academia and industry to maximize our research investment;
- expand cancer prevention and detection research programs;
- strengthen our current efforts in cancer survivorship research to ensure the highest quality of life after cancer; and,
- added support, such as the NCI scholars program, to enable outstanding new investigators in basic, clinical or population-based biomedical research to establish independent research careers.

In order to be most effective, funding must be provided in a manner that enhances creativity—encourages the risk taking inherent in innovation. Research funding must be sustained, also, in order to prevent the detrimental interruptions to investigators and research institutions that have long lasting effects.

Maintaining the integrity of a group of top-notch academic health centers and strengthening a related group of research universities is of vital importance. Clearly, these institutions provide the “environment” and many of the resources necessary to a full spectrum of investigational and educational programs.

The preservation and enhancement of these centers of excellence is an urgent matter of public concern. The chaotic conditions of the “health care marketplace” and the increasingly severe financial constraints that result, are forcing academic health centers devoted to research and education toward the “endangered species” designation. A strong and vital national research program is one of the cornerstones of preservation for these centers.

Patient-centered research merits careful attention because it is the link between laboratory discoveries and the advances in prevention, diagnosis and treatment that improve medical practice and the quality of life of patients and their families. This transition is currently threatened by the practices of various health care management companies and by the payment practices of insurers. Further, the nominal support provided by the NCI to this endeavor—less than 10 percent of NCI’s total budget—is causing many talented clinical researchers to go the way of the dinosaur as they are forced away from research and into clinical practice.

It should be remembered that in many circumstances (e.g., certain cancers, multiple sclerosis, Alzheimer’s disease) experimental therapy administered under the aegis of a fully approved clinical trial is the best therapy available to many patients. It is important that patients not be denied access to clinical trials. The knowledge gained through these studies is important to progress, and the treatment offered may represent the best alternative available to the patient participants. Yet insuring participation in clinical trials due to charges in the health care marketplace is compromising our capacity to translate research from the laboratory bench to the bedside.

Progress depends in no small extent on insuring the continued and sustained renewal of the intellectual resources at the heart of the creative process—the dedicated, highly educated, creative scientists that determine the success of these endeavors. Regrettably, there is a trend of the “brightest and best minds” in our country away from the biomedical sciences into careers that appear more challenging and a more important part of our nations future. This trend must be reversed.

Of NCI’s five medical research “areas of emphasis,” to which a large percentage of the Administration’s requested increase will be directed, the Coalition is particularly supportive of the “genetics of medicine” initiative. Our knowledge of “cancer genetics” is expanding rapidly and promises great benefits to people at risk of developing cancer. The full realization of this potential will involve patients in research protocols and apparently healthy family members, as well. The complex scientific and social issues that surround “genotyping” endeavors are well known and do not merit repetition here. However, a constructive disentanglement of the issues and the development of rational and socially responsible policy guidelines in critical areas will facilitate future research of great importance to society at large.

The Senate’s appropriations for cancer research in the past are a success story. Over a million Americans are alive today—largely because of the Subcommittee’s commitment to this cause. Further, continuing commitments:

- create American jobs since 85 percent of the money appropriated to the National Cancer Institute (NCI) is invested in research institutions across the country. Each year, NIH grants contribute toward an estimated at \$44.6 billion in sales; \$17.9 billion in employee income, and over 726,000 jobs;
- support the basic research engine which provides the basis for our biotechnology and pharmaceutical industries to translate research progress from the laboratory to the patient;

- The biotechnology and pharmaceutical industries together contribute some \$100 billion annually to the American economy supporting 200,000 high-paying, high skilled jobs;
  - There are 215 drugs in development by 98 research-based pharmaceutical companies and the National Cancer Institute; and,
  - The number of companies involved in cancer drug development have doubled in the past three years from 49 to 98.
- The number of drugs being developed has increased by 91 since 1993, contain health care costs, for example:
- In a 1994 NIH report it is estimated that approximately \$4.3 billion invested in clinical and applied research supported by the NIH had the potential to realize annual savings of between \$9.3 billion and \$13.6 billion;
  - NCI-funded research has led to new technologies to make affordable and effective bone marrow transplantation as a treatment option for breast cancer. In a sample of over 800 patients, decreased death rates and health care costs resulted, reducing the costs of the transplantation from \$140,000 to \$65,000 per transplant;
  - A 17-year total investment by the government of \$56 million in testicular cancer research has enabled a 91 percent cure rate, with an increased life expectancy of 40 years, and a savings of \$166 million annually; and,
  - An \$11 million NIH-supported study of breast cancer realized a savings of \$170 million annually in the management of women with breast cancer.
- The costs, both human and economic, of cancer in this country are catastrophic. Our national investment in cancer research remains the key to bringing down spiraling health care costs, as treatment, cures and prevention remain much cheaper than chronic and catastrophic diseases, like cancer.
- Finally, the National Coalition for Cancer Research opposes:
- earmarks in cancer research funding which are not accompanied by new (additive) resources; and,
  - arbitrary reductions, through a cap or across-the-board cut, in the facilities and administrative costs associated with the conduct of research. These research tests, referred to frequently as indirect costs, are a legitimate cost of research. The ongoing regulatory review of indirect cost payments is a rational approach to addressing government-wide cost reimbursement.
- The Coalition of Cancer Research thanks the Subcommittee for this opportunity. The Coalition hopes that the Senate Subcommittee will find the rationale on which the Coalition bases its recommendations to focus on cancer research compelling, and that the Subcommittee will be able to direct funds to cancer research to open the doors for researchers to find new methods for the prevention and treatment of cancer.

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PREPARED STATEMENT OF THE FRED HUTCHINSON CANCER RESEARCH CENTER

The Fred Hutchinson Cancer Research Center (FHCRC) appreciates the opportunity to submit public witness testimony for the written record as the Labor, Health and Human Services, Education and Related Agencies Subcommittee prioritizes programs for fiscal year 1998. Our testimony will address the following priorities:

- Funding for the National Cancer Institute (NCI) and the National Institutes of Health (NIH), Basic and Clinical Research Funding and Women's Health Initiative; and,
- Funding for the Centers for Disease Control and Prevention (CDCP), Hanford Thyroid Disease Study.

The FHCRC is a non-profit, federally-funded Comprehensive Cancer Center whose mission is the elimination of cancer as a cause of human suffering and death. The Hutchinson Center carries out a multi-disciplinary strategy:

- Biological scientists conduct fundamental research to discover mechanisms underlying the life of normal cells and the changes in these processes that cause disease;
- Clinical research scientists develop and test new forms of diagnosis and therapy; and,
- Public health scientists develop and apply new knowledge to help individuals and communities reduce the occurrence of, and mortality from, cancer and related diseases.

The FHCRC has achieved international excellence in medical research. We were the pioneer in bone marrow transplantation and the 1990 Nobel Prize in Medicine was awarded to Dr. E. Donnall Thomas for his work in this regard. Today, more

than 400 patients from the United States and throughout the world come to the FHCRC for bone marrow transplants each year, and we perform this procedure more than any institution. To date, more than 6,000 patients have received a bone marrow transplant at the FHCRC.

Biomedical research has a tremendous economic impact on the Seattle metropolitan area. The FHCRC is one of the nation's largest recipients of NCI support and our workforce of nearly 2,000 includes more than 500 employees who hold either M.D. and/or Ph.D. degrees. Many other FHCRC employees are health professionals also. Further, Seattle is home to one of the nation's largest concentrations of biotechnology firms, the majority of which are working in health care. The FHCRC's laboratories have led to the establishment of 11 biotech companies.

Biotechnology can be thought of as an example of what the government does best. By creating strong research and university systems, proactive technology transfer regulations, and pro-business regulatory and tax codes, the federal government can make it possible for the most promising research opportunities to be tested, developed, and marketed.

#### NATIONAL CANCER INSTITUTE/NATIONAL INSTITUTES OF HEALTH

The FHCRC strongly supports a federal cancer program that supports the full breadth of cancer research priorities in basic science, as well as clinical and translational initiatives. Research project grants (RPGs) are a major catalyst for research breakthroughs, yet translational and clinical research programs are no less important—the knowledge that is gained from basic research will not benefit the cancer patient unless it can be “translated” from the “bench to the bedside.” The NCI must have the capacity to support the full range and appropriate mix of all types of research. In addition, today's cost containment health care marketplace threatens to compromise our ability to bring basic research breakthroughs to the cancer patient, as health insurers are increasingly unwilling to support unproven therapies. We urge you to work diligently with your colleagues on the Finance and Ways and Means Committees to insure that no barriers exist to individuals with cancer who are willing to participate in clinical trials.

Research opportunities in cancer have never been greater. We are at a critical crossroads in which our progress on all research fronts—cancer biology, molecular genetics, prevention, clinical and translational research—has positioned the nation to make tremendous strides in areas fundamental to human cancer. Researchers are optimistic about their ability to develop cancer-specific drugs and therapies so that “good” cells are not killed with cancerous cells.

Breakthroughs in genetic research are also a reason for optimism. The discovery of the BRCA1 breast cancer gene holds tremendous promise for women who have a family history of the disease due to a genetic defect. Women who inherit a flawed BRCA1 gene have up to an 85 percent risk of developing breast tumors in their lifetimes. By identifying these women, we can improve our ability to detect and treat their disease early. Ninety percent of patients with the earliest forms of breast cancer are cured and investigators at the FHCRC are hard at work to cure more advanced forms of the disease.

In addition, significant new research opportunities into prostate cancer are emerging. The Hutchinson Center is studying prostate cancer from several angles with new projects beginning each year. Researchers at the Center are evaluating how diet relates to prostate cancer risk; testing the drug finasteride as a possible preventive measure; and conducting genetic research that, in the future, may lead to tests for early detection of prostate cancer and therapies that will cure it.

The impact of cancer is significant in both health and economic terms. Cancer will kill more than 560,000 men, women, and children this year—more than 1,500 every day, and cancer is expected to be the leading cause of death by disease by the year 2000. However, basic and clinical research in cancer are progressing and the scientific opportunities that exist are very encouraging. To exploit these research opportunities the FHCRC supports a doubling of NIH appropriations over five years, as proposed by Senator Mack in S. Res. 15 and by Congressmen Gekas and Porter in H. Res. 83. This would require a 15 percent increase for fiscal year 1998. As an absolute floor, we support the recommendation of the Ad Hoc Group for Medical Research Funding for a 9 percent increase in fiscal year 1998.

#### *Women's Health Initiative*

The FHCRC is the national coordinator of the 15-year Women's Health Initiative sponsored by NIH. The Women's Health Initiative is a cross-institute study regarding the prevention of conditions affecting post-menopausal women, including cancer. It is the largest study of women's health issue ever undertaken and the clinical trial

component of the study will involve more than 46,000 subjects. We urge your continued support of this important study to enable it to remain on schedule.

*Facilities and Administrative Expenses*

Facilities and administrative expenses are as much a part of the real and necessary costs of medical research as are direct costs. While these costs are not directly attributable to a specific research project, they cover operations support such as utilities, maintenance, plant operation, administrative costs, library expenses, and depreciation. Further, a significant portion of facilities and administrative expense is the direct result of federal regulations, including auditing requirements, animal care, hazardous and other environmental standards, laboratory standards, etc.

Perhaps the most critical component of facilities and administrative expense is facility depreciation. Since the depreciation period is much longer than the period budgeted for research projects, this portion of facilities and administrative expense is critical to enable the FHCRC and other institutions to maintain the world's best scientific facilities. An arbitrary change in the facilities and administrative expense formula would diminish our ability to provide quality scientific facilities for the future and would dramatically affect our ability to repay long-term debt, which is based on agreements made years ago. We recognize the interest that this Committee has had in the past regarding facilities and administrative expenses. We urge the Committee to continue to support the regulatory oversight of this important policy initiative.

HANFORD THYROID DISEASE STUDY

In 1988, Congress directed the Centers for Disease Control (CDC) to conduct a study of thyroid morbidity among persons who lived near the Hanford Nuclear Site between 1944–1957. The Hanford Thyroid Disease Study (HTDS) will determine whether thyroid morbidity is increased among persons who were exposed to releases of radioactive iodine from the Hanford site relative to persons who received a very low or negligible dose. This research will provide the only pivotal data in existence to determine the long-term health effects in people who were exposed to radioactive iodine from Hanford.

The CDC awarded a contract to the FHCRC in 1989 to carry out this mandate, and based upon the current contract configuration, the study is projected to be completed this year. The CDC has funded the study since 1989. Further, the U.S. Department of Energy provided supplemental support through a Memorandum of Understanding in fiscal years 1995–1997. The HTDS is in its eighth year and \$3,800,000 in federal funding is required to complete the project in fiscal year 1998. It is of paramount importance that these resources be made available in fiscal year 1998 so as to bring the study to conclusion without postponement. Otherwise, it is expected that the costs for the study will increase if it is not completed in fiscal year 1998.

Thank you for your consideration of our request.

PREPARED STATEMENT OF DONALD S. COFFEY, PH.D., PRESIDENT, AMERICAN ASSOCIATION FOR CANCER RESEARCH

As President of the American Association for Cancer Research (AACR), a professional society consisting of 13,000 scientists who conduct laboratory, clinical, and translational research, I am privileged to submit this testimony on behalf of the AACR. A substantial number of our members are directly involved in the treatment and care of persons with cancer, while the rest are dedicated to the basic and translational research needed to develop better diagnosis, treatment, and prevention of cancer.

I would like to take a moment to thank this Committee for its extraordinary support and leadership on behalf of the National Institutes of Health (NIH) and the National Cancer Institute (NCI). The AACR is fully aware of the restrictive fiscal environment with which Congress is faced and we are most appreciative of the fact that the Members of the Committee have made NIH and NCI a top priority.

First, I would like to point out that one out of every three Americans will develop cancer. These citizens may be faced with the need for toxic, sometimes life-threatening, but also potentially curative treatment.

The problem of cancer is immense. Each year, 1,400,000 Americans are diagnosed with cancer and for 560,000 Americans cancer is a death sentence. Contrast this with the fact that 291,000 Americans gave their lives in the four-year course of World War II. Cancer is an intolerable national tragedy that can no longer be ac-

cepted. Even more intolerable is the pervasive, defeatist attitude that cancer cannot be cured, and that research advances have not substantively changed the lot of the person diagnosed with cancer.

Twenty-five years ago the nation enacted legislation to wage a war against cancer, funding a program of research, the establishment of cancer centers, and the development of national programs to improve diagnosis and treatment. The progress made has been extraordinary. Yet now, at a time when the possibility of eliminating these diseases has never been greater, we are facing a critical loss of national will. Although I recognize the heavy responsibilities that you bear to control the national debt and to guide the judicious use of funds provided by American citizens, I am still struck dumb by the extraordinary tragedy of the current funding situation for cancer. The cost of care for persons with cancer exceeds \$104 billion annually, yet the research budget proposed for cancer is only \$2.4 billion. No company in America would stay in business with such a paltry research and development investment. No general would ever go to war with such limited resources. What a terrible irony: \$61 billion was spent on the Gulf War, a sizable proportion of which was used to ensure that no more than 10,000 Americans lost their lives; yet we tolerate 560,000 deaths from cancer every year—one person every 57 seconds. We also accept the fact that our nation's programs of clinical research, which have led in the development of curative treatments for many cancers, are accessed by no more than 6 percent of the nation's adults afflicted with these diseases.

Some say that the amount of money proposed for cancer research is enough. This is an erroneous contention, and the AACR challenges it vigorously. Indeed, can we responsibly accept this status quo, when so many are suffering from cancer and the continuing inadequacies of current diagnostic approaches and treatment? Before we ask you to consider what the AACR believes should be done, it is important to understand what has been accomplished, and what is not being done now because of a lack of support.

When the National Cancer Act was enacted, a child with leukemia was believed to have an incurable disease. Less than 20 percent of these patients survived 5 years. It was deemed unethical at several academic centers to talk about a cure. Today, over 80 percent of children with acute lymphoblastic leukemia will be cured with intensive combinations of anticancer drugs. Advances in other pediatric cancers are no less dramatic. Indeed, prospects for cure have increased by 20–40 percent for all but one of the common pediatric cancers over the last 10 years alone. As a result, one out of every 900 Americans entering the 21st century will be a survivor of childhood cancer. Advances in the treatment of several cancers affecting adults have been no less dramatic. You have heard about the high cure rates now associated with Hodgkin's disease and several types of lymphoma. Strategies invoking intensive chemotherapy, surgery, and radiation are also making major inroads in the cure rates for men with testicular cancer and women with cancers of the breast and uterus. Even brain tumors, so long refractory, are now being cured in a significant proportion of patients. Application of intensive regimens coupled with genetically matched transplants from normal relatives has ensured cures for 50–80 percent of patients afflicted with different forms of leukemia when such transplants have been applied early in the course of disease. The national effort spawned through the Congress which led to the development of the National Bone Marrow Donor Program now has over 2.4 million volunteers, and over 1,500 such transplants are performed yearly, with success rates now approaching those achieved with matched transplants from siblings.

Over the last ten years alone, a striking array of new, active drugs and biologicals has been introduced, many of which have already radically improved our capacity to treat and cure cancers. Examples include Taxol, which is the most active agent in the treatment of breast and ovarian cancer; the biological agents interferon and trans-retinoic acid and the drugs Fludarabine and 2CDA which have so profoundly improved our treatment of several leukemias; and the marrow-stimulating factors GCSF, GmCSF, and now thrombopoietin which stimulate the recovery of blood cells after chemotherapy or radiation and allow us to treat many cancers in adults with a potentially curative intensity that previously could be applied only to children.

Today, targeted agents are being introduced in clinical trials, agents that selectively kill cancer cells, prevent their spread, and inhibit their capacity to establish a blood supply: agents like immunotoxins (antibodies linked to toxic proteins), now being used to seek out and selectively kill leukemias, lymphomas and other tumors; proteinases that inhibit metastasis; angiogenesis inhibitors that inhibit the growth of blood vessels feeding tumors; and antisense molecules that selectively interfere with the activity of genes that permit cancerous growth.

Many of the advances that have been made over the last 10 years in our diagnostic approaches to cancer will only be realized fully in the next decade. The wide-



spread use of mammography to detect breast cancer, the use of colonoscopy and screening tests to detect traces of blood in the feces for earlier diagnosis of colon and rectal cancer, and the increasingly broad use of blood tests to detect prostatic specific antigen are already leading to earlier diagnosis, earlier treatment, and higher potential for cure. As a result, surveys conducted between 1991–1995 by the NCI have detected a decline in the cancer death rate of nearly 3 percent, the first sustained decline since the 1930's, when such surveys were initiated. It is important to note, however, that certain cancers continue to wreak disproportionate damage on medically underserved populations and, in particular, on minorities; additional research is needed to understand and combat this phenomenon.

Dramatic progress has also been made in research into the molecular events that lead to cancer and the genetic faults that predispose to cancer. Over the last few years, lessons learned about genes that, once mutated, can induce cancer growth, have led to the development of drugs that may selectively counter this process. We now also recognize a series of genes which, when mutated, identify a patient who is at risk for certain kinds of cancer later in life. The genes associated with inherited forms of colon cancer and the genes predisposing to breast cancer, such as BRCA1 and BRCA2, are but a few of the recent examples of progress in this area. We have also been able to identify a large series of genes that controls the genetic machinery of cells and prevents abnormal growth. These tumor suppressor genes, such as p53, the retinoblastoma gene, and others, can be altered during life or, in rare instances, can be passed in mutated form to the next generation, thereby limiting the cell's capacity for control of normal growth and radically increasing the chances of tumor transformation. What has only recently been recognized is that these same mutations in suppressor genes, which place a cell at risk for a transformation event, may also radically alter the resistance of that cell to the cancer drugs commonly used today. Thus, these mutations represent a double-edged sword: on the one hand, they increase a patient's chances for developing cancer; on the other hand, they decrease the chances that the patient can be effectively treated. While this presents an extraordinarily difficult obstacle to oncologists and cancer biologists, the ingenuity of scientists and the careful observation of clinical investigators have already demonstrated that the deleterious effects of these mutations can often be circumvented through the action of other genes or through the activity of biologicals which can insert normal controls where such controls are lacking.

We have also begun to see the fruits of a long and often frustrating campaign of research aimed at understanding and harnessing the body's resistance systems to fight cancer. For example, in the last two years, clinical investigators have discovered that immune cells from normal donors can induce durable remissions of certain forms of human leukemia and virus-induced lymphomas. New approaches have been developed for isolating peptide fragments of proteins selectively expressed on tumor cells, making possible the development and clinical trials of vaccines for melanoma and certain other forms of cancer. Immunization strategies that use specialized cells bearing cancer-associated peptides to stimulate the immune system are now being introduced for other solid tumors, including prostate cancer.

Thus, if we look back on the last 25 years, considerable progress has been made and this progress has been translated into significantly improved cure rates for several lethal cancers affecting men and women. Unfortunately, however, as the complexity of science has increased and, conversely, the complexity and, often, the toxicity of modern treatments have escalated, the valley between those discovering molecular relationships in the laboratory and those who translate those discoveries into meaningful treatments has widened and deepened. There has also evolved a disturbing and inaccurate perception that the process of new discovery is a one-way street, from the laboratory to the bedside. But discoveries made by clinical scientists observing disease may have effects no less profound. For example, clinical scientists studying myeloma discovered malignant B-cells producing the homogeneous antibody molecules that started modern immunochemistry and ultimately led to the development of monoclonal antibodies. Similarly, clinical observations led to the discovery of the effects of Vitamin A derivatives on promyelocytic leukemia, opening a whole field of scientific inquiry into the signaling pathways controlling blood cell maturation. The rapid progress now being made in cancer genetics has been catalyzed by extraordinary advances in our capacity to analyze DNA at the molecular level, yet it is observations made by clinicians tracing pedigrees of families in which multiple members have been afflicted with retinoblastoma, Wilms' tumor, breast or ovarian cancer, and colon cancer that have provided a foundation making rapid advances possible. The path to discovery is multifaceted, dependent on continuous productive interactions between basic and clinical scientists both in the laboratory and at the patient's bedside.

Some scientists argue that our current knowledge of the events that lead to cancer is still too fragmentary and immature. We agree. Yet, the opportunities provided by the many discoveries that have already been made could significantly improve prospects for cure for many people who now despair. Our critical needs at this time for research in cancer are two-pronged. First, at a basic level, we need to understand better the events that lead to cancer, and to construct strategies to interfere selectively with that process. Second, we need to develop further the infrastructure for translational and clinical research necessary to translate this information into meaningful, clinically effective strategies for the diagnosis, treatment, and prevention of cancer in patients already afflicted with malignancies and those at risk for developing cancer later in life. This two-pronged approach is critical if we are to develop treatments that more selectively target cancer cells or prevent their emergence.

We have made dramatic advances against some cancers through research. For example, we have developed transplantation strategies which allow us to provide a normal blood system to any child or adult afflicted with leukemia or other lethal blood disease. Indeed, such transplants are the only curative approach and clearly a treatment of choice for several forms of leukemia. However, such treatments exact a great cost. To put this in perspective, in preparing a leukemia patient for transplant, we first attempt to eradicate the patient's cancer by administering doses of radiation equivalent to standing within 600 yards of the epicenter of the bomb at Hiroshima. On top of that, we regularly give additional high doses of chemotherapy. A large proportion of patients are cured in this way, but we still lose many and, despite having survived this brutal treatment regime, some will later relapse with their disease. If we do not resolve to develop better therapies that are more targeted to kill cancer cells and to spare normal tissues, the legacy of our work will be a mixed blessing.

Never in our history have we been more prepared through our science to develop such targeted approaches. Yet there is a real danger that, as close as we are, we will let this opportunity slip away. If we do so, future generations should judge us harshly. The only obstacle to continued progress and to the ultimate eradication of these horrific diseases is a lack of will and commitment. The ideas are there to be explored. The young creative minds are there whose commitment is no less ardent than those who have gone before. We must meet this challenge, take on this awesome task and commit our great nation to this profoundly worthy and achievable goal. We must not allow this unique time of promise and opportunity to slip away. People with cancer face death every day, accepting the challenge of this awful disease and the limited options for treatment with enormous grace. But they deserve better. Given the immensity of the cancer problem, can our nation afford to stand by while such a large portion of the citizenry is so gravely affected?

To exploit the research opportunities that exist and to build on the promising developments of just the last few years alone, the AACR believes that a real War on Cancer is warranted. Congressional support of cancer research has been considerable over the past 25 years but far too much work remains to be done—and our casualty rate is far too high. The AACR urges that funding for the NCI be at least doubled.

Why a doubling? The budget proposed for cancer research still funds too small a proportion of grants proposing important ideas and substantive programs of research—approximately half the rate as when the “War on Cancer” was declared in 1971. In addition, the budget simply does not provide the support necessary for the translational and clinical research required to move the basic discoveries made in the laboratory to persons with cancer and at risk for developing cancer.

To demonstrate what could be done in contrast to what is not being done, compare the current status of clinical research applied to pediatric malignancies, which are rare, with that applied to cancers in adults. Since the early 1970's, the treatment of children with cancer has been considered a national priority by pediatricians and many supporting groups. Pediatric oncologists, who are almost exclusively based in academic institutions, formed effective cooperative efforts which were strongly supported by the American Academy of Pediatrics. In 1996, of the 10,000 children estimated to develop cancer, over 9,500 were registered in one of the two major cooperative groups and over 90 percent were participating in the clinical research programs of these cooperative groups, either in diagnostic or therapeutic studies. As a result, advances made in cancer centers and research laboratories have been rapidly translated into national trials, testing best current treatments against what has often emerged as a better approach. Given the stepwise approach that has marked this program of clinical research and this level of national intensity, I suggest that it is perhaps not surprising that dramatic improvements in the treatment of children have been achieved. Contrast this with the treatment of adults, where less than 6

percent are registered with cooperative groups or cancer centers and only 1–2 percent are actually treated on research protocols testing the best available in current or future therapies. Given the fact that the entire history of cancer treatment has provided continuous testimony to the concept that clinical research is the best therapy, it is clear that expansion and indeed establishment of a truly comprehensive national effort is long overdue.

What I have just talked about is the current situation. However, as the Senators know, the increasing impact of managed care organizations in decisions regarding where patients are to be treated and how they are to be treated threatens to restrict further the proportion of Americans who will have the best of current and developing therapies available to them. Patient access is a critical issue. Denying a child access to an academic center because it does not participate in a managed care plan more often than not will deny a child access to a pediatric oncologist trained in modern therapy and participating in national treatment protocols, potentially reducing that child's prospects for cure to those achievable in the 1970's and 1980's, but unacceptable today.

Managed care companies have generally taken the position that they will not pay for costs associated with clinical research. Indeed, in certain plans, patients are specifically precluded from entering clinical trials. Given the existing inadequacies and the extraordinarily limited availability of current advanced protocols for the average adult American coupled with the new challenges presented by the managed care environment, very few adults are able to benefit from the opportunity to receive cutting-edge therapy, even when their lives depend on it. Further, unless more substantive funding and a better approach is developed to sustain clinical research, the possibilities for translating discoveries made in the laboratory into meaningful treatments will be eliminated.

This is the status of current patient-and disease-oriented research—the “good news.” I have previously mentioned but a few of the many discoveries which have been made recently which could permit us to identify patients at risk for cancer, to develop specific diagnostic and treatment strategies which could radically improve their prospects for the cure, and, indeed, to develop rational approaches for practicable prevention. Yet if the infrastructure for conducting diagnostic and therapeutic trials for even 6 percent of the population is under siege, how do we rationally expect these discoveries to be translated? Assuming we have a test which can identify a large proportion of patients at risk for cancer in a high risk family, we do not yet have the mechanisms or the research base needed to more broadly apply it. Furthermore, for the patient identified, new approaches must be developed so that the risk of cancer can be converted from risk of cancer death to probability of cancer cure. This progress will require a national clinical research effort more akin to what has worked for children than that which exists for adults. Without this type of development and careful evaluation, patients who undergo genetic testing will be left with a sword of Damocles hanging over their heads. The NIH must be given the wherewithal to mount a legitimate effort in translational and clinical research. Right now, NCI devotes less than 10 percent of its budget to this priority. These programs will require more than a doubling of the NCI budget to adequately address research needs.

This national effort, if it is to be effective, will also need a new generation of physician-scientists trained in scientific disciplines of translational and clinical research. Make no doubt about it, the research conducted over the last 25 years has led not only to dramatic new scientific discoveries, but has also revolutionized the way that clinical investigations are conducted. We have accrued extraordinary knowledge about how to design, implement and analyze clinical studies to make sure that patients are safeguarded and that the maximum benefit accrues both to the patient subjects as well as to the public at large. However, due to lack of resources, we have not kept pace with the development of young investigators trained in this scientific discipline. Soon, it will be too late. The proportion of trained physicians willing to initiate a career in clinical investigations is declining radically. There is little grant support for it. Academic centers can no longer provide for it.

In summary, we believe the nation's efforts in cancer research are in grave crisis. We are deeply concerned that the support of research requested in the proposed budget is grossly inadequate. At this time of national need and exceptional opportunity, research into cancer must not be viewed as a “contracting scientific enterprise.” The opposite is called for. We as scientists and clinicians have often sat back and remained silent when activism was required. The reality of cancer, however, is too monstrous, too ghastly a reaper of human life in its bloom as well as in its old age to be allowed to persist. This crisis in national will must be met. The time is now.

On behalf of the members of the American Association for Cancer Research, I would again like to thank the Committee for its continuing efforts to provide strong and appropriate support for the biomedical research needs of our country and for the opportunity to present our concerns at this most promising and yet most critical stage in our nation's quest to eradicate cancer.

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PREPARED STATEMENT OF MATT EMMENS, PRESIDENT, ASTRA MERCK

Thank you, Chairman Specter, for inviting me to submit testimony for the record in your fiscal year 1998 bill.

I want to begin by thanking you and the members of your Subcommittee for your leadership in the field of biomedical research. This Subcommittee has clearly recognized the importance of this investment, and because of your leadership, we are closer to treatments and cures for many diseases than ever before. One exciting example of the result of investment in research is peptic ulcer disease. As a result of a strong investment in medical research, a cure now exists for the millions of Americans who suffer from ulcer disease.

Peptic ulcers affect approximately five million Americans each year. It is estimated that 10 percent of the population will develop an ulcer during their lifetime. Until recently, doctors believed that lifestyle factors such as diet and stress, along with acid and pepsin, caused ulcers. Recent research has demonstrated that most ulcers develop as a result of infection with a bacteria called *Helicobacter pylori* (*H.pylori*). Studies show that *H.pylori* infection in the U.S. varies with age, ethnic group, and socioeconomic class. *H.pylori* is most common in older adults, African Americans, Hispanics, and lower socioeconomic classes.

Until recently, ulcers were treated as a chronic disease with an unknown cause. Today, because of federally-supported research on the bacteria *H.pylori*, this disease can be cured by the eradication of *H.pylori*, resulting in significant cost savings to patients and to our health care system. There are an estimated 500,000 new cases of ulcer disease and over 1,000,000 hospitalizations per year. Studies have estimated that the direct and indirect costs of ulcer disease to the nation total between \$8 billion and \$10.5 billion annually, most of which could be saved through eradicating *H.pylori*. In a 1995 report to the Senate Appropriations Committee, the National Institute of Diabetes and Digestive and Kidney Diseases quoted the Archives of Internal Medicine study, "Costs of Duodenal Ulcer Therapy with Antibiotics," by A. Sonneberg and W.F. Townsend, which found that the cost of treating *H.pylori* over 15 years was \$900 compared to \$11,000-\$18,000 for maintenance therapy and surgery. Put another way, the cost effectiveness ratio of curing peptic ulcers through *H.pylori* eradication versus maintenance therapy is 16:1 over the average 15 year span of lifetime treatment of peptic ulcers.

Unfortunately, despite this exciting medical breakthrough, most of the American public is unaware of the connection between *h.pylori* and ulcers and the potential for its eradication in as little as two weeks through the use of antibiotics and an acid-reducing mechanism. A survey conducted in 1995 by the American Digestive Health Foundation showed that nearly 90 percent of Americans with digestive disorders are totally unaware of *H.pylori*. Ninety percent of those surveyed still believed that stress causes ulcers, and 60 percent thought that poor diet was the cause.

In 1994, NIH convened a Consensus Development Conference which concluded that *H.pylori* causes most ulcers, and that most ulcers can be cost-effectively cured by eradicating *H.pylori*. In a 1995 report to Congress, NIH endorsed these findings and stated as one of its objectives for future research the enhanced communication between physicians and their patients on optimal treatments for *H.pylori*.

In fiscal year 1997, Congress asked CDC to initiate a trans-department public education campaign to foster more effective communication between consumers and health care providers on *H.pylori* and its link to ulcer disease. I am pleased that CDC has allocated \$4 million in fiscal year 1997 for an *H.pylori* public education campaign. CDC has issued a draft education campaign which has three objectives: educate the public about the role of *H.pylori* in peptic ulcer disease, establish a continuing education campaign to educate health care providers about the role of *H.pylori* in peptic ulcer disease, and continue research to gather additional information about *H.pylori*. CDC has also convened a meeting with representatives of academia, national associations, pharmaceutical companies, and federal agencies to: review existing educational campaigns; review remaining gaps in public and provider knowledge and how to assess them; discuss the new campaign's implementation and evaluation; discuss the research needed to determine the appropriate educational messages.

For fiscal year 1998, an additional \$4 million will be necessary to execute the full range of communications activities required. As Congress well understands from the government's experience in smoking cessation, AIDS prevention, childhood immunization, and screening for heart disease, breast cancer and many other public health problems, breaking through to a level of public conscienceness on the nation's health priorities is always a daunting challenge. To put this in perspective, it is telling to highlight the cost of a few successful public education campaigns led by the NIH: National Cholesterol Education Program (\$5 million); National High Blood Pressure Education Program (\$27 million); National Cancer Institute Information Services Program (\$30 million). Certainly, the potential for improving the quality of life of thousands of Americans and of producing substantial cost savings to our healthcare system warrants additional funding for this important H.pylori public education campaign to ensure that it is comprehensive and effective.

Thank you, Mr. Chairman, for the opportunity to submit testimony on this important subject. I look forward to continuing to work with you and the members of your Subcommittee to educate the public and physicians about H.pylori and its link to ulcer disease.

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PREPARED STATEMENT OF ROBERT WILSON, THE WILSON FOUNDATION

Thank you, Chairman Specter, and members of the Subcommittee for the opportunity to submit testimony on the need for a continued Federal commitment to Neurofibromatosis research and to highlight the exciting advances that have been made in recent years as a result of your Committee's support for NF.

I am Robert Wilson, President of the Wilson Foundation, a private charitable foundation. My 10 year old son, Michael, suffers from Neurofibromatosis. I am here today on behalf of Michael, the 100,000 other Americans who suffer from NF, as well as the tens of millions of Americans who will also benefit from advances in NF research.

NF, incorrectly but commonly known as elephant man disease, involves the uncontrolled growth of tumors along the nervous system which can result in terrible disfigurement, deformity, deafness, blindness, brain tumors, cancer, and death. It is the most common neurological disorder caused by a single gene and affects three times as many people as other disorders such as Cystic Fibrosis or Muscular Dystrophy. While not all NF patients suffer from the most severe symptoms, all live their lives with the uncertainty of knowing whether they too will be severely affected because NF is a highly variable and progressive disorder.

With a relatively small investment, NF has become one of the great success stories of the current revolution in molecular genetics. Researchers have already determined that NF is closely linked to many of the most common forms of human cancer, including leukemia, colon cancer, and melanoma, because NF like cancer involves tumor suppressor genes. Dr. Samuel Broder, former Director of the National Cancer Institute, stated that NF was at the "cutting edge" of cancer research. Accordingly, advances in NF research bolsters hope for a treatment not only for NF but also for cancer, brain tumors, and learning disabilities which would benefit over 100 million Americans in this generation alone.

This cancer connection was at the heart of a major conference on NF held in 1995 at Cold Spring Harbor Laboratory in New York, one of the world's leading cancer and neuroscience research laboratories headed by Dr. James Watson, the co-discoverer of DNA. The Conference brought together basic researchers, clinicians, biotech and pharmaceutical companies from the United States, Canada, and Australia specifically to find a treatment and a cure for NF.

The Cold Spring Harbor Conference has been hailed throughout the research community as a turning point for NF. After the Conference, more than 20 leading NF researchers worked for over one year preparing a detailed blueprint for finding a treatment for NF. This document has been circulated throughout the research community and NIH, and has been well received.

The future promise of NF research is based on past success. Let me highlight the enormous advances in NF research that have occurred since 1990:

- The discovery of the NF1 and NF2 genes and gene products;
- Determining that NF is closely linked to many of the most common forms of human cancer, brain tumors, and learning disabilities which affect over 100 million Americans;
- Determining the function of the NF genes and gene products;
- Developing animal models for NF1 and NF2;
- Developing a diagnostic blood test and pre-natal testing for NF;

- Commencing a national trial drug treatment program for NF patients which can serve as the infrastructure for future clinical trials;
- Determining the connection between the phenotype/genotype in NF; and,
- Substantially increasing the number of NF researchers.

In addition, two breakthrough discoveries relating NF to learning disabilities have recently occurred. Dr. Alcino Silva, a microbiologist at Cold Spring Harbor Laboratory, has completed a study of mice and has concluded that a lack of neurofibromin, the protein expressed by the normal NF1 gene, may be at the root of learning disabilities. He has also discovered that the tumors and learning disabilities manifested in NF patients may originate from the same molecular origin. This discovery is a significant breakthrough because it could open a new path for research on learning disabilities and cancer. In a related development, researchers at Cold Spring Harbor Laboratory, in conjunction with researchers at Massachusetts General Hospital, have cloned the NF1 gene and discovered the NF1 protein neurofibromin in the fruitfly. The researchers have identified a new function of the neurofibromin which impacts on the pathway related to learning disabilities. This is a significant breakthrough because it opens the possibilities for new pharmaceutical treatments for NF in addition to those already under development related to NF tumor suppressor functions.

After breathtaking discoveries during the past six years, NF now stands on the threshold of a treatment. Dr. Michael Wigler of Cold Spring Harbor Laboratory and one of the world's leading researchers of RAS, a critical protein implicated in both cancer and NF, has stated that "there are enough tangible tools already in place in NF research to deliver the knockout blow" and concluded that "finding a treatment and cure for NF would be the medical equivalent of the Apollo Program." And Dr. Bruce Korf of Harvard Medical School, has recently predicted that clinical trials for therapies for NF are likely to occur in the next few years.

The enormous promise of NF research—and its potential benefits for many common cancers, brain tumors and learning disabilities—have gained increased recognition from Congress and the National Institutes of Health. Last year, your Subcommittee included language in your fiscal year 1997 Report that recognized the enormous promise of NIH-funded NF research and urged the National Cancer Institute and the National Institute of Neurological Disorders and Stroke to pursue an aggressive program in basic and clinical research in NF. Over the last six years, the NIH has doubled its NF portfolio, from approximately \$6 million to \$12 million annually, with the bulk of the research funded by NCI and NINDS.

For Fiscal 1998, we seek this Subcommittee's continued support in funding the research essential to finding a treatment and cure for NF. The specific areas of opportunity where NF research dollars should be focused are:

- Developing drug treatment therapies for NF1 and NF2;
- Further determining the function of the NF genes and gene products;
- Further determining the connection between NF and cancer, tumors and learning disabilities;
- Further development of the NF animal models; and,
- Increasing the number of NF researchers, clinics and research centers.

These objectives should serve as the basis of a four-part NF research agenda for fiscal year 1998. In furtherance of this plan, we request that Congress:

- Increase appropriations for NIH. I recognize the difficult funding decisions faced by your Subcommittee in these tight budgetary times. However, I encourage you to support NIH's professional judgement budget and the recommendation of the Ad Hoc Group for Biomedical Research which advocates a 9 percent increase for NIH in fiscal year 1998. This increase will enable all scientists to capitalize on many of the promising research opportunities that exist in basic and clinical research and help our nation maintain its world-renowned leadership in biomedical research;
- Increase appropriations for NF research. Given the track record of success in NF research with modest funding and the implications for finding a treatment and cure for so many other diseases affecting over 100 million Americans, research into NF is extremely cost effective. We therefore request a substantial increase above the current level of spending for NF research;
- Continue cooperation and coordination between NINDS and NCI through targeted NF research programs. The Committee should encourage NCI and NINDS to continue to coordinate their efforts in expanding their NF research portfolios in fiscal year 1998 through the use of: requests for applications, as appropriate; program announcements; the national cooperative drug discovery group program; and small business innovation research grants; and,
- Target funding for the implementation of the clinical research initiatives generated at the Cold Springs Harbor Conference. As developed by Cold Spring

Harbor Laboratory at its NF conference in October 1995, NF should become the model for scientist-initiated proposals to fund clinical treatment research for specific diseases which offer the potential for significant advances in broader areas, like tumor suppressor genes. The Committee should encourage NIH to explore this new and exciting avenue in promoting dramatic advances in select research areas.

In closing, Mr. Chairman, with only a small investment, dramatic advances in NF research have been made with far reaching implications for many other diseases. Many of the world's leading NF researchers, such as: Dr. Frances Collins, Director of the National Human Genome Project; Dr. Bruce Korf of Harvard Medical School; Dr. Vincent Ricardi of the NF Institute in Los Angeles; Dr. David Gutmann of Washington University School of Medicine; and Dr. Michael Wigler of Cold Spring Harbor Laboratory, among others, now believe with an increased investment and a research agenda focused on all aspects of the NF research portfolio, from basic research in the labs to drug development, a treatment and cure for NF can be found by the turn of the century. But we need your continued support.

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PREPARED STATEMENT OF WILLIAM R. BRODY, PRESIDENT, JOHNS HOPKINS  
UNIVERSITY

I am pleased, on behalf of the Johns Hopkins University, to submit a statement for the Committee's consideration as it evaluates funding priorities for fiscal year 1998.

Although Johns Hopkins is a multi-faceted university offering education and research in a broad variety of areas, we probably are best known for the high quality of our academic health center. It is there that we carry out the mission of an academic health center with a strong commitment to patient care, education and research. Academic health centers are a unique national resource responsible for discovering and translating research progress into clinical practice. In fact, the majority of major advances which have impacted human health in this century would not have been possible without the specific contribution of academic medical centers. Without the important role of these centers in bringing together diverse scientists to examine complex medical problems and pushing the frontiers of science, medicine would remain in dark ages.

Before we address the tremendous opportunities which exist in medical research, we must recognize the leadership of this Committee in garnering Congressional support for medical research. We recognize the grave fiscal constraints that this Congress is facing. We also recognize that the basic research supported through the National Institutes of Health serves as the economic engine for science and medicine in this country. Therefore, we believe that medical research supported by the NIH is a sound investment in our future—for the future of our citizens as well as our economy.

To that end, we support the recent proposals in Congress to double the budget of the NIH. Specifically, we support HR 83 and S.R. 15 which seek to double the NIH budget over the next five years. This would require a 15 percent increase in fiscal year 1998. We are pleased that Congress has seen the beneficial contributions of the NIH to our citizens and the economy and believes that the NIH should remain a priority as we move into the next Century. The exciting opportunities in medical research are greater than ever before and to reduce our investment now will diminish our capacity to respond to real and growing threats to the health and well being of our citizens, such as cancer, heart disease, Alzheimer's, and neurological disorders.

*Economic Aspects of Medical Research and Innovation*

We believe that a resource commitment of this level is a wise and sound investment. The United States spends less than 2 percent of health costs on research to prevent, detect, treat and cure the diseases which plague Americans. This is astounding when you look at the research and development investment that corporations must make to stay competitive in the marketplace. As an example, the pharmaceutical industry invests almost 22 percent of its annual U.S. sale revenues to research and development. A doubling of the NIH budget is vital in charting a course to make the necessary investment in the catastrophic, chronic and costly diseases that know no social or economic boundaries. Only then will we be able to advance the scientific frontiers and realize the full potential of our past medical research investment.

The Office of Technology Assessment has noted in its most recent report that the U.S. has led the world in the commercial development of biotechnology because of

its strong research base—most notably the biological sciences. Biotechnology is not an “industry,” rather it is a set of biological techniques, developed through decades of research in academic medical centers, that are now being applied to research and product development in the industrial sector. It is interesting to point out that dedicated biotechnology companies are almost exclusively a U.S. phenomena. The U.S. Biotechnology and medical device industry have not only provided rapid economic growth, they are significant net exporters of products to foreign countries.

Because of its importance to U.S. competitiveness in an increasingly global economy, medical research is seen as one of the keys to U.S. competitiveness in the years ahead. However, there are several signs that our world leadership in science and engineering is eroding:

- Between 1971 and 1991 real growth in U.S. civilian research was less than in five of our primary competitors for world markets, including Germany and Japan;
- In 1986, foreign competitors (Japan and Germany) began investing a larger percentage of their GNP into research and development than did the U.S.;
- U.S. non-defence R&D is now quite low—1.9 percent of the GNP—as compared to important economic rivals Japan (2.8 percent) and Germany (2.4 percent); and,
- Between 1961 and 1980, the U.S. introduced 23.6 percent of all new technology products, Japan introduced 10.3 percent. In 1983, Japan introduced 38.4 percent of all new biotechnology products, while the U.S. only introduced 12.5 percent.

#### *Human Face of Disease*

The human contributions made by our medical research enterprise are enormous. Treatments for people with chronic diseases have stemmed from medical research and innovation. People with life threatening and chronic diseases look to medical research and innovation for the promise and hope of a cure. Medical research and innovation have prevailed to improve the quality of life for millions of us, but the challenge remains to find answers for millions more who face disease and disabilities.

Unfortunately, every day Americans suffer or die from cancer, heart disease, strokes, stomach ulcers, Alzheimer’s disease, Parkinson’s disease, cystic fibrosis, neurodegenerative disorders and HIV infection. For millions of Americans, time is running out.

#### *Comprehensive Support of the Costs of Research*

One important factor in realizing our full research potential is to provide state-of-the-art research facilities where novel and cutting edge research can be fostered. All research costs—research, administrative, plant operations and facilities costs—are real and legitimate costs of NIH-supported research. Continued support for the full spectrum of costs of research is vital to maintain the stability of medical research infrastructure and to enable our research enterprise to flourish and compete in the global marketplace.

We are aware that this Committee has been interested in research costs and the federal policies that govern them. The administration and management of indirect cost reimbursement policies is regulated government-wide by the Office of Management and Budget and implemented by the federal agencies. This process has worked well for several decades. The basis for regulatory oversight of the costs of research is based on the recognition that arbitrary or temporary actions undermine the financial stability of the country’s research capabilities and are detrimental to technology development. Further, it is believed that government-wide uniform policies are the best approach. Administrative and facilities costs are expenditures that have been made by the universities which the federal government has already agreed to reimburse through regulatory guidelines and formal agreements entered into with universities. Any alteration of these agreements must be very carefully considered to assure that any changes do not impact negatively on the integrity of our research infrastructure.

Over the past six years, significant changes have been made in federal policies regarding reimbursement for these costs. It has been estimated that these changes save over \$100 million annually. In addition, the Office of Management and Budget is expected to announce additional changes in cost accounting standards and revisions to A-21 Circular within the next several months. These changes will further strengthen the regulatory oversight of the costs associated with the conduct of research.



We look forward to continuing to work with this Committee in the important issues related to our medical research enterprise. Thank you for the opportunity to present a statement for your consideration.

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PREPARED STATEMENT OF JOSEPH W. KEMNITZ, PH.D., INTERIM DIRECTOR,  
WISCONSIN REGIONAL PRIMATE RESEARCH CENTER

Chairman Porter and Members of the Subcommittee: I am Dr. Joseph Kemnitz, Interim Director of the Wisconsin Regional Primate Research Center and Senior Scientist in the Department of Medicine at the University of Wisconsin School of Medicine. I am here to represent the seven Regional Primate Research Centers which are located at distinguished universities in the states of California, Georgia, Louisiana, Massachusetts, Oregon, Washington and Wisconsin. They receive support as part of the Comparative Medicine Program of the National Center for Research Resources of the National Institutes of Health (NCRR-NIH). I am proud to have served the Wisconsin Regional Primate Research Center for 20 years, and I welcome the opportunity to come before this Committee and talk about the accomplishments and current needs of the primate centers.

Congress acted with great wisdom and foresight in 1960 to establish the national Primate Center Program by appropriating funds to build the seven centers we have today. In the nearly forty years since their establishment, it is increasingly clear that this was an excellent investment. These centers provide specialized and unique scientific capabilities not available through any other program within the Department of Health and Human Services. For a variety of reasons, including the ever-increasing complexity and sophistication of research questions and methodologies, the Primate Center Program is even more important today than when the centers were established. Well over 1,000 investigators depend on the Regional Primate Research Centers to conduct research supported by the National Institutes of Health as well as other governmental and private-sector sources. These investigators are not only those based at the primate centers, but also include regional, national and international scientists who rely on resources and expertise at primate centers to conduct their research.

The importance of nonhuman primates to progress in biomedical research cannot be overestimated. These animals are the closest surrogates for our own species, sharing more than 90 percent of the genetic makeup with humans. This close genetic similarity results in marked similarities in anatomy, physiology and behavior that make these animals outstanding models, in some cases the only appropriate choice, for understanding human health and disease processes. Nonhuman primates are often the vital link between basic research and human application. Examples of significant accomplishments resulting from primate research abound in the fields of neuroscience, reproduction and developmental biology, and infectious diseases, among others.

Recent advances at Regional Primate Research Centers include increased understanding of the pathobiology of AIDS and the development of vaccines for protection against the disease. Indeed, the most prevalent model of AIDS, simian immunodeficiency virus, was established at Primate Centers. Our Center and others are now also engaged in research to prevent the AIDS virus from being transmitted from HIV-infected mothers to their babies.

Other advances include better understanding of fertilization and early prenatal development, another example of a research area where the nonhuman primate offers unique benefits because of similarities to humans and differences from other laboratory species. Nonhuman primate research is also leading to enhanced knowledge of the genetic basis of disease and immunity, of development of obesity and its complications such as diabetes and hypertension, and of specific women's health issues such as endometriosis, polycystic ovary syndrome, and of changes during and after menopause.

Very significant advances have also been made in the area of primate neuroscience. As Congress recognized in declaring this the "Decade of the Brain", neuroscience is now a highly productive and exciting research frontier, fueled by rapidly developing technologies. Primate center research has made significant strides in elucidating the neural mechanisms controlling voluntary movement, emotional behavior, and higher cognitive brain functions.

Older people represent the fastest growing segment of our population. People are living longer and there is a need to improve the quality of life of older individuals. Efforts are underway at our Primate Center and elsewhere to uncover the basic processes of aging in primates and to develop new approaches to postpone the development of age-related infirmities, such as osteoporosis, loss of muscle mass, im-

paired vision and neurological problems. We have promising preliminary evidence to suggest that diet can reduce the incidence, delay the onset and lessen the severity of some metabolic diseases associated with aging. New hypotheses regarding the mechanism of these beneficial effects of reduced caloric intake are now being tested.

In spite of their productivity the infrastructure at the Regional Primate Research Centers have had to cope with static base operating budgets. At one time the support for primate centers covered operating costs and research projects conducted at the centers. Today those base grants cover only a portion of the operating expenses and little or none of the research costs. The research projects themselves are now primarily funded through a rigorous system of peer review at NIH. The sum of these competitively awarded grants exceeds the size of the base grant by more than five-fold at some centers and requires resources exceeding those available in terms of animals, laboratories and support functions. We need additional operating funds in order to meet expeditiously the operational needs of the biomedical research community now.

The use of primates in research represents less than 1 percent of laboratory animal use overall, but the demand for primate research is increasing because of the unique insights these animals can provide to human health issues. It is noteworthy that nearly half of academic primate research is conducted at the Regional Primate Research Centers, where there is multidisciplinary focus on questions of basic biological and medical interest. Greater numbers of external investigators are requesting access to primate center resources for projects that require the nonhuman primate model. The increasing concentration of primate research at the Primate Centers reflects the need for special facilities for these complex animals and special expertise for their husbandry, veterinary care and psychological well-being that are available at these sites. The centers are cost-effective because of their already established expertise and also because of economies of scale. It is very important that the primate centers continue to provide continuity of research context in which to address new questions and challenges as they arise. Life-long care of these animals in a laboratory setting has also greatly extended their life-expectancy enabling initiatives in the study of aging.

The centers attempt to maintain self-sustaining colonies of the most commonly utilized species (for example, rhesus monkeys), which greatly reduces the need for removing animals from their natural environments and also provides better research subjects. For example, offspring of generations of laboratory-raised monkeys have completely known histories and pedigrees, which are essential for better understanding of the genetic basis of disease susceptibility.

The Regional Primate Research Centers are nearly 40 years old and some renovation and replacement of facilities is becoming urgent, while expanded facilities are also required to catalyze the scientific opportunities into the next century. This is especially necessary for AIDS research and investigation of other infectious diseases which require special biocontainment capability. NCRP obtained construction authority from Congress in 1993 for the first time since 1969, and we are grateful for this support during the past few years. We are very concerned, however, that the President's budget request for next year's construction funding to NCRP is only \$4M, which is 20 percent of the award for last year. We request that every effort be made to restore the NCRP budget allocation to at least last year's level and that a portion of this be specifically targeted for the Regional Primate Research Centers, so that we can maintain state-of-the-art, competitive facilities and equipment.

In summary, the seven Regional Primate Research Centers have made substantial contributions in the realm of biomedical research and they will continue to do so. In order to accelerate progress, we ask that the base operating budgets for the primate centers be increased and that additional funding be allocated to renovation and new construction at these centers. Mr. Chairman, that concludes my testimony and I would be happy to answer any of your questions.

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PREPARED STATEMENT OF WARREN GREENBERG, PH.D., PROFESSOR OF HEALTH ECONOMICS AND OF HEALTH SCIENCES, DEPARTMENT OF HEALTH SERVICES MANAGEMENT AND POLICY, GEORGE WASHINGTON UNIVERSITY; AND CHAIRPERSON, COMMITTEE ON LOBBYING/LEGISLATION, MENDED HEARTS, INC.

My name is Warren Greenberg. I am a professor of health economics and of health care sciences at The George Washington University. I am married and have a 22-year-old daughter.

I advocate an increased appropriation for the National Heart, Lung, and Blood Institute. I am a victim of heart disease and as a beneficiary of the efforts of medical researchers to overcome this disease. I might also add that I am a member of Mend-

ed Hearts, Inc., a support group of 24,000 members throughout the United States who have heart disease, and I have been appointed lobbying and legislation chairperson of that group—a volunteer position.

I am 54 years old. I was born with aortic stenosis, a narrowing of the heart valve. Throughout my entire life I have lived with heart disease, often incredibly severe.

When I was in my early teens, my physicians did not allow me to play high-school inter-mural sports, although I was a fine young athlete. At the age of eighteen I was told not to play ball under any circumstances. In my early 20s I was told to climb no more than two flights of stairs. By my early and mid-thirties I began to climb steps more and more slowly, often pausing to rest. I never carried an attaché case home from work. It was too heavy. I would often balance a large book on my hips, rather than carrying it outright, in order to blunt the weight. I would walk two or three blocks on a level street to avoid going up three or four steps at the end of particular blocks. I could barely lift my newborn child; I could not help my wife take in the grocery bags.

On May 7, 1982, at the age of 39, I had open-heart surgery at the Cleveland Clinic to replace my diseased valve with the valve of a pig. After my six-week recuperative period I was amazed to find that not only was I able to walk, but was also able to play tennis, to jog, and to exercise. I was able to live a normal life.

By August 1988, however, my new valve had failed. On August 31, I again had cardiac surgery at the Cleveland Clinic to replace the failed pig valve with an artificial plastic valve, known as the St. Jude's valve. I am again able to live a relatively normal, very productive life. And I am deeply thankful for it.

I still take a blood-thinning medicine, coumadin, which helps prevent clots on my new valve. At the same time, because of the medicine, I must be cognizant and careful of excessive bleeding. In 1983 I contracted bacterial endocarditis, an infection of the heart valve, from dental surgery which kept me in the hospital for six weeks. Whenever I have dental work, I now get intravenous penicillin to protect me against such infections. I realize that my valve, as a mechanical device, may fail at any time in the future.

For nearly fifteen years, thanks to the fruits of medical research, I have been able to travel abroad at least once a year, to jog in the park, to be a productive author of many scholarly articles and a number of books on the health care economy. I have been quoted often on my views of the U.S. health care system and have made many television appearances. If it were not for the advances in research leading to improved techniques in open-heart surgery, I would not have seen my fortieth birthday. I would not be able to look forward to a life of many rewards and enjoyments.

As an economist, I observe continually the link between monetary resources and the development of innovation and technology. Health care research, and cardiovascular research in particular, is no exception. I also understand as an economist that there are always competing uses for appropriated monies. However, cardiovascular diseases last year killed more than 954,000 Americans, more than 155,000 of whom are under age 65. Despite advances in medical research, these diseases remain the number one killer in the United States and a leading cause of disability. From my personal perspective and for those in Mended Hearts Inc. and others in the United States who have heart disease or will get it in their lifetime, consistent with congressional resolutions for the NIH, I ask for a doubling of NHLBI budget by the year 2002. To reach this funding goal, I advocate a fiscal year 1998 appropriation of \$1.65 billion for the NHLBI to help reduce further the incidence and degree of heart disease.

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PREPARED STATEMENT OF PATRICK WATERS, PRESIDENT, MONTGOMERY COUNTY,  
STROKE CLUB, INC.

My name is Patrick Waters and I am a left hemiplegic stroke survivor of seven years. I am currently the President of the Montgomery County, Maryland Stroke Club. The stroke club is a non-profit organization for stroke survivors and their families and numbers about 400 as well as about 100 professionals.

Stroke can happen to anyone and stroke is the third leading cause of death in the United States and strikes about 500,000 Americans each year, killing more than 154,000. Think about this, anyone of your loved ones could be struck down by a stroke. It happened to three of our United States presidents. I pray that none of you or yours will ever know this terrible suffering.

My stroke occurred in February 1989. I had taken an early retirement and I planned to begin a second career, travel and manage my investment portfolio. My last two of four children were nearly finished in college and everything seemed to

be going as planned. My stroke was due to an AVM, which as far as I can understand, is a birthmark in the brain.

My stroke was devastating enough, but was compounded by a severe fall in the hospital that involved a second hemorrhage. Soon after my surgery, I began to have severe burning pain on my entire paralyzed side. It was described as post stroke syndrome by some, as supersensitivity by others and also as thalamic pain since my AVM was in the thalamus. The National Institutes of Health was the only place where I was able to get literature on this condition.

The burning pain I suffer is encountered when I walk on rugs. Shock waves travel up my weak side. I feel this pain whenever anyone or anything touches my left side. Even my own arm assaults me when it rests on my lap or dangles at my side. This pain is extremely exhausting. In recent years I have heard from other stroke survivors who say they too suffer this pain. At this time we are mostly told to learn to live with it.

The long arduous task of physical therapy so I could walk again was lengthy, frustrating and extremely expensive. But, at least I had hope. With this pain I feel despair for myself and others because until help is found, we suffer.

Please allocate \$93 million for National Institute of Neurological Disorders and Stroke-supported stroke research and prevention in fiscal year 1998 so those in pain may find relief, and, if not for us, for those who may be struck in the years to come. Being associated with a stroke club you see many young people whose futures are altered forever by stroke and most have no future. Please give them hope through this funding.

As a retired electrical engineer on the space program, I know this country is capable of achieving the near impossible. I believe this country can and will be the first to prevent strokes and possibly even undue the damage they have wreaked.

Thank you for allowing me to bare my soul.

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#### PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

##### INTRODUCTION

The American College of Cardiology is a 23,000-member professional medical society and educational institution whose mission is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and guidelines and the formulation of health policy.

The Subcommittee's support for the National Heart, Lung, and Blood Institute (NHLBI)—the institute charged with enhancing the prevention, diagnosis, and treatment of cardiovascular disease—is vitally important to the health of millions of Americans. Each day about 2,600 people die from cardiovascular disease. This is attributable to the fact that more than 57 million Americans—one in five—have some form of cardiovascular disease. Beyond better public awareness, reducing the number of cardiovascular-related deaths is greatly dependent upon research sponsored by the NHLBI.

The NHLBI has been the impetus for miraculous advances in the treatment and prevention of cardiovascular disease. This Subcommittee's acknowledgment of the need for consistent funding levels for the Institute has made possible many of the major health accomplishments in the past decade. As we approach the next century, our nation's dedication toward cardiovascular research will not only lead to improved technology and effective treatments, but toward an increasing knowledge of prevention. Now more than ever it is important that the Subcommittee renew its long-standing support for the NHLBI.

##### MEDICAL RESEARCH FUNDING AND COST SAVINGS

Throughout the past decade, funding levels for the NHLBI have remained consistent. There is concern, however, about future funding for the National Institutes of Health (NIH) and NHLBI. Physicians, who are operating in an era of tightening health care resources and within an ever-changing marketplace, can appreciate the fiscal constraints placed on the federal budget. Nevertheless, medical research must be viewed as an investment that yields substantial returns such as saved lives, increased productivity, and wiser health care expenditures.

The total economic cost of heart disease in 1997 was \$167 billion, of which nearly \$92 billion were direct costs (costs of providers, hospital and nursing home services, medications, and home health). The remaining \$75 billion were costs associated with lost productivity. In 1995, Medicare paid \$29 billion for the treatment of heart disease. That is more than expenditures for arthritis, cancer, kidney and liver dis-

eases combined. Yet, the fiscal year 1997 appropriation dedicated to heart disease was only \$902.8 million.

Some people will argue that the results of medical research—improved technology and innovation—drive up the cost of care. Yet, outcomes studies show that modern treatments for heart disease lead to decreased costs, fewer hospitalizations and better functional status. The recent release of a study by researchers at Duke University shows that fewer elderly people were classified as disabled in 1994 (21.3 percent) than in 1982 (24.9 percent), supporting the view that medical research is not only prolonging life, but improving its quality as well. The drop in the prevalence of disability among the elderly (8.3 million in 1982 versus 7.1 million in 1994) is evidence that medical research can be cost effective and has the potential to produce Medicare and Medicaid savings.

Reduced rates of cardiovascular disease, and thus cost savings to all payers, will not happen without increased prevention efforts and better methods for early detection and treatment. We now know, thanks to medical research, that heart disease is linked definitively to hypertension, high cholesterol, diabetes, physical inactivity, and obesity. NHLBI must be given the financial support to take this knowledge one step further and find better ways to manage these risk factors. The following is a sample of NHLBI-sponsored initiatives that are a step in that direction:

—New findings by NHLBI-funded researchers show that 91 percent of congestive heart failure cases were preceded by hypertension. Congestive heart failure affects 4.8 million Americans and is the leading cause of hospitalization among those 65 years of age and older. Therefore, effective hypertensive drug breakthroughs are important. The NHLBI is sponsoring clinical trials to determine if newer antihypertensive treatments such as angiotensin converting enzyme (ACE) inhibitors, are effective in reducing the incidence of congestive heart failure and nonfatal myocardial infarction in high-risk hypertensive patients. Just last week, results of an NHLBI-sponsored clinical trial, “Dietary Approaches to Stop Hypertension,” provide new dietary guidelines to help prevent hypertension and possibly reduce the need for antihypertensive medication and other accompanying long-term costs.

—The results of a NHLBI-sponsored study, “Pathobiological Determinants of Atherosclerosis in Youth,” found for the first time ever that three risk factors present early in life—high density lipoprotein (HDL), low density lipoprotein (LDL), and smoking—affect the progression of atherosclerosis at a later age. The study shows that risk factors important in adulthood are also crucial in childhood, and that healthful habits and appropriate pharmacologic interventions should begin as early as possible.

These accomplishments are encouraging. But the simple fact remains that cardiovascular disease is still the number one killer of men and women in the United States, accounting for 42 percent of all deaths. Even with the modernization of heart disease treatments, death due to heart disease is not a problem that is likely to disappear any time soon especially as the baby boom generation ages. It is for this reason that the American College of Cardiology supports increased funding for NHLBI in fiscal year 1998.

The President’s fiscal year 1998 budget proposal would fund NHLBI at \$1.467 billion, a 2.4 percent increase over fiscal year 1997. The majority of funds allocated to the NHLBI are committed to projects that extend over several years. To maintain these commitments and support the increasing sophistication of medical research, the NHLBI requires a steady level of funding from year to year. In addition, the NHLBI needs an increase in funding to allow it to pursue new and promising endeavors of research, to recruit and retain talented investigators, and to support investigator-initiated research across the country.

The College supports the efforts of several members of Congress who are advocating an overall NIH funding increase beyond the president’s proposed 2.6 percent, and we believe the time has come when this country should commit to explore a more secure funding source for medical research. One potential solution is S. 441, the “National Fund for Health Research Act,” sponsored by Sens. Tom Harkin, D-IA, and Arlen Specter, R-PA. The bipartisan plan would provide the NIH and NHLBI with expanded and more stable funding support for health research beyond the amount appropriated annually.

#### OTHER AREAS OF RESEARCH

Other areas of important research and new initiatives by the NHLBI include the following:

*Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), (initiated in 1993).*—This initiative will determine whether the com-

bined incidence of coronary heart disease and nonfatal myocardial infarction (heart attack) differs when high-risk hypertensive patients are treated by diuretic-based treatments versus antihypertensive treatments (ACE inhibitor, calcium channel blocker, or alpha blocker);

*Coronary Revascularization.*—Each year more than 600,000 coronary revascularizations (coronary artery bypass, angioplasty, and other procedures which restore blood flow to blocked or narrowed arteries) are performed in the United States. Although these interventions are highly successful, revascularization must be re-examined from the following standpoints: cost effectiveness of different types of procedures; race-specific effects of various procedures; optimal management for patients with evidence of silent ischemia and/or stable angina; and support of registries which will allow researchers to follow the outcomes of patients who undergo revascularization using new devices;

*Clinical Trials in Cardiovascular Disease and Diabetes.*—More than 80 percent of people with diabetes die from some form of heart or blood vessel disease. The NHLBI is undertaking activities to explore which cardiovascular interventions are best for diabetics. A recent Institute-sponsored clinical trial, “Bypass Angioplasty Revascularization Intervention,” revealed that diabetics with multi-vessel coronary heart disease have better outcomes when their revascularization is performed through surgical intervention rather than through balloon angioplasty. More trials are needed to answer questions relating to blood sugar control and its effects on cardiovascular outcomes;

*Gene Transfer Principles for Heart, Lung, and Blood Diseases.*—New research efforts are needed to develop the basic tasks involved in gene transfer. In fiscal year 1997, the NHLBI will support a program to provide the basic science necessary for gene transfer technology and its application to heart, lung and blood diseases. Gene transfer technologies hold particular promise for coronary artery disease, as researchers hope that it will ultimately result in the ability to stimulate the heart to grow blood vessels to carry blood around obstructed arteries; and,

*Intervention Studies in Children.*—Consistent with its longstanding interest in promoting pediatric research, the NHLBI is exploring the opportunity to conduct randomized clinical trials (RCTs) on children as they pertain to cardiovascular disease. The majority of therapeutics developed and used daily for children have never been subjected to RCTs to document efficacy and safety.

#### *Genetics and Molecular Medicine*

The United States is on the edge of entering a new era in genetic medicine, which may hold the key to important cardiovascular treatment and prevention methods. Just this year the locus for a gene responsible for inherited atrial fibrillation, the most common cause of irregular heart beats, was discovered by a group of researchers sponsored in part by the NHLBI. It is hoped this discovery will lead to new ways to diagnose and treat people with atrial fibrillation, a condition which can lead to stroke. Other Institute-sponsored projects include exploring the relationship between genes and nutrients in the identification, treatment, and repair of congenital heart defects, and investigating and mapping the genes responsible for hypertension. Researchers also hope to discover, through genetic research, why patients with hypertension develop varying, if any, pathophysiological disease states (heart failure, kidney failure, stroke). Because of the complexity of genetic research, a significant commitment of resources is needed in this area.

#### *Education and Prevention*

Education and prevention is fundamental to the Institute’s mission. Funding for the Institute allows the medical community and the American people to capitalize on the advances in the treatment, diagnosis, and prevention of heart disease. The Institute’s public education programs—the National High Blood Pressure Education Program, the National Cholesterol Education Program and the National Heart Attack Alert Program—provide information directly to patients, families and health professionals. In keeping with this theme of rapid dissemination and new technology, educational information for both health care providers and the public are continuously updated on NHLBI’s web site.

#### *Women and Minorities*

Heart attack is the single largest killer of women. The NHLBI has initiated several programs devoted exclusively to women. These programs include studies to improve the diagnostic reliability of cardiovascular testing in the evaluation of ischemic heart disease, and trials to assess hormone replacement therapy and/or antioxidant treatments to inhibit and treat atherosclerosis. Several clinical trials are also underway examining the use of estrogen to prevent heart disease.

Black men and women continue to suffer disproportionately from cardiovascular disease and many of its related causes, particularly hypertension. The NHLBI continues to emphasize the importance of including minorities in clinical research and trials. Currently, in two NHLBI Specialized Centers of Research, researchers are studying the issues surrounding the expression of heart disease in blacks. Another program, initiated in 1988 by the NHLBI, is entering its third phase of studying cardiovascular disease risk in American Indians.

#### *Nutrition*

The NHLBI continues to make considerable progress in understanding the role of nutrition in cardiovascular disease and has increased its involvement in this important area. In 1991, the NHLBI Obesity Education Initiative was established to consider the identification, evaluation and treatment of obesity in adults, particularly those with other risk factors for cardiovascular disease. As mentioned previously, the NHLBI has just released new dietary guidelines for lowering blood pressure. The Institute continues to conduct clinical trials to assess the effectiveness of school and home-based interventions to prevent obesity and reduce other cardiovascular disease risks in children. There is also a need for clinical trials to determine whether micronutrient supplements, such as magnesium, folic acid and other B vitamins, can provide cardiovascular benefit.

#### CLOSING REMARKS

The United States must maintain its status as the world leader in developing new cardiovascular technology and procedures, especially as science enters the exploding era of gene therapy for many cardiovascular conditions. With continued investment in NHLBI funding, researchers will be able to forge ahead into new medical frontiers, allowing cardiovascular specialists to perform procedures and prescribe treatments that were once unimaginable. That vision is one that benefits every segment of the U.S. population and, in fact, all people.

In summary, the American College of Cardiology would like to stress the critical importance of cardiovascular research and the contributions of the NHLBI to the advancement of cardiovascular care. The College asks that the NHLBI be funded at the maximum this committee can provide.

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#### PREPARED STATEMENT OF STANLEY HERRERA, PRESIDENT, ALAMO NAVAJO SCHOOL BOARD, INC.

The Alamo Reservation is a ten square mile non-contiguous part of the Navajo Reservation located near the small town of Magdalena in east-central New Mexico, about 250 miles from the Navajo Nation headquarters in Window Rock, Arizona. Due to the Alamo Reservation's geographic isolation from the Big Navajo Reservation, the Alamo Navajo School Board has become the primary source of nearly all governmental services to the 1,800 residents of the Alamo Reservation.

The Alamo Navajo School Board has, since 1983, successfully operated a Head Start Program for Navajo children who live on or near the Alamo Reservation. The Board operated the Head Start program as a sub-grantee of the Navajo Nation Head Start Program until March of 1997 when it became a direct grantee under the American Indian Programs Branch of the Head Start Bureau. The Alamo Navajo Head Start Program enjoys the active involvement of the Local Parent Policy Committee and the support of the Alamo Chapter of the Navajo Nation.

*Summary of Request.*—Focusing specifically on the fiscal year 1998 Head Start budget items of highest priority to the Alamo Navajo School Board, we respectfully ask the Subcommittee to: support the Alamo Navajo School Board's request for \$794,000 in funding for a new Head Start facility to meet the existing and growing needs of children on the Alamo Navajo reservation; and provide the Administration's requested funding of \$4.3 billion for the Head Start program and, within those funds, prioritize funding for construction of new Head Start facilities.

*President's fiscal year 1998 Head Start Request.*—We appreciate the support of Congress and the President for the nation's premier early childhood program, Head Start, and ask the Committee to fund the program at the President's requested fiscal year 1998 level. This funding level will enable Head Start to serve 836,000 low-income children and their families through comprehensive education, nutrition, health and social services and put the program on track to meeting the President's goal of serving one million children by the year 2000. In previous years, 3 to 4 percent of Head Start children were served in full-day, full-year programs. With welfare reform, the need for full-day child care will be increased. The President's Head Start request includes \$227 million to provide up to 50,000 additional children with

full-day, full-year Head Start services. An important part of extending this program will be providing the necessary funding to expand existing facilities and construct new facilities to meet the educational space needs for the increased number of children served by the program.

*Proposal of a new Alamo Navajo Head Start Facility.*—The Alamo Navajo School Board requests that the Committee designate part of the Head Start appropriations for the facility needs of the Head Start program operations. To emphasize why this is important, we want to describe our plans for a new 8,000 square foot, modular construction facility at the Alamo Navajo Reservation in which to house our Head Start program.

Our proposal for a new facility meets the requirements for construction under the authorization statute: other suitable facilities are not available to the tribe; the lack of suitable facilities inhibits the operation of the program; and, construction of a new facility is more cost effective than purchase of available facilities or renovation of the existing facility.

In order to fund construction of a new Head Start facility, the Alamo Navajo School Board has put together a \$994,000 funding proposal and sought collaborative financing for the project. While efforts to seek a \$200,000 capital grant from the New Mexico State Legislature were unsuccessful, we have been able to secure authorization from the New Mexico Finance Authority to finance the project. The Board is requesting funding for project costs from the Head Start Bureau through one of two funding options; a \$794,000 facilities construction grant; or, allocation of a down payment and authorization to amortize the building costs through monthly lease payments from Alamo's annual Head Start budget. Financing for the second option (if approved) would come from the New Mexico Finance Authority.

The Board's recent experience with the construction of a modular health clinic on the reservation has proven the cost-effectiveness and flexibility of this construction option. The Board has already designated a construction site for the Head Start facility and site development activities (site, archaeological and environmental surveys and soil testing) have been completed. The proposed site is conveniently located near both the Alamo Navajo Community School and Adult Education Center, and the Alamo Health Center and would serve the Alamo Navajo community well.

Additional information detailing the background on the limitations imposed by the current facility in meeting existing program needs, the structural problems of our current facility, and the unmet demands of a growing population on the Alamo Navajo Head Start program follows.

*Need for a larger Alamo Navajo Head Start facility.*—Space limitations at the Alamo Navajo Head Start facility have prevented our Board from serving all of the Head Start-eligible children in our area since the inception of our program, and from expanding our program to provide full-day, full-year service to the Head Start children we serve. Our current facility, a two room school built in 1972 (which formerly served as a BIA day school) limits the number of children we may serve to a maximum of 35 children at one time. Since the program began in 1983, we have served the maximum number of children that could physically be accommodated in our facility, and we have still had a waiting list of 10 to 12 children each year; and we have had to limit the children served to four years olds.

In 1988, in an effort to serve more children, the Alamo Navajo program applied and received expansion funds to serve 55 children. In order to serve the added children, however, we had to institute double shifts. Some children attend morning sessions, others the afternoon session. While this arrangement has not been totally satisfactory, it is a compromise that the Board reached in an effort to serve as many children as possible given our space limitations.

*Growing population and unmet need.*—Alamo's Head Start program has never been able to accommodate three year olds, even though they are eligible for services. Nor has Alamo been able to serve children under the age of 3 who are eligible for Early Head Start. Nationwide, five percent of the Head Start budget is devoted to providing service to infants, toddlers, and pregnant women in the Early Head Start program.

With each passing year in our existing facility, the Alamo Head Start program serves a smaller percentage of those reservation children eligible for the Head Start program. An indicator of the growing reservation population is the number of births each year. In 1986, there were 35 births. The number of births grew to 52 births in 1995. In 1996, another 43 children were born. We can anticipate that based on the 1995 and 1996 birth rates, we will have approximately 95 Head Start-eligible children in the near future. Of these 95 children, current program funding levels would allow us to serve 55 children or 58 percent of those 3- and 4-year old children eligible for the Head Start program.



*Structural and programmatic problems with existing facility.*—Alamo's current Head Start facility has reached its expected life cycle of 25 years and warrants replacement. Settling of the foundation has produced large cracks in both the exterior block walls and throughout areas of the floors. The poor structural condition of the building has been documented by the IHS Office of Environmental Health in its annual health and safety survey. In addition, the facility has never been able to meet the real needs of the program—bathroom equipment is not child-sized, and the kitchen is too small to allow preparation of meals in the quantities necessary.

There are no alternative facilities to house the Head Start program and renovation or expansion of the current facilities is not a cost-effective option. The combination of the facility age, functional deficiencies and poor building performance make any attempt to renovate or expand the facility an ill-advised one that would not be cost-effective.

#### *Summary*

The Alamo Navajo School Board respectfully asks the Committee for its commitment to making new construction funding within the Head Start budget a priority at the national level and specifically requests funding of \$794,000 to construct a new, and much-needed Head Start facility on the Alamo Navajo Reservation.

We appreciate the opportunity to express our views on the fiscal year 1998 Head Start budget and thank the Committee for its consideration of our request for a new Head Start facility. We would be happy to provide any additional information concerning our testimony to the Committee.

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#### PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS

On behalf of the Academy and the endorsing organizations, the Society for Adolescent Medicine and the Ambulatory Pediatric Association, we would like to submit this statement for the record.

Fortunately, most infants are born healthy and continue to grow and develop if they have access to and receive basic health care services. Unfortunately, there are still far too many that suffer needlessly from disease, injury, abuse, or a host of societal problems. Our task as pediatricians is to promote preventive interventions and to diagnose, treat and manage acute and chronic problems of children and adolescents. Your task is to provide the funds to sustain vital federal programs that underpin and complement these efforts. As pediatricians we recognize the integral tie between basic research and the care we provide; we see the impact of poverty and violence on the health of our children and adolescents; and we know that the future of our workforce depends on the decisions we make today. We ask that you recognize the correlation among preventive and chronic health services, research, and the training of new health professionals and to appropriate the necessary funds to the extent possible.

A chart at the end of this statement will offer funding recommendations for many programs, but we would like to focus on a few.

#### *Preventive Health Care:*

*Childhood Immunization Program.*—The CDC's childhood immunization program is the cornerstone of preventive health care for children served in the public sector and for uninsured children. Tremendous strides in establishing effective immunization programs have been made over the past few years. In addition to the cost-effectiveness of vaccines, the number of reported cases of vaccine preventable diseases are at or near all time lows and immunization levels of two-year old children are the highest ever recorded. We attribute this, in part, to the Vaccines for Children (VFC) Program and encourage Congress to maintain its commitment to ensuring its viability. The VFC program combines the efforts of public and private providers to accomplish and sustain vaccine coverage goals for both today's and tomorrow's vaccines. It removes vaccine cost as a barrier to immunization for some and reinforces the concept of a "medical home." To date, its successful implementation has resulted in the enrollment of approximately 37,000 public and private provider sites. However, despite this good news, the most recent National Immunization Survey reports that more than 1 million children in America are under-immunized. Continued investment in CDC efforts to assist states in developing immunization information systems will serve to sustain high immunization levels by reminding parents when immunizations are due/overdue. It also help providers know the immunization status of the children they serve. Also, in order to most effectively access children at highest risk for under-immunization, the Academy continues to support CDC's efforts to collaborate closely with the WIC program. Immunizations are an important investment in our children. Our request for funding includes support for the key

strategies mentioned above, which when implemented locally, are critical to raising immunization coverage levels among our nation's children. In fiscal year 1998 the Academy and the endorsing organizations recommend at least \$528 million for CDC's Childhood Immunization program. The Academy is cognizant that the Administration's fiscal year 1998 budget proposal for immunizations is predicated upon a reduction in the current vaccine excise tax, a change that we support. However, we urge you to ensure that the funding for the Childhood Immunization program is not compromised if there is no change in the vaccine excise tax law this year.

*Maternal and Child Health Service Block Grant*—The MCH Block Grant is a "block grant" that works. Currently, the MCH Block Grant provides preventive and primary care services to 17 million women and children, including 3 million infants, 8.3 million children and adolescents, 900,000 children with special health care needs as well as preventive services to approximately 4.8 million women—including one-third of all pregnant women in the U.S. Authorized under Title V of the Social Security Act, the MCH Block Grant is a federal and state partnership that exemplifies key elements in any successful block grant—it is logically organized around similar programs and expertise, emphasizes preventive health, targets similar populations and problems and utilizes similar public and private provider networks. It is the crucial framework upon which States have built and maintained their systems of care for children and women. It is the "glue" that brings together multiple services and agencies for children and adolescents by coordinating, integrating and filling gaps. An important component of the MCH Block grant is that it addresses both the physical and mental health needs of adolescents. The Office of Adolescent Health supports initiatives such as health care programs for incarcerated youth, health care services for minority group adolescents, and violence and suicide prevention. The MCH Block Grant includes an important set-aside of 15 percent to support the Special Projects of Regional and National Significance (SPRANS) to improve maternal and child health and promote more effective delivery systems. We support the funding of the MCH Block Grant program at its full authorization of \$705 million—a modest 3.5 percent increase which will help to preserve and improve crucial public health services for children and mothers including improving the health of low and very low birthweight babies.

*Folic Acid to Prevent Birth Defects*—Each year 150,000 children are born with serious birth defects causing one out of every five infant deaths. These birth defects are also the leading cause of disabling conditions in children, which cost families and our government billions of dollars each year. Vitamin supplements containing folic acid have been proven to prevent common and disabling birth defects, such as spina bifida and anencephaly. Currently only 25 percent of women of reproductive age consume sufficient folic acid every day. If American women of childbearing age consumed an adequate daily supply of folic acid, 2000–3000 cases of birth defects could be prevented each year, saving nearly \$245 million. By implementing a national multimedia campaign and assisting states and private partners with educational programs, the CDC hopes to increase the consumption of folic acid in women of reproductive age, thereby doubling the number of women who consume a sufficient quantity to 50 percent. We recommend \$20 million for the CDC folic acid supplement initiative.

*Emergency Medical Services for Children*—Although issued several years ago, a 1993 Institute of Medicine report describing the serious deficiencies in emergency medical services for children (EMSC) is still very relevant. There continues to be significant problems in emergency services for children; for example, many ambulance services and hospital emergency departments do not even have child-sized equipment, such as, oxygen masks, IV-tubes, and neck braces, needed to treat critically ill and injured children. Many emergency medical personnel need additional training to adequately treat children, whose medical needs are very different than those of adults. (Children have more serious breathing problems, are less tolerant of blood loss, are more vulnerable to head injuries, have different time requirements for procedures and transport, and require special splints, airway devices, drugs and dosages.)

The EMSC program has saved lives. Just last month in Massachusetts, 18 children at a local community center dance overdosed on illegally obtained prescription muscle relaxants. Many of the children were in immediate danger of respiratory arrest and the treatment provided by the Emergency Medical providers on the scene saved their lives. These providers had received special training in pediatric resuscitation, training implemented State-wide as part of the EMSC grant program.

To date, approximately 48 states have received some form of EMSC funding for systems development and training. Mississippi and Delaware have not yet received a basic EMSC grant. Grantees have developed training and research programs which other states and localities have replicated, increasing the cost-effectiveness of

federal dollars. Currently a study is being conducted in Los Angeles and Orange County, California to evaluate the outcome of pre-hospital pediatric airway management. Several thousand EMTs and paramedics are being trained in both intubation and bag mask ventilation. The study will then evaluate how the children respond depending on which type of treatment they received. This study will have significant implications for the training and practice of EMTs and paramedics throughout the country.

We recommend funding this program at \$15 million, which will enable the program to continue to assist all states to ensure that children have the best possible emergency care; to continue to develop a new services research focus; to expand efforts to integrate EMSC into our health care system; and to more fully incorporate the concerns of family members into the delivery of emergency medical services.

*CDC Injury Prevention*—Injury is the leading cause of death among children ages one through nineteen and all Americans ages one through forty-four, and is a major cause of long-term disability for both children and adults. Injury is costly on multiple levels—in the emotional toll it takes on its victims and on their families; in direct medical expenses (acute and chronic); and in long-term economic costs due to the years of potential life and productivity lost (especially with respect to children). Therefore, efforts to reduce the incidence and severity of injury are extremely cost-effective, and the National Center for Injury Prevention and Control (NCIPC) fulfills a unique function in this undertaking. The NCIPC works closely with other federal agencies, national, state, and local organizations, state and local health departments, and research institutions in its study of home and recreational injuries and violence prevention. For example, in several states, including Texas and California, CDC is working to evaluate school and community based violence prevention programs including mentoring, peer mediation, public information campaigns, and conflict resolution education. In Oklahoma, Maryland, and Arkansas, CDC is funding projects to promote the use of smoke detectors and reduce residential fires. In New York and California projects are funded to promote the use of bicycle helmets to reduce related head injuries to children. In some of these areas, projects are sponsored in collaboration with the Indian Health Service for the establishment of injury prevention programs in Native American communities. Deaths due to unintentional injuries are twice the rate for Native American children than for children of all other races. We recommend that the CDC injury prevention program be funded at \$65 million.

We also support the Coalition for Health Funding's overall recommendation for the U.S. Public Health Service of \$26.6 billion.

*Pediatric Research:*

*National Institutes of Health*—Pediatric research today is not only exciting, but rapidly changing. Pediatric research covers the entire spectrum of research—basic, clinical, applied, and health services—and is supported substantially by the federal government through the NIH. Research in prevention of premature births and treatment of its medical consequences has continued to reduce infant mortality. For example, research conducted at NICHD on Sudden Infant Death Syndrome (SIDS) has clearly shown a relationship between infant sleep position and SIDS. The NICHD in partnership with the Academy and other national organizations, has launched a national public education “Back to Sleep” campaign to advise parents, caregivers, and health professionals to place babies preferably on their back or side to sleep. Consequently, whereas 80 percent of babies were sleeping on their stomach four years ago, only 25 percent are today. More importantly, SIDS deaths have fallen by more than 30 percent in the last three years. Consider another important example, the development of surfactant, which can be administered into the lungs of premature infants, has resulted in fewer deaths of infants from Respiratory Distress Syndrome (RDS) and has saved an estimated \$90 million a year in hospital costs.

We join with the Ad Hoc Group for Medical Research Funding in recommending a 9 percent increase for NIH consistent with the collective recommendations of agency personnel as well as national advocacy groups within the Ad Hoc Group. We also join the Friends on NICHD in supporting \$690 million for the National Institute of Child Health and Human Development. In order to increase pediatric biomedical and behavioral research within NIH, we recommend \$20 million for the Pediatric Research Initiative. We believe that these requests represent the best and most reliable estimate of the level of funding needed to sustain the high standard of scientific achievement embodied by the NIH.

*Agency for Health Care Policy and Research*—The AHCPR is the primary federal agency charged with developing clinically-based, policy relevant information for use in improving the health care system, providing leadership in health services research and providing training for new health services researchers, such as pediatri-

cians. It uniquely serves the interest of both health care consumers and providers. Important outcomes research supported by AHCPR have shown that improving quality of care can save taxpayers hundreds of millions of dollars per year. For example, universal implementation of AHCPR's guideline on the treatment of otitis media with effusion, a common condition of the middle ear in young children, could cut the total cost of care in half and annually save over \$700 million. In addition, funding from AHCPR has supported the management of acute asthma in pediatric practices and the assessment of fevers in very young infants. In the latter study, the Academy is collecting data on how pediatricians assess febrile infants less than 3 months of age. One product of the study will be a revised guideline for diagnostic work-up for infants with fever. It is anticipated that such a guideline will make it possible to eliminate at least 10 percent of the hospitalizations for observation and diagnosis of these infants that currently occur. Such a result would save \$36 million in current hospital costs. We recommend funding of \$160 million for AHCPR in fiscal year 1998.

*Training:*

*Health Professions Training.*—Title VII of the Public Health Service Act, Primary Care Training Grants for General Internal Medicine and General Pediatrics, remains a small but vital incentive program for the generalist training of pediatricians. These grants provide support for a large number of residents to receive intensive primary care training in diverse ambulatory settings—this is the only federal support targeted to training primary care practitioners. Faced with increases in the incidence of AIDS, substance abuse, adolescent pregnancy and other health concerns, pediatricians of the future will be expected to manage both acute and chronic health problems, care for children with disabling conditions, and provide counseling for problems that are psychosocial or behavioral in nature. Given the complex needs of their patients, pediatricians will also be called upon to utilize community resources and to collaborate with other health care providers. Title VII grants in pediatrics have supported training in a variety of community and non-hospital based settings such as juvenile detention centers, homeless shelters, child nutrition programs, child care centers and community health centers.

We are extremely concerned that the Administration's fiscal year 1998 budget request, which reduces funding for these programs by 55 percent, will seriously jeopardize the future training, supply and distribution of primary care providers in this country. We are very grateful for the support this committee has demonstrated in the current fiscal year for health professions training and we recommend fiscal year 1998 funding of \$25 million for General Internal Medicine/General Pediatrics and join with the Health Professions and Nursing Education Coalition in supporting, a modest increase of \$302 million in total funding for Title VII and Title VIII, which is last year's level plus medical inflation.

The National Health Service Corps is a key component of any effort to remove barriers to health care and to ensure an adequate distribution of health care providers across the country. The scholarship and loan repayment programs are another integral part of national efforts to increase opportunities for minorities to become health professionals. We support funding of \$125 million.

*Substance Abuse Prevention:*

Adolescents continue to use illegal drugs at alarming rates—40 percent of high school seniors interviewed in the annual Monitoring the Future Survey said they had used illegal drugs in the past year; half indicated that they had tried drugs sometime in their lives. The Substance Abuse and Mental Health Services Administration (SAMHSA), through its Center for Substance Abuse Prevention (CSAP) supports prevention programs for high-risk youth which involves early intervention targeted to millions of vulnerable children in school and neighborhoods. The Academy strongly supports the Administration's Youth Substance Abuse Prevention Initiative which includes funding to develop State-wide prevention plans that work; to raise public awareness and counter pro-drug messages through a national media campaign; and to expand the National Household Survey on Drug Abuse to increase accountability through data system development. We support funding of \$1.8 billion for the Substance Abuse Prevention and Treatment Programs at the Substance Abuse and Mental Health Services Administration.

*Tobacco:*

The American Academy of Pediatrics has fought for decades to prevent the use of tobacco products by children and adolescents. This is a silent and deadly plague. Each day 3,000 children nationally begin to use tobacco. Of those people who will ever smoke, ninety percent begin before age 19. Young smokers suffer from respiratory problems, asthma, chronic cough and phlegm production. Among teens who

are regular smokers, one in three will die from smoking. And tobacco-related illnesses claim the lives of over 400,000 Americans each year. These facts alone confirm that tobacco use truly is a “pediatric disease” that is completely preventable.

The Academy endorses the Administration’s efforts on behalf of children to reduce access to tobacco products by children and adolescents. We recommend \$36 million for CDC’s Office on Smoking and Health and \$25 million for the tobacco prevention and cessation program at the National Cancer Institute (ASSIST). We urge Congress to avoid any legislative action that could weaken or delay the FDA’s efforts to reduce tobacco use by children and adolescents.

In summary, the following list highlights programs, along with funding recommendations, of importance to children. The Academy joins with its many friends in other organizations and coalitions in presenting these recommendations.

*Recommendations for fiscal year 1998*

Department of Health and Human Services:	
Centers for Disease Control and Prevention .....	\$3,000,000,000
Childhood Immunization Funding .....	528,000,000
Injury Control .....	65,000,000
Lead Poisoning .....	50,000,000
Office on Smoking and Health .....	36,000,000
Folic Acid Supplement Program .....	20,000,000
Health Resources and Services Administration .....	3,734,000,000
Ryan White (total) .....	1,390,200,000
Ryan White Pediatric Demos .....	61,000,000
EMSC .....	15,000,000
Family Planning (Title X) .....	250,000,000
MCH Block Grant .....	705,000,000
National Health Service Corps .....	125,000,000
Health Professions Training (Total) .....	302,000,000
General I.M/Pediatrics (Title VII) .....	25,000,000
Consolidated Health Centers .....	882,000,000
Agency for Health Care Policy and Research .....	160,000,000
National Institutes of Health .....	13,800,000,000
NICHD (Child Health) .....	690,000,000
NIEHS (Environmental Health) .....	336,000,000
NCI—Assist Program .....	25,000,000
Pediatric Research Initiative .....	20,000,000
Administration for Children and Families:	
Child Abuse Prevention and Treatment .....	100,000,000
Head Start .....	4,300,000,000
Child Care and Development block grant .....	1,000,000,000
Substance Abuse and Mental Health Services Administration:	
Children’s Mental Health Services .....	80,000,000
Substance Abuse Prevention and Treatment .....	1,800,000,000
Indian Health Service .....	2,400,000,000
Department of Education:	
IDEA part B .....	4,607,500,000
IDEA part H .....	400,000,000
IDEA section 619 .....	776,130,000

PREPARED STATEMENT OF KRISTIN THORSON, PRESIDENT, FIBROMYALGIA NETWORK;  
AND PRESIDENT AMERICAN FIBROMYALGIA SYNDROME ASSOCIATION

“Most of the pain experienced by FMS patients has a physiological or biochemical explanation. It is not the patient’s responsibility to change his or her disease into something that we know more about. Rather, it is our task as researchers to better understand the problems that exist.”—I. Jon Russell, M.D., Ph.D., Professor of Medicine, UTHSC—San Antonio Editor, *Journal of Musculoskeletal Pain*.

“Uncovering two or three new revelations about FMS could make a substantial difference in the direction of research. There are few other medical conditions to research that could have such a significant impact on the treatment of a syndrome and the quality of life of those who suffer with it.”—Daniel J. Clauw, M.D., Professor of Medicine, Georgetown University.

Goals for fiscal year 1998: Publish a collaborative NIH PA or RFA for pain research related to FMS and overlapping pain syndromes. The emphasis should be on clinical research that focuses on: understanding the central nervous system pain processing changes that occur in chronic pain syndromes, identifying

neurotransmitters or pain receptors that have potential therapeutic significance, searching for diagnostic markers that are essential for the testing of therapeutic interventions, and developing novel, non-addictive, pain-relieving drugs for FMS and related chronic pain syndromes. Involvement of the NIH Pain Research Consortium is strongly urged.

#### *Introduction*

Mr. Chairman and Members of the Subcommittee, I wish to thank you for supporting language pertaining to fibromyalgia syndrome (FMS), chronic fatigue syndrome (CFS) and related pain disorders for the past few years. Last year you encouraged both the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS) and the National Institute for Allergy and Infectious Diseases (NIAID) to step up their funding on FMS and CFS, respectively. You also urged the Office of Research on Women's Health to develop a policy for addressing the research needs for FMS, CFS and other overlapping pain syndromes. A collaborative Institute approach at NIH will be crucial to furthering our understanding of the body-wide, multi-system nature of these disorders.

The research on FMS and CFS is still in its infancy and objective laboratory markers that could aid physicians in supporting these diagnoses are not available. Although a tender point exam is used by some doctors who are skilled in this area, for the most part, the diagnoses of both FMS and CFS are often made based on a person's symptoms. Given that the symptom checklist for both conditions overlap by 70 percent, many researchers view these disorders as being indistinguishable or, at the least, in the same family of syndromes.

#### *The Two Most Common Symptoms: Pain and Fatigue*

Pain: "I invite you to recall the last time that you experienced severe pain. What else besides pain occupied your attention? \* \* \* For most of us, it was precious little else, but the desire to be rid of the pain."—Peter Fagen, Ph.D., Professor of Medicine, Johns Hopkins University.

Body-wide pain is the hallmark of FMS. A large percentage of patients will have other symptoms that add to their discomfort, such as headaches, irritable bowel and bladder, and jaw pain (TMJ dysfunction). Looking at the 1994 CDC criteria for CFS, five of the eight symptoms (after fatigue) relate to pain. These include muscle pain, multi-joint pain, headaches, tender lymph nodes, and sore throat.

Fatigue: "When you ask CFS patients about their fatiguing symptoms, they say, 'I'm tired.' Unfortunately, 'tired' is an ambiguous word in the English language. It can mean a lot of things, such as sad, bored, unmotivated, et cetera. These people are physically and mentally exhausted! And, if you pose the same question to patients with FMS, they will respond with the same answer."—Harvey Moldofsky, M.D., Professor of Psychiatry, University of Toronto Director, The Chronobiology and Sleep Disorders Clinic.

Expounding further on the issue of fatigue, two other related problems such as sleep disorder and memory/concentration difficulties, have been documented by researchers as common occurrences in both FMS and CFS.

Conclusion: The invisible yet life impacting nature of the above symptoms reinforce the need for additional research in these areas. Recently, a PA and an RFA have been published to further explore the physiology of fatigue, but the problem of chronic pain has thus far been omitted from the NIH research funding agenda.

#### *Looking "Normal" but Feeling Awful*

Everyone knows what it is like to be on the front end of the initial ravages of a rapidly encroaching and merciless flu bug. The situation is similar to what FMS and CFS patients face on a daily basis. There are no routine lab tests to identify the cause of the patient's illness or to validate how miserable the person feels. Only a handful of medications have been shown in drug trials to be of some benefit, but their effectiveness in alleviating FMS and CFS symptoms is about as good as aspirin is when a cell-destroying virus is storming the body. Then there is the issue of appearance versus reality. Patients with FMS, CFS and those with the initial onset of a flu bug look normal, but they feel awful. With the flu, one can predict a return to health within days, but people with FMS and CFS can't simply ride out the storm.

"When you follow patients with fibromyalgia over time, you find changes in pain intensity and changes in severity of symptoms. However, even after a ten-year period, the majority of patients continue to have pain and other symptoms," said Laurence Bradley, Ph.D., Professor of Medicine at the University of Alabama at Birmingham. Dr. Bradley chaired the chronic pain section of the July 1996 NIAMS workshop on FMS, and the persistence of symptoms beyond the ten and fifteen year marks has been widely published in the medical journals.

Just because standard lab tests are unrevealing for FMS and CFS, it doesn't mean that there are no relevant abnormalities. Using single photon emission computed tomographic (SPECT) imaging, Dr. Bradley has found a significantly reduced blood flow in two of the pain processing structures in the brains of patients with FMS. "This indicates that the functional activity of these structures has been reduced," says Bradley. "Similar changes in functional brain activity also have been documented in chronic pain syndromes associated with nerve injuries and metastatic cancers." SPECT imaging abnormalities in CFS patients have been found as well and need to be correlated with Dr. Bradley's work.

Other important research findings that are not part of routine testing include: a threefold increase in spinal fluid substance P levels (believed to be an objective indicator of pain), a fourfold increase in spinal fluid nerve growth factor which stimulates substance P production, low growth hormone production, dysregulation of cortisol output from the adrenal glands, sleep disturbances, and electroencephalogram alterations.

So while FMS and CFS patients look normal, investigators have found many relevant laboratory abnormalities. Unfortunately, none of the findings to date can be used as an objective and universally accepted lab marker for diagnosing these syndromes or documenting illness severity.

This situation of looking healthy and not yet having a diagnostic marker contributes to the difficulties that patients face:

- The symptoms become trivialized by family members, friends, employers, treating physicians, and the media.
- A prompt, correct diagnosis is rarely provided.
- Therapy options are limited when doctors can't find abnormalities to treat.
- Patients become the prime target of cost-conscious health insurance companies who clamor: If you can't prove your symptoms exist by standard tests, we won't cover them.
- The pharmaceutical industry shows less interest in developing new drugs than it might if a diagnostic marker were readily available.

The bottom line: Without a universally accepted lab marker, more FMS and CFS patients will fall through the medical system cracks and become disabled. This shifts the cost burden of these conditions from employers and insurance companies, to the federal government. It also cuts into tax dollars even though patients would much prefer effective therapies over unemployment and disability.

#### *NIH Progress Update*

NIAMS convened a scientific workshop on FMS in July 1996 to cover three major topics in FMS/CFS research: chronic pain, neuro-hormonal abnormalities and sleep. Later in 1996 both a PA on CFS and an RFA on sleep were published, with NIAID cosponsoring the PA and NIAMS cosponsoring both research announcements. Both Institutes are to be commended for taking positive steps toward soliciting researchers to better elucidate the neuro-hormonal basis for fatigue and sleep disorders in CFS and FMS patients. However, the issue of pain was left out of the funding equation for fiscal year 1997.

Many useful avenues for researching chronic pain states, such as FMS, were provided at the NIAMS scientific workshop. These areas should be avidly pursued in order to better understand the physiological mechanisms involved in FMS and related chronic pain syndromes.

#### *Benefits of FMS and Related Pain Syndrome Research*

"Our standard therapies for FMS/CFS work only in a minority of patients. They only help partially and improve some symptoms but not others."—Stephen Campbell, M.D., Professor of Medicine, Oregon Health Sciences University.

According to pain researcher at the University of Arizona, John Leslie, M.D., "In 1996 the dollars spent by the private sector on health-related research was twice that of the amount awarded annually by NIH." The major player in the private sector biomedical research is the pharmaceutical industry. So far, drug companies haven't had much interest in sponsoring research studies on FMS/CFS, but this could change in years to come if we had a better biochemical understanding of these illnesses and reliable markers of disease severity (as well as a good diagnostic marker for screening drug-trial participants).

The prevalence of FMS is well-documented as being 2 percent of the general population so it affects roughly five million Americans. The number of people battling FMS and its related chronic pain syndromes, however, is believed to be well above 20 million. A multi-center disability study on FMS alone indicates that the direct costs of FMS to the U.S. economy is close to \$16 billion per year. As stated by Dr. Daniel Clauw at the beginning of this testimony, even a modest improvement in

FMS therapies for patients could lead to a significant reduction in this condition's staggering economic burden.

During the July 1996 NIAMS workshop on FMS, many suggestions were provided as a road map for future research directions on this syndrome. In particular, the central nervous system and its pain processing centers were highlighted as fruitful areas of investigation, especially since the most pronounced and potentially disabling symptom of FMS is pain.

It is now recognized that central nervous system changes occur in patients with chronic pain such as FMS due to a process called neuroplasticity.

"Neuroplasticity can lead to a spreading of localized pain to involve the whole body. The stress engendered by this persistent pain causes many important feedback loops, such as depression, anxiety, hormonal changes, sleep loss, behavioral changes, a reduction in exercise and activities, and other lifestyle changes. When you look at our current treatment of FMS, most of what we are doing is trying to reduce the negative impact of these feedback loops (i.e., help patients sleep and increase functional activity) \* \* \* We are not good at treating these central changes yet, but rapid progress in the science of neurotransmitters may provide new effective strategies for the relief of chronic pain."—Robert Bennett, M.D., Professor of Medicine, Oregon Health Sciences University.

"The bottom line," says Dr. Bennett, "is that it is possible to experience pain, and still look normal and healthy." Referring to brain imaging techniques such as the SPECT scans mentioned in this testimony as a research tool used by Laurence Bradley, Ph.D., Dr. Bennett adds: "It is now also possible to image pain."

#### *Recommendations*

In the opening statement made by Dr. I. Jon Russell, it shouldn't be up to the patients to change their medical condition into something that is well understood; identifying the causes and effective therapies for a medical condition is a job for the research establishments. Additionally, patient organizations are already doing everything that they can to seed research on FMS and CFS. However, these patients should not be expected to bear the full cost of researching their own disease. To improve the status quo, this Subcommittee is urged to consider the following two recommendations:

The publication of an RFA or PA for pain research related to FMS and overlapping pain syndromes with a strong focus on clinical studies and covering such areas as: improve understanding of the central nervous system pain processing changes that occur in FMS and related pain syndromes; identify neurotransmitters and pain receptors that have potential therapeutic significance; search for objective abnormalities that correlate with disease severity; and, develop a diagnostic marker.

This RFA or PA should be primarily sponsored by NIAMS. Co-sponsorship by NIAID and Institutes representing the new NIH Pain Research Consortium is urged.

Continue to encourage ORWH to help collaborate NIH research efforts due to the body-wide nature of FMS and CFS, as well as their high frequency of symptom overlap with other regional pain syndromes, many of which afflict mostly women.

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#### PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

Thank you for the opportunity to provide written testimony for review and inclusion in the hearing record on the fiscal year 1998 appropriation for the National Institutes of Health (NIH). The American Society for Microbiology (ASM) represents over 42,000 life scientists who work in research, clinical, public health and industrial laboratories. We would like to thank Chairman Specter for his leadership and the members of this Subcommittee for their efforts to increase funding for biomedical research, especially in view of the fiscal constraints that require difficult decisions about budget allocations to federal programs.

Through the NIH, the federal government's premier institution for funding biomedical research, Congress wisely has made a long-term investment which has returned enormous dividends in scientific achievements that have improved the health of the nation's citizens as well as people worldwide. Advances in biomedical research have led to the dawn of an era of breakthroughs in medicine unprecedented in history. Federal investment in basic molecular biology research supported by the NIH has yielded revolutionary advances in medical diagnosis and treatment and launched the new biotechnology industry. The U.S. biotechnology industry has created more than 108,000 high wage jobs in less than 20 years, and biotechnology is responsible for hundreds of medical diagnostic tests that detect medical conditions at an early stage.



At the same time, despite enormous medical progress, we urgently need more research to discover new cures, preventions and treatments for a myriad of diseases that still plague humankind, such as acquired immunodeficiency syndrome (AIDS), alzheimer's disease, arthritis, cancer, depression, diabetes, heart disease, stroke, to name just a few, and a growing number of infectious diseases which we will highlight in our testimony. These diseases affect over 100 million Americans each year and cost society more than \$500 billion annually in direct and indirect costs. Given the magnitude of the burden of disease and disability to society, the untold human suffering to patients and their families from disease, and the many research opportunities that are ready to be exploited, we urge Congress to continue to make basic and clinical biomedical research supported by the NIH the highest priority in order to capitalize on past research achievements and to pursue vigorously new research opportunities that are desperately needed to address current and future health needs.

To ensure that the fiscal year 1998 funding level for the NIH is sufficient to sustain ongoing research progress and to take advantage of new biomedical research opportunities, the ASM recommends that Congress attempt to increase funding for the NIH by 9 percent in the coming fiscal year. Although we recognize that a 9 percent increase for the NIH may be a difficult goal to achieve in the current budgetary climate, we hope that Congress will seriously consider such an increase because it is based on the professional judgment budget identified by scientific experts as the best estimate of needed funding for NIH in fiscal year 1998. The recommended increase of 9 percent, supported by the Ad Hoc Group for Medical Research Funding, a coalition of 200 organizations, is necessary for biomedical research to keep pace with inflation, to maintain a strong research infrastructure and to fund the range of research opportunities that are needed to improve all areas of health.

In the following testimony, the ASM would like to bring a number of issues to the attention of the Subcommittee: the need to fund peer reviewed investigator initiated research project grants; the urgent need to fund adequately research required to address threats from new and reemerging infectious diseases and the National Institute of Allergy and Infectious Diseases (NIAID), the federal government's lead agency for research on infectious diseases; the vital role of the National Institute of General Medical Sciences (NIGMS), which funds basic, nondisease specific research; adequate support for NIH research management and support (RMS), and research training and infrastructure needs.

#### *Individual research project grants*

Basic research into fundamental life processes, which is supported primarily through individual investigator initiated research project grants, is critical to continued technological innovation. To ensure that top quality research opportunities are not missed, the NIH should fund approximately 35 percent of meritorious research project grant applications. A 9 percent increase in funding for NIH would help achieve this goal. The peer review process is essential to develop scientific and budgetary priorities and should be sustained and strengthened to maintain scientific excellence.

#### *Research required to address threats from new and reemerging infectious diseases and the leading role of the National Institute of Allergy and Infectious Diseases*

In 1996, infectious diseases in the United States ranked as the third leading cause of death. Five of the ten top causes of death in 1996 were related directly or indirectly to infectious diseases (pneumonia, AIDS, chronic liver disease, chronic obstructive lung disease, and immunosuppression related to cancer chemotherapy). Data presented in the *Journal of the American Medical Association* (275: 189-193, 1996) indicate that the death rate from infectious diseases has increased 58 percent since 1980. Trends in death due to respiratory tract infections, HIV, and bloodstream infections, account for most of these increases. It is estimated that 9,000 people in the United States die annually from foodborne illnesses, a number unheard of for a developed country. In 1994, 1995 and 1996 locally acquired cases of malaria have been reported in the United States, where the disease has been nonexistent for 50 years. The appearance of dengue fever in the United States, the marked increase of Lyme disease, the reemergence of tuberculosis and rabies are just a few examples of the rising tide of infectious diseases. In 1993, the largest (>400,000 cases of diarrhea due to *Cryptosporidium*) waterborne disease outbreak in the U.S. history occurred. An outbreak of acute, fatal respiratory distress syndrome in the Southwestern United States was shown to be due to hantavirus, a newly identified virus spread to humans in the feces and urine of the deer mouse. Initially thought to be limited to the Southwest, it appears that the deer mouse is one of the most common rodents in the country and fatal hantavirus cases have been reported as

far away as Miami and New York. The virus is now known to be carried by other rodents as well and another strain of the virus has been identified.

Antibiotics are now the most commonly prescribed category of drugs. Yet the efficacy of these miracle drugs is threatened by an alarming increase in the antibiotic resistant bacteria. Although defining the precise public health risk of emergent antibiotic resistance is not a simple undertaking, there is little doubt the problem is global in scope and very serious. Today more than 90 percent of the strains of *Staphylococcus aureus* are resistant to penicillin and other related antibiotics. This common bacterium causes a range of infections such as boils, toxic shock syndrome, and serious diseases of the lung, heart, and bone. Enterococci (a kind of streptococcus) are the most common cause of hospital acquired infections. The antibiotic vancomycin often is the last weapon available to treat these potentially deadly microbes. According to the U.S. Centers for Disease Control and Prevention, the incidence of vancomycin resistant enterococci in the United States increased 20 times from 1989 to 1993. One of the miracles of modern medicine has been our ability to treat successfully bacterial pneumonia with penicillin. Before 1987, antibiotic resistant *Streptococcus pneumoniae* (pneumococci) were uncommon in the United States. Recent reports indicate that in some parts of the country as many as 40 percent of strains of pneumococci are resistant to penicillin and other antibiotics. These bacteria are a leading cause of deadly bloodstream infections, pneumonia, and meningitis in the elderly and are one of the most common causes of middle-ear and sinus infections in children.

Infectious diseases account for 25 percent of all visits to physicians in the United States, and approximately \$120 billion, or 15 percent, of all 1992 health care expenditures in the United States were related to direct or indirect costs of infectious diseases. The annual financial cost of common infectious diseases in the United States is estimated by the National Science and Technology Council and the NIH as follows: Intestinal infections: \$23 billion in medical costs and lost productivity; Foodborne diseases: \$5 to 6 billion in medical costs and lost productivity; Sexually transmitted diseases: \$5 billion in treatment costs (excluding AIDS); AIDS: at over \$10 billion in costs annually now the leading cause of death among adults aged 25 to 44; Hepatitis B virus infection: over \$720 million in combined direct and indirect costs; Influenza: \$17 billion in medical costs and lost productivity; Otitis media: over \$1 billion in medical costs; and, Antibiotic-resistant bacterial infections: \$4 billion in medical costs.

*Combating infectious diseases requires increased funding for research*

Like the organisms themselves, the challenges of detecting and preventing infectious diseases are constantly evolving. A strong, stable research and training infrastructure is needed to investigate the mechanisms of molecular pathogenesis (cause of disease), the evolution of pathogenicity, drug resistance, and disease transmission. This fundamental knowledge is required to design new vaccines, discover new classes of antimicrobial compounds, and devise other novel means of preventing and treating infectious diseases.

The NIH's National Institute of Allergy and Infectious Diseases is the federal government's lead agency for funding scientific research on causes of infectious diseases, pathogenic mechanisms, host defense mechanisms, vaccines, and antibiotics. In collaboration with other Public Health Service agencies and industry, NIAID sponsors basic and clinical research that yields multiple public health and economic benefits. The following are just a few examples of persistent biomedical research efforts that have paid off in the past: Before the development and introduction of a vaccine, *Haemophilus influenzae* type b (Hib) was the leading cause of pediatric bacterial meningitis in the United States with more than 16,000 cases reported each year, of which 10 percent were fatal. Since the introduction of the Hib vaccine in 1989, Hib infection has decreased by 95 percent among children under age 5, resulting in savings estimated at more than \$400 million per year; Protease inhibitors used in combination with other drugs such as AZT were shown to block the protease enzyme of HIV, thereby preventing HIV from replicating itself. In the past year, we have learned that many people with AIDS can experience dramatic improvement after treatment with these drugs; Chlamydial infection is the most common bacterial sexually transmitted disease in the United States, with about 4 million new cases each year at an annual cost exceeding \$2 billion. If undetected and untreated the infection can lead to long-term complications such as infertility and tubal pregnancy. A highly sensitive and noninvasive urine assay that allows earlier detection of this infection even before it becomes symptomatic has been developed.

Increased funding for the NIAID is needed to address the current threats from new and reemerging infectious diseases through the development of better diagnostic tests, new drugs and vaccines. In addition, increased funding would provide

new opportunities for making major advances to define the potential role of infectious agents in chronic diseases, such as cancer, that currently have no known causes. The link between infectious diseases and cancer is becoming increasingly clear. According to the World Health Report 1996, up to 84 percent of some cancer cases worldwide are attributed to viruses, parasites, or bacteria. The following are several examples:

*Stomach cancer.*—Approximately 550,000 new cases of stomach cancer per year are attributed to the bacterium *Helicobacter pylori*, first isolated from humans in 1982 (in university research supported by NIH finding), this bacterium has been shown to cause duodenal ulcers and gastritis. Although other factors are likely to be involved, infection with this bacterium has been shown to lead eventually to the development of stomach cancer. More research is needed to develop effective therapy and vaccines to prevent *H. pylori* infections and to understand its role in cancer.

*Cervical cancer.*—Human papilloma virus infection, a sexually transmitted infection of the cervix, involves a very high risk of developing cervical cancer. The infection is most prevalent in sexually active young adults. More research is needed to develop sensitive and specific diagnostic tests and to better establish the link between the virus and the development of cancer.

*Liver cancer.*—The World Health Organization estimates that globally there are about 527,000 new cases of liver cancer per year: 82 percent of which are attributable to infection with the hepatitis B and C viruses. More research is needed to determine the host factors and mechanisms involved.

In addition to cancer, there is growing evidence that other chronic illnesses may have infectious origins or “co-triggers”. Research suggests that some forms of arthritis, infertility, coronary artery disease, asthma, hypertensive renal disease, and juvenile-onset diabetes are associated with infections. The autoimmune intestinal disorders—Crohn’s disease and ulcerative colitis—are very likely to be triggered initially by a microbial factor. Consequently, the full costs of infectious diseases may be far greater than previously estimated. Confirming the infectious origins of such diseases would greatly reduce health care costs by treatment with antibiotics and other drugs and perhaps by prevention through immunization.

#### *The role of NIAID research and new and reemerging infections*

The ASM recommends that the following language be included in the Senate report to recognize the important role of NIAID research in addressing new and reemerging infectious diseases:

*New and reemerging infections.*—The Committee believes that it is essential that the national strategy to address the threat of new and reemerging diseases be broad based, incorporating research as well as surveillance activities. Biomedical research supported by the NIH/NIAID forms the foundation upon which surveillance and response are ultimately based, providing the basic research tools (diagnostics, vaccines and therapies) necessary to detect and limit the impact of new and reemerging infections. Ongoing research support also contributes to the scientific training infrastructure required to maintain the capability to identify and control new diseases, both nationally and internationally.

#### *National Institute of General Medical Sciences*

The NIGMS has sponsored and continues to sponsor leading edge basic research on recombinant DNA which contributes to direct payoffs in the biotechnology industry. The basic, nondisease targeted research supported by the NIGMS provides the underpinning for all the disease oriented research done by the other Institutes. NIGMS research is showing remarkable progress in areas such as new approaches to drug design, developmental biology in model organisms, understanding of cell-cycle mechanisms and control. Among areas being studied are the structures of key molecules, mechanisms by which genetic information is stored and transmitted and chemical reactions that sustain life. This research provides valuable new knowledge about disease processes and new technologies that underlie advances in disease diagnosis, treatment, cure and prevention. NIGMS research also contributes to commercial applications in the pharmaceutical and agricultural industries. One reflection of the importance of past work done by NIGMS is the frequent selection of Institute grantees for high scientific honors, including Nobel prizes in physiology and medicine.

The NIGMS also has a major involvement in ensuring a highly trained workforce which is essential for the future of biotechnology and for maintaining the future health of the biomedical research enterprise. NIGMS’ role in predoctoral research training helps bring a cadre of well trained new investigators into the research system. Efforts must be continued to try to increase the numbers of minority PhD’s by strengthening the capabilities of institutions to recruit and retain qualified stu-

dents. The ASM urges Congress to provide increased funding for NIGMS research and training programs.

*Research training and infrastructure needs*

NIH support of grants and contracts to universities has a significant impact on the research and educational activities of academic institutions across the country and helps to create jobs at these institutions. This support of higher education and scientific literacy is necessary to ensure that Americans have skills to compete in the international arena. Federal investments in basic biomedical research have also produced the world's finest scientists. Adequate support for research training is necessary to build a foundation for the future to maintain U.S. preeminence in biomedical technology. Successive generations of talented young individuals bring new ideas and renewed energy necessary for continued scientific and technology discovery, which is key to the ability of the U.S. to compete internationally. Adequate funding should be provided for NIH supported National Research Service Award (NRSA) training programs for predoctoral and postdoctoral students at academic institutions.

Increased investment in NIH is also necessary for infrastructure development and enhancement of state-of-the-art research equipment and supplies. Equipment and instrumentation are increasingly expensive, but are necessary to support high caliber research. With the advances in genetics, the need for high quality research involving animal models of human diseases has never been greater. The costs associated with use of transgenic animals are increasing due to the need for disease surveillance and specialized facilities required for these animals. The NIH's National Center for Research Resource (NCRR) supports essential resources for biomedical research. The federal commitment to infrastructure needs should be long-term, stable and allocated on the basis of merit. The Shared Instrumentation and Small Grant Programs and the Comparative Medicine Program for Animal Research require additional funding to provide the necessary underpinning for research efforts.

*NIH research management and support*

The ASM is concerned about continued budget reductions for the RMS budget. Erosion of funding for RMS will impact negatively on science. RMS helps fund scientific workshops and conferences, peer review of grants, site visits for oversight of research programs, outreach programs, communication activities about biomedical research, and adequate stewardship, mentoring, planning and accountability for NIH research and expenditures. The communication of scientific and health information is essential to NIH's mission. It is crucial that NIH communicate effectively with many groups, including scientists engaged in biomedical research, health care practitioners, patients, the general public, the media and the Congress. NIH represents a \$13 billion investment by Americans based upon an expectation of substantial returns to themselves and their loved ones. This investment must be managed wisely to ensure continued public confidence and adequate stewardship of public funds is critical to success. Innovative and quality managers and management systems are necessary to achieve responsible stewardship. Reductions below necessary levels for RMS could interfere with efforts to streamline and reinvent grants management and could impede program growth at NIH.

Thank you for the opportunity to share our concerns with the Subcommittee.

PREPARED STATEMENT OF THE NATIONAL MINORITY PUBLIC BROADCASTING  
CONSORTIA

The National Minority Public Broadcasting Consortia (Minority Consortia) submits this statement on the fiscal year 2000 appropriation for the Corporation for Public Broadcasting (CPB). Our primary missions are to bring a significant amount of programming by and about our communities into the mainstream of public broadcasting. And our primary message today is that we want to get back on course with CPB in our working partnership to increase the diversity of programming available through public broadcasting. We therefore request that Congress provide:

- \$5 million for the Principles of Partnership initiative as agreed to by CPB in 1994 in addition to the current funding provided to the Minority Consortia. We request that any funding increase up to \$5 million over the fiscal year 1999 level be provided for this far-sighted initiative; and
- \$325 million in fiscal year 2000 CPB funding as requested by the Administration.

A commitment of \$325 million by the federal government to public television and public radio is a wholly reasonable contribution toward this national treasure. If there is one thing that the past few years debate on public broadcasting has shown

is how highly people in this nation value it. The three years of CPB recessions should be reversed in the fiscal year 2000 CPB appropriation.

Public broadcasting is particularly important for minority and ethnic communities. While there is a niche in the commercial broadcast and cable world for quality programming about our communities and our concerns, it is in the public broadcasting industry where minority communities and producers are more able to bring you quality programming for national audiences. In 1994, CPB initiated research among Asian American and Native American communities documenting that respondents felt their communities were negatively stereotyped on commercial television but that public television had more realistic portrayals.<sup>1</sup> This survey also revealed that both groups wanted increased visibility in public television and further recommended that there be expanded promotion of public broadcast programming utilizing Asian-American community groups and tribal organizations. Earlier CPB surveys of the Latino and African American communities showed similar findings.

It is clear that we and our communities<sup>2</sup> and CPB need each other to address the Congressional mandate regarding minority communities and minority programming in the CPB authorizing statute. CPB, the Public Broadcasting System (PBS) and America's Public Television Stations (APTS) and the stations want and need the culturally diverse programming for public broadcasting that the five Minority Consortia organizations can help develop, produce and distribute. We, on the other hand, need continued financial and in-kind resources from CPB and public broadcasting to increase our programming production capacity and to facilitate business planing toward financial self-sufficiency. We have had some promising negotiations with CPB, PBS and APTS over the past several years on both of these counts, but neither effort has yet carried through to fruition.

Principles of Partnership Initiative. Below is a brief description of partnership effort between the Minority Consortia, CPB, APTS and PBS which we urge Congress to support:

In 1994, after protracted discussions, CPB publicly announced funding to formalize partnerships between the Minority Consortia organizations with CPB, PBS, APTS and television stations to maximize all our resources in an effort to increase multicultural educational programming for television. The funding for this Principles of Partnership initiative, \$5 million, was to begin October 1, 1995. Concurrent with this funding, the Minority Consortia agreed on a joint plan of distribution methodology, allocating funds for production, community capacity-building, and program support functions. This agreement between the Minority Consortia and CPB was announced with considerable fanfare in a CPB newsrelease and reported in the public broadcast press in June, 1994. There is also a lengthy section (attached) on the Principles of Partnership agreement in the CPB report presented to the 103rd Congress, *Reaching Common Ground: Public Broadcasting's Services to Minorities and Other Groups*, July 1, 1994.

The Principles of Partnership included:

- establishment of an annual \$5 million Minority Program Fund for development, production and capacity-building, including promotion and outreach;
- each Consortia organization would enter into a partnership with a public television station;
- producers of all races and backgrounds and from consortia, stations, and regional networks would be eligible to submit proposals and receive grants;
- grants would be available to national and regional programs as well as audience-building and outreach services and "capacity building" activities;
- CPB would create system advisory panels including top CPB, PBS and APTS programmers, station executive and independent producers;
- programming supported by the Minority Program Fund would be available to all PTV stations;
- after five years, the arrangement would be evaluated and changed if advisable.

<sup>1</sup> *Reaching Common Ground: Public Broadcasting's Services to Minorities and Other Groups*, July 1, 1994, pages 41–42 of the Appendix.

<sup>2</sup> The communities we represent are not marginal in number. We are an increasingly large portion of the U.S. population. According to 1996 figures, the communities represented by the Consortia collectively constitute more than 27 percent of the U.S. population and are projected by the Census Bureau to constitute nearly 50 percent of the U.S. population by the year 2050. In addition, children, who are a primary focus of public broadcasting, comprise a much greater percentage of the minority population than the public at large. The Census Bureau, in an August 1995 publication, shows that while 20.4 percent of people in the U.S. are under age 15, children and youth constitute a much higher proportion of minority groups. Persons under age 15 make up the following proportions of our communities: African American, 36.5 percent; Indian/Aleut/Inuit, 29.8 percent; Asian American/Pacific Islander, 27.6 percent; and Hispanic, 30.7 percent.

Unfortunately CPB, citing budget cuts, decided not to provide the \$5 million funding for the partnership initiative. However, CPB did create an \$11 million "Futures Fund" which contained no specific initiatives for the work of the Minority Consortia. Because the Principles of Partnership funding was to be in lieu of funding increases (as supported by Congress) for infrastructure and program development, we feel strongly that CPB, despite budget pressures, should have committed funding for the Principles of Partnership—the timing was optimum. By the end of 1994, we had been working with CPB, APTS, and PBS, and others in the public broadcast field for over a year to reach this agreement. Understanding and good will was at an all time high among the "principals" of this partnership.

*Crossing Cultures Initiative.*—Following the demise of the Principles of Partnership plan, the Minority Program Consortia worked with CPB and submitted to the Corporation in January of 1996, a multi-faceted proposal entitled Crossing Cultures.<sup>3</sup> That proposal focused on efforts to attain financial self-sufficiency through diversifying and expanding our revenue sources and developing joint ventures in marketing and distribution services to better meet the growing needs of our increasingly diverse audiences. This proposal also involved streamlining operational efficiencies and strengthening partnerships with public broadcasting stations and organizations. While this proposal is consistent with the types of activities CPB is funding through its \$11 million Futures Fund, we do not have a clear idea of CPB's commitment to our proposal. And the proposed fiscal year 2000 CPB budget has no specific vision for continued mission and support of the Minority Consortia and increased multicultural programming.

The Minority Consortia tried to assist CPB in finding a consultant who could work with each of us on the fact finding and assessment necessary to make sound business decisions about developing these joint ventures and revenue streams. Last fall CPB hired a consulting group whose work is currently in progress. We now look for assurances that CPB will commit funding resources to implement the plan. The report of the consulting group is to be completed by June 1997.

*Congressional Support/Funding History.*—Since 1988, eight House and Senate authorizing and appropriations reports have expressed support for CPB funding of the Minority Consortia<sup>4</sup> and multicultural programming.

Despite good Congressional interest, funding for the work of the Minority Consortia has remained extremely modest and has certainly matched the overall increases for CPB since the 80's. For instance, in fiscal year 1982, the first year that CPB provided organizational support funding for four consortia organizations, we collectively received \$581,000, or .36 percent of the CPB budget. By fiscal year 1986, that figure was up to .42 percent, or \$663,500 for organizational support of out a total CPB appropriation of \$310 million.

In fiscal year 1990 CPB provided the first Multicultural Program Funds<sup>5</sup> (\$800,000) to the Minority Consortia organizations. These Multicultural Program funds are not retained by our organizations, but rather are regranted to producers for public television programs.

The most recent Congressional report (H. Rpt. 102–363)<sup>6</sup> accompanying a CPB reauthorization Act states:

The Committee is concerned that despite the mandate of the 1988 legislation, funding for the five minority consortia as well as the production of na-

<sup>3</sup>NLCC was not a participant in the proposal as originally presented.

<sup>4</sup>House Report 100–825, report of the House Committee on Energy and Commerce on the Public Telecommunications Act of 1988; Senate Report 100–444, report of the Senate Commerce, Science and Transportation Committee, on the Public Telecommunications Act of 1988; House Report 102–363, report of the House Committee on Energy and Commerce on the Public Telecommunications Act of 1991; Senate Report 102–221, report of the Senate Commerce, Science and Transportation Committee report on the Public Telecommunications Act of 1991; House Report 102–708, report of the House Appropriations Committee on the Fiscal Year 1993 Labor, HHS, Education Appropriations Act (fiscal year 1995 CPB funding); House Report 103–156 report of the House Appropriations Committee on the Fiscal Year 1994 Labor, HHS, Education Appropriations Act (fiscal year 1996 CPB funding); House Report 103–553, report of the House Appropriations Committee on the Fiscal Year 1995 Labor, HHS, Education Appropriations Act (fiscal year 1997 CPB funding); and House Report 104–659 report of the House Appropriations committee on the Fiscal Year 1997 Labor, HHS, Education Appropriations Act (fiscal year 1999 CPB funding).

<sup>5</sup>The Multicultural Program Fund was mandated by the Public Telecommunications Act of 1988. Congress left the decision of the funding level to CPB, which has funded the program at about \$3 million annually.

<sup>6</sup>House Report 102–363, the House Committee on Energy and Commerce report accompanying the Public Telecommunications Act of 1991 (Pub. L. 102–366, signed August 26, 1992), which applies to fiscal years 1994, 1995, and 1996. Congress has not enacted reauthorization legislation since Public Law 102–366.

tional programs by and about ethnic minorities in America remains inadequate. The Committee encourages CPB to increase significantly (emphasis added) its funding both for the five minority consortia and the Minority Program Fund.

The above language applied to fiscal years 1994, 1995, and 1996. During that time the CPB organizational or administrative support for the Minority Consortia increased from \$1.25 million to \$1.5 million—not what we would term a significant increase to support all minority programming for public broadcasting. During these years, CPB decided to increase the amount of Multicultural Program Funds that we would administer—we had been administering about \$1 million of the \$3 million Multicultural Program Fund. Beginning in fiscal year 1994, we received \$1.6 million in Multicultural Program Funds. Beginning in fiscal year 1995 we administered the entire Multicultural Program Fund. As of fiscal year 1997 we will receive 1.7 percent of the CPB budget in combined organizational support program funds (\$1.45 million in organization support and \$3.3 million in Multicultural Program funds for the five organizations combined). Despite ups and downs in annual appropriations, funding for CPB grew 72 percent from fiscal year 1985 through 1997. During this same time CPB funding for the minority consortia organizational support went from \$663,500 (.44 percent of the CPB budget) to \$1.4 million (.55 percent of the CPB budget).

Last year the House Appropriations Committee in House Report 104-659 instructed the CPB President to be prepared to testify during the fiscal year 2000 hearing (which will be March 19, 1997) regarding steps CPB has taken during fiscal years 1996 and 1997 to strengthen and enhance minority programming, and to support minority media professionals career development.

Common Concerns. When we say that we want increased programming by and about our communities, we do not mean that our programming is limited in its value to members of our communities. Nothing could be further from the truth. The notion that minority producers cannot produce programming of interest to the general viewing audience has permeated the system for too long. Our concerns are common to all of America—crime, drugs, literacy, education, teen age pregnancy. Examples of minority programming well received by the general viewing audiences include *Stand and Deliver*, *Maya Lin*, *Daughters of the Dust*, *Storytellers of the Pacific*, and *In the White Man's Image*. The list is very long.

It is true that we are extremely interested in bringing to the general public our histories—histories which include family traditions, educating our youth, the civil rights movement—which have for too long been unreported and misrepresented. It is in the national interest that the many peoples who form the mosaic of the United States better understand and appreciate each others history, culture, and contributions to today's society.

Thank you for consideration of our request to fund the Principles of Partnership Initiative. Congress has the power to help public broadcasting renew its commitment to the work of the Minority Consortia in expanding the diversity of public programming and attract new audiences to the public broadcasting system.

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PREPARED STATEMENT OF LYNN A. DRAKE, M.D., PRESIDENT-ELECT, AMERICAN ACADEMY OF DERMATOLOGY

Mr. Chairman and members of the Subcommittee: My name is Lynn Drake, M.D. I am a Professor of Dermatology and Chairman of the Department of Dermatology at the University of Oklahoma Health Sciences Center. I am also President-elect of the American Academy of Dermatology.

My colleagues and our patients thank you, Chairman Specter, and members of the Subcommittee for your continued support for the National Institutes of Health (NIH) and the CDC. The Academy acknowledges the very difficult choices that this Subcommittee has made over the last few years. We are grateful that the biomedical research enjoys bipartisan support in this Subcommittee and in the Congress.

Our nation's biomedical research infrastructure is an intricate relationship of academia, industry, and the federal government. The NIH serves as the primary source for basic research through universities and independent research institutions. This synergy has alleviated suffering for millions of Americans by fostering the development of innovative drugs and vaccines. Biomedical research is also the foundation upon which all medical care is based. Without the NIH we would not be the world leader in research and patient care.

Support for biomedical research has been very good for our patients and our economy. This investment has spawned the development of the biotechnology industry and it is estimated that medical research annually contributes more than \$40 billion

to our economy in non-health areas from spin-off discoveries. For example, research advances in fiber optics made important contributions to the development of laser medicine. As the saying goes, "A rising tide lifts all boats."

Dermatologists are trained to treat over 3,000 disorders of the skin, hair, nails and mucous membranes. Support for the NIH, most especially NIAMS, has broadened our knowledge of common as well as rare skin diseases.

To ensure that NIH funding levels are consistent with the research opportunities identified in the NIH professional judgment budget, the American Academy of Dermatology supports a funding increase of 9 percent for the NIH in fiscal year 1998. In addition, the Academy also requests an increase for the Centers for Disease Control and Prevention's Skin Cancer Prevention Program. This program is currently funded at a level of \$1.8 million. We request that funding for this program be increased to \$3 million.

Skin cancer is the most frequent cancer diagnosis, more than all other cancers combined. This year, over 1 million new cases of skin cancer will be diagnosed in the United States. Nearly 80 percent of the new cases will be nonmelanoma skin cancers, namely basal cell or squamous cell carcinomas. Although both basal cell and squamous cell carcinomas have a cure rate of 95 percent if detected and treated early, 1,200 Americans will die of these nonmelanoma skin cancers.

Melanoma is the most deadly form of skin cancer. It is estimated that 40,300 new cases of melanoma will be diagnosed this year, an increase of 12 percent over 1995 levels. Melanoma is deadly. This year, 7,300 Americans will die from melanoma, accounting for six out of every seven skin cancer deaths. While the death rate from melanoma continues to be highest for older white males, melanoma strikes across the age spectrum and is now the most common cancer among people between the ages of 25 and 29.

Skin cancer is preventable. A determined public health effort of prevention, education and early detection, combined with basic biomedical research into the mechanisms of skin cancer, will reduce the incidence of skin cancer and skin cancer-related deaths. The Academy believes that this important skin cancer prevention program should receive additional resources to enhance the multi-faceted activities of the National Skin Cancer Prevention Program. If funding levels were to be increased from the current level of \$1.8 million to \$3 million in fiscal year 1998, the funds would be well spent. These additional dollars would allow the CDC to expand its efforts to teach children and their care givers about healthy skin behaviors, to strengthen professional education activities, to disseminate skin cancer prevention guidelines to our nation's schools and to monitor the behavioral risk factors for skin cancer.

Skin cancer can also be effectively treated, if found early. I invite all the members of the Subcommittee to participate in an upcoming annual skin cancer screening of Congress. Members of the Washington, DC Dermatological Society will conduct a free skin cancer screening on May 7, 1997 between 10:00 am and noon in the Rayburn First Aid Station, Room B344.

Biomedical research is beginning to provide answers to our questions about skin cancers. Earlier this year, researchers supported by the National Institute of Musculoskeletal and Skin Diseases (NIAMS) and the National Cancer Institute (NCI) significantly advanced our understanding of skin cancer. Scientists identified the gene that is the cause of a rare inherited disorder, basal nevus syndrome, and acquired basal cell carcinoma. We are hopeful that NCI-supported scientists will be successful in their efforts to develop a melanoma vaccine.

Researchers believe that their findings may eventually lead to innovative treatments for basal cell carcinomas. Today, dermatologists treat basal cell carcinoma with some type of surgery, although radiation and chemotherapy are sometimes used alone. Innovative treatments that could block the mutation of this gene would have many benefits and should lower costs.

In December, I organized an NIH workshop on Patient Outcomes in Basal Cell and Squamous Cell Skin Cancer. The goals of this workshop were to examine the adequacy of data sources now available; to examine the morbidity and socio-economic burden of nonmelanoma skin cancers; to review ongoing programs; and to identify research opportunities to improve patient outcomes across the health spectrum. I cannot stress, enough, the importance of outcomes research. This research is especially critical to understanding better the success of diagnostic and treatment decisions for skin and other disease. In fact, outcomes research will provide key information on such important issues as quality of life, patient satisfaction, and cost-effectiveness, and will greatly influence medical decision-making. Outcomes research should be funded.

The research supported by the NIH is crucial to our fight against other chronic, debilitating and sometimes fatal skin diseases. Skin diseases are an important



health concern for this country. This year, it is estimated that 60 million Americans will be affected by skin disease, costing our economy over \$7 billion in treatment costs and lost productivity. Occupational skin disease remain one of the most common causes of worker's compensation claims. An increase of 9 percent would provide \$280 million to the NIAMS, or approximately 2 percent of the total cost of skin disease.

Psoriasis is a common skin disorder, affecting 1–2 percent of the population. Previously scientists believed psoriasis to be a primary disorder of the keratinocytes, the most common cell in the outer layer of the skin. Recent investigations have greatly altered our understanding of psoriasis. Some researchers now view psoriasis as an immunologic disorder, and this observation has led to new treatments for psoriasis. A tissue bank established by the National Psoriasis Foundation and supported by the NIAMS is helping scientists make progress in identifying the genes linked to this disease.

Eczema is a term often used to describe a family of conditions that include: atopic, contact, occupational, seborrheic, and stasis dermatitis. Millions of Americans suffer from some form of eczema. While bench to bedside research is beginning to pay dividends, there is much we do not know about how to prevent and best treat eczema. There is considerable interest around the world in identifying the numerous allergens that trigger eczema and protecting patients from them.

Rosacea is a common, chronic skin disease that we are now just beginning to understand. Although this disease may affect children, it is usually a disease of adults. Some estimate that rosacea affects at least 20 percent of the adult population, and that perhaps 40 percent of those over age 50 are affected. It is characterized by extended blushing or by redness of the central area of the face due, in part, to telangiectasias, the dilation of the small blood vessels. Rosacea is frequently misdiagnosed as adult acne, because acne-like blemishes are a main symptom of the disorder. Unlike acne, comedones (blackheads) are rare. When severe, individuals can have disfigurement of the nose, which is commonly mistaken for alcohol abuse. Rosacea is a complex problem and its cause remains unknown. Emotional stress, exposure to UV radiation, extremes in temperature, alcohol, menopause, and some food preservatives can aggravate the condition. More research is needed to determine the cause of this disorder, to better understand how environmental conditions affect patients, and to discover more effective treatments.

Mycologic or fungal infections are a major health problem, affecting nearly 18 percent of the U.S. population. Dermatologists treat fungal infections of the nails, skin, and hair. Fungal infections can vary in severity, but can be most serious in individuals who are already immune-compromised—individuals suffering from diabetes, cancer, AIDS or other diseases. In these individuals, the infection may be atypical, serious and aggressive, making treatment more difficult. More research is needed to develop antifungal treatments which are less costly and less toxic.

Alopecia areata is a disease which causes hair loss on the scalp and elsewhere on the body. In its most severe form, alopecia universalis, all hair on the entire head and body is lost, leaving the skin unprotected from the sun and other environmental hazards. The nose and sinuses are also unprotected from foreign particles and bacteria. Children are the most often affected by this disorder. While alopecia areata is not life threatening, it is emotionally and psychologically devastating to these young children. To date, there have been two international workshops on this disorder, but much remains unanswered. Researchers are still unclear as to what triggers the attack on the hair follicle. Is alopecia areata an autoimmune disease, an immune-mediated disease, what is its genetic link? Without answers to these basic questions, we cannot hope to develop more effective treatments or a cure.

Systemic lupus erythematosus (lupus or SLE) is a disease affecting disproportionately young African-American women, and a disease of great interest to members of this subcommittee. Research has significantly broadened our knowledge of the genetic factors involved in lupus, including those infectious agents and other environmental factors that trigger this disease in susceptible individuals. Research advances in lupus have been cost effective—delaying kidney failure due to nephritis, the most serious common complication of this disease.

Scleroderma is another serious disease that predominantly strikes women of childbearing years. Scleroderma is a chronic, auto-immune disease of the connective tissue. Scleroderma patients overproduce the protein, collagen. Its cause or causes are unknown. The treatment program for these patients varies widely, depending on the severity of the symptoms. Women with this disease may have thickening of the skin, especially around the joints; Raynaud's Phenomenon, an abnormal sensitivity to cold; gastrointestinal, renal, cardiac and pulmonary problems. The NIAMS supports both basic and clinical research on scleroderma. Recently, NIAMS

added scleroderma to the list of diseases eligible for applications under the Specialized Centers of Research (SCOR) program.

Vulvodynia is a spectrum of chronic vulvar pain disorders. Today, no one knows what causes vulvodynia. Some cases of this disorder may be attributed to compression or disease of the pudendal nerve, others to Human Papilloma Virus (HPV), chronic candida infection and reactions to the anti-fungal treatments for candidiasis, but there is no clear agreement. There is also no specific test for vulvodynia and diagnosis is often after ruling out other illnesses or infections. Unfortunately, there are no cures for this disorder, treatment is symptomatic. Additional research is desperately needed to answer the numerous questions concerning this disorder.

Sjogren's Syndrome is a third auto-immune disease that predominantly strikes women. The clinical manifestations of Sjogren's Syndrome are the result of decreased exocrine gland function throughout the body. Dry skin, sweating and itching are frequent symptoms as are drying of the eyes and other mucosal surfaces. In addition, Sjogren's Syndrome is associated with a number of life-threatening complications, including renal disorders and vascular complications. Currently, there is no known cure for Sjogren's Syndrome and the treatments available are aimed only at relieving the many symptoms of this syndrome.

Dermatitis herpetiformis is an intensely itchy, chronic disorder that may start at any age, including childhood. Most patients who suffer from this disease have an associated sensitivity to gluten, a protein found in wheat, oats, barley, rye and other grains. Dermatitis herpetiformis may often be confused with many other conditions, including scabies, chickenpox and eczema, and patients may be misdiagnosed before being effectively treated. Like Sjogren's Syndrome, individuals with dermatitis herpetiformis have a marked increase in the incidence of certain histocompatibility antigens and it is not uncommon that these two disorders are occasionally seen in the same patient.

The Ichthyoses are a family of skin diseases in which there is abnormal development of the outermost layers of the skin. Researchers have discovered that the genes for many of the molecules involved with the structure of our skin are clustered on chromosome 1, in an area called the epidermal differentiation complex. Recent findings have linked several forms of ichthyosis, including a form that causes self-amputation, to mutations of a region of chromosome 1—the first time that disease was clearly linked to the epidermal differentiation complex.

Epidermolysis bullosa (EB) is another rare skin disease that has provided us with a great deal of information about skin. Researchers have identified specific genetic defects that cause several forms of EB. The establishment of an EB registry has allowed scientists to collect medical information and tissue and blood samples from EB patients, greatly facilitating efforts to identify the genetic causes of EB. Recently, researchers have uncovered an exciting link between the molecular mechanisms leading to skin fragility in EB and the muscle wasting associated with a variant of muscular dystrophy.

Pemphigus, like EB, is a blistering skin disease. In pemphigus, patients produce autoantibodies that attach the desmosomal proteins that hold the skin together. Future research in this disease is needed to learn how and why these autoantibodies form as well as to determine the relative role of environmental factors—such as viruses, bacteria, allergens and toxins—to this disease.

Ehlers-Danlos Syndrome is another group of rare inherited disorders that affects the skin as well as the joints and other organs. Patients with Ehlers-Danlos Syndrome have extremely fragile skin that bruises and tears easily, and these wounds may take weeks or even months to heal. The NIAMS has been the lead institute in research efforts to understand the mechanism of wound healing and this effort must continue to be supported.

Marfan Syndrome is a heritable disorder of the connective tissue, caused by single abnormal or mutant gene. In addition to the skin, patients with Marfan Syndrome suffer from abnormalities in three areas: the eye, the skeletal system and the cardiovascular system. The severity of this syndrome varies greatly; and as there are no objective tests for diagnostic confirmation, diagnosis can be difficult. There is still no cure for Marfan Syndrome, although a variety of treatments have been used with some success.

Ectodermal Dysplasia (ED) is not a single disease, but a group of closely related disorders. More than 130 types of ED have been identified. Individuals with ED have absent or poorly functioning sweat glands; abnormal hair and hair follicles, and the natural hair and skin oils may be missing. Patients with ED are prone to rashes and are slow to heal when they are bruised or cut. Many are photosensitive, but the most common trait is the absence of teeth. Although many types of this disease have been identified and documented, there is a great deal that we do not

know about these disorders. Additional research is needed to improve the care and management of these patients.

Pseudoxanthoma elasticum (PXE) is a heterogeneous inherited disorder, the hallmark of which is the dystrophic calcification of the elastic tissue of the skin, the eyes and the arteries. PXE may be inherited as either an autosomal recessive or dominant trait, but environmental influences may modify the clinical expression of this disease. As are most inherited diseases there is no known cure for PXE. Because the skin manifestations of this disease are so prominent, the dermatologist is often the specialist who makes initial diagnosis and who can coordinate the care of the PXE patient with the ophthalmologist, cardiologist, vascular surgeon, plastic surgeon, and other health professionals. Additional research is desperately needed to answer the many now unanswerable questions about PXE—what is the genetic cause for this disease, how can we best treat it, how can we prevent it?

Sturge-Weber Syndrome is characterized by an extensive vascular nevi or port wine stain at birth, involving the upper eyelid and forehead. In Sturge-Weber, the port wine stain is associated various neurological abnormalities as well as irregularities in the eyes and internal organs. Children with Sturge-Weber begin to have seizures at one year of age. These convulsions are caused by an excessive growth of blood vessels on the brain and often appear on the opposite side of the body from the port wine stain. The cause of this syndrome is unknown and more research is needed.

Porphyrias are a group of seven, rare and complex disorders. The porphyrias are characterized by a mutation in genes that code for various enzymes of the heme biosynthetic pathway; and each porphyria is biochemically unique. What causes these genes to mutate is still unknown. These diseases are often manifest as a variety of cutaneous lesions and patients are also very sensitive to sunlight and to many drugs. There is no cure for porphyria and treatment varies depending on the type. Additional research is needed to better understand what causes the genes to mutate. Better understanding of this process could eventually lead to the development of new and better treatments.

Vitiligo is a disease in which patients develop white spots in the skin that vary in size and location. These “spots” develop when the pigmented cells of the skin, melanocytes, are destroyed and melanin can no longer be produced. It is estimated that 1–2 percent of the population suffers from vitiligo, and in earlier times, these individuals were often confused with lepers. Although more noticeable in darker complected individuals, vitiligo strikes all races equally. More research is needed to understand why the body destroys these cells as well as to understand the relationship of this skin condition to its many complications, including Graves’ Disease and other diseases of the thyroid, deafness and blindness.

The Academy also supports adequate funding for other institutes at the NIH. The National Institute for Allergy and Infectious Diseases (NIAID) funds important research on AIDS, sexually transmitted disease (STD), and other infectious disease. Dermatologists daily treat the many cutaneous manifestations associated with HIV infection. These diseases include bacterial infections, viral infections, fungal and yeast infections, protozoal infections, hyperkeratotic and neoplastic diseases of the skin. Dermatologists also treat other STDs, such as genital herpes, human papilloma virus, and genital warts. Future research opportunities for HIV and other STDs include the development of topical microbicides, new and more effective therapies, vaccines and improved prevention strategies.

Our skin is our first defense against disease and toxins in the environment. The Academy supports increased funding for the National Institute of Environmental Health Sciences (NIEHS). Our specialty has taken a lead on environmental hazards to the skin, at home and at work. Increased funding for NIEHS will allow this institute to expand research on the action spectrum for melanoma, percutaneous absorption of toxic and other chemicals and how that absorption may be affected by exposure of the skin to ultraviolet radiation.

Expanding our basic knowledge of the human skin will provide insight into other systemic disease and may provide better treatments. The skin is an excellent delivery system for drugs. The development of skin patches and other devices allow for sustained release of drugs.

Mr. Specter and members of the Subcommittee, as I stated earlier, biomedical research is the foundation upon which all advances in medical treatment is based. I appreciate your attention and the opportunity you have given the American Academy of Dermatology today and welcome the opportunity to answer any questions.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS

ANAD is America's oldest non-profit organization dedicated to the prevention and treatment of eating disorders. Founded in 1976, ANAD provides free helping services for the estimated eight million victims in the United States.

ANAD's goal is the recognition of anorexia nervosa, bulimia and other illnesses for research, education and prevention efforts so that eating disorders can be eradicated.

The Association supports equal treatment under insurance and medical reimbursement rules for these illnesses, which affect individuals both physically and mentally. Access to appropriate care is severely limited in today's managed care environment.

Eating disorders strike all segments of our population, ruin lives, and often cost tens of thousands of dollars to treat a single case. Anorexia, bulimia and related illnesses have one of the highest mortality rates of any psychiatric illness—as many as six percent of serious cases die. Some studies indicate that the incidence of eating disorders is growing rapidly in increasingly younger populations.

An ANAD 10-year study documents that 43 percent of victims report the onset of their illness by age 15 and 86 percent by age 20, but only 50 percent report being cured. Large numbers of sufferers are now in their twenties, thirties, forties or older.

Dr. Timothy Brewerton of the Medical University of South Carolina surveyed 3,100 fifth through eighth grade students. Forty percent felt they were too fat or wanted to lose weight even though less than 20 percent actually were overweight. One third of these children said they dieted, 10 percent had fasted, and almost five percent had vomited to lose weight. Any child who maintains these behaviors for any length of time runs the risk of developing a serious illness.

It is not surprising, given our culture's obsession with thinness, and billion dollar industries dedicated to weight loss, that large numbers of young people abuse and misuse diet products sold over the counter and without any restrictions. They are not aware that these potentially dangerous products can cause lifelong problems or even death.

While other illnesses, including alcoholism and chemical dependency, receive massive levels of funding for research and prevention, eating disorders remain the major illnesses in our nation which receive totally inadequate support and understanding.

For these reasons we ask Congress to allocate \$10,000,000 to prevent eating disorders through education and public awareness programs. We ask another \$10,000,000 be allocated for research and that part of the research funding be allocated to study and promote primary prevention.

Prevention programs available at an early age could be instrumental in reducing the incidence of eating disorders. We need to teach correct notions about nutrition, body development and growth in an atmosphere which also encourages emotional health. We need programs designed to support the best life decisions. Our young people need to learn self-respect, appropriate responses to both successes and failures, and ways of handling change, which is always difficult for a person with an eating disorder.

Although eating disorders have many causes, funding is desperately needed to develop a comprehensive public health program to educate our youth and our citizens in general to overcome our mistaken and dangerous fascination with thinness as an ultimate ideal and to focus on the real values in life and health. The media barrage which promotes thinness is so enormous that inaction regarding these issues is unthinkable!

ANAD urges the Senate to act on this issue, thereby saving both money and needless suffering. ANAD's track record indicates that low-cost education and health services can be effective in helping individuals with these illnesses and preventing them.

SIGNIFICANT CONCERNS TO BETTER UNDERSTAND EATING DISORDERS ISSUES

*Need for Access to Treatment:*

High-quality treatment for eating disorders is available. Unfortunately, large numbers of victims are unable to actually access this treatment. Victims of eating disorders who have private insurance routinely are refused reimbursement for the treatment they require.

Typically, people who have eating disorders require specialized medical and psychiatric treatment. But, because insurers often treat eating disorders only as a mental illness, patients are both denied the medical treatment they require and subjected to the extremely low caps on benefits for treatment of mental illnesses.

For example, patients with serious eating disorders often require extensive medical treatment to restore the weight they have lost. Ideally, this weight restoration should occur concurrently with the provision of psychological services and behavior modification. Yet most insurance companies will not cover medical services and psychological services concurrently—making it hard for patients to receive comprehensive treatment.

Action must be taken on many different fronts to improve patients' access to treatment for their illnesses. On the legislative front, proposals for insurance reform and health care reform must ensure that patients with eating disorders can receive reimbursement for both medical treatment and mental health care.

ANAD is working for equal treatment of mental and physical disorders under both federal and state insurance laws. The cost of not treating eating disorders is often hidden by confused and fragmentary diagnosis and reporting. Eating disorders are often categorized by their most severe symptoms, including gastrointestinal problems, kidney failure, and loss of bone density. Early recognition and equal coverage by insurance carriers and managed care organizations will assure that the staggering costs of care for a full-blown case will be avoided.

Large numbers of victims, for example, having lost more than 15 percent of their ideal body weight, require extensive medical monitoring and treatment, often in an inpatient facility at a cost of \$30,000 or more monthly. The cost of outpatient treatment, generally lasting two years or more, can exceed \$100,000.

*Need to Train Health Care Professionals to Recognize and Treat Eating Disorders:*

Because eating disorders are complicated illnesses requiring multidisciplinary treatment, it is also important to educate health care professionals from all disciplines on the recognition and treatment of these illnesses. We believe it is particularly important to provide this training to internists, pediatricians and other health care professionals who are not specialists in eating disorders, because these are the health care professionals most likely to first come in contact with a person who has an eating disorder. In many cases—especially in managed care systems—these are also the doctors who are responsible for authorizing referrals and specific treatments, so it is critical that they know as much as possible about these illnesses.

*Research Evaluating Prevention and Self-Help Strategies:*

We also need to encourage and fund research that evaluates which prevention and self-help support strategies are most effective. We want to emphasize, however, that it is urgent to begin implementing promising strategies to primary prevention now. If we hold off on implementing primary prevention strategies until the value of each and every prevention strategy has been thoroughly documented, it will be years before we can adequately address the dangerous—and growing—problem of eating disorders in America.

ANAD: AN ASSOCIATION OF LAY AND PROFESSIONAL PEOPLE DEDICATED TO ALLEVIATING THE PROBLEMS OF EATING DISORDERS

*Programs and Services:*

ANAD serves the nation, and increasingly the world, as an Association concerned with providing programs for the entire eating disorders field. Twenty-one years after its inception on March 4, 1976, ANAD leads the fight in the battle against deadly eating disorders with a multi-faceted program.

**Counsel:** Through its hot-line and response to mail inquiries, ANAD provides counsel and information to thousands of anorexics, bulimics, compulsive eaters, their families, and to health professionals from all parts of the globe.

**Referral List:** ANAD's referral list includes over 2,000 therapists, hospitals and clinics which treat eating disorders in the U.S., Canada and several other countries.

**Early Detection:** This program alerts parents, teachers and the general public to the dangers of eating disorders and to the value of early detection and treatment.

**Education:** ANAD distributes information about eating disorders to health professionals and interested people to inform them on the various aspects of eating disorders. Libraries, schools, universities and other institutions use ANAD as a resource center.

**Publicity:** Through ANAD's efforts, articles on eating disorders have appeared in hundreds of newspapers and magazines. ANAD has participated in numerous national and community radio and television programs.

**Support Groups:** ANAD assists in the formation of chapters and self-help groups so that victims and their families may meet others with similar problems. There are now chapters in 46 states and in fifteen foreign countries.

**National Newsletter:** ANAD distributes the newsletter to tens of thousands of sufferers and concerned family members, health professionals and schools to provide educational information and an exchange of feelings and ideas.

**Research:** ANAD research projects have helped significantly to increase the understanding of eating disorders in the United States, especially in demonstrating that anorexia nervosa, bulimia nervosa and compulsive eating are at epidemic levels and strike every segment of American society. The Association has encouraged and participated in numerous other research projects designed to better understand eating disorders.

**Insurance Discrimination:** ANAD is working to halt widespread discrimination against the sufferers of anorexia nervosa and bulimia.

**Consumer Advocacy:** ANAD has successfully prevented dangerous slogans such as "You can never be too rich or too thin" from appearing in national ads. ANAD continues to monitor advertisers, and has initiated a campaign against the sale of over-the-counter diet products such as diet pills, laxatives, diuretics, and emetics to adolescents.

**Presentation at Congressional Hearings:** ANAD representatives have appeared at congressional hearings to testify on the dangers of adolescent dieting and potentially dangerous diet products, to promote sound governmental programs and consumer protection in the eating disorders field.

**Conferences/Seminars:** ANAD provides national and community education and training conferences, seminars and lectures for health professionals and lay people. All services are free.

#### ANAD PREVENTION/EDUCATION PROGRAMS

A primary purpose and program thrust of the National Association of Anorexia Nervosa and Associated Disorders—ANAD—is to prevent eating disorders.

Prevention programs are undertaken throughout the year and are carried through in the following manner:

- Each year, ANAD prevention/education packets are sent to thousands of primary and secondary schools, colleges and universities, groups and associations to alert professionals, students, parents and other concerned people to the dangers of anorexia nervosa, bulimia and compulsive eating, to educate them regarding the symptoms of these epidemic illnesses and to enlist their participation in helping others to understand and support efforts to prevent eating disorders. Materials are sent throughout the United States and to several foreign countries.
- Thousands of talks, lectures, workshops and seminars on understanding and preventing eating disorders are made each year by ANAD group leaders, trained volunteers and staff. These presentations are made to students, school counselors, athletic directors, health professionals, parent groups, professional associations, sororities, hospitals, etc. Hundreds of speakers are located in most states and in several foreign countries. Printed material on preventing and coping with eating disorders are made available to those who attend these presentations.
- ANAD is represented at hundreds of health fairs each year.
- Video tapes representing the dangers and problems of eating disorders are used in many lectures and workshops. These tapes are made by network and community companies and are used with their permission.
- ANAD officers, staff, volunteers, Advisory Board members, and affiliated health professionals have appeared on numerous national and local television and radio programs directed toward preventing and coping with anorexia nervosa, bulimia and compulsive eating.
- Through ANAD's efforts, articles warning of the destructive nature of eating disorders have appeared in hundreds of newspapers and magazines.
- The Association actively fights against the production, marketing and distribution of potentially dangerous diet programs and diet products and the use of misleading advertising.
- ANAD's numerous national and regional conferences and seminars cover extremely important issues. These meetings help train health professionals to treat eating disorders and lay people to better understand and cope with these illnesses as well as prevent them.

## PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

The Association of American Medical Colleges (AAMC) Council of Academic Societies. The AAMC<sup>1</sup>—which represents all 125 accredited U.S. medical schools; some 400 major teaching hospitals; 86 professional and academic societies, representing 87,000 faculty members; and the nation's medical students and residents—appreciates this opportunity to comment on the fiscal year 1998 appropriations for the National Institutes of Health (NIH), the health professions education programs funded through the Health Resources and Services Administration, and the Agency for Health Care Policy and Research (AHCPR). The AAMC thanks the Subcommittee for its continued support of these programs.

*Medical Research*

The Federal Government, through the NIH, plays a unique and vital role in the support of this nation's biomedical and behavioral research efforts. This investment has provided, and continues to yield, the abundance of fundamental and applied biological and biomedical knowledge that fuels the advances in the practice of medicine that have distinguished the United States globally. NIH-supported research continues to make enormous contributions to improving the health and quality of life for all Americans.

In addition, NIH-sponsored research has made significant economic contributions, both locally and nationally. Research conducted and supported by the NIH played a major role in the development and continues to provide the basis for much of the sustained success of the biotechnology, pharmaceutical, and medical device industries.

Still, America faces serious health problems and new threats constantly appear. Congressional support of biomedical and behavioral research has produced a wealth of scientific opportunities to answer these challenges. A testimony to the abundant opportunities available is the NIH Director's professional judgement budget, which calls for a 9 percent funding increase in the coming fiscal year.

For fiscal year 1998, the AAMC endorses the recommendation of the Ad Hoc Group for Medical Research Funding that the NIH budget be increased by 9 percent, as proposed by the NIH Director in his professional judgement budget. The AAMC and the Ad Hoc Group believe that this budget represents the best and most reliable estimate of the level of funding needed to sustain the high standard of scientific achievement embodied by the NIH.

Within the NIH budget, the AAMC has three major areas of concern. First is peer-reviewed, investigator-initiated basic research, which is supported primarily through research project grants. Basic research is the heart of the NIH. Without these inquiries into the fundamental cellular and molecular events of life real, progress toward conquering disease is unlikely. Funding for new research project applications is a particularly critical issue. The innovative ideas proposed in such applications drive medical progress. There is consensus within the research community that the NIH should fund approximately 35 percent of meritorious research project grant applications. A 9 percent increase in funding in fiscal year 1998 would enable the NIH to achieve this goal.

Support for clinical research is the second area of concern. The knowledge gained through fundamental research is only part of the solution. It is the application of this knowledge to clinical problems in the diagnosis, treatment, and prevention of disease that ultimately fulfills the mission of the NIH. Clinical research not only furthers the application of basic research findings, but often provides important leads to identify further basic research opportunities. In recent years, NIH funding for clinical research activities has not kept pace with available research opportunities or with current health needs.

One area of clinical research activity that is of particular interest to the AAMC is the General Clinical Research Centers (GCRC) program, which supports clinical research centers at university-based hospitals throughout the country. GCRCs provide infrastructure to academic institutions through the support of inpatient and outpatient research facilities and other resources crucial to state-of-the-art, patient-oriented research. The network of GCRCs also provides an effective locus for training and career development in clinical research.

The third area of concern is the institutional research infrastructure: the resources and personnel at the medical schools, teaching hospitals, and other research institutions, that enable NIH-supported research to thrive. The GCRC program is an example of the infrastructure support provided by the NIH's National Center for

<sup>1</sup>For fiscal years 1994–96, the AAMC received \$2,385,000 in Federal funding from the National Institutes of Health and the Health Resources and Services Administration.

Research Resources (NCRR). The NCRR is a critical component of the NIH, assuring that the programs of the disease-oriented institutes will have the essential elements of a vigorous research environment. The NCRR provides state-of-the-art instrumentation, advanced technologies, essential animal and non-animal models and resources, and comprehensive support for clinical research.

In addition, NCRR programs emphasize shared resources, which promote the efficient use of scarce Federal research dollars. These programs encourage interactions among scientists, which stimulate interdisciplinary efforts. By providing new research technologies and providing shared resources, the NCRR enhances the productivity of the Federal-academic research partnership. Therefore, the AAMC urges the Subcommittee to pay particular attention to the needs of the National Center for Research Resources.

There is growing concern about the ability of medical schools and teaching hospitals to sustain their research mission. The transformation of the health care system to a market-driven, price-competitive structure poses a significant threat to the fiscal stability of medical schools and teaching hospitals and their ability to maintain an environment for research and innovation. To address many of the unmet needs caused by these increasing fiscal constraints, the AAMC strongly urges the Congress to review the history of the Biomedical Research Support Grant (BRSG) program as a potential model for a program of flexible institutional support. The BRSG program evolved from legislation, enacted in 1960, to provide flexible funds to strengthen and stabilize NIH-supported research programs.

The fundamental rationale for the BRSG Program—that effective health research requires a strong institutional base of support—is even more important in the current unstable environment than it was in 1960. The financial structure of medical schools and teaching hospitals is heavily dependent on clinical revenues and other forms of contributed support made possible by payments for patient care services. There is a growing, pervasive sense that changes in the health care marketplace are endangering this base of support.

A flexible institutional support program would fund biomedical research needs not served by other programs. The program should allow NIH-grantee institutions to exercise on-site judgment regarding emphasis, specific direction, and content of activities supported, thus enabling the institutions to respond quickly and effectively to emerging opportunities and unpredictable requirements, to enhance creativity, to encourage innovation, to provide for pilot studies, and to improve research resources, both physical and human. Such a program would provide flexible biomedical research support to fund new investigators, explore new and unorthodox research ideas and techniques, respond promptly to opportunities that develop in the course of active research programs, and provide central shared resources.

#### *Health Professions Education*

The geographic and specialty maldistribution of physicians in the United States are critical issues facing both the Congress and the nation. The National Health Service Corps (NHSC) and the health professions education programs authorized under Titles VII and VIII of the Public Health Service Act are designed to play a major role in addressing these problems.

The NHSC was established to assist in the recruitment of primary care health professionals for service in shortage areas. In the 1990s, the Corps has seen an overdue but welcome increase in funding, reaching a highpoint in fiscal year 1994 with \$126.7 million. However, more recently, funding has been decreased to \$115.4 million in fiscal year 1997. As a result, the Corps, which made a total of 259 physician awards in 1993–4, could only support a total of 180 physicians in 1996–7. Since the NHSC plays an important role in redressing the geographic imbalance in physician distribution, the AAMC urges the Subcommittee to increase funding for the NHSC to at least \$127 million in fiscal year 1998.

The AAMC thanks the Subcommittee for restoring funding in fiscal year 1997 for the Title VII and VIII health professions and nursing education programs to the fiscal year 1995 pre-rescission level of \$293 million. The AAMC joins the more than 40 national organizations of the Health Professions and Nursing Education Coalition (HPNEC), representing a variety of schools, programs, and individuals dedicated to educating professional health personnel, in urging the Subcommittee to continue its support of the Titles VII and VIII programs by providing no less than \$302 million for fiscal year 1998. This represents a 3 percent inflationary increase in the fiscal year 1997 funding level.

The Title VII programs are designed to meet the nation's needs for an expanded supply of primary health care providers, improve the geographic distribution of health professionals, and increase access to health care in both urban and rural under served areas. Within Title VII, three programs provide support to medical



schools and teaching hospitals for planning, developing, and operating programs that emphasize the education of students and residents in generalist medicine. The AAMC urges the Subcommittee to provide an appropriate level of support for these three programs: general internal medicine and general pediatrics residencies, family medicine training, and preventive medicine residencies.

The AAMC also recommends continued support for geriatric education centers and geriatric training programs for physicians and other health professionals. These centers were created to provide physicians and other health professionals with the skills necessary to care for the growing number of elderly Americans. Support for geriatric training must keep pace with the rising demand for specialized services necessary to care for an aging population.

Title VII also provides grants for the creation and operation of area health education centers (AHECs) and health education and training centers (HETCs). These programs provide clinical training opportunities for medical students and residents in predominately rural settings by extending the resources of academic health centers to communities in need of health care and health education. Through these linkages, AHEC projects, which eventually become state- or self-supported, form networks of institutions that simultaneously provide health care to underserved populations and educational services to students, faculty, and practitioners. The AAMC urges the Subcommittee to continue its commitment to AHECs and HETCs, which exemplify the synergies possible in well-crafted federal-state and public-private partnerships.

As medical schools continue with the AAMC's Project 3000 by 2000 initiative, several Title VII programs assist toward the Project's goal of matriculating at least 3,000 underrepresented minority students in medical schools by the year 2000 and each year thereafter. Grants made to medical schools under the Health Careers Opportunity Program (HCOP) are used to identify and recruit disadvantaged students, facilitate their entry into medical school, and help them complete their education. The Centers of Excellence program extends grants to health professions schools for the establishment and expansion of programs to enhance the academic performance of minority students. The AAMC hopes the Subcommittee's funding recommendations will recognize the crucial support these two programs provide to efforts in recruiting and retaining qualified minority medical students.

In addition, Title VII includes four loan and scholarship programs that assist needy and disadvantaged medical students in covering the costs of their education: the Exceptional Financial Need scholarship; the Financial Aid for Disadvantaged Health Professions Students scholarship; Scholarships for Disadvantaged Students; and Loans for Disadvantaged Students programs. The AAMC hopes the Subcommittee will recommend funding for these programs that is sufficient to help poor and otherwise disadvantaged students overcome the financial barriers they face in pursuing their medical education.

#### *Agency for Health Care Policy and Research*

A fervent drive to cut health care costs, coupled with fierce competition among all sectors of the delivery system, characterize the current health care market place. While these market trends have resulted in reductions in the rate of increase of health care expenditures, many experts have concerns about the impact on quality and appropriateness of care and the choices available to consumers.

The Agency for Health Care Policy and Research (AHCPR) directly responds to these concerns. AHCPR is charged with sponsoring health services research designed to improve the quality of health care, decrease health care costs, and provide access to essential health care services. The agency works in partnership with other federal agencies and private organizations to support research, clinical guideline activities, and the development of quality measurements that bring practical science-based information to medical practitioners, consumers, and other health care purchasers.

The AAMC believes strongly in the value of health services research as this nation continues to strive to provide high-quality health care to all of its citizens. The AAMC endorses the Friends of AHCPR recommendation of a fiscal year 1998 funding level of \$160 million for AHCPR. We urge the Subcommittee to appropriate the necessary funds to allow this agency to sustain its current activities and to continue to advance its mission through new initiatives.

However, the AAMC urges the Subcommittee to limit the transfer of funds to AHCPR from the so-called one percent evaluation set-aside in the Public Health Service. This transfer of appropriated funds to AHCPR causes a certain amount of difficulty in other Public Health Service agencies, particularly the NIH, as the level of transfers increases. In fiscal year 1997 thirty-three percent of AHCPR's budget was derived from other PHS agencies. The President's fiscal year 1998 budget raises

the portion of transferred funds to forty-two percent. The AAMC recommends that funding for the agency should be provided directly through the regular appropriations process.

AHCPR's budget includes a number of projects designed to improve health care quality in a changing health care environment. For example, the Research on Health Care Outcomes and Quality Program supports inquiries into the development of fair and consistent quality measures. These measurements are used in quality management activities to determine whether a particular treatment has the desired effect. To this end, AHCPR partnered with the Center for Health Policy Studies of Columbia, Maryland and the Harvard School of Public Health in the Measurement Typology Project to develop a prototype for measuring clinical quality. AHCPR's fiscal year 1998 budget contains \$5 million for projects designed to develop new measures of health care quality where needed and strengthen the linkage from performance measurement to clinical quality improvement.

To improve clinical practice, AHCPR has re-focused its efforts in the development of clinical practice guidelines. The agency will continue its efforts in this area by supporting evidence-based practice centers to assemble evidence reports on various health conditions. These evidence reports will be designed to assist provider societies, managed care organizations, purchasing groups and others to produce and implement their own clinical practice guidelines and other quality improvement efforts.

Finally, the AAMC continues to support the activities of the Physician Payment Review Commission and the Prospective Payment Assessment Commission. These organizations provide extensive data collection and analytical capabilities that we believe greatly inform the policy-making debate in their respective areas. As Congress continues to address issues in health care, the expertise and unique abilities of these two organizations are valuable national resources that should be preserved.

The AAMC appreciates the continued support the Subcommittee has given these programs. We emphasize again their critical importance and look forward to working with the Subcommittee members and staff to achieve their implementation.

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PREPARED STATEMENT OF THE AMERICAN COLLEGE OF RHEUMATOLOGY

*Arthritis Research at the National Institutes of Health (NIH)*

The American College of Rheumatology is an organization of physicians, health professionals and scientists that serves its members through programs of education, research and advocacy that foster excellence in the care of people with arthritis, rheumatic and musculoskeletal diseases. We are pleased to have the opportunity to provide our views concerning fiscal year 1998 funding for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Allergy and Infectious Diseases (NIAID) within the NIH.

As we look toward the end of the century, the "baby boomer" generation is approaching the stage of life when having arthritis becomes commonplace and the importance of nonfatal conditions (such as arthritis) is the major factor determining the health of the population. No condition impairs the quality of life of more older adults—and does so to a greater extent—than does arthritis. In the elderly population, there is an increased likelihood that an individual will have two or more chronic conditions, and there is an association between the number of conditions present in one person and the occurrence of disability. The provision of care to people who are disabled contributes significantly to the financial costs paid by the government, private insurers, and to society as a whole; and this is expected to increase in the decade ahead.

Arthritis means swelling, pain and loss of motion in the joints of the body. There are more than 100 diseases that cause this condition. These diseases are typically chronic—causing life-long pain and disability. These diseases are also very common and extremely costly. Although some forms of arthritis are predominant in older individuals, arthritis also affects children and adults of all ages.

—Arthritis ranks number 1 among the ten leading health problems of individuals age 50 and older.

—One in 7 Americans has some form of arthritis; by the year 2020, it is expected that this will increase to one in 5.

—Total costs of all types of arthritis and related diseases amount to about \$55 billion each year.

Through increased investment in research, better treatments and management strategies can be developed which will lead to reduced costs, and improvements in the quality of life for individuals with these diseases. Our ability to take advantage

of this opportunity will become increasingly important as arthritis and related diseases become more prevalent in our nation's aging population.

Recent advances in many different fields (including immunology, genetics, infectious diseases, cartilage biology and gene regulation, for example) have brought scientists to the edge of numerous breakthroughs that will be important in our understanding and treatment of many different forms of arthritis. For example, the NIAMS has initiated a multi-pronged approach to understand and treat osteoarthritis (OA). OA can be caused by a variety of genetic, biochemical, and biomechanical factors, but the precise mechanisms by which these various factors cause disease are unknown. Recent research results have provided some fascinating clues to help understand and develop approaches to osteoarthritis.

For the first time, scientists have zeroed in on the location of a gene that predisposes people to systemic lupus erythematosus (SLE, or Lupus), a chronic autoimmune rheumatic disease. Researchers have localized the gene to a region near the end of the long arm of human chromosome 1 in Caucasians, Asians and African Americans with lupus. Identifying genes for lupus will provide new insights as to why people get the disease, and should help researchers develop new treatments or preventive measures.

Researchers have identified six distinct regions that control inflammatory arthritis in rats. Through genetic analysis of rats with different disease susceptibilities and severity, the researchers found that the genetic basis in the inflammatory arthritis bore a striking similarity to what is known about genetics of rheumatoid arthritis. To gain further insight into possible causes of rheumatoid arthritis and other autoimmune diseases, a comprehensive study is being undertaken via a national project involving 800 sibling pairs affected with rheumatoid arthritis.

Rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and perhaps scleroderma fall within the category of autoimmune disease. All are potentially devastating chronic diseases which exact a huge toll in human suffering and economic costs. Because many of these diseases affect women, basic studies will be conducted to increase our understanding of the ways in which gender influences the development of autoimmune diseases and the regulation of immune responses in people with these diseases.

The ACR recommends an appropriation for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of \$280 million for fiscal year 1998.

Arthritis research is also supported by the National Institute of Allergy and Infectious Diseases (NIAID). We therefore support a sufficient increase in funding for NIAID for fiscal year 1998 so that continued emphasis on arthritis research can be maintained. Overall, the ACR joins the Ad Hoc Group for Medical Research Funding in supporting at least a 9 percent increase for NIH as a whole, to bring funding to a level of \$13.9 billion for fiscal year 1998.

Another area of concern to us is support for training new scientists. The ACR believes that there is an overwhelming need to provide for the renewal and expansion of the intellectual capital that is essential to the research enterprise. When the likelihood of an approved research grant proposal being funded declines, the brightest young scientists become discouraged from pursuing research careers—something this country can ill-afford. Steps must be taken now to increase the grant success rate, in order to actively encourage new scientists to undertake, and remain in, research careers.

Discussion of medical research opportunities and the emerging health care needs of an aging nation is properly a part of the national political debate. Even at a time when policymakers are locked in disagreement over the role of the government in our daily lives, there is broad consensus that the federal government must continue to invest in biomedical research. Americans understand that NIH-supported research saves lives, saves dollars, and stops human suffering.

In a 1995 public opinion poll conducted by Louis Harris & Associates for Research America!, a strong majority of citizens opposed cuts in federal support for medical research. Ninety-four percent of those surveyed believed that it is important that the United States maintain its role as a world leader in medical research. The survey also showed that medical research takes second place only to National Defense for tax dollar value. Overall, we believe that the results of this poll mean that the importance of research funding directed to chronic conditions such as arthritis, as it relates to savings in national health care costs is recognized by most citizens.

*Arthritis research is cost-effective.*—While arthritis and related diseases cost our nation more than \$55 billion each year, we have the potential to reduce the costs through research. For example, a new drug therapy for kidney disease resulting from lupus has been found to save between \$90 and \$120 million per year in health care costs in the U.S. This is all the more impressive since this drug regimen cost only about \$12 million to develop. Thus, nearly a ten-fold return is being reaped by

this investment in research. The use of long-term estrogen/progestogen replacement therapy for certain postmenopausal women, has resulted in significant reductions in instances of osteoporotic fractures, which amount to a savings of over \$300 million per year in patient care costs and lost wages.

These are only two examples. If our federal commitment can be strengthened, biomedical research will continue to yield improvements in treatment for patients and better management strategies. As such advances are made, costs of insurance and other costs borne by the government—including costs associated with long-term care and worker's compensation—will significantly decline. If our federal investment in arthritis research is increased, Members of Congress can feel confident that research progress is being made in disease prevention so that fewer resources will be needed to support disability care of our aging population.

In addition, long-term positive outcomes were achieved in chronically ill patients who participated in the NIAMS-sponsored Arthritis Self-Management Program. The Program improved patients' perceptions of their own self-efficacy. Unrelated to perception of level of pain, these improvements nonetheless reduced the frequency of doctor visits by at least once a year, on average. Extrapolated to all patients with arthritis, this program could represent a significant savings in health care costs attributable to office visits.

*Arthritis research provides economic stimulation.*—NIH-supported research is largely responsible for the growth of the American biotechnology and pharmaceutical industries. One study has shown that sales of biotechnology products can be expected to increase more than ten-fold to over \$50 billion in the decade of the 90's. In fact, American firms dominate most of the businesses that employ leading edge technologies, (including pharmaceuticals and biotechnology) according to recent economic findings. Although this is good news, investment in these areas by the federal government must be maintained—and increased—if we are to expect the “public-private partnership” to continue to yield such results. This is especially important in terms of investment in the basic research that serves as a necessary “precursor” for clinical research on drugs, and vaccine development, and in developing new treatments that directly benefit patients.

*Arthritis research improves people's lives*—Almost fifty million of our nation's citizens must face, every day, a variety of limitations due to reduced mobility and function, as well as interrupted social lives, and depression which may occur due to these illnesses. While it is difficult for those of us blessed with good health to comprehend fully the implications of arthritis and related diseases, it is obvious that the advances in treatment that are made possible by federal funding for arthritis research do indeed mean the difference between illness and health; between disability and function; and between dependence and self-sufficiency for affected individuals and their families.

*Health Care Delivery Research at the Agency For Health Care Policy and Research (AHCPR):*

The ACR has long been concerned about the need for research focusing on the organization and delivery of medical care. The Agency For Health Care Policy and Research (AHCPR) generates and disseminates information that improves the delivery of health care. AHCPR's research goals are to determine what works best in clinical practice; improve the cost-effective use of health care resources; help consumers make more informed choices; and, measure and improve the quality of care. AHCPR has been designated lead agency in the Department of Health and Human Services for the Secretary's initiative to improve health care quality, a recognition of the Agency's leadership role in this area.

Private market forces have acted to transform the country's medical care system. Major trends include cost cutting, increasing competition within and among all sectors of the delivery system, and continuing consolidation of providers and payers. While these trends have resulted in reductions in the rate of increase of health care expenditures, they have also raised questions about the impact on the quality and appropriateness of health care and the choices available to consumers. AHCPR is supporting a collaborative project with the managed care industry to explore how organizational and financing variables within managed care affect quality of care and disease specific medical outcomes for chronic conditions. We should acknowledge that simply knowing what works and at what cost does not automatically translate into improved practice. The singular contribution of AHCPR-supported research is that it focuses specifically on how to achieve improvements in practice in typical practice settings. AHCPR is currently soliciting priorities for outcomes research from consumers, providers, health plans, purchasers and researchers to guide the next phase of research in outcomes and cost-effectiveness for clinical conditions.

The conference report on the fiscal year 1997 Labor-HHS-Education Appropriations bill (S. Rpt 104-368) directed AHCPR to study potential cost-savings derived from direct patient access to specialists. The ACR looks forward to seeing the results of research that we expect will show the outcome and cost benefits of direct access to rheumatologic care for people with arthritis and related disorders. The rapid changes in the health care system have created a critical need to understand what works best in the organization, financing, and delivery of health care. Based on our belief that AHCPR-supported research can provide these answers, ACR joins with the Friends of AHCPR in supporting funding AHCPR at \$160 million for fiscal year 1998. This is \$16 million over the fiscal year 1997 level, but approximately equal to the level at which the Agency was funded in fiscal year 1995.

#### *Conclusion*

As providers of health care to the millions of Americans who have arthritis and related diseases, we hope we have given Congress some insight in its effort to answer an important question about investment—one that individuals ask themselves as they weigh their own investments, although on a larger scale: What investment reaps the biggest “bang for the buck?” We acknowledge that federal dollars can always be dumped into remedial measures and into federal subsidies for an increasing disabled and dependent population. There is a better way, however, through a strengthening of our nation’s commitment to biomedical and health services research. The ACR commends the subcommittee for doing just this in past years, and we urge you to continue the good work that you do in recognizing our citizens’ health needs.

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#### PREPARED STATEMENT OF THE ARTHRITIS FOUNDATION

The Arthritis Foundation appreciates the opportunity to submit public witness testimony in support of fiscal year 1998 appropriations for the National Institutes of Health and the Center for Disease Control and Prevention.

The Arthritis Foundation is a national, voluntary health organization that works on behalf of the nearly 40 million people affected by any of the more than 100 forms of arthritis or related diseases. Our primary mission is to support research to find a cure for and prevention of arthritis, advance professional and community education about the disease, and provide services for those afflicted.

#### *Prevalence and Cost*

Arthritis is the leading cause of disability in the United States, severely disabling over 7 million Americans. It disproportionately afflicts women, with 60 percent more cases in women than in men. Over the next 25 years, as the population ages and as people live longer, the prevalence of arthritis is expected to increase by about 12 million for a total of 60 million by the year 2020. It is estimated that the annual cost of arthritis alone is \$64.8 billion in medical care and lost wages. Musculoskeletal diseases account for another \$61.4 billion in medical care and lost wages, for a total of more than \$126 billion. As arthritis and related diseases effect older Americans with much greater frequency than the young, the cost to the Medicare program is staggering.

Certainly, the economic consequences of the disease make prevention and finding a cure particularly important. But, even more debilitating is the physical toll arthritis takes on its victims. Arthritis leaves you with increasingly debilitating mobility and severe pain. It severely limits and restricts everyday activities such as dressing, climbing stairs, walking, or even getting in or out of bed.

Arthritis manifests itself as pain, stiffness and often swelling in and around joints. Osteoarthritis, the most common form of arthritis, is characterized by the breakdown of cartilage and bones in the fingers and weight-bearing joints. Affecting over 16 million people, 12 million of whom are women, this disease accounts for more than half of all total hip replacements and 85 percent of all total knee replacements.

Other common forms of arthritis all of which occur more frequently in women than in men include fibromyalgia, a form of arthritis in muscles surrounding joints which affects five million people, and rheumatoid arthritis, an immune-related inflammation or swelling of the joint lining that damages cartilage and bone, appearing most often in 20–50 year olds. Arthritis can also take the form of gout, lower back pain, bursitis, systemic lupus, and juvenile rheumatoid arthritis.

#### *Targeting the Effects of Arthritis*

According to a study by the Centers for Disease Control and Prevention (CDC), six million people believe that they may have arthritis, but have never consulted

a physician (even though more than 75 percent of them saw a physician for other problems). Part of the reason for the delay in seeking treatment may be attributable to misconceptions about the availability of treatment—in an interview of patients with musculoskeletal conditions, 40 percent thought that nothing could be done for them. Clearly, we must do a better job of getting the message out and of reaching everybody who needs our assistance.

To this end, the Arthritis Foundation requests that \$2 million be provided through the CDC in 1998 so that the full dimensions of the problems of arthritis can be more accurately understood and that the needs of all people with arthritis can be better served. With additional resources, the CDC can conduct enhanced surveillance activities, especially in minority populations; it will be able to support special studies to characterize risk factors and design appropriate interventions; it will be able to work with state health departments, academic institutions, and voluntary organizations to evaluate the cost-effectiveness and the dissemination of existing interventions; and it will be able to evaluate how managed care affects the long-term costs and health of individuals with arthritis.

#### NIAMS

With this Committee's tremendous support and leadership, we have accomplished much in the past ten years toward relieving the burden of arthritis, through Congressional support of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Among recent biomedical, technological, and research accomplishments, scientists and researchers have:

- located a gene that predisposes people to lupus, a chronic autoimmune rheumatic disease, which should help researchers develop new treatments and preventions;
- gained a better understanding of implant wear, making joint replacement surgery more feasible for younger people;
- identified six distinct regions that control inflammatory arthritis in laboratory rats which built the foundation for human research with 800 sibling pairs affected with rheumatoid arthritis; and,
- conducted the first gene therapy trial for rheumatoid arthritis.

Important technological advances include those on monoclonal antibodies, genetic engineering, new animal strains, the ability to manufacture large amounts of genetic materials from small pieces, and magnetic resonance imaging giving a better "view" of joint structure. Recent research has also shown an association of genetic factors with juvenile arthritis, Lyme disease, and osteoarthritis; improvements in joint replacements through advances in computer measuring, prosthetic devices, and adhesives; and new applications for existing drugs as treatments for arthritis.

These and many other advances in arthritis research would not have occurred without the strong commitment to biomedical and behavioral research that Congress has provided. However, many exciting and promising research opportunities remain unfunded, including further research on arthritis in children and genetic therapy by immunization for rheumatoid arthritis to name but two.

Researchers hope to improve their understanding of arthritic diseases through the development of new plastics and adhesives that will lead to even greater surgical success and improved prostheses as well as thorough identification of "triggers" for those at high risk for arthritis and the means to minimize its chronic effects. Other potentially promising research includes identifying gene(s) for different types of arthritis and genetic engineering to replace defective DNA.

The Arthritis Foundation respectfully requests \$280 million for NIAMS for fiscal year 1998, a 9 percent increase over the 1997 appropriation. The success rate for NIAMS in fiscal year 1997 is estimated to be only 21 percent, compared to 28 percent for all of NIH. This level of support would enable NIAMS to support more of the meritorious grant applications that it receives and to continue to find ways to control, cure, and ultimately prevent arthritis.

We thank you again and we urge you to continue to provide leadership and strong support for NIH, NIAMS, and CDC.

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PREPARED STATEMENT OF THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

The College on Problems of Drug Dependence (CPDD) is pleased to submit public witness testimony to urge your continued support of the National Institutes of Health (NIH), the National Institute on Drug Abuse (NIDA), and the Substance Abuse and Mental Health Services Administration (SAMHSA). CPDD is the nation's longest standing organization that addresses the problems of drug dependence and

drug abuse and we are the leading scientific society in the field of drug dependence research.

*National Institute on Drug Abuse*

First, the members of CPDD wish to thank you for the tremendous support and leadership you have provided during the last two years. We know that your subcommittee was faced with many difficult funding decisions for many worthy programs, and we sincerely appreciate the funding increases for the NIH for 1996 and this year.

Every Member of this distinguished Subcommittee, indeed, every Member of Congress, is aware of the recently reported increase in drug use among our nation's children. Of particular concern is the dramatic increase among our very young, including pre-teens. The message we bring to you today is that, while some drug use is on the rise, we must remember that drug abuse in fact is a preventable behavior. Drug addiction is a social problem and a legal problem. But it is also a health problem. We believe that part of the explanation for the rise in the use of marijuana lies in the weakening of our resolve to implement the best prevention and treatment programs that research shows can work.

The scientific opportunities that exist, if adequately supported, can help find solutions to drug abuse and addiction. We are extremely appreciative of the Administration's proposed \$33 million increase for NIDA, which we believe indicates the President's awareness and concern about this complex public health problem, and we are optimistic that the NIDA budget request will support the research that is needed to determine the most effective prevention and treatment programs. We know that drug addiction is a treatable disease. We also know that treatment is cost effective. According to a 1994 Rand Corporation study, \$34 million invested in treatment reduces cocaine use as much as \$783 million for source-country programs or \$366 million for interdiction.

It is important for Congress to recognize that what we really need in order to produce significant and long lasting changes in illegal drug use is more research. We have learned a lot about the causes of drug abuse, and our latest treatment advances reflect some of that knowledge. Some of what leads people to abuse drugs is inherited from their parents. Availability of drugs is also an important determinant of initial use, but much less important to addicts, who will do whatever it takes to obtain drugs. Something happens to the brains of people who use drugs regularly. We are learning a tremendous amount about this, taking advantage of some of the latest techniques from the neurosciences. Drug abuse research is coming of age. NIDA was established just over two decades ago. It funds virtually all drug abuse research in the United States and more than 85 percent of all drug abuse research worldwide. There is little pharmaceutical industry research in this area. Few foundations support any basic research and few other governments do either. The problem of inadequate support for drug abuse research has been recognized by Office of National Drug Control Policy (ONDCP) Director General Barry McCaffrey and the proposed \$33 million increase for NIDA is part of the President's National Drug Control Strategy. We do not want to sound alarmist, but scientists know that there are new, even more powerful drugs than heroin and cocaine that could become a problem for us in the near future. The recent outbreak of abuse of methamphetamine is an example of this. We must be scientifically equipped to meet not only the challenges of the day, but those of tomorrow.

Great strides are being made in understanding the causes of drug abuse, and the scientific community is well aware of the excellence of research supported by NIDA. Researchers now have the ability to show in detail what drugs are actually doing to and in the brain—we can actually visualize as it happens where drugs are binding in the brain. We have discovered the specific brain circuits involved in drug use and we are beginning to unveil the changes in activity patterns in these circuits during the processes of addiction and withdrawal. Researchers have identified the genes for the receptor sites for practically every illegal substance. The next step is to develop new addiction medications.

To build upon these and other past breakthroughs and to exploit the opportunities that exist, CPDD recommends additional research in the following broad areas:

- Increase basic drug abuse research. The explosion of new information in neuropharmacology and other neurosciences has the potential to provide major breakthroughs in drug abuse treatment and prevention. We need to better understand the role of heredity and other sources of individual differences as risk factors for drug abuse. We also need additional information on the harmful effects of acute and chronic exposure to drugs of abuse.
- Maintain and expand our knowledge of trends in drug abuse practices. Continued support is needed for large scale surveys that provide an informed public

policy. We need better access to existing data, which would facilitate our understanding of drug abuse and its consequences; we need improved methods for obtaining scientific data on newly emerging drug abuse problems; and we need to support more long-term prospective studies on risk factors that co-vary with the development of drug abuse problems.

- Increase research on the effectiveness of drug abuse prevention and public policy initiatives aimed at reducing demand for drugs among our youth. Programs such as DARE and Safe and Drug Free Schools have been widely implemented but have not been sufficiently evaluated. Additional research is also needed on prevention programs for high risk youth.
- Increase research on the development of new drug abuse treatments and on the evaluation of existing treatments. Improved treatment strategies that combine the use of medications and behavioral treatments are needed, as are new treatments that reduce relapse. We also need additional evaluations of treatment effectiveness for special populations. For example, what are the best ways to link drug abuse treatment to the criminal justice system, in order to take maximal advantage of the leverage of criminal sanctions?
- Increase research on the relationship between drug abuse and the transmission of AIDS. We need a better understanding of how drugs alter the likelihood of risk-taking behaviors that increase HIV transmission since an estimated one-third of HIV cases result from drug use, and we need improved treatments targeted to the abuse of drugs by persons who are infected with the HIV virus. Further, we need a better understanding of the effects of drug abuse on the immune system in order to better prevent and treat AIDS and its associated opportunistic infections.

#### *Substance Abuse and Mental Health Services Administration*

The research dissemination and training programs of the Substance Abuse and Mental Health Services Administration (SAMHSA) are also an essential part of our national drug abuse treatment and prevention strategy. We are especially supportive of the training and demonstration grant functions of the Center for Substance Abuse Treatment (CSAT) and the Center for Substance Abuse Prevention (CSAP).

Much more needs to be done to determine the feasibility of implementing NIDA-supported research advances in clinical environments. There is a tremendous gap between what is known about prevention and treatment effectiveness and what is actually being done in many communities. We need more research on the barriers to the implementation of effective new treatment and prevention programs. The treatments and the prevention strategies that emerge from NIDA-supported research require community-based programs to evaluate their effectiveness. CSAT and CSAP demonstration grants provide a critical link between research and its implementation. Furthermore, SAMHSA training programs are needed to insure that counselors, educators, and other professionals have the necessary knowledge of new advances in the field. The large cut that these programs experienced in fiscal year 1996 have severely curtailed their effectiveness.

#### *Funding Request*

We hope that Congress will be able to provide an increase for NIH over the Administration's Budget Request. If this occurs, we request an increase of \$48 million over the fiscal year 1997 appropriation to ensure that NIDA maintains the priority status that it received in the President's Budget. We are confident that this would be effectively used given the scientific opportunities that exist. For SAMHSA, we do not have a specific recommendation but we request that adequate support be provided for the demonstration and training programs supported by CSAT and CSAP.

Thank you for your consideration of our request.

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#### PREPARED STATEMENT OF THE FDA-NIH COUNCIL

#### *Introduction*

Mr. Chairman, Members of the Committee, thank you for the opportunity to present a statement to the Committee as you deliberate funding priorities for fiscal year 1998.

The FDA-NIH Council is a coalition of 24 organizations comprised of patient advocates, academic scientists, health professionals, and medical research-based corporations. These partners in the process of medical discovery and innovation have come together to seek common ground in addressing the complex challenges the Food and Drug Administration (FDA) and the National Institutes of Health face. The Council appreciates the opportunity to submit testimony concerning the impor-



tance of a sustainable, predictable funding base for the National Institutes of Health (NIH). In past years, this Committee has been vitally important in addressing the funding needs of the NIH, and we are grateful for your support of the agency.

Before I address the issue of the funding for the NIH, please allow me to make a few comments about my own organization. Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines and services to patients throughout the world and to the healthcare providers who serve them. These medicines benefit patients through improved health, longevity and quality of life. Operations of Glaxo Wellcome circle the globe and address a common purpose—providing innovative medicines that prevent and treat disease. True to that mission, Glaxo Wellcome scientists and other employees are searching for new and better treatments for a variety of diseases. Glaxo Wellcome's research and development expenditures worldwide total nearly \$2 billion annually.

There is an intricate process of medical discovery and innovation that relies on the relationship of inter-dependent partners—government, academia, biomedical research industries, foundation, health professional and consumers. As a representative of industry, I welcome the opportunity to address the unique contributions of the government in this regard as it is the national commitment to the NIH which lays the foundation of our ability to bring research discoveries from the laboratory to the consumer.

All of the partners in the process of medical discovery are interdependent, each contributes a piece to the puzzle. The success of our national enterprise is not possible without each piece being vibrant and strong. A healthy partnership between government, industry, academia and non-profit foundations is critical to maintain the U.S. position as the world leader in medical research and innovation. Most importantly, the millions of Americans afflicted with catastrophic, acute and chronic diseases are the REAL beneficiaries of this partnership.

Medical research and innovation has enabled significant strides in the 20th Century.

- Treatments for people with chronic diseases have stemmed from medical research and innovation: antihypertensives control blood pressure; diabetics can stay health by using insulin and the potential of gene therapy approaches to this disease offer great hope for the future; new biotech products help thin the dangerously-thick mucus of people with cystic fibrosis and we have thousands of individuals with CF living into their 30's and 40's who would have died if not for this type of research advance; asthmatics breathe normally, work and enjoy sports, and, in fact, have represented the U.S. in the Olympics in swimming and other sports.
- People with life threatening and chronic diseases look to medical research and innovation for the promise and hope of a cure. Today, we have drugs to cure testicular cancer, childhood leukemia, and Hodgkin's disease, and to prevent strokes or permanent heart damage from heart attacks. Heart surgeries fix hardening of the arteries and aneurysms, and new medical technologies help premature babies survive without brain damage, vision loss and digestive disorders.
- Medical research and innovation have prevailed to improve the quality of life for millions of us, but the challenge remains to find answers for millions more who face disease and disability. Every day Americans suffer or die from cancer, heart disease, strokes, stomach ulcers, Alzheimer's disease, Parkinson's disease, multiple sclerosis, cystic fibrosis and other devastating diseases.

In short, medical research and innovation have won many battles, but the war is far from over, and for many, the battle has hardly begun.

The health of our nation is dependent upon a strong national commitment to medical research. The research opportunities have never been greater, or more exciting, and the drive to diminish the federal commitment to discretionary spending priorities, including medical research, has never been more paramount. Further, our leadership in the international arena in medical research and innovation is at a critical juncture, due to our international competitors' expansion of their research investment over the past two decades. Today, Japan and Germany devote a greater percent of their GNP to research and development than the U.S. does. This is a warning sign which should be taken seriously as we contemplate national priorities.

At the close of this decade, we are on the brink of great medical breakthroughs. We have attracted some of the best scientific minds to our national enterprise, and initiated ground-breaking programs that have already yielded critical knowledge, and improved patient care and quality of life. However, we are confronted with the extraordinary challenge of how to maintain the integrity of our research efforts, and rapidly and cost-effectively translate that research and development into use by health professionals and consumers, in both the public and private sectors. We are

in a race against the clock when it comes to many forms of cancer, heart disease, Alzheimer's, Cystic Fibrosis, A-T, and many other catastrophic diseases.

The NIH is the primary funding source for basic research through universities and independent research institutions throughout the country. The NIH also plays a critical role in support of clinical and translational research. NIH-supported research has led to major advances in the understanding and treatment of various diseases and disabilities. NIH-funded researchers are now at the forefront of the global effort to build upon these findings and develop new, more effective treatment regimens. Success against disease will only be possible with a strengthened national research effort. Therefore, continued support of the NIH is critical to the vitality of our medical research enterprise.

Industry presently devotes 21.2 percent of its U.S. sales to research and development. This investment, which is greater than that of the NIH, is directed toward efforts quite different from the NIH but complimentary. Our basic research efforts are more targeted and our clinical research initiatives more directed toward the end product. Industry does not, and cannot, devote resources to the discovery of new knowledge at the basic, fundamental level the NIH supports. Industry's responsibility in this partnership is the maturation of scientific knowledge and the translation of research discoveries from the bench to the bedside through targeted basic and applied research efforts.

#### *Budget Request*

Our national capacity to translate research from the laboratory to the patient is challenged on many fronts. We must: continue to recruit bright young scientists into research careers; provide a sustainable, predictable funding base for the National Institutes of Health and the Food and Drug Administration, which guarantees the safety and effectiveness of medical products; and, ensure regulatory policies which support the rapid translation of research and public health protection.

While the NIH has received strong Congressional support over the past several years—a 6.9 percent increase in funding for fiscal year 1997, and a 5.7 percent increase for fiscal year 1996—the NIH needs a sustainable, stable base of funding augmented by new resources in order to pursue the extraordinary research opportunities available now. With its current level of support, the NIH is only able to fund 1 in 4 of all approved research grant applications. It is clear that innovative treatments will only be realized through a conscious, planned, and broadly supported investment in medical research and development.

Congress holds the key to realize this vision by virtue of the mandates it places on and the resources it provides to the NIH. The FDA-NIH Council also recognizes that the Members of this great body have a very tough job in terms of weighing the available resources and numerous worthy federal programs. We recognize the tough choices that you have ahead of you. And, we recognize and are extremely grateful for the support that this Committee has provided to the NIH in the past.

The FDA-NIH Council supports the vision articulated in H.R. 83, S.R. 15 and S. 124 which call for a doubling of the budget for the NIH in response to our declining commitment to research, based on the proportion of GNP invested in research, over the past 30 years. In that regard, we urge that the Committee take the first step in meeting this objective and provide a 15 percent increase to the NIH.

Let me reiterate one point. The FDA/NIH Council understands the severe budget constraints which exist presently, but we also believe that the functions of the NIH are too vital to consider appropriating any less. Health must be one of our nation's top priorities, for a wealthy and economically sound country is predicated on the health and well being of its citizens.

Thank you for the opportunity to present a statement before the Committee today. We appreciate your support of this agency and look forward to working with you in the coming months.

The members of the FDA/NIH Council are: the A-T's Children Project; Candlelighters Childhood Cancer Foundation; Allergy and Asthma Network—Mothers of Asthmatics, Inc.; Alliance for Aging Research; Schering-Plough Corporation; American Medical Association; Merck & Co., Inc.; Pfizer, Inc.; American Veterinary Medical Association; Joint Council of Allergy, Asthma and Immunology; Impotence World Association, Inc.; American Society of Tropical Medicine and Hygiene; National Multiple Sclerosis Society; Monsanto Company; Arthritis Foundation; Glaxo Wellcome, Inc.; American Social Health Association; Cystic Fibrosis Foundation; Bristol-Myers Squibb Company; American Association for Cancer Research; National Depressive and Manic-Depressive Association; Society of Toxicology; Research Society on Alcoholism; and the Autism Society of America.

## PREPARED STATEMENT OF THE JOINT COUNCIL OF ALLERGY, ASTHMA AND IMMUNOLOGY

The Joint Council of Allergy, Asthma and Immunology (JCAAI) is pleased to submit public witness testimony in support of fiscal year 1998 appropriations for allergy, asthma and immunology programs supported by the National Institutes of Health (NIH). The JCAAI is a professional, nonprofit organization comprised of the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology, and it consists of more than 4,000 researchers and clinicians who are dedicated to providing care for the 50 million Americans who suffer from allergic or immune disorders.

First, we would like to express our appreciation for the tremendous support this Committee has provided to the NIH during the past two years. We know that you have been faced with tremendous budget constraints and we sincerely appreciate your making the NIH a priority for funding increases. We urge your continued leadership for NIH and for the allergy, asthma, and immunology programs supported by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Heart, Lung, and Blood Institute (NHLBI).

We would like to identify three areas of research where we believe additional support is necessary.

*Sinusitis*

*Incidence and Cost.*—Chronic sinusitis, an inflammatory disease of the sinus, affects an estimated 35 million Americans (14 percent of the population), and its prevalence is rising. Between 1980 and 1992, individuals with sinusitis reported 73 million restricted activity days, compared to 50 million during 1986–1988. It was the most frequently reported disease in the 1993 National Health Interview Survey.

The 1993 National Hospital Discharge Survey reported 16,000 discharges for acute sinusitis and 29,000 discharges for chronic sinusitis. Approximately 11.6 million physician visits for chronic sinusitis were reported for 1991. Direct medical costs of sinusitis were nearly \$2.4 billion in 1992. The number of antibiotic prescriptions for acute and chronic sinusitis was 13 million, compared to 5.8 million in 1985.

*Research.*—Chronic sinusitis is an inflammatory process in which instigating agents have been difficult to identify or prove. Better methods are needed to dissect the pathologic process of chronic inflammation in order to understand the critical cellular elements, cytokines, and mediators that are involved. More research is also needed on possible bacterial, viral, and fungal organisms.

No convincing evidence exists that supports a role of environmental pollutants in causing or prolonging sinusitis. However, occupations may have a role. Host susceptibility may influence the inflammatory reaction to toxicant exposure, including perhaps in conjunction with a genetic basis. Interaction with a pre-existing condition such as hay fever may also aggravate inflammatory reaction.

Sinusitis frequently complicates asthma, yet more research is needed to evaluate this relationship. Some individuals with chronic cough are thought to have asthma, but it is possible that the cough may be due to sinusitis. Surgery has shown to benefit some sinusitis patients with asthma. Physicians frequently associate nasal inflammation with sinus inflammation, assuming that rhinitis precedes sinus disease and that its treatment can prevent or improve sinus disease. However, the evidence for causality between rhinitis and sinusitis is not always certain.

Although the roles of viruses and bacteria in the etiology of acute infectious sinus disease are well established, the role of microbial infection in chronic sinus disease is less well-defined. More research is needed on how viruses cause sinus disease, what risk factors lead to secondary bacterial infection, and what new approaches to treatment will prove useful.

The analysis of various treatments for chronic sinusitis is only in its early stages. For example, the use of corticosteroids is controversial. Potential benefits include the ability to reduce mucosal swelling, and corticosteroids have the proven ability to shrink nasal polyps, which occur frequently in chronic sinusitis. However, no studies exist that prove the unequivocal efficacy of topical corticosteroids in sinusitis. Studies are needed to compare antibiotic and topical corticosteroid treatment.

Clearly, additional research is needed to determine who is at risk of developing sinusitis, why they get it, and how it should be treated. This must include a definition of the clinical and pathologic state of sinusitis; the role, if any, of infectious agents including viruses, bacteria, and fungi; and an investigation of host responsiveness to pathogens, environmental toxicants, irritants, and allergens.

*Allergic Diseases*

*Incidence.*—As many as 50 million Americans—one in five people in this country—suffer from allergic diseases. One out of every 11 physician office visits is for

an allergic disease. Allergic rhinitis (hay fever) alone affects as many as 35 million Americans and is the most common chronic disease. Food allergies and food intolerances are also a major problem. Eight percent of children under six years of age experience food intolerances. Allergy to natural rubber latex is becoming an increasingly important health problem, especially as medical personnel are wearing latex gloves more frequently to protect against HIV and hepatitis B. More than 1,000 allergic reactions to latex were reported to the Food and Drug Administration from 1988 to 1992, including 15 deaths.

Allergic reactions can be minor, such as reactions to pollen, mold, or dust, or they can be severe and potentially fatal, such as reactions to penicillin, insect venom, or allergic reactions to food. As many as 2 million people experience severe reactions to insect stings every year, and many experts believe life-threatening allergic reactions to food may occur just as frequently.

*Research.*—A variety of therapies have been developed to treat allergies, but researchers still do not fully understand certain critical aspects of allergies. When an allergic individual comes in contact with an allergen (the allergy-provoking substance), immune system cells produce an unusual type of antibody known as immunoglobulin E, or IgE, which starts the allergic reaction. Researchers are attempting how to comprehend how the immune system recognizes an allergen, why some people have a more severe reaction to an allergen, and what factors, including environmental and genetic, might be responsible for allergic diseases.

NIAID-supported researchers are among the leaders in the study of allergies. For example, they identified the IgE antibody and they have identified the structure of the IgE receptor. By blocking the activity of the receptor, researchers may be able to provide a new therapy for allergies. NIAID-supported research has also demonstrated that DNA vaccines are capable of stimulating an immune response that may diminish allergy symptoms. Such vaccines could provide a more potent, consistent, and convenient treatment than the current therapy of allergy shots.

Researchers have also identified the biologic events that are responsible for late phase reaction (LPR). LPR usually occurs about 4 to 6 hours after the allergen has entered the body. The discovery that LPR involve inflammatory cells and that they resemble allergic reactions has led to the recognition that inflammation is a central feature of allergic diseases (as well as asthma). Researchers have also learned that inhaled corticosteroids inhibit LPR. The inflammatory process is very complex but these and other breakthroughs are providing insights.

#### *Asthma*

*Incidence and Cost.*—Asthma is a major health problem. As many as 15 million people in the U.S. have asthma, and the number of people with self-reported asthma increased from 10.4 million in 1990 to 14.6 million in 1994. The actual number of asthmatics may be higher—asthma is sometimes difficult to diagnose because it often resembles other respiratory problems such as emphysema. Children have a 41 percent higher prevalence of asthma than that of the general population and an estimated 4.8 million children under age 18 have asthma. It is one of the most common reasons for missed days of school (parents are also forced to miss work to care for their asthmatic child).

Asthma is approximately 25 percent more prevalent in African-American children than in Caucasian children, and asthmatic African-American children experience more severe disability and have more frequent hospitalizations than their Caucasian counterparts. In 1993, African-Americans aged 5 to 14 were four times more likely to die from asthma than Caucasians, and those aged to 4 were six times more likely to die from asthma. Asthma is also more prevalent in African-American adults than in Caucasians. Their hospitalization rate in 1992 was 400 percent higher than for Caucasians and their age-adjusted mortality rate was 300 percent higher. The reason for the higher incidence is uncertain; however, lack of access to proper medical care is related to the poor outcomes.

Direct and indirect costs for asthma were an estimated \$6.2 billion in 1990, 43 percent of which was associated with emergency room use, hospitalization, and death. Inpatient hospital costs represented the largest single direct expenditure, totalling \$1.6 billion, and emergency room use cost another \$295 million. In 1993, asthma was the first-listed diagnosis in 468,000 hospital admissions and asthmatic children under age 15 experienced 159,000 hospitalizations (asthma is the leading cause of hospitalization of children).

*Mortality.*—The death rate for asthma is increasing. From 1983 to 1993, asthma accounted for 3,850 deaths among persons up to age 24. For children 5 to 14 years of age, the asthma death rate nearly doubled, and it did double during this period for persons aged 15 to 24.

*Research.*—Asthma varies from person to person—symptoms range from mild to severe. While there is not a cure for asthma, it can be controlled with proper measures, including medications, learning to manage episodes, and learning to identify and avoid what triggers an episode. Triggers include controlling irritants in the air—90 percent of children with asthma and half of adult asthmatics have allergies; avoiding excess physical exertion; and managing emotions. Medications consist of anti-allergy drugs, corticosteroids, and bronchodilators.

In 1989, the NHLBI initiated a 5-year demonstration program at five universities to develop, implement, and evaluate interventions to reduce morbidity from asthma among African-American and Hispanic children. The goals were to develop programs to reduce asthma morbidity, decrease inappropriate use of health care resources, and enhance the quality of life of these children. The demonstration program resulted in improved educational and management programs, strategies for recruiting patients and staff, and techniques and resources for community and professional education. NHLBI's National Asthma Education and Prevention Program has disseminated this information to researchers, clinicians, and community health officials. NHLBI emphasized: the importance of antiinflammatory medication; the use of home peak flow meters to monitor asthma; and, educational and behavioral techniques to improve adherence to treatment programs.

In August 1996, researchers (Weinstein, et al) published a report that summarized the results of a study to examine the economic impact of a short-term inpatient hospitalization program for children with severe asthma. The program, based in part on programs developed by NHLBI, significantly reduced inpatient and emergency care days for the subsequent 4 years of follow-up. In a study of 59 children, the median of 7 inpatient days the year prior to rehabilitation was reduced to zero (0) days during each of the following 4 years. Emergency care visits were reduced from 4 in the year prior to rehabilitation to zero. The year before rehabilitation, medication charges as a percentage of medical charges was 9 percent; by the third and fourth years of follow-up they were 45 percent of total medical charges.

The NIAID National Cooperative Inner-City Asthma Study has designed new strategies to reduce asthma morbidity and mortality. The first phase of the study looked at over 1,500 children and discovered factors including high levels of indoor allergen, especially cockroach allergen (the leading asthma-producing material that children were exposed to), high levels of smoking among family members; and exposure to high levels of nitrogen dioxide. In the second phase, 1,000 high risk children and their families were assisted by a nurse practitioner in managing the child's condition and instituting environmental controls. This resulted in significant reduction in asthma symptoms, improved school attendance, and a 30 percent decrease in asthma-related hospitalizations and unscheduled physician and emergency room visits. The NIAID has continued the study to disseminate the results.

*Drug Development.*—Pharmaceutical researchers are providing new hope for asthmatics. The Food and Drug Administration recently approved two asthma drugs in an entirely new chemical class of drugs, the first since the 1970s, and more than 40 companies worldwide are at work on new asthma drugs. Existing drugs usually work—if taken properly. Many asthma drugs are delivered through the use of an inhaler, which patients often misuse by inhaling too fast or by exhaling when the medicine is released. Furthermore, as highlighted by NHLBI recently, some drugs including corticosteroids may have side effects. Thus, while there is a lot of work remaining, the potential for new therapies is significant.

#### *Summary*

Allergies and asthma are serious health problems, affecting millions of Americans in both acute and chronic forms. Through research supported by the NHLBI and NIAID, researchers and clinicians have learned much about how to diagnose and treat these diseases, but much more remains to be done. The JCAAI requests a 9 percent increase for the NIH in fiscal year 1998 to explore some of the exciting research opportunities that exist in these areas.

Thank you for your consideration of our request.

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#### PREPARED STATEMENT OF THE RESEARCH SOCIETY ON ALCOHOLISM

The Research Society on Alcoholism (RSA) is pleased to submit public witness testimony in support of the National Institutes of Health and the National Institute on Alcohol Abuse and Alcoholism. The RSA is a professional research society whose 1,100 members conduct basic and clinical research on alcoholism and alcohol abuse.

Alcoholism is a tragedy that touches all Americans. One in ten Americans will suffer from alcoholism or alcohol abuse, but their drinking will impact on the family,

the community, and society as a whole. Alcohol is a factor in 50 percent of all homicides, 40 percent of motor vehicle fatalities, 30 percent of all suicides, and 30 percent of all accidental deaths. Every American is affected and all Americans bear the cost. Children exposed to alcohol during pregnancy are afflicted with birth defects and mental retardation. Nearly 7 million children live with an alcoholic parent, often in chaotic homes where they suffer physical and emotional abuse. Ominously, a recent study reported that 30 percent of high school seniors drink heavily or consume more than 5 drinks at a time at least once every 2 weeks.

Alcoholism and alcohol abuse cost the nation nearly \$100 billion annually. One tenth of this pays for treatment; the rest is the cost of lost productivity, accidents, violence, and premature death. Prohibition did not solve the problem of alcoholism, and current therapy is simply not good enough. Only research holds the promise of effective prevention and treatment of alcoholism; however, alcohol research is woefully underfunded. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) funds over 90 percent of all alcohol research conducted in the United States. For 1997, the budget of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is \$211 million. We are committing to alcohol research only 2 dollars for every 1,000 dollars lost from alcohol abuse and alcoholism and only 12 dollars for every affected individual. In 1996, NIAAA could fund just 21 percent of all grant applications; in 1997 they will fund fewer. The comparable figure for NIH is 28 percent.

The inability to fund outstanding grant applications comes at a time of unprecedented opportunities in alcohol research. In the next few months you will learn of important new findings on the genetics of alcoholism. For the first time scientists, funded by the NIAAA Collaborative Study on the Genetics of Alcoholism (COGA), have identified discrete regions of the human genome that contribute to the heritability of alcoholism. This first success in the genetic mapping of a complex biological and behavioral disorder must be followed by an expensive, labor intensive effort to pinpoint and identify the genes of interest. Armed with this knowledge, health providers may one day be able to identify individuals at risk and target these individuals for prevention programs. Genetic research will accelerate the rational design of drugs to treat alcoholism and may improve our understanding of the interaction between heredity and environment in the development of alcoholism.

One of the most promising areas of alcohol research is in the field of neuroscience. The development of effective drug therapies for alcoholism requires an improved understanding of how alcohol changes brain function to produce craving, loss of control, tolerance, and the alcohol withdrawal syndrome. Naltrexone, a drug that blocks the brain's natural opiates, reduces craving for alcohol and helps maintain abstinence. Ongoing clinical trials will help determine which patients benefit most from naltrexone and how the drug can best be used. Another promising drug, nalmefene, has potential advantages over naltrexone, including a longer half-life, less liver toxicity, and more complete blockade of opioid receptors. Scientists have recently discovered a new class of drugs known as neurosteroids. Planned studies on neurosteroids may lead to improved treatment of alcohol withdrawal and more effective control of alcohol craving.

One of the most tragic consequences of alcoholism is Fetal Alcohol Syndrome (FAS). FAS is a permanent condition characterized by mental retardation, small size, behavioral problems, and specific facial abnormalities. Fetal alcohol syndrome is the most common, preventable cause of mental retardation in the United States. If pregnant women did not drink, there would be no fetal alcohol syndrome; however, as we know too well, many individuals cannot stop drinking, even when the consequences are well known.

From animal studies we have learned that alcohol's effects during pregnancy depend on the timing, pattern, and amount of alcohol intake. Magnetic resonance imaging, brain wave recordings, and behavioral assessments of affected children have identified specific changes in brain structure and function that result from heavy prenatal alcohol exposure. A better understanding of alcohol's effects on the developing brain will allow us to better target the treatment of exposed people. This research will allow those with FAS to maximize their potential and circumvent some of their deficits. An improved understanding of risk factors will help us target and prevent FAS.

Recent research has shown that even light drinking during pregnancy can interrupt normal development. Consequently, most researchers recommend that pregnant women abstain totally from drinking. In the laboratory, it has been shown that low doses of alcohol can interfere with normal processes of development. We are optimistic that understanding the mechanism by which alcohol disrupts fetal development will lead to effective strategies for reducing deficiencies associated with FAS.

Alcohol abuse and alcoholism are devastating problems of national importance. Alcohol research has now reached a critical juncture, and the scientific opportunities are numerous. With the continued support of this Committee and the Congress, we are optimistic that the next few years will bring significant advances in alcohol research.

The Research Society on Alcoholism requests that funding for NIAAA in fiscal year 1998 be increased by \$31.7 million (15 percent) to \$243.6 million. This request balances the impact of the disease, the abundant research opportunities, the low success rate of NIAAA grant applications, and well-known fiscal constraints. We deeply appreciate your past leadership on behalf of NIH and urge your continued efforts for 1998.

Thank you for your consideration of our request.

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PREPARED STATEMENT OF THE AUTISM SOCIETY OF AMERICA

The Autism Society of America (ASA) appreciates the opportunity to present written testimony in support of fiscal year 1998 funding for the National Institutes of Health (NIH).

We would like to thank the Committee for its previous support of an autism focused research effort at NIH. Currently, the NIH is engaged in some exciting research relating to the neurobiology and genetics of autism, however, much remains to be learned about this greatly misunderstood disease and how to assist not only those unborn, but also the more than 400,000 individuals who live with this disorder every day.

The Autism Society of America was founded in 1965 by parents of children with autism. It was established to help parents, family members, professionals and caregivers to learn about autism and how to effectively deal with this disability. ASA provides information to our members through a toll-free information line, an extensive library, a bi-monthly newsletter "The ADVOCATE", and an annual national conference. In addition, ASA has recently established a research foundation, the Autism Society of America Foundation, which is funded by grassroots support. Parents of children with autism are struggling every day to find treatments to help their children deal with this disease and they are willing to put their own money into much-needed research efforts.

What do we know about autism? We know it is not a mental illness. Children with autism are not unruly kids with a behavior problem. Autism is not caused by bad parents who gave their children too little attention. In fact, no known factors in the psychological environment of a child have been shown to cause autism.

Autism is a developmental disability that typically appears during the first three years of life. It is believed to be a genetically-based neurological disorder that affects more than 400,000 individuals in the United States, making it the third most prevalent developmental disability. Autism is more common than Down Syndrome. Autism is four times more prevalent in boys than girls, and knows no racial, ethnic nor social boundaries. Family income, lifestyle, and educational levels do not affect the chance of autism's occurrence. At the present time, there is no prevention, treatment, or cure for autism. The estimated health care cost associated with autism is greater than \$13 billion a year.

There is no "typical" manifestation of autism. It is a spectrum disorder, meaning the symptoms and characteristics of autism can present themselves in a wide variety of combinations, from mild to severe. Although autism is defined by a certain set of behaviors, children and adults can exhibit any combination of the behaviors in any degree of severity. Two children, both with a diagnosis of autism, can act very differently from one another.

*National Institutes of Health*

When questioned recently, Dr. Varmus stated that this is a promising time in research on autism. The Autism Society of America agrees with this assessment. After many years of neglect and lack of sufficient funding, researchers at several institutes are now working to unlock the mysteries of this disease—a "new era" of autism research is underway.

This process began in earnest in the Spring of 1995 when NIH convened a state-of-the-science conference focused solely on autism at the urging of this Committee. The Autism Society of America initiated this conference. The President of ASA, Sandra H. Kownacki, participated in the NIH Autism Working Group which issued a report to the NIH after the Conference reviewing the current research on autism, identifying gaps in knowledge, and making recommendations for future research ac-

tivities. This report is being used today to guide autism research activities at the NIH.

Follow-up conferences on autism were held during 1996. These conferences included more than 1,000 researchers and clinicians, as well as over 1,000 parents of individuals with autism. Results of the first conference were shared with those present, and a multi-disciplinary, multi-institute research effort was initiated by the NIH.

The National Institute on Child Health and Human Development (NICHD) has taken the lead in coordinating this effort. NICHD joined with the National Institute on Deafness and Other Communication Disorders (NIDCD) in issuing a Request for Applications (RFA) on the neurobiology and genetics of autism. The response to the RFA was so outstanding that the NIH Office of the Director gave NICHD additional funds to ensure that the most promising proposals could be funded.

In addition, NIH has established an internal NIH Autism Coordinating Committee co-chaired by the Directors of NICHD and the National Institute of Mental Health (NIMH). Because autism is such a complex disease, many different institutes are engaged in research that might be beneficial in advancing our understanding of the disease, developing treatments, and continuing our hope of finding a cure. This coordinating committee will ensure that the research is most effectively conducted throughout all of the institutes currently engaged in autism research.

As a result of all of these efforts, autism research is expanding in many areas including genetics, molecular biology, neuropathology, the development of animal models, and behavioral and cognitive neuroscience. Several examples of these research opportunities include the following:

- NIMH supported researchers have conducted research which indicates more clearly that genetic factors are related to the cause of autism, and most likely trigger disruption in brain development during early fetal life. It is possible that these researchers will be able to identify autism's genetic triggers within the next several years. This genetic research will be facilitated by work being done by the National Institute on Human Genome Research.
- An animal model is being utilized to examine brain development during gestation and researchers hope to learn more about the onset of autism.
- Research on treatments is being expanded to examine more closely the benefits of behavioral interventions, especially at an early age.
- Research on cognition in autism also appears to have relevance to treatment and is being expanded to better understand sensory processing in individuals with autism. This has implications as one looks at attention, perception, memory, communication, socialization, reasoning, and motor output.

The Autism Society of America is encouraged by the research efforts currently being undertaken by the NIH. We believe that progress is only possible through a coordinated approach. We hope NIH, with the support and encouragement of the Congress, will continue this autism-focused effort. We must make up for the years of neglect in NIH's autism research efforts.

The impact of autism is significant in both health and economic terms. As parents of children with autism, members of the Autism Society of America are keenly aware of these impacts. Basic and clinical research in this area is progressing and the scientific opportunities that exist are very encouraging. With additional support, we are optimistic that significant improvements can be made in the prevention and treatment of autism. Therefore, to exploit these research opportunities, the Autism Society of America strongly supports a doubling of NIH appropriations over five years as proposed by Senator Mack and Specter in S.Res. 15. This would require a 15 percent increase for fiscal year 1998. As an absolute floor, we support the recommendation of the Ad Hoc Group for Medical Research Funding for a 9 percent increase in fiscal year 1998.

#### *Special Education*

The Autism Society of America also supports full funding of the Individuals with Disabilities Education Act (IDEA). We understand that you might be contemplating a significant increase in funding for Part B, which we support, but we would also like to mention the importance of providing sufficient funding for Part H, the early intervention programs.

Due to the unique nature of autism, education is the only chance children with autism have to reach their highest potential. Early intervention is critical to ensure that students with autism enter school ready to learn. Part H of IDEA provides the opportunity for children from birth to three to gain these skills.



*Conclusion*

On behalf of the more than 24,000 members of the Autism Society of America, thank you again for this opportunity to present testimony. We look forward to working with the Committee as you develop funding priorities for the coming year.

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PREPARED STATEMENT OF THE ALLIANCE FOR EYE AND VISION RESEARCH

The Alliance for Eye and Vision Research (AEVR) thanks you for the opportunity to present written testimony to the Committee. The Alliance is a coalition of the stakeholders in eye and vision research—industry, researchers, health care providers, and lay advocates. AEVR's ultimate goal is to achieve optimal eye care for all Americans through research and public education.

AEVR appreciates the leadership role that the Committee has taken in stabilizing the funding base for the National Institutes of Health (NIH) over the past several years. As you have met the challenges posed by the deficit, and the pressing spending priorities that have been so articulately placed before Congress, the eye and vision research community is grateful for the strong support pledged to the NIH. Thank you.

Our eyes are the gateway to the world. Yet, eye and vision disorders touch all of our lives in some way. More than 120 million Americans wear corrective glasses or contact lenses. More than 12 million Americans suffer from some form of irreversible visual impairment such as retinitis pigmentosa. More than 1 million Americans are legally blind, and that number promises to grow as the proportion of our population continues to age. Four common, aging-related eye diseases—Age-related Macular Degeneration, Glaucoma, Diabetic Retinopathy and Cataracts—will account for the sharp increase in eye and vision disorders. If left unchecked, these sight-robbing diseases will undermine the quality of life of millions more and place an enormous economic burden on families, their communities and the health care delivery system that we can ill afford.

Our nation spends approximately \$38.4 billion every year in direct and indirect costs associated with eye diseases and disorders. As our population ages, these costs will increase, and challenge our health care delivery system in dramatic ways. It is only through further advances in research that we are going to gain a better understanding of vision disorders so that we can find cost-effective treatments and cures, and hopefully, give back something that few Americans can imagine doing without—their sight.

According to experts in the field of eye and vision disorders related to aging who participated in the White House Conference on Aging Mini-Conference hosted by the Alliance, the scientific and technological capability now exists to make substantial progress in a number of age-related disorders, if an expanded research effort is supported. This research progress will only be possible if we can insure that the National Eye Institute (NEI) has the resources necessary to pursue initiatives in key areas.

We would like to raise several issues regarding the funding of the NEI, the primary Federal agency devoted to research, training, and education focused on eye and vision disorders.

First, funding for the NEI has not kept pace with the funding growth seen by the NIH as a whole—11 percent versus 40 percent. We have attached a graph to the testimony which demonstrates this pattern. We understand the rationale as to why the Committee has not been altering the proportional allocation recommended in the Administration's proposal for the categorical Institutes, and that you believe that the scientific priorities have been established by the agency in that budget submission. However, we are concerned that the NEI has been unintentionally disadvantaged in the budget development process and that the Administration's proposal over the past several years has not recognized the very serious ramifications of underfunding this key scientific area. Specifically, the repetitive practice of allocating a smaller percentage increase to the NEI than most of the other NIH Institutes has served to disadvantage research programs in areas of growing incidence, especially age-related eye and vision disorders.

Second, NEI has a great track record for scientific discovery. Major research breakthroughs have resulted from NEI-supported research. For instance, the retinoblastoma gene, isolated, cloned and sequenced by NEI-supported investigators, serves as the prototype of a class of human cancer genes and will have a tremendous impact on future cancer research progress. The molecular basis for converting light to an electrical signal in the photoreceptor rod has been identified. This information will have important implications as to how sensory information is transmitted in the brain—a finding which will impact not only vision research but neuro-

science research as well. NEI is supporting researchers around the country who are working to find the mechanisms, including genetic triggers, that cause some of the most serious eye diseases of the retina and the cornea, as well as glaucoma. Given the long-term financial ramifications of research in age-related disorders, this type of initiative should be accelerated.

NEI is one of the most cost effective and efficiently managed institutes at NIH. For example, the average cost of an NEI grant is \$223,000, while the NIH average is \$267,000. An NEI grant costs about 20 percent less. Workload studies of NIH program staff have demonstrated that the workload of the NEI program staff is about twice the NIH average. In addition, the cost of management overhead for NEI grants is less than half of that of some NIH Institutes.

We believe that the NEI is a tremendous success story within the NIH. We believe that NEI could be more successful in pushing the frontiers of science to find effective cures and treatments for age-related eye and vision disorders if the Committee develops a plan to redress the long-standing problem of NEI growth vs. NIH growth. We urge you to do so.

#### *Age-Related Macular Degeneration*

We would like to highlight a particular eye disease that has enormously grave implications for millions of Americans over the age 65, but remains a largely unknown threat. It has received considerable notoriety in the press as of late, with considerable discussion on shows like 20/20 and National Public Radio. This disease is age-related macular degeneration or AMD.

AMD is a disease of the retina which affects central vision. It is the leading cause of blindness in people over the age of 65 and affects nearly 5 percent of this population—1.7 million people. It is expected to affect 6.3 million individuals by the year 2030.

One of our members organizations, Prevent Blindness America, which is a large eye health and safety advocacy organization, knows first-hand about the devastating impact of AMD. Each day they receive phone calls from people all over the United States who are losing their vision as a result of this disease. They are terrified of losing their independence and their ability to interact socially with others.

Imagine waking up one morning and not being able to read the newspaper. Imagine not being able to recognize your loved ones because their faces are a blur. Imagine putting on a brown socks with your blue suit because you can't distinguish colors. All of these things are painful for those in the grip of AMD.

Recently, National Public Radio did a segment on living with AMD. The elderly woman interviewed described her everyday life from trying to read her mail, to making a tuna fish sandwich with cat food, to putting her fingers in the dip at a cocktail party because she thought it was a bowl of nuts.

Writer Henry Grunwald recently wrote an article in The New Yorker entitled "Losing Sight" in which he describes his own personal struggle with AMD. He writes about seeing life in a "haze" and relates several experiences where he has greeted strangers on the street as old friends and walked right by good friends because their faces are a blur. He explains his frustration about no longer being able to use his word processor to write because he cannot read the words on the screen. He now dictates and has an assistant who types the text and reads it back to him line by line—an arduous process, and one unavailable to those without his resources.

Initially, AMD affects the ability of an individual to see details, such as facial features, road signs, and fine print. In the early stages, vision may become blurred and gradually worsen resulting in a loss of central vision. 90 percent of individuals with AMD suffer from the "dry" form which manifests itself through a slow, progressive shrinking of the macula in the retina, eventually leading to loss of central vision. The other form of AMD is referred to as "wet" AMD and it occurs in 10 percent of AMD cases. However, wet AMD is accounts for 90 percent of all blindness from the disease. Wet AMD is caused when new blood vessels grow under the retina and leak or bleed, thereby damaging the macula and causing loss of central vision.

At the present time, there is no cure for AMD and treatment remains limited. While laser treatment has been found to have some effect in delaying "wet" AMD, no current treatments exist that will reverse the slow loss of central vision that results from this disease. The only hope of slowing down the progression of this disease is by increasing our investment in medical research.

NEI is already engaged in research efforts focused on AMD. NEI is currently spending \$75 million for research on macular degeneration, of which \$16 million is directly targeted to AMD. According to experts in the eye and vision research field, there are many areas of AMD research which are ripe for exploration. These include:

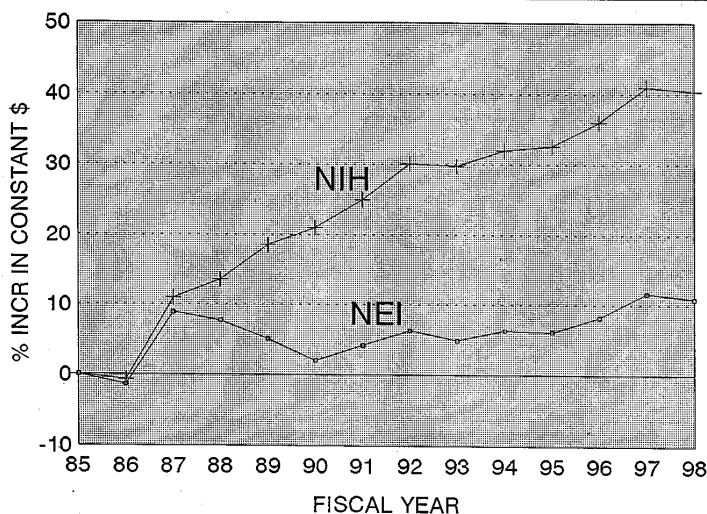
- Expanding research on the macula of the retina and the retinal blood supply to identify genetic, nutritional, or other age-related changes which contribute to the development of AMD;
- Exploring retinal immunology and retinal rescue by transplantation of neural retina and retinal pigment epithelium to determine if transplantation can be used therapeutically in AMD;
- Studying growth factors and genetic approaches for rescuing or regenerating diseased retinal tissue;
- Expanding the search for genes contributing to the development of AMD and the linkage between these gene defects and the death of photoreceptor cells in the macula;
- Developing animal models of AMD to investigate the mechanism of photoreceptor cell death in this disease and subsequently developing a means of prevention and treatment;
- Exploring the use of biological factors and inhibitors to prevent the development of abnormal blood vessels in AMD;
- Expanding basic and applied research on low vision and developing better devices and other strategies to enable enhanced vision by those individuals with AMD by means of optical or electronic aids; and
- Developing noninvasive techniques for the early diagnosis of AMD and better methods to prevent and treat the disease.

The members of the Alliance for Eye and Vision Research are supportive of an increased research focus on eye and vision disorders, such as AMD, and hope the Committee will allocate additional funding to NEI to allow these critically important research efforts to continue and expand.

While we recognize the budget constraints facing the Committee this year, AEVR believes a significant medical research effort funded by the NIH is critical to the longterm security of our nation. Therefore, we support a doubling of the NIH budget over the next five years as proposed in S. Res. 15. This would require a 15 percent increase in funding in fiscal year 1998. At a minimum, AEVR requests that you support funding for the NEI in fiscal year 1998 at \$362.7 million as requested by the National Eye Institute Advisory Council in their "Citizens Budget Proposal".

Our investment in eye and vision research continues to bring dividends, but much remains to be learned about eye and vision disorders. When asked, Americans fear the loss of eyesight more than the loss of any other sense. We must ensure that we are doing our best to find cures and treatments for eye and vision disorders, and providing quality eye care services and devices for those already visually impaired.

COMPARISON OF PERCENTAGE INCREASE IN FUNDING FOR NEI & NIH  
FY 1985 - FY 1998



## PREPARED STATEMENT OF THE NATIONAL DEPRESSIVE AND MANIC-DEPRESSIVE ASSOCIATION

The National Depressive and Manic Depressive Association appreciates the opportunity to present written testimony in support of fiscal year 1998 funding for the National Institutes of Health (NIH) and in particular the National Institute of Mental Health (NIMH).

The National Depressive and Manic-Depressive Association is dedicated to increasing the awareness of depressive illnesses, and encouraging those individuals who are affected by these diseases to seek help. In any given year, 17.4 million American adults have some form of depressive illness such as major depression, bipolar disorder, or chronic, moderate depression. Women are twice as likely as men to experience major depression. Two out of three people with mood disorders do not get proper treatment because their symptoms are not recognized, are misdiagnosed, or due to the stigma associated with mental illness are blamed on personal weakness. While the cause of depression is not fully understood, it is clear that genetic, biochemical and environmental factors can play a role.

As a patient-based organization, we are committed to educating patients, families, professionals, and the public about the nature of depression and manic depression as treatable medical diseases. We have a Scientific Advisory Board of over 60 distinguished researchers and practicing mental health professionals; a toll-free information line; a quarterly newsletter; annual conferences; and a grassroots network of more than 300 chapters throughout the United States.

We strive to promote self-help for patients and families. Our support groups provide information and support for patients throughout the United States. These groups also give patients the opportunity to be with others who share these illnesses, and to share their knowledge and experiences with each other.

Another of our goals is to eliminate discrimination and the stigma that is too often associated with mental illness. The fact is, many people who have depression are just like other Americans. We have successful careers, we take care of our families, and we live productive and fulfilling lives.

Most importantly, National DMDA is an advocate for research. Research is the only hope people with depressive illnesses have to look forward toward a bright and productive future. Research advances are providing scientists with promising opportunities to better study the brain function and systems, but there is still a tremendous amount of research to be done. Depressive illnesses will affect millions of Americans during their lifetime and is more widespread than AIDS, cancer and coronary heart disease. The lack of awareness about the nature and treatments of depression along with the social stigma associated with mental illness has hindered society's ability to address the issue of depression. However, continued research promises to help us learn more about mental illnesses and to develop and improve treatment options. Hopefully, leading us one day to a cure.

The National Institute of Mental Health leads the nation's research efforts to identify the causes of and the most effective treatments for mental illnesses. These conditions annually account for more than \$148 billion in direct health care costs, and indirect costs, such as lost work days for patients and care givers. The costs and treatment of these illnesses account for almost 10 percent of total U.S. annual health care expenditures. Investments in biomedical and behavioral research on mental disorders are imperative for preventing and treating these debilitating problems and controlling the costs associated with them.

As a patient-based organization, we are pleased about the emphasis NIMH is placing on translational research. These efforts will ensure that clinical researchers are able to test and develop the promising discoveries of basic researchers, giving patients hope of new and better treatment options.

There have been many exciting advances recently as a result of NIMH supported research on depression and manic-depression. For example, researchers have identified several chromosomes that may include genes that are linked to manic-depressive illness; clinical researchers have conducted an effective drug trial which appears to significantly improve treatment outcomes for children with depression; and researchers have helped to increase education about depression by developing a collaborative model of care which has been particularly helpful to primary care professionals.

These research advances, in this the Decade of the Brain, have allowed many of us with depression to regain our lives. For that reason, National DMDA supports an increase in funding for NIMH as requested by the President in his budget. We are hopeful, however, that the Committee will provide a larger increase in funding for the NIH overall than requested by the President and that NIMH will receive an increase in funding proportional to the overall NIH increase.

Therefore, on behalf of the millions of Americans who suffer from depression and depend on this research, the National Depressive and Manic-Depressive Association strongly supports a doubling of NIH appropriations over five years, as proposed by Senator Mack and Specter in S. Res. 15. This would require a 15 percent increase for fiscal year 1998. As an absolute floor, we support the recommendation of the Ad Hoc Group for Medical Research Funding for a 9 percent increase in fiscal year 1998.

Thank you again for the opportunity to present testimony. The National Depressive and Manic-Depressive Association looks forward to working with you to increase our national commitment to medical research, especially as it relates to mental illness.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES

Thank you, Chairman Specter, for inviting the American Association of Critical Care Nurses (AACN) to submit testimony for the hearing record in support of funding for the National Institute of Nursing Research (NINR), the Nursing Education Act, and the Agency for Health Care Policy and Research (AHCPR) for fiscal year 1998.

AACN is a not-for-profit service association dedicated to the welfare of people experiencing critical illness or injury. Our energies are primarily directed toward advancing the art and science of critical care nursing and promoting environments that facilitate comprehensive professional nursing practice for those experiencing actual or potential illness or injury. Our vision is one of a health care system driven by the needs of patients where critical care nurses make their optimal contribution.

AACN was founded in 1969 and has grown to become the world's largest specialty nursing organization with nearly 80,000 members representing the United States and 35 countries around the world. AACN has chapters in every state in the U.S. and overseas, numbering over 270.

*The National Institute of Nursing Research*

The National Institute of Nursing Research (NINR) at the National Institute of Health (NIH) improves the quality of life for all Americans by promoting healthy lifestyles and behaviors that will ease the effects of disease. AACN strongly supports the NINR's goals of health care effectiveness, cost effectiveness, and assuring that the scientific agenda has a human aspect and is directly relevant to applying research findings to improve the nation's health. Nursing research findings, once thought to affect nursing practice alone, are now understood to be relevant to the work of all health care practitioners, and NINR supports research on the biological and behavioral aspects of critical health problems confronting the nation.

As nurses providing care to the critically ill, one of the most important things we can do for our patients is provide relief from their pain and suffering. AACN is pleased that NINR is playing a major role in NIH's pain research initiative. Nursing affords a unique vantage point from which to examine the way pain affects patients and their caregivers. NINR-sponsored scientists are conducting research investigating whether women and men respond in the same way to drugs used for pain relief. This research is important because it offers the potential for providing women with increased pain relief for surgical pain, as well as pain associated with nerve damage, cancer, and other disease conditions. Pain is also a costly health problem, costing our nation over \$100 billion annually in lost productivity and health care expenses.

AACN currently sponsors Thunder Project II, a large-sample, multi-site research project in partnership with seven other nursing organizations. The purpose of the research is to examine pain perceptions and responses of acutely or critically ill pediatric and adult patients to selected procedures. Specifically, the research will: describe patients' pain perceptions and responses for each selected procedure across different phases of the procedure; compare patients' pain perceptions and responses across procedures; examine relationships between patients' pain perceptions and responses to selected procedures and factors such as the patient's age, gender and ethnicity; and, describe distress associated with selected procedures. AACN is pleased that NINR has identified research in the area of end-of-life care as a priority initiative for fiscal year 1998. NINR is planning to sponsor research addressing four objectives: managing the transition to palliative care; understanding and managing pain and other symptoms, such as nausea and depression in the context of end-stage illness; measuring outcomes (relief of symptoms); and, documenting costs incurred by patients and family caregivers during end-stage illness.

AACN is disappointed in the President's budget request of a 2.6 percent increase in funding for NIH in fiscal year 1998. AACN strongly supports a doubling of NIH appropriations over the next five years, which would require a fifteen percent increase for fiscal year 1998. As an absolute floor, AACN supports the recommendation of the Ad Hoc Group for Medical Research Funding for a nine percent increase for fiscal year 1998.

#### *Nursing Education*

AACN believes that education is fundamental to professional growth and to excellence in clinical practice and optimal patient outcomes. Practitioners must commit to life-long learning to assure they remain competent in fulfilling their obligations to the patients and families they serve.

AACN is extremely disturbed by the cuts to health professional education programs included in the President's fiscal year 1998 budget request. The budget request consolidates existing multiple categorical grant programs under Title VII and Title VIII of the Public Health Service Act and replaces them with five program clusters. The Nursing Education/Practice cluster includes the following programs: Nursing Special Projects, Advanced Nurse Education, Nurse Practitioner/Nurse Midwife Education, Professional Nurse Traineeships, Nurse Anesthetist Training, and Nursing Education. Overall, funding for health professions training is cut from \$290 million to \$130 million. And funding for these specific nursing programs is cut from the current level of \$63 million to \$7.7 million for fiscal year 1998. These programs are essential in providing support to strengthen the capacity for basic nurse education and practice, train nurse practitioners and other advanced practice nurses, and increase nursing workforce diversity.

These drastic cuts would force a number of programs to close completely, and would affect approximately 4,000 students who rely on traineeships to help finance their education.

In addition to affecting these students, AACN is concerned about these cuts because we believe that it is not sound public policy. According to the Bureau of Labor Statistics, demand for health professionals is expected to grow by 47 percent by the year 2005, with the need for advanced practice registered nurses among the greatest. In addition, an Institute of Medicine study on the role of nursing staff in hospitals and nursing homes found that a more advanced, or more broadly trained registered nurse (RN) workforce will be needed in the future. Such training is currently being provided under the programs funded under Title VIII of the PHS.

AACN supports funding for the Title VII and Title VIII health professions programs at the fiscal year 1997 plus inflation, which amounts to \$302 million.

#### *The Agency for Health Care Policy and Research*

AACN firmly believes that research is needed to develop a scientific basis for critical care nursing practice and to achieve a broad understanding of the role and impact of critical care nurses on patient outcomes. The science-based research supported by the Agency for Health Care Policy and Research (AHCPR) is an important compliment to the biomedical research conducted at NIH. AHCPR's clinical research goes the next step by evaluating the effectiveness of new and existing medical interventions in clinical practice.

Our health care delivery system continues to undergo dramatic changes, making outcomes research and objective measures more important than ever before. AHCPR is the principal federal agency responsible for determining what is effective and cost-effective in health care. AHCPR's goals are to determine what works best in clinical practice, improve the cost-effective use of health care resources, help consumers make more informed choices, and measure and improve the quality of care.

Many research projects funded by AHCPR are gradually helping our communities refocus health care so that it is truly driven by the needs of patients and their families.

As you know, in 1990 Congress passed the Patient Self Determination Act, with the goal of educating Americans about their right to make their own health care choices. This is of particular interest to critical care nurses in light of a Robert Wood Johnson study that followed 9,000 critically ill patients and found discrepancies between patient's end-of-life care directions and their actual treatment.

This act requires hospitals and nursing homes to inform patients admitted to their facility about their options in completing an advanced directive or living will. The act is designed to help health care providers, patients and their families. But since there was no provision for implementation funding, patients and their families have not been helped. Advanced directives such as living wills and medical power of attorney are the only vehicle to let health care providers know patients' wishes in case they should become incapacitated and unable to make treatment decisions.

In addition, advanced directives can do away with much of the wasteful emotional cost of guilt and suffering as a result of being forced to make difficult decisions about treatment for someone else without knowing their wishes as well as wasteful treatment costs. AACN is currently working to educate consumers about the Patient Self Determination Act and its importance. The Committee's support for AHCPR has provided AACN with the resources to design a community outreach program to improve completion rates for advance directives. AACN's program, Research on Advance Care Planning Including Advanced Directives, has a specific emphasis on an education program stressing definition and documentation of care preferences so that in the event of catastrophic illness or injury and thus inability to participate in health care decision making, individual care preferences can be honored.

The Research on Advance Care Planning Including Advanced Directives is an excellent project, and AACN encourages the Committee to include additional funds in its fiscal year 1998 bill to complete the project.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND  
HYGIENE

The American Society of Tropical Medicine and Hygiene (ASTMH) is pleased to submit public witness testimony to urge your continued support of the infectious diseases activities, including emerging infectious diseases and tropical infectious diseases, of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). ASTMH is a professional society of 3,100 researchers and practitioners dedicated to the prevention and treatment of infectious and tropical infectious diseases.

*Background*

Remarkable advances made in science, medicine, and public health throughout this century have resulted in tremendous improvements in the fight against infectious diseases. However, these successes have also given us a false hope and a perception that infectious diseases are a thing of the past. Nothing could be further from the truth. The microorganisms (parasites, bacteria, and viruses) are getting resistant to our drugs and the globalization of our food supply and international travel bring increasingly worrisome infectious diseases to our doorstep, such as hantavirus, drug-resistant streptococcal infections, and chlorine-resistant cryptosporidial parasites. Between 1980 and 1992, the death rate due to infectious diseases increased 58 percent in the United States, making it the third leading cause of death in the country.

Worldwide the threat is even greater. Approximately 2.5 billion people are at risk of tropical infectious diseases and 500 million people presently suffer from them. I would like to take a few moments to discuss just two of these, diarrheal diseases and malaria, which are among the most common causes of morbidity and death in children under the age of 5.

*Diarrheal Diseases*

Diarrheal diseases kill 3-4 million children each year (over 9,000 children each day). In some areas of Brazil, 1 child in every 4 may never reach his or her 5th birthday, over half of whom die of diarrheal diseases. Many children experience 8 to 10 dehydrating, malnourishing diarrheal illnesses each year in their more critical developmental first 2 years of life. Yet these children are teaching us new approaches to diagnosis and a new glutamine-based oral rehydration and nutrition therapy that have direct application to U.S. patients in hospitals, day care centers, and nursing homes. Further, work on another enteric infection, *H. pylori*, is curing ulcers and preventing stomach cancer in the United States.

*Malaria*

An estimated 200 to 300 million cases of malaria occur annually and at least 1.5 million of these are fatal. Mosquito resistance to pesticides, and parasite resistance to drugs have resulted in a dramatic resurgence of malaria. While mosquito-borne malaria was interrupted in the U.S. during the 1940s, localized outbreaks sporadically occur. For example, CDC reported a case in Georgia in June 1996 in a man who had never been to an area in which malaria is common.

The ASTMH is very encouraged by NIH Director Varmus' efforts to bring renewed attention to malaria, including his role in a recent gathering of international scientific leaders in Dakar, Senegal. In 1998, the National Institute of Allergy and Infectious Diseases (NIAID) will launch a new malaria clinical research initiative to expand our understanding of human immunity to *Plasmodium falciparum*, the etiologic agent of the most severe form of malaria. Earlier this year, researchers at the

Walter Reed Army Institute of Research in Washington, D.C. reported that an experimental vaccine devised by the U.S. Army and a private pharmaceutical company worked well in a preliminary test. A synthetic compound based on a protein in *Plasmodium falciparum* protected six of seven people after they had been bitten by infected mosquitoes.

#### *National Institutes of Health*

NIH efforts in infectious diseases are primarily conducted by the NIAID. Basic research supported by NIAID is the essential underpinning of our disease surveillance, prevention, and control efforts, and NIAID works in full partnership with the CDC to respond to the public health threat of emerging infectious diseases. NIAID programs directed toward tropical and emerging infectious diseases include the following:

- The Expanded Research on Emerging Diseases, which was initiated in 1997. This will provide support to basic and applied research on emerging and re-emerging diseases of parasitic, viral, bacterial, and fungal etiology. A second initiative will be launched in 1998.
- The Modern Vaccines for Targeted Emerging and Reemerging Diseases was also begun in 1997. This will expand research on mycoses and measles, both of which have a need for improved vaccines. NIAID is the lead federal agency for vaccine research and development. Next year, it plans to start a new initiative entitled Basic Mechanisms of Vaccine Efficacy, which will provide support for innovative strategies in vaccine development.
- Special Emphasis Program Projects such as the International Collaboration on Infectious Diseases Research program; the Tropical Medicine Research Centers; and the Tropical Disease Research Units.

NIH also supports research and research training through the Fogarty International Center (FIC). FIC's purpose is to support the missions of the NIH institutes and to meet the broader global health needs of the U.S. through international programs. International partnerships are critical to identify areas of disease, conduct laboratory and field investigations, and test interventions.

FIC provides awards to enable foreign scientists to train in the U.S. and to enable American scientists to conduct research abroad. This can have a tremendous impact on diseases that are common in the U.S. In 1997, FIC will fully initiate a new program, the International Training and Research in Emerging Infectious Diseases program in collaboration with NIAID, to train scientists from developing nations in infectious diseases research, control, and prevention strategies.

#### *Centers for Disease Control and Prevention*

The ASTMH is very appreciative of the generous increase that this Committee provided to the CDC Infectious Diseases program in 1997. We are also appreciative that you recommended that CDC use a portion of the additional resources to address the infrastructure component of the CDC's 1994 plan, "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States." The deterioration of federal, state, and local health laboratories is a serious problem.

As part of this critical need, the CDC has planned for a new laboratory building to provide facilities for investigations on infectious pathogens requiring medium- to high-level containment. Without additional resources, highly infectious pathogen facility needs cannot be met. A new facility is needed to replace the outdated and overcrowded laboratories presently in use, including many in which security and safety are of concern.

For 1998, the ASTMH urges that Congress support the Administration's request for a \$25 million increase in CDC Infectious Diseases activities, including a \$15 million increase to continue the implementation of the Emerging Infections plan. These funds will be used in part to continue the expansion and improvement of our national public health laboratory facilities. While the ASTMH is very appreciative of the significant funding increases provided by Congress for CDC Infectious Diseases activities over the past five years, it is essential that adequate resources be made available to provide CDC and state and local authorities with the capacity to fully address emerging and reemerging infectious diseases, as outlined in the 1994 CDC plan.

#### *Summary*

We know that infectious agents will continue to be discovered and that some previously recognized pathogens will continue to reemerge as serious public health problems. However, many uncertainties exist. For example, we do not know where or when they will appear, what they will look like, or how they will behave. To be prepared, we must have an adequate surveillance system and modern infrastructure facilities, coupled with scientific expertise in both basic and applied areas, to de-



velop whatever tools are necessary to rapidly respond to and control the threats posed by these diseases.

The ASTMH urges your continued support of these activities. We request a nine percent increase for the NIH. Furthermore, we request that Congress support the Administration's proposed \$25 million increase for Infectious Diseases activities at the CDC.

Thank you for your consideration of our request.

PREPARED STATEMENT OF J. ALFRED RIDER, M.D., PH.D., PRESIDENT, CHILDREN'S  
BRAIN DISEASES FOUNDATION

I am Doctor J. Alfred Rider, President of the Board of Trustees of the Children's Brain Diseases Foundation. It is a pleasure to submit testimony on behalf of the Foundation for inclusion in the Senate Appropriations Committee, Labor-HHS Education Subcommittee hearing record for fiscal year 1997/1998. I am submitting my testimony on behalf of the Children's Brain Diseases Foundation and the thousands of children and their families who are affected with Batten disease.

Specifically, I would like to address the need for continued funding at least at the previous 1994 level plus a modest increase for Batten disease. Batten disease is a neurological disorder affecting the brains of infants, children and young adults. It occurs once in every 12,500 births. There are approximately 440,000 carriers of this disorder in the United States. It is the most common neuro-genetic storage disease in children. Although there are four major types of Batten disease, the usual case is characterized by motor and intellectual deterioration, visual loss, behavioral changes, the onset of progressively severe seizures and terminates in death in a vegetative state. This irreversibly severe illness constitutes an enormous nursing and financial burden to families with afflicted children. Patients may live in a deteriorating state, from 10 to 43 years. The changes that occur in the brain in these children are quite similar to many of the changes that occur in the aging person. Thus, effective treatment for Batten disease may also allow us to alter the aging process and age associated senility in our aging citizens.

Batten disease is now recognized world wide, but continued research money is needed to successfully advance the research to determine the exact cause of this disease.

The Children's Brain Diseases Foundation, begun in 1968, has had a direct role in stimulating interest in Batten disease world wide by granting money to various investigators. The Foundation has sponsored six world wide symposiums; the most recent in Helsinki, Finland, June 1996. There are now over 100 investigators world wide. Their work must continue to be encouraged and supported.

A major impetus to these advances occurred as the direct result of your committee's perseverance and interest which began to achieve fruition in 1991 when for the first time, the committee recognized that not enough attention was being spent on Batten disease, and they directed the National Institute of Neurological Disease and Stroke (NINDS) to expand its research in this direction.

I am happy to say that the NINDS heeded your requests and suggestions and actively solicited research grants for Batten disease by sending out an official Request for Applications (RFA). A special committee was established to review Batten disease grants since it was felt that the usual committees did not have sufficient expertise to make proper evaluations. Numerous applications were received and a significant increase in money was spent on Batten disease research. In 1994, \$3,272,699 was spent.

In 1995, a group in Finland, in collaboration with the University of Texas, isolated the gene defect; mutations in the palmitoyl protein thioesterase gene localized on chromosome 1 p32, causing the infantile form of Batten disease, and the International Batten disease Consortium isolated the genetic defect in the juvenile form of Batten disease and have found it to be on chromosome 16p12.1. Just recently, a group in England, headed by Doctor Mark Gardiner, identified the region that contains the gene for the classical late infantile form of Batten disease. It lies on chromosome 11p15, and the gene for the variant form of the late infantile lies on chromosome 15q21-23.

It is now possible to make an absolute definitive diagnosis by a simple blood test, and it is also possible to identify carriers in the three forms. The whole field is now opened up for treatment by gene and enzyme replacement, and the possible prevention of three forms of the disease by genetic counseling, including in vitro fertilization.

In spite of these three unprecedented major significant breakthroughs, the NINDS in fiscal year 1996 has only spent \$2,459,885 on research grants. This is approxi-

mately 22 percent less than the \$3,272,699 in fiscal year 1994. We are at a loss to understand this and are afraid that this decrease may cast a damper on the whole research process. Our scientists are there. They are like expensive finely tuned complicated scientific machines and like all machines, they need fuel. Instead of traditional fuels, these individuals need American dollars in sufficient amounts so that they may pay for their expensive new scientific equipment as well as being able to hire the technical help necessary to expedite the research.

Much needs to be done. The exact genetic defect in the late infantile and adult forms of Batten disease must be isolated. The enzyme defects resulting from gene abnormalities in all four types must be determined. This should then lead to definitive therapy by gene replacement or specific enzyme therapy. Several laboratories are already set up to make definitive diagnosis in the infantile, late infantile and juvenile forms of Batten disease.

We are cognizant of the difficulty in getting funds for research. However, the amount requested is a small price to pay to solve a disease which wrecks havoc on the victims and families and is draining our national resources by approximately 712 million dollars per year based on approximately 300 children born with Batten disease each year and others living with this disease at an average treatment and maintenance cost of over \$150,000 per year for each year of life. This lifetime, in a vegetative state, can last 10 to 43 years.

Although there have been three significant breakthroughs with regard to gene localization in Batten disease, we were disappointed that the funding for fiscal year 1996 was approximately 22 percent less than in fiscal year 1994. Consequently, we would like to suggest the following wording.

*Suggested Wording*

“The Committee continues to be concerned with the pace of research in Batten disease. The Committee believes that the Institute should actively solicit and encourage quality grant applications for Batten disease and that it continue to take the steps necessary to assure that a vigorous research program is sustained and expanded. The Committee requests that the funding for Batten disease research for fiscal year 1997 be at least equal to the funding provided for fiscal year 1994”.

PREPARED STATEMENT OF THE NATIONAL ALOPECIA AREATA FOUNDATION AND THE COALITION OF PATIENT ADVOCATES FOR SKIN DISEASE RESEARCH

Chairman Specter and members of the Senate Subcommittee on Appropriations for the Departments of Labor, Health and Human Services, and Education, I am Jan Shapiro, a person with alopecia areata for the past fifteen years, and a support group leader in Northern Virginia. I am testifying on behalf of the National Alopecia Areata Foundation (NAAF). The National Alopecia Areata Foundation<sup>1</sup> is the largest organization in the nation dedicated to finding a cure for alopecia areata. It also provides support for those with alopecia through a publication program and support groups. The support groups provide information and direction to thousands of people with alopecia areata. As a support group leader I am sometimes the first person, outside of the medical community, that a person turns to for help and information. Frequently people call who are scared, misinformed and afraid. The support group provides a forum to reach out to others, problem-solve and grow.

The National Alopecia Areata Foundation is also a member of, and currently the headquarters for, the Coalition of Patient Advocates for Skin Disease Research. The Coalition, which operates as a voluntary organization and as such receives no public or private money, provides an umbrella to over 22 “lay” skin groups. These groups represent millions of people who suffer from a wide range of skin diseases. We work together for two reasons. First, to provide information to others about why research is needed. And secondly, so that we may push for a wide ranging research agenda. Many of us believe that diseases such as alopecia, lupus and others are the result of a malfunctioning immune system. When the key is found to one of our diseases then it is likely that many of the other diseases represented in the coalition will be cured. By working together we will make a difference.

Alopecia areata is a disease that strikes over four million Americans. It is the loss of hair. For some it is a quarter size patch that can be easily covered, for others it is the loss of every hair follicle on their body. For over half of the people with alopecia areata it starts between the ages of 5 and 9. It strikes members of all eth-

<sup>1</sup>The National Alopecia Areata Foundation receives no federal grants or sub-grants, nor do we receive federal contracts or sub-contracts. Through the generosity of federal employees throughout the United States and around the world we receive contributions of approximately \$5,000 through the Combined Federal Campaign.

nic groups. The loss of hair has several types of impacts. Hair provides significant protection for the body. The loss of eyelashes means that even the simple act of opening and closing ones eyes to keep the dust out is a difficult process.

However, alopecia is not simply a physical problem, it has surprisingly serious psychological demands. For many people, when they first discover their hair falling out they are devastated. They think that they are the only ones in the world with the disease. Frequently when they go to their doctors they discover that even their physicians have little idea of what is happening, why it is happening, or even if others suffer from it. For some treatment options stop there, while for others they begin the long process of finding someone who knows something about the condition.

Unfortunately in our society the lack of information is not the only problem. Frequently people with alopecia believe that they are vulnerable to the stares and grimaces of those around them. People have lost their jobs. A noted news anchor lost his on-air job because he was suddenly perceived as being unappealing. This lack of being appealing (either real or perceived) causes many people to lose confidence in themselves and they begin to withdraw from society.

Recently, two parents called me about their children. These two girls, one 12, the other 14, are loosing their hair right now. They are staying inside their homes, fearing that going outside will lead to harassment, non-acceptance, and not being accepted as normal. It seems to be hardest on children.

Fortunately, there are people who can help, and in many of our support groups people learn how they can help themselves both cosmetically and psychologically. They learn that they are not alone and that they can do something about their sense of vulnerability and isolation. But the real solution will be when we find a cure for alopecia areata.

Over the past ten years the Foundation has raised and provided almost \$1½ million for research studies. Our privately funded research studies have been studying the genetic structure of hair, the function of the immune system, and supporting non-human research studies looking for the cause of alopecia.

Part of our research program is to continue to work with the National Institute of Arthritis, Musculoskeletal and Skin Disorders to create a research agenda. In 1990 and 1994 NIAMS and NAAF conducted two international research symposiums on what is known about alopecia areata. One of the many results from this joint program was that NIAMS funded a significant study on the structure of the disease. Another result was the discovery of animals with alopecia—thus NAAF was able to support the first non-human host of the disease.

We are now planning for the Third International Symposium on Alopecia Areata, with NIAMS. This symposium, as with the earlier meetings will bring researchers, clinicians, and patients together from around the world to study what progress has been made and how new studies should be structured. The convening authority of NIAMS is critical for this sharing of knowledge.

Working together in this unique private-public partnership is a significant step toward finding a cure. We hope to continue this relationship with NIAMS providing limited funds for critical studies, while we continue to work to support the research effort as well. With this partnership we have been able to sharpen the research agenda so that we are looking at questions that are building on a wider and more informed base of knowledge.

The Coalition of Patient Advocates for Skin Disease Research ask that you continue to support NIAMS. We are asking for an increase of 9 percent. This increase would allow the Institute to increase its ability to fund more research projects and support more programs that will help the over 60 million people who are impacted by skin diseases. We also believe that work done in any of the disease areas represented by the Coalition of Patient Advocates for Skin Disease Research, will have a profound impact on the lives of over 60 million Americans who suffer from one or more than one of the diseases that NIAMS is charged with investigating. We also believe that when a cure is found for any of these diseases that there is a good chance that it will help in finding a cure for many of the other skin diseases.

Thank you for your time and concern.

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PREPARED STATEMENT OF FELICE J. LEVINE, PH.D., EXECUTIVE OFFICER, AMERICAN SOCIOLOGICAL ASSOCIATION

Thank you for the opportunity to submit a written statement regarding fiscal year 1998 appropriations for the National Institutes of Health. I am Felice J. Levine, Executive Officer of the American Sociological Association, a scientific society of more than 13,000 sociologists who are in research, teaching, and practice. Every day, sociological research makes important contributions to understanding the causes and

consequences of our nation's most pressing health issues—including violence, AIDS, children's health, and aging.

In appropriating funds for the National Institutes of Health, this Subcommittee's record is so impressive because you have sent strong signals that funds should be used to coordinate among federal health institutes, support essential health research, and train the next generation of scientists. That focus on coordination, research, and training has resulted in crucial advances that otherwise would not have been possible. I commend and applaud your commitment and ask that you extend it in fiscal year 1998 and in the years ahead. Our nation will benefit tremendously if you do.

I also commend your support for balance in the types of research conducted by the National Institutes of Health. Your Subcommittee has recognized that social and behavioral factors—such as lifestyle choices, the desire and ability to maintain exercise and medical regimens, social and psychological functioning, socioeconomic conditions, and the larger social and cultural environment—all affect health. Today, because you recognized the compelling need to expand the types of research we conduct, we have a better balance of biomedical and behavioral and social science research. That balance is essential if the National Institutes of Health is to succeed in its mission. You have done a great service to this nation.

#### OBSSR: MAKING A DIFFERENCE

Perhaps one of Congress' most important recent accomplishments regarding the National Institutes of Health has been to conceive and support the Office of Behavioral and Social Sciences Research (OBSSR). Since 1995, OBSSR has coordinated social and behavioral science research across the National Institutes of Health, and integrated it with biomedical research. The work of OBSSR is based on the premise that behavioral, social, and cultural factors affect health—and that they do not act in isolation. We know that molecular, physiological, behavioral, and social factors interact in complex ways that affect health. With an innovative strategic plan for the future and continued support from Congress, OBSSR is poised to continue to create synergy and vastly improve the outcomes of health research for years to come.

In just two years, OBSSR's efforts to promote coordination among agencies has resulted in progress on a number of critical issues. One of those issues is violence. No topic deserves more attention. Violence has had devastating effects on all the core social institutions in our society. Even with recent declines in some types of violence in some large cities, violence has invaded our homes and streets, affecting virtually every aspect of society. Social and behavioral science research is our best hope to understand and address the violence that pervades our society.

In fiscal year 1996, OBSSR addressed the violence issue by co-sponsoring a request for applications entitled Research on Violence Against Women Within the Family. OBSSR took the lead in this initiative in collaboration with the Department of Justice's National Institute of Justice and also coordinated Department of Health and Human Services activity among eight other agencies—the NIH Office of Research on Women's Health, NIH Office of Research on Minority Health, National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, National Institute on Aging, National Center on Child Abuse and Neglect, and Centers for Disease Control and Prevention. This remarkable collaboration was the first inter-departmental initiative to address violence from a multitude of perspectives, bringing together health, mental health, public health, criminal justice, and other social science experts. As a result, ten promising new research projects are now underway, including studies of interventions for rape victims, battered women and their children, and domestic violence among Latinos. This is precisely the kind of approach that has been lacking, as the American Sociological Association underscored in its book, *Social Causes of Violence: Creating a Science Agenda*, distributed to every Member of Congress last year.

I could cite similar examples of OBSSR's leadership in advancing the cutting edge of science through conferences, science writers' workshops, and training initiatives. They, too, would make the same point that OBSSR is playing a catalytic role in addressing some of our most pressing health problems. Given OBSSR's remarkable track record, impressive capacity, and proven ability to use a small amount of resources to leverage tremendous gains, we urge the Congress to expand resources for this office. A budget of \$4 million for OBSSR in fiscal year 1998 would have a multiplier effect for every additional dollar beyond its fiscal year 1997 allocation.

## INVESTING IN RESEARCH: A COMPELLING PRIORITY

Mr. Chair and members of the Subcommittee, I now want to turn to the importance of investing in basic health research and doing so fully inclusive of the social and behavioral sciences. With approximately half the deaths in this country attributable in part to social and behavioral factors such as lifestyle and diet, health research must include these considerations. Quite simply, investing in fundamental science in these areas ultimately creates a healthier nation.

*AIDS*

One topic where we can see the powerful, positive impact of conducting social and behavioral science research relates to AIDS. Epidemics of the size and scope of AIDS require examination of the social contexts in which they occur. By examining social relationships, families, communities, institutions and cultures, social science research has and can continue to uncover features of the HIV/AIDS environment which contribute to the transmission and potential prevention of this disease.

This kind of cutting edge research is occurring in sociology today because funding is available to support it throughout our federal health institutes. For example, sociological research demonstrates that, when drug users educate other drug users about how AIDS is spread, they share equipment less, use shooting galleries less often, decrease their injections, and are more likely to use new needles or sterilize used needles. Obviously, this research has important implications for stopping the transmission of AIDS. Yet, despite such emerging knowledge, we still have considerable work to do to understand fully how best to address the AIDS epidemic.

*Children's Health*

We have an urgent priority, too, to fund children's health initiatives and to include a focus on behavioral and social science research. I need not remind this Subcommittee of the ground-breaking work supported by the National Institute of Child Health and Human Development (NICHD). In a society with ever-changing social and family structures and mounting pressures on individuals and families, NICHD is funding multi-faceted research to improve the health and development of children.

This research is so important that a coalition representing scientists, health professionals, and a wide range of advocates have created Friends of NICHD. The American Sociological Association is proud to be part of that effort. NICHD is supporting critical research on a range of children's health issues that includes crucial social and behavioral factors. This work is worthy of strong support. It addresses crucial health issues in our society—how to teach parenting and nurturing skills, prevent injuries and fatalities in young children, address learning disabilities, and teach parents steps that can prevent sudden infant death. It addresses strategies to reduce unintended teen pregnancy, stop teens from using drugs or alcohol, understand and improve fathers' role in child care and child rearing, and develop behavioral interventions that address risks minority youth face. It supports and promotes research such as the sociological studies that have produced essential data on the economic impact of divorce and the consequences of growing up in homes without both parents.

Our work in learning to protect and improve children's health is not nearly done. Our nation's rates of youth drug abuse, school drop-outs, and juvenile violence is compelling evidence of the need to continue funding research into children's health. Our children's health is our nation's future. Therefore, we should not under-fund this essential research.

*Aging*

The third research area I want to highlight is aging. The demographics of our society demand that we move quickly to better understand aging. The National Institute on Aging supports essential research on the social and behavioral aspects of aging, as well as the physical implications of getting older.

Federally funded research today is examining a range of emerging issues, including health service delivery in an aging society, ways to promote preventative self-care among older people, influences on individuals' ability to cope with illness and disability, and the nature and effectiveness of evolving types of home-and community-based services for older Americans. In one example, social scientists working with the National Institute on Aging have documented a slowing in disability rates among older people over the past decade and are exploring the reasons and implications. But, with so much more to learn, it is imperative that we increase federal resources for research on aging.

In focusing on the need for social science knowledge, I have discussed initiatives and research on AIDS, children's health, violence, and aging. These are but a few

examples of the critically important research being conducted today with federal support. More work will be needed in these and other fields tomorrow—and for years to come. But our nation will not be able to do that work unless we continue to produce scientists who are prepared and capable of meeting emerging challenges.

#### TRAINING: A COMMITMENT TO THE FUTURE

Adequate funding is essential to developing the training programs that create future generations of scientists. Only a stable commitment to health research and investments in training will encourage future generations to enter these scientific fields. Anything less would deny our children and their children access to the health-related knowledge they need.

One example of how this training can pay off is the Minority Fellowship Program, a collaborative effort between the American Sociological Association and the National Institute of Mental Health. The 23-year-old Minority Fellowship Program has trained more than 360 minority scholars in the sociology of mental health. Through this long-term investment, we have produced scientists of color who are currently engaged in research on mental health and mental illness, including stress and coping strategies; identity, self-esteem, and emotional/psychological well-being; mental health and aging; violence and traumatic stress; substance abuse; homelessness; HIV/AIDS; utilization of health services among the mentally ill; and poverty, emotional, and physical well-being, among others. Plain and simple, this is knowledge we need.

A more recent and similarly important training initiative is the B/START grant program. B/START stands for Behavioral Science Track Awards for Rapid Transition. The National Institute of Mental Health launched this program in 1994 to increase the number of behavioral researchers in the field. The National Institute on Drug Abuse launched its B/START program in 1996. The program provides seed money to junior researchers to let them pursue their work and overcome financial difficulties. The B/START program is an effective way to promote and nurture recently trained social and behavioral scientists, and it provides evidence that government recognizes the value of the work done in these fields. We recommend expanding this program across institutes and sending an explicit signal that B/START includes attention to social aspects of health and disease.

Investing in training pays off, and failing to do so creates problems that take years to overcome. In 1994, the National Academy of Sciences emphasized the importance of increasing the number of social and behavioral scientists in health-related fields. In the report, *Meeting the Nation's Needs for Biomedical and Behavioral Scientists*, the Academy recommended allocating more National Research Service Awards to expand the workforce in behavioral science.

#### *Conclusion*

Adequate funding is essential to the effort to improve our nation's health. It enables coordination and integration across disciplines and fields. It supports research into health and well-being. It promotes training programs that develop the next generations of scientists.

For these and other reasons, I urge this Subcommittee to build upon its impressive past commitment by ensuring that future research, training, and coordination at the National Institutes of Health is funded at levels adequate to meet current and emerging challenges. For fiscal year 1998, we support a funding increase of nine percent over the fiscal year 1997 budget to a total of \$13.9 billion. Even in this era of financial constraint, this investment is vital to the health of our nation. The American people deserve no less. Thank you.

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#### PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF BLOOD BANKS

The American Association of Blood Banks (AABB) offers this statement in support of increased funding for the National Institutes of Health (NIH) and the National Heart, Lung, and Blood Institute (NHLBI). The AABB appreciates the generous support that transfusion medicine researchers have received from the NIH via the Congressional appropriations process. This statement briefly discusses the current state of transfusion medicine research and signals areas that our Association believes merit continued research support.

#### THE AMERICAN ASSOCIATION OF BLOOD BANKS

The AABB is the professional society for almost 8,500 individuals involved in blood banking and transfusion medicine. It represents more than 2,200 institutional members including community and Red Cross blood collection centers, hospital-

based blood banks, and transfusion services as they collect, process, distribute and transfuse blood, blood products and hematopoietic stem cell products. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. Throughout its 50-year history, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply.

Many AABB physicians and scientists conduct research designed to assure that the American people have access to the safest transfusion services possible. The NHLBI and other Federal agencies fund much of this research.

Through the National Blood Foundation (NBF), the AABB is developing a cadre of transfusion medicine researchers by supporting early career research in issues affecting transfusion medicine. NBF grant recipients have the opportunity to demonstrate superior research ability in NBF grant-sponsored research which often enables them to secure larger grants for additional research.

#### SCOPE AND IMPORTANCE OF TRANSFUSION MEDICINE

Transfusion medicine is a multidisciplinary medical specialty encompassing both clinical practice and basic research responsibilities. Each year in the United States, over 20 million blood components are transfused into approximately four million patients, providing fundamental support for many different surgical and medical treatments. Blood is needed for the care of patients with cancer; for accident and burn victims; for newborn babies needing intensive care; for transplant patients; for millions of patients who undergo surgery; and for individuals with heart, lung, liver or bowel diseases. A ready supply of safe blood is vital to the military.

Future advances in the health care of the nation will depend on continued progress in the provision of safe and effective transfusion services.

As a direct result of transfusion medicine research—much of it funded by the federal government through the NIH—the U.S. blood supply is now safer than ever.<sup>1</sup> The NIH is currently sponsoring several important transfusion medicine research projects that can be expected to lead to further improvements in the safety and efficacy of blood transfusion. However, there are important research opportunities in this field that require additional investigation to assure that patients have access to the safest possible blood supply.

#### RECOMMENDATIONS FOR IMPROVING TRANSFUSION SAFETY

Despite the great progress that has been made in the selection of donors who are at low risk for disease transmission and the use of and improvements to an extensive battery of tests to eliminate infected donors, the prevention of HIV and other transfusion-transmitted diseases remains a top priority of transfusion medicine researchers and all recipients of blood. The AABB urges the NIH and private sector researchers to continue research into the development of enhanced infectious disease tests and donor screening methods to further improve blood safety.

##### *Infectious Disease Testing:*

Current blood screening tests detect the presence of the antibodies produced in response to the targeted virus, rather than the virus itself. Each improvement to the test has led to a decrease in the "window period" (the period of time between infection with HIV and the ability to detect the virus via screening tests).

To improve infectious disease tests even more, the NHLBI is funding research into the use of gene amplification technology for the detection of the genetic material of viruses that cause AIDS and Hepatitis C. If successful, this research could lead to blood screening tests that further reduce the window period. However, before this technology can be implemented for screening blood collected for transfusion, more research is needed to address substantial technical and operational challenges.

##### *Pathogen Inactivation:*

The risk of acquiring identified pathogens through transfusion is lower than ever, yet world-wide travel and changing demographics could spread new viruses and bacteria into the U.S. blood donor population. To address these threats, technologies to sterilize cellular blood components are under development. Unfortunately, current sterilization methods also destroy the blood cells. Nevertheless, emerging strategies hold promise for pathogen inactivation that does not destroy the efficacy of cellular blood components. The AABB is pleased that the NHLBI recently co-sponsored with

<sup>1</sup>According to the December 28, 1995 issue of *The New England Journal of Medicine*, the Centers for Disease Control and Prevention revised its estimate of the chances of acquiring HIV infection through a blood transfusion from one case for every 450,000 donations to one in every 660,000 blood donations.

the FDA a workshop on pathogen inactivation and is funding research on viral and pathogen inactivation in cellular blood components with clinical trials set to begin in this year. Research in this area is also proceeding in the private sector.

*Donor Screening:*

Donor questioning is a critical step in maintaining a safe blood supply. Over the years, the questions presented to blood donors have been continuously revised, and today, questioning more directly addresses issues such as travel to regions with endemic disease patterns and sexual and drug use patterns. As a result of improved donor screening and education efforts, the volunteer donor pool is now primarily comprised of persons with lower infectious disease risks.<sup>2</sup>

Despite this progress, additional research is needed to refine donor screening protocols. A report of the NHLBI funded Retrovirus Epidemiology Donor Study published in the March 26, 1997 issue of the *Journal of the American Medical Association* concludes that, although a stringent donor screening system is in place, a small percentage of donors with risk for infectious disease continue to donate blood.<sup>3</sup> Although sophisticated laboratory testing that is conducted on all donated blood would have detected virtually all HIV or other infections among most of these donors, it is disturbing that this link in the blood safety process appears to be incomplete. The AABB urges the NHLBI to fund research to develop more effective donor screening methods to emphasize the potential adverse impact on patient health of providing misleading or inaccurate information during the blood donation process.

PERIPHERAL BLOOD STEM CELLS AND CORD BLOOD

Red blood cells that carry oxygen, white blood cells that fight disease and platelets that stop bleeding are all produced from a single progenitor cell known as a hematopoietic stem cell. Transplants of these stem cells are increasingly replacing bone marrow transplants for reconstituting bone marrow in chemotherapy patients. Because of their ability to multiply into many different types of blood cells, stem cells may also become the ultimate vehicle for curing diseases through gene therapy.

Recently, it has been found that considerable quantities of stem cells can be collected from the blood stream. Stem cells are also increasingly collected from the blood remaining in the placenta and its attached umbilical cord after delivery of newborn babies. Although the total volume of blood is small and is normally discarded after birth, research indicates that the amount of stem cells is great enough to perform stem cell transplantation in children with leukemia and other diseases.

The AABB is pleased that the NHLBI is funding a five-year multi-center study of the transplantation of stem cells collected from cord blood. To establish the necessary infrastructure for this research, the institute established a network of umbilical cord blood banks and transplant centers. This research will help determine the clinical efficacy of cord blood stem and progenitor cell transplants.

This initiative is expected to pose new questions on the proper use of peripheral blood stem cells and cord blood. A variety of both biological and technical issues require continued investigation. These include proper immunologic and functional characterization of the stem cell, investigation of methods of stimulating stem cell production in normal donors, and optimum methods for the collection, processing and storage of stem cells. The AABB supports additional stem cell research.

IMMUNE MODULATION RESULTING FROM TRANSFUSION

Blood transfusion involves the transplantation of living cells from the blood donor to the recipient. This procedure can suppress the transfusion recipient's immune system, thereby decreasing the recipient's defenses against postoperative bacterial infection and tumor recurrence. Preliminary research suggests that when standard blood components are modified in certain ways, such as by exposure to gamma irradiation or by removal of donor leukocytes or donor plasma, the immune altering effect of transfusion may disappear. The role of cytokines as mediators of transfusion-associated immune modulation may represent a fruitful avenue of research.

Blood transfusion can also stimulate alloimmunization to HLA antigens, platelet antigens, and erythrocyte antigens, significantly impairing the ability to support transfusion-dependent patients. The AABB urges the Subcommittee to support research to prevent transfusion related immune suppression.

<sup>2</sup>See GAO/PEMD-97-2 Blood Supply: Transfusion-Associated Risks.

<sup>3</sup>The study found that 186 of every 10,000 survey respondents (1.9 percent) reported some risk for infectious disease that would have resulted in deferral during the donation process had that risk been revealed.



## PLATELET BIOLOGY AND TRANSFUSION

Blood platelets are needed to stop bleeding during surgery and to prevent bleeding in patients with platelet deficiencies. Platelet transfusion therapy allows greater treatment of cancer, organ transplant and trauma patients. Last year, over seven million units of platelets were transfused in the United States. Transfusions of blood platelets are increasing at a faster rate than any other blood component. However, because of the nature of this blood cell, platelets can be stored for only five days. Not only do platelets rapidly lose their biological activity during storage, but they must be stored at temperatures that can facilitate the proliferation of bacteria.

Research into the basic biochemistry and energy requirements of platelets is needed to prevent platelet storage lesion and to assess platelet function in living patients. Research is also needed to improve immunological matches between platelet donors and recipients. In addition, we need clinical research on the optimum use of platelets so that limited supplies are used to their best advantage.

## FISCAL YEAR 1998 FUNDING LEVELS

The AABB is sensitive to the many demands on the discretionary funds in the federal budget. However, we view medical research funding as an investment in America's future competitiveness. Consistent with the Ad Hoc Group for Medical Research Funding, the AABB endorses a 9 percent increase in NIH funding for fiscal year 1998. This level of funding would provide sufficient resources for the NIH to move toward its goal of funding at least one-third of the competing research project grant applications, rather than the current one-in-five.

On behalf of the many scientists devoted to improved blood transfusion practice, the thousands of health care professionals who work daily to deliver blood services, and the millions of American transfusion recipients, the AABB thanks the Subcommittee for this opportunity to discuss federal support for research in transfusion medicine.

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PREPARED STATEMENT OF MARSHALL A. LICHTMAN, M.D., EXECUTIVE VICE PRESIDENT FOR RESEARCH AND MEDICAL PROGRAMS, LEUKEMIA SOCIETY OF AMERICA, INC.

Mr. Chairman and Members of the Subcommittee, thank you for providing me the opportunity to submit a statement regarding funding for biomedical research, including research on leukemia, lymphoma, and myeloma. I am the Executive Vice President for Research and Medical Programs of the Leukemia Society of America, Inc., a non-profit, voluntary health agency representing the health care and medical research interests of more than 450,000 patients, survivors, and their families. The Society's mission is to cure leukemia, lymphoma, and myeloma and improve the quality of life for patients and their families.

As a result of the efforts of staff and volunteers in chapters across the country, the Leukemia Society raises funds to support more than \$12 million in research grants annually, as well as a patient aid program, support groups, and information and referral services. The Leukemia Society has historically funded primarily basic research grants, but we are pleased to report that the Society is now also supporting a translational research program. That program is providing valuable support to some dynamic young researchers who are investigating promising new cancer therapies.

*Fiscal Year 1998 NIH Funding*

The Leukemia Society of America offers a sincere thank you to the Subcommittee for taking a leadership role in securing substantial increases for NIH in the past two years. Biomedical research will advance only if there is a strong research infrastructure, including well-equipped facilities at research institutions, well-trained and dedicated scientists, and adequate funds to support research. And biomedical research requires patience. Members of Congress must realize that their support for NIH must continue for the long term, because science is often unpredictable and slow—but sometimes also serendipitous. Congress, the public, and even scientists themselves must develop some tolerance for the lack of certainty about the course of science.

A recent research advance in leukemia suggests that your patience and tolerance will be rewarded. A researcher who had synthesized a drug for an entirely different purpose discovered that the drug is a lifesaver for the small population—500 to 1000 patients each year—who have hairy cell leukemia. This drug puts 90 percent of all patients in remission, with much less toxic side effects than previous treatments.

The Leukemia Society of America is in agreement with the recommendations of other research organizations that NIH funding be increased in fiscal year 1998 by 9 percent. We understand that this level of funding was identified by officials at the National Institutes of Health as the funding required to support the ongoing programs at NIH and allow them to fund promising research opportunities. The Leukemia Society understands that this is an ambitious goal for NIH funding, but we believe that level of funding would be invested wisely.

Although the Leukemia Society of America has not endorsed any of the various resolutions calling for a doubling of the NIH budget or proposing the establishment of trust funds for the support of biomedical research, we applaud the efforts of Members of Congress to plan for the future and think creatively about funding of research.

*Research on Leukemia and Related Cancers*

Leukemia is often cited as a cancer research "success story." In fact, there have been impressive improvements in the treatment of certain types of leukemia. The cure rate for childhood leukemia has improved from about 4 percent in 1960 to 76 percent today. Despite the strides we have made in the treatment of certain forms of leukemia, more than 57,000 people die each year from all hematologic cancers, more than from any cancer except lung cancer. For adults with leukemia, myeloma, and many lymphomas, clinical outcomes have not improved significantly during the last 20 years. Therefore, our work is far from done.

We do not advocate earmarked funding for leukemia research. We have a great deal of confidence that the scientific marketplace will reward the best research ideas and that the leadership at NIH will capitalize on new research developments in ways that are most beneficial to researchers and the American public. The Leukemia Society of America recently decided, after reviewing its own research portfolio of primarily basic research, that it needed to increase its emphasis on the transfer of the findings of the bench to the bedside. Therefore, we are now funding a translational research program.

We believe there are exciting new possibilities—the result of this nation's basic research investment—for improving the treatment of cancer, and the work to translate these good ideas into treatments must be adequately funded. This type of research must receive more attention—and more funding—from the NIH.

The potential of translational research is great. In the area of leukemia research, immunotherapy and techniques for modifying the genetic basis of cancer are two exciting new research avenues. In leukemia, we have the advantage of knowing which genes start the process of cancer development, and therefore we know which genes we must interrupt in order to prevent disease. That sort of genetic therapy—not the classic gene therapy—might be combined with radiation or chemotherapy to improve the patient's treatment options and outlook. We have only recently begun to understand that immune cells might be used to attack cancer cells. If this therapy can be developed successfully in patients, it might also be used in combination with more traditional therapies.

The Leukemia Society will continue—and perhaps even expand—its translational research program. But real progress in translating basic research to treatment depends on the commitment of the NIH. The uncertainty of science may be even more pronounced in clinical research, where there is not a high level of assurance about which treatment will work. However, this research is absolutely critical to our shared goal of helping those who have cancer or other serious diseases. We encourage the NIH to strengthen its commitment to patient-oriented cancer research.

The Leukemia Society appreciates the opportunity to submit testimony for the record.

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PREPARED STATEMENT OF MARY KAYE RICHTER, NATIONAL FOUNDATION FOR  
ECTODERMAL DYSPLASIAS

All of us yearn to live long life spans unimpeded by anything that demeans our quality of life. We want to greet each new day with all of our faculties intact and with the knowledge that we will be able to function at 100 percent throughout the course of the day. Unfortunately, those individuals challenged by birth defects, systemic conditions and diseases and disorders of every known description are often limited in their abilities to participate fully in life. Their only hope lies in scientific research that can improve understanding of a particular condition and enhance treatment, if unable to provide a cure. This testimony has been written on behalf of individuals affected by ectodermal dysplasia (ED) to illustrate the importance of the National Institutes of Health, in general, and the National Institute of Dental

Research and the National Institute of Arthritis, Musculoskeletal and Skin Diseases, in particular, in enabling quality of life improvements in their lives.

Charles Darwin was among the first to recognize this interesting group of syndromes. His perception was that the condition only affected males who had received an errant gene from their mothers. What Darwin did not know was that the ectodermal dysplasias are actually a broad group of disorders affecting both men and women in varying degrees. Ectodermal dysplasia is a genetic disorder primarily affecting the hair, nails, sweat glands and teeth with effects to other body structures as well. There are 150 variations of the condition ranging from mild to devastating in their effects. Even though ED was first identified more than 200 years, improvements in our understanding of the conditions were not seen until the last fifteen years, largely due to efforts at the National Institutes of Health.

While a lack of hair and unusual nails can be troublesome, those problems pale in comparison to the inability to perspire and extraordinary dental complications associated with ED. Because understanding of the conditions was so poor, individuals in prior generations suffered intense humiliation because of their appearance. With just a few fang-shaped teeth in their mouths, these individuals were called all sorts of names from "monster" to "Dracula". The dental profession was often unsure as to the type and timing of treatment and patients were subjected to care based on guess rather than on knowledge. The results were often tragic.

Equally problematic was how to keep the individual cool. Often subjected to living in cellars, affected individuals who lived earlier in this century were uneducated and unable to participate fully in life. Although answers to our questions about non-functioning sweat glands still do not exist, improvements in management techniques have enabled today's generation of children affected by ED to fare much better. While they must be ever vigilant to problems related to overheating, they can function much like their peers with some, relatively minor, adjustments to their lifestyles.

Although once thought to be a population in which mental retardation was a common feature, today's generation of children who are affected by ED can have high expectations for all that life offers. While minor adaptations in life style may always be necessary, they can expect success in the classroom, at work, at home and in whatever they choose to do in life.

How have such great strides been made, in so little time and at so little expense? The answers await in the remainder of this document, however, it is without question that efforts at the National Institutes of Health have had much to do with improvements.

The first dramatic change came about through a program at the National Institute of Dental Research to improve the oral condition of individuals affected by ED. Forty persons above the age of 13 were selected to have osseointegrated implants placed in their jaws in addition to another smaller group between the ages of seven and 10. Because of the congenital absence of teeth, the alveolar ridge in these individuals is often diminished, greatly compromising their ability to wear traditional dentures. In essence, the implants are titanium screws which are imbedded in the jaw bone to which prosthetics are ultimately attached. With dentures, bite force is often limited to 15 percent or less of normal. However, implants improve that number to 85 percent or more. The bonus in this project is that much was learned about the use of implants in children and other adults. Any individual who loses a permanent tooth can now have it replaced with an implanted tooth with the knowledge that the procedure is safe and efficacious.

Funding from the National Institute of Arthritis, Musculoskeletal and Skin and the National Institute of Dental Research also was greatly responsible for the identification of the gene which causes the most common type of ED, X-linked recessive hypohidrotic ectodermal dysplasia. The identification of a particular gene involves many years of research and discovery. Through research grants and access to patients affected by H.E.D., Dr. Jonathan Zonana, at the Oregon Health Sciences University, was a key figure in the identification of this particular gene. In collaboration with Dr. Juha Kere of the University of Helsinki and Dr. Anand K. Srivastava of J.C. Self Research Institute of Human Genetics, the principle researchers, Dr. Zonana was able to provide a critical piece to solve this genetics puzzle. With the identification of the gene, additional research will be necessary to identify errant proteins which may then be altered at which point discussions about possible cures can commence. A small investment in time and money has enabled the most important scientific breakthrough to date.

Equally important was a workshop held in November of 1996. It was a multi-institute effort with cooperation from the N.I.D.R., N.I.A.M.S., N.I.C.H.D. and the Rare Disease Office at the N.I.H. With leadership from Dr. Hal Slavkin, the Director of the N.I.D.R., the various institutes came together to sponsor a workshop de-

voted to the ectodermal dysplasias. Interested researchers from throughout the United States, Canada and Europe participated. Through the course of the workshop, it became quite clear that the ectodermal dysplasias could provide a unique scientific opportunity which may lead to improvements in the lives of those affected by these particular conditions as well as to shed a great deal of light on human development and developmental biology which, of course, affects every human being. Unlocking the doors to tooth development, hair follicle function and sweat gland genesis will be of importance to individuals affected by a wide ranging group of disorders from alopecia to multiple sclerosis or individuals with male pattern baldness. Beyond that, this landmark meeting was a dynamic example of the possibilities for cooperative efforts among multiple institutes.

While our understanding of the ectodermal dysplasias has improved, much remains to be learned. One primary concern is the classification of the ectodermal dysplasias. Presently, a wide ranging group of conditions are included, however, the boundaries are often vague complicating diagnosis and treatment. When a specific diagnosis cannot be made, appropriate genetic counseling is impossible thereby greatly complicating family planning issues. Further study is a must so that these conditions can be identified a part from other similar but fundamentally different syndromes.

It is probable that a type of ectodermal dysplasia with a significant immunosuppression feature also exists. A number of cases have been identified throughout the United States and elsewhere. Care for these children is often very complicated and frequently results in death. The circumstances they endure defy description and tear at the heart. Because the skin is a key component to the immune system and is the structure most affected in the ectodermal dysplasias, it would appear to be obvious that this patient group could, once again, yield important information for themselves as well as for the remainder of humankind. It is also possible that a more subtle form of ED exists which has a greater incidence rate than that of hypohidrotic ectodermal dysplasia, currently thought to be the most common type. While this type of ED may not be as devastating as others, more must be learned so that affected individuals can be more frequently diagnosed and the genetic implications better understood.

While we have learned much about the possibilities for osseointegrated dental implants, prolonged follow-up is needed to determine the effects of implants over time. The ectodermal dysplasia subjects that participated in the original study should be followed to further enhance what has already been learned. Other issues of concern include severe problems with reflux, carrier detection, breast development and lactation, tear dysfunction, respiratory disease and the mapping of genes for the other 149+ types of ED which remain to be addressed.

The efforts of the National Institute of Dental Research have been pivotal in the improvement of the lives and lifestyles of those affected by ectodermal dysplasia. As a parent of such a child, I cannot begin to adequately express my appreciation to the Congress for the financial support for the N.I.D.R. and the other institutes at the N.I.H. which has enabled such remarkable progress in such a short time. Unless you have been the parent of a child affected by a rare disorder, you have not experienced the extraordinary maze which must be confronted when such a diagnosis is made. Where does one turn for help? What should be done? Who can best help? Does anyone know anything? All of those questions are typical of those we experienced. However, now we look ahead with hope to a brighter future.

Your support of \$212,561,000 during fiscal year 1998 for the National Institute of Dental Research will continue to solve problems associated with conditions like the ectodermal dysplasias in addition to supporting wide ranging efforts designed to improve the lives of every citizen in this country. Through outstanding intramural and extramural research as well as services like the National Oral Health Information Clearinghouse, the N.I.D.R. continues to give millions and millions of Americans a very good reason to smile.

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PREPARED STATEMENT OF DAVID JAFFE, THE JAFFE FAMILY FOUNDATION

Thank you Mr. Chairman and members of the Subcommittee for allowing me the opportunity to testify. I am David Jaffe. I serve on the board of directors of the Jaffe Family Foundation which my parents, Elliot and Roz Jaffe, created. I am the father of three young children with food-related allergies. My only nephew, my brother Richard's son, also has food allergy.

In 1996, the Jaffe Family Foundation decided to make a significant, long-term commitment to the area of food allergy. We made this decision because of our own

experience, growing evidence of increasing incidence of food allergy, and the lack of attention and resources in this field.

Food allergy is an adverse reaction to food involving the immune system. Food allergies are estimated to affect between 3 and 6 percent of children and these numbers are on the rise. While some children will outgrow food allergies, others will continue to suffer throughout their adulthood. Shellfish, eggs, cow's milk, soy, wheat, and tree nuts are the cause of most food allergic reactions. Although symptoms of food allergic reactions are often mild, it is estimated that 100 people each year die of an allergic reaction to food, and reports of death from food-allergic reactions after ingestion of even minute quantities of food are increasing.

My own children are at risk of having a fatal reaction to peanuts and have, after being unintentionally exposed to food with peanuts in it, suffered reactions which fortunately were recognized early enough so that they could be treated with medication. These experiences, however, created an awareness of how serious the situation can become. As a parent, I can tell you that my children's food allergies have affected my family's life in ways that I would never have imagined. My wife and I had several years of sleepless nights as we tended to our children while they suffered through atopic dermatitis, a common condition resulting from food allergy. Over a four year period my wife and I grew accustomed to drawing oatmeal baths every two hours throughout the night just so my oldest daughter could feel relief from the intense itching and discomfort. We also take strict precautions by providing our children with their own food whenever they leave the house to attend a playgroup.

Right now, the only way to protect a child who suffers from food allergies from an allergic reaction is to avoid the offending food, and this requires constant vigilance on the part of food allergy sufferers and their families. It often means keeping the food out of your home entirely to avoid accidental contamination. Restaurants, schools, visits to friends' homes, sporting events—anywhere that your child might be exposed to the food—are additional sites of potential exposure. And it is not enough to tell your child to avoid the food to which she or he is allergic, because many of these foods are commonly used as ingredients in items that most people would never suspect. Peanut butter might be used, for example, to thicken spaghetti sauce, as one person who suffers from peanut allergy discovered after beginning to eat a plate of pasta. All too often, full information about ingredients is not available even to those extremely cautious and assertive customers who carefully question waiters. Even well informed waiters and chefs cannot spot the cross-contamination of food, which results from careless handling in the manufacturing plant or one food inadvertently touching another.

I want to express my appreciation to you, Mr. Chairman, and to the other members of this committee for the work you have done in making sure that despite the need to find savings in federal programs, the funding for basic science research at the National Institutes of Health (NIH) is maintained and even increased each year. I thank you for your leadership and urge you to continue.

The basic scientific research that NIH supports is critical to the advancement of the field of food allergy research. For example, a recent scientific meeting concluded that developing an understanding of the molecular nature of IgE-dependent histamine releasing factor and an understanding of the genetics of allergic disease are key to understanding and curing food allergy.

As you know, innovative approaches are sometimes necessary to bring more focus and attention to issues that have previously not been addressed through NIH research. I would like to talk to you today about why I believe that is now necessary in the field of food allergy.

Despite the severity of this problem, very little attention or resources are being directed toward finding solutions to the complex scientific issues connected to food allergy. We do not have answers to some of the most basic scientific questions such as why some people develop food allergies while others do not or why some children outgrow food allergies and others do not. As a result, we have no idea how to cure food allergy. Furthermore, pediatricians learn very little about diagnosis or treatment of food allergy, causing children and their families long periods of frustration, distress, and illness before a diagnosis is made. What is worse, very little research that could yield solutions to these problems has been supported in the past either by NIH or by private institutions.

Over the last two years, the Jaffe Family Foundation has begun a long-term effort to change this. We are contributing both financially and with our own time. We believe in working collaboratively with organizations, including industry, that share our commitment to find ways to treat, prevent, and cure food allergy. Our program is built on partnerships with three important institutions in this field: the NIH, the Food Allergy Network, a vital resource for consumers and physicians, and a soon

to be announced collaboration with an academic medical center in New York City where we plan to establish a national center of excellence for food allergy research, clinical practice, and patient and public education.

Last summer, we joined with the American Academy of Allergy, Asthma, and Immunology, The Food Allergy Network, The International Life Sciences Institute, and the National Institute of Allergy and Infectious Disease to cosponsor a historic scientific meeting at the NIH. The purpose of the meeting was to stimulate dialogue around the issue of food allergy and to explore and encourage new research in the field. Twenty-seven leading scientists from the field of food allergy and the related fields of genetics and immunology met to review state-of-the-art information about food allergy and related basic science research. Several key research priorities were identified at this meeting. The Executive Summary which describes these findings and a participant list are attached to my testimony.

The meeting last summer created an unprecedented potential for advancement in the field. To make it possible to take full advantage of this potential, the Jaffe Family Foundation is working with three of the institutes at the NIH to develop a partnership that will combine our private funds with the NIH's public funds for the purpose of supporting research on food allergy. Public-private partnerships for research such as this one are still a recent development, and figuring out the best way to structure and implement them presents challenges to all of us, but it brings opportunities as well.

As a private citizen with a demonstrated commitment to scientific research, I believe that public entities need to maintain the openness and flexibility that will allow them to respond to the interests of private partners without undercutting the scientific basis for research funding decisions. I recognize and strongly support the evaluation of research for its scientific merit by rigorous and objective standards. At the same time, I believe that the development of public-private partnerships creates an opportunity for NIH to reexamine the mechanisms it uses for evaluation and to consider whether there are new ways to do this that might lead to more funding in new research areas.

I hope, Mr. Chairman, that this Committee will allocate appropriate funds to the NIH so that it will be able to continue its important work. I also hope that you will support the efforts of the NIH officials who are trying to maximize their limited funds by reaching out to private partners with an interest in scientific research. Alliances between the public and private sectors may be the best way to enhance the federal commitment to health research and to enable federal dollars to go further.

In conclusion, Mr. Chairman, food allergy is a very serious problem that affects many children and adults. Very little is known about food allergy and, despite the seriousness of the problem, current efforts to increase resources and attention are only the beginning. There must be more research to increase our knowledge about the very serious problem of food allergy and improve the medical system's ability to respond to people suffering from allergies to food. The Jaffe Family Foundation has dedicated significant financial and personal resources to this field. We are committed to working in a public-private partnership with the NIH to expand the research that is being done to improve the health and welfare of people who suffer from food allergy. I ask for your support of that partnership through your continued commitment to funding of basic science research at the NIH. Thank you very much.

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#### PREPARED STATEMENT OF IN DEFENSE OF ANIMALS

##### INTRODUCTION

As Congress considers 1998 appropriations for the National Institutes of Health (NIH), In Defense of Animals (IDA) feels it imperative that the House Committee on Appropriations consider waste, fraud and abuse in current NIH spending programs. As an example, we would like to call your attention to two egregiously wasteful NIH research-related programs. In our experience, these programs are just symptoms of the overall problem of wasteful NIH spending on needless research that does more to advance the interests of individual scientists and research institutions than it does the interests of public health.

##### NIH SUPPORT FOR THE COULSTON FOUNDATION

The NIH currently allocates in excess of \$2.1 million annually to The Coulston Foundation (TCF), a private, New Mexico-based primate laboratory whose troubling history includes: repeated violations of the Animal Welfare Act; scientific misconduct; repeated falsification of records; and an anachronistic, hostile view of chimpanzees.

With an estimated 600 chimpanzees—almost one-half the total in all U.S. laboratories—TCF currently controls the world's largest captive chimpanzee colony. NIH's continued expenditure of taxpayer dollars on this facility whose dubious record has prompted strong criticism from mainstream scientists and animal protection groups, as well as multiple investigations by the U.S. Department of Agriculture, cannot be justified.

#### *Animal Care Problems at TCF*

In 1995, the USDA filed formal charges against TCF for multiple violations of the Animal Welfare Act ("the Act"). Violations included the overheating deaths of three chimpanzees in 1993 and the deaths from water deprivation of four monkeys in 1994. In 1996, TCF settled these charges by agreeing to pay a \$40,000 fine—the second largest ever levied against a research institution in the history of the Act. As part of the settlement, TCF agreed to "cease and desist" violating the Animal Welfare Act. With the "unintended" deaths of two young, healthy chimpanzees in January and March of 1997, TCF appears to have violated this cease and desist order, as circumstances surrounding these deaths indicate extreme negligence and further violations of the Act. Additional charges are likely to result from current USDA investigations of TCF.

Animal care problems at TCF are long-standing. In 1994, an NIH site visit team cited TCF for deficiencies in veterinary staff. Today, with the recent departure of the one veterinarian whom NIH deemed qualified to care for the facility's hundreds of chimpanzees and monkeys, the situation has intensified. In fact, seven veterinarians with combined decades of clinical experience have left TCF since May 1994. The deteriorating situation prompted the USDA to express "official concern" about TCF's veterinary staffing earlier this year.

In summary, TCF's lack of adequate veterinary staffing and repeated violations of federal law have contributed to a worsening animal care situation that has seen the "unintended" deaths of at least 25 non-human primates at the facility since October 1993.

#### *Scientific Misconduct*

U.S. News & World Report reported in August 1995 that Coulston employees had falsified data in the study of remifentanyl, a painkiller for women in labor. The experiment was designed to test the physical and behavioral effects of the drug on infant monkeys. IDA subsequently discovered that the falsification occurred in the height and weight data taken from the infants. Because the physical effects of the drug were an integral part of the study, falsification of such results would constitute extremely serious scientific misconduct, and would have enormous ramifications for the health and well-being of pregnant women and their babies. The USDA has already found that TCF animal caretakers falsified daily care logs during the course of this remifentanyl study.

The record clearly shows that TCF has repeatedly failed to adhere to federal regulations regarding the conduct of scientific research.

#### *TCF is Out of Step with the Mainstream Scientific Community*

At present, there is consensus in the scientific community that a surplus of chimpanzees available for research exists. The NIH itself has issued a directive to curtail breeding at the five federally-supported chimpanzee breeding centers in the U.S. At the behest of NIH director Harold Varmus, the National Academy of Sciences has convened a panel to make recommendations for the long term care of chimpanzees no longer needed for research.

At a time when most primate centers are attempting to reduce their chimpanzee populations, TCF head Fred Coulston is actively increasing the number of chimpanzees under his control. Of Dr. Coulston's efforts, Dr. Thomas Insel, Director of the Yerkes Primate Center in Atlanta said, "I'm amazed that anybody would be trying to expand a chimp empire." (New York Times, February 4, 1997) Dr. Coulston's zest for expansion may be tied to his self-professed "unusual view" of chimpanzees, as "models" for "toxicology/pharmacology." As reported in the New York Times, Dr. Coulston's ideas about chimpanzees—humankind's closest genetic cousin—clearly place him outside the mainstream of science.

#### *NIH Support for TCF*

Time and time again, Dr. Coulston has turned to the federal government to support his burgeoning private chimpanzee empire. And, despite TCF's scientific transgressions and repeated violations of federal law, the NIH has rewarded TCF handsomely:

*National Center for Research Resources (NCRR) Chimpanzee Breeding and Research Program (5-U42RR-0358-07).*—\$3 million in direct costs, with another at

least 50 percent in indirect costs, since 1993. In addition, to being underwritten by NIH, TCF's breeding program is subsidized by the Food and Drug Administration (FDA) which pays upwards of \$60,000 per chimpanzee used in FDA studies (FDA contract Nos. 223 901 004 and 223 871 004). Why TCF is receiving money from NCCR and the FDA for chimpanzee breeding, especially when there is a surplus of chimpanzees for research, is a question that Congress should answer.

*National Cancer Institute (NCI).*—\$861,479.00 for the period 4/1/96 through 3/31/97 to support 12 chimpanzees on an NIH AIDS study.<sup>1</sup>

*National Institute on Allergy and Infectious Disease (NIAID).*—\$718,152.00 for the period 4/1/96 through 3/1/97 to support 12 chimpanzees on an NIH AIDS study.

*Coulston Attempt to Secure Further Federal Subsidy*

One of the most scientifically baseless, corporate welfare uses of limited research money would be TCF's proposed "National Center for the Study of Aging in Primates." TCF announced its intention to obtain federal money for such a center in March 1996—less than one month before NCI and NIAID cut by approximately 50 percent their support of AIDS chimpanzees at TCF, from \$2.9 million for the period 4/1/95 through 3/31/96 to \$1.5 million for the period 4/1/96 through 3/31/97. Is it coincidental that TCF announced its proposal to obtain federal money less than one month before it lost \$1.5 million in federal support? When one considers the absolute total lack of scientific, medical or public policy merit in TCF's proposal, the answer seems clear. In fact, it appears to be TCF's latest and perhaps most transparent ploy to obtain a "sweetheart deal" from the federal government.

TCF has a history of obtaining such "sweetheart deals" from both publicly- and privately-funded entities. For example, over the last four years, it has obtained millions of dollars, hundreds of chimpanzees and buildings and equipment from New Mexico State University and New York University. In 1995, TCF attempted to get Congress to give it ownership of 150 Air Force chimpanzees and a new \$10.5 million, taxpayer-funded housing facility. That proposal was defeated, in part because of the serious questions raised about TCF's dubious record of research and animal care, as well as the lack of an open bidding process. Indeed, TCF attempted to become the "sole source" for this giveaway, just as NIH "sole-sourced" to TCF its AIDS chimpanzee subcontracts discussed above.

The scientific, medical, financial and public policy arguments against the very existence of TCF's proposed Aging Center, let alone for taxpayer funding of it, are overwhelming:

- TCF lacks any expertise or experience in aging research, has no current NIH peer-reviewed, investigator-initiated grants in any field of scientific research, including aging, and key personnel have no aging-related scientific publications;
- The National Institute on Aging—which funds over 2,000 aging-related grants—funds absolutely no studies involving chimpanzees and the diseases associated with aging, nor does Medline link the search term "chimpanzees" with aging-related illnesses, clearly indicating that chimpanzees are not widely-accepted animal models for aging research;
- More than 150 aging research centers already exist in the U.S.—28 for Alzheimer's Disease alone. Taxpayer funding for TCF could take money away from those far more worthy centers with extensive expertise in aging that are already conducting important research. In fact, the American Federation for Aging Research warned in March 1996 that proposed cuts in the NIA budget "threaten [aging] research" and human health;
- TCF has a documented record of animal abuse, alleged scientific misconduct, multiple violations of the Animal Welfare Act, repeated falsification of records, formal USDA charges, repeated failure to adhere to federal law, and is currently the subject of USDA investigations regarding the entirely preventable deaths of additional young, healthy chimpanzees;
- TCF is not accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC), and its veterinary staff's lack of clinical experience and deficient care have prompted the USDA to express its official concern.

<sup>1</sup>These payments are made as part of one subcontract (No. 6S1655). TCF has submitted budgets to both NCI and NIAID for maintaining 24 chimpanzees, including clinical testing and pathology. The total submitted budget, excluding overhead, is less than \$150,000. The remaining \$1.3 million is unaccounted for. Is TCF charging the federal government \$1.3 million in overhead? The standard, fully-loaded (including overhead) per diem rate for maintaining chimpanzees is \$40/per day. TCF, by contrast, is charging a per diem of \$180 per day to maintain chimpanzees. This appears to be a straightforward case of price gouging the government, which we believe mandates a serious Congressional investigation. Since July of 1993, TCF has received over \$8 million on this subcontract alone; it is not yet known what financial figures from periods prior to 4/1/96 will show.



According to the February 4, 1997 New York Times, TCF is attempting to obtain a special Congressional appropriation for its proposed Aging Center. Considering the overwhelming arguments against this proposal, it is perhaps no surprise that, in lobbying Congress for taxpayer funds, TCF is attempting to bypass the normal, scientifically-accepted channels for federal funding. Instead of submitting the proposal for peer review, most appropriately at the National Institute on Aging, as thousands of researchers do each year, Coulston is attempting to get a special \$45 million appropriation, which would no doubt be buried in a complex government spending bill. It is unlikely that TCF's proposed Aging Center would withstand objective peer review by experienced aging researchers.

If Congress is interested in a \$45 million appropriation of taxpayer money for aging research, then we suggest that the money could be far better spent at any of the existing, credible aging research centers, of which there are over 150 in the U.S. TCF's proposed "National Center for the Study of Aging in Primates" is simply corporate welfare at its most obvious, a naked attempt to force U.S. taxpayers to permanently subsidize—year after fiscal year—Dr. Fred Coulston's struggling private chimpanzee empire and to fulfill his publicly stated goal of making TCF the "sole source of chimpanzees for research."

#### NIH SUPPORT FOR THE MONKEY CRACK-SMOKING EXPERIMENTS OF RON WOOD

As of 1996, the NIH, through its member institute the National Institute on Drug Abuse (NIDA) has awarded \$3.2 million in research grants to psychologist Ron Wood, formerly of New York University (NYU) and currently employed by the University of Rochester. Dr. Wood's drug addiction experiments on primates and other animals have long been controversial. Scores of physicians and drug treatment experts have condemned them as irrelevant to human drug abuse and wasteful of nearly one-half million dollars annually. His current NIH grant is entitled "Behavioral Pharmacology of Abused Inhalants: Crack" (R01 DA05080-08). The experiments involve placing monkeys in restraining devices, strapping monkeys to an elaborate \$250,000 "crack pipe" and forcing the animals to inhale the smoke from crack cocaine.

#### *Federal Investigations Reveal Scientific Misconduct/Animal Welfare Violations*

In October 1993, based on internal documentation obtained from whistleblowers, In Defense of Animals (IDA) filed formal complaints with the U.S. Department of Agriculture (USDA) and the NIH's Office for Protection from Research Risks (OPRR) alleging inadequate veterinary care and program-wide abuses at NYU during the conduct of Dr. Wood's experiments. Both agencies upheld many of IDA's allegations. In fact, the USDA filed formal charges against NYU in April 1995 for 378 violations of the Animal Welfare Act committed in Dr. Wood's laboratory. In addition, OPRR found a veritable laundry list of Public Health Service (PHS) Policy violations committed by NYUMC and Dr. Wood. In 1996, NYU settled USDA charges for Wood's and other violations by agreeing to pay \$450,000—by far the largest fine ever assessed against a research institution for violations of the Animal Welfare Act. (Interestingly, NYU, which for years vigorously defended Wood's research and denied any wrongdoing, also recently agreed to settle with the U.S. Attorney's Office charges that it had overbilled the federal government on research overhead. The settlement included a \$15.5 million dollar fine—by far the largest ever paid by a research institution in the ongoing research overhead scandal.)

Evidence accumulated during the two federal investigations of Wood's research revealed shocking negligence, misconduct and cruelty in Dr. Wood's laboratory, including documentation that Dr. Wood:

- Deprived monkeys of water for 21 hours/day, resulting in thirst so severe that animals were forced to dip their tails in urine collection pans in a desperate search for moisture. Wood violated federal law by failing to obtain permission from NYU's research oversight committee for this prolonged water deprivation regimen;
- Allowed animals in his lab to become deathly ill from infections before seeking veterinary care;
- Used sick monkeys in experimental procedures, in some cases only days after invasive surgeries from which they would never recover, fatally compromising not only the health of the animals, but also the validity of his research results;
- Allowed surgical procedures to be performed on monkeys and guinea pigs by incompetent veterinary personnel, resulting in animal deaths;
- Failed to properly monitor the health of monkeys in his lab;
- Made misrepresentations to the NYU research oversight committee and to NIDA about various aspects of his research; and

—Failed to keep accurate or adequate experimental or clinical records on his animals.

In August 1995, following the USDA charges, Dr. Wood's monkey crack-smoking experiments came to an end. At that time, Dr. Wood's NIDA grant expired, he took an "indefinite" leave of absence from NYU and his laboratory there permanently closed.

By the fall of 1996, however, Dr. Wood re-surfaced at the University of Rochester and NIDA re-funded Dr. Wood's experiments to the tune of \$420,000 per year, despite overwhelming evidence that Dr. Wood had committed scientific fraud as well as animal abuse.

#### *NIH Decision to Re-Fund Dr. Wood's Research*

Critics of federal research funding have long maintained that once a researcher is on the federal gravy train, he or she is virtually guaranteed lifetime support. Even former NIH director Bernadine Healy remarked on this phenomenon: "You get the sense that the NIH was a social security agency for scientists," she said in *New York Times*, November 1, 1992. Certainly, there is no better example than the case of Ron Wood.

In defending its decision to re-fund Wood, NIH has claimed that its peer review panels have deemed Wood's research to be "outstanding." However, this assessment does not square with the formal charges against NYU for violations of federal law committed by Dr. Wood, the vast amount of documentation impugning the scientific validity of Dr. Wood's research, and the failure of Dr. Wood to publish a single scientific paper in more than eight years on the results of his crack experiments on monkeys. (Dr. Wood's experiments are also currently the subject of a federal False Claims Act lawsuit, brought by Jan Moor-Jankowski, M.D., a world-renowned medical primatologist, member of the prestigious French Academy of Medicine, and former member of the NYU research oversight committee charged with overseeing Dr. Wood's research. That lawsuit asserts that "Dr. Wood's experiments are so scientifically flawed in conception and execution as to constitute fraud.")

The fact that NIDA peer reviewers apparently recommended re-funding of Dr. Wood's research indicates a very serious problem. If the reviewers saw the documented evidence of Dr. Wood's scientific and veterinary misconduct, and recommended refunding his research anyway, then it appears that these peer reviewers are not sufficiently objective as to render honest recommendations about the merit of scientific research proposals. If, on the other hand, the peer review team did not review the evidence, the peer review system is failing because reviewers are making decisions based on grievously incomplete information. Whatever the answers, this situation does not bode well for the integrity of the National Institute on Drug Abuse or the integrity of the peer review process. If the peer review team was aware of the documentation cited above and still deemed Dr. Wood's research "meritorious" of funding, then the peer review process is demonstrated to be incapable of providing objective assessments of worthy research projects. If the peer review team made determinations about Dr. Wood's research in the absence of the results of federal investigations into his research, then the NIH has failed utterly to provide oversight to federally-funded animal research as required by law.

Since Dr. Wood's research is underwritten by significant amounts of tax dollars, we believe that it is incumbent upon the Congress to examine NIDA's actions in this matter as this case demonstrates NIH's utter failure to provide proper oversight to federally-funded research as required by law.

#### NIH SUPPORT FOR CAT STUDIES OF ALAN D. MILLER

For fiscal year 1996, researcher Alan D. Miller at Rockefeller University received well over a half million dollars from the NIH to pursue his two research interests. Both of his projects stem from a 35 year-long project conducted by his mentor and colleague, Victor J. Wilson, also at Rockefeller University. Project R01 NS20585, now in its twelfth year, receives \$332,354 annually from the National Institute of Neurological Disorders and Stroke to trace the neurophysiological pathways of the vomiting reflex in the cat. Dr. Miller's second grant, Project R01 DC02644 received \$322,979 from the National Institute on Deafness and other Communication Disorders to study the vestibular control of respiration in the cat. These two projects combined totaled \$655,333 in fiscal year 1996 alone.

#### *Vomiting Reflex in the Cat*

Dr. Miller's vomiting project primarily examines a phenomenon he calls "fictive vomiting," in which he takes neural recordings of the cells which would produce vomiting under normal circumstances. However, his experimental design is far from normal. The cats used in Dr. Miller's experiments are intubated, wired up with elec-

trodes, drugged, shocked and otherwise manipulated, subjected to brain surgery wherein their brains are separated from their spinal cords, suspended and restrained in stereotaxic devices, and paralyzed with the use of neuromuscular blocking agents which essentially paralyze the muscles involved with vomiting. Thus, the animal is prevented from vomiting, but rather the brain is stimulated in a way similar to the way it might react if the cat was vomiting. "Control cats"—neither decerebrate nor paralyzed—have also been used. One of these unfortunate animals was forced to vomit 97 times over a three and one-half hour time period.

All of Dr. Miller's work is done to gain an understanding of the physiological and anatomical actions associated with a process that cannot and does not occur in the experimental animal, nor in the human being to which he claims his results apply.

After reviewing the research of Alan D. Miller, neurologist Robert S. Hoffman wrote: "One can see from reviewing his results that not much has been accomplished by Dr. Miller's work in this area over the last 11 years and at a cost of more than \$2.5 million. Whatever conclusions Dr. Miller has arrived at in his studies were already 'intuitively obvious.'" Indeed, in a meeting between In Defense of Animals and Rockefeller University officials in February 1997, IDA requested that the university produce journal citations of Dr. Miller's research in human medical journals which point to this research as being clinically useful. We have made this same request in writing twice following our meeting and have still not received a response. Our search of the clinical literature has been unable to locate any such citations.

After a thorough analysis of Dr. Miller's research, veterinarians have testified that the animals do experience pain and suffering, despite the decerebration. Anatomists have pointed out that factors that might affect or control vestibular-induced vomiting in four-legged animals cannot apply to two-legged humans. Clinicians have commented that phony, experimentally induced nausea produced by invasive procedures in the laboratory have nothing to do with spontaneous and naturally occurring nausea and vomiting found in humans. Even if the researchers have learned something about vestibular control of vomiting or other reflexes, which is doubtful because of the many confounding laboratory variables, they have learned absolutely nothing about the human condition because of crucial differences between cats and humans. There is no evidence that any human beings have benefited, or could ever benefit, from Dr. Miller's research.

It is particularly appalling that, in project number 2 R01 NS 20585, Dr. Miller implies that his research could prove to be of some value in AIDS patients. This typifies the kinds of experiments recently criticized in a report commissioned by the NIH's Office of AIDS Research that showed that much of the \$1.4 billion of federal money being spent on AIDS research supports studies only marginally related to the disease. This is as marginal as it gets.

Dr. Miller has introduced a word that he uses to describe vomiting that isn't vomiting; this is fictive vomiting. Since fictive is defined as not genuine, or imaginary, it can be accurately concluded that his results are similarly not genuine. These kinds of non-genuine research projects should be terminated in our real world of limited funds and serious diseases that must be treated.

#### *Vestibular Reflexes in the Cat*

Dr. Miller's second project, the vestibular control of respiration, is a direct extension of the research of Victor J. Wilson at Rockefeller University. Wilson, who retired from active research in 1996, received a single grant spanning 36 years to study the control of vestibular reflexes in the cat. The cost for that project was over \$4.4 million and produced no information of importance to the treatment of human disease. A similar request for any clinical citations for Wilson's research was posed to Rockefeller University, again with no response.

Victor J. Wilson can be credited with spawning a network of researchers to follow in his footsteps. These researchers have become masters at creating a myriad of variables so they can keep the vestibular project alive. Year after year, they come up with new parameters for their studies including a wide variety of locations for injections and lesions, different places to do recordings or to place electrodes or a new way to manipulate the inputs/outputs, or in developing different ways to measure or produce damaged sensory capacities, or in the use of different reagents, recording devices, lab equipment and so forth. Their area of expertise has become designing experiments that produce large amounts of data. The fact that this data has no relevance does not seem matter to the researchers, or to the NIH, which continues to fund them.

The work of these investigators displays a long-standing problem in the funding of research with public money—the continued funding of multimillion dollar projects, year after year, which have no purpose other than, at best, to satisfy curi-

osity in order to subsidize scientists without providing anything of value to the taxpayers who support the work.

NIH'S OFFICE OF PROTECTION FROM RESEARCH RISKS DIVISION OF ANIMAL WELFARE

With numerous staff members, including at least two veterinarians, the operations of the Office of Protection from Research Risks (OPRR) Division of Animal Welfare cost taxpayers significant amounts of money annually. It is the experienced opinion of In Defense of Animals that this office has failed woefully and consistently to uphold its mandate under the 1985 Health Research Extension Act. That Act (Public Law 99-158, November 20, 1985) established OPRR's Division of Animal Welfare to ensure that all research institutions in receipt of NIH grants are in full compliance with Public Health Service Policy (PHS) Regarding the Humane Care and Use of Laboratory Animals. IDA can supply voluminous documentary evidence showing OPRR's willful ignoring of continued non-compliance with PHS policy on the part of NIH-funded research institutions. Since the Health Research Extension Act compels OPRR to act upon such non-compliance, the office's willful failure to uphold the law merits serious review.

It is IDA's considered opinion that taxpayer money spent on this office is completely wasted and that the enforcement functions outlined in the 1985 Act should be transferred to an office that can demonstrate an ability and willingness to uphold and enforce this Act of Congress.

CONCLUSION

In this time of hard choices to balance the budget, an increasing outcry against corporate welfare, and a scarcity of research funding for responsible, much-needed studies with direct applicability to human health, U.S. taxpayers must not be forced to permanently underwrite—year after fiscal year—the researchers or research facilities with poor track records, including repeated violations of federal law. The continued federal support for The Coulston Foundation and for the experiments of Ron Wood and Alan Miller is an indication that something is seriously wrong with the way NIH allocates funding appropriated to it by Congress.

PREPARED STATEMENT OF THE UNITED OSTOMY ASSOCIATION

Thank you for the opportunity to submit written testimony to the Chairman and Members of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. The United Ostomy Association appreciates the Committee's past support for digestive disease research and colon cancer prevention and education programs, particularly those programs provided for through the Centers for Disease Control and Prevention (CDC).

The United Ostomy Association is a volunteer-based health organization dedicated to assisting people who have had or will have intestinal or urinary diversions. Our national organization and 550 chapters provide educational services and psychological support to these individuals and to their families. We also advocate and promote increased awareness about the many digestive diseases that can lead to ostomy surgery. The United Ostomy Association currently has chapters throughout the United States and Canada and has more than 35,000 members.

More than one million people in the United States currently have an ostomy, and 70,000 to 80,000 people have either temporary or permanent ostomy surgery each year. Colorectal cancer accounts for approximately 60 percent of ostomy surgeries.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States and the second leading cause of cancer related deaths. Although survival rates are greatly enhanced when colorectal cancer is detected and treated at an early stage, recent studies have shown a tremendous need to encourage the public to seek screening and to educate health care providers about colorectal screening guidelines. The United Ostomy Association is supportive of the CDC's colon cancer outreach initiative and encourages its work with national partners in developing an information program emphasizing the value of early detection.

The CDC has begun collaborative work with the United Ostomy Association in response to report language supported by the Committee last year. In the past, the Association has been concerned that a lack of information about persons who have had ostomy surgery hampers the coordination of cancer research and limits the effectiveness of prevention outreach and education efforts. Learning more about those patients who have been at risk would be helpful in carrying out colon cancer preven-

tion efforts. This information also would help to better direct federal efforts to reduce the incidence of colon cancer and to provide needed information to patients and physicians about the prevention of ostomy-related complications.

The United Ostomy Association looks forward to continuing to work with CDC, as part of its colon cancer initiative, regarding the need for better information about colon cancer risk factors and effective prevention techniques and outreach.

*Recommendation.*—The United Ostomy Association encourages the Committee to provide \$5 million in fiscal year 1998 funding for CDC's colon cancer prevention and outreach campaign.

#### NATIONAL INSTITUTES OF HEALTH

##### *National Institute of Diabetes and Digestive and Kidney Disease*

The United Ostomy Association also is encouraged by the research being conducted through the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK). Millions of Americans around the country who suffer from a variety of digestive disorders pin their hopes for a better life—or even life itself—on medical advances made through the basic and genetically-based research conducted at NIDDK.

While digestive diseases are poorly understood, recent scientific evidence has shown that interactions between the immune system, inherited susceptibility, and the environment are involved. New advances in molecular biology now permit the most advanced research into digestive disease to provide a better understanding of digestive disease and possible future treatments and cures.

The United Ostomy Association supports the Institute's continued research in the areas of inflammatory bowel disease, dietary prevention of diverticulitis recurrence, urological disease, and birth defects that led to digestive complications. We also emphasize the need for NIDDK to pursue a balanced allocation of its research funds to digestive disease needs. Development of a coordination committee within the National Institutes of Health, similar to the one currently in place for sleep disorders, would be helpful in setting priorities for digestive disease research and maximizing the utilization of the resources available in this area.

*Recommendation.*—The United Ostomy Association recommends that the Committee provide NIDDK with a nine percent increase in funding for fiscal year 1998, bringing NIDDK's total appropriation to \$889 million.

The United Ostomy Association appreciates the opportunity to submit this written testimony to the Committee on fiscal year 1998 appropriations for digestive disease research and education.

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#### PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the American Academy of Physician Assistants and the nearly 26,000 PAs in clinical practice, we appreciate this opportunity to present our views on the fiscal year 1998 appropriations for Physician Assistant education programs, which are funded through Title VII of the Public Health Service Act.

PA programs provide students with a primary care education that prepares them to practice medicine with physician supervision. The first PA program was started at Duke University approximately 30 years ago, and today there are 96 accredited programs in the United States. The typical PA program is 25 months long, requires at least two years of college and some health care experience prior to admission. The majority of students have a baccalaureate degree and 48 months of health care experience before admission to a PA program. PAs are certified by the National Commission on Certification of Physician Assistants. They are re-registered every 2 years based on 100 hours of continuing medical education, and re-certified every six years by examination. Approximately 88 percent of PAs hold at least a bachelor's degree, while 18 percent hold either a masters or doctorate. The latest AAPA census data indicate that family/general practice remains the most common area of PA practice.

As members of this committee know, federal funding for PA education programs serves many needs. Fundamentally, Title VII helps to ensure that areas of our country most in need of health care services, specifically rural and urban medically underserved areas, have access to quality, affordable and cost-effective care. This is accomplished by funding PA education programs that have a demonstrated track record of: 1) placing PA students in medically underserved communities; 2) exposing PA students to medically underserved communities during the clinical rotation portion of their training; 3) and recruiting and retaining students from minority and disadvantaged backgrounds.

To ensure that Title VII programs meet the needs of the nation's medically underserved, Congress adopted significant changes to the health professions statute with

the Health Professions Education Extension Amendments of 1992. These amendments established new areas of emphasis, including minority representation, rural areas, and HIV/AIDS, while maintaining a strong focus on primary care. The restructuring was designed in large part to increase the number of graduates practicing in underserved areas and was incorporated by establishing funding preferences as part of the grant review and award process.

We believe PA programs have responded extremely well to the intent of the 1992 amendments, and the AAPA is pleased to share with this committee the following examples of how PA programs are using Title VII funding to meet these very critical objectives:

- A Texas PA program established the objective of having its PA students do their family medicine rotation in medically underserved sites. Through assistance from Title VII funding, the PA program has established enough clinical training sites to require each student to complete a family medicine rotation in a rural medically underserved area. As a result, over the past three years, 75 percent of the program's graduates have entered family medicine, and approximately 30 percent of the PA graduates took positions in medically underserved areas.
- A Washington state PA program recently placed two PA graduates in the Yakima Valley Farmworkers Clinic. One PA was previously a medical assistant from a migrant family, but having completed her PA education, she now serves as a PA in the clinic. The other PA student was previously a respiratory therapist in Walla Walla. Upon completing his PA education, he has committed to primary care practice and is now also working in the Farmworkers Clinic.
- Several PA programs, including the University of California—Davis, the University of Texas—Galveston, and the University of Washington, have utilized Title VII funding to train “place bound” students. These PA students receive training in their home communities, and then practice there upon graduation. These programs specifically targeted Hispanic and rural disadvantaged students.

Without Title VII funding, many of these special PA training initiatives would not be possible. Institutional operating budgets and student tuition fees simply do not provide sufficient funding to meet the special, unmet needs of medically underserved areas or minority students. Nevertheless, the need is very real, and Title VII is critical to meeting it.

As members of this committee know, a growing number of Americans lack access to primary care, either because they are uninsured or underinsured or there are not enough providers to see them. We anticipate an increase in the demand on all public health programs as a result of the welfare legislation enacted in the 104th Congress, by those patients who will be disenrolled from the Medicaid program. Simultaneously, the number of medically underserved communities continues to rise, from 1,949 in 1986 to 2,492 today. Despite these unfortunate realities, funding has not increased for the Title VII programs that are designed to alleviate these very problems. Between fiscal year 1994 and fiscal year 1997, PA program funding went from \$6.5 million down to \$5.9 million and, as of fiscal year 1997, was restored to \$6.4 million. And while we appreciate the budget constraints that federal appropriators face, without at least modest increases in funding, it is nearly impossible for PA programs to generate the needed supply of PAs who can help to preserve access to our nation's most vulnerable populations.

To address some of the concerns that exist in today's health care delivery system, the states have begun to take aggressive steps to increase access to health care, the most comprehensive of which is their pursuit of Section 1115 and 1915 waivers from the Health Care Financing Administration. These waivers are an attempt to expand health care access through savings realized from managed care, as well as to guarantee a “medical home” to Medicaid and AFDC recipients.

As the states proceed with their waiver efforts and the impact of the new welfare law is felt, more primary care providers will be needed. But the states have never shouldered the responsibility for educating and training providers. Since the establishment of Medicare, the costs of physician residencies, nurses and some allied health professions training has been paid through Graduate Medical Education funding. However, GME is not and never has been available to PAs. More importantly, GME was not intended to nor does it generate a supply of providers willing to work in the nation's medically underserved communities. That is the purpose of Title VII, which makes the work of this committee all the more important.

Ensuring an adequate supply of health care providers, particularly in rural and urban medically underserved areas, is an issue in which Congress has long played an important role. There are several reasons why this should continue. Congress has long recognized that it has a role in addressing the geographic maldistribution

of health care providers, as well as the under-representation of minority and disadvantaged students in the health professions.

As this committee knows, the PA profession has a long standing commitment to practice in our nation's small towns, rural areas, and medically underserved communities. More than 40 percent of PAs practice in communities of less than 100,000, and nearly 15 percent practice in areas with a population of less than 10,000. Further, according to 1993 Health Personnel in the United States, Ninth Report to Congress, PAs "are more likely than are physicians to practice in rural and medically underserved areas."

We sincerely appreciate that this committee has long supported the creation and expansion of PA programs as a way to make a substantial contribution to meeting our nations primary care needs in underserved areas. However, if PAs are to meet these needs, Congress must consider increasing Title VII funding to PA programs. Clearly, federal support of PA training is highly cost effective. In fiscal year 1995, 35 PA programs received federal funds over a 3-year grant period, with an average grant of \$135,000 per year. With an average first and second year class size of approximately 70 students, the per pupil support equals \$1,928. By any standard that is a sound investment.

We also believe Congress' support has been used very effectively by the PA profession, particularly when compared with other professions. For instance, a report compiled by the School of Nursing at the University of Pennsylvania for the Department of Health and Human Services, points out that "a greater number of [advanced practice nurses] have been trained than are presently practicing." Of 49,500 registered nurses who had received formal training as nurse practitioners (NPs) as of 1992, "an estimated 23,659 practiced with the title of nurse practitioner" or approximately 48 percent. At that same time, 23,000 PAs were in clinical practice out of 27,000 graduates, or approximately 85 percent. Today, approximately 93 percent of AAPA's members are in either full or part-time clinical practice.

According to the same report, in 1991, \$14 million in Title VIII funds were awarded to 52 nurse practitioner programs, compared to \$5 million awarded to 40 PA programs. However, as noted above, less than half of trained NPs are in clinical practice, compared to 93 percent of AAPA's members. With increasingly scarce resources, we believe Congress must invest in those providers most likely to meet the objectives of Title VII, namely, to educate and train PAs who practice and deliver critically needed primary care services.

Title VII is all the more important because the demand for PAs today is quite strong, with the Department of Labor projecting that the number of PA positions is expected to increase by 36 percent between 1992 and 2005. Further, AAPA's latest census data shows that salaries for PAs continue to rise, reflecting strong market demand. With such demand, it is even more critical for Title VII funding to be increased. Without PA programs that have and dedicate resources to placing PA students in medically underserved sites during their clinical training, PA graduates are far more likely to practice either where they grew up or near where they went to school. Title VII is the critical link to addressing the natural geographic maldistribution of health care providers, by exposing students to underserved sites during their training, where they frequently choose to practice upon graduation.

We sincerely appreciate the 12 percent increase in PA program funding that was passed by the House Appropriations Committee and Congress during the 104th Congress. However, that increase only restored PA programs to their fiscal year 1995 levels, and in and of itself will not be sufficient to meet the increasing demand for PA graduates in the growing number of medically underserved sites. Therefore, we respectfully request that PA programs be funded at their current authorized level of \$9 million.

We also urge members of Congress and this Committee in particular to remember the inter-dependency that all of the Public Health agencies and programs have on one another. For instance, while it is important to fund clinical research at the National Institutes of Health and have an infrastructure at the Centers for Disease Control that ensures a prompt response to an infectious disease outbreak, the good work of both of those agencies will go unrealized if the Health Resources and Services Administration is inadequately funded. HRSA administers the "people" programs, such as Title VII, that bring the cutting edge research discovered at NIH to the patients—through providers such as PAs who have been trained in Title VII-funded programs. Furthermore, the CDC is heavily dependent upon an adequate supply of health care providers to be sure that disease outbreaks are in fact reported, tracked, and contained. In this sense, NIH, CDC and HRSA are the proverbial three-legged stool, no one of which can remain standing without the other.

In conclusion, the Academy respectfully requests that the Appropriations Committee carefully examine the reform activity occurring in the states, the impact of

changes to welfare and Medicaid recipients, the inevitable need for more primary care providers, particularly PAs, that will logically follow, and the need to support the entire public health infrastructure. We hope you will agree that not just continued but ideally expanded federal support of PA education is of fundamental importance to the nation as a whole as we strive to provide primary care to those citizens who now go without. Thank you for the opportunity to present the Academy's views on fiscal year 1998 appropriations.

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PREPARED STATEMENT OF TERRY-JO MYERS, INTERSTITIAL CYSTITIS ASSOCIATION

Honorable Chairman and Members of the Committee: Thank you for giving me the opportunity to submit my written testimony. I would like to tell you about interstitial cystitis and to ask your help in continuing to fund research to find a cure for this painful, debilitating disease. My name is Terry-Jo Myers. I am a professional golfer completing my 12th year on the LPGA tour. I also have interstitial cystitis. While I appear as a seemingly healthy person to anyone who meets me, that is because the effects of interstitial cystitis are not visible to others. But I can assure you that my work, my family and social life, and my pursuit of many dreams have all been dramatically affected by the experience of IC. I hope to give a voice to all those IC patients who are too ill to leave their homes.

Interstitial cystitis is a chronic inflammatory bladder condition. Its cause is unknown and, at present, there is no uniformly reliable treatment. The symptoms, which can be severe and unrelenting, include urgency and frequency of urination—up to 60 or more times in 24 hours; and pain in the bladder which IC patients have described as burning, like “electric shocks,” or being so severe that it feels like “razor blades in the bladder.”

I was diagnosed with IC shortly after I developed symptoms at the age of 21, but I was told that nothing could be done: I would just have to live with the pain—a prescription that far too many IC patients still receive. Every step I took was painful, and for a tour player, it was torture. Often I could not even bend down to line up a putt. I had to urinate about 50 times a day, including 10 to 20 times at night. I played in non-stop pain and had constant anxiety about being able to make it to the next bathroom.

Travel is especially difficult for many people with IC. Players on the LPGA tour travel about 28 weeks a year, and it was a nightmare for me. I arrived at tournaments exhausted. While my fellow players were practicing, I was often forced to remain in the locker room.

Saddest of all for me personally, IC affected my golf game. As a junior athlete, I won many tournaments, but as a professional with IC, my performance was terribly hindered by the disease. Because LPGA rules prohibit players from leaving the course for any reason, I have had to withdraw from tournaments in the middle of the round because I needed to go to the bathroom. In 1988, I won the Mayflower Classic, but I attribute much of that win to the fact that there were two rain delays that allowed me to go to the bathroom and keep playing.

For the last two years, I have been able to complete a full schedule in relative comfort, and look forward to continuing to do so. Last year, when I was 33, I said publicly that I felt confident that I had a good ten years left in my career, and in many ways I felt as though it would be my first ten years. I am very happy to report that on February 16th of this year, I won the Los Angeles Women's Championship in Glendale, California, and I believe that I will win again. I attribute much of this victory to the oral drug Elmiron, which was recently approved for distribution by the FDA, but which only provides relief in less than half of the IC sufferers who use it.

So while I am enjoying better health and reclaimed success, there are many many others who have not been as fortunate. I have had IC for 13 years, but it is only five years since I was able to find a doctor to help me. This doctor put me in touch with the ICA and motivated me to take steps to help me cope with my illness. This doctor was aware of Elmiron and assisted in helping me to obtain it through the FDA's Compassionate Use Program. Not all IC patients have been as lucky. Many can't travel, work, or meet their family obligations. Many become financially destitute as they lose their health insurance coverage and try to keep up with their IC treatments. Some have their bladders removed, only to encounter a whole new array of medical problems. The pain of IC can be unbearable and we have many suicides each year because of it.

Because it is a comparatively rare disease that affects mostly women, and historically, urology and urological research have focused primarily on male urological problems, interstitial cystitis is a disease that continues to be ignored by many



members of the medical community. But it is a serious and costly condition. An epidemiological study sponsored by the Urban Institute found that an estimated 450,000 people in the U.S.—men and women both—may suffer from IC, with an economic impact as high as \$1.7 billion per annum.

Fortunately, there is hope, thanks to previous Congressional funding, the NIDDK has built the IC Database, an extensive pool of IC patient information collected at nine sites around the U.S., and stored and analyzed at the Pennsylvania State University, Hershey Medical Center. Database staff have taken detailed patient and family medical histories and asked questions about diet, symptoms and experiences with diagnosis and treatment. Medical tests have also been performed on patients whose symptoms warrant them.

Researchers have already begun to publish reports analyzing data obtained from this study, with the expectation that the Database will provide clues as to how IC develops, how to diagnose and categorize patients, and how to treat the disease more effectively. In short, the Database is providing the first systematic long-term look at a large number of IC sufferers.

The Interstitial Cystitis Association and all IC patients are so grateful to all Members of this Subcommittee, and in particular, to Chairman Specter and Senator Reid for their ongoing support of research on IC and other urological diseases. Without your help, we would be nowhere in our struggle. Because of your commitment, we are beginning to see some progress. In conclusion, I respectfully ask that the momentum continue in the IC research initiative started by this Subcommittee and:

- That at least \$2.5 million in additional funds be provided to the Urology Program of the NIDDK in fiscal year 1998 specifically to support further IC research;
- That \$2 million of these funds be used to support further research into IC, solicited through an RFA focusing on clinical studies which would address the areas of IC diagnosis, prevention, treatment and epidemiology; and
- That the remaining \$.5 million be added to the current funding of the IC Database to support multi-centered clinical trials utilizing patient characteristics and sub-groups that have been identified in the IC Database.

Our need is great. But we are confident that with your help and with adequate, continued funding for IC research through the NIDDK, results will be no less than miraculous. As a victim of IC, I know what it is like to endure chronic, unrelenting pain. Please help us to end our suffering. Help us find a cure for interstitial cystitis. Thank you.

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#### PUBLIC HEALTH

##### PREPARED STATEMENT OF THE FAMILY PLANNING COALITION

The Family Planning Coalition, a group of health care providers and organizations dedicated to improving access to voluntary, comprehensive family planning services, is pleased to submit testimony in support of the Title X (ten) Family Planning Program. For more than 25 years, the Title X program has provided comprehensive, voluntary family planning services to millions of poor and low-income women. The program provides federal funds to public and private nonprofit organizations for the provision of family planning and other basic health care services which improve maternal and infant health, lower the incidence of unintended pregnancy, reduce the incidence of abortion, and lower rates of sexually transmitted diseases (STDs).

Title X clinics are community based providers located in every state and in three-fourths of all counties in the United States. Each year, they are able to provide primary preventive health services to more than four million Americans at over 4,200 Title X-funded sites across the country. These clinics often serve as the entry point to the health care system—and the only source of service—for millions of American women. The range of services supported by Title X includes contraceptive information and the provision of all contraceptive services; gynecological examinations; pregnancy testing; basic lab tests; screening services for high blood pressure, anemia, breast and cervical cancer, HIV, and other STDs; sterilization services; natural family planning; and community education and outreach. Since its inception, Title X has prohibited the use of federal funds to pay for abortions.

Title X was established in 1970 with broad bipartisan support. The original measure was introduced by Representatives James Scheuer (D-NY) and George Bush (R-TX) and Senators Joseph Tydings (D-MD) and Charles Percy (R-IL). Even today, in an era of tighter budgets and increasing political polarization within Congress, the House and Senate, in a bipartisan manner, have consistently affirmed the value of

the Title X family planning program by supporting funding and voting down attempts to place additional restrictions on access to services.

The health and economic benefits to women, children, and families of improved access to family planning are well documented. Research studies have consistently shown that bearing children less than two years apart and unplanned pregnancies that occur very early or very late during a woman's reproductive years often has adverse health, social, or economic consequences both for mothers and for their children. The National Commission to Prevent Infant Mortality estimated that infant mortality could be reduced by 10 percent, and the incidence of low birthweight babies could be reduced by 12 percent, if all pregnancies were planned. In addition, the long-term consequences of early and unintended pregnancy are often lower levels of educational and job attainment as well as a greater risk for these families of living in poverty.

Increased access to family planning services is critical because more than half of all pregnancies in the U.S. and three-quarters of teen pregnancies are unintended at the time of conception. Approximately half of these unintended pregnancies result in a live birth, while the other half end in abortion. It also is important to note that the 10 percent of sexually active American women of reproductive age who do not use contraception account for 53 percent of all unintended pregnancies. While Title X by itself cannot reduce the staggering rate of unintended pregnancy to zero, enhancing access to family planning services is critical if we are to reach our national goal of ensuring that every pregnancy is intended. The contribution of Title X toward this goal is evidenced by 1994 data that indicate that nearly one million unintended pregnancies were averted among women who sought services at Title X funded clinics.

Family planning is indisputably cost effective. In 1991, the cost of an uncomplicated vaginal delivery alone was approximately \$4,720. For every public dollar spent to provide family planning services, over \$3 are saved in publicly funded medical costs alone. According to a 1995 study, by helping low-income women to prevent unintended pregnancies, publicly funded family planning programs assist 123,000 women already on welfare to avoid pregnancy each year, and prevent pregnancies to 80,000 women at risk of going on welfare if they had a child.

Teen pregnancy rates have been a particular focus of congressional attention. While teenage pregnancy rates have begun to decline for the first time in recent memory, the teenage pregnancy rate in the United States remains high—over 12 percent of teens, ages 15 to 19, become pregnant each year, resulting in over half a million births. In addition, the teenage pregnancy rate in the United States is much higher than in many other developed countries—twice as high as in England, Wales, France, and Canada; and nine times as high as in the Netherlands or Japan. Providing teens with access to contraception information and supplies, as well as information on abstinence and the prevention of STD infection, is one way to allow teens to act responsibly and address our nation's high rate of teen pregnancy and teen STD infection.

Title X family planning clinics provide confidential screening and treatment for STDs, which affect 12 million Americans annually, one quarter of whom are teens. The increasing number of clients testing positive for HIV and other STDs also speaks to the importance of increases in funding for Title X. Title X clinics are on the front lines providing the counseling, screening, and treatment of STDs. Between 1980 and 1990, visits to Title X clinics that involved either testing or treatment for an STD increased by 30 percent. Women are particularly vulnerable to STDs because they are biologically more susceptible to certain infections than men. STDs increase the risk of HIV infection. Women bear a disproportionate burden of STD-associated complications, including infertility, ectopic pregnancy, and chronic pelvic pain. Chlamydia, an STD reaching epidemic proportions, causes infertility but often has no symptoms. The absence of symptoms commonly results in delayed diagnosis and treatment. Cervical cancer related to STDs kills over 300,000 women each year.

Given the high rates of unintended pregnancy among teenage and adult women as well as the cost-effectiveness of family planning, the need for a funding increase for the Title X program is clear. Title X funding declined precipitously during the 1980s and has regained little ground since this period. At the same time, health care costs soared, the number of eligible patients increased, and the cost of contraceptive supplies rose dramatically. The ranks of the uninsured and underinsured continue to swell, while the cost of contraceptives also continues to rise. For example, between 1991 and 1992, the average price that publicly funded clinics paid for oral contraceptives rose 42 percent.

The Coalition applauds Congress for approving a modest funding increase for the Title X program for fiscal year 1997 to \$198.452 million. The fact remains, however, that clinics continue to be asked to do more with less. The overall decline in infla-

tion adjusted funds for Title X has forced some family planning clinics to cut back or eliminate outreach efforts to underserved communities and patients, cut back hours of operation, accept fewer patients who need subsidized services, and place patients on waiting lists for long-acting methods of contraception, including Depo-Provera, IUDs, and voluntary sterilization which have high up front costs, but are cost effective over the long term. Had the program's 1980 funding level of \$162 million simply kept up with the rate of inflation as calculated using the medical care services index, funding for the program would now be \$515.16 million.

Given the proven effectiveness of the Title X Family Planning Program, the Coalition respectfully requests a funding level of \$250 million for Title X in the fiscal year 1998 Labor, HHS, and Education Appropriations bill. While the Coalition recognizes the budgetary constraints which Congress is working under, the cost-effectiveness of family planning speaks for itself—investing more in the Title X program now will save many more federal dollars down the road. This increase, which would leave program funding at less than half of the inflation adjusted level for 1980, will allow Title X grantees to serve a larger number of clients and make more widely available the most effective forms of contraception and improve outreach and screening services, thereby further reducing the incidence of unintended pregnancy and sexually transmitted diseases.

Family planning is the common ground on which we can all agree. Over the last two years, Congress has repeatedly voted to support funding for and access to family planning services for all Americans. The Coalition urges the subcommittee to carefully consider the well-known benefits associated with family planning and the support of the American electorate for these vital services when determining the fiscal year 1998 funding level for the Title X program. Family planning reduces the need for abortion, provides positive health benefits for women, children, and families, and saves American taxpayers money in the long run. As such, family planning remains a very wise investment in the future of our country and its children.

This testimony is submitted on behalf of the undersigned members of the Family Planning Coalition: Advocates for Youth; American Association of University Women; American Civil Liberties Union; American Jewish Congress; American Medical Women's Association; American Nurses Association; American Psychological Association; American Public Health Association; American Society for Reproductive Medicine; Association of Maternal and Child Health Programs; Association of Reproductive Health Professionals; Association of Schools of Public Health; Center for Reproductive Law and Policy; National Abortion and Reproductive Rights Action League; National Association of City and County Health Officials; National Association of Nurse Practitioners in Reproductive Health; National Council of Jewish Women; National Family Planning and Reproductive Health Association; National Women's Law Center; NOW—Legal Defense And Education Fund; People for the American Way Action Fund; Physicians for Reproductive Choice and Health; Planned Parenthood Federation of America; Sexuality Information and Education Council of the United States; The Alan Guttmacher Institute; Union of American Hebrew Congregations; Women's Legal Defense Fund; and Zero Population Growth.

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PREPARED STATEMENT OF DANIEL ZINGALE, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL

Mr. Chairman and Members of the Committee. I am Daniel Zingale, Executive Director of AIDS Action Council, the Washington voice for over 1,400 community-based AIDS service providers from across the country and the people living with HIV/AIDS they serve. AIDS Action Council is the only national organization dedicated solely to shaping federal AIDS policy. This work is supported by our members and individual donations. AIDS Action Council does not receive any federal funding.

We are at a pivotal moment in the history of the AIDS epidemic. I am sure you are all aware of the many news reports about the recent dramatic advances in the care and treatment of HIV disease. The good news is that last year, for the first time in the history of the epidemic, the number of people dying from AIDS decreased significantly—by 13 percent overall. This dramatic drop in AIDS deaths is attributable to a combination of factors: the development of improved treatments for battling both HIV and the opportunistic infections that accompany it, improving standards of care, and increased access to care.

The bad news is that although the overall number of AIDS deaths declined last year, the death rate for women with HIV disease actually increased by 3 percent, and death rates among people of color declined only nominally. The increase in deaths of women and the lower death rate reductions among people of color is a poignant reminder that not all Americans are reaping the benefits of high quality

AIDS care and more effective treatments. These disparities highlight stark inequities in the availability of state-of-the-art health care for women and people of color, care that people with HIV/AIDS need to stay alive.

“Access to care” means much more than the ability to purchase drugs. Drugs alone are not the answer. The unfortunate reality is that the new combination therapies with protease inhibitor drugs are not effective for all infected individuals. We are still learning about the potential of these new treatments, and we do not yet have the answers we need about why these treatments seem to produce dramatic health improvements for some people living with HIV/AIDS and not others, or whether the improvements we have seen will be sustained over time. Clearly, there is still an urgent need to invest in additional research, not only to answer these questions, but to develop even more effective treatments, and ultimately, to discover a vaccine and a cure.

To benefit from new drug therapies, people must have access to affordable, comprehensive medical and supportive services provided by well-trained and culturally competent health providers. To access medical care, people must have a stable home and vital enabling services, like child care, transportation, appropriate case management, and substance abuse treatment services.

This epidemic is far from over. While the overall number of people dying from AIDS declined significantly last year, the number of people living with AIDS did not. Blacks, hispanics and women accounted for increasing proportions of new AIDS cases in 1996. In 1996, blacks accounted for 41 percent of adults with AIDS, exceeding the proportion of people living with AIDS who were white for the first time. Women accounted for an all-time high of 20 percent of AIDS cases reported in 1996.

And tragically, the number of people newly-infected with HIV is not declining. Even now, over a decade into the epidemic, too many individuals do not realize they are at risk for HIV infection. Far too many people are not learning of their HIV status until they are hospitalized with a major AIDS-defining opportunistic infection, lamentably too late to realize the full benefits of early intervention with state-of-the-art therapies. Greater community-based education efforts and easier access to HIV counseling and anonymous testing is vital. The benefits of early intervention care services that hold the promise of significantly delaying disease progression can only be realized through aggressive education efforts that encourage individuals who realize they are at high-risk to be tested for HIV, so they can immediately be linked with comprehensive and coordinated systems of care.

Early intervention is not “true” prevention, of course. It is far less expensive—and far more humane—to prevent someone from becoming infected in the first place than to care for that person once they are infected. HIV infections continue to increase disproportionately among women, communities of color, and adolescents. Much of this increase is attributable to injection drug use and substance abuse generally, which contributes to unsafe sexual behavior among drug users and their sexual partners. Clearly, increased funding for community-based HIV prevention programs targeted to women, communities of color, adolescents, and drug users and their partners is urgently needed. But we cannot forget that substance abuse treatment also constitutes a potent HIV prevention strategy. Increased funding for substance abuse treatment and the removal of barriers that now prevent local communities from implementing syringe exchange programs, which have been scientifically proven to reduce HIV transmission and save lives, are essential parts of an overall HIV prevention strategy.

There is great promise in many of the recent developments in the fight against the AIDS epidemic and notable challenges and opportunities. The federal government must fulfill its responsibilities to safeguard and enhance the public health by adequately funding HIV prevention, research, care, training and substance abuse programs. This committee has shown extraordinary leadership in the past by making tough choices that have succeeded in providing funding for programs that save lives. If we are to continue to make progress in our fight against AIDS, we must look to you once again to provide increased resources. The national response to the AIDS epidemic must continue to reflect a comprehensive approach by providing adequate financial support for research, prevention, care, training and substance abuse treatment.

#### *Prevention*

Absent a preventive vaccine, our only hope of halting further HIV transmission is through a comprehensive, targeted approach to AIDS prevention throughout the nation. Chronically underfunded for years, the Centers for Disease Control and Prevention (CDC) spearheads the federal government’s prevention strategy. We propose a \$212 million increase over fiscal year 1997 for the Centers for Disease Control & Prevention’s (CDC) HIV prevention-related programs.

AIDS continues to be the leading cause of death among American women and men between the ages of 25 and 44, cruelly depriving them of years of productive life. Every year, 40,000 to 80,000 more Americans become infected with the human immunodeficiency virus (HIV), the virus that causes AIDS. Tragically, nearly 50 percent of the new infections occur in people younger than 25 years of age. And while men who have sex with men still account for a majority of cases among youth and men of color, rates of new infections are growing fastest among women, doubling every 1–2 years.

As I stated earlier, it is far less expensive—and far more humane—to prevent individuals from becoming HIV-positive in the first place. People become infected with HIV because they do not realize they are at risk or do not really know how to protect themselves from infection. As the recent NIH Consensus Conference on HIV Prevention made clear, we have prevention strategies that are scientifically proven to work. The problem is that as a nation, we have lacked the political and moral will to implement these proven community-based HIV prevention strategies. Educating people about behaviors that may place them at risk and providing them with the tools to protect themselves from becoming infected—whether that means explicit information about sexual practices, distributing condoms, or providing clean needles—are scientifically sound approaches to HIV prevention.

Prevention interventions are cost-effective. The Center for AIDS Prevention Studies at the University of California, San Francisco, estimates that adding \$500 million to HIV prevention targeted to high-risk groups would yield medical care savings totaling \$1.25 billion. HIV prevention programs have proven to save lives. Declines in infection rates among certain groups, most notably adult white gay men, is proof that targeted prevention efforts are successful. However, the increasing infection rates among people of color, women, and youth highlights the work and investment that is still needed.

We know what works. Now we must make sure local communities have the information and the resources they need to implement community-based prevention strategies geared to the specific demographics of the epidemic locally. Increased funding for the CDC's cooperative agreements with states and localities will enable those states and localities to implement the community-based prevention plans developed by local health departments and community groups through the HIV prevention community planning process.

States and localities must be given greater resources and the flexibility to design comprehensive strategies that include prevention education, outreach, counseling and anonymous testing, as well as continuing local surveillance and partner notification programs that are responsive to the local needs, and not be subjected to one-size fits all solutions from Washington.

Increased funding for the CDC will also enable the CDC to increase dissemination of scientific research related to risk behavior and methods to reduce HIV transmission, and to strengthen CDC's minority and youth initiatives, which are critical to the development and implementation of effective, culturally-sensitive, age-appropriate prevention strategies targeted at those communities most at risk.

#### *Care*

The Ryan White CARE Act, which provides primary medical care, AIDS drugs, viral load testing, case management and other enabling services for thousands of individuals living with HIV/AIDS, plays a vital role in ensuring access to appropriate care for Americans living with HIV/AIDS. We propose \$393.9 million in increases over fiscal year 1997 for the medical, social services and training programs in the Ryan White CARE Act.

The appearance of new treatments and new hope has led to a dramatic increase in demand for primary care and support services for people living with HIV and AIDS. People are living longer and correspondingly requiring services over a longer time period. The intricate, fragile, AIDS care infrastructure that was constructed over the past 15 years to ensure basic health care for people with AIDS who had nowhere else to turn is struggling to keep pace with new demands.

While Medicaid provides health care to at least 53 percent of all adults and over 90 percent of the children living with AIDS, many low-income people living with HIV disease do not become Medicaid-eligible until they have an AIDS diagnosis. Ryan White is often the only safety net to respond to the urgent need for early intervention medical care, prescription drugs and vital enabling services. The erosion in private health insurance coverage and proposed limits on future federal Medicaid funding will only further strain the ability of Ryan White-funded programs to provide comprehensive services.

Waiting lists and impossible choices between funding life-sustaining prescription drugs, primary medical care or home health care will become more common as Ryan

White providers work to deliver more services for more people without adequate resources. Ryan White Title IIIB clinics have documented a 41.1 percent increase in the number of new patients within the last year alone, and St. Vincent's Hospital in New York City saw a 30 percent increase during 1996 in new patients seeking early intervention services.

Each of the five titles of the CARE Act plays a critical role in making it the health care and social service safety net of last resort for Americans living with HIV/AIDS. Increased funding for all of the Titles of the Ryan White CARE Act is needed to ensure that the health care and support services infrastructure can continue to meet service needs and to successfully support the provision of effective medications.

For Title I, which provides emergency formula and competitive grants to those metropolitan areas most heavily affected by the HIV/AIDS epidemic, we propose a \$96.1 million over fiscal year 1997. Title I funds are used to deliver outpatient medical care, substance abuse and mental health treatment, and other critical support services. Forty nine eligible metropolitan areas (EMAs) now receive Title I funds.

For Title II, which provides formula grants to the state health departments in all 50 states, the District of Columbia, and the territories, we propose a \$220.6 million increase over fiscal year 1997. This request includes an increase of \$130.6 million specifically to the AIDS Drugs Assistance Program and \$90 million for state formula grants. Title II funds are used to provide medical care and support services, and are also used to operate HIV care consortia, fund state health insurance continuation, home-based care services, and to purchase AIDS-related drugs for low-income individuals through the AIDS Drug Assistance Program (ADAP). Title II must also shoulder an increasing health care burden associated with the fact that no new jurisdictions will become eligible for Title I funding. The number of new Title I EMAs was effectively capped by the reauthorized Ryan White CARE Act. In addition to the health care and social service demands, ADAP continues to face substantial challenges to meeting the demand for new and potentially lifesaving and life-extending drug therapies. As a result, additional funds are required specifically for ADAP so that, at least in the short term, it can continue to address this explosive growth in demand from uninsured and underinsured people with HIV/AIDS.

For Title IIIB, which provides competitive grants to existing community-based clinics and public health providers serving traditionally underserved populations, we propose a \$44 million increase over fiscal year 1997. Title IIIB funds are used to deliver early intervention and ongoing comprehensive HIV/AIDS health care services, including HIV counseling and testing, primary care, and prescription drugs.

For Title IV, which provides competitive grants to pediatric, adolescent and family HIV care programs, we propose a \$25 million increase over fiscal year 1997. Title IV funds are used to provide coordinated care services and access to clinical research by linking care services to clinical research programs.

For Title V, which provides competitive grants for projects of national significance and to educate and train health care providers in HIV/AIDS care through the AIDS Dental Reimbursement Program and the AIDS Education & Training Centers (AETCs), we propose a \$6.7 million increase over fiscal year 1997 for the AETCs and \$1.5 million increase over fiscal year 1997 for the Dental Reimbursement program. As the training arm of the CARE Act, the AETCs ensure that health care providers have access to the most up to date information and training on competent HIV/AIDS care and treatment and the HIV/AIDS Dental program helps to provide training in and access to much needed HIV dental care.

#### *Substance Abuse Prevention and Treatment*

Substance abuse is inextricably linked to the HIV epidemic. We cannot stem the spread of AIDS or provide care and treatment for those substance abusers who are already infected if we do not address the need for prevention and treatment for drug dependence and alcoholism. Injection drug use is associated with over one-third of all AIDS cases. But substance abuse also plays a significant role in sexual transmission of HIV since it contributes to impaired judgement and increases in high-risk sexual practices. We propose a \$140 million increase over fiscal year 1997 for the Substance Abuse Prevention and Treatment Blockgrant at the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Substance Abuse Prevention and Treatment Block Grant at SAMHSA is the primary funding source for public substance abuse prevention and treatment services. The goal of the block grant is to ensure that all Americans have access to appropriate drug prevention and treatment services. Alcohol and drug prevention and treatment services promote good health and reduce high risk sexual behavior. Substance abuse prevention and treatment prevent HIV disease, cost far less than HIV medical care, and drastically reduces the human suffering and cost associated with AIDS.

*Research*

While both a cure for HIV disease and a vaccine to prevent new infections remain elusive, AIDS research has experienced significant achievements. The productive life span of Americans diagnosed with HIV has doubled since 1987 and may easily double again with the recent advances in basic research coupled with the new drugs. But we must remember that the new drugs are not a cure and we are still years from the development of an effective vaccine. To continue to make these advances, funding for overall research efforts at the National Institutes of Health must increase. We support the professional judgement recommendation of a \$134.5 million increase over fiscal year 1997 in AIDS-related biomedical and behavioral research.

In the last year alone, AIDS research led to the discovery of the means by which HIV infects cells and to the approval of the protease inhibitors and the non-nucleoside reverse transcriptase inhibitors. These new drugs, when taken in combination, can lower viral load—the amount of HIV in the blood—to undetectable levels in many people for extended periods of time, cutting death rates significantly and greatly reducing the rates of opportunistic infections.

NIH AIDS research is also part of our nation's larger commitment to biomedical research. As such AIDS research enhances and stimulates research in other fields, with broad implications for human diseases such as cancer, heart disease, Alzheimer's disease, and others. Twenty five percent of NIH AIDS research funds are used for basic science research, which has broad implications across scientific disciplines.

This Subcommittee and the Congress have made a bipartisan commitment to maintain a vigorous national commitment to the flagship biomedical and behavioral research enterprise at the National Institutes of Health. However, the size and breadth of the AIDS research portfolio conducted by all 24 NIH Institutes requires a coordinated and strategic plan to ensure that federal resources are effectively managed to facilitate answers to the scientific questions which hold the greatest promise. In order to accomplish this, a consolidated budget administered by the Office of AIDS Research must be maintained. It is only by continuing to support this funding mechanism that the resources devoted to AIDS research will be allocated to the most promising areas of medical and scientific exploration. Ultimately, biomedical and behavioral research will provide the critical answers for treatment and prevention of HIV infection. Without a concentrated, planned commitment to an effective research agenda, we will be unable to find new ways to prevent HIV infection, develop new treatments, a vaccine or a cure.

Our nation is at a crucial moment in the fight against AIDS. We have made incredible progress on several fronts. However, so much more remains to be done. AIDS Action Council calls upon the federal government, in partnership with communities across the country, to act quickly and assertively to ensure that the new hope touches the lives of all people affected by HIV/AIDS.

FISCAL YEAR 1998 APPROPRIATIONS LEVELS FOR FEDERAL AIDS PROGRAMS AS OF  
FEBRUARY 19, 1997

[In millions of dollars]

Federal program	Fiscal year 1997 Actuals <sup>1</sup>	Fiscal year 1998 Presi- dent's Budget Request 2/6/97	Fiscal year 1998 need <sup>2</sup>
CDC—Prevention .....	617.0	643.0	829.0
		(+ 17.0)	(+ 212.0)
HRSA—Ryan White CARE Act Total .....	996.3	1,036.3	1,390.2
		(+ 40.0)	(+ 393.9)
Title I .....	449.9	454.9	546.0
		(+ 5.0)	(+ 96.1)
Title II—Care Services .....	250.0	265.0	340.0
		(+ 15.0)	(+ 90.0)
Title II—ADAP .....	167.0	167.0	297.6
			(+ 130.6)
Title IIIb .....	69.6	84.6	113.6
		(+ 15.0)	(+ 44.0)
Title IV .....	36.0	40.0	61.0

FISCAL YEAR 1998 APPROPRIATIONS LEVELS FOR FEDERAL AIDS PROGRAMS AS OF  
FEBRUARY 19, 1997—Continued

[In millions of dollars]

Federal program	Fiscal year 1997 Actuals <sup>1</sup>	Fiscal year 1998 Presi- dent's Budget Request 2/6/97	Fiscal year 1998 need <sup>2</sup>
		(+ 4.0)	(+ 25.0)
Title V—AETCs .....	16.3	17.3	23.0
		(+ 1.0)	(+ 6.7)
Title V—Dental Reimbursement .....	7.5	7.5	9.0
			(+ 1.5)
NIH—Research .....	1,501.7	1,541.7	1,636.2
		(+ 40.0)	(+ 134.5)
HUD—HOPWA .....	196.0	204.0	250.0
		(+ 8.0)	(+ 54.0)
SAMHSA—Substance Abuse Prevention and Treatment Block grant .....	1,360.1	1,370.0	1,500.0
		(+ 10.0)	(+ 140.0)

<sup>1</sup>Funding for Labor/HHS programs was provided through H.R. 4278 The Omnibus Consolidated Appropriations Bill of 1997. Funding for HOPWA was provided through the fiscal year 1997 VA/HUD Appropriations Bill signed by the President on 9/26/96.

<sup>2</sup>Need figures are supported by the NORA Coalition and represent the resources needed to respond to growing case loads, unmet needs and unfunded research opportunities.

Note.—Increases or decreases from the fiscal year 1997 numbers are in parentheses.

PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH  
PROGRAMS

For over 60 years, programs within the Title V Maternal and Child Health Services Block Grant have helped fulfill our nation's strong commitment to improving the health of all mothers and children. State Maternal and Child Health (MCH) programs, supported by the federal Maternal and Child Health Services Block Grant, have demonstrated their ability to adapt through decades of change by responding to the emergence of new diseases, discovery of new vaccines, and evolving health delivery systems while still fulfilling the core mission of improving the health of all mothers and children. Congress has remained committed to this program because it provides proven, preventive health care to a vulnerable population with demonstrated results. These results include reducing maternal and infant mortality, improving the health of newborns, immunizing and screening children to prevent life-threatening diseases, and helping children with disabilities function to their full potential.

Investment in programs serving children and pregnant women are cost-effective, preventive in nature, and result in improved health outcomes for mothers and children. For every dollar invested in prenatal care, three dollars are saved in subsequent health costs for the care of a low-birthweight baby. MCH programs also invest in the delivery of immunizations to children. Immunizations are widely known to be cost-effective, and for every dollar spent on measles, mumps, and rubella vaccine \$21 is saved.

Another important MCH program, newborn screening, prevents chronic diseases and disability through early detection, diagnosis and treatment. Currently, nearly all 4 million newborns receive screening in order to avert tragic health consequences from genetic, metabolic, hearing and other disorders. In addition to newborn screening, MCH programs provide early intervention and coordination of care for children with chronic diseases and disabilities. Through these efforts, children are able to function more independently and avoid institutionalization. Florida estimates saving \$21,000 per disabled child over a 20 year period. With demonstrated, preventive programs such as prenatal care, immunizations, newborn screening, and care for children with disabilities, the MCH Block Grant is a sound investment for the health of children and pregnant women.



## POPULATIONS SERVED

The Maternal and Child Health Services Block Grant directly serves over 17 million women and children. Through grants, contracts, or reimbursements to private and public sector providers, state MCH programs support the availability and accessibility of community health and family support services, especially for the uninsured and underinsured families. Most recent data indicate that MCH programs supported preventive, primary, and speciality services to: Approximately 4.8 million women; Almost 11.3 million infants, children and adolescents; and Approximately 900,000 children with special health care needs.

In addition to direct services, the program reaches many more women and children indirectly through population-based services. These include services such as newborn screening, sudden infant death syndrome (SIDS) counseling, lead poisoning prevention, outreach activities, and media campaigns that offer basic information to a wide segment of the population to encourage healthy behaviors among women and children and promote preventive health care.

## STATE PROGRAMS

States benefit from the broad nature and flexibility of the Maternal and Child Health Services Block Grant. The block grant's flexibility allows states to pool MCH dollars with other public and private sector funds to develop new, community-based projects. The broad responsibility and function of the program allows state MCH programs to address the unique health needs of their states' population.

*Targeting Resources*

One of the program's greatest advantages is its ability to adapt to the needs of a particular state and target resources to at-risk groups in particular communities. Through the assessing of needs of the MCH population and tracking health status over time, states can respond to a variety of health problems, including low immunizations rates in a particular county or high blood lead levels in children living in a specific neighborhood.

For example, the Texas MCH program helps reduce birth defects along the Rio Grande River, while also expanding access in underserved communities in Arkansas, by contracting with pediatricians to staff rural health clinics. In Mississippi, children with chronic diseases and disabilities receive surgeries at Jackson University Medical Center and follow-up treatment at 22 community-based sites. The Florida MCH program has had success in improving low-income women's access to prenatal care in cities such as Miami, St. Petersburg, and Sarasota. The state's infant mortality rate has dropped over the last ten years through these and other efforts.

In New York, Chicago, Philadelphia, San Francisco, Seattle, Baltimore, and other cities throughout our country, the emergence of new diseases and treatments for health problems affecting women and children have required specific responses. The increased spread of HIV among women has threatened their health and the health of their babies. Effective coordination of MCH programs with Ryan White Titles II and Title IV programs has enabled communities to better respond and treat women in order to decrease the risk of infection to their newborns. In recent months, MCH programs have been involved in assuring counseling and testing of pregnant women to reduce perinatal transmission of HIV infection.

*Addressing New Health Delivery Systems*

MCH programs must also address a rapidly changing health care system to assure that the needs of children and families are appropriately addressed. To accomplish this, MCH program expertise assists in developing managed care delivery systems that effectively assure key preventive maternal and child health needs.

In cities such as Milwaukee, the MCH program has played a key role in bringing together managed care executives, Medicaid officials, physicians, and consumers to improve the health of women and children enrolled in Medicaid managed care. The group has focused on improving the responsiveness of the Medicaid HMO system for the population, simplified the Medicaid eligibility procedures, and secured the commitment of foundations to involve families in funded projects. Through the MCH Block Grant's structure, states can better target the health needs of the communities and respond to emerging issues affecting women and children.

## UNMET NEED

*Uninsured children and pregnant women*

Low-income children and pregnant women are at increased risk of losing health coverage through changes in employment-based health coverage. According to recent General Accounting Reports (GAO), employers are dropping dependent coverage at

an alarming rate. GAO reported that between 1989 and 1995 the percentage of children under 18 with health insurance decreased from more than 73 percent to 66 percent. If private coverage levels had not decreased, about 5 million more children would have private insurance today. GAO estimated that in 1994 over 10 million children lacked health coverage. Trends in decreasing employer-based coverage are only expected to get worse as more employers find it too costly to pay for dependent coverage. Congress should work to enact bipartisan legislation to increase coverage for these 10 million children and an estimated 500,000 pregnant women. State MCH programs have provided access to care for a portion of these low-income women and children, and can continue to play an integral part of any federal expansion of health coverage to children and pregnant women.

Even when women and children have coverage, they still may lack access to care.

State MCH programs:

- ensure the availability of public and private providers in underserved areas;
- support and coordinate services for children who have complex medical conditions or disabilities; and
- use media campaigns and toll-free hotlines to link families with Medicaid, other insurance sources, and providers of prenatal and well-child care, and additional services necessary to improve birth outcomes and prevent childhood diseases.

*Over 135,000 children with chronic conditions and disabilities will lose SSI*

Changes in the welfare system will have serious consequences for pregnant women and children. Denial of SSI benefits to 135,000 children will have a major impact on the health of these children, their families, and the safety-net programs and providers that serve them. Up to 50,000 of these children are expected to lose Medicaid. The families of these children will turn to care provided at hospitals and clinics supported by the MCH Block Grant. This new demand on services will put a further strain on already-limited MCH funds. Also, it is anticipated that other children and pregnant women who lose benefits through changes in welfare reform will need services to prevent critical problems facing the community including infant mortality and the spread of infectious diseases.

FUNDING FORMULA/SET-ASIDES

The MCH Block Grant is a permanently authorized discretionary federal grant program. Its current authorization level is \$705 million; in fiscal year 1997, \$681,000 million was appropriated for the program. Of this \$681,000 million, \$2.8 million was earmarked for the traumatic brain injury demonstration projects. The Association of Maternal and Child Health Programs recommends that new initiatives such as the traumatic brain injury demonstration projects, be funded separately in fiscal year 1998. For appropriations up to \$600 million, 85 percent of the appropriation is allocated to the states, and 15 percent is set-aside at the federal level for demonstration, research and training, and service projects. For appropriations exceeding \$600 million, 1989 amendments created a second set-aside of 12.75 percent to fund six types of demonstration projects: home visiting; provider participation; integrated service delivery; non-profit hospital MCH centers; rural programs; and community projects for children with special health care needs. States match 3 dollars for every four federal dollars; many states provide additional funds. States must limit administrative costs to 10 percent; maintain state MCH funding levels at 1989 levels; and spend 30 percent of funds on preventive and primary care for children and adolescents, and 30 percent on services for children with special health care needs.

The MCH Block Grant's two federal discretionary programs or set-asides: are the Special Projects of Regional and National Significance (SPRANS) program and the Community Integrated Service System (CISS) program. SPRANS grants are authorized as special projects that must respond to national needs and priorities, have regional or national significance, and demonstrate some way to improve state systems of care for mothers and children. SPRANS funds are reserved at the federal level for the purpose of supporting projects in five areas of research, training, hemophilia, genetic diseases, and maternal and child health improvement projects. SPRANS grants support technical assistance training and research policy development centers that work to build states' maternal and child health infrastructure and develop tools and information to help states improve the health status of pregnant women and children. While SPRANS grants focus on regional and national priorities, the CISS program targets communities through increasing the capacity for service delivery at the local level and fostering formation of comprehensive, integrated, community-level service systems for mothers and children.

## FUNDING RECOMMENDATION

To maintain cost-effective, preventive public health services protecting all our nation's mothers and children, the Association of Maternal and Child Health Programs recommends an appropriation of \$705 million for the Maternal and Child Health Services Block Grant for fiscal year 1998. While AMCHP recognizes that there are limited federal resources, it should be noted that if the block grant's appropriation were to have kept pace with constant 1980 dollars, its funding level would now be approximately \$730 million. With sufficient funding, this program can continue to play a vital role in improving the health status of all children and pregnant women.

## PREPARED STATEMENT OF THE AMERICAN SOCIAL HEALTH ASSOCIATION

This testimony is on behalf of the American Social Health Association, the only national non-profit organization dedicated solely to the elimination of all sexually transmitted diseases (STDs). For over eighty years, the American Social Health Association has addressed American's on-going epidemic of STDs through programs of education, research and public policy.

ASHA appreciates this opportunity to provide the Subcommittee with information about the health crisis caused by the skyrocketing rates of STDs in America and about the programs of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) that combat these diseases. Before I mention our funding recommendations, I will take a brief moment to highlight the consequences of the STD epidemic in the United States.

On November 19, 1996, the Institute of Medicine in a ground-breaking report entitled, "The Hidden Epidemic, Confronting Sexually Transmitted Diseases (STDs)," detailed the inadequacy of the current treatment and prevention services for STDs in the United States and offered solutions to this problem. The report highlights the high rates of STDs in the United States.

Each year, 12 million Americans suffer from a new STD infection—this translates into 33,000 infections every day. This is the highest infection rate of curable STDs in the industrialized world. A great tragedy of the epidemic is the disproportionate impact STDs have on women, adolescents and children. Many STDs are asymptomatic in women and lead to life-long consequences, including infertility, cervical cancer, increased risk of HIV transmission, ectopic pregnancies and severe pelvic pain.

Research by physicians at Johns Hopkins University has shown that 93 percent of all cervical cancer cases are caused by one STD—human papillomavirus (HPV). Annually, five thousand women die from cervical cancer and 16,000 new cases of invasive cervical cancer are diagnosed. Unfortunately, cervical cancer will remain a problem in the near future. As many as 46 percent of all college-age women in America are infected with HPV. Currently, the Breast and Cervical Cancer Prevention division and the STD division at the Centers for Disease Control are collaborating on a study to determine the feasibility of performing HPV screening and pap smear screening in STD clinics. Additional funding for this project would allow the STD division and the Breast and Cervical Cancer division to collaboratively continue this project.

Two-thirds of all STD infections occur in persons under age 25. The IOM report recommends that the CDC design and implement essential STD-related services in innovative ways for adolescents and underserved populations. One out of every five sexually active teenagers has acquired an STD by the age of 21. The CDC's Accelerated Prevention Program is developing new strategies to reach out to this population at risk. The disturbing trend in this population places young women at an increased risk of developing life-threatening and expensive medical complications.

One of the most devastating lifelong consequences of STD infection is the increased risk for HIV infection. The IOM report points out that both ulcerative STDs (e.g. syphilis) and inflammatory STDs (e.g. chlamydia and gonorrhea) increase the risk of HIV infection. Studies have shown that a woman who has gonorrhea is nine times more likely to become infected with HIV. Other studies have estimated that successfully treating or preventing 100 cases of syphilis, among high-risk groups for STDs would prevent 1,200 HIV infections that would otherwise result from those 100 syphilis infections during a 10-year period. It is no surprise then, given the high rates of STDs among young women, that this population is acquiring HIV at a higher rate than any other demographic group. In the absence of a vaccine or a cure for HIV/AIDS, STD prevention is one of the best strategies to control the spread of AIDS. To reduce the incidence of AIDS among the youth of the United States, Congress would be wise to invest in the CDC's STD prevention program.

In addition to the emotional and physical toll exacted by STDs, the health care expenditures are also staggering. The IOM report estimates that approximately \$10 billion was spent in 1994 to treat STDs and their consequences. When one compares the total costs of STDs with the total investment, the results are staggering. The STD-related health care costs were approximately 43 times the national public investment in STD prevention and 94 times the investment in STD related research. Much of the economic toll of STDs could be avoided, as the long term consequences result from the failure to detect and treat STDs in their early stages. For example, nearly three-fourths of the \$1.5 billion cost associated with untreated and preventable complications related to chlamydial infections could be saved with effective screening and treatment programs.

Fortunately, effective programs to combat the STD epidemic do exist. The CDC's Infertility program focuses on screening and treating chlamydia and gonorrhea, the STDs that cause infertility. This program is very successful and has been found to be cost effective in those regions of the country that are screening approximately 40 percent of the women at risk. Infection rates have dropped by as much as 61 percent, screening costs have dropped by 50 percent, and treatment costs have decreased by 80 percent due to bulk purchasing and centralization of testing. In California, estimates have shown a savings of more than \$60 million during the first five years of the implementation of this program. A recent study conducted at the Group Health Cooperative of Puget Sound in Washington state found that screening for chlamydia reduced incidence rate by 56 percent. Unfortunately, fiscal pressure has constrained the CDC from implementing this program across the country.

Every year, the American Social Health Association joins the Coalition to Fight Sexually Transmitted Diseases in recommending funding levels for the STD prevention, treatment, and research programs of the Federal government. For fiscal year 1998, the Coalition recommends a \$28 million budget for the CDC Infertility Prevention Program, a \$15 million increase. With the proven track record of this program, ASHA suggests that this \$15 million may be the best investment the Congress can make to improve the health of our nation's young women and reduce health care costs.

In addition to the Infertility Prevention Program, funding for the CDC's STD programs supports the efforts of state and local health departments and community-based organizations to implement prevention strategies that are responsive to this continually changing epidemic. CDC's grants to states support essential programs including partner notification programs, clinician training, epidemiological surveillance and targeted prevention programs. For these grant programs, the Coalition recommends fiscal year 1998 funding of \$145 million, a \$19 million increase. This increase will allow the CDC to begin to address this exploding epidemic and improve the lives of thousands of Americans.

STD research conducted by the NIH provides our public health system with the tools to treat and control the STD epidemic. Advances are being made. For instance, research is being conducted on topical microbicides, which will provide a simple and effective method of stopping STDs at the point of transmission. The NIAID hopes to begin extensive research on pelvic inflammatory disease, an infection that leads to infertility, ectopic pregnancies and chronic pelvic pain in thousands of young women. The Coalition recommends fiscal year 1998 funding of \$83.7 million for the STD branch of the NIAID, an increase of \$15 million. Funding at this level will allow increased research into the role of STD treatment in HIV prevention, and the testing of topical microbicides.

As recommended by the Institute of Medicine, Congress needs to confront the "hidden epidemic" of STDs. Greater investment in federal STD prevention and research programs will yield enormous dividends in ameliorating cervical cancer, infertility, and the risk of HIV transmission.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

The National Association of Community Health Centers (NACHC) is pleased to have this opportunity to comment on the fiscal year 1998 funding for the Consolidated Health Centers program, and related HRSA programs. The members of NACHC thank the Chairman and the members of the Subcommittee for recognizing the importance of health centers and for providing an increase for these program in fiscal year 1997.

NACHC is a membership organization which represents over 940 community, migrant, homeless and public housing centers and FQHC look-alikes in nearly 2,700 communities across America. Together, these health centers care for over 10 million

children and adults in every state, Commonwealth and Territory, and the District of Columbia. Health Centers are local non-profit, community-owned health care programs serving low income and medically underserved urban and rural communities with few or no resources. Health centers are governed by members of the community who have an interest and responsibility to ensure that responsive and affordable health care is provided to all who need it. They are staffed with interdisciplinary teams of more than 5,000 physicians (98 percent board certified), as well as nurses, dentists, other health professionals and community residents. Health centers offer a wide range of primary and preventive medical and dental care, including: diagnostic laboratory and radiologic services, pharmaceutical services and preventive services such as immunizations, well child examinations, preventive dental care, family planning, prenatal and postpartum care. Health centers also provide health education, community outreach, transportation, and support programs (including literacy and other education programs) in collaboration with other organizations and agencies like schools, Head Start programs, and homeless shelters.

Without health centers, residents of inner-city and rural underserved areas would face great unmet health care needs. Health center patients include uninsured low-income persons, minorities, rural residents, high-risk pregnant women and children, migrant farm workers, persons with AIDS, persons with drug and alcohol problems, homeless persons and families, the frail elderly and other high-risk groups. The level of need has escalated due to the increasing number of uninsured individuals, the new welfare law, and the emergence of health conditions and public health threats that were either unknown or thought to have been eliminated a generation ago. Additionally, many health center patients also face severe environmental and occupational risks.

The following reflect the profiles of health center patients:

- Health Centers serve 1 of every 6 low income American children (4.5 million children).
- In 1995, the 400,000 births to Health Center patients accounted for 1 of every 10 births (and 1 of every 5 low income births ) in the United States.
- 1 in every 10 uninsured persons (and 1 in every 7 uninsured children) in the United States uses Health Centers.
- Health Centers are the family doctor for 1 in 10 rural Americans.
- 1 of every 8 low income Americans uses Health Centers.
- Almost 7 million minority persons are Health Center patients.
- Health Centers are the provider of choice for 1 of every 10 people covered by Medicaid.

There are over 41 million uninsured Americans who suffer financial, geographic or cultural barriers to health care. This number of uninsured Americans is growing rapidly. Studies have shown that this number could reach 50 million or more over the next five years. Nearly three-fifths of the uninsured are members of low income working families who cannot afford to buy health insurance, are not registered in managed care systems, and therefore have no place to go for health care but to costly hospital emergency rooms or to health centers.

Many studies have concluded that health centers, in the process of providing primary care to medically uninsured and underserved communities, actually achieve cost savings through fewer hospital admissions and specialty care referrals, and less frequent use of costly emergency care for routine services. A 1996 study shows that Health Centers face rising numbers of pregnant teens, homeless individuals, and persons with HIV and AIDS, as well as growing numbers of farm workers and unemployed individuals seeking their care. Health Centers have special expertise in meeting the unique needs of these most vulnerable populations and are often the only source of non-hospital, community-based primary care for them.

Few government programs have made as significant a contribution to low-income families as cost-effectively, or in as high quality a manner as health centers.

- Health Centers provide a vital community service: Every federal health center grant allows communities to serve an average of 10,000 people, keeping children healthy and in school and helping adults remain productive on the job.
- Health Centers make a difference in the health of people: Studies of Health Centers credit them for a 40 percent reduction in infant mortality, improved immunization and prenatal care rates, and increased use of preventive health services among their patients.
- Health Centers create jobs and provide an economic base: Health centers employ more than 50,000 persons, many of whom are community residents. They also help to retain other local businesses and stabilize neighborhoods by bringing in other forms of community or economic development.
- Health Centers triple the value of investment: Every \$100 million invested in Community Health centers brings an additional \$200 million in other resources

into communities, and helps 1 million people (including 350,000 uninsured persons) get the care they need, creating invaluable community assets.

Despite achieving remarkable progress in responding to the current health care crisis, Health Centers increasingly are feeling the strains brought on by the continuing erosion of private insurance coverage, stagnant or shrinking public subsidies and the pressures of a restructured marketplace now driven by competitive forces. Over the past three years, centers have added more than 1 million new uninsured patients to their roles (out of 2 million total new patients). This growth in new uninsured health center patients is widespread and underscores the declining ability of providers in all communities to continue to serve the uninsured. The expansion of managed care and the implementation of welfare reform is likely to make this situation even more pervasive in the future.

New funds were appropriated in fiscal year 1997 but that amount will enable the funding of only 30 new Health Centers, and care for another 120,000 new uninsured patients across the country. Over the past 5 years, nearly 700 community group requested funding but could not be funded due to lack of funds.

NACHC believes additional federal investment is needed to assure the availability of primary and preventive health care in every medically underserved community. Health centers have been faced with the challenge of caring for an ever-increasing number of people seeking care in an era of stable or declining resources and shortages of primary care health professionals. As the number of uninsured persons increase, there must be a system in place that will provide essential health care services, especially for the most vulnerable, underserved people in our communities and in our nation. The Health Center system is already in place, it is cost-effective, efficient, accountable, and it works. We urge you to build on it.

As you consider the fiscal year 1998 appropriations, we recommend the following investments:

- Community Health Centers (i.e., community, migrant, homeless and public housing): \$882 million.*—This amount would support the development of health center services for an additional 300,000 low income uninsured persons, in addition to the 4 million uninsured and 6 million others we currently serve. Of the increase provided for Community Health Centers, we recommend that the Committee make available up to \$5,600,000 for loan guarantees for loans to be made to health centers for the costs of developing and operating managed care networks or plans, and for loans to be made for the construction, renovation and modernization of facilities that are owned and operated by health centers. Similar language was included by the Subcommittee in its fiscal 1997 bill and Committee report.
- National Health Service Corps: \$145 million.*—This amount would provide for the placement of an additional 300 primary care health professionals in underserved areas. The NHSC works with local communities, and delivers health care services where the unmet need is greatest, enhancing the ability of health centers and other health care organizations in frontier, rural and inner city communities to care for significant numbers of uninsured persons, as well as Medicare and Medicaid recipients. Over half of the NHSC providers work at Health Centers and 60 percent of practice in rural HPSAs. In addition, the NHSC supports 29 State Loan Repayment Programs, which leverages state matching funds to place primary care health professionals in HPSAs, and the NHSC Fellowships Program, which provides community-based experiences for health professions students with the goal of encouraging them to practice in underserved areas. Without the NHSC, many of these areas would not be just underserved, they would be unserved.
- Black Lung Clinics.*—\$5 million. This amount would provide black lung services for another 5,000 coal miners. Black Lung Clinics are a vital source of care for coal miners suffering from Coal Workers Pneumoconiosis, commonly called Black Lung disease, which affects an estimated 4.5 percent of all coal miners today. These clinics provide medical diagnosis, treatment, education, and preventive care to more than 20,000 individuals, helping to substantially reduce the need for costly hospital or specialty care services. Without federal support through the Black Lung Clinics program, many of these clinics will be forced to reduce or discontinue services to this needy population.
- Ryan White AIDS/Title III-B: \$113.6million.*— This amount would provide care to an additional 75,000 individuals with (or at risk for) HIV or AIDS. The Ryan White Early Intervention (Title II-B) program supports comprehensive ambulatory HIV/AIDS services, including risk reduction counseling/testing and prevention, for more than 125,000 low income persons through Health Centers and other community-based health providers in underserved inner-city and rural areas.

Even with these support levels, Health Centers would be able to offer care to less than 1 out of every 3 Americans who will lose their health insurance this year alone.

We have labeled our recommended funding levels as an investment. It is an investment that will help to reverse an alarming trend toward a growing under class in this country. Compelling need dictates that we act to utilize proven systems of care to foster wellness and prevention. If funded adequately, the expanded presence of health centers and the availability of basic health services will contribute to a healthier, more productive America.

Health Centers were founded with a vision of community and consumer empowerment, and their experience over the past 30 year provides an object lesson on how consumer involvement can succeed where other models fail. Invest in health centers, build upon what has worked, look at the long history and success of the program and continue to invest in programs that mobilize communities to solve problems at the local levels.

NACHC appreciates the opportunity to comment on these vital programs and look forward to working with the Subcommittee in support of them.

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#### PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

The American Association of Nurse Anesthetists is the professional association that represents over 26,000 certified registered nurse anesthetists (CRNAs) in the United States. AANA appreciates the opportunity to provide our experience regarding federal funding for nurse anesthesia educational programs under Title VIII, the Nurse Education Act (NEA). Many members of our association have benefited greatly over the years from the Title VIII programs, which in turn has benefited the health care system by assisting in the maintenance of a stable supply and adequate number of anesthesia providers.

#### BACKGROUND INFORMATION ABOUT CRNAS

In the administration of anesthesia, CRNAs perform many of the same functions as physician anesthetists (anesthesiologists) and work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, health maintenance organizations, and the offices of dentists, podiatrists, ophthalmologists, and plastic surgeons. Today, CRNAs administer approximately 65 percent of the anesthetics given to patients each year in the United States. CRNAs are the sole anesthesia provider in more than 70 percent of rural hospitals which translates into anesthesia services for millions of rural Americans. CRNAs are also front line anesthesia providers in underserved urban areas, providing services for major trauma cases, for example.

CRNAs have been a part of every type of surgical team since the advent of anesthesia in the 1800s. Until the 1920s, anesthesia was almost exclusively administered by nurses. In addition, nurse anesthetists have been the principal anesthesia provider in combat areas in every war the United States has been engaged in since World War I. Though CRNAs are not medical doctors, no studies have ever found any difference between CRNAs and anesthesiologists in the quality of care provided, which is the reason no federal or state statute requires that CRNAs be supervised by an anesthesiologist. Anesthesia outcomes are affected by such factors as the provider's vigilance rather than the title of the provider—CRNA or an anesthesiologist.

The most substantial difference between CRNAs and anesthesiologists is prior to anesthesia education, anesthesiologists receive medical education while CRNAs receive a nursing education. However, the anesthesia education offered is very similar for both providers and both professionals are educated to perform the same clinical anesthesia services: (1) preanesthetic preparation and evaluation; (2) anesthesia induction, maintenance and emergence; (3) postanesthesia care; and (4) peri-anesthetic and clinical support functions, such as resuscitation services, acute and chronic pain management, respiratory care, and the establishment of arterial lines.

There are currently 87 accredited nurse anesthesia education programs in the United States, 84 of which offer a master's degree. The other 3 programs are modifying their curricula to meet the requirement for all programs to offer master's degrees by 1998.

#### THE GOALS OF THE HEALTH PROFESSIONALS EDUCATION PROGRAM

Title VIII has supported the education of our nation's nurses since the 1960s. It provides programs for direct student assistance as well as grants to institutions for expansion or maintenance of education. While initially the programs focused on in-

creasing enrollments, in the mid-1970s they began to shift toward increasing the number of primary care providers and increasing the number of professionals serving in rural or underserved areas.

In the last reauthorization of Title VIII in 1992; Congress directed that Title VIII programs target funds to schools placing graduates in medically underserved communities and emphasized primary care. More recent proposals for the reauthorization of this program have also identified the goal of improving the distribution of health professionals in underserved areas. The investment in the education of nurse anesthetists would assist in all of these goals:

*Increased Access to Primary Care*

CRNAs are traditionally not defined as primary care providers, but provide services that support primary care. For example, a facility or professional that provides obstetrical care to pregnant women is generally recognized as providing primary care. Offering an epidural during labor and delivery is part of that obstetrical care; therefore, the CRNA provides services and supports primary care, and are vital to the quality of primary care. Often the CRNA is the only provider of such services in rural areas. Because of the interdependence between primary care and anesthesia, continued federal support for nurse anesthesia education will assist in reaching the federal goal of increasing access to quality primary care across the country.

*Service in Underserved or Rural Areas*

CRNAs are the sole providers of anesthesia in more than 70 percent of rural hospitals. Anesthesia provided by CRNAs allows these rural facilities to provide obstetrical, surgical, and trauma stabilization that would otherwise not be possible for millions of Americans in rural areas. Continued federal support of Title VIII programs will ensure a stable supply of CRNAs to rural facilities all across the country. In addition, many nurse anesthesia programs are located in medically underserved urban areas and produce graduates that eventually enter practice after graduation in these same communities.

Since the educational costs of preparing CRNAs are far less than those of preparing anesthesiologists, yet they provide virtually the same care, the federal government has received a generous return on their investment of Title VIII funding in the education of CRNAs. The average annual program cost per student nurse anesthetist is \$11,741. With the average length of a nurse anesthesia program being 27 months, the total cost per student is \$26,417 (\$11,741 per year  $\times$  2.25 years). In contrast, according to data from the Health Care Financing Administration, the average annual cost per medical resident in a residency program was \$84,837 in 1990. Therefore, the total cost per student for a four year anesthesiologist residency is \$339,400 (\$84,837 per year  $\times$  4 years). Therefore, for the same cost of preparing one anesthesiologist, you can prepare at least 10 CRNAs.

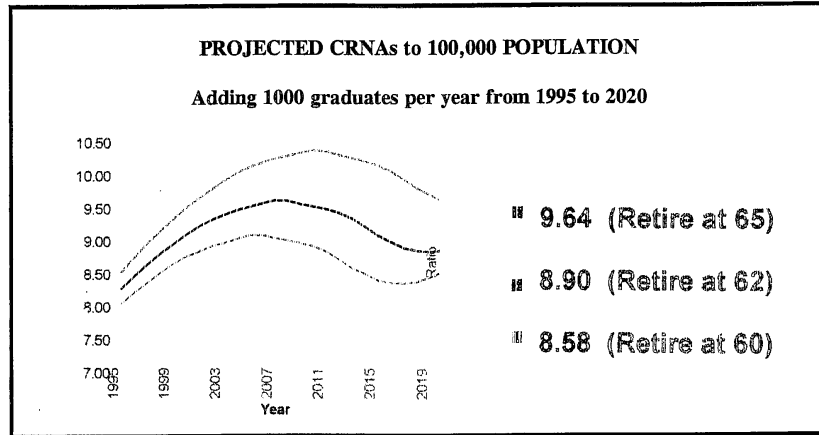
NURSE ANESTHESIA PROGRAMS PRODUCE STABLE SUPPLY OF PROVIDERS

A 1994 General Accounting Office (GAO) study on Health Professions Education reported that the overall number of primary care physicians providing patient care rose by 75 percent between 1975 and 1990; yet, the population as a whole rose by only 17 percent. The result has been a physician surplus, while a maldistribution of providers remains.

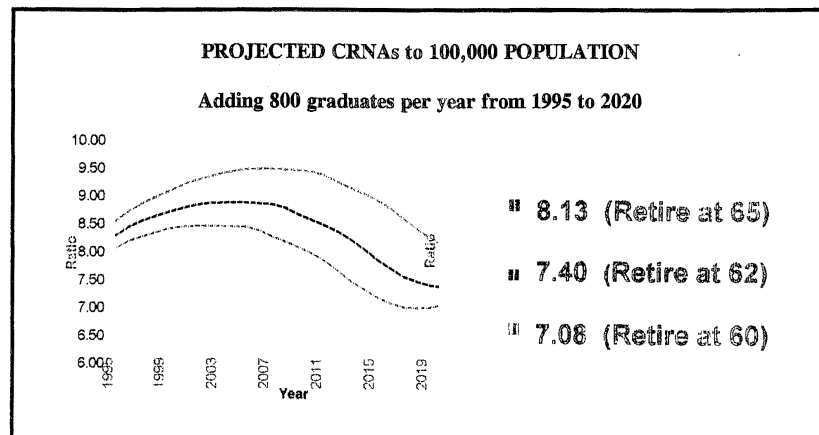
Yet the same is not true for other professions. The surplus of physicians as found in the GAO report does not necessarily translate to a surplus of all providers. Nurse anesthesia programs across the country have stabilized in the number of graduates produced each year, averaging approximately 900–1000 new nurse anesthetists entering practice annually. In 1995 there were 1045 graduates, and 1996 produced 1069.

Data has shown that a continued supply of 1000 graduates per year will provide the country with a stable, adequate source of anesthesia providers. Ongoing research by Michael Fallacaro, CRNA, DNS, past Chairman of the AANA Education Committee, has established that the current ratio of approximately 8.5 CRNAs per 100,000 population is adequately meeting societal demands. In addition, his research shows that adding 1000 new nurse anesthetist graduates into the system each year through 2020 would ultimately result in a similar ratio of 8.5 to 9.6 CRNAs per 100,000 population, depending on the average retirement age.





On the other hand, a drop in the number of graduates to 800 per year would result in an eventual decrease in the number of CRNAs to 7.0 to 8.1 per 100,000 population.



Therefore, by continuing the trend of graduating approximately 1000 students per year, nurse anesthesia programs appear to be producing not a surplus of providers, but an adequate number to meet societal needs.

In order to maintain this number of graduates, CRNA students need continued federal support. Nurse anesthesia programs require a rigorous course of study that does not allow students the opportunity to work outside their educational program. Nurse anesthesia programs are virtually all full-time, with part-time study a rare occurrence. Therefore, nurse anesthesia students rely heavily on federal funding to assist them in meeting financial obligations during their study. Without this assistance, the number of nurse anesthesia graduates would surely decline. A decline in the number of nurse anesthetists would then result in a decline in the accessibility to services, primarily in rural areas that depend on non-MD providers for the majority of their care.

#### RECOMMENDATION FOR FISCAL YEAR 1998

In the past, CRNAs had a \$4 million authorized line-item appropriation within Title VIII which was divided between direct student support in the form of traineeships, faculty fellowships to increase the number of doctoral-prepared faculty, and toward the start-up costs and expansion for new nurse anesthesia programs. This line-item has proven extremely successful in the past, and each year the appro-

priation for nurse anesthetists has been totally expended. AANA would like to see it continue in the future.

AANA recommends continued federal funding for all nursing education at the level of \$67.32 million, including a \$2.848 million set-aside for nurse anesthetists in fiscal year 1998.

For further information, please contact Greta Todd, AANA Associate Director of Federal Government Affairs, at 202/484-8400.

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PREPARED STATEMENT OF THE AMERICAN COLLEGE OF PREVENTIVE MEDICINE AND  
THE ASSOCIATION OF TEACHERS OF PREVENTIVE MEDICINE

The American College of Preventive Medicine (ACPM) and the Association of Teachers of Preventive Medicine (ATPM) are pleased to submit jointly this statement concerning appropriations for federal activities in disease prevention and health promotion. ACPM is the national medical specialty society of physicians whose primary interest and expertise are in preventive medicine. ATPM is the professional organization of academic departments, faculty and others concerned with undergraduate and postgraduate medical education in preventive medicine. Together, these organizations are proud to offer the public a high degree of knowledge and skill in disease prevention and health promotion.

ACPM and ATPM urge the Subcommittee to maintain federal support for prevention. In particular, we urge a minimal increase in the level of funding for preventive medicine residency training and for training other public health professionals included in Title VII of the Public Health Service Act. We also urge an increase for the activities of the Centers for Disease Control and Prevention and an earmark for the invaluable work of the Office of Disease Prevention and Health Promotion in the Office of the HHS Secretary.

We are well aware of the fiscal constraints that this Subcommittee faces and we do not make these recommendations lightly. However, we are deeply concerned that weakening our nation's efforts in disease prevention and health promotion will become an unintended consequence of necessary reductions in discretionary appropriations. At a time when the private sector is struggling mightily to contain medical care costs, the nation can ill afford a diminution in public health efforts to prevent disease that only the government can conduct. Compared to the vast sums of public funds that are spent on curative medicine, the amounts that we recommend be targeted to prevention are small indeed.

*Training in Preventive Medicine and Public Health—\$9 million*

Prevention, in its broadest sense, is practiced by all physicians and other health professionals who help their patients stay healthy. It also is the principal goal of our nation's state and local health departments, who perform core functions in health protection and promotion that no single private institution or health provider can fulfill. The specialty of preventive medicine bridges the gap between the perspectives of clinical medicine and public health.

The tools of preventive medicine are the population-based health sciences, including epidemiology, biostatistics, environmental and occupational health, planning, management and evaluation of health services, and the social and behavioral aspects of health and disease. These are the classic tools of practice in public health agencies, but they have grown in importance in other health care settings where there is increasing recognition that improving the health of a patient population and reducing the costs of medical care also require application of the population-based health sciences.

Departments of preventive medicine, community medicine, or social medicine in medical schools, schools of public health, and preventive medicine residency programs (which are located in medical schools, schools of public health, and a few health departments), are the loci of expertise in the population-based health sciences. Federal support for preventive medicine training and public health training is essential to help meet the workforce needs not only of public health departments, but also of a rapidly-evolving health care system that must be cost-effective and accountable.

The small sums appropriated for preventive medicine residency training under Section 763 in Title VII of the Public Health Service Act have been the exclusive federal support for programs training physicians in general preventive medicine and public health (other than the residency programs conducted by the Centers for Disease Control and Prevention and the military). Medicare graduate medical education funds have been largely unavailable to these programs because they are based not in hospitals but in community outpatient and public health settings. Be-

cause preventive medicine programs derive little or no revenue from one-on-one patient care, this common source of funds for physician training also is unavailable.

Currently, residency programs scramble to patch together funding packages for their residents. Funding from any source is available for only 60 percent of preventive medicine residency positions. The remainder of the openings go unfilled due to lack of funds, and potential applicants must be turned away.

A 1991 survey of all 1,070 graduates of general preventive medicine/public health residency programs from 1979 to 1989 conducted by Battelle, an independent consultant under contract to the Centers for Disease Control and Prevention and the Health Resources and Services Administration provided a clear picture of the accomplishments of the training programs and the impact of these federal funds. A majority of the graduates have initiated or managed major programs in prevention and control of infectious disease, chronic disease, sexually transmitted diseases, or maternal and child health. In addition to creating and running community health programs such as these, 60 percent of the graduates engage in research in disease prevention and health promotion, and 70 percent also take care of individual patients.

This survey also documented that funds invested in training these physicians have a lasting impact. Ninety percent of preventive medicine graduates remain involved in public health or preventive medicine. Moreover, Title VII funds were shown to be directly related to the viability of preventive medicine residency programs. In programs that have received federal grants, the number of graduates has more than doubled since 1983. Conversely, the number of graduates of programs that no longer receive federal funds has decreased significantly.

The training of public health professionals is closely linked to preventive medicine. The nation's 28 schools of public health provide training for physician specialists in preventive medicine as well as for many other health professionals who comprise our public health workforce. In addition to the shortage of physicians trained in preventive medicine, there are shortages of epidemiologists, biostatisticians, environmental and occupational health specialists, public health nutritionists and public health nurses. In addition to Section 763, Sections 761 and 762 of Title VII (Public Health Traineeships and Public Health Special Projects) support public health training in these areas. An appropriation of \$9 million for Sections 761, 762, and 763 in fiscal year 1998 will allow for the continuation of efforts to build the nation's cadre of prevention professionals. Finally, ACPM and ATPM support the Health Professions and Nursing Education Coalition's (HPNEC) recommendation of \$302 million for all of the health professions education programs funded under Titles VII and VIII of the Public Health Service Act.

#### *Centers for Disease Control and Prevention—\$3 billion*

Physicians working in preventive medicine and public health rely heavily on the expertise and activities of the Centers for Disease Control and Prevention, the nation's premier agency for disease prevention and health promotion. Therefore, we support, alongside many other organizations and coalitions with a concern for prevention, including the Coalition for Health Funding and the CDC Coalition, a total CDC appropriation of \$3 billion.

Through funding of state and local prevention programs, research, training and surveillance, CDC has a major impact on every important issue in prevention. Compared to the billions that are spent on acute health care, our national investment in prevention continues to lag. The increases in health care costs we have witnessed are not a reason to cut back on funds appropriated for prevention. They are a reason to make a large investment now. Given the resources, CDC can play a critical role in revitalizing programs and services of proven effectiveness in reducing death and disability in this country. Reducing CDC funds would be an act of extraordinary short-sightedness. Time and again we have seen, as in the cases of tuberculosis and measles, when public health efforts falter, the nation pays a high price later in the costs of preventable disease.

#### *Office of Disease Prevention and Health Promotion—\$4.6 million*

The Office of Disease Prevention and Health Promotion (ODPHP) stands out among federal agencies for its ability to leverage small amounts of funding into large accomplishments in highly innovative ways. ODPHP manages the Healthy People 2000 initiative, the national prevention strategy used by health agencies across the nation to set measurable objectives for health improvement. ODPHP provides guidance and prototype materials to health practitioners through the Put Prevention Into Practice project. It is conducting ground-breaking research concerning the cost-effectiveness of preventive services, and has long served as the focal point for coordinating departmental activities in prevention as well as innovative public-private partnerships. Explicit support for ODPHP is vital in signaling a continued

federal commitment at the Secretary's level to leadership in prevention. We urge the Subcommittee to earmark \$4.6 million for this office, an amount equivalent to fiscal year 1995 funding, before the budget for this office was incorporated into the amounts appropriated for the Office of the Secretary.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 85,000 member American Academy of Family Physicians would like to submit this statement for the record on an issue of critical importance to our organization, appropriations for Section 747 of the Public Health Service Act for family practice training, appropriations for the Center for Primary Care Research at the Agency for Health Care Policy and Research and funding for rural health programs.

The American Academy of Family Physicians strongly supports increased funding for Section 747. Section 747 is the only federal program that provides targeted funding through grants for family practice residency training and funding for establishing and maintaining medical school departments of family medicine, predoctoral programs and faculty development. While Section 747 must be reauthorized this year, it is currently authorized at \$54 million and received an appropriation of \$49.3 million in fiscal year 1997.

*Recommendation*

Based on a review of future needs of the country for a more appropriate number of family physicians, the Academy supports a fiscal year 1998 funding level of \$87 million for Section 747. This recommendation would provide funds for 20 new and developing residency training programs, 12 new and developing departments, 24 medical school clerkships, 700 new faculty and a number of innovative demonstration projects. The recommendation is the result of a strategic plan developed by the Academic Family Medicine Organizations, which includes all five family medicine organizations.

*Background*

Any attempts to control costs and maintain quality in the American health care system will be frustrated by a structural problem in our country: the shortage of generalist physicians. While in most countries at least 50 percent of physicians are generalists (family physicians, general internists and general pediatricians), the US physician workforce is made up of more than 70 percent subspecialists and only 30 percent generalists. Family physicians make up only 13 percent of the total.

Most experts believe that a physician workforce of 50 percent generalists and 50 percent subspecialists would best meet America's health care needs. The Physician Payment Review Commission, Council on Graduate Medical Education, The PEW Foundation, Institute of Medicine, American Medical Association and Association of American Medical Colleges all advocate increasing the supply of generalist physicians.

During the 1960's, 1970's and 1980's, the nation's primary care workforce declined from a majority of the workforce to approximately one-third today. Section 747 grants were a response to that decline, and the infrastructure they have helped establish is beginning to reverse the downward trend in primary care. During the 1990's, the number of medical students electing primary care residencies, participating in family practice residencies, is increasing, however, the percentage is still only about one-third of graduating medical students. Much more progress is needed to begin to affect the national shortage. Section 747 support needs to be enhanced maintained to provide a modest incentive for training more of the physicians America needs most. A recent March, 1996, study by the Institute of Medicine "encourages support for training of a primary care workforce."

Medicare payment policies contribute significantly to the overspecialization of physicians. These policies promote training in the expensive inpatient specialties that involve numerous procedures rather than in family practice and other generalist specialties. Medicare GME payments go exclusively to hospitals, where subspecialist physicians are primarily trained, rather than to ambulatory care sites, i.e., clinics and offices, where generalist doctors receive much of their training. A May, 1994 General Accounting Office (GAO) report reiterated that "barriers to primary care training persist in Medicare's payment method.

NIH funding also contributes to the overspecialization of physicians. NIH grants, amounting to billions of dollars, go primarily to the subspecialist projects in the nation's medical education complexes, providing powerful incentives to promote subspecialization to develop the capacity to secure grants.

Moreover, a recent study conducted by KPMG Peat Marwick in September, 1995, indicated that Medicare spending could be reduced by at least \$48.9 billion and as

much as \$271.5 billion over the next six years if primary care physicians were 50 percent of the total physician workforce. The analysis revealed a direct correlation between the availability of primary care physicians and the reduction of health care costs. *The Role of Primary Care Physicians in Controlling Health Care Costs: Evidence and Effects* is a comprehensive review of existing studies on the role of primary care physicians in controlling health care costs.

#### *Federal Funding for Family Practice*

Section 747 is essential to provide at least a small incentive to offset the financial disadvantages that family medicine residencies and departments face. Until Medicare GME preferentially supports primary care training, and until primary care medical research is funded at more than a tiny fraction of subspecialist research, family practice residency programs and medical school departments will remain highly dependent on grants from Title VII.

#### *Unmet Need for Family Physicians*

Family physicians are distributed in urban and rural areas in the same proportion as the US population as a whole—unlike any other physician specialty. Even so, 149 counties representing 550,000 individuals have no physician at all. In addition, family practice residency training programs that receive Section 747 funding place greater numbers of graduates who locate in rural and underserved areas than programs that do not receive that funding.

Managed care organizations are preferentially recruiting family physicians. However, 43 percent of salaried and 29 percent of capitated plans report that it takes one year or more to recruit a new primary care physician.

In community health centers, which rely heavily on primary care physicians, 52 percent report difficulty recruiting primary care physicians.

The US population 65 years of age and older will rise about 2 percent per year between now and the year 2020. Older people will require a wide range of health care services, including preventive, primary, long-term, rehabilitative and hospice care—services that will require a substantial increase in the number of family physicians.

### DATA AND OUTCOMES THAT PROVE SECTION 747 WORKS

#### *Family Practice Residency Training Programs*

Approximately 90 percent of physicians who complete family practice residency programs work in direct primary patient care and are able to handle 85–90 percent of their patient's problems. (By contrast, over half of internal medicine residents subspecialize along with one-third of pediatric residents.) Section 747 grants to family practice residency programs have helped increase the number of training programs from 175 to 380 between 1975 and 1996. However, the nation needs 20–30 new programs and significant expansion of many existing programs to achieve a balanced workforce.

In contrast to other specialties, 80 percent of family practice residencies are located in community settings rather than in major tertiary care teaching hospitals. These residencies provide more ambulatory training than any other residencies. As a result, family practice residencies do not have access to the considerable resources that flow to teaching hospitals. Further, 25 percent of family practice residencies occur in public hospitals. These hospitals receive low reimbursement for patient care services, as well as fewer Medicare patients. As a result, they do not receive substantial Medicare graduate medical education dollars. Section 747 is vital to the survival and expansion of these critical residency programs.

#### *Family Medicine Departments in Medical Schools*

Section 747 grants for establishing departments of family medicine have resulted in eight new departments in the past five years. However, twelve of the nation's 124 medical schools still do not have departments of family medicine. An October, 1994 GAO report indicated that "students who attended schools with family practice departments were 57 percent more likely to pursue primary care." The same report indicated that "students attending medical schools with more highly funded family practice departments were 18 percent more likely to pursue primary care." Section 747 dollars are crucial to establishing these family practice departments and to graduating students into primary care careers, as well as to keep these important departments financial solvent.

#### *Predoctoral Programs*

Funding for predoctoral programs—third-year medical school clerkships in which students learn primary care clinical skills—under Section 747 encourages medical

schools to create required third-year clerkships in family medicine. However, 24 of the nation's 124 medical schools still do not have required third-year clerkships in family medicine. Requiring a third-year clerkship of more than four weeks duration results in 15.6 percent of a school's graduates choosing careers in family medicine, compared to 6.9 percent of the graduates of schools without required third-year clerkships. Moreover, the October, 1994 GAO report indicated that "students who attended schools requiring a third-year family practice clerkship were 18 percent more likely to pursue primary care." Section 747 funding increased the number of medical schools with clerkships to 100, but continued funding is necessary to maintain and increase that number.

#### *Faculty Development*

There is an acute shortage of faculty for family practice residency programs and family medicine departments as the discipline has been successful at placing its graduates in practice settings serving communities of need rather than in full-time faculty positions. Without adequate funding, there is a risk that even the progress that has been made so far will be compromised for lack of faculty.

#### AGENCY FOR HEALTH CARE POLICY AND RESEARCH

While American medicine is praised worldwide for its excellence in biomedical research, it has often failed to translate these breakthroughs to practical treatment that will apply to the population at large. It is imperative that US research facilities complement their superb understanding of high-tech research with a similar dedication both to applying state of the art medicine to primary care settings and research to improve the delivery of primary care and preventive medicine so that there is less of a need for high-tech subspecialty care.

Therefore, the Academy strongly supports the Center for Primary Care Research within the Agency for Health Care Policy and Research (AHCPR). The Academy supported AHCPR's establishment and, in particular, the agency's statutory authority to support clinical practice research to include primary care and practice-oriented research. In fact, the 1992 Senate Report 102-426 accompanying Public Law 102-410, which reauthorized AHCPR most recently, states that the Agency should strengthen its commitment to family practice and primary care research. The report asserts that: "The committee believes that inadequate attention has been given to conditions that affect the(se) vast majority of Americans—that is, the undifferentiated problems individuals present to their generalist physicians. A focus on family practice/primary care research is essential if we are to redirect the US health care system that is currently skewed toward high technology medicine for catastrophic diseases."

Although over 95 percent of all medical conditions have been evaluated and treated outside of hospitals over the last 30 years, physicians are educated and trained using a knowledge base derived from hospitalized patients, or patients with complex conditions who were referred to specialists. This base of knowledge has frequently little relevance to the basic, entry-level concerns that affect most people. As a result, American health care is tilted toward institutions and systems that employ highly technological methods to treat catastrophic and end-stage disease. The consequences of this situation are serious; the US health care system has inadequate emphasis on cost-saving preventive care, scarce medical resources are delivered inefficiently, and costs continue to spiral upward.

#### *Primary Care Research*

As a result, a primary care research agenda is crucial. This agenda should be designed to provide new tools to family physicians and other generalist physicians as they serve the millions of patients they see each year. Such an agenda would include research to improve diagnostic accuracy because most people go to doctors with cluster of ill-defined symptoms. The job of the generalist physician is to make sense out of these symptoms; determining whether or not they constitute a short-term problem or one requiring ongoing or intensive treatment, and then initiating effective therapy. Primary care research would assist physicians in streamlining the diagnostic process and increasing accuracy while at the same time reducing their use of expensive, unnecessary or potentially dangerous medical tests.

Finally, generalists and subspecialists must learn to work together to provide a continuum of appropriate medical care. Familiar symptoms such as chest pain, headache, fatigue and insomnia bring millions of Americans to their physicians each year, symptoms that may or may not represent serious conditions. It is imperative that generalists and subspecialists work together to discern the causes, evolution and management of human suffering.

To support this critical—and timely—line of research, the Academy requests that additional appropriations be provided to the Agency for Health Care Policy and Research, and that dollars be targeted specifically to the Center for Primary Care Research. We believe that supplementary funding, coupled with direction from Congress, will permit AHCPH to address primary care issues. We recommend \$50 million for this effort.

#### *Rural Health Programs*

Finally, the Academy supports continued funding for several rural health programs. In particular, we support the state offices of rural health, the federal office of rural health, area health education centers and the National Health Services Corps. Continued funding for these programs is vital if we wish to provide health care services to America's rural citizens.

#### *Conclusion*

Section 747 of the Public Health Service Act is a program that successfully produces family physicians who serve both urban and rural parts of our nation, are preferentially recruited by managed care organizations and who can take care of 85–90 percent of their patient's problems. Numerous organizations and reports point out the cost-effective nature of family physicians, as well as how family practice residency programs, departments, predoctoral programs and faculty development programs efficiently produce more family physicians for this country.

At a time when policymakers are critically reviewing government programs for their cost-effectiveness and overall value, Section 747 is a program that scores high on both fronts; it works. On behalf of the American Academy of Family Physicians, we ask you to appropriate funding for Section 747 of \$87 million. In addition, scant research is available on basic patient care. The American Academy of Family Physicians recommends \$50 million for the Center for Primary Care Research at the Agency for Health Care Policy and Research. Finally, we ask for continued funding for the rural health programs that help provide health care to rural Americans.

Thank you for your attention to these important requests.

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#### PREPARED STATEMENT OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH

We are grateful for the opportunity to submit testimony on behalf of our association<sup>1</sup> regarding the fiscal year 1998 appropriations request for the academic public health programs administered by the U.S. Public Health Service of the Department of Health and Human Services (DHHS). These programs support our graduate students (traineeships), public health faculty (special projects), public health physicians (preventive medicine residencies), minority recruitment programs (HCOP), prevention related research at NIH, maternal and child health training initiatives, health services research (AHCPH), CDC training (NIOSH) and prevention activities (prevention centers, injury control centers), among others.

While there are no scientific studies to accurately establish the precise national shortages of public health professionals, experts agree that there is a shortage of adequately trained, public health professionals, including epidemiologist, biostatisticians, environmental health specialists, public health nurses and physicians, among others: ("HHS Secretary's Report to Congress on the Status of Health Personnel in the U.S., 1991). The 28 schools of public health (list attached), in 20 states and Puerto Rico, constitute the primary source of comprehensively-trained public health professionals and specialists to serve the federal government, the 50 states, and the private sector.

According to the a DHHS report to Congress, the need for trained public health professionals could double the current level. The need has intensified with the proliferation of health programs mandated by Congress, and the expanded responsibilities of health organizations under managed care. In 1994, a report by Robert Har-

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<sup>1</sup>The Association of Schools of Public Health (ASPH) is the only national organization representing the deans, faculty, and students of this nation's 28 accredited schools of public health in the United States and Puerto Rico. These schools have a combined faculty of over 2,500 and educate more than 15,000 students annually from every state in the U.S. and most countries throughout the world. The schools graduate approximately 5,000 professionals each year. The 28 schools of public health constitute a primary source of comprehensively trained public health professionals and specialists in short supply to serve the federal government, the 50 states and private sector. According to the Pew health professions commission, managed care will increase the need for public health professionals. And according to saDHHS, "significant shortages of professionals and academic faculty in the public health fields of epidemiology, abiostatistics, environmental and occupational health, public health nutrition, public health nursing, maternal and child health and preventive medicine."

mon, MD, MPH, to the DHHS assistant secretary for health, sustained earlier DHHS observations on the need for more public health professionals. His findings revealed “significant shortages of professionals and academic faculty in the public health fields of epidemiology, biostatistics, environmental and occupational health, public health nutrition, public health nursing, and preventive medicine.”

State/local health department directors have reported that the lack of practical knowledge and skills in the core sciences of public health and preventive medicine have restricted the effectiveness of their agencies. In order to improve the quality of the American public health infrastructure, and therefore, to properly set the stage for reform and prevention, we must provide adequate training, education and continuing education to the public health workforce. National health groups—especially maternal and child health agencies and state/local health officials—agree that regional shortages of adequately trained professionals present the most significant barrier to providing population-based prevention initiatives, in general and ensuring the delivery of quality health care to underserved individuals and under represented populations, in particular. Health professionals trained to handle the unique demands of rural and inner-city public health issues are in the shortest supply.

The Council on Graduate Medical Education (COGME) has reported continued shortages in the field of preventive medicine and has recommended increasing the percentage of physicians trained and certified in public health and preventive medicine as a national goal. Practitioners of population-based medicine are playing increasingly more important roles in building health care systems that are accountable for quality and health outcomes, especially now under the managed care environment.

Also, the Pew Health Professions Commission reported that managed care will increase the need for public health professionals (“Critical Challenges: Revitalizing the Health Professions for the 21st Century,” Nov. 1995). The Pew commission is right. Recent trends in the changing health care system will force the health professions enterprise to focus its attention on teaching population-based approaches. Managed care will steer academic leaders in most schools of the health professions, specifically medicine, nursing, pharmacy and dentistry, to collaborate with faculty in schools of public health having the expertise in disciplines and areas of concentration that focus on improving the health of the public: epidemiology, biostatistics, outcomes research and analysis, risk assessment, chronic and infectious disease prevention, among others.

Mr. Chairman we need to provide students with skills, competencies and knowledge to address the “characteristics” of the emerging care system that Pew commission outlined: orientation toward health; population perspective; intensive use of information; focus on the consumer; knowledge of treatment outcomes; constrained resources; coordination of services; reconsideration of human values; expectations of accountability; and growing interdependence. These skills, competencies, values and knowledge are taught principally in the 28 accredited schools of public health.

I would like to focus your attention on one CDC program in particular that merits specific recognition: prevention centers. In 1995, CDC asked the IOM to review the program and to examine the extent to which it is meeting congressionally mandated objectives. The report was released last month and the committee found that the CDC prevention centers program “has made substantial progress and is to be commended for its accomplishments in advancing the scientific infrastructure in support of disease prevention and health promotion policy, programs, and practices.”

Mr. Chairman, we would like to go on record in support of the fiscal year 1998 recommendations of the following coalitions that will testify (or have testified) before your subcommittee: Ad Hoc Group for Biomedical Research; CDC Coalition; Coalition for Health Funding; Friends of AHCPR; Friends of NIOSH; Friends of Title V; and Health Professions and Nursing Education Coalition

Mr. Chairman, the requests outlined by these coalitions represent the needs assessment that was derived from the views and expert opinions of this country’s most respected administrators, scholars, scientists, and leaders in the volunteer sector. I know you and the subcommittee members will take them into serious consideration when marking-up the fiscal year 1998 appropriations bill.

Mr. Chairman, public health is not just practiced in state and local health departments. In the next century, it will be practiced in hospitals, insurance companies, managed care organizations, community-based organizations (e.g., community health centers, United Way supported agencies, etc.), academic institutions, factories, religious, civic and fraternal organizations, among others. We must plan ahead and ensure that these organizations are staffed by a competent workforce equipped with the necessary skills, knowledge and competencies in the population-based sciences.



Mr. Chairman, the 28 deans of the U.S. schools of public health appreciate the opportunity to express their views on continued federal support of public health programs, in general, and for public health professions, in particular. Your thoughtful consideration of our suggestions outlined below would be greatly appreciated.

ASPH urges Congress to appropriate the following fiscal year 1998 amounts for PHS programs of concern to the academic public health community.

[In millions of dollars]

	Fiscal year 1997 appro- priations (estimate)	ASPH fiscal year 1998 requests
Public Health Traineeships (HRSA); Public Health Special Projects (HRSA); Pre- ventive Medicine Residencies .....	8.0	9.0
MCH Training (HRSA) .....	5.0	8.0
CDC Prevention Centers .....	8.0	14.0
NIOSH Training (CDC) .....	13.0	14.0
CDC Injury Centers .....	7.0	8.0
AHCPR (Total) .....	143.6	163.0
CDC Total (Billion) .....	2.3	2.5
HRSA Total (Billion) .....	3.4	3.5
NIH Total (Billion) .....	12.7	13.8

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF AIDS EDUCATION AND  
TRAINING CENTERS

The AIDS Education and Training Centers (AETCs) are a network of 15 regional training centers with more than 75 local performance sites that cover the entire nation, Puerto Rico, and the Virgin Islands. The AETCs provide HIV clinical training, information and technical assistance as part of the Ryan White CARE Act—Title V. The AETCs build capacity among health care and social service providers for effective and efficient HIV service delivery by providing access to state of the art treatment and prevention information. The AETC network provides training in the full spectrum of HIV care in urban and rural areas. The AETCs sustain and expand the base of health care providers who are educated and motivated to counsel, diagnose, treat and manage individuals with HIV infection and to assist in the prevention of high risk behavior that may lead to infection.

Recent advances in the care and treatment of persons with HIV disease marks a time of cautious optimism for persons living with HIV disease and health care providers. Promising new drugs are prolonging the lives of many people living with AIDS and providing a renewed sense of hope to others. In the past year, clinicians have reported reduction in mortality of patients in clinical practice.

However, the advent of these new drug therapies presents new challenges to AIDS health care providers, policy makers, people living with AIDS and those affected by this disease. Concerns have been raised within the AIDS community regarding the cost of these new treatments and their accessibility to those who need them. Current data suggests that these new therapies will not only extend and save lives, but also reduce health care costs for persons with HIV disease by reducing hospitalizations, emergency room visits, and more expensive clinical and diagnostic procedures.

Given these new treatments, persons with HIV disease require not only drug therapy with new drugs such as protease inhibitors, but also a range of psychosocial and specialty clinical services provided by qualified and informed health care providers. Health care providers must be competent to prescribe the AIDS drug treatments that are administered in combination with other drugs and require the measurement of viral load and other clinical markers to monitor their effectiveness.

It is critical that health care providers are informed about how to utilize these drugs in clinical practice. The new drugs are more complex to administer, requiring clinical decisions based upon patient clinical response. To avoid the development of viral resistance, clinicians need sophisticated skills to effectively monitor persons on combination antiretroviral therapy. The development of viral resistance has serious consequences for the patient since increases in viral burden have shown to correlate with more rapid disease progression.

Such clinical knowledge and informed clinical decision making is clearly beyond the current knowledge base of all primary care providers. The dissemination of information about these drugs and appropriate prescriptive regimens requires continuous information exchange among experienced providers. Expert consultation regarding clinical management must be available to individual health care providers to assist them in this complex clinical management of their patients.

The existing network of AIDS Education and Training Centers is the most effective means of providing this critical education to health care providers. The 15 AETCs are based in prestigious health science centers and work in collaboration with community based health centers and organizations. These programs now have almost a decade of experience developing and tailoring educational programs and clinical skills training to provider communities based upon regional and local needs. These recent clinical research advances translate into the need to expand health provider training to enhance the following areas of clinical capacity.

- The AETCs have an established reputation for providing primary care physicians, nurse practitioners, nurses, physician assistants, and dentists with the knowledge and skills to identify persons with HIV and initiate antiretroviral treatment early. There has been an increase in the number of HIV infected persons being identified and seeking HIV early intervention. As more people seek care, additional health professionals will require education in order to meet the growing demand for experienced and knowledgeable clinicians.
- Health care providers must be trained to appropriately prescribe and initiate complex monitoring of patient on these new combinations of antiretroviral drugs in order to maximize treatment effectiveness, improve the longevity and quality of life for persons with HIV, and reduce the chance of viral resistance. These new protocols include the need for absolute adherence to the plan of care in order to avoid resistance caused by viral mutation. Therefore, expert evaluation, prescribing and monitoring is essential. The AETCs are the only national program capable of providing intensive clinical training for health care providers in the identification of persons at risk, those requiring early antiretroviral treatment, as well as those needing on-going clinical management. Each regional AETC has developed the capacity for this type of clinical training.
- Health care providers must continue to be updated with the clinical treatment regimens for opportunistic diseases and other complications of HIV infection. This is critical, despite promising advances, because persons who continue to progress in their disease require careful management of opportunistic diseases and perhaps palliative care. The AETCs have a structure and process for delivering programs on state of the art treatment nationwide.
- The demographic profiles of persons infected with HIV have shifted to include more persons with a history of substance use. Health care providers must be trained about the unique issues involved in providing appropriate care for these populations. Health care providers require training in substance use treatment and the development of integrated service delivery systems.
- Recent trends show that the most vulnerable populations, the poor, women, and the homeless, are at highest risk for HIV infection and AIDS. Providing primary care services for these populations requires health care providers sensitive to the special needs of these communities. Most health care providers have limited experience in delivering care to these populations. The AETCs have demonstrated the ability to provide education and training programs to prepare providers to deliver HIV services to these under-served populations.
- The HIV epidemic is not over. While new therapies have begun to reduce the annual rate of death due to AIDS, Americans continue to acquire HIV infection at a steady rate. In fact, the absolute number of Americans with HIV infection and AIDS will continue to increase well into the next century. Health care providers must be continually trained in risk reduction for patients who are at risk for HIV infection to prevent the continued spread of HIV. The AETCs serve as educational and training resources for all HIV risk reduction and prevention programs nationally.
- Recent advances in the use of antiviral treatment for the reduction of viral burden further underscore the importance of early intervention for persons infected with HIV to prevent disease progression. Health care providers need to be cognizant of the importance of early intervention and have the knowledge and skill to adequately manage persons with early HIV infection.
- Now, more than ever, the development of “systems of care” for the delivery of more complex HIV clinical management is critical to assure that persons with HIV disease have access to appropriate and current medical and psychosocial treatment intervention. The AETCs provide important technical assistance to AIDS service organizations and groups, enhancing the HIV service delivery in-

rastructure and its functioning, avoiding duplication of effort to enhance the utilization of limited resources for service provision.

—The care and treatment of persons with HIV is changing so rapidly that mechanisms for the dissemination of new clinical, psychosocial, and behavioral interventions and approaches must respond rapidly in order to save lives and reduce new infections. The development of newly developed clinical management guidelines will require that this information be provided to practicing clinicians. The AETCs are in the process of disseminating these new guidelines and have created a standardized education and training response to them.

In the history of the AIDS epidemic, the need has never been greater for experienced, clinically up-to-date service providers. The public health approach of the AETC's utilizing program planning, evaluation and rapid dissemination of best clinical practices is an important vehicle for rapid response to national treatment developments. The AETCs have been faced with level funding since 1990 and in 1996–97 funding was actually reduced. The impact of this reduction has had serious implications for the quality and availability of experienced clinicians caring for persons with HIV disease. The National Association of AIDS Education and Training Centers is therefore requesting \$23 million for fiscal year 1998–99 in order to meet the growing demand for experienced, clinically up-to-date providers.

The National Association of AIDS Education and Training Centers appreciates the opportunity to provide this testimony. We are available to assist with any additional information if needed.

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PREPARED STATEMENT OF KATHYE GOROSH, PROJECT DIRECTOR, THE CORE CENTER

I would like to thank the Chairman and the Members of this sub-committee for their support for the Cook County/Rush Health Center, which has been permanently named "The CORE Center—For the Prevention, Care and Research of Infectious Disease." Their commitment has made a critical difference in the availability of appropriate health care services for those affected by and living with HIV and other infectious diseases in the greater Chicago area.

*The CORE Center: A Unique Solution for Chicago's Public Health Crisis:*

Today, despite major technological and scientific advances, devastating infectious diseases such as HIV/AIDS, Tuberculosis and Sexually Transmitted Diseases (STDs), these diseases remain prevalent in Chicago and around the world. Efforts must be sustained with continued vigilance to detect, treat, and cure Tuberculosis and STDs or their resurgence will be devastating. The HIV/AIDS epidemic continues to be one of the most serious public health problems facing the nation today. It is currently the leading cause of death among Americans between the ages of 25 and 44 years of age. Today, the Centers for Disease Control and Prevention (CDC) estimate that there are between 650,000 and 900,000 Americans living with HIV in the United States. In 1995, the CDC reported that our country had unfortunately reached another milestone in the AIDS epidemic—over a half million Americans had been diagnosed with AIDS. In 1996, it was reported that 362,004 Americans had died of AIDS. These numbers continue to increase.

Although the number of AIDS cases is what primarily gets reported by the press, the real focus should be on HIV, the virus that cause AIDS. While the development of new and more effective drugs has allowed people to remain healthier longer and to delay the progression from HIV to AIDS, it remains critical that we stop the spread of HIV as well as provide early and comprehensive care to those already infected. It is also critical to recognize that regardless of a decline in the number of AIDS related deaths in the U.S., there is not a decline in the need for adequate care, treatment and research for HIV/AIDS.

Because of the resurgence of infectious diseases and HIV/AIDS, the Chicago area is in the midst of a severe public health crisis. Over 35,000 people in the Chicago metropolitan area are currently infected with HIV/AIDS. Approximately, two-thirds of those infected are not receiving treatment.

An examination of the profiles of patients who receive HIV services at Cook County Hospital reveals that Cook County Hospital cares for 75–80 percent of infected women and roughly one-third of infected children in the Chicago Eligible Metropolitan Area (EMA). Seventy-two percent of program clients at Cook County Hospital are African American. Of all the patients seen at the Cook County HIV Primary Care Center last year, 916 (46.4 percent of all clients) of the patients seen were HIV positive and 986 (49.9 percent of all clients) of the patients seen were AIDS diagnosed.

One in every 9–10 beds at Cook County Hospital is occupied by a person with HIV/AIDS. Approximately 30 percent of those inpatients could be seen on an outpatient basis if specialized services were available—saving \$6 million per year.

In addition to HIV/AIDS, sexually transmitted diseases continue to be a major cause of morbidity in the greater Chicago area. STDs, which increase the likelihood of HIV transmission three to five fold, have increased at alarming rates since the 1980s. In fact in 1996, the CDC reported that STDs—most of which are curable through the use of conventional treatments and drugs—accounted for 87 percent of the top 10 percent of transmissible diseases in the nation.

The landscape of the AIDS epidemic is changing daily—much faster than care providers are able to handle. Today, people of color make up nearly 50 percent of all reported AIDS cases. Those indirectly affected by AIDS also present a rapidly increasing need. For example, by the year 2000, it is expected that 144,000 children will be left motherless by the AIDS epidemic. Obviously, these new dimensions require new and innovative community-based prevention and care strategies.

While the federal government has and will continue to provide leadership in the battle against AIDS and other infectious diseases, these afflictions will ultimately only be conquered at the local level through the implementation of comprehensive systems of care which involve every sector of the community.

Regardless of these dramatic statistics, the serious increase in the demand for outpatient services and the obvious public health crisis, no comprehensive community-based system of specialized outpatient care and support services has been available to help reduce unnecessary, disruptive, and costly hospitalization while maintaining the quality of life for people with HIV/AIDS—until now.

*The CORE Center: For the Prevention, Care and Research of Infectious Disease:*

It is clear that we must take immediate and decisive action to address the HIV/AIDS crisis in the greater Chicago and across the nation. A community-based commitment is required to develop and coordinate the complex medical and social interventions necessary to address these diseases effectively. Both public and private local health care providers must develop the resources and linkages needed to effectively address this health crisis. As a result, Cook County Hospital and Rush-Presbyterian-St. Luke's have combined their resources to develop "The CORE Center: For the Prevention, Care and Research of Infectious Disease."

Construction of The CORE Center, the result of an unprecedented public/private partnership, is scheduled to begin by this summer. The Center's design is the culmination of a focused team effort that has involved collaboration between HIV/AIDS patients, architects, doctors, nurses, other health care professionals, community members, representatives from the business community and government officials. It will provide a system of specialized health care and an array of support services for community-based health care providers to improve the care of persons with HIV or related infectious diseases who do not need to be hospitalized. As people continue to live longer with HIV/AIDS the demand for services, especially outpatient services, continues to increase. The CORE Center will provide that care and, at the same time, provide access to clinical trials and emphasize the importance of prevention and education in combating this epidemic.

With a full range of services available for the first time in a centralized location, the Center will provide a missing link in the public health system thus creating a full continuum of community-based outpatient medical care for people with HIV disease who currently do not receive adequate care.

The new 60,000, square foot, state-of-the-art, Center will boast many times the space now available for HIV/AIDS services at Cook County and Rush combined. The facility will combine and expand the capabilities of both institutions. The new Center will effectively house current programs and make it possible to address the growing numbers and needs of infectious disease patients.

*Prevention and Education:*

The HIV program at Cook County Hospital has responded to the current health crisis by providing extensive outreach, prevention and education services. In 1995 alone, the Women and Children's Program at Cook County Hospital went out into the community and educated 6,979 children ages 11–14 about HIV risk reduction.

Prevention and education are essential components of the Center's comprehensive approach to the care of HIV/AIDS and other related infectious diseases. The CORE Center will focus significant resources on community-wide prevention strategies and education programs. The Center's programs will include a major specialized training program for physicians and other health care professionals, including: clinical care, lectures, clinic observations and psychosocial interventions; targeted programs for people at risk, especially women, children, and minorities; HIV counseling and test-

ing; and bilingual community forums to extend the reach of the Center's prevention and education programs. Prevention programs will be tailored for specific populations and the Center will actively recruit members of these populations to their peer education courses.

*Key Features and On-Site Services:*

The design of The CORE center is meant to provide a sense of security and dignity to patients and families. A primary focus in the design of the facility is the comfort and ease of use by patients and staff. Key design features include:

- Graduate levels of care on each ascending floor of the four-floor facility—moving from education, prevention and screening programs on the first floor to treatment areas for the most seriously ill patients on the fourth floor.
- Multi-functional space throughout the building so that clinical and administrative areas can be easily reconfigured to adjust to the development of new modes of treatment.
- Medical care services which are integrated with essential support services, such as: child care, mental health and case management, and integrated with research in new treatments.
- Specialized space and programs for adolescents, people with chemical dependency and for women, children and families with HIV.
- A resource center library and classrooms to enhance the effectiveness of prevention and education programs.

*Research:*

Recent breakthroughs in drug therapies give reason to be hopeful for the successful treatment of HIV/AIDS now and in the future. The Center will carry out critical research to continue the search for a cure, as well as develop new treatments that will help prolong the comfortable and functional lives of HIV/AIDS patients.

*Resource and Referral Site:*

The CORE Center will serve as a resource and referral center for the growing network of primary care providers currently delivering community-based care for people with infectious diseases. It will provide increased access to the sophisticated medical services of institutions like Cook County Hospital and Rush-Presbyterian-St. Luke's Medical Center. The Center will supplement services available through the providers in the community-based system, enabling them to serve clients more efficiently and effectively and avoiding costly duplication of services. Community providers will now be able to refer patients to the Center for a definitive diagnosis, specialized care or participation in clinical trials. Patients can then return to their own primary care provider or clinics for continuing care.

*Cook County Hospital and Rush-Presbyterian-St. Luke's Medical Center: A Tradition of Excellence:*

As leaders in HIV/AIDS research and model service delivery, Cook County Hospital and Rush-Presbyterian-St. Luke's Health Center are highly capable of delivering programs of highest quality care and are uniquely qualified to develop and operate the Center in response to this urgent, community identified, health crisis.

Each institution has in-depth experience with infectious diseases, especially HIV/AIDS, and a history of successful affiliation with one another. They are Illinois' largest public and private hospitals. Traditionally, Cook County Hospital has cared for approximately 30 percent of the HIV population receiving care in the Chicago area and has an international reputation for HIV model care programs, prevention and research. The Infectious Disease Section at Rush has been nationally recognized for its HIV treatment program since it was created in 1986. Rush, a leader in clinical HIV related research also coordinates an acclaimed service of national physician training sessions on HIV/AIDS. In addition, the two hospitals are already integrated for the provision of training and clinical care.

It is these existing strengths and collaborations that will enable The CORE Center to provide the most comprehensive and expert care available in the country.

*A National Prototype:*

This unique partnership and model system of care will be a prototype for national efforts to meet the challenges posed by infectious diseases, especially, HIV/AIDS.

It is estimated that in its first full year of operation, operating and programmatic costs will be approximately \$14.5 million.

In light of the Subcommittees support for community-based solutions to unique public health problems, and the current public health crisis in Chicago, we are requesting that you include \$2 million for the operational and programmatic support

of The CORE Center in the fiscal year 1998 Labor, Health and Human Services and Education Appropriations Bill.

Thank you Mr. Chairman for your consideration of our request.

PREPARED STATEMENT OF SPENCER FOREMAN, M.D., PRESIDENT, MONTEFIORE  
MEDICAL CENTER

Mr. Chairman and Members of the subcommittee, thank you for the opportunity to submit this testimony for the record on the Montefiore Medical Center in the Bronx, New York and the exciting new Bronx Health Initiative that we are undertaking.

*The Bronx*

The Bronx has a population of 1.2 million residents, placing it among the top 10 largest "cities" in the United States. Approximately 400,000 of those residents are children. Neighborhoods in the Bronx rank among the poorest in the nation—30 percent of residents in the Bronx are on some form of public assistance and/or Medicaid (31 percent). Over one-quarter of the residents have incomes under \$10,000 annually and 60 percent have incomes below \$30,000 annually.

The Bronx population is largely composed of historically underserved and uninsured minorities with 28 percent African American and 50 percent Hispanic persons. Three-quarters of the Bronx population is non-white. The Bronx is among the nations most underserved urban areas with sociodemographic and health status indicators which underscore its need for health services. Those health and social indicators include:

- The infant mortality rate of 12:1 is among one the nation's highest ratios;
- The rates of teenage pregnancy and low birth weights are higher than the proportions for the city and nation;
- The incidence of Asthma is six times greater than the national average; and
- The lack of industry and strong economic base leaves the borough with extreme housing problems, drug abuse and crime—all underlying problems of poverty and unemployment.

*Montefiore Medical Center*

Established over 100 years ago as a chronic care hospital, Montefiore has become a critical resource in addressing the health and social needs of the residents of the Bronx. Today, the Montefiore Medical Center system is a four hospital, 2,326 bed system with two skilled nursing facilities, a home health agency, nine community based primary care centers and a range of other outreach services operating in the Bronx and surrounding communities. This public/private health system provides more than one-third of all inpatient acute care, over 42 percent of all tertiary care, and \$50 million in uncompensated care annually.

Montefiore Medical Center was the first hospital to create a community-oriented care program in the late 1960's and early 1970's to meet the needs of underserved residents in the Bronx. MMC has traditionally been a critical element in successfully addressing the social health and physical well-being of the those residents.

The Medical Center strives for excellence in patient care, medical education, scientific research and community services. Staff and faculty at MMC, practice "family-centered care" working with families to promote health, prevent diseases, and alleviate the burden of illness.

In 1995, Montefiore Medical Center performed an extensive review of the health of their population, specifically children. The study revealed that children in the Bronx are among the city's most needy with rates of low birth weight infant mortality, HIV infections and other reportable diseases which rank among the cities most disadvantages. It also revealed that hospitalization rates for children (0-19 years) in the Bronx are excessive at 65 admissions for every 1,000 persons—nearly twice the average of more affluent areas.

The study also demonstrated that child health programs at MMC are at great risk for the future. While MMC offers a comprehensive array of child health, prevention and education services through a network of inpatient, outpatient, and community programs and facilities, these programs are fragmented and uncoordinated. The four-site program is hard to sustain, and utilization declines (due to managed care) threaten the viability of the system. It was determined that many inadequacies exist due to the limitations of the physical environment. Existing programs and services at MMC lack focus for the specific needs of children and lack child and family-friendly elements. Among the four hospitals, inpatient services for children are inadequate and fragmented. Ambulatory services for children are scattered throughout the system and not well housed and primary and specialty ambulatory care are

not adequately articulated to meet the health and related needs of children. In addition, there are no existing ancillary services specifically designed for children. Finally, the fragmented nature of existing children's services makes it increasingly difficult to staff the four-site program. Rather than having a critical mass of pediatric primary and specialty care in one location, this expertise is dispersed throughout the multi-site system making departmental cooperation and consultation difficult and staff retention very challenging.

It is clear that a restructuring and consolidation of services for children at MMC must take place to ensure the livelihood of the hospital as well as the longevity of children's health services in the Bronx.

In response to this crisis—Montefiore has established the "Bronx Health Initiative." We have undertaken the daunting task of consolidating all of our children's services into a central location—a new Children's Medical Center. The new Children's Hospital will serve as "hub" of the new "Bronx Health Initiative"—eliminating fragmentation within the existing child health network, enabling the provision of services in a more direct, cost-effective manner and enabling MMC to better and more efficiently address the ever growing health needs of the children in the Bronx.

#### *The Bronx Health Initiative*

The traditional model of children's hospitals are designed for and focus on chronic care. There has been very little preventive, supportive or specialty care at children's hospitals. With the more sophisticated understanding of childhood illness, the resulting need for advanced care, and with the increased understanding of the connection between an individual's health status and his/her lifestyle and family life—a new model of children's hospitals has emerged.

The Bronx Health Initiative at MMC, comprised of both the child health services within the existing Ambulatory Care Network and the planned Children's Medical Center, is a unique example of a modern and aggressive approach to the provision of comprehensive children's primary and specialized health care services.

The Bronx Health Initiative proposes a unique model of care which will assure MMC's continued leadership in the provision of health care and related services to children in the Bronx and surrounding areas. That proposal includes:

- A New Philosophy of Family Centered Care: At Montefiore Medical Center we believe that the well-being of children is dependent upon the understanding and participation of the family. We promote a respectful, collaborative partnership with the families of our patients, relying on their expertise as the primary source of strength and support for their children. We work with families in designing individual health care and general services, facilities, research, and medical education, respecting their needs, beliefs, culture, values, and knowledge. We value families as central to a child's health and are committed to supporting them in this vital role.
- A Child Health Network: The establishment of a child health network, which builds on the existing services available through the Ambulatory Care Network, is a necessity in the rapidly changing environment in the Bronx. The Bronx Health Initiative will ensure that a Child Health Network provides each child with: access to high quality primary and specialty care; effective connections and communication between existing primary and specialty care services/providers; cohesion among the different parts of the network to ensure a full continuum of child health and related services; access to the secondary and tertiary services at the Children's Medical Center so that children and families will have the option of receiving care in an organized, cost effective and accountable system of care.

The Bronx Health Initiative will provide the consolidation and coordination necessary to effectively and efficiently provide a full continuum of care for the children and families of the Bronx.

The network aspects of the Bronx Health Initiative will play a key role in ensuring that a full continuum is and remains available for children and their families through the existing impressive array of services throughout the Bronx, including:

- 3 hospital outpatient departments, providing primary and specialty care and special programs for children;
- 30 ambulatory care sites—receiving over 300,000 visits annually;
- 21 school based health clinics—providing services to over 11,000 children annually;
- The New York Children's Initiative—an innovative outreach care programs for homeless children providing care to over 6,300 children annually;
- An extensive base of privately practicing pediatricians throughout the Bronx and Westchester.

The “front door” to the planned Children’s Medical Center, the core of the Bronx Health Initiative, is through any one of the affiliated ambulatory care sites in our network. Within the network each child will have an identifiable primary care provider responsible for their continuum of care. Any site in the system will have the ability to assess the need for specialty services and to provide those services and consultations on-site or through referral. There will be constant communication between the primary care providers in the community and the specialty care providers at the Children’s Medical Center or in the community.

The network currently offers specialty services specifically geared to meet the special health and social service needs of children in the community. It is critical to note that these programs do not simply target health needs. They target some of the underlying economic and social issues that cause illness in children by providing prevention and education services for at-risk youth and families in the Bronx. Those existing special services include:

- Child Abuse Center;
- Pediatric Resource Center;
- Child Health and Safety Initiative;
- Ambulatory care to adolescents with HIV infection;
- Breast Cancer Screening, Outreach and Education;
- A nationally recognized mobile lead screening and safe house program;
- School based health program providing direct medical services at 21 schools in the community;
- A drop out prevention program;
- Outreach to and prenatal/child care services to pregnant women who are either HIV infected or at-risk for infection; and
- Community redevelopment/commercial revitalization.

#### *A New Children’s Hospital*

The planned Children’s Hospital will provide the critical connection between the providers of children’s health services in the Ambulatory Care Network. It will serve as the “hub” of the entire Bronx Health Initiative.

The new hospital will not stand alone but will be connected to a tertiary care center. The hospital will be programmed and staffed specifically with the special needs of children and families in mind. Those special features and services include:

- State-of-the-art pediatric emergency room;
- Medical and surgical subspecialty ambulatory clinical modules designed specifically for children;
- A short stay “Day Hospital;”
- Family support services;
- Diagnostic and treatment services;
- Age appropriate units specifically designed to care for the individual needs of infants, school age children, and adolescents.
- A State-of-the-art Pediatric Critical Care Unit designed with adequate space for parents to stay with their child with specialized activities such as dialysis and transplant technologies;
- All single occupancy rooms will have parent sleep-in accommodations;
- A playroom on each unit with age appropriate toys, staffed with child life professionals to assist in the developmental needs of children;
- School facilities are available and specially designed to meet the needs of each age group;
- Liaison child psychiatry services; and
- Medical information stations on each unit.

The implementation of the Bronx Health Initiative will elevate the quality and scope of primary and specialty health care services to children and their families in the Bronx.

Montefiore Medical Center, with our 100 year tradition of community service and community-based health care programs, is uniquely qualified to implement and operate the Bronx Health Initiative which could serve as a national model of how complete health systems can adapt to and address the very unique health and social needs of today’s inner-city, minority, children.

Montefiore Medical Center looks forward to developing relationships with the federal government to make this plan a reality and to serve as a model to other cities and hospital systems.



## PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

Chairman Specter, members of the subcommittee, my name is Colleen Mortensen, MT(ASCP). I am a medical technologist at the Great Plains Regional Medical Center in North Platte, Nebraska, and a graduate of a medical technology program funded by Title VII Allied Health Project Grants.

I hope you will indulge me while I explain my story. As a native of the city of Omaha, I went to school at Creighton University in 1971, but did not complete my degree because both of my parents suddenly died. Fortunately, I met a wonderful man and we had four children—three boys and a girl. My husband is a fourth generation farmer and rancher in Curtis, Nebraska. In case you are not familiar with the territory—we are six hours from Omaha, where the University of Nebraska Medical Center is located, 90 miles from Kearney, where the nearest university is located, we travel 30 miles on dirt roads to get to North Platte, which is where I work, and we are two miles from our nearest neighbor. During a major snowstorm, it took 17 days to have the power company come out to us to restore our electricity. Mind you, I'm not complaining, I love living in rural America.

Once my children were in school, I wanted to continue my education, and complete my bachelor's degree. While at Creighton University, I had studied medical technology, but traveling to Omaha, where the only classes in this discipline were held, was not even a remote possibility. Then, I heard about a special University of Nebraska Medical Center program that would be offered in rural Nebraska.

This new program, which was awarded start-up funds by the Title VII Allied Health Project Grants program, established a student laboratory in Kearney, where students receive their education through satellite lectures and curriculum from the University of Nebraska Medical Center in Omaha. I was accepted to the program at the age of 40, and drove the 90 miles to Kearney for a year in order to continue my baccalaureate degree in medical technology. Then, because the Allied Health Project Grants program encouraged students to remain in the rural area, the rest of my clinical laboratory education and training was set up close to home in North Platte.

North Platte is a town of 25,000 people that has had difficulty finding qualified individuals to work in the hospital laboratory. The medical center there provides service to people in Nebraska, Wyoming, and Kansas, and the laboratory personnel often travel in small planes to reach outlying clients. I am pleased to tell you that I am now a professional, nationally certified medical technologist working at the Great Plains Regional Medical Center in North Platte. In my spare time, I work at the local nursing home, where I can draw blood for the elderly patients. In the past, these patients had not been able to have blood drawn on a consistent basis, since a trained individual had not always been available.

According to Linda Fell, MS, MT(ASCP)SH, Education Coordinator with the Division of Medical Technology at the University of Nebraska Medical Center in Omaha, with the \$358,000 awarded in 1992 to the University of Nebraska Medical Center Division of Medical Technology from the Allied Health Project Grants program, 45 students graduated from the rural education program. Of these, 93 percent are working in rural communities. Because of the initial funds from the allied health grant, the success of the program has increased over the years. Our rural education program in Nebraska is now self-sufficient, and this program has increased its percent of graduates accepting jobs in rural areas from 8 percent prior to the grant to 50 percent in 1996.

The Allied Health Project Grants program, under section 767, Title VII of the Public Health Service Act, has been effective in addressing the training and educational needs of allied health personnel, but further strides in funding are still needed to increase the number of allied health professionals to an adequate level. This shortage is clearly illustrated by the current vacancy rates of some of the allied health professions. Histologic technicians, who prepare tissue specimens, have a vacancy rate of 11.7 percent. Cytotechnologist supervisors, who are responsible for examining cells for signs of cancer, have a vacancy rate of 14.1 percent.

Eliminating shortages in rural areas are but one focus of the grants. Meeting the national goal of creating a successful minority recruiting and retention program for medical technologists is another one. This was the focus of a University of Maryland project initiated by allied health grant funding in 1991. Through utilizing a four phase design, which begins with career awareness activities for elementary and middle school students, this model provides a continuum of activities which progressively focuses on identifying, retaining, and advancing interested students to the completion of a baccalaureate degree. Because of this program, the University of Maryland has attained a current 52 percent minority medical technology student

enrollment at a majority institution, and an average 95 percent student retention rate, placing it among the highest in the country.

The field of allied health represents over 200 distinct health care specialties and encompasses 60 percent of the nation's health care workforce. Allied health professionals are an invaluable asset to the nation's public health. Allied health professionals are represented in almost every tier of America's health care delivery system including hospitals, clinical laboratories, hospices, extended care facilities, health maintenance organizations, physicians' offices, and schools.

In light of the success of these programs, and the continuing need for additional allied health professionals in our nation's health care delivery system, we urge you to consider funding the Allied Health Project Grants program at \$10 million for fiscal year 1998.

Thank you for your kind consideration.

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PREPARED STATEMENT OF THE NATIONAL ENERGY ASSISTANCE DIRECTORS'  
ASSOCIATION

The National Energy Assistance Directors' Association (NEADA) is pleased to submit this statement to the Senate Subcommittee on Labor, Health and Human Services, and Education as it considers fiscal year 1998 appropriations for the Low-Income Home Energy Assistance Program (LIHEAP). NEADA is the primary educational and policy organization for the state LIHEAP directors. NEADA also works closely with the National Association of State Community Service Programs (representing the state weatherization program offices) and the National Association of State Energy Officials (representing the state energy offices) to more effectively share ideas on the delivery of state energy services through a new Energy Programs Consortium.

The members of NEADA urge the Subcommittee to consider providing a program funding level of \$1.3 billion for fiscal year 1998 and advance funding of \$1.3 billion for fiscal year 1999. The higher funding level would be used to restore LIHEAP services to the estimated 1.1 million low-income elderly, disabled and working poor households that lost program benefits as a result of funding reductions enacted in fiscal year 1996 and to restore benefit levels to the remaining 4.6 million households that are current recipients of program benefits.

The funding decreases mandated since fiscal year 1996 have forced the states to tighten eligibility standards and, in some cases, reduce benefit levels. On the basis of information we have today, the number of recipients has been cut by more than one million households during the same time period, while average benefits have declined by about 10 percent. Prior to the dramatic reduction in fiscal year 1996, LIHEAP was serving 20 percent of the eligible population (15 million individuals in those households), with one-half of the recipients as elderly or disabled Americans living on fixed incomes, and one-quarter were the working poor.

LIHEAP provides heating and cooling assistance to close to an estimated 4.6 million households in the United States. All users of fuels are eligible for assistance, with the primary fuels being natural gas, heating oil, electricity, and propane. Recipient households are poor; the majority earn an income of less than \$8,000 per year. The energy burden for these households is extremely high, averaging approximately 15 percent of household income, approximately four times the rate for all households. Program recipients include the working poor. For many of these families, earned income is not sufficient to pay high winter heating or summer cooling bills.

In short, LIHEAP is very successful in helping low-income households pay their energy bills, thereby preventing fuel supply shut-offs. The alternative to program assistance is unfortunately clear—families would have to choose between paying their home energy bill and purchasing other necessities of daily living, such as food, medicine, and rent.

The LIHEAP statute provides states with considerable flexibility in administering the program to deliver services effectively at the lowest possible costs. The program is highly targeted and has been successful in helping needy populations. LIHEAP has also served as a successful bridge in helping many families through difficult periods, while keeping them off long-term assistance. About half of the states rely on local community action agencies to provide outreach and counseling; others use local government agencies and state welfare offices. The net result is that program services are delivered for about \$25 per household.

States have been taking steps to leverage LIHEAP funds by actively supporting partnerships with utilities and other fuel providers. Programs include utility rate discounts, arrearage forgiveness, and state supplemental aid. In addition, states

have encouraged utilities to establish fuel funds, allowing individuals to contribute funds to help poor families meet their home energy expenses.

Innovative programs have been developed across the states which have stretched the funds further. Some of these programs are noted below. Co-pay programs, as noted above, permit clients to enroll for 6–12 month periods and attend budget counseling sessions, energy efficiency training, and other programs that help clients become self-sufficient. Alaska developed a mail-in outreach/application process to help keep administrative costs low to deal with the dispersed needy population.

Comprehensive case management has been applied in Arizona, including necessary follow-up. Colorado has developed a crisis intervention program to remedy non-fuel emergencies, such as malfunctioning furnaces and broken windows to avoid needless waste of scarce fuel assistance funds. Assistance is provided in Kansas if recipients can actively demonstrate a regular payment history. Rhode Island has developed a prototypical percentage-of-income payment plan (PIPP), which requires copayments and arrearage forgiveness, and enhances client self-sufficiency. In Wisconsin, the state has developed a program to identify residents in greatest need by identifying problem households in coordination with local providers.

Funding for supplemental program activities has leveled-off in recent years, and further increases are not likely. Rather, it is highly likely that as a result of electric utility restructuring, supplemental funding will decline, thereby increasing the burden on low-income households. The Energy Policy Act of 1992, led to more direct competition between traditional franchised utilities and new market entrants that supply generation without countervailing responsibilities to support “public benefit” programs, such as LIHEAP. This Congressional action led to the issuance of Orders 888 and 889 by the Federal Energy Regulatory Commission, which accelerated the process. Thus far, residential consumers have not been the big beneficiaries of this process. Commitments to all types of “public benefit” programs by utilities, such as LIHEAP-type activities, energy efficiency, energy research and renewable energy programs, has dropped dramatically since 1994.

Additionally, during the past five years, there has been an increase in price volatility for heating oil, propane, natural gas and other products. For example, this past winter dramatic seasonal price spikes occurred in many of these fuels, attributable in large part to low inventory levels. At the onset of the winter season, primary inventories of heating oil were at the lowest levels recorded since the Department of Energy’s Energy Information Administration (EIA) began systematic record-keeping in the 1970s. Up to 40 percent of low-income energy consumers are not served by electric and gas utilities for LIHEAP purposes; these fuels include heating oil, propane and kerosene.

This industry-wide policy of “just-in-time” inventories, also known as “keep inventories low and lean” (KILL), especially for petroleum products, has had highly negative effects on low-income consumers who generally do not have the disposable income to purchase fuels off-season at lower costs. Thus, while energy prices have remained fairly stable on an annualized basis, the seasonal price spikes have severely affected the poor.

The increase in price volatility has been coupled with real reductions in LIHEAP appropriations since the peak of \$2.1 billion in fiscal year 1985, and further reductions in fiscal year 1996. Thus, the funding of \$1 billion in fiscal year 1997, with \$300 million in emergency funds, has resulted in dramatic reductions in services to the needy populations including the poor, elderly, disabled, working poor and those seeking a one-time bridge to prevent longer-term dependency. The fiscal year 1985 funding level would be more than \$3 billion today, if inflation was taken into account.

Additionally, some have suggested that LIHEAP is just a heating program. Cooling programs are critical throughout the country. Many of the states with cooling programs have been highly successful in targeting needy populations and preventing serious illness or death. The gravity of that situation cannot be ignored. The situation a few summers ago in Chicago, where deaths numbered in the hundreds, provides an example of why cooling programs are needed through LIHEAP.

LIHEAP also works in partnership with the Weatherization Assistance Program. By law, states are allowed to use up to 15 percent of LIHEAP funds to help families reduce energy costs by upgrading heating systems, and applying window treatments, insulation, caulking, storm windows and doors and other energy efficiency measures. The effect of this partnership is to reduce the long-term need for assistance by reducing the need for energy.

NEADA is pleased to have had the opportunity to share its views with the Subcommittee and stands ready to provide any additional information about the importance of LIHEAP in meeting the home heating and cooling needs of the nation’s low-income, disabled, and elderly residents.

PREPARED STATEMENT OF GEORGE A. ZITNAY, PH.D., PRESIDENT AND CEO, BRAIN INJURY ASSOCIATION, INC.

Dear Mr. Chairman and Members of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies:

Thank you for allowing me the opportunity to submit testimony on behalf of the Brain Injury Association, Inc. for the record. My name is George A. Zitnay, Ph.D., and I am the President and Chief Executive Officer of the Brain Injury Association. My testimony focuses on the implementation of the Traumatic Brain Injury Act of 1996 and the need for \$8 million in fiscal year 1998, to accomplish this goal.

Below is background information on brain injury, the Brain Injury Association, and the importance of funding the Traumatic Brain Injury Act:

BRAIN INJURY

Traumatic brain injury (TBI) is defined as an insult to the brain, not of a degenerative or congenital nature but caused by an external physical force, that may produce a diminished or altered state of consciousness, which results in an impairment of cognitive abilities or physical functioning. It can also result in the disturbance of behavioral or emotional functioning.

Traumatic brain injury has become the number one killer and cause of disability of young people in the United States. Motor vehicle crashes, sports injuries, falls, and violence are the major causes of traumatic brain injury. Long known as the silent epidemic, TBI can strike anyone—infant, youth or elderly person—without warning, and often with devastating consequences. Traumatic brain injury affects the whole family and often results in huge medical and rehabilitation expenses over a lifetime.

An estimated 1.9 million Americans experience traumatic brain injuries each year. About half of these cases result in at least short-term disability, and 52,000 people die as a result of their injuries. The costs of TBI in the United States is estimated at more than \$48 billion annually. Every year over 90,000 people sustain severe brain injuries leading to debilitating loss of function.

THE BRAIN INJURY ASSOCIATION

The Brain Injury Association, is a national, non-profit advocacy organization dedicated to improving the quality of life of persons with brain injury, as well as promoting research, education and prevention of brain injuries. It is composed of individuals with traumatic brain injury, their families, and the professionals who serve them. What began as a small group in a mother's kitchen has blossomed into a national organization with 44 state associations, over 400 local support groups and thousands of individual members.

THE TRAUMATIC BRAIN INJURY ACT OF 1996

In July 1996, the Congress enacted "The Traumatic Brain Injury Act," Public Law 104-166, "to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury." As you know, under the law three federal agencies are charged with responsibility for implementing TBI programs. The Centers for Disease Control and Prevention (CDC) is responsible for activities related to reducing the incidence of traumatic brain injury, the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB) is responsible for implementing the TBI State Demonstration Program, and the National Institutes for Health (NIH) has been delegated responsibility for conducting basic and applied research and a consensus conference.

*CDC Surveillance/Prevention*

The TBI Act authorizes CDC to use \$3 million for each of fiscal years 1997-1999, to support studies in collaboration with State and local health-related agencies to: determine the incidence and prevalence of traumatic brain injury; and develop a uniform reporting system under which States report incidents of traumatic injury. Funds are to be used to identify common therapeutic interventions which are used for the rehabilitation of individuals with such injuries, and develop practice guidelines for the rehabilitation of traumatic brain injury at such time as appropriate scientific research becomes available.

Approximately \$2.6 million was appropriated for fiscal year 1997. Additional funding for fiscal year 1998 is necessary to meet the objectives of this portion of the TBI Act.

On February 12, 1997, CDC published a notice in the Federal Register announcing the availability of funds (\$1.55 million) for approximately eleven Traumatic Brain Injury Surveillance programs for fiscal year 1997.

The Notice states that “[d]espite the magnitude of the problem of TBI, surveillance systems in only a few U.S. jurisdictions are adequately monitoring its impact. In the past, most of the data on TBIs have been collected in: hospital based clinical case series; epidemiological studies restricted to particular times and locales; registries maintained by government agencies responsible for providing services for persons with these injuries; and state-based public health surveillance systems for TBI.”

The Notice explains that these methods of data collection do not provide sufficient information to develop a multi-state surveillance system. Epidemiological studies frequently use incompatible case definitions and data sets, making comparison and aggregation of data impossible. Thus, these studies have not produced data to define patterns in TBI over time, to assess changes in such patterns, and to evaluate the effectiveness of current rehabilitation and prevention programs.

The CDC National Center for Injury Prevention and Control (NCIPC) has defined TBI and published TBI surveillance methods and guidelines for public health purposes. Although NCIPC currently funds four states with developed TBI surveillance systems, expansion of this multi-state, uniform reporting system is needed to provide nationally representative data on groups at higher risk, causes and circumstances of injury, and outcomes of injury. These data are critical to plan, implement, and then evaluate programs for preventing TBI and preventing disabilities from occurring after TBI.

Full funding to meet the goals of determining the incidence and prevalence of traumatic brain injury as established in the TBI Act would require \$3 million for fiscal year 1998.

#### *HRSA/MCHB TBI Demonstration Grants Program*

Congress authorized HRSA/MCHB to establish a program of grants to States for the purpose of carrying out demonstration projects to improve health and other services for persons with traumatic brain injury.

TBI Demonstration Grants are intended to help States implement state-wide systems that ensure access to comprehensive and coordinated TBI services. Under the Traumatic Brain Injury Act, these projects are to involve all relevant disciplines, organizations and consumers.

In fiscal year 1997, three-fifths of the funds authorized for this program were appropriated. The Brain Injury Association urges the Committee to fully fund this program at the \$5 million level in fiscal year 1998.

#### *State Planning Grants*

During 1997, HRSA will make planning grants available to those States that may need assistance in establishing the necessary infrastructure core capacity components before developing an implementation plan. Four core capacity components have been identified as the essential elements in any plan for state implementation of TBI services. These grantees will have the opportunity to develop the following:

- A Statewide TBI Advisory Board;
- A designated State agency and staff position responsible for State TBI activities;
- A Statewide needs assessment, to address the full spectrum of care and services from initial acute treatment through community reintegration for individuals with TBI; and
- A Statewide action plan to develop a comprehensive, community-based system of care that encompasses physical, psychological, educational, vocational, and social aspects of TBI services and addresses the needs of the family as well as the TBI survivor.

#### *State Implementation Grants*

HRSA will make State implementation grants to help each State move toward a statewide system that assures access to comprehensive and coordinated services for individuals with TBI. The following are priorities within the program:

- Interagency collaboration and linkages;
- Education and training programs for survivors, families, and/or professionals;
- Data collection to track programs, resources, and enhance program evaluation;
- Development of materials to meet the needs of low literacy and culturally or ethnically distinct populations;
- Development of a pre-discharge model to be used in acute care sites in the development of long term resource plans for TBI survivors; and

—Development of a model to coordinate financial resources to provide services that most effectively meet the needs of TBI survivors.

An unusual and important aspect of this program is that in order to receive a grant, States must make available, in cash, non-Federal contributions toward the costs of their programs in an amount that is not less than \$1 for each \$2 of Federal funds provided under the grant. Therefore, States applying for such grants would clearly have an interest at stake and would have already made a serious commitment to establishing their TBI system.

The MCHB is moving forward with this program, and the Brain Injury Association has reason to expect that many states will apply for both the planning and implementing grants. Already, MCHB has issued a "Notice of Availability of Funds" (for fiscal year 1997) on March 27, 1997 in the Federal Register. The "Notice" states that the agency is "committed to achieving the health promotion and disease prevention objectives of Healthy People 2000 \* \* \* [and] the TBI grant program will directly address the Healthy People 2000 objectives related to chronic disabling conditions, particularly in relation to service system expansion and objectives related to secondary injury prevention."

Applications for grants are due by May 29, 1997. It is the Brain Injury Association's understanding that many more States will be applying than the funding can accommodate.

Although the TBI Act authorizes \$5 million for this program for three consecutive years (fiscal year 1997–fiscal year 1999), only \$2.87 million was appropriated for fiscal year 1997. It is critical to provide means to maintain continuity of these projects initiated in fiscal year 1997, that the two subsequent years (fiscal year 1998 and fiscal year 1999) be fully funded. An appropriation of \$5 million in fiscal year 1998, is critical to assisting States to better care for their citizens with brain injury.

#### *NIH Consensus Conference*

The National Center for Medical Rehabilitation Research within the National Institute for Child Health and Human Development at the National Institutes of Health, is to conduct a national consensus conference on managing traumatic brain injury and related rehabilitation concerns.

Already a work plan has been put together by the Agency for Health Care Policy and Research (AHCPR) and preliminary meetings have been held between AHCPR, NIH and the Brain Injury Association. AHCPR is to assist by reviewing and synthesizing the existing scientific evidence on the common therapeutic interventions for the treatment of traumatic brain injury as specified in the TBI Act. The AHCPR developed evidence review is to serve as the foundation for the development of consensus recommendations by the NIH panel. The next planning meeting to discuss the consensus conference is scheduled to be held later this month. It is the Brain Injury Association's understanding that the \$500,000 that was authorized, was appropriated to the National Institutes of Health's budget for the purpose of this conference.

Thank you for your continued support for these important programs. I appreciate your time and attention in assuring that they are fully funded.

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#### PREPARED STATEMENT OF THE AMERICAN NURSES ASSOCIATION

The American Nurses Association (ANA), joined by the Emergency Nurses Association, appreciates this opportunity to comment on fiscal year 1998 appropriations for nursing education, nursing research and workforce programs.

ANA is the only full-service professional organization representing the nation's 2.5 million registered nurses, including staff nurses, nurse practitioners, clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetists through its 53 state and territorial nurses association.

The Emergency Nurses Association is a voluntary national membership association of over 24,000 professional nurses committed to the excellence of emergency care.

We gratefully acknowledge this Subcommittee's support for nursing education and research. You have continued to recognize the importance of nurses in health care delivery and have funded programs for nursing education and innovative practice models. We recognize that you will continue to make difficult choices in this year's appropriations recommendations especially in light of the Administration's fiscal year 1998 Budget proposal which decimates funding for nursing education programs. Although the nursing community at large is appalled and outraged with the Administration's proposal, we believe that our shared mutual goal of ensuring the nation of an adequate supply of well-educated nurses, to meet the increasing de-

mands of our rapidly changing health care system, will reaffirm the need for continued funding of these programs. Today, we offer our professional recommendations for federal funding of nursing education, nursing research and workforce programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS NURSE EDUCATION ACT

More than 100,000 advanced practice nurses—registered nurses with education and clinical experience generally at a master's degree level—are providing primary care in the place of physicians or are providing an expanded type of primary care, either as nurse practitioners, certified nurse midwives or clinical nurse specialists. Due to unprecedented changes in our health care delivery system and the changing demographics and complexity of care, nurse practitioners will be in increasing demand and the nurse education system will be stretched to provide first-quality training for them. These changes call for the fullest utilization possible of the multi-disciplinary providers who care for patients and families in an ever-increasing array of settings: hospitals, subacute care facilities, rehabilitation facilities, long term care facilities, schools and universities, workplaces and communities.

Federal support for nursing education in Title VIII of the Public Health Service Act (PHSA) is unduplicated and essential to achieve future goals for the public's health. Under current law, specific authorizations are made for nurse practitioners/nurse midwives; professional nurse traineeships; nursing special projects; advanced nurse education; nurse anesthetists; and disadvantaged assistance. Although the Nurse Education Act was not reauthorized during the 104th Congress, a proposal was developed which would give the Secretary of Health and Human Services broad discretion to determine which projects to fund, with priority given to projects which would substantially benefit rural or underserved populations, including public health departments. In this proposal, the Division of Nursing would have the needed flexibility to focus on curriculum development and other programs to help change the focus of nurse education from acute care settings to the preparation of more nurses who are able to function where there is a greater demand. It would also better address the need for increasing the numbers of minority nurses available to provide culturally competent, linguistically appropriate health care services to underserved communities. These nurses would be better prepared to assist these populations in changing the way they access our health care system, and in helping these patients understand the advantages of developing relationships with primary providers. By itself, the behavior change from accessing health care services through emergency departments to one in which the consumer routinely seeks care through a primary provider decreases health care costs exponentially.

As work on a reauthorization proposal progresses, it is crucial that the Division of Nursing be able to continue the administration of nursing education programs at current funding levels until the new programs can be implemented. For fiscal year 1997, the Nurse Education Act was funded at \$65.3 million. For fiscal year 1998, we are requesting level funding of \$65.3 million for the programs funded under the Nurse Education Act. The following provides a brief description of these programs, along with the fiscal year 1998 individual funding recommendations.

*Nursing Special Projects (Section 820)*

Title VIII of the PHSA is the only specific source of funds for innovation in nursing practice. Examples of innovation include nurse managed clinics, fifty percent of which have been developed or expanded with Title VIII support. The dramatic shift in health care delivery systems from inpatient to outpatient settings further emphasizes the need for workforce retraining and the development of new programs to address this educational need. We recommend level funding at \$10.6 million.

*Nurse Practitioner and Certified Nurse-Midwife Program Grants (Section 822)*

Advanced practice continues to hold the nation's greatest promise of providing primary care access in rural, inner-city and underserved areas of the country. Title VIII of the PHSA has provided support to more than 80 percent of the nurse midwifery programs in the U.S. and 60 percent of the nurse practitioner programs in the country. We recommend level funding at \$17.6 million.

*Nursing Education Opportunities for Individuals from Disadvantaged Backgrounds (Section 827)*

Over-utilization of costly emergency care, decreased access to primary care providers and a general lack of trust in the health care system has frequently been attributed to the lack of representation of minorities among health care providers. Funds from Title VIII of the PHSA have increased the number of minority nurses available to provide culturally competent, linguistically appropriate health care services to underserved communities. Evaluative studies have determined that this program has

been the driving force behind many of the efforts nationwide to increase diversity in the nursing profession. We recommend level funding at \$3.7 million.

*Traineeships for Advanced Education of Professional Nurses (Section 830); Nurse Anesthetists (Section 831); and Advanced Nurse Education Program (Section 821)*

Nursing education at the graduate (master's and doctoral) level provides the skilled clinicians for promoting excellence in practice and the faculty needed to maintain the nursing education pipeline. Professional nurse traineeships under Title VIII of the PHS support over 93 percent of all full-time graduate students in nursing. Preference is given for traineeship programs which provide significant learning experiences at rural health facilities and those where students come from health professional shortage areas. We recommend funding for Professional Nurse Traineeships at \$15.9 million, Nurse Anesthetists program at \$2.8 million and Advanced Nurse Education Programs at \$12.5 million.

*Nurse Loan Repayment (Section 836)*

This program provides for up to 85 percent repayment of student loans for nurses who agree to a service payback in nursing shortage areas. We recommend funding at approximately \$2.2 million.

*National Institute of Nursing Research (NINR)*

The second funding priority for nursing is funding for the NINR, on the campus of the National Institutes of Health (NIH). Again we applaud this Subcommittee's commitment to advancing behavioral science research. Nursing research is an integral part of the effectiveness of nursing care. The NINR provides the knowledge base for practice of 2.5 million registered nurses. Advances in nursing care arising from nursing and other biomedical research improves the quality of patient care and has shown excellent progress in reducing health care costs and health care demands. The trend for earlier discharge from the hospital can potentially reduce hospital charges, but patients may and frequently require rehospitalization, increased acute care visits, and home care that families may be unable to provide. Research funded by NINR has shown that a model consisting of a carefully planned hospital early discharge program with follow-up care in the home by nurse specialists can result in improved recovery of patients at substantially reduced health care costs. The model was tested on three groups of women. Hospital costs were reduced by an average of 38 percent for diabetic mothers and their babies; 29 percent for mothers with cesarean births and their babies; and 6 percent for women undergoing hysterectomies. Moreover, the women had fewer rehospitalizations and expressed greater satisfaction with their care. This model needs further testing in different patient populations. However, if its initial promise holds true for other groups of hospital patients, then earlier discharge with qualified home follow-up care can improve recovery and save increasingly scarce health care dollars. We support the Administration's proposed 2.6 percent increase above fiscal year 1997 funding which is \$61 million for this program and would not oppose the NINR professional judgment recommendation of a 9 percent increase over the fiscal year 1997 level of \$59.7 million.

*Substance Abuse and Mental Health Services Administration (SAMHSA) Clinical Training Program*

The SAMHSA Clinical Training Program has been a major source of the nation's mental health clinical training funds, and is a source of funding for ANA's Minority Fellowship Project (MFP). Since fiscal year 1994 the program had been funded at \$2.5 million. The funding is allocated through SAMHSA to the minority mental health training programs in Nursing, Psychology, Social Work and Psychiatry. The MFP graduates have an outstanding record of public service to minority and indigent communities.

MFP graduates receive doctoral degrees and work as teachers in schools of nursing that serve minority students. They serve as role models and provide leadership to future nurses. As clinicians, graduates work in high risk urban and rural areas providing care to children and families who are victims of violence, HIV/AIDS, and substance abuse as well as the mentally ill. Nurses work in community based clinics and outreach programs and often are the primary care providers for indigent clients who might otherwise go without needed mental health services. In addition, these nurses generate research on minority mental health services, treatments and client outcomes. Culturally appropriate research helps us to identify ways to provide services faster and to more people, ultimately improving health care outcomes and reducing health care costs. This works to change the poor health outcomes and high risk health status that continues to plague minority communities. Unfortunately, last year this program was only funded at slightly above \$1 million. We believe this



program is a good investment in reducing mental health care costs and recommend funding of \$2.5 million for fiscal year 1998 and a separate line item in the budget for the SAMHSA Clinical Training program to secure funding.

*Substance Abuse and Mental Health Services Administration (SAMHSA) AIDS Clinical Training Grant*

The SAMHSA AIDS Clinical Training grant is a small categorical program that provides funds for the training of mental health care providers to provide HIV related services to their patients and to address the complex psychological, psychosocial and neuropsychiatric needs of people with HIV and their families and those at increased risk for HIV infection secondary to chronic mental illness. We recommend funding of \$2.9 million for fiscal year 1998 for the SAMHSA AIDS Clinical Training Grant.

*AIDS Education and Training Centers (AETC)*

The AETC program in the Bureau of Health Professions at the Health Resources and Services Administration provides specialized training for health care personnel who care for patients with AIDS. Emerging and evolving scientific information with profound impact on individual and public health requires a ready network for information dissemination and technology transfer. AETC's reduce care costs, promote private sector voluntarism and ease the suffering of families and communities. It is for this reason that we recommend a funding level of \$23 million for fiscal year 1998 for the AETC's.

*The National Institutes for Occupational Safety and Health (NIOSH)*

NIOSH is the only federal agency with the mission to conduct research and develop practical solutions to prevent work injury and illness. NIOSH played a key scientific role in the development of the bloodborne pathogens standard. This standard provides significant protection to front-line health care providers from possible exposure to bloodborne pathogens, such as HIV, Hepatitis-B and Hepatitis-C. In addition, NIOSH funds Educational Resource Centers. These multi-disciplinary, university based occupational health and safety training and research centers as the primary vehicle for the development and training of a corps of trained occupational health nurses and other safety professionals. We recommend fiscal year 1998 funding of \$149 million for NIOSH.

OTHER WORKFORCE FUNDING RECOMMENDATIONS

As an advocate for the economic and general welfare of registered nurses, the American Nurses Association also recommends appropriate funding for the Department of Labor and related agencies that serve to ensure a safe and fair workplace. ANA believes the work done by the Bureau of Labor Statistics, with respect to the ongoing collection and analysis of employment and economic data, is necessary for tracking changing economic conditions and essential to making workforce projections. We urge your support of the Bureau.

*National Labor Relations Board (NLRB)*

ANA is concerned about the ability of the NLRB to meet its statutory responsibility of enforcing and interpreting the National Labor Relations Act (NLRA). Current cutbacks have created delays in processing of complaints and holding representation elections thus jeopardizing the progress in employee and employer relations. ANA considers this a core independent agency function that must be preserved. We recommend fiscal year 1998 funding of \$186 million for the NLRB.

*Occupational Safety and Health Administration (OSHA)*

The rapid restructuring of the health industry has increased and in some cases exacerbated the risk of exposure to illness and injury for nurses and other health care workers. Hospitals and HMOs are downsizing both to cut costs and be competitive in the health care marketplace. These economic pressures have led to a reduction in the number of registered nurses providing care at the bedside. The remaining nurses in these acute care settings have to work harder and take care of more and sicker patients than ever before. The nurses themselves are sustaining more frequent incidences of injury and illness. According to the Bureau of Labor Statistics, in 1993, back and shoulder injuries accounted for 50 percent of the 31,422 injuries and illnesses that kept registered nurses away from work. Overall, lifting was specified as the cause of 26 percent of all registered nurse injuries. ANA is concerned about these increased incidences and adamantly opposes any proposal which would prevent OSHA from developing an ergonomic regulation.

Overall, there are an estimated 50,000 deaths per year that result from illnesses caused by workplace chemical exposures and six million nonfatal workplace injuries

that occur annually. Budgetary reductions place OSHA at risk in meeting its statutory responsibility of establishing and enforcing national health and safety standards. ANA continues to be concerned about the strength of the Office of Occupational Health Nursing and its parity with similar offices. Occupational health nurses are the largest group of health care providers at the nation's work sites. As such, they are uniquely qualified to assess the practical realities of work sites and related regulatory activities. This office must be fully staffed in order to accomplish its critical task of linking the ongoing work of occupational safety and health nurses to OSHA. We recommend fiscal year 1998 funding of \$348 million for OSHA.

#### *Conclusion*

We appreciate the opportunity to comment on funding for nursing education, research and workforce programs. We thank you for your continued support and look forward to working with you as you proceed through the appropriations process.

#### PREPARED STATEMENT OF THE TRI-COUNCIL FOR NURSING

The Tri-Council for Nursing, a body comprised of 4 major national nursing organizations appreciates this opportunity to comment on fiscal year 1998 appropriations for nursing education, nursing research and workforce programs. The Tri-Council organizations are:

- The American Nurses Association with 178,000 registered nurse members in 53 constituent state and territorial nurses associations;
- The American Association of Colleges of Nursing representing over 510 senior colleges and universities with baccalaureate, master's and doctoral nursing education programs across the United States;
- The American Organization of Nurse Executives representing 5,500 nurses in executive practice in 60 chapters nationwide; and
- The National League for Nursing including 1,620 accredited nursing programs, 46 constituent state leagues, 104 health care institutions and 15,000 individual members, including consumers, faculty in schools of nursing and nurse practitioners in community nursing centers.

These organizations are committed to ensuring a strong federal role for nursing education and nursing research. In the midst of unprecedented changes in our health care delivery system and the changing demographics and complexity of care, sound federal funding for nursing education programs, including advanced practice nurses and nursing research, has never been more critical. We appreciate the support this Subcommittee has shown for nursing education and research. Today, the Tri-Council offers its professional recommendations on key federal programs for nursing. A list of the specific recommendations is attached at the end of this testimony.

#### *Nurse Education Act*

Last year this committee took a hard look at the costs versus benefit of federal support for these programs and provided an increase in funding. This Subcommittee believed this was a good investment in our country's health care. It remains abundantly clear that there continues to be a lack of primary care providers to address the evolving health care needs of our citizens. Unfortunately, the President's fiscal year 1998 budget proposed a drastic cut in funding for these programs. We are appalled that the Administration could make such an irresponsible recommendation, especially in light of last year's overwhelming support and expressed need for primary care practitioners. This year as the movement towards a balanced budget proceeds, the Tri-Council realizes that budget constraints will force this Subcommittee to make difficult choices among domestic discretionary programs. We appreciate the support that this Subcommittee has consistently provided and look forward to continued support. For NEA programs, including advanced nurse education, nurse practitioners/nurse midwives, special projects, nurse disadvantaged assistance, professional nurse traineeships, nurse anesthetists and nurse loan repayment for shortage area service, the Tri-Council recommends a funding level of \$65.3 million for fiscal year 1998.

The funding provided through the NEA helped educate nurses throughout the country to meet the demands of an ever changing health care system and improve care to patients. Maintaining support for these vital education programs is of paramount importance, given the dramatic shifts occurring in the delivery of health care and the growing need for primary health care providers, especially in our nation's rural and inner city areas. Nurses play an essential role in meeting the health care needs of our citizens. In particular, advanced practice nurses (APNs) are uniquely qualified to meet the current shortages and the evolving needs. They can provide

a majority of primary and preventive care services in a cost effective way and have continued to demonstrate a willingness to reach out to the elderly, disabled and children. The NEA plays an important role in preparing APNs.

Section 822, provides grants to prepare nurse practitioners and certified nurse midwives to provide primary care in ambulatory care facilities, home care, outpatient and community-based settings. Nearly 50 percent of the nurse practitioner program graduates are employed in inner city and rural areas and over 80 percent of current practicing nurse midwives devote a significant portion of their service to low-income or uninsured women. (Fiscal year 1996 supported 62 grants in the education of about 1,364 nurse practitioners and nurse midwives; the fiscal year 1997 appropriation should produce 69 awards).

Stipends for graduate nursing students are provided through Section 830. These students include clinical nurse specialists, nurse educators and public health nurses. Eighty percent of graduate-level nurses are in clinical practice, providing health care on a daily basis to our nation's citizens. The remaining twenty percent have roles in teaching and administration, where they prepare our nurses of the future and design the care delivery systems to meet the needs of our communities. The proportion of supported nurse graduates serving in medically underserved communities has increased by 36 percent in just the past two years. (The fiscal year 1996 funding provided support for the education of more than 4,013 nurses at 254 schools. The fiscal year 1997 funding will support students at 264 schools.)

Section 820, Special Projects, provides funding for expansion of enrollment in professional nursing programs, continuing education and primary care training. Special project funds have established and/or expanded over 50 percent of the currently operating nurse managed clinics providing care to high risk and vulnerable populations. All 28 federally-funded clinics are in medically underserved areas. In fact these clinics provided nearly 32,000 primary care visits in elementary schools, senior citizens centers, colleges, housing complexes, homeless shelters, and other areas of need last year. Special Project funds have supported the development of nearly 100 percent of all the initial State and regional outreach models. These prototypes deliver undergraduate and/or graduate training through advanced audio/visual technology to nursing students who otherwise would not have had access to such training. These models have spurred private sector development of similar training programs. (Fiscal year 1996 appropriation funded 57 special projects; fiscal year 1997 should fund about 62 projects.)

Funding to prepare students at the master's and doctoral level for teaching, public health or other professional nursing specialties is provided in Section 821. For example, this funding supported over 50 percent of the programs to train nurses to provide care in coronary care units, intensive care units, burn units, prisons, schools and in homeless settings. (Fiscal year 1996 funded 57 awards; fiscal year 1997 should fund about 63 awards)

Grants for traineeships and education projects for registered nurses to become certified registered nurse anesthetists (CRNA) are provided through Section 831. Also funded are grants to enable CRNA faculty to obtain relevant advanced education. Nurse anesthetists are the sole providers of anesthesia in 85 percent of rural area hospitals. (Fiscal year 1996 funded over 70 programs with 1108 students.)

Section 827 assists schools and education programs in their recruitment of individuals from minority or disadvantaged backgrounds, and provides the students with nursing opportunities through training, counseling and modest stipends. Evaluative studies have determined that this program has been the driving force behind many of the efforts nationwide to increase diversity in the nursing profession. (The fiscal year 1996 appropriation provided support for 500 nursing students in 21 programs; the fiscal year 1997 appropriation will fund about 23 programs.)

Funding to help students repay loans for their nursing education in exchange for service in areas of critical nursing shortage is derived through Section 846. Of the 185 awards made in fiscal year 1996, 53 percent went to nurses in LA, MS, ND, and SC.

Our nurses have observed the changes from health care being delivered in hospitals to a new emphasis on care delivered in a variety of settings throughout the community including home care and community centers. With this transition to shorter hospital stays comes the need for more intensive patient education and prevention services. These needs are creating new delivery models developed by nurse practitioners and clinical nurse specialists in partnership with physicians to improve the health of vulnerable populations. Nursing centers which incorporate the best managed care concepts are providing primary health care services to families in a cost-effective manner. These centers focus care on education, prevention and wellness while improving access to appropriate medical services. Federal dollars,

through the NEA, are a way to support the changes in education and training of nurses that will meet the new health care delivery needs of our communities.

*National Institute of Nursing Research*

Programs of the National Institute of Nursing Research (NINR) at the National Institutes of Health (NIH) support research which improves nursing practice and the delivery of quality health care. This research is essential to the development of improvements and data in clinical effectiveness and patient outcomes—information which is vital to the continual improvement of quality health care in an environment that is increasingly cost-conscious and focused on improved outcomes.

NINR's initiatives include support for chronic illness adaptation issues and lifestyle changes, cognitive impairment intervention research, HIV and AIDS prevention and treatment and symptom management. Other projects include pain research and genetics.

The Tri-Council supports the President's fiscal year 1998 proposed funding of \$61 million for NINR. However, we understand that NINR's professional judgement recommendation is a 9 percent increase over fiscal year 1997 funding of \$59.7 million and the Tri-Council would not oppose such an increase in funding. NINR appropriations have consistently increased since its inception, but due to its small funding base, NINR appropriations have never been adequate. Our recommendation for an increase in funding for NINR represents the need to adequately support the science of nursing research.

For other related nursing education, and Public Health Service training programs, the Tri-Council recommends the following:

*Disadvantaged Minority Health Scholarships*

This program helps disadvantaged and minority health professions students complete their education with funds going directly to the student. The Tri-Council recommends an fiscal year 1998 appropriation of \$18.6 million for this program.

*National Health Service Corps*

The National Health Service Corps (NHSC) uses an array of scholarships and loan repayments to direct health professionals into underserved rural and urban areas. Nurse practitioners, nurse midwives, and physician assistants are entitled to 10 percent of the scholarship dollars and are also eligible for the loan repayments program. The Tri-Council recommends an fiscal year 1998 appropriation of \$78.2 million for NHSC recruitment. These funds would provide assistance to health care professionals to meet the health care needs of our nation's citizens living in designated Health Professions Shortage Areas.

*Rural Health Outreach Grants*

This program supports coalitions of health care providers or systems to enhance the level of health care services in rural communities that are not adequately served by traditional providers. Nursing professions and schools are among the providers who can participate in this program. The Tri-Council recommends an fiscal year 1998 appropriation of \$28 million.

*Interdisciplinary Training for Rural Health*

This program addresses shortages of health professionals in rural areas through interdisciplinary training projects for several health care disciplines. The Tri-Council recommends an fiscal year 1998 appropriation of \$4.1 million.

*Substance Abuse and Mental Health Services Clinical Training (SAMHSA)*

This program trains mental health personnel, including nurses, to address prevention, treatment, social and physical aspects of substance abuse and mental health, in exchange for repayment through service to underserved or priority populations. The program includes a special Minority Fellowship Program to help increase diversity in the field. The Tri-Council recommends an fiscal year 1998 appropriation of \$2.7 million.

In conclusion, the changing health care system creates a demand for nurses throughout the continuum of care, particularly for nurses with advanced degrees. The tremendous increase in the aging population requires not only more health care, but more home and community-based care which depends on nursing. The Tri-Council for Nursing believes that the demand for nurses will be focused in the areas of primary care, home care, and other forms of community based care. The support provided by the NEA, the NINR and other public health service programs has been invaluable in providing the funding for needed programs, which are essential to provide the nursing care needs of our nation's citizens.

## TRI-COUNCIL FOR NURSING FISCAL YEAR 1998 APPROPRIATIONS RECOMMENDATIONS

[In millions of dollars]

Nurse Education Act	Fiscal year 1997	Tri-Council fiscal year 1998 request
Advanced Nurse Education .....	12.5	12.5
Nurse Practitioner/Midwife .....	17.6	17.6
Nursing Special Projects .....	10.6	10.6
Nurse Disadvantaged Assistance .....	3.7	3.7
Professional Nurse Traineeships .....	15.9	15.9
Nurse Anesthetists .....	2.8	2.8
Nurse Loan Repayment .....	2.2	2.2
Total Nurse Education Act .....	65.3	65.3
Disadvantaged Minority Scholarships (30 percent of this funding is for nursing) .....	18.6	18.6
National Service Corps .....	78.0	78.0
Rural Health Outreach Grants .....	28.0	28.0
Interdisciplinary Training Rural Health .....	4.1	4.1
Substance Abuse/Mental Health Training .....	1.9	2.7
National Institute of Nursing Research .....	59.7	61.0

## PREPARED STATEMENT OF THE NATIONAL COALITION FOR PROMOTING PHYSICAL ACTIVITY

The National Coalition is a collaborative partnership of organizations who have identified physical activity and health as their primary mission. The need for this coalition is important because the benefits from exercise are far reaching. Physical activity helps control weight, reduces the risk of dying of heart disease and stroke, and reduces the risk of developing diabetes, high blood pressure and some cancers. Over 1/3 of all Americans are obese. Nearly 60 percent of all Americans are not regularly active and 25 percent of the adult population is not active at all. Poor diets and the lack of regular physical activity claim nearly 300,000 lives per year. At 420,000 deaths per year, only tobacco use causes more preventable deaths.

The National Coalition is extending physical activity public education and awareness to our federal and state policy makers. We hold the key to changing the national health agenda. For this reason the National Coalition has formed, in Washington, D.C., an office of public affairs. Over 50 groups work together and sit on the National Coalition's Public Policy Advisory Council. Quarterly the National Coalition's Office of Public Affairs and other like-minded groups strategize and formulate legislative policy. The Public Policy Advisory Council has developed fact sheets and lobbying materials and has generated grassroots support for increased physical activity awareness among the executive and legislative branches of government.

The National Coalition clearly communicates to the public, government and regulatory agencies the value of physical activity. We support research, training, and education programs that promote the benefits of physical activity. These important issues will be addressed in our testimony.

## FISCAL YEAR 1998 FUNDING RECOMMENDATIONS

*Centers for Disease Control and Prevention*

The Centers for Disease Control and Prevention and their national partners, including the NCPPA, have provided national leadership in the development of a strategy for a nationwide prevention program. Part of the plan includes enhancing programs and facilities for physical activity and promoting healthy food choices. The NCPPA, along with other public/private partners, will continue to educate the public on the importance of prevention for good health. Prevention efforts will decrease the number of heart attacks, strokes, and cases of diabetes, obesity, and some forms of cancer. But education and the promotion of good health behaviors cannot be properly implemented by all 50 states without adequate funding. Therefore, the National Coalition supports a total fiscal year 1998 appropriation of \$3 billion for the CDC.

The Centers for Disease Control and Prevention's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. As the nation's premier prevention agency the CDC monitors this nation's health, con-

ducts research to enhance prevention, develops and advocates sound public health policies, and promotes healthy behaviors. Primarily the NCPPA works with the CDC's National Center for Chronic Disease Prevention and Health Promotion. This center works toward the prevention of premature deaths and disability from chronic diseases and the promotion of healthy personal behaviors.

**Nutrition and Physical Activity Program.**—With targeted funding, the CDC could build a comprehensive program of physical activity and nutrition promotion to reach children, adolescents, and adults in the United States. Specifically the components would include the development and testing of practical strategies that can be implemented in schools, worksites, and communities; support for the states to develop fully comprehensive, integrated physical activity and nutrition programs; a coordinated communications effort to disseminate effective nutrition and physical activity messages to the public; and education for health professionals on the benefits of regular exercise, and on effective physical activity and nutrition counseling and interventions. The NCPPA recommends \$15 million for fiscal year 1998.

**Preventive Health and Health Services Block Grant.**—The Preventive Health and Health Services Block Grant was established in 1982 to meet the nation's objectives for Healthy People 2000. It includes provisions for states to develop health plans, improve annual reporting of program activities, and target public health interventions to populations in need. All 50 states are eligible grantees of the block grant program. In fact, the block grant serves as the states' primary funding for states' health education and risk reduction activities. States can also use the money for cholesterol and high blood pressure screenings as well as cancer prevention and sex offenses prevention programs. The state grants are flexible. States can administer health plans and prevention program activities to meet the states' particular and unique population needs. Increased block grant funds will help ensure that states get maximum return on their block grant dollars and enable them to target additional health goals cited in Healthy People 2000. The NCPPA recommends \$21.5 million for fiscal year 1998.

**Adolescent Health Program.**—Risky behaviors, such as a lack of physical activity, are established by children, some at an early age. Clearly our nation's children and youth need to be educated on the harmful affects physical inactivity can have on their health. If healthy behaviors are promoted to our children through a comprehensive health education program in the schools then the United States may see a decline in preventable deaths. Education is cost-effective. For example, every one dollar spent on health education saves 14 dollars in avoided health care costs. The CDC currently funds 13 states to implement a comprehensive school health education program. These states provide youth with the information and skills needed to avoid risky behaviors. Ideally, NCPPA would like to see more states funded with the proper resources to battle physical inactivity and poor nutrition. Additional appropriations for adolescent health would extend to all 50 states the benefits of an overall health education. The NCPPA recommends \$25 million for fiscal year 1998.

The CDC has the framework to prevent chronic diseases. CDC initiatives promote healthy behaviors, expand the use of early detection practices, provide young people high-quality health education in schools and community settings, and create healthier communities. With proper funding the CDC, as the nation's prevention agency, can drastically improve health and prevent many of our nation's unnecessary deaths, diseases, and disabilities.

#### *National Institutes of Health and Agency for Health Care Policy and Research*

Investment in biomedical research ensures the good health and well-being of our nation, families, and children. Polls reflect this need and show that an overwhelming majority of Americans believe that more money should be spent on medical research to better diagnose, treat, and prevent diseases. The public is also aware that biomedical research extends well beyond the basic treatment of diseases, but also to the prevention of diseases. Prevention efforts must include a strong message to Americans that physical inactivity is a primary risk factor for many diseases.

While many people know that exercise is good for them, many do not know why nor do they understand how much or what kind of activities are right for them. Study after study has demonstrated a link between physical activity and the prevention of cardiovascular diseases, osteoporosis, and diabetes. Exercise also appears to strengthen immunity, control weight, reduce blood pressure, promote good mental health, and prevent some cancers.

To supplement the public's understanding of physical activity and deliver clear, concise messages in order to get Americans physically active, the National Coalition promotes basic biomedical and outcomes research. NCPPA supports a total fiscal year 1998 appropriation of \$14.65 billion for the NIH and \$160 million for AHCPR

The National Coalition for Promoting Physical Activity supports:

- National Institutes of Health-supported biomedical research nationwide. To ensure growing support of the research process and capitalize on all opportunities for scientific breakthroughs. Possible mechanisms include:
  - An increase in federal funding for research grants and training to adequately support efforts related to physical activity.
  - Increase public awareness and assist in the prevention of diseases, the National Coalition advocates significant real growth in federal funding for biomedical research programs of the National Institutes of Health, in particular the National Heart, Lung and Blood Institute; the National Institute on Neurological Disorders and Stroke; and the National Institute on Aging.
- Federal funding for clinical, behavioral, and outcomes research under such agencies as the Agency for Health Care Policy and Research. The AHCPR plays an important role through the establishment of practice guidelines and conduct of outcomes research. Practice guidelines and outcomes research help insure that high quality and cost-effective medical services are provided.

*President's Council on Physical Fitness and Sports*

The President's Council on Physical Fitness and Sports promotes, encourages, and motivates the development of physical fitness and sports participation for all Americans of all ages. Since 1956 the President's Council has assisted the President and the Secretary of Health and Human Services on how to get more Americans physically active. This year the President's Council, along with the Department of Health and Human Services and the CDC's National Center for Chronic Disease Prevention and Health Promotion, released the landmark Surgeon General report on physical activity. The NCPPA recommends \$1 million for fiscal year 1998.

A YEAR IN REVIEW: FISCAL YEAR 1997

Last year the NCPPA advocated that more money be appropriated for physical activity programs. Thanks to the work of the subcommittee the following programs were funded:

- The Surgeon General released the first-ever report on physical activity. The report highlighted the benefits of physical activity and the hazards of leading a sedentary lifestyle. The NCPPA has used the Surgeon General's report to invigorate Americans in the same way that the first Surgeon General's report on smoking and health motivated people against the dangers of smoking and tobacco.
- The CDC released physical activity guidelines for school and community programs. These guidelines help young people build healthy bodies and establish healthy lifestyles by including physical activity in their daily lives. The guidelines were developed in collaboration with experts from other federal agencies, state agencies, universities, voluntary organizations, and professional associations. The guidelines help parents, students, teachers, and communities develop effective physical activity programs for young people.

CONCLUSION

America is on the cutting edge of physical activity research. The previous examples are just a few of the many reasons why more Federal dollars are needed to promote and examine the many benefits of physical activity. And the benefits are far reaching. Everyone feels the immediate improvement in their health after accumulating 30 minutes a day of physical activity over most days of the week. However, often what is studied is how physical activity can be used to prevent some diseases, stimulate the healing process, or improve disabilities.

The key research need is not more information on the benefits of physical activity. Rather, it is understanding how to get individuals and communities to make the changes needed to become more active. There is a clear need for: developing and testing effective interventions to increase physical activity; and implementing and disseminating those programs, which have been demonstrated to be effective.

Thank you for this opportunity to submit written comments on the fiscal year 1998 budget.

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PREPARED STATEMENT OF RUSS MOLLOY, ESQ., DIRECTOR OF GOVERNMENT  
RELATIONS, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

The University of Medicine and Dentistry of New Jersey (UMDNJ) is the largest statewide health sciences university in the nation. The UMDNJ system consists of seven health sciences schools in five different geographic locations throughout the state and includes schools of medicine and osteopathic medicine, nursing, dentistry,

and health professions. It is a system that involves over 100 affiliations with other hospitals, community centers and clinics, and education and research entities throughout the entire state.

*An International Center for Public Health at University Heights Science Park:*

Infectious disease poses a profound threat to American citizens, and travel to new geographic areas and an increasingly global economy have contributed to a resurgence of infectious microbes. Because New Jersey is surrounded by eight international air and seaports, it is particularly vulnerable to the spread of global infectious microbes. The creation of an International Center for Public Health is a direct response to this looming public health crisis.

The International Center for Public Health is a strategic development initiative to create a world-class infectious disease research and treatment complex in University Heights Science Park in Newark. The Science Park facility will house two core tenants: The Public Health Research Institute (PHRI) and UMDNJ's National TB Center (one of three federally funded TB Centers).

The Public Health Research Institute is a nationally prestigious, 55-year-old biomedical research institute that employs 110 scientists and staff in the research of infectious diseases and their underlying molecular processes. This facility will permit PHRI to double its staff who currently conduct research programs on tuberculosis, AIDS, drug discovery, diagnostic development, and the molecular pathogenicity of a broad range of infectious diseases. A major focus of PHRI is the study of antibiotic resistance of life-threatening bacterial organisms and the development of a new generation of antibiotics.

University Heights Science Park (UHSP) is a collaborative venture of the four institutions of higher education located in Newark: UMDNJ, Rutgers University, New Jersey Institute of Technology (NJIT)—which together conduct \$100 million of research annually in the City, much of it federally-funded—and Essex County College, which trains technicians in 11 science and technology fields.

The building which houses the Council for Higher Education in Newark (CHEN), the higher education institutions that founded University Heights Science Park, was completed in phase one of Science Park. For almost two decades, CHEN has jointly sponsored educational, housing, and retail/commercial projects in Newark's public schools and the neighborhoods of University Heights. The construction of the International Center will anchor the second phase of Science Park and serve as a magnet to attract pharmaceutical, diagnostic and other biomedical companies to the Center.

*Violence Institute:*

As the nation's largest public health sciences university, UMDNJ is well acquainted with an epidemic gripping this country: the threat or perceived threat of violence that jeopardizes our citizen's safety, sanity and overall health. We now recognize violence itself as a national health problem. The University's declared mission—to teach, to discover, to heal, to care—requires that we respond with intelligence and effectiveness to violence.

UMDNJ boasts no fewer than 40 programs statewide which deal with violence in a direct way through research, prevention, intervention, and/or education. From studying the neuroanatomy of aggression, the neurochemistry of violence in alcoholics, and the effectiveness of therapeutic services for sexually abused children and their families, UMDNJ has developed programs which address elder abuse prevention, mediation training, school curriculum development of social problem solving, and suicide prevention.

Over the past five years, these programs have achieved national and local recognition, and, collectively, they have garnered almost \$24 million in funding—only half of which came from federal sources. Our goal is to coordinate a comprehensive approach to understanding and preventing various aspect of violence, including child abuse, youth abuse, juvenile violence, violence against women, elder abuse, substance abuse, the development of aggression, the biological mechanisms of violence, and the treatment of traumatic injury as a result of violence. We seek your assistance to build on our efforts and to develop a Violence Institute which will organize these ongoing activities in a comprehensive manner.

The results to be achieved include enhancing the resources of a state-wide health sciences university to combat violence, developing new ways to attack this problem, determining the most effective approaches, making resources more readily available to community partners, and ultimately, reducing the incidence, impact and costs—financial, social and personal—of violence.

*Child Health Institute of New Jersey:*

The knowledge and technology to unravel the miracles of development, the biologic mechanisms that convert the one-celled fertilized ovum into a feeling, thinking,



conscious individual, are now at hand. The Child Health Institute of New Jersey will implement a novel vision for the integrated study of human development and its disorders. Our strategy explicitly recognizes that changing environmental conditions alter gene function during development, maturation and aging, necessitating study of the whole individual as well as the individual gene. The human child during development appears to be more sensitive to the impact of the environment, both chemical and social, than at any other period of life. Employing this approach, Institute scientists will study human growth and development and the emergence of cognition, emotion, consciousness and individuality. Since growth mechanisms are now known to govern function throughout life, abnormalities of development, maturity and aging will be characterized employing unique insights obtained during development.

New Jersey serves as an ideal laboratory for this project. Our state is the most densely populated, leads the country in the emerging suburbanization of America and is the heartland of the US medical-pharmaceutical industry. The state also possesses some of the poorest urban environments in the nation, and the impact of the decaying urban environment has enormous implications on human growth and development. The Child Health Institute will examine not only the biological and chemical effects on childhood, but the effects of behavioral and societal influences as well.

Ongoing insight into mechanisms regulating growth and development holds the promise of altering medical approaches to recovery of function after illness and injury. For example, recent discoveries at our UMDNJ-Robert Wood Johnson Medical School (RWJMS) and elsewhere now indicate that brain nerve cell division is governed by special growth factors in utero. These factors can be used in the adult to accomplish a feat long thought impossible: the regeneration of nerve cells. This striking discovery points the way to regrowth and recovery of function after stroke, head and spinal trauma, and Alzheimer's and Parkinson's diseases. Parallel discoveries in other areas of developmental biology suggest that a variety of tissues, including skin, bone and blood vessels, should now be regarded as renewable resources. These and related findings now prompt a thoroughgoing reevaluation of the entire process of aging. The new Institute is designed to pursue these revolutionary findings and forge this new approach to medicine.

*National Tuberculosis Center:*

The New Jersey Medical School National Tuberculosis Center at UMDNJ was founded in January, 1993, as a joint venture between the UMDNJ-New Jersey Medical School and University Hospital and the New Jersey Department of Health and Senior Services.

In November, 1993, it successfully competed for funding from the National Centers for Disease Control and Prevention and achieved designation as one of the three Model TB Prevention and Control Centers in the United States. Since then it has developed into an internationally and nationally recognized institution dedicated to the diagnosis and treatment of patients with tuberculosis and multidrug resistant tuberculosis, as well as a training and education center for all aspects of tuberculosis and tuberculosis control. Additionally, extensive clinical studies have been and are being carried out on new treatment and diagnostic and behavioral measures in TB control.

Directly observed therapy for tuberculosis adopted by the World Health Organization as its global standard was first used in our Center's predecessor clinic in the mid 1970s. In addition, the Center's educational staff have been asked to help implement and replicate our nurse case management TB care system for use in many different areas in the United States.

National TB rates have fallen for the past four years, validating the expenditure of major funds for national TB control efforts. In our basic catchment area in Newark, TB rates for 1996 were down 30 percent. In Jersey City, our control community without benefit of a model center, TB rates were up almost 30 percent resulting in an invitation and support to replicate our Hudson County program in Jersey City.

It is extremely gratifying to be able to document the direct effect that a federal expenditure has had on the health and welfare of its citizens. The New Jersey Medical School National Tuberculosis Center at UMDNJ has achieved its initial goals and continues to perform its mission to decrease mortality and morbidity for tuberculosis and drug resistant TB both in New Jersey and the rest of the nation.

*Geriatric Education Center:*

Geriatric Education Centers (GECs) offer education and training opportunities for health care professions faculty, practitioners, students and others to enhance the quality and availability of health care for older citizens. Since the inception of GECs

in 1983, more than 300,000 people have been trained in geriatric care. These Centers offer technical assistance and consultation to academic institutions and health care facilities on issues of program planning, curriculum development, and legislative and policy issues in geriatric care.

Established in 1990 through a federal grant from the Department of Health and Human Services/HRSA/Bureau of Health Professions, the New Jersey Geriatric Education Center (NJGEC) is a collaborative effort among the schools of UMDNJ including its three medical schools and its schools of dentistry and health related professions, along with Seton Hall University, the East Orange Veterans Administration Medical Center and Newark Beth Israel Medical Center. Administered by the UMDNJ-School of Osteopathic Medicine (SOM) in Stratford, NJ, all NJGEC programs and goal-related activities are initiated, coordinated and monitored through SOM's Center for Aging.

The NJGEC offers training and continuing education programs for multiple disciplines and technical assistance and consultation in the field of aging. Over the past six years, the NJGEC has worked with various state agencies, Area Health Education Centers (AHEC's), health care facilities and academic institutions in supporting training needs in geriatrics and gerontology across the state. Since 1990, the NJGEC has provided almost 150 continuing education and in-service training programs to some 6,400 health care professionals. The NJGEC achieves statewide penetration and regional accessibility for health care professionals through programs in the north, central and southern regions of New Jersey.

Although New Jersey ranks ninth among all states in the number of citizens 65 years of age or older, it is one of only two states for which federal funds for its GEC have expired. Also, recent changes in New Jersey have profoundly affected the state's long-term care system and have led to the development of long-term care alternatives such as assisted living facilities and alternative family care homes so that older individuals can remain in their communities in a less restrictive, less medicalized environment. In 1994, the State Department of Health designed a "single point of entry" program—known as New Jersey EASE—for all geriatric services. This program has streamlined the structure and led to the reorganization of the department into a new entity—the Department of Health and Senior Services (DHSS)—that consolidated more than 20 state and federal programs into one cabinet-level agency.

These changes in New Jersey's health care environment have created the need for additional training of health professionals to implement the EASE system and thus have created a unique opportunity for NJGEC to enter into a new "consortium" with Rutgers University and the New Jersey DHSS. The consortium exemplifies a true academic-public partnership that will permit the partners to work together under the aegis of the NJGEC to accomplish what no single entity could do effectively alone: provide health promotion and case management training emphasizing the interdisciplinary approach to geriatric care.

*National Family and Pediatric HIV Resource Center:*

Since 1990, the National Pediatric and Family HIV Resources Center has assumed a highly visible role in providing training and technical assistance to professionals from throughout the United States related to children, youth, and families with HIV infection. Located at UMDNJ's New Jersey Medical School in Newark, the Center has access to information on the cutting edge of HIV services in the areas of health care delivery, research, and education and has served as a clearing house of information for HIV care and providers and families alike.

The Center is the only national organization providing technical assistance and training to meet the needs of children, women, and families with HIV. Health care providers from around the United States and the world come to the Center to observe clinical care of children with HIV, techniques to integrate research and care, organizational approaches to program development, and approaches which foster and mobilize community support. The Center, which is primarily funded through the Pediatric AIDS demonstration of the Ryan White CARE Act, is dedicated to supporting the development of community-based care systems for children, women, youth and families afflicted with HIV/AIDS throughout the United States.

*AIDS Education and Training Center:*

New Jersey cities lead the United States in the percentage of 25 to 44 year-olds dying from AIDS. Furthermore, the state leads the nation in the percentage of AIDS cases among women; the state is third in the nation in number of pediatric cases, and is fifth-highest among states in the numbers of adult and adolescent AIDS cases.

UMDNJ, at University Hospital and Medical Center in Newark, serves the state of New Jersey as one of the nation's 15 national AIDS Education and Training Centers (AETC). The New Jersey Center (NJAETC), which is funded through the Ryan White CARE Act, serves to sustain and expand the base of health care providers who are effectively educated and motivated to counsel, diagnose, treat and manage individuals with HIV infection and assist in the prevention of high-risk behaviors which may lead to infection. The Center was established in 1989 and is administered through the Center for Continuing Education in the Health Professions at UMDNJ.

Because it is based at UMDNJ, the NJAETC is well situated for the rapid dissemination of state-of-the-art HIV-related clinical information to primary care providers throughout the state. The NJAETC works with expert faculty to quickly translate new scientific and epidemiologic information for use in critical clinical practice settings such as community health centers and agencies providing Medicaid managed care. Although the number of HIV-trained health care providers has not kept pace with the scope of the epidemic in New Jersey, NJAETC's "train-the-trainer" programs maximize the impact of dollars spent on training and creates a core of HIV experts throughout the state. Prevention is the central weapon in the fight against AIDS, and 25 percent of the Center's training resources are dedicated to programs providing health professionals throughout New Jersey with the latest information and training on behavior change interventions.

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PREPARED STATEMENT OF DENNIS E. LOWER, EXECUTIVE DIRECTOR, UNIVERSITY HEIGHTS SCIENCE PARK, NEWARK, NJ

#### PROJECT DESCRIPTION

Due to an increasingly global economy, infectious diseases now pose a profound threat to national and international security. In 1980, there were 280 million international travelers. By the year 2000 there will be 400-600 million international travelers. Recently, Vice President Gore declared that our national security now includes defending the nation's health, and "there is no more menacing threat to our global health today than emerging infectious diseases" (American Society of Microbiology News, September, 1996). Diseases arising in any part of the world are repeatedly and rapidly introduced into the United States where they threaten our national health and security. Dr. Anthony Fauci, Director of the National Institute of Allergies and Infectious Diseases (NIAID), states that the "problem posed by emerging and re-emerging infections is one of unparalleled complexity \* \* \* A plan to prepare for future challenges must emphasize fundamental research \* \* \* (and) research capacity building." Central to the NIH approach are a strong national infectious disease research infrastructure, collaborative international studies, multidisciplinary studies, and public-private sector interaction. The creation of the International Center for Public Health is a direct response to the emerging national and international infectious disease crisis.

The International Center for Public Health is a strategic initiative that will create a world class, infectious disease research and treatment complex in University Heights Science Park, Newark, New Jersey. Science Park is located in a Federal Enterprise Community neighborhood. The International Center will have substantial local, regional, national and international impact as it addresses many critical social, economic, political and health related issues. The Center is a \$70M anchor project that will launch the second phase of a fifty-acre, \$300M mixed-use urban redevelopment initiative, University Heights Science Park. The facility will total 144,000 square feet and house two tenants: the Public Health Research Institute (PHRI) and the University of Medicine and Dentistry of New Jersey's (UMDNJ) National TB Center, one of three Federally funded TB centers. Included in the development costs for the Center are funds to prepare three adjacent building pads. These sites will be simultaneously marketed to private biomedical companies, and will generate \$60M of additional construction. Development of the International Center for Public Health is a priority project for UMDNJ, Rutgers Newark, the New Jersey Institute of Technology, Essex County College and the City of Newark.

PHRI, the core tenant for the International Center, is a nationally prestigious, 55 year old biomedical research institute that currently employs 110 scientists and staff in the research of infectious diseases and their underlying molecular processes. This facility will permit them to double their scientific staff. Presently they conduct research programs in tuberculosis, AIDS, drug discovery, diagnostic development, and the molecular pathogenicity of a broad range of infectious diseases. A major

focus of PHRI research is the study of antibiotic resistance to life-threatening bacterial organisms, and the development of the next generation of antibiotics.

Joining PHRI to form the International Center will be UMDNJ's National Tuberculosis Center. The TB Center is one of three Model Tuberculosis Prevention and Control Centers in the United States funded by the CDC. It will add an important clinical component to the International Center for Public Health, since many TB patients also manifest other infectious diseases. The TB Center was founded in 1993 in response to a national resurgence of antibiotic resistant tuberculosis strains. At that time Newark had the nation's second highest rate of TB cases for a major city. Together PHRI and the National TB Center will create a world class research and treatment complex having substantial local, regional, national and international impact.

Other collaborators in the development of the International Center include the New Jersey Department of Health & Senior Services (NJDHSS) and the pharmaceutical industry. Responsible for overseeing all statewide public health initiatives, NJDHSS will contract with the International Center to have cutting edge molecular epidemiology services provided to the State of New Jersey. Expanding the strategic use of molecular epidemiology to direct public health activities will facilitate prompt identification and containment of emerging and re-emerging pathogens. New Jersey's major biomedical companies will also participate in the International Center. An infectious disease consortium will be developed to serve as a forum for disseminating fundamental research on the underlying molecular processes of infectious disease organisms. This research will contribute to pharmaceutical industry development of new drug therapies for antibiotic resistant microorganisms. Private industry R&D facilities contiguous to the International Center are also being explored.

#### THE ANCHOR PROJECT FOR UNIVERSITY HEIGHTS SCIENCE PARK

The International Center for Public Health will be located in University Heights Science Park (UHSP). UHSP is a collaborative venture of Newark's four higher education institutions, the City and Community of Newark, and private industry designed to harness university science and technology research as a force for urban and regional economic and community development. The university sponsors, New Jersey Institute of Technology (NJIT), The University of Medicine & Dentistry of New Jersey (UMDNJ), Rutgers University at Newark, and Essex County College annually conduct nearly \$100 million of research in Newark.

At buildout UHSP will include one million square feet of technology commercial space, 75,000 square feet of technology incubator space, 20,000 square feet of retail business opportunities, an 800 student technology high school, two blocks of new and rehabilitated housing and a community day care center. The \$10M first phase of Science Park is complete and includes a technology business incubator, a 100 child day care center and industrial prototype laboratories for biomaterials and medical devices. The construction of the International Center will anchor the second phase of Science Park, and serve as a magnet to attract pharmaceutical, diagnostic and biomedical companies to Science Park. Phase II includes the preparation of three additional building pads that will be marketed and built simultaneously with the construction of the International Center. The Center will have the same impact on the Park as an anchor store does in a retail shopping mall.

#### WHAT THIS PROJECT MEANS TO NEWARK

The International Center means urban technology job opportunities, improved health care, and creative educational opportunities for Newark's youth. For minority and urban residents it is one challenge to acquire necessary job skills, but it is another to have the means to travel to where the jobs are. In the last 20 years Newark has lost 35,000 private sector jobs, many having moved to the western suburbs. Science Park is a development strategy to bring well-paying jobs back to Newark's urban center, providing City residents with access to the technology jobs of the 21st century. This project, including three additional private sector buildings that it will leverage, will provide 3,000 direct and indirect construction and permanent jobs. The permanent job opportunities are well paying with a wide range of qualifications and educational requirements. They include custodial and clerical positions, lab technicians, medical personnel, researchers, and administrators.

The City of Newark is New Jersey's largest municipality with 275,000 residents, 84 percent of whom are minorities, plus a significant number of undocumented and uncouncted aliens. It is also the State's most at-risk municipality when considering the health of its residents. With unemployment hovering around 14 percent, Newark carries a heavy burden of poverty reflected not only in low per capita wages, but also in the highest rate of infectious diseases in the State (tuberculosis, AIDS and

sexually transmitted diseases). Being located on the front line of infectious diseases, the new International Center will provide cutting edge diagnostic and treatment support to the City's health care providers, thereby ensuring that Newark residents will benefit from the latest discoveries in the battle against infectious diseases.

Today's youth are tomorrow's scientists. As a commitment to the education of Newark's youth, Science Park projects include school linkages and programs with technology tenants. PHRI, the proposed core tenant in The International Center for Public Health, will establish two educational programs to nurture and develop the interest of urban and minority students in science and science-related careers. ScienceLab will be a collaboration with The Newark Public Schools to provide a year-round science education program for Newark high school students and science teachers in a "real-time" private research institute environment. The International Center will also sponsor a BioMentors program and be part of the Westinghouse Science Talent Search program. The goal of these educational programs is to influence and encourage Newark high school students to pursue careers in biomedical sciences, and one day employ their skills in Science Park companies.

HOW THE INTERNATIONAL CENTER FOR PUBLIC HEALTH ENHANCES AND IMPLEMENTS DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AND DEPARTMENT OF EDUCATION OBJECTIVES

The International Center for Public Health (ICPH) is a creative and unique public/private partnership located in University Heights Science Park, Newark, New Jersey that will combine: infectious disease research; pharmaceutical industry participation; international, state and regional public health collaborations; high school urban and minority science education initiatives; urban economic and community redevelopment; and high-technology job creation in a federally designated Enterprise Community.

The Centers for Disease Control and Prevention (CDC) has established specific goals in the areas of surveillance, applied research, prevention and control, and infrastructure. The ICPH will serve as an invaluable resource for the CDC in achieving critical objectives in each of those areas.

*Surveillance.*—One CDC goal is the establishment of a "global consortium of closely linked epidemiology/biomedical research centers to promote the detection, monitoring, and investigation of emerging infections." Another specific focus is the "detection and monitoring of trends of antimicrobial resistance in institutional as well as community settings." The International Center will contribute to the achievement of these objectives as follows:

- Since the 1980's, *Staphylococcus aureus*, the leading cause of post-surgical infections, has shown increasing resistance to methicillin, the last effective antibiotic to treat it. If current trends continue, modern medicine as practiced today (bypass surgery, transplants, chemotherapy) will be in serious jeopardy. The first multi-hospital study of methicillin resistant *Staphylococcus aureus* (MRSA) is currently being performed by the Public Health Research Institute (PHRI), the core tenant of the proposed International Center.
- PHRI has forged a research coalition and established the Bacterial Antibiotic Resistance Group dedicated to understanding and combating antibiotic resistance problems.
- The UMDNJ National TB Center is a regional referral center providing clinical consultation and services to patients with primary and acquired resistance to anti-TB medications. In addition, it provides consultation services to the State of New Jersey, which requires all patients with drug resistant diseases to have their treatment regimens reviewed by the TB Center.
- The TB Center currently is involved with the CDC in testing software applications which tracks screening and prevention for Health Care Workers (Stafftrac).

*Applied Research.*—CDC goals focus "on applied research and the integration of laboratory science and epidemiology with public health practice." An important emphasis is to accurately characterize the "public health and economic impact of both well established and emerging infections." Partnerships with "public agencies, universities and private industry to support research in surveillance, epidemiology, and prevention of emerging infections" are recognized explicitly as critical linkages to achieve CDC's applied research goals. The International Center will contribute to the achievement of these objectives as follows:

- PHRI is currently conducting the first economic impact study of antibiotic resistance. In a contract with the Lewin Group, a model is being developed which will calculate the cost impact of MRSA in New York City. The model can be applied nationally, as well.

—PHRI is the only independent research institute focused on infectious disease research and the implications of that work for public health. Research includes drug discovery, vaccine development, rapid diagnostic techniques, and the underlying molecular mechanisms of infectious organisms and the host (immune system) response.

—The TB Center is a member of the Clinical Trials Consortium of the CDC, with a relationship and mechanism in place to test vaccines, drug delivery and diagnostic techniques.

*Prevention and Control.*—CDC goals include the “creation of an accessible and comprehensive U.S. infectious disease database that increases awareness of infectious diseases and promotes public health action.” The ICPH will contribute to the achievement of these objectives as follows:

—PHRI maintains the world’s largest collection of drug resistant tuberculosis strains, genetically characterized and accessible by electronic means. PHRI has implemented computer matching programs so that new strains can be compared with others already known, thus detecting potential transmission between previously unconnected patients and supporting epidemiological means to stop such transmission.

—The International Center will expand its database to include other microbial organisms, including MRSA, VREF, and PRSP, thereby establishing a basis for broad molecular epidemiology of other infectious agents, including those which cause food-borne disease.

—The TB Center has established a case management system utilizing directly observed therapy as the standard of care. This model is now being developed for national replication.

—The National TB Center currently provides prevention and control training to physicians, nurses, EIS officers, case managers and TB control officers in PA, MD, OH, AR, DE and Chicago.

*Infrastructure.*—The CDC infrastructure goals recognize the need for “state-of-the-art physical resources—laboratory space, training facilities, and equipment,” and for “facilities for maintaining specimen banks of etiologic agents and clinical specimens.” The International Center will contribute to the achievement of these objectives as follows:

—Included in the International Center will be BL-3 facilities to handle dangerous strains under safe conditions.

—The Center will expand its current practice and ability to teach others and establish similar labs elsewhere in U.S. and overseas. Currently PHRI and the TB Center are either in discussions with or provide services to Egypt, Singapore, Indonesia, Russia, the Netherlands, China, India and the thirteen nation European Economic Community.

The National Institute of Allergy and Infectious Diseases and National Institutes of Health (NIAID, NIH) have established specific research goals regarding ecological and environmental factors, microbial changes and adaptations, host susceptibility, vaccines, therapeutics and other control strategies, and infrastructure. The ICPH will provide an invaluable resource in achieving critical objectives in each of those areas.

*Ecological and Environmental Factors.*—The NIAID research agenda includes multidisciplinary studies on the natural history of disease, the implementation of field applicable transmission control strategies, the development of rapid, sensitive, and field applicable diagnostic techniques, and new technologies to predict disease outbreaks. The International Center will contribute to the achievement of these objectives in the following way:

—PHRI is a working model, financed in part through private sources, which accomplish all of the above objectives and demonstrates the feasibility of public-private initiatives in this area.

—The TB Center’s directly observed therapy case management model is ideal for conducting clinical research by permitting accurate reporting of events and objective measurement of outcomes.

*Microbial Changes and Adaptations.*—The NIAID research agenda includes new targets for drug and vaccine development, greater public-private sector interaction in such development, antimicrobial resistance, access to pathogen isolates from well-characterized patient populations in order to relate molecular or functional characteristics of the microbe to its disease causing properties. The International Center will contribute to the achievement of these objectives in the following way:

—PHRI currently is involved in significant public and privately research in anti-bacterial and anti-fungal drug discovery.

*Host Susceptibility.*—The NIAID research agenda includes the identification of targets and mechanisms of protection against emerging or re-emerging pathogens

as the basis of vaccine development, and population-based studies to understand the genetic basis of individual susceptibility to disease. The International Center will contribute to the achievement of these objectives in the following way:

—PHRI is presently sponsored by the U.S. Army in AIDS vaccine studies, with large animal trials to begin this summer.

*Infrastructure.*—The NIAID research agenda includes expanding opportunities for international collaborations, creating cooperative research centers where relevant aspects of basic, clinical and field-based research can be concentrated on emerging disease agents, and utilization of domestic and international clinical studies for collection of data on the epidemiology and natural history of disease. The International Center will contribute to the achievement of these objectives in the following way:

—The coordination and collaboration of PHRI, the National TB Center, and the NJ Department of Health Laboratories, along with research activities of both PHRI and UMDNJ, will create a unique combination of research, clinical, patient, and public health resources. To this will be added strong private participation by the pharmaceutical industry of NJ, representing many of the world's largest and most significant companies.

*Science Education.*—In addition to its infectious disease research interests, the NIH is also concerned with the science education of students from an early age through high school, with a particular focus on minority student education. The International Center will contribute to the achievement of these objectives in the following way:

—For the past seven years, PHRI has operated a summer high school minority student program. As the core tenant of the International Center for Public Health, PHRI will collaborate with University Heights Science Park and the Newark Public Schools, who are now developing a new science and technology high school, and include state-of-the-art teaching laboratories in the International Center. Two year-round science education programs for Newark high school students and science teachers will be created (BioMentors and ScienceLab). Their purpose is to expose students to the biomedical sciences and careers, and give science teachers laboratory experience that will update and enrich their classroom teaching. In addition, the TB Center conducts a summer student research internship program for college students interested in the medical sciences. Together, these programs provide a national model.

#### REQUEST FOR ASSISTANCE

The University Heights Science Park is requesting \$3M (three million dollars) from the House Appropriations Subcommittee on Labor, Health and Human Services and Education for fiscal year 1998 to support the Phase II development of Science Park; the construction of the International Center for Public Health. Such support will leverage Phase II development that totals \$130M, and creates nearly 3,000 direct and indirect construction and permanent technology jobs. These funds will be used specifically for construction related project costs. This project is a top priority for UMDNJ, Rutgers Newark, the New Jersey Institute of Technology, Essex County College and the City of Newark.

I want to thank the Committee for the opportunity to present this request. We appreciate your consideration of our proposal, and hope to receive your support for the creation of the International Center for Public Health at University Heights Science Park, Newark, NJ.

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#### PREPARED STATEMENT OF ALICE BARNETT, DIRECTOR, HEALTH AND HUMAN SERVICES, CITY OF NEWARK, NJ

Mr. Chairman and Members of the Subcommittee: On behalf of the City of Newark, New Jersey, I appreciate the opportunity to appear before you today. I am Alice Barnett, Director of Newark's Department of Health and Human Services. I am here to urge your support for a very important initiative to reduce teen pregnancy and to provide a comprehensive prevention, intervention and case management program to reduce infant mortality and low birth weight babies for those pregnancies that do occur. The City of Newark like many other urban areas across the country is facing a host of extraordinary public health challenges. We are unique, however, in that our high rates of teenage pregnancy and infant mortality are matched by corresponding increases in the incidence of HIV and AIDS infection rates, tuberculosis and substance abuse amongst our adolescents. I am respectfully requesting your assistance with the ever escalating rate of teenage pregnancies in an already seriously at-risk and compromised adolescent population.

The City of Newark has implemented without federal resources, a comprehensive prenatal program. We have also implemented, through various maternal and child health consortia several programs to promote early prenatal care for adolescents. We know however that the complex issue of adolescent pregnancies, adolescent sexuality, requires a far greater and innovative response. We need to, we must, provide sex education information, while we are promoting abstinence for girls and boys. We must urge the reinforcement of this message by every adult, every parent, every school health education program and class, every child protection agency, every church and mosque, every athletic and social service agency and each volunteer and mentor in our City. Our task requires a city-wide, united effort: we must capture the imagination of our young children and redirect their energies and their focus. Teaching abstinence is useless if it is directed only at the few who are readily willing to hear the message. Many of our teens are already sexually active. Many are already involved with drugs. Many are already infected with HIV. We must encourage abstinence through a very urban, cutting edge, uniquely Newark program, that permits young men and women to reinvent themselves; to put on the armor that permits you at 16 to refrain from sexual activity, and still be the 90s version of "cool". We must encourage our teens to adopt a new and healthy lifestyle and outlook: A Bright Futures outlook. Also, through this new initiative, we must reach out to the adolescent most at risk: the homeless, the abused, and the adolescent involved with the juvenile justice system and, the alternative school system.

We realize that such initiatives are not new or unique. What is unique is the level of commitment from this City and its core health, education and social service providers. We have always had the support of our maternal and child health consortium, for this new effort we have secured the support of the institutional and community based agencies that convened for our empowerment zone application planning process.

Our proposal in fact seeks to empower the adolescent to refrain from early sexual activity, learn the public posture that enables continued abstinence through adolescence to marriage. We seek also to create an atmosphere of trust for our adolescents. Pregnant teenagers must learn that caring, responsive adults must be immediately informed of unintentional pregnancies. This will then facilitate the early, first trimester, entry of adolescents into a prenatal care system, the critical entry point for good birth outcomes. The City already secured the support of a host of local partners, including the Newark Division of Health, the Newark Board of Education, AD House, the Division of Public Welfare and a major hospital in our area.

The City must address all of these problems I've mentioned, but we are asking you to consider discretionary assistance so that we may focus especially on this initiative to reduce teen pregnancy by promoting abstinence as the preferred choice of the Newark teenager. And, for pregnancies that do occur, with their corresponding poor infant outcomes because of delayed prenatal care; a comprehensive program consisting of the early identification of at-risk adolescents, education, and case management. Accordingly, Mr. Chairman and Members of the Subcommittee, I would ask you to consider supporting this worthy initiative with \$900,000.00 in discretionary assistance to help us give Newark's teenagers and its infants a healthier start.

Mr. Chairman this project will not only help to identify and assist young women who stand in, desperate need of empowerment training and appropriate health education training, but it also provides them with the tools and resources to access and obtain the care that they need to lead them through a full term pregnancy and to a healthy live, baby.

The goal of this initiative is to reduce teen pregnancy and, for those pregnancies that do occur, the corresponding infant mortality rate through a comprehensive program consisting of prevention, intervention and case management. In implementing this program, Mr. Chairman, we have developed 4 core objectives:

- To increase utilization of existing services through a central case management unit;
- To improve the health of students receiving case management services with the provision of primary health and dental care in an adolescent clinic at the Newark Division of Health;
- To reduce teen pregnancy through the expansion of human growth and development curriculum, which promotes abstinence as the only safe option, to 500 fourth grade students and continue to provide for those same students through the tenth grade; and
- To reduce adolescent pregnancy, a school based male responsibility curriculum starting in the fourth grade and continuing through the tenth grade.

Mr. Chairman, this project will reduce unintentional teen pregnancies by strengthening and empowering adolescents to adopt abstinence. It will also help to



identify and assist young women who stand in desperate need of improved prenatal care, but it also provides them with the tools and resources to access and obtain the care that they need to lead them through a full-term pregnancy and to a healthy live baby.

Again, Mr. Chairman and Members of the Subcommittee, we thank you for your time, and urge you to provide the funding needed to undertake the demonstration effort we have outlined and give Newark adolescents a Bright Future.

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PREPARED STATEMENT OF MICHAEL WEINSTEIN, PRESIDENT, L.A. AIDS HEALTHCARE FOUNDATION

My name is Michael Weinstein, and I am President and co-founder of AIDS Healthcare Foundation (AHF), the largest community provider of HIV medical and residential services. It is a leader in HIV medicine and has distinguished itself by detecting trends and taking action, particularly when emerging patterns of disease have a major impact on the quality and delivery of care. This philosophy permeates its outpatient healthcare clinics as well as its residential nursing facilities, generally referred to as Houses.

I am here to request your assistance in funding two demonstration projects of national significance: A Comprehensive Residential Care Treatment Facilities Project for people with HIV/AIDS—and a Medicaid Managed Care Initiative for HIV/AIDS victims.

COMPREHENSIVE RESIDENTIAL TREATMENT FACILITIES INITIATIVE

AHF is engaged in the transition from exclusively hospice care to adding skilled nursing care at the houses and will continue to serve those regardless of their ability to pay and is seeking \$3.5 million for the project which could be funded by the Healthcare Financing Administration and/or the Health Resources and Services Administration. Presently, over 70 percent of the 50 beds operated by AHF are Skilled Nursing/stepdown care (aggressive treatment) beds under the state of California's Congregate Living Health Facilities (CLHF) licensure. About 30 percent are hospice (palliative) beds. A year ago, 100 percent of the beds were hospice care. With the introduction of more effective anti-HIV retro viral therapies, the hospice population began to dramatically decrease while the skilled nursing need population continuously grew. AHF will be re-opening Chris Brownlie House, its third facility in May, 1997. We expect an even higher ratio of residents at Brownlie housed under the CLHF/Skilled nursing need program. The houses are strategically located in three of the major HIV/AIDS epicenters: Downtown, West Hollywood and South Central Los Angeles. The demographics in these areas represent a mixture of ethnic, gender, sexual orientation, drug users, socio-economic, cultural and linguistic diversity.

AHF houses presently operate three programs: Hospice, Skilled Nursing (Intermediate/step down care), and ARV (anti-retro viral) Drug Monitoring.

*Hospice*

AHF opened the first AIDS Hospice in the nation when it founded the Chris Brownlie House in 1988. Many national international models have been patterned after Chris Brownlie, creating a network of facilities where people with AIDS have died with dignity and comfort. Hospice is a multi-disciplinary program involving the disciplines of medicine, nursing, pharmacy, bereavement, spiritual psycho-social, dietary, and psychiatry. This is supplemented by energetic volunteer and activities programs. All admitted residents under must be certified by a physician and have a life span prognosis of six months or less. On an average, AHF had three times as many residents die in the first six months of 1996 than in the second semester. Although this population is presently shrinking, the impact is still very palpable at our facilities.

*Skilled Nursing Care*

The Skilled Nursing program formally began at all three facilities in May, 1996. Any individuals who have a continuous-to-intermittent skilled nursing need qualify for this program. The majority of our residents at the AHF houses qualify for this type of care. Some of these skilled nursing needs may include, but are not limited to, a combination of the following: wound care, tracheotomy/nasal catheter maintenance, gastronomy or other tube feeding, comatose or bedridden, incontinence, IV therapy, complex drug regimen monitoring, skin conditions such as decubitus ulcers, or acute pulmonary conditions. This program is also multi-disciplinary in nature with much more emphasis on the medical and clinical aspects of care. Neither Medi-

Cal nor Medicare provide reimbursement for this type of need. It is also unusual for private insurance entities to compensate for this service.

*Anti-retro viral Drug Monitoring*

The ARV drug monitoring program at the AHF houses officially began on April 1, 1997. This inpatient drug adherence program is designed to start off or to support individuals who have issues of compliance with their "HIV cocktail" therapy, and who do not have a supportive home environment. The goal is to alter their behavior and inculcate positive drug regimen habits. In addition to the in-house disciplines of medicine, psycho-social, dietary, and psychiatry, AHF will integrate outside support on which the resident will depend once this 4-8 week program ends. This includes the resident's significant others, family and close friends, and other community-based organizations involved in housing, treatment advocacy, case management, outpatient support groups, job developers and career counselors. Multi-disciplinary protocols have already been developed addressing the variety of issues and populations associated with this program. The goal is to have the patient internalize successful treatment adherence strategies with the purpose of putting the virus in remission and medically stabilize these individuals. Many of them are slated to return to work.

AHF started to make the transition over two years ago from exclusive hospices, where individuals who had a prognosis of six months or less to live, to adding skilled nursing care. Hospice does not attempt to "cure" the underlying disease. Instead, it is designed to relieve symptoms and pain of the end stage disease, allowing it to follow its normal course without an aggressive or interventionist approach; therefore concentrating on the quality of life. In HIV, however, aggressive anti-viral therapy is many times the best way to provide palliative care, as it could enhance quality of life. For instance, AZT is considered aggressive therapy as it is an anti-retro viral. It is also one of the most effective drugs that penetrate the central nervous system and therefore it is utilized to ameliorate dementia and relieve symptoms. What we started to see over two years ago was that some patients would get better and were ready to be discharged but did not have appropriate places to go, with their chronic condition, they were too healthy to go an acute hospital-like setting, but too fragile and still in need of skilled nursing care for a board and care facility. They needed a sub-acute/intermediary type of program that would handle their non-acute but chronic condition. The choice was expensive hospitalization or board and care living arrangements. The first choice was too intensive and the second unprepared to handle this level of care. Many times individuals would be released to residential facilities, home shelters, or previous home situation regardless of availability of home support. This resulted in a return to the hospices in much worse shape than when they had left. Their situation went from a stabilized chronic condition to that of recurrent acute episodes requiring either hospitalization or skilled nursing, starting the cycle all over again.

AHF formalized its intermediary/skilled nursing care program in May, 1996 to better serve this growing but unattended population. These individuals must show a skilled nursing need and have an estimated life expectancy of five years or less. They may need skilled nursing intervention such as but not limited to those listed in the skilled nursing need section above. Once these individuals are stabilized from an acute episode to a relieved or a manageable chronic status, they are moved to an appropriate level of care within or outside the AHF system of care when available. Many of these individuals are referred from the among 3,000 patients presently managed through AHF's outpatient healthcare centers. The need has shifted from hospice to skilled nursing need. However, the funding sources have not followed this shift.

With the ARV drug monitoring program, AHF is again innovating to meet a growing need. The consequences of either not starting combination therapy or starting without the appropriate guidance and support could be disastrous for the individual and other individuals with whom they might have an HIV high risk involvement. There is a tremendous fear among healthcare providers that individuals who have false starts with anti-retro viral combination therapy may develop a resistant strain of the virus, which in essence will make current therapies impotent. Furthermore, this strain may be directly passed on to an HIV negative person in the usual transmission modes of bodily fluids exchanges such as semen, mother's milk, or blood. This newly infected person will also be unresponsive to existing anti-retro viral therapy. Some providers throughout the nation are beginning to ration and deny these medicines to those individuals who have issues with compliance and depriving them of these life-saving medicines. We want to provide an effective program that can start them off and keep them on track with their new drug regimen. A successful

program like this will result in stabilizing their health and in many cases a return to work.

AHF wants to enhance this model and use it as a demonstration project for replication in other areas of the country. Some needed upgrades include augmented staff training to keep up with the fast developments in HIV medical therapy, facility upgrade to qualify for Medicare certification and diversify funding, and equipment enhancement to address the multiple needs of this population. The intent of the AHF Houses program is to medically rehabilitate individuals who are able to go back to less intense level of care or gainful employment once they have gone through either the skilled nursing and/or the drug adherence programs. AHF believes that some transition funds will go a long way in making this program stable and financially feasible once some basic infrastructure is in place.

This proposal requests programmatic funds to finance uncompensated care for the first two years of this National Demonstration Project for Comprehensive Residential Treatment Facilities for People with HIV/AIDS. With this initial funding, AHF expects to continue the financing of this program by upgrading its facilities to meet various certifications so it could have access to other sources of governmental, corporate, foundation and private funding.

#### *Staffing*

Given the pace of HIV treatment therapy, it is crucial not only to have an upgraded facility that meets the needs of licensing and payor source agencies, but also the latest training and knowledge. With the introduction of protease inhibitors, the field of HIV has become more complex than ever. The advent of a newer generation of drugs and assessment assays ranging from viral load measurement to tests detecting viral resistance to a particular drug by genotyping, will only increase demand for providing sophistication. It is a challenge to organize all this knowledge and create a systematic program that leads to effective training and development. An organized team of staff members solely dedicated to this task of on-going training and development is very crucial for the success of this program. These individuals will also collect and categorize the body of knowledge gained through the planning, implementation and evolution of this program. This information could be of tremendous value to institutions throughout the United States. This component is estimated to cost \$304,000 for the first year and \$315,000 for the second year.

This uncompensated care is estimated to cost \$2,070,850 the first year and \$872,350 the second year. Both components, the staffing and uncompensated care, total \$3,568,200 for two years.

After the re-opening of Chris Brownlie House, AHF will be operating 66 beds with a total annual budget of \$6,830,974. Previous to the shifts of population from Hospice to skilled nursing care, in addition to Los Angeles County Ryan White Care Act and County net funds, the revenue requirements were supplemented by Medi-Cal, Medicare, and private insurance payments. Neither of the latter three streams of revenue finance skilled nursing or ARV drug monitoring, leaving a temporary hole in our budgets until the facilities are upgraded to meet skilled nursing Medicare requirements and have the ability to access other sources of revenue. AHF estimates a two year period for the completion of this process.

#### MEDICAID MANAGED CARE INITIATIVE

Managed care programs can provide quality health services and can also manage costs for services to HIV infected if such programs are designed to provide specialized care. The Committee is aware of efforts by the Health Care Financing Administration (HCFA) to respond to emerging combination drug therapies which have been credited with forestalling the onset of illness and therefore disability among the HIV-infected. Demonstration projects extending Medicaid services to individuals with HIV who currently do not qualify for Medicaid for lack of disability could assist in delaying and even preventing disability among individuals who might otherwise develop disability. AHF has demonstrated two years of experience in providing such services to the disabled in a managed care environment, but is precluded from offering such services to the non-disabled, a population which is rapidly incurring higher medical costs as a result of promising new treatments. AHF will reach out to an estimated 4,000 non-disabled individuals who currently are not participating in the existing Medi-Cal AIDS managed care program but who would receive a higher level of medical services through the continuous quality improvement mechanism in AHF's managed care program in a manner which seeks to control increases in costs through capitated rates. We hope that the Committee will encourage the Health Care Financing Administration (HCFA) to consider a demonstration project proposal from AIDS Healthcare Foundation in California for a managed care program for

persons with HIV who would otherwise not qualify for Medicaid services because of lack of disability.

Thank you for your consideration. I will be happy to answer any questions you may have.

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PREPARED STATEMENT OF DR. RAYMOND E. BYE, JR., ASSOCIATE VICE PRESIDENT  
FOR RESEARCH, FLORIDA STATE UNIVERSITY

Mr. Chairman, thank you and the Members of the Subcommittee for this opportunity to present testimony. I would like to take a moment to acquaint you with Florida State University. Located in the state capitol of Tallahassee, we have been a university since 1950; prior to that, we had a long and proud history as a seminary, a college, and a women's college. While widely-known for our athletics teams, we have a rapidly-emerging reputation as one of the Nation's top public universities. Having been designated as a Carnegie Research I University several years ago, Florida State University currently exceeds \$100 million per year in research expenditures. With no agricultural nor medical school, few institutions can boast of that kind of success. We are strong in both the sciences and the arts. We have high quality students; we rank in the top 25 among U. S. colleges and universities in attracting National Merit Scholars. Our scientists and engineers do excellent research, and they work closely with industry to commercialize those results. Florida State ranks seventh this year among all U. S. universities in royalties collected from its patents and licenses. In short, Florida State University is an exciting and rapidly-changing institution.

Mr. Chairman, last year, Florida State University (FSU) and the University of Miami (UM), jointly submitted two collaborative NIH projects to this Subcommittee seeking your support. As background, in June 1996, the Presidents of FSU and UM signed a unique research and education partnership. Two of the areas identified for collaboration were risk assessment activities and structural biology and magnetic resonance technologies. Last year, this project received strong supportive language from your Subcommittee. We greatly appreciate the past support for this joint venture and look forward to your continued support for our efforts in fiscal year 1998. Let me briefly describe these two collaborative projects.

The FSU/UM Risk Assessment and Intervention Consortium is dedicated to reducing the medical and social costs of health care through the development of cost efficient, behaviorally effective interventions. The Consortium is currently focusing its efforts on two specific activities. First, the Consortium is developing strategies to assess the access, medication compliance, and transmission risk implication of the new antiretroviral protease inhibitor therapies for various HIV infected populations. These new therapies represent a major step forward in efforts to reduce the onset of AIDS and the incidence of AIDS-related mortality. These medications have been effective in reducing and regulating viral load in HIV-infected patients to the point where many can lead more productive lives. While the advantages of these therapies are clear, they also have constraints. First, to be effective, patients must adhere to strict and complex treatment regimens. Second, although the protease inhibitor therapies are effective treatments to prevent the onset of AIDS and reduce and control viral load, they do not prevent HIV-infected persons from transmitting the virus. The characteristics of many HIV-infected persons suggest a difficulty in maintaining compliance. Thus, as health is restored, behaviors that could put the individual and others at risk must be examined.

The projects proposed are divided into two phases. The primary objectives of phase one are to identify the factors that contribute to non-compliance of medication regimens, and to investigate the types and frequencies of risk and risk reduction behaviors engaged in by HIV-infected persons. The accomplishment of phase one objectives will allow our team to move toward the development and testing of further medical compliance and risk reductions models in our second phase of this project.

The second area of focus for the Consortium is adolescent substance use. Substance use among adolescents is frequently associated with other health risk behaviors and has costly long-term implications. Data from two recently-released national surveys show that substance use is increasing among adolescents, that the age of first use has become younger, and that adolescents are increasingly viewing substance use as an acceptable behavior. These patterns of behavior and attitude prevail across all categories of drugs, and arose after the Drug Abuse Resistance Education (DARE) program had been introduced across the country. Current trends—coupled with several independent evaluations of the DARE program and its lack of theoretical grounding—clearly indicate that the DARE program is not an effective intervention program. A proposal is being developed which will allow the Consor-

tium to develop and test alternative interventions for adolescent substance use and associated risk behaviors.

Funding is being sought for the Risk Assessment and Intervention Consortium at the \$4 million level for fiscal year 1998 through the Department of Health and Human Services.

Our second SSU-UM collaborative effort involves structural biology and magnetic resonance technologies. With this collaboration, the universities, along with the National High Magnetic Field Laboratory (NHMFL), will initiate a major research and instrumentation effort that is built around macromolecular structure and functions—research key to drug development, delivery, and aspects of molecular function and binding—all of which are critical to many medical areas.

The FSU/UM collaboration, working closely with the NHMFL, and, with the aid of NMR instrumentation, will maximize the vast potential for biomedical research, training, and clinical utilization of magnetic resonance imaging (MRI), cellular and structural biology, and a broad range of other exciting research initiatives. Further, it is our long-term intent to establish a national network, where universities throughout the United States can benefit.

To help facilitate a nationwide program, the collaborators will first create a State-wide demonstration project, directed at the establishment of a high speed data network to support the use of shared instrumentation and human resources. This network will provide an opportunity to develop and test required human and hardware interfaces and protocols critical to the successful implementation such a concept. This initiative will serve as a demonstration for a larger network linking most universities in the United States to the NHMFL and the establishment of a national “collaboratorium” for shared instrumentation and resources.

Funding is being sought for this Magnetic Resonance network from the National Institutes of Health at the \$4 million level for fiscal year 1998.

Having concluded the discussion regarding the FSU/UM collaborations, I would like to discuss, FSU’s proposed, Rosa Parks Institute in Civil Liberties. The purpose of the Institute is to develop, produce, and disseminate programs and materials that not only highlight diversity but forge positive change in the work and school environments. Consistent with the life and works of Mrs. Parks, the Institutes’ ultimate objective is to assist individuals in realizing and achieving their highest potential.

The Institute will incorporate various projects including the following: A leadership development activity that will utilize individuals at mid-career who have dedicated their lives to actualizing the ideals of positive values at home, school, and the workplace. These individuals will become mentors and role models in this effort. Next, a university and community collaboration will include working with various partners such as civic organizations, educational institutions, business, and industry in order to promote educational dialogue concerning human rights, organizational, and societal change, and the importance of volunteerism. Thirdly, an oral history activity will focus on gathering direct personal perspectives from several leaders in the civil rights movement on their assessments of our past, present, and future with regard to racial diversity. Finally, a distance education technology program which will promote cultural diversity programs that can be utilized in education and employment settings.

The Institute will present a broad range of programs comprised of short courses and lectures which will be delivered both at the Institute and at remote sites around the Nation. New technologies will be crucial in the delivery and assessment of the programs. A Website Clearinghouse will be established for individuals, schools and businesses, around the country, to disseminate information provided by the Institute. Further, the Institute will obtain feedback, via the website, from participants to evaluate the effectiveness of the programs that are offered.

Funding for the Rosa Parks Institute in Civil Liberties is being sought from the U.S. Department of Labor at the \$1 million level. Mr. Chairman, these activities discussed will make important contributions to solving some key problems and concerns we face today. Your support would be appreciated. And, again, thank you for the opportunity to present these views for your consideration.

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PREPARED STATEMENT OF CYRUS M. JOLLIVETTE, VICE PRESIDENT FOR GOVERNMENT RELATIONS, UNIVERSITY OF MIAMI

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity to present testimony on behalf of the University of Miami and Florida State University. Both of the institutions which I represent today are deeply appreciative of your leadership, Mr. Chairman, and the Subcommittee’s confidence. At no time in the past have you and your colleagues on the Committee on Appropriations faced more

difficult constraints. Yet I am certain that you will continue to make the difficult choices with the best interests of the nation guiding your decisions. My colleagues and I hope that you will find it possible to fund the important initiatives in fiscal year 1998 detailed below.

First, the University of Miami has embarked on the construction of one of the major children's research facilities in the nation, a state-of-the-art research building to house all basic and clinical research for the Department of Pediatrics in the University of Miami/Jackson Memorial Medical Center. The goals and mission of the facility are for the benefit of the children of Florida and the nation. We seek to create a children's clinical and basic research center of unmatched excellence, to facilitate consolidated, coordinated, interdisciplinary research efforts in pediatrics, and to study, treat, and ultimately cure childhood diseases.

Through the Department of Health and Human Services, the University seeks a \$5 million project grant which will be leveraged with \$40 million in private contributions to construct a state-of-the-art pediatric research facility in Miami's urban core.

The \$45 million facility will contain 145,000 square feet. The facility will contain outpatient research facilities for broad ranging clinical investigations including AIDS, cystic fibrosis, asthma, other lung problems, genetics, behavioral sciences, gastroenterology, endocrinology, critical care, neonatology, maternal lifestyles (and their effects on children), clinical research in Touche and many others.

Major space will be allocated for parent/patient education, in addition to extensive education programs of medical students, house-staff, and fellows in all areas of pediatric medicine. State-of-the-art laboratories are planned for cardiology, critical care, cancer, endocrinology, gastroenterology, neuromuscular genetics, infectious diseases/immunology, AIDS, pharmacology/toxicology, neonatal, pulmonary (asthma and cystic fibrosis), core facilities, shared research, and a vivarium.

The University of Miami Environmental Health Sciences Center has two themes: Marine Toxins and Dietary Risk, and Marine Models of Human Disease. Center programs are well developed, and successful Pilot Projects continue to fuel the increase in interdisciplinary productivity. Facilities Cores provide standardized marine toxins, aquacultured marine organisms as models, an experimental manipulations core of sophisticated analytical and molecular technology, and electrophysiology. Two Research Cores provide for interactive research and discussion, and for development and implementation of new research and education programs.

Within the Marine Toxins and Dietary Risk research area, research interests span the five types of marine toxins and draw on the expertise of 6 investigators in molecular enzymology, ligand (toxin)—receptor (ion channel, enzyme, or chemoreceptor) interactions, orphan receptor biochemistry, molecular pharmacology, electrophysiology, site mutagenesis, organic chemistry, computer simulation, and molecular modeling. The ultimate goal is to define each intoxication syndrome at the molecular level, and develop diagnostics and therapies. With the advent of Hazard Analysis Critical Control Point (HACCP) Programs, which require certification of seafood as being safe for consumption, the mechanisms we discover and the tests we develop will provide a science-based solution to an increasing human health hazard.

The Center has been designated by NIH as a national resource for the high quality toxin standards it produces, and for the molecular toxin probes it has used to describe the molecular aspects of toxin action. The toxins under study represent some of the most potent pharmacological agents known. Of six classes of toxins, four interact with voltage-gated sodium channels, one interacts with mammalian protein phosphatases, one binds to central nervous system glutamate receptors, and all are effective in the nanomolar to picomolar concentration ranges. It is a long-standing goal of several Center investigators to use collaborative studies to unravel the biophysical aspects of toxin action, and to describe their deleterious effects on humans.

The Marine Models of Human Disease component involves 7 faculty. The systems they study include: model systems of Damsel Fish for Human Neurofibromatosis (NF1); *Aplysia* as models for developmental neurotoxicology (currently used as models for memory and learning) and as a general model of neurotransmission and synaptic transmission; and immune function in damselfish and in sharks, and transgenic research in zebrafish to study enzyme induction. Non-mammalian models have proved invaluable in studies of memory and learning, neurophysiology, and cancer. Development of marine species as models of human disease require tight integration of basic physiology and biochemistry with ecology and animal life history. The use of marine animals in research reduces the use of higher warm-blooded vertebrates, and provides systems for study that can address issues of cancer, liver disease, neurodegenerative disorders, and maladies of the immune system.

The Center provides a national resource for the culture of *Aplysia*, an excellent invertebrate model of memory and learning. Through the further development of

this model, Center investigators have the unique opportunity to provide a new mechanism for studying developmental learning disabilities, neurotoxicology, and deficiencies of memory like Alzheimer's disease.

What we propose is fundamentally different, and is based on a model of integrated 'crossover-training'. We propose to support postdoctoral students for up to three years. The trainees will be principally located within one department, but will address ongoing, interdisciplinary problems through their selected paired investigators and through Center interaction. Trainees may take formal courses as non-degree students and attend seminars in their home and secondary departments to broaden their background, but the principal training will be at-the-bench.

Interdisciplinary training will not weaken their knowledge of their primary discipline; on the contrary, it will broaden it by bringing new ideas and new ways of thinking into the mind of the trainee. Such individuals will then enter the workforce (academic, government, or industry) with a unique spectrum of interdisciplinary training that equips them to undertake a broader spectrum of problems and to interact with a wider range of colleagues than more traditionally schooled graduates.

Within the context of research, we believe the research aspects that deal with the interdependence of scientists in studying a common set of problems would provide the most efficient use of funds. That is to say, those investigators who can provide (or appreciate) a variety of viewpoints towards solving public health problems are most valuable to Society. The marine seafood toxins problem provides an ideal avenue for such interaction and delivery of a useful set of "products" to the consuming public. These "products" are returned to the taxpayer in the form of toxin test kits that can be used by industry to accurately identify potential human health hazards in seafood while at the same time protecting the industry from litigation; toxin tools that can be used in diagnostic and clinical settings; trained interdisciplinary scientists and physicians who can provide a holistic approach to human health and who can provide the science-based leadership and advice to industry, academia, congress, and the public; research aimed at providing the molecular mechanism of the toxins, thereby instigating the development of therapies and potential new drugs. The University seeks \$3 million to support this initiative.

Next, through the Department Health and Human Services, the University seeks to establish a Diabetes Research Center to marshal the expertise and resources in diabetes, immunology, transplantation, and of the closely affiliated Miami VA Medical Center, Jackson Memorial Hospital, and the University of Miami School of Medicine's Diabetes Research Center.

This partnership in one of the nation's largest academic medical centers will contribute greatly to the enhancement of diabetes care at the Miami VA Medical Center and stimulate and facilitate multidisciplinary research in diabetes at the Diabetes Research Center. The VA/JMH/UM Medical Center is the only tertiary care academic medical center in South Florida, with a patient catchment area embracing more than 5 million people, as well as a large and growing number of referrals from outside the region.

The University of Miami's International Center for Health Research is dedicated to improving controls on the emergence and migration of infectious diseases. The incidence of emerging and re-emerging infectious diseases has dramatically increased within the past two decades. The United States is vulnerable to these emerging and re-emerging diseases as evidenced by the advent of the HIV virus, and resurgence of tuberculosis, particularly in densely populated areas, and among ethnic minorities. Other infectious diseases have emerged, including malaria, dengue, and cholera. Introduction of these diseases into the United States is enhanced by increased air travel and migration among the countries of the Western Hemisphere, particularly from Latin America and the Caribbean.

Over the past year we have seen significant interest in early brain development and the importance of the early years in the lives of America's children. It is now well known, even to lay audiences, that the brains of children continue to develop after birth and the development is dependent to a large extent, on the early experiences of children. Parents can shape those early experiences and make a difference in their children's development. For many of America's children born with significant risk factors already associated with poor school-related outcomes, this means they will fail to arrive at school ready to learn. Unfortunately, with less than 36 months remaining until the year 2000, we have done little to meet the number one National Education Goals, established by the President and all 50 state Governors, which was: "By the year 2000, all children in America will start school ready to learn."

The Centers for Disease Control and Prevention sees the prevention of mental retardation and school failure as an important goal for the future and wants to focus

some of their energies on this topic. To this end they are interested in identifying the most cost effective means of providing early intervention to children who are likely to be at risk for these problems. The University of Miami has done several important studies that hold promise for effective outcomes with this population—for example, our recent work with children born to teenage mothers. Our findings demonstrated that short-term, cost effective intervention is possible and can have a significant impact on child outcomes. We encourage support of the budget and programs proposed by the Centers for Disease Control and Prevention as in turn, these will benefit all our nation's children, and particularly those who reside in Florida's urban and rural areas.

As background, in June 1996, the Presidents of Florida State and Miami formalized a unique research and education partnership. Two of the areas identified for collaboration were risk assessment activities and structural biology and magnetic resonance technologies. Last year, our collaboration received supportive language from your Subcommittee. We greatly appreciate the past support for this joint venture and look forward to your continued support for our efforts in fiscal year 1998. Let me briefly describe these two collaborative projects.

The UM/FSU Risk Assessment and Intervention Consortium is dedicated to reducing the medical and social costs of health care through development of cost efficient, behaviorally effective interventions. The Consortium is currently focusing its efforts on two specific activities. First, the Consortium is developing strategies to assess, the access, medication compliance, and transmission risk implication of the new antiretroviral protease inhibitor therapies for various HIV infected populations. These new therapies represent a major step forward in efforts to reduce the onset of AIDS and the incidence of AIDS-related mortality. These medications have been effective in reducing and regulating viral load in HIV-infected patients to the point where many can lead more productive lives. While the advantages of these therapies are clear, they also have constraints. First, to be effective, patients must adhere to strict and complex treatment regimens. Second, although the protease inhibitor therapies are effective treatments to prevent the onset of AIDS and reduce and control viral load, they do not prevent HIV-infected persons from transmitting the virus. The characteristics of many HIV-infected persons suggest a difficulty in maintaining compliance. Thus, as health is restored, behaviors that could put the individual and others at risk must be examined.

The projects proposed are divided into two phases. The primary objectives of phase one are to identify the factors that contribute to non-compliance of medication regimens, and to investigate the types and frequencies of risk and risk reduction behaviors engaged in by HIV-infected persons. The accomplishment of phase one objectives will allow our team to move forward the development and testing of further medical compliance and risk reductions models in our second phase of this project.

The second area of focus for the Consortium is adolescent substance use. Substance use among adolescents is frequently associated with other health risk behaviors and has costly long-term implications. Data from two recently-released national surveys show that substance use is increasing among adolescents, that the age of first use has become younger, and that adolescents are increasingly viewing substance as an acceptable behavior. These patterns of behavior and attitude prevail across all categories of drugs, and arose after the Drug Abuse Resistance Education (DARE) program had been introduced across the country. Current trends—coupled with several independent evaluations of the DARE program and its lack of theoretical grounding—clearly indicate that the DARE program is not an effective intervention program. A proposal is being developed which will allow the Consortium to develop and test alternative interventions for adolescent substance use and associated risk behaviors.

Funding is being sought for the Risk Assessment and Intervention Consortium at the \$4 million level for fiscal year 1998 through the Centers for Disease Control and Prevention.

The second UM-FSU collaborative effort involves structural biology and magnetic resonance technologies. With this collaboration, our two universities, along with the National High Magnetic Field Laboratory (NHMFL), will initiate a major research and instrumentation effort that is built around macromolecular structure and functions—research key to drug development, delivery, and aspects of molecular function and binding—all of which are critical to many medical areas.

The UM/FSU collaboration, working closely with the NHMFL, and, with the aid of NMR instrumentation, will maximize the vast potential for biomedical research, training, and clinical utilization of magnetic resonance imaging (MRI), cellular and structural biology, and a broad range of other exciting research initiatives. Further, it is our long-term intent to establish a national network, where universities throughout the United States can benefit.



To help facilitate a nationwide program, the collaborators will first create a state-wide demonstration project, directed at the establishment of a high speed data network to support the use of shared instrumentation and human resources. This network will provide an opportunity to develop and test required human and hardware interfaces and protocols critical to the successful implementation of such a concept. This initiative will serve as a demonstration for a larger network linking most universities in the United States to NHMFL and the establishment of a national "collaboratorium" for shared instrumentation and resources. We seek funding for this Magnetic Resonance network at the \$4 million level for fiscal year 1998 through the National Science Foundation.

Mr. Chairman, my colleagues and I know what a difficult appropriations year you face. However, again, we respectfully request that you give very serious consideration to these projects so that the research progress already made is not lost. In the long-term, these national investments will provide continuing dividends in our mutual search for cost-effective solutions for the nation's problems.

PREPARED STATEMENT OF JOE L. MAUDERLY, SENIOR SCIENTIST AND DIRECTOR OF  
EXTERNAL AFFAIRS, LOVELACE RESPIRATORY RESEARCH INSTITUTE

It is proposed that the Department of Health and Human Services (HHS) play a participatory role in an interagency effort to establish and maintain a National Environmental Respiratory Center for the purpose of integrating research and information transfer concerning health risks of breathing airborne contaminants in the environment. The support of HHS through NIH, NIEHS, and CDC/NIOSH for the Center's research is requested, along with support from other Agencies, to fulfill its mandate for understanding and mitigating disease and health risks from occupational and environmental, exposures to toxic agents.

THE ENVIRONMENTAL RESPIRATORY HEALTH DILEMMA

*U.S. Health Burden of Respiratory Disease*

The magnitude of the national health burden caused by respiratory diseases is not widely appreciated. These diseases now kill one out of four Americans. Among cancers, the second leading cause of death, lung cancer is the single largest killer. Nearly 195 thousand new cases of respiratory tract cancer will be diagnosed this year, and 166 thousand Americans will die from these cancers. Lung cancer kills more than twice as many women as breast cancer, and more than twice as many men as prostate cancer. Pneumonia and heart-lung failure are the terminal conditions for many of our elderly. Excluding cancer, chronic respiratory diseases and pneumonia are the third leading cause of death in the U.S., killing over 188 thousand Americans in 1995. Asthma, growing unaccountably in recent decades, now afflicts 15 million Americans, including 5 million children. The incidence of asthma increased 61 percent between 1982 and 1994, and asthma deaths among children nearly doubled between 1980 and 1993. Viral respiratory infections are the most common cause of hospitalization of infants and cause a tremendous loss of productivity in the adult workforce. Occupational lung disease is the number one work-related illness in the U.S. in terms of frequency, severity, and degree of "preventability". Worldwide, three times more people die from tuberculosis than from AIDS.

*Critical Uncertainties Regarding Contributions of Airborne Environmental Contaminants*

Pollutants inhaled in the environment, workplace, and home are known to aggravate asthma and contribute to respiratory illness, but the extent of their role in causing respiratory disease is not clear. It is known that it is possible for airborne irritants, toxins, allergens, carcinogens, and infectious agents to cause cancer, degenerative disease, and infections directly, or indirectly through reduction of normal defenses, but the portion of such diseases caused by, or strongly influenced by, pollution is uncertain.

We are repeatedly faced with estimating the health effects of environmental air pollution on the basis of very limited information and in the presence of large uncertainty. For example, environmental radon gas is estimated to be the second leading cause of lung cancer (after smoking), but this estimate comes from our experience with uranium mining, in which the exposure conditions and exposed population were quite different from those in the general environment. As another current example, it is estimated that as many as 40 thousand Americans may die annually from breathing particulate environmental air pollution, but this estimate comes from epidemiological data that do not provide a clear understanding of individuals who were affected, the nature and magnitude of their exposure, the biological proc-

esses by which death might have occurred, or the extent to which the effects of particles were independent of other pollutants.

It is difficult to associate health effects with specific pollutant sources. Most environmental air contaminants have multiple sources which produce species of overlapping, but slightly different physical-chemical types. There are few biological markers of exposure which can be used to link health effects to past exposures to pollutant classes, much less to specific pollutants and sources. This makes it very difficult to associate specific pollutant species with specific health effects, identify and prioritize the sources whose management would most efficiently reduce the effects, and compare potential health gains to the financial, technological, and lifestyle commitments required to achieve them.

We presently have little scientific or regulatory ability to deal with pollutant mixtures. It is recognized that all exposures to air pollutants involve inhalation of complex mixtures of materials, but there is very little research on the health effects of mixtures, or the significance of interactions among combined or sequential exposures to multiple pollutants. Air quality regulations address individual contaminants, or contaminant classes, one at a time. We know that multiple pollutants can cause common effects, such as inflammation. We know that some pollutants can amplify the effects of others. We can presume that a mixture of pollutants, each within its acceptable concentration, could present an unacceptable aggregate health risk. We face the possibility that a pollutant occurring in a mixture might wrongly be assigned sole responsibility for a health effect that, in fact, results from the mixture or an unrecognized copollutant that varies in concert with the accused species. The mixture issue will become increasingly important as pollutant levels are pushed ever lower, and needs coordinated, interdisciplinary attention.

As air pollutant levels are reduced, the problems of correctly linking health effects to the correct species and sources, and of making difficult cost-benefit judgments, will increase. The levels of many environmental air contaminants have decreased due to technological developments and regulatory pressures. For example, between 1985 and 1995, concentrations of airborne lead, sulfur dioxide, and carbon monoxide in the U.S. decreased 32 percent, 18 percent, and 16 percent, respectively, and levels of airborne particulate matter decreased 22 percent between 1988 and 1995. Levels of ozone and other pollutants have also decreased. As background levels are approached, decisions regarding: (a) the benefits of further reductions in man-made pollution; (b) the need to consider pollutants as a mixture rather than as individual species; and, (c) the point at which small biological changes represent health effects warranting control, will become more difficult and will require more focused, coordinated research.

We are repeatedly faced with estimating effects in particularly sensitive or susceptible subpopulations. For example, the proposed new National Ambient Air Quality Standards for ozone and particulate matter are driven largely by effects thought to occur in exercising asthmatics and elderly people with heart-lung disease, respectively. It is seldom appropriate to conduct studies in which adverse effects are intentionally elicited in the most sensitive people. Until recently, there has been little emphasis on developing laboratory animal models of human heart-lung conditions thought to render people susceptible to pollutants. More emphasis needs to be given to developing and validating these research tools, and to coordinating such efforts across agencies and research disciplines.

HHS and other agencies repeatedly face uncertainties regarding the relevance of laboratory results to human health risks. As one of several examples, uncertainties about the relevance of the lung tumor response of rats to inhaled particles to human lung cancer risk has complicated hazard identification and risk assessment activities. Much of our understanding of the toxicity of inhaled airborne materials comes from studies using animals and cells to identify toxic agents, understand biological responses, and determine relationships between dose and effect. Such studies produce detailed information on the response of animals or cells, but there is too little emphasis on ensuring that the responses are similar to those that occur in humans. Development of information having little relevance to humans wastes resources. The validation of responses of animals and cells used to provide the scientific basis for national energy and environmental policies needs to be given greater emphasis and coordination.

#### *Lack of Interagency and Interdisciplinary Coordination*

HHS does not have the mandate or resources to resolve all of these interrelated issues alone; the resources of other agencies and non-federal sponsors are critical. Current efforts are funded by HHS and other agencies, including DOE, EPA, FDA, DOD, and by health advocacy organizations, industry, labor, and private foundations. Existing coordinating activities within and among these groups do not provide

sufficient integration and synergism. Progress will require a wide range of laboratory researchers, atmospheric scientists, epidemiologists, and clinical researchers. Focusing and resolving the issues will require interactions among researchers, health care professionals, and policy makers in an iterative manner that fosters rapid information transfer and development of joint investigative strategies. There is no mechanism for national coordination of this interagency and interdisciplinary effort. As a result, some efforts are duplicated and some important issues are being inadequately addressed. The lack of a national center for focusing and facilitating this effort will increasingly create inefficiencies and impede progress.

There is no national center for collecting and disseminating information on the health impacts of airborne environmental contaminants. Researchers, federal agencies, congress, industry, and the public do not have a centralized source of information on ongoing research or recent findings.

There is no designated national interagency user facility with the specialized facilities, equipment, core support, and professional collaboration required for many types of investigations to study the complex airborne materials and health responses of concern. HHS provides specialized user facilities, and Investigators seek access to these other laboratories on an individual basis, but there is no coordinated national effort to facilitate the work of investigators in universities, federal laboratories, and industry by identifying and providing shared resources or standardized samples.

HHS and other agencies have intra-agency research centers and administrative structures that serve internal programmatic coordination needs, but these efforts rarely extend across agency lines. HHS funds laboratories and universities, and other agencies also fund extramural centers to study, or facilitate the study, of specific issues related to environmental respiratory health. For example, EPA's Mickey Leland National Urban Air Toxics Research Center funds research and information transfer on the class of compounds designated in the Clean Air Act as "air toxics". The Leland Center serves a useful coordinating and research sponsorship function for air toxics, but does not have the facility or scientific resources to meet the broader needs described above. NIEHS center grants at universities provide core support and coordinating functions for thematic collections of projects on occupational and environmental health, but again, are not suited to meeting the broader needs.

The lack of a national coordinating center is notable, considering its small cost compared to the loss of productivity, the reduction in quality of life, and the loss of life caused by respiratory diseases and considering the importance now ascribed to the role of environmental factors in respiratory disease.

#### THE NATIONAL ENVIRONMENTAL RESPIRATORY CENTER (NERC)

##### *Location and Staffing*

The Lovelace Respiratory Research Institute (LRRI) proposes to establish a national center to meet the coordinating, user facility, and information needs described above. The physical location of the NERC will be the government-owned Inhalation Toxicology Research Institute facility on Kirtland AFB in Albuquerque, NM. This facility is already developed at taxpayer expense, having been established by the DOE to conduct research on long-term health risks from inhaled radioactive particles. Having fulfilled that mission, the facility was recently released from DOE laboratory status, and is now leased by LRRI to conduct respiratory health research for federal agencies, industry, and private sponsors. This 270,000 square foot, world-class facility contains \$50 million in government-owned equipment, and has unmatched potential as a national user facility. The facility is well equipped and staffed for intramural and collaborative research on airborne materials of all types, including reproducing pollutant atmospheres, conducting inhalation exposures of animals, determining the dosimetry of inhaled materials, and evaluating health effects ranging from subtle genetic and biochemical changes to clinical expression of disease.

The interests and expertise of LRRI are well-matched to the proposed activities of the Center. While managing the facility for DOE, LRRI contributed heavily to our present understanding of the respiratory health impacts of airborne pollutants. LRRI has contributed heavily to the research cited as scientific basis for air quality regulations and worker protection standards. The group is well-known for its efforts to understand airborne materials, link basic cellular and tissue responses to the development of disease, validate the human relevance of laboratory findings, and coordinate complex interdisciplinary studies. The LRRI group has conducted the world's most extensive research program on the effects of combined and sequential exposures to multiple toxicants. The group is well-known for its participation in

HHS and other advisory roles, and for coordinating multidisciplinary and inter-institutional efforts.

LRRI envisions a "virtual center" that will also encompass nearby institutions and an expanding group of collaborating investigators nationwide. Academic affiliation with the University of New Mexico, primarily through its Health Sciences Center will extend research and training capabilities. Other local technology and collaborative resources include Sandia and Los Alamos National Laboratories, the National Center for Genome Resources, and the growing New Mexico biotechnology and clinical research communities. The NERC would interact closely with the Leland Center and with intramural research centers within EPA and other agencies.

*Principal Functions*

*Provide information resources.*—The Center will provide centralized information resources to researchers, HHS and other agencies, congress, industry, and the public. Literature searches, topical summaries, and answers to specific inquiries will be provided via the internet, electronic mail, and telephone. Emphasis will be given to providing access to relevant information nationwide through a single point of contact and assistance.

*Facilitate interagency and interinstitutional coordination.*—The Center will coordinate meetings, workshops, information transfer, and other activities aimed at integrating and prioritizing national research efforts and integrating results into useful summaries.

*Provide user facilities and facilitate access to research resources.*—The Center will disseminate information on the availability of specialized facilities, equipment, collaborative resources, and samples at the Center and elsewhere, and will facilitate the use of these resources by researchers in other institutions.

*Provide training.*—The Center will provide graduate training through the Toxicology, Biomedical, and Public Health programs at the University of New Mexico, and by hosting thesis research from other universities. Postdoctoral and sabbatical appointments will also be provided. Workshops and training courses will be conducted.

*Conduct and sponsor research.*—While it is envisioned that limited intramural research will be conducted with Center funding, intramural research will be principally funded by direct sponsorship of Agencies, industry, and the public through grants, contracts, and donations. Through the Center, extramural research aimed at critical information gaps not addressed by other sponsors will be funded.

FUNDING OF THE NATIONAL ENVIRONMENTAL RESPIRATORY CENTER

LRRI seeks authorization and subsequent appropriations through a lead agency for core funding, with complementary sponsorship through grants and contracts from HHS and other agencies for research aligned with individual agency mandates and strategic goals.

An initial appropriation of \$2 million per year for 5 years, beginning in fiscal year 1998, will establish the Center and its core information, educational, and administrative functions. This amount will provide for critical computing and communication infrastructure, and limited facility renovations and equipment acquisitions. This amount will provide very little intramural or extramural research support; additional support for these purposes will be sought in coordination with the lead sponsoring agency as the Center is established. The goal is to develop research support principally through sponsored programs, and to use the core Center support principally to provide coordinating and information services and sponsor limited collaborative research.

Support is sought from HHS through funding of related, independent research programs having special relevance to HHS' mission, and through such participatory support of the Center's core functions as established on an interagency basis.

PREPARED STATEMENT OF THE ORGANIZATIONS OF ACADEMIC FAMILY MEDICINE

Mr. Chairman, this statement is on behalf of the listed academic family medicine organizations in support of critical funding of family medicine training programs and research. Mr. Chairman, you and your committee have been extremely supportive of family medicine training programs in the past. We appreciate how difficult this past year has been for the committee and thank you for your continued support of our training programs. We know the fiscal year 1997 appropriations process will be just as difficult, with extremely hard choices. We ask that you continue to value the family medicine training programs under Title VII as federal funds targeted where they can do the most good. We believe that the small amount of funding

spent on Section 747, family medicine training, is money well spent. It is money that achieves its purpose—the production of generalist physicians, and ones who serve in rural and urban underserved areas. Moreover, this funding sows the seeds for a more cost-effective utilization of health care dollars in the future.

The organizations of academic family medicine ask this committee to support these programs at a new authorized and appropriated level of \$87 million for Section 747, family medicine training. Section 747 family medicine training funds are used to help develop and maintain an infrastructure for the production of family physicians. Funding is used for the establishment of departments of family medicine within medical schools, the development of third-year clerkships in family medicine for medical students, the training of family practice residents, and development of teaching and education skills for family medicine faculty.

There is good justification for this funding level. Our recommendation would provide funds for 60 new residency training programs, 15 new departments, 51 additional predoctoral programs, 900 new faculty and a number of collaborative demonstration projects. This recommendation is the result of a strategic plan for the future needs of family medicine developed by the Academic Family Medicine Organizations, which is represented by all five family medicine organizations. At the very least, we require the current fiscal year 1997 level of \$49.3 million for family medicine training plus inflation, (within a combined authority of \$302 million for all health professions programs), to maintain the production of needed family physicians.

*How Do We Know This Title VII Money Is Well Spent?*

Two Government Accounting Office (GAO), reports have addressed this question. A July 1994 report, states that “the programs were important for funding innovative projects and providing “seed money” for starting new programs. For example, Title VII was considered important in the creation and maintenance of family medicine departments and divisions in medical schools \* \* \*” (GAO/HEHS-94-164).

The GAO, in another, more recent report, states in October 1994, that “students who attended schools with family practice departments were 57 percent more likely to pursue primary care.” In addition, the report goes on to say that “students attending medical schools with more highly funded family practice departments were 18 percent more likely to pursue primary care and students attending schools requiring a third-year family practice clerkship were [also] 18 percent more likely to pursue primary care.” The money spent on Section 747 of Title VII is directly targeted in these areas. (GAO/HEHS-95-9)

Title VII has helped build much needed family medicine training capacity and quality. Here are just a few examples that illustrate the importance of these programs:

*Boston University (predoctoral and department establishment grants).—*A predoctoral grant over the last two years led to a major increase in programming associated with AHECs and community-based physicians. The grant had the effect of doubling class size of students going into family practice this year. This 100 percent increase made family practice the 2nd most popular career choice; up from 10th a year ago. Most importantly it resulted in the adoption of a required third-year clerkship in family practice; something the GAO found increased the choice of primary care careers by 18 percent. Boston University found the Department development grant to be critical in providing the groundwork for the successful initiation of a department of family medicine at the medical school, and attracting a highly regarded physician to chair the new department. The mission statement of the new department is directed toward education, research, and service to the underserved.

*University of North Carolina at Chapel Hill (residency grants).—*A series of residency grants to the University of North Carolina Department of Family Medicine has produced an impact on the institution and the surrounding health care system that would have been impossible without these grants. A grant-supported rural rotation, with practicing rural physicians as teachers, has led to rural preceptors taking care of their own patients in the university hospital on the Family Medicine service and participating in resident evaluation. These working relationships formed the essential groundwork for new joint initiatives now underway to develop a small-town birthing center and rural residency track. These grant-supported curricula also allowed us to leverage resources, such as links to the university medical center’s clinical information system, from the medical center to local community health centers. As a result, the impact of the training grants has extended well beyond their initial scope. More importantly, the percentage of residents going to underserved areas after graduation increased from an occasional graduate to over 50 percent (1995).

*University of Utah, (predoctoral education).—* The infusion of federal training funds for predoctoral education in family medicine facilitated the final approval for

a required third-year clerkship in family medicine. Without this support, this program would have been further delayed by several years. The third-year clerkship has clearly had an effect on student career choice. In the words of a third-year medical student who had just finished the four week experience in a rural site:

“This experience has ruined my life \* \* \* I came to medical school with no interest in family practice and had made a decision about a career choice. But this experience was so outstanding that I can’t imagine any other career path but family medicine. I know the deadline has passed to apply for the senior Student Honors Program in Family Medicine (which is also supported by the Title VII predoctoral training grant) but do you think I could get admitted.”

*Why is a continued and enhanced federal role necessary?*

Simply put, now is not the time to withdraw life-line funding from programs that are successfully meeting and achieving federal policy goals. America needs family physicians to provide care to all individuals, from cradle to grave, in all areas of the country, in a cost-effective, high-quality manner.

The Consensus Statement on the Physician Workforce<sup>1</sup> states that “It is likely that many traditionally underserved communities will continue to have an inadequate number of physicians, particularly generalist physicians [emphasis added], to meet the needs of the population.” The statement goes on to request that federal funds be provided to increase medical school student experiences in rural and inner city communities, and to call for “federal incentives to encourage students to pursue careers as generalist physicians and to establish practices in these communities.”

Although the need is great, the federal government has instituted conflicting incentives that have made it fiscally difficult to develop a family medicine infrastructure. Medicare reimbursement rates for procedural services, Medicare reimbursement for graduate medical education in a hospital setting, and the more than \$10 billion a year spent on NIH research all serve to induce the academic medical environment to produce significantly more subspecialists than primary care physicians. Given the current state of federal incentives, market forces alone are not enough to bring about the necessary changes in the time-frame needed. There is ample evidence of a tremendous unmet need for family physicians and other primary care physicians. The Physician Payment Review Commission, the Council on Graduate Medical Education, the American Medical Association and the Association of American Medical Colleges all advocate increasing the supply of generalist physicians. Now is not the time to dilute, or diminish, the only federal program designed to produce more family physicians.

Eighty percent of family practice residency programs are located in community hospitals, half of which have no other specialty residency. This is a key reason family medicine produces physicians who practice in all areas of the country, but also one of the reasons there is not a great deal of outside funding available to these programs. This is especially true because Medicare does not reimburse hospitals for graduate medical education (GME) training that occurs in the ambulatory setting—the hallmark of family medicine residency training. Not only does Medicare GME not reimburse programs for such training, but this type of training is more labor-intensive and more expensive than in-hospital training.

*Title VII family practice training funds are directly targeted to those programs producing graduates to serve in rural and urban underserved areas.*

Studies underway within HRSA (personal communication, Mar. 1997) indicate that if current levels of physicians in training for family practice continue, we will see an increase in the number of rural and urban family physicians by one third in the next decade. Family physicians are at least three times as likely as other generalists to locate in rural areas.

Currently half of the U.S. rural counties are shortage areas. We have approximately 35 family physicians per 100,000 people in rural areas. By the end of the next decade we expect to have 50 family physicians per 100,000 individuals, in rural America. This will go a long way toward alleviating current rural physician shortages, but is dependent upon future funding of family practice training programs.

<sup>1</sup>American Association of Colleges of Osteopathic Medicine, American Medical Association, American Osteopathic Association, Association of Academic Health Centers, Association of American Medical Colleges, National Medical Association.

*The need for support for faculty in family practice training*

The need for more faculty in family medicine departments of medical schools and residency programs, and the training of these faculty to be teachers, are key challenges currently facing our discipline. Currently, departments and third-year clerkships all over the nation are operating on less than full staff. Faculty in charge of predoctoral and other departmental activities are uniformly spread too thin and face burnout and exhaustion, while chairs and program directors scramble for additional faculty. When new hires are made, they are typically assigned to clinical work, not to academic or teaching responsibilities. Despite the challenges which these dedicated faculty face, their efforts are beginning to pay off in the increasing numbers of students who are experiencing family medicine clerkships and choosing family practice residency training. As we face the social and political pressures to produce more family physicians, faculty development is needed more keenly now than ever before to help recruit and train new faculty.

A survey study conducted in early 1994 by the Academic Family Medicine Organizations Steering Committee (AFMO) Family Medicine, February 1995) demonstrated a need for approximately 1,173 new family medicine faculty by late 1995. The authors found that family medicine is virtually the only discipline which needs new faculty, and commented that these new academicians must be "equipped with the necessary tools to build a successful academic career." A recent national survey of family medicine departments and residency programs shows that nearly 500 departmental and residency positions were unfilled in 1994, and that 700 faculty would be needed in the next two years. (Fam. Med. 1995; 27: 98-102). This situation is even more dire since we are experiencing at faculty shortages in a time of burgeoning student interest.

It is this faculty role to which Section 747 is crucial. Family medicine training funds are decisive in providing departments and residency programs with the minimum funding necessary to build the infrastructure needed to produce the family physicians needed to meet our nation's health care needs. The federal partnership with family medicine has been critical to the development of the discipline, which is still in its early stages. Now is not the time for the federal government to withdraw this much needed support.

*Title VII funds needed now more than ever to invest in development of innovative curricula.*

Preferential recruitment of family physicians requires a larger investment in family medicine education. A recent Journal of the American Medical Association<sup>2</sup> article described the increased need for family physicians this way "The continual rise in advertisements for family physicians suggests a delivery system preference for more broadly trained primary care physicians over physicians in other generalist fields." This is in addition to the marketplace being more interested in family physicians over specialists. This creates an even larger demand for "new, rigorously designed and evaluated curricula to teach skills essential to optimal practice in diverse managed care environments".<sup>2</sup> New, innovative curricular development historically has been an important part of Title VII funding, and needs to continue.

## AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR)

Also of great concern to the academic family medicine community is funding for the Agency for Health Care Policy and Research (AHCPR). AHCPR's mandate specifies clinical practice research to include primary care and practice-oriented research. Research funding availability is an important factor in increasing the number of physicians going into primary care medicine. We support at least \$25 million in funding dedicated to primary care research within the Agency for Health Care Policy and Research. This money should be targeted to the newly established Center for Primary Care Research. This supplemental funding, with direction from Congress, will urge AHCPR to devote increased attention to primary care issues.

It is estimated that less than \$10 million of the total federal investment in medical research is awarded to family medicine investigators. This has precluded family medicine researchers from developing vigorous investigational programs to guide family physicians and others in providing primary care. Consequently, while our country has invested in basic medical science research through NIH programs, there has been little support to answer questions of major concern to family physicians or to develop clinical applications from new basic science knowledge. As a con-

<sup>2</sup>Sarena D. Seifer, MD; Barbara Troupin, MD, MBA; Gordon D. Rubenfield, MD, "Changes in Market place Demand for Physicians", *JAMA*, Vol. 276, No. 9 (September 4, 1996), p. 698, 726

sequence, physicians in family practice although they provide the majority of care to the American people, have had little support in answering research questions arising from their own experience.

Accordingly, a primary care research agenda is crucial. The AHCPR recently committed itself to establishing a Center for Primary Care Research within the agency. Such a center, if adequately financed, would provide new tools to family physicians and other generalists as they serve hundreds of millions of patients each year. The agenda would include research to improve diagnostic accuracy and streamline the diagnostic process while at the same time reducing inappropriate use of expensive, unnecessary or potentially dangerous medical tests. Such research also would help primary care providers and subspecialists to better coordinate their efforts to provide a continuum of care to those patients with serious medical problems. Finally, much of primary care research focuses on the development and assessment of protocols of care that are intended to make the best use of this country's strained health care dollars.

Although a bit simplistic, one can look at primary care research as research into the best ways to implement the successes of biomedical research. In other words, how do we put the critical information derived from biomedical research to use in the population. This mandate to the agency has given hope that much needed primary care research would receive federal attention and support and be able to provide the nation with a great deal of information to help control costs of health care and improve, or reduce, morbidity and mortality. If we are ever to change the status quo in this country and examine the root causes of expensive and unnecessary medical care, research in family medicine and primary care is essential. This research has no home elsewhere in the federal government. We implore you to recognize the need for such a home and support the Center for Primary Care Research with dedicated funding within AHCPR.

#### RECOMMENDATIONS FOR FAMILY MEDICINE TRAINING AND RESEARCH

The Organizations of Academic Family Medicine have three main recommendations for the fiscal year 1998 Labor/HHS Appropriations bill. They are as follows:

- We ask that you continue your support for family medicine training, and bring the appropriations level for section 747 up to \$87 million for fiscal year 1998.
- We ask the committee to express, in its report, the need for designated funding for family medicine training programs, even in light of a single authorization for primary care training programs.
- In order to support critical practice-oriented primary care research we are asking that at least an additional \$25 million be targeted to the new Center for Primary Care Research at the Agency for Health Care Policy and Research.

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#### PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION

The American Psychological Association (APA) is pleased to have the opportunity to submit this testimony concerning the fiscal year 1998 appropriations for the Departments of Health and Human Services. APA represents 151,000 members and affiliates, many of whom conduct behavioral research funded by the National Institutes of Health, work in community programs funded by the Centers for Disease Control and Prevention, train the next generation of psychologists with funds from the Bureau of Health Professions, or who, in helping their patients reach their full potential, are otherwise affected by this subcommittee's funding decisions.

#### NATIONAL INSTITUTES OF HEALTH

Chairman Specter, APA commends your leadership, and the work of this Subcommittee, in sustaining the growth and accomplishments of the National Institutes of Health. The generous increases of the past two fiscal years have speeded progress in the prevention and treatment of disease and disability. APA supports the request of the Ad Hoc Group for Biomedical Research of 9 percent for NIH in the coming fiscal year.

Psychologists funded by the National Institutes of Health are conducting vital basic research on human development, perception and cognition, and applied research on the prevention of illness, management of chronic conditions, adherence to treatment regimens and rehabilitation. By one measure, NIH funds nearly one billion dollars in research on the connections between behavior and health. This is money well spent, since the World Health Organization's recent report, "The Global Burden of Disease," shows that worldwide, chronic conditions with major behavioral



components (i.e. ischemic heart disease, cancer, substance abuse, injuries) by the year 2020 will account for 73 percent of mortality, up from 55 percent in 1990.

Behavioral research is conducted by almost every Institute, Center and Division at NIH. The Office of Behavioral and Social Sciences Research (OBSSR) in the Office of the Director was established to coordinate this research, since behavioral and social factors contribute significantly to human health. OBSSR is making a strong contribution to NIH by facilitating cross-talk among the ICDs and making possible the pooling of resources to answer basic and applied behavioral and social questions that are relevant to more than one institute. One current example is a new Request for Applications on Strategies for Health Behavior Change, to which the National Cancer Institute and other ICDs have contributed, that will encourage research on health behaviors including sustaining improvement in diet and exercise habits. OBSSR has a modest budget, \$2.5 million in 1997. APA encourages the committee to allocate \$4 million for OBSSR in fiscal year 1998. This will substantially increase the ability of OBSSR to cofund interdisciplinary training programs (so that geneticists, for example, may learn behavioral research paradigms, and vice versa).

#### CENTERS FOR DISEASE CONTROL AND PREVENTION

APA also urges this Subcommittee's support for the Centers for Disease Control and Prevention (CDC). The CDC has led federal public health efforts to address behaviorally-based public health problems, such as community-based HIV/AIDS prevention, the spread of sexually transmitted diseases, accidental injury and death, violence, suicide, and many other issues. We urge the subcommittee to provide funding for these programs equivalent to the President's fiscal year 1998 budget request.

*National Institute for Occupational Safety and Health (NIOSH).*—Since 1971, NIOSH has conducted a sound program of research to improve worker health and productivity that is not duplicated by any other federal agency or private entity. In the area of workplace stress, for example, NIOSH has supported applied laboratory and field studies of risk factors for occupational stress, health and performance effects, and intervention strategies. Psychological disorders resulting from stress are among the nation's major workplace issues, affecting job productivity and health care costs. Stress-related absenteeism, lower productivity, medical insurance costs, and the re-hiring and re-training of workers result in estimated losses to U.S. businesses of more than \$150 billion each year. In response to these concerns, NIOSH has led the federal effort to explore ways to promote healthy workplaces and to create less stressful job sites. We urge Congress to provide sufficient support to NIOSH to expand these essential programs.

*HIV/AIDS Community Prevention Planning Program.*—AIDS-specific prevention efforts at CDC, as highlighted by the CDC Advisory Committee on the Prevention of HIV Infection, should shift from the past emphasis on counseling, testing, and partner notification programs toward the "front end" of the epidemic—that is, the development and implementation of behavioral technologies to reduce risk behaviors among target populations. Such behaviorally-based prevention strategies are the most effective and least costly means of slowing the AIDS epidemic.

Conceived as a means of providing local control, flexibility, and community empowerment for the development of prevention programs, the CDC Community Prevention Planning model has proven successful as a strategy for developing locally driven, scientifically-based HIV prevention plans. Non-competitive grants are provided to states and localities hardest hit by the epidemic on the basis of these plans, for which the CDC provides technical guidance and assistance.

*National Center for Injury Prevention and Control.*—The National Center for Injury Prevention and Control (NCIPC) has provided federal leadership in epidemiological research, intervention, and prevention of accidental injury and death. NCIPC is engaged in the study and prevention of disability and human suffering caused by: fires and burns; poisoning; drowning; violence; and other injuries. In particular, we urge that the subcommittee support NCIPC's efforts in the areas of suicide and youth violence prevention. Since the 1950's, suicide rates among youth have nearly tripled, and youth violence rates have increased at similar proportions. Suicide rates have also increased dramatically among older Americans. The APA therefore urges that the subcommittee provide additional funding to NCIPC to support these critical activities.

#### SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

The rise in adolescent substance use and abuse, persistence of mental health and substance abuse problems among some of the nation's most vulnerable populations (e.g., homeless youth and adults, families lacking health insurance and access to preventive health and mental health care, etc.) are best addressed through strong

federal leadership. The Substance Abuse and Mental Health Services Administration (SAMHSA) has provided innovative leadership and programming in these areas. In particular, we urge that the subcommittee support the following programs within the Mental Health Knowledge, Development, and Application (KDA) grant programs:

*Training of Mental Health Professionals.*—Pre-service and in-service training of mental health professionals is critically needed to help improve the public mental health workforce infrastructure. In 1993, for example, there were approximately 47.5 million children and adults who suffered from mental disorders, most of whom did not receive services. There is a severe shortage of minority providers, and of professionals willing to work in underserved areas.

CMHS Clinical Training programs at the Center for Mental Health Services (CMHS) provide funding and assistance to meet the training needs of mental health professionals working with special populations. As such, it is critical to retain these programs, which are geared to meet the needs of specific underserved populations. The CMHS training programs for mental health professionals have been highly successful. By the beginning of 1994, 7,219 trainees had completed training and 83 percent of them had paid back one month of service for each month of their traineeship support. Approximately 80 percent of former trainees continue to work in public or non-profit mental health facilities. The average federal investment per trainee in the Clinical Training program has been \$11,000, a modest amount to prepare professionals, mostly minorities, to provide mental health services in underserved areas.

*CMHS HIV/AIDS Training.*—Persons with HIV infection and their families face unique mental health needs. Professionals working with HIV-infected people often need to help clients develop adequate coping skills for stress associated with the disease, for associated stigma and discrimination, and for sustained behavior change to reduce the risk of further transmission. Given the growing number of people infected with HIV, especially among underserved or disadvantaged populations, the need for adequately trained mental health and other health professionals to address HIV-related needs is increasing rapidly. In the late 1980's Congress recognized these needs and appropriated \$7 million in fiscal year 1986 for this program. Currently, appropriations have dropped to less than \$3 million, despite the increased need. The APA therefore urges the subcommittee to include report language recommending funding for this program within the CMHS KDA at levels equal to fiscal 1995 appropriations.

*HIV/AIDS Mental Health Service Demonstration Grants.*—Over two years ago, HHS Secretary Donna E. Shalala announced the first federal grants ever awarded specifically to develop mental health services for persons living with HIV/AIDS and their families. These grants, managed cooperatively among the Health Resources and Services Administration, the National Institutes of Health, and the Center for Mental Health Services, fund ten sites to develop programs specifically for the delivery of mental health services for persons with HIV/AIDS.

While the \$4.1 million program represents a small amount of money relative to the overall HHS budget, these demonstration grants serve as a model of government efficiency and responsiveness to a critical public health need, and therefore should be maintained. Providing mental health services to people with AIDS not only helps to address the emotional distress, anxiety, and depression that may follow a diagnosis of AIDS, but these services also improve the quality of life of HIV-infected persons, reduce the number of primary care visits (thus reducing health care costs), help infected persons continue to lead productive lives, and reduce the possibility of continued transmission of the disease by promoting behavioral change.

In addition, we urge support for SAMHSA's Children's Mental Health Services Program supports the development of community-based, interagency systems of care, and reflects the state-of-the-art in treating children with serious emotional disorders. By recognizing the unique and multiple needs of children, by supporting a broad array of services, and by requiring collaboration among a range of child-serving agencies—including mental health, child welfare, juvenile justice, and education—this program helps to improve the quality and availability of appropriate child mental health services while reducing expenditures that have formerly gone to expensive, noncommunity-based residential care. The APA urges continued funding of this program at levels at least as great as the President's recommendation for fiscal 1998.

#### OTHER PROGRAMS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

Congressional efforts to reform the nation's health care financing system raise the prospect that many more vulnerable Americans will receive inadequate or insuffi-

cient care in the near future. Senior citizens, pregnant women, persons with serious mental illness, and young children, infants, and adolescents living at or below the poverty line face greater health risks without improved access to and utilization of quality preventive health and mental health care services. Despite cuts in Medicaid and Medicare, health risks to these populations continue to cost all Americans billions of dollars in avoidable medical costs.

In particular, the APA urges the subcommittee to provide funding at the President's requested levels for DHHS programs such as the Maternal and Child Health Block Grant, the Healthy Start Initiative, Family Planning (Title X), programs of the Office of Adolescent Health and the AIDS Education and Training Centers. In particular, the APA urges the subcommittee to support the President's request of \$203 million for Title X programs, to provide comprehensive health and reproductive health care for low-income women.

In addition, the APA wishes to highlight the importance of federal Violence Against Women Act programs. For both the victim of domestic violence and the family, domestic violence and abuse may lead to destructive long-term psychological and physical consequences. The research of psychologists and other behavioral scientists has shown the effectiveness of comprehensive services for victims of domestic violence, as well as the effectiveness of domestic violence education and prevention programs. VAWA programs authorized under DHHS as well as the Department of Justice need to receive full funding as a package, to improve prevention and prosecution of domestic violence.

#### THE BUREAU OF HEALTH PROFESSIONS & NATIONAL HEALTH SERVICE CORPS

APA recommends an appropriation of \$302 million for the Bureau of Health Professions for fiscal year 1998, which is a three percent inflationary increase over the fiscal year 1997 funding. This appropriation is necessary to maintain current efforts to address our nation's rapidly changing demographics and to meet the health needs of underserved populations. This is also the only federal program with a focus on increasing the number of minority persons in the health professions. A severe shortage of minority psychologists exists despite the fact that by the year 2000, over one-third of the U.S. population will be minorities. There is a critical need for health professionals who specialize in behavioral change, considering the report by the World Health Organization (1996) stating that most health problems by the year 2020 will have large behavioral components (i.e. lung cancer and heart disease). In addition to behaviorally-based health problems, psychologists also address debilitating mental illnesses. For both men and women, mental illnesses (unipolar major depression, bipolar disorder, schizophrenia) are three of the ten leading causes of disability worldwide. In order to meet the behavioral and mental health needs now and in the future, it is imperative that funding be available for minority psychology students in the Health Professions Education Programs.

APA recommends \$145 million for the National Health Service Corps for fiscal year 1998, which is a modest increase over fiscal year 1997. This unique program provides loan repayment (or other assistance) to psychologists and other health professionals in exchange for service in underserved areas, primarily rural. Currently, there are approximately 500 mental health professional shortages areas (NHSC, 1997) nationwide (and these only represent the communities who have requested designation). Until 1995 there were no psychologists enrolled in the program—presently there are only 12. However, there are hundreds of psychologists interested in the program and would gladly participate given the opportunity. Further, it has been demonstrated that psychologists who serve in underserved areas tend to remain in underserved areas (Center for Mental Health Services, 1994). Finally, the large number of mental health shortage areas and the increasing need for health professionals to deal with such behavioral and mental health problems as violence, substance abuse, diet, and mental illness demands that more psychologists be allowed to participate in the National Health Service Corps.

Again, the members of the American Psychological Association appreciate your willingness to accept our testimony and funding recommendations.

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PREPARED STATEMENT OF K. KIMBERLY KENNEY, EXECUTIVE DIRECTOR, CFIDS  
ASSOCIATION OF AMERICA

Mr. Chairman, thank you for the opportunity to present testimony to the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee. My name is Kimberly Kenney, and I am executive director of The CFIDS Association of America. The Association is the world's largest and most active charitable organization dedicated to conquering chronic fatigue and immune

dysfunction syndrome, or CFIDS, also known as chronic fatigue syndrome or CFS. The Association has more than 23,000 members and a mailing list of nearly 200,000. In its mission to conquer CFIDS, the Association supports education, public policy and research programs. Over the last decade since the Association was founded in 1987, we have funded over \$2.6 million in direct research grants and have published and distributed hundreds of thousands of copies of our quarterly magazine, *The CFIDS Chronicle*. The CFIDS Association of America is a non-profit 501(c)(3) organization governed by a board of directors comprised of persons with CFIDS, family members of persons with CFIDS and healthy professionals. The Association raises nearly all of its funds from persons with CFIDS and those who care about them.

CFIDS is a serious and complex illness that affects many different body systems. The cause has not yet been identified and there is no cure. The illness is characterized by bone-crushing fatigue, persistent flu-like symptoms, intractable pain and Alzheimer-like cognitive deficits. These and other symptoms can come and go, complicating treatment and the ability to cope with the illness. In addition, most symptoms are invisible making it difficult for others to understand the vast array of debilitating symptoms that persons with CFIDS have. The impact of this illness is often severely disabling; it can last for many years. Further, it is often misdiagnosed because it closely resembles other disorders including multiple sclerosis, Lyme disease, lupus and post-polio syndrome. Studies using the restrictive research definition of CFS have reported conservative estimates indicating that 500,000 adults in the United States suffer from CFIDS. Early preliminary studies of the number of children and adolescents affected are inadequate to fully assess the impact of this illness on our nation's young people. However, one thing is certain—kids do get CFIDS and the illness and the lack of understanding about it by pediatricians, school teachers and administrators and other children can make for a nightmarish experience for the young patient and his/her parents.

I wish to report on the progress being made in gaining an improved understanding of CFIDS. I also would like to make requests of this committee for its continued support of activities which have been critical to this improved understanding. This committee has provided leadership and vision for the federal agencies which must meet the needs of persons with CFIDS. The CFIDS-related report language contained in the fiscal year 1997 appropriations omnibus bill was greatly appreciated by the CFIDS community.

Through its education, public policy and research programs, The CFIDS Association leads efforts to make CFIDS a mainstream medical concern. The courageous efforts of CFIDS advocates and pioneering researchers and clinicians have created a foundation of knowledge and experience. The research effort has expanded over the years to include many fine minds representing numerous disciplines and dozens of universities and countries. Patient care and diagnosis remain more art than science, but meaningful advances promise to be imminent and initiatives underway to educate healthcare professionals will improve understanding of the complexity of this illness among providers.

Please allow me to recount some of the specific accomplishments of the past year that underscore the value of continued federal investment in these activities:

- Thanks to the direction provided by this committee, on September 5, 1996, Secretary for Health Dr. Donna Shalala signed the charter for the Chronic Fatigue Syndrome Coordinating Committee. This charter guarantees that a forum exists for government agencies to regularly share information with one another and the patient and medical communities. The National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA) and Social Security Administration (SSA) are required to appoint representatives to this committee. Seven individuals selected by Dr. Shalala will represent the patient community, the research community, and the healthcare community. I am honored to inform you that I have been invited to serve a four-year term as one of the seven appointees. We look forward to the first meeting of this chartered committee on May 29 and I will keep you and your staff apprised of the conduct of this important body.
- Dr. Robert Suhadolnik of Temple University has discovered a new enzyme in CFIDS patients that is present in neither healthy controls nor several disease control groups. The studies leading to this finding were financially supported by The CFIDS Association of America, however the NIH has provided Dr. Suhadolnik with significant bridge funding to ensure that his work can continue unimpeded while the application for extended NIH funding proceeds through the lengthy review process. Dr. Suhadolnik is hopeful that this finding will lead to a diagnostic test.

- Eight institutes of the National Institutes of Health joined together to issue a Program Announcement on chronic fatigue syndrome that outlined 32 areas of promising study. This announcement came as a result of a meeting held at NIAID in September 1995 in which the NIH-supported CFS program was reviewed and priorities were recommended by a multi-disciplinary group of experts from prestigious universities. The first round of grant applications resulting from this Program Announcement will be peer-reviewed this May; we eagerly await funding announcements.
- In similar fashion, last August the CDC assembled a peer-review group of which I was one member, to examine its CFS-related research program. At the end of the two-day session, our group presented numerous recommendations to CDC officials and the CFS research team; these recommendations were also presented to the CDC's National Center for Infectious Diseases Board of Counselors. We were delighted that key recommendations made to CDC were highlighted in the Appropriations Conference Report and in a colloquy on the floor between Senator Specter and Senator Harkin.
- For the first time in its 10-year history, last fall The CFIDS Association received a federal contract. This small contract, extended by HRSA, enabled the Association to convene representatives from the nation's Area Health Education Centers (AHECs) to discuss methods of educating healthcare professionals about CFIDS through the AHEC program. In recent meetings with HRSA staff we have discussed implementation of the strategies identified to be most promising by this task force.
- Finally, Dr. Philip Lee's leadership before his retirement from the Assistant Secretary for Health post led to the development of an HHS satellite program about CFIDS which will be presented to healthcare providers, CFIDS patients and other interested parties on September 18 of this year. The NIH, CDC, private researchers and clinicians and patient advocates are working together to develop this program which will feature pre-taped and live segments and an interactive question and answer session. Our hope is that providers across the country will meet at universities, hospitals, community colleges, even sports bars, to receive the satellite transmission of this first government-sponsored educational program about CFIDS.

These achievements have been facilitated through a significant, though comparatively small combined federal investment of \$13.7 million.

This evidence of progress, though certainly encouraging, has not yet translated into the kinds of advances that affect the individual patients who have watched their former healthy lives be erased by this devastating disease. Diagnosis is still made by excluding all other possible causes of symptoms. For those patients who find a physician knowledgeable and willing to treat them, the "state of the art" is commonly a discouraging (and potentially dangerous) process of trial and error using any number of usually inadequate symptomatic medicines. And for patients who cannot continue working due to the physical and cognitive limitations imposed by CFIDS, the process of applying for Social Security benefits regularly takes two years to complete and is successful only 14 percent of the time—half the national average for all other disabilities. Finally, researchers intrigued by reports in the peer-reviewed literature or by findings they make in their own patient cohorts are often discouraged from pursuing promising studies because of the lack of available funds. For example, The CFIDS Association of America has experienced a four-fold increase in the number of dollars requested by researchers for projects which were deemed meritorious by our Scientific Advisory Committee. This same situation is likely to befall the NIH as these investigators make application for federal support.

To encourage continued growth in the CFIDS research effort and to undertake programs that will begin to address the real-world needs of CFIDS patients for earlier detection, better care, and improved access to Social Security disability benefits, we must request an expansion of resources dedicated to these crucial efforts. The CFIDS Association of America offers the following recommendations for fiscal year 1998 appropriations and committee report language:

*Secretary for Health*

The Association requests that Congress specifically provide \$1 million of discretionary funds allocated to the Secretary of Health and Human Services to maintain the Department of Health and Human Services Chronic Fatigue Syndrome Coordinating Committee (DHHS CFSCC). We ask that the committee include report language directing the Assistant Secretary for Health to chair the CFSCC and use this body to coordinate CFIDS research across the Public Health Service by creating a yearly action plan. Included in the purview of the CFSCC, we recommend oversight into programs, performance, budget allocations, and priorities.

*National Institutes of Health*

Despite the recent growth in NIH funding of \$800 million for fiscal year 1997 (compared with fiscal year 1996), funding of CFIDS research at the NIH has remained level. The Association requests that Congress specifically appropriate an additional \$10 million to NIH, most of which should be directed to extramural grants focused on promising areas of biomedical research. We ask that the committee include report language continuing to direct NIH spending priorities to investigations that will define the pathophysiology of the illness and identify diagnostic markers. We are concerned that the cross-institute partnership demonstrated by last year's CFS Program Announcement noticeably did not include participation by the National Institute on Child Health and Human Development. We ask that the Committee include report language establishing the need for a special Program Announcement dedicated to the study of all facets of pediatric CFIDS. Finally, the Association asks for report language urging NIH officials to identify appropriate NIH advisory committees for CFIDS representation and ensure appointment of appropriate persons thereon.

*Centers for Disease Control and Prevention*

At the CDC, growth in the CFIDS research program has stalled and promising research is not being published in a timely manner. The Association requests that Congress direct an addition of \$5 million to expand CFIDS laboratory studies (including serial analysis of genomic expression (SAGE) studies) and surveillance projects, including outreach to populations not formerly recognized as being affected by CFIDS, namely minority populations and children and adolescents. Although last year this Committee encouraged CDC to commence such studies, there has been no commitment by CDC to address these populations in a meaningful way. Further, we request language that directs CDC to conduct as part of these surveillance projects studies of the natural history of pediatric CFIDS so that future large scale studies of the prevalence of pediatric CFIDS might be carried out more effectively. Congressional support for the addition of a neuroendocrinologist to the CDC's CFS research group would enable expansion of research initiatives to follow up on productive findings from the NIH and private sector.

*Social Security Administration*

Despite the regular attempts by this Committee to secure the attention of SSA officials to the unique problems that CFIDS patients encounter in the process of applying for SSDI benefits, the situation remains that CFIDS patients regularly encounter SSA employees unfamiliar with or erroneously informed about CFIDS and its diagnosis and the functional limitations the illness imposes. We are encouraged by very recent meetings with top officials from the Office of Disability to examine the obstacles to benefits for persons with CFIDS and we ask the Committee to express its strong support for the continuation of this process. The Association asks the Committee to direct the SSA, through report language, to develop appropriate training agendas and materials for SSA and Disability Determination Services employees at all levels of the adjudication process. We also request report language indicating that three years ago the Committee recommended that SSA establish a CFIDS Advisory Committee to review current medical standards and investigate the training and information resource needs of regional SSA offices. Since SSA has resisted creating such an advisory board, the Association asks the Committee to include language noting that the Appropriations Committee will closely monitor the progress of the informal study group now assembled.

*Health Resources and Services Administration*

The Association requests an appropriation of \$500,000 to HRSA to undertake new CFIDS-related healthcare provider education programs through the existing Area Health Education Center Program. These programs would be directed at primary care providers (including those in training) and would have the objective of improving the detection, diagnosis, treatment and management of CFIDS patients. Effective programs could yield healthcare spending savings equal to many times this small investment.

Members of the Committee familiar with our issue will recognize some of these requests from previous years. The Association has strived to make consistent, reasonable requests with the goal of providing greater clarification of issues critical to those who suffer from the disease. Using this strategy, we have been rewarded through the progress in many areas which I spoke about earlier. However, there are still great challenges ahead.

We sincerely hope that, once again, Congress will work with us to secure a dedicated and effective federal response to CFIDS so that we can put an end to the suf-

fering caused by CFIDS at the earliest date possible. Last year Representatives Fazio, Pallone, Engel, Farr, Stearns, McHale, Morella and Gilman demonstrated their support for constituents affected by CFIDS by circulating a "Dear Colleague" letter underscoring the need for a significant federal response to CFIDS. The CFIDS Association of America will continue its efforts to inform Congress about CFIDS to secure support for this committee's leadership on the illness, as well as that shown by other individual Members. On May 16 the Association will host Congressional briefings being sponsored by Senator Harry Reid. We will also continue our efforts to hold the federal agencies accountable for the direction delivered by Congress through the Appropriations bill and its accompanying report language. Together, the Congress and CFIDS advocates will work to maximize the federal contribution to the battle against CFIDS.

Mr. Chairman, we have all worked diligently to develop a basic understanding about CFIDS. The investment we've made over the last decade will soon generate dividends in terms of more definitive means of diagnosing, treating and, perhaps, preventing the illness. Your commitment to this effort is needed now more than ever. We must capitalize on the opportunities now before us so that the children, teens and adults with CFIDS experience improved care and function. They wish desperately to return to productive lives as students, parents, employees and citizens. Thank you for your thoughtful consideration of our requests.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF DENTAL SCHOOLS

The American Association of Dental Schools (AADS) represents all of the dental schools in the United States, as well as advanced dental education, hospital dental residency programs, and allied dental education institutions. It is within these institutions that future practitioners, educators, and researchers are trained; significant dental care provided; and the majority of dental research conducted. The AADS is the one national organization that speaks exclusively for dental education.

While dentistry has made significant progress in preventing oral disease and developing primary care treatments, less than half of all Americans have access to routine dental care. Consequently, oral diseases are still among the most prevalent and common of all chronic health conditions. Eighty-four percent of all children have experienced dental decay by age 17. Oral conditions left untreated severely impair a child's ability to concentrate in school and result in more than 52 million hours of time away from the classroom annually. If we are serious about having all children ready to learn by the time they enter school, we must improve access to comprehensive health services, including adequate oral health care.

Periodontal disease is also pervasive among adults 18 and over due to the lack of dental coverage in employer-provided health plans. Oral cancer is more common than leukemia, Hodgkin's disease, melanoma of the skin, and cancers of the brain, cervix, ovary, liver, or stomach. Each year there are approximately 30,000 newly diagnosed cases of oral cancer, and 8,000 deaths. Accordingly, poor oral health has a tremendous economic impact on our country, causing our nation's workforce to miss more than 164 million hours of work annually.

Our funding requests for fiscal year 1998 reflect the expanding role of dentistry in our nation's health care system and the changing nature of the profession. Because the Subcommittee is under severe fiscal constraints, we have focused on dental education and research programs that are extremely cost-effective and will yield a significant return for the federal investment in improving access to primary health care.

*General Dentistry Residency Program:*

With the concern about returns on federal investments, we are pleased to present a primary care success story. The General Dentistry Residency Grant program provides support to dental schools, hospitals, medical centers, and other postgraduate dental training institutions to expand or establish General Dentistry Residency programs. These residency training programs provide dentists with the skills and clinical experience needed to treat the oral health needs of patients throughout life. Because the General Dentistry program emphasizes primary care, dentists are trained to deliver a broader range of services to patients and as a result, consistently refer fewer patients to specialists. This is especially important to populations which would otherwise be underserved, including the elderly, indigent, people in rural areas, and other patients requiring specialized or complex care such as developmentally disabled individuals, high risk medical patients, and patients with infectious diseases. These patients often face financial or logistical problems that make dental care unobtainable. The training offered under the General Dentistry Residency pro-

gram is similar to the internship year in medicine and also the dental equivalent to family medicine. The experience obtained from participating in General Dentistry Residency programs often inspires program graduates to continue to serve special population patients in their professional practice. In fact, a HRSA evaluation reveals that 87 percent of those who receive General Dentistry residency training remain primary care providers.

What does this mean in terms of patient treatment? HRSA found that compared to private practice, residents in these programs treat four times the number of developmentally disabled, six times the number of medically compromised, and 26 times the number of HIV/AIDS patients. General dentistry residencies prepare dentists to treat: individuals suffering from diseases such as diabetes, cystic fibrosis, and rare or so-called orphan diseases and conditions such as ectodermal dysplasia, Sjogren's syndrome, and cleft lip and cleft palate; elderly patients whose treatment must often be significantly altered because of their medical history; individuals who suffer oral complications because of cancer chemotherapy or radiation to the head or neck; patients with primary oral conditions such as oral cancers and certain chronic pain conditions; and patients who need major facial reconstructive surgery because of developmental disorders or trauma.

The General Dentistry Residency program is a true partnership with the federal government which has proven its cost-effectiveness. HRSA funding provides grantees the "seed money" for the start-up of new General Dentistry Residency positions. Federal grant funds are limited to only three years—one of the selection criteria for grant recipients is the ability to be self-sustaining at the end of the three year grant cycle—unlike most other Title VII programs. The federal government makes this initial investment because of the recognition of the high cost of start-up funding for dental equipment and instrumentation and other factors associated with initiating residency training positions. Once the federal funds end, it takes considerable skill to maintain programs, because they must attract enough self-pay patients and patients with dental insurance to offset the losses incurred in treating the indigent.

Recent evaluations continue to confirm the success of General Dentistry Residency programs in meeting federal primary care objectives. The Bureau of Health Professions' evaluation of this program found that "Considering the relatively modest investment of funds by the federal government the impact on the growth and scope of General Dentistry programs and the subsequent effect on dental care has been substantial."

Here are a few key profiles of the General Dentistry Residency program from around the country:

- Lutheran Medical Center in Brooklyn, New York, is a general dentistry program that serves 12 community health centers. One of the rotations in this General Dentistry program is the Floating Hospital (known also as New York's Ship of Health), which is alternately docked at piers on the Hudson River and South Street Seaport. General Dentistry Residents provide oral health services to New York school children and adults, including the homeless and poor.
- General Dentistry programs in New Jersey have established residency rotations throughout the state, to sites such as community, migrant, and rural health centers, and other clinics aimed at providing care to under-served communities.
- Boston University has a current grant that has provided for residents to treat underserved populations in two community health centers in Boston. In addition, residents treat pediatric AIDS patients through a special program at Boston Medical Center. The grant has also spurred outreach programs to inner city elementary schools and senior citizens with unmet needs. Residents also provide care for those who otherwise would not receive dental treatment, such as spinal cord injury patients, transitional care unit patients from acute care hospital stays, and homeless/battered women at shelters in the city. They want to expand by 6 residents by applying for a future grant, to meet growing unmet oral health needs in the community and expand community outreach activities.
- The University of Pennsylvania's program has a very strong clinical component: approximately 75 percent of the work week is spent in primary patient care with faculty supervision. Students integrate basic sciences (such as anatomy, pharmacology, physiology, biochemistry, internal medicine, oral medicine, pathology, histology and immunology), with the practice of clinical dentistry to develop a multi-disciplinary approach to total patient care. Residents deliver care to a diverse patient population, thus gaining the clinical experience and skills to administer comprehensive care services in their professional practice.
- Ohio State University received grants at four different times over 12 years which has helped the program grow to 15 residents. This program is the primary oral health resource for special needs adults and some children in the southern two-thirds of Ohio. Their target populations are migrant/rural work-



ers, low income and homebound elderly patients (and those in nursing homes), HIV and other high risk groups, disabled patients, and the medically compromised. 90 percent of their graduates remain primary care providers. Their underrepresented minority enrollment is 13 percent and enrollment of women is 38 percent (both figures are higher than the percentages among dental school graduates).

- Cleveland Metrohealth Hospital has benefited from General Dentistry funding. One success story from the program is Dr. William L. Ebbs, Chief of Dental Services at the Whitman Walker Clinic in Washington, D.C., devoted to treating HIV/AIDS patients. Because people are living longer with the disease, they continue to need services such as basic oral health care. Because of his broad-based training, including receiving a dental degree from Howard University and teaching at the Case Western Reserve University's School of Dentistry, he is able to manage the complex oral health needs of people living with HIV/AIDS, including the interaction of new drug therapies with oral health care.
- The University of Vermont's General Dentistry program is vital to treating medically compromised patients in the rural areas of Maine, New Hampshire, and Vermont, as it is the only such program in those states. Their residents spend eight months in the dental clinic treating medically compromised patients and the other four months in the hospital doing surgical rounds. The clinic slogan is "eliminate the \$600 ambulance ride with a \$15 dental visit." The program is 50 years old, and has graduated 250 dentists, 80 percent of whom go on to practice in rural areas. Its continuation may depend on the ability to compete successfully for HRSA General Dentistry grants.
- Another General Dentistry individual success story is Dr. Mayra Suero-Wade. Six years ago after completion of a General Dentistry residency program, she started her own business in New York City called "Dentistry in Motion." This provides oral health care via a mobile dental clinic to agencies that do not have access, such as foster care agencies and nursing homes. Dr. Wade has revolutionized the oral health care system for low income children by bringing the care to them rather than making them seek out the care themselves. She and the four dentists she supervises see real devastation in their young patients' mouths because they have never seen a dentist before; it is common to see gum disease in the 3-5 year-olds. The mobile clinic goes out in five hours intervals and sometimes sees 20 kids at a time. Dr. Wade also has a private practice, but her innovative outreach activity is not uncommon among those receiving General Dentistry training. Such trainees become very attuned to the access problems and barriers to oral health care in their communities.

It is important to understand that without the impact of the HRSA General Dentistry grant program, many of these developments and individual achievements would not have been possible. If the program is severely restricted and not adequately funded, many of the future activities described will be thwarted.

Demand continues to outpace supply for this primary care training as approximately 300 additional training positions are needed to accommodate the number of current applicants. Without Federal support it would be extremely difficult to create new programs because of the lead time needed for these programs to become self-sufficient, and because of the high cost of start-up funding for dental equipment and instrumentation.

Currently, approximately one out of every four applicants for a General Dentistry residency position is turned away. The continually increasing demand for this training is a strong testament to its value. The Institute of Medicine's 1995 report on dental education, "Dental Education at the Crossroads," recommends the creation of additional General Dentistry positions to meet existing demand, with a goal over five to ten years of expanding sufficient positions to meet the demands of all U.S. dental schools graduates seeking such training.

It is important to understand that this program is not increasing the supply of dentists, but provides additional training of dental school graduates to meet society's primary oral health care needs. However, the General Dentistry Residency program turns away approximately 300 applicants each year. The increasing demand for this training is a strong testament to its value. Over the past 20 years, federal support for General Dentistry training programs has created 59 new programs and established 560 new training positions.

Despite this progress, accepting the Administration's proposal to cluster the General Dentistry Residency program with seven other Title VII programs and slash the overall budget would eviscerate the General Dentistry Residency program and make it impossible to achieve important oral health policy goals. The AADS urges the Subcommittee to support the IOM recommendation by appropriating a \$2.3 million

increase over 1997 levels for this cost-effective and proven primary care program in fiscal year 1998.

*Ryan White HIV/AIDS Dental Reimbursement Program (Title V, Ryan White CARE Act):*

Federal support of this reimbursement program increases access to oral health services for HIV positive individuals and, at the same time, educates dental students and residents to care for persons living with HIV/AIDS. Thus, two major federal objectives—service to patients of limited means and education of future practitioners—is accomplished with this important, but very modest, federal program.

HIV/AIDS patients suffer a high incidence of oral disease. As a result of an immune system breakdown, AIDS patients are more susceptible to very severe oral herpes, rampant fungal diseases, and oral disease found only in patients who suffer from AIDS, including an extremely painful form of gum disease that frequently involves exposure of the bone. A survey of 857 clients of the Robert Wood Johnson Foundation's AIDS Health Services Program in nine cities found that more respondents (52 percent) reported a need for dental care than any other service. For example, oral lesions, common in HIV-infected individuals, can cause significant pain and oral infection leading to fevers, difficulty in eating, speaking, or taking medication, and weight loss. Moreover, the development of some oral problems may signify that HIV infection is progressing. Recognition of these oral problems indicates the need for initiation of treatment with antiretroviral therapy, drugs to prevent complications such as pneumonia, or involvement in a clinical drug or vaccine trial. Oral health care has continued to be a major need of HIV/AIDS patients.

It is important to remember that private insurance and Medicaid coverage for dental services is very limited or simply unavailable for adults. This lack of sufficient reimbursement particularly affects those dental clinics that serve as the safety net for a significant number of Medicaid and HIV/AIDS individuals.

This program represents a partnership between the federal government and dental education programs in which the government partially offsets the costs that dental education programs incur by serving a disproportionate share of HIV/AIDS patients. We accept this partnership because it helps us to continue to deliver and expand care for people living with HIV/AIDS. The program has also enhanced relationships dental education institutions have with state and local AIDS care programs. We are concerned, however, about the ability of dental education programs to maintain the current level of services with increased patient loads the evolving chronic nature of this disease, and dwindling clinical revenues.

The Woodhull Medical and Mental Health Center in New York is currently conducting a HRSA-funded evaluation of this program. While the results are not yet available, a recent survey of program participants found that this program had a positive impact in the following areas: integrating oral health care with other services, increasing the support and commitment among providers to HIV/AIDS education and provision of care, increasing the providers' knowledge about infection control and treatment, and increasing patient access to oral health. Mr. Chairman, clearly this program is a critical component of our national effort to fight the AIDS epidemic. AADS urges a modest increase of \$1.5 million over the fiscal year 1997 levels for this important program recently reauthorized under the Ryan White CARE Act.

*National Health Service Corps Scholarship and Loan Forgiveness Programs:*

We strongly support the NHSC Scholarship and Loan Forgiveness Programs, which assist students with the rising costs of financing their health professions education while promoting primary care access to underserved areas.

Over the last several years, and most recently in fiscal year 1997, the appropriations report language has instructed the NHSC to increase dental participation in the loan repayment and scholarship awards programs. The number of dental loan repayment awards has increased slowly in recent years, and fiscal year 1997 awards for dentists already outpace the fiscal year 1996 number. However, problems continue to exist in the scholarship program, which has almost completely abandoned dental scholarships (only 8 scholarships have been awarded since 1992: none were awarded in 1995). We believe it is critical that the NHSC commitment to dentistry be maintained and strengthened as the need for dental providers is becoming more pronounced in underserved areas throughout the nation. When the Department of Health and Human Services updated the dental Health Professions Shortage Areas (HPSAs) in 1993, it became clear that the situation worsened for dentistry. Currently, 2,600 dentists are needed to service 935 designated HPSAs, as compared to 1,400 dentists needed for 792 dental HPSAs prior to 1993.

Oral health services are still needed throughout the U.S. to assure rural and urban underserved people relief of pain and elimination of oral infections. Without these services, dental and oral diseases will result in diminished employment prospects for those without jobs, decreased ability of school children to concentrate, lower worker productivity, and increased medical problems. Unless more dentists are made available in shortage areas, we will continue to see costs climb as hospital emergency rooms are used to provide extensive care for what began as a dental problem and has evolved into a systemic condition. AADS asks the Subcommittee to include language in its report reaffirming the need for increased dental participation in both the NHSC scholarship and loan repayment programs.

*Health Professions Education and Training Programs for Minority and Disadvantaged Students:*

We want to express our strong support for the various programs that play a critical role in the recruitment and retention of disadvantaged students and the recruitment of disadvantaged faculty. We request funding for the Scholarships for Disadvantaged Students at \$20 million and the Exceptional Financial Need Scholarships at \$15 million, the Loan for Disadvantaged Students program at \$10 million, the Centers of Excellence program at \$28 million, the Disadvantaged Assistance program (Health Careers Opportunity Program/Federal Financial Assistance for Disadvantaged Health Professions Students) at \$35 million, and the Faculty Loan Repayment program at \$2.5 million. These funding levels will maintain our nation's strong commitment to diversity and opportunity in the health professions.

Increasing the federal investment in these programs, even by a modest amount, would greatly enhance the ability to both recruit and retain more disadvantaged students in the health professions and address the severe access and public health problems plaguing those areas of our country experiencing a significant shortage of health care professionals. The AADS urges the Subcommittee to seriously consider the important impact of these programs.

*Other Programs Under Title VII of the Public Health Service Act:*

We also urge the Subcommittee to fund the following programs at adequate levels because of their importance in promoting access to healthcare for special populations: Rural Health Training and the Health Education and Training Centers programs, Geriatric Initiatives, Area Health Education Centers, and Allied Health Special Projects. The AADS endorses the fiscal year 1998 budget recommendation proposed by the Health Professions and Nursing Education Coalition.

In addition, the AADS remains very concerned about the targeted elimination of the Health Education Assistance Loan (HEAL) program and the impact on the ability of dental students to pursue their training. We urge the committee to either reconsider this issue or strongly encourage the Department of Education to meet this need under the unsubsidized Stafford Loan Program to compensate for the elimination of the HEAL program. Without an alternative to the HEAL program, a dental education will be out of reach for all but the wealthiest students because of the high expense of borrowing in the private loan market. It is important that all dental students have access to financial assistance that will not leave them with an insurmountable debt.

AADS urges the strong support of the Subcommittee for the Health Professions Student Loan (HPSL) program, that could provide additional low cost student loan funds to meet the financial needs of health professions students previously served by the HEAL program. HPSL funds should be used to assist institutions in developing and maintaining a sufficient revolving fund. The AADS requests \$10 million for this program in fiscal year 1998.

*National Institutes of Health/National Institute for Dental Research:*

We are extremely grateful for Chairman Specter's leadership in the area of biomedical research. Support for the National Institutes of Health, and the National Institute of Dental Research (NIDR) in particular, has yielded results applicable not only to oral health, but to health in general. NIDR's objective is to promote the advancement of research in all sciences pertaining to the mouth and facial structures, to seek ways of treating and preventing oral diseases, and to facilitate the transfer of knowledge into practical help for the public. Research funded by NIDR has opened new pathways to better diagnosis, prevention, and treatment of oral disease. Increased funding is essential to the continuation of important research into the general health and primary care of America's children, adults, and senior citizens. The AADS endorses the testimony of the American Association for Dental Research regarding priorities and funding of \$212.5 million for the NIDR in fiscal year 1998.

*Agency for Health Care Policy Research (AHCPR):*

The AADS joins the Friends of AHCPR in supporting a budget of \$160 million in fiscal year 1998. A particularly important AHCPR activity is the Dental Scholar in Residence program, which was established to assist the agency in conducting research to improve the delivery of effective dental and oral health services and to facilitate collaborative relationships among professional, educational, research, and other health industry sectors involved with oral health care. The very first recipient of this award was selected earlier this year, and is working in the area of measuring quality of health care and examining the integration of oral health services into comprehensive primary care systems. This work will help improve the knowledge base for informed oral health care policy.

Mr. Chairman and members of the Subcommittee, the AADS appreciates the opportunity to present the views of its membership on these programs which are imperative to addressing the access and workforce issues that are critical to meeting the future oral health needs of our nation.

## PREPARED STATEMENT OF THE NATIONAL HEMOPHILIA FOUNDATION

Thank you for the opportunity for the National Hemophilia Foundation (NHF) to present testimony to the Chairman and Members of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. NHF is a national voluntary health organization dedicated to improving the health and welfare of people with hemophilia, von Willebrand's disease, and other bleeding disorders. The federally-funded hemophilia and hematologic programs provided for in the annual Labor, Health and Human Services Appropriations Bills are of great importance to the hemophilia community and to the general public who rely on the safety of the nation's blood supply. NHF appreciates the Committee's continuing support and leadership in advancing the research, treatment, and consumer-based patient outreach needs of the hemophilia community.

The hemophilia community continues to be the first marker in the event of any complication or virus that contaminates the blood supply. While new safer blood products are available and today's blood manufacturing processes inactivate the HIV virus, blood and blood products remain susceptible to other viruses and pathogens.

Historically, the hemophilia community has been impacted by a number of viruses through the blood supply. While HIV has been the most devastating, other viruses continue to plague the hemophilia community, including Hepatitis A, Hepatitis B, Hepatitis C, Parvovirus B19, and Creutzfeldt-Jakob disease. Strong evidence of the need for a more responsible and responsive blood safety system compounds as new announcements of blood product recalls are issued, often weeks after the seriousness of a problem has been detected. Our organization issued 12 medical bulletins in 1996 regarding product investigations, recalls and/or withdrawals and already has issued six notices this year.

Last year the Committee included in its fiscal year 1997 report a series of actions to be taken by the Public Health Service agencies to substantially improve surveillance, research, patient notification, and outreach efforts in addressing blood safety concerns. Programs funded by the Committee also provided for hemophilia and bleeding disorder programs aimed at HIV/AIDS risk reduction and clinical studies, prevention of the complications of bleeding disorders, and research for a cure for hemophilia and related disorders. Further, the Committee again called for a collaborative effort between the three Public Health Service agencies responsible for blood safety issues—the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH)—to work together to improve the safety of the U.S. blood supply and blood products.

With regard to programs appropriated under the Labor, Health and Human Services, Education Appropriations Bill, NHF strongly believes that the CDC and the National Heart, Lung, and Blood Institute (NHLBI), working in collaboration with FDA, should continue to broaden current hemophilia programs to incorporate critically needed work on ensuring a safe and efficacious blood supply. Together, these programs sustain our nation's response to the needs of the hemophilia community and address the concerns of all Americans regarding blood safety.

## CENTERS FOR DISEASE CONTROL AND PREVENTION

Funding provided by the Committee has enabled CDC to continue its collaborative relationship with NHF in establishing peer-outreach programs such as the Men's Advocacy Network (MANN), the Women's Outreach Network (WONN), and the Chapter Outreach Demonstration Project. Through these programs, CDC, working with the Foundation, has been able to address the HIV epidemic and provide vital

prevention information about blood safety and the elimination of the complications of hemophilia to families affected by bleeding disorders. These programs are essential to our community, and we support their continuation.

NHF also strongly supports CDC's surveillance activities through its hematologic disease intervention program. A critical part of a strengthened surveillance effort is the continued expansion of studies on blood pathogens that may adversely affect blood safety.

#### NATIONAL INSTITUTES OF HEALTH

##### *National Heart, Lung, and Blood Institute*

NHF supports NHLBI in pursuing gene therapy and a cure for hemophilia and appreciates the Committee's strong support of these efforts. NHF does remain concerned about the progress of NHLBI regarding its study on the vulnerability of the hemophilia community to blood contaminants, specifically CJD, and anxiously waits for the results of this study.

##### *National Institute of Allergy and Infectious Diseases (NIAID)*

NHF also works in cooperation with NIAID to ensure access for people with hemophilia to clinical trials for HIV and AIDS. With the support of this Committee, NIAID funds clinical trials utilizing the existing network of hemophilia treatment centers to ensure ready access to breakthrough therapies and newly available drugs such as protease inhibitors.

#### MATERNAL AND CHILD HEALTH BUREAU

Through the Maternal and Child Health programs, Congress has been very supportive of the regional network of hemophilia treatment centers, whose expertise in treating hemophilia and its complications is a key part of the federal effort to reduce and begin to eliminate the costly complications of bleeding disorders, ensure adequate surveillance, and foster patient education. This program serves as a model for the treatment of other chronic diseases, demonstrating remarkable cost-effective health outcomes, including substantially reduced hospitalization.

#### FUNDING RECOMMENDATIONS

*CDC.*—NHF recommends an additional \$2.0 million for CDC's hematologic disease intervention activities focused on:

- Fully implementing a nationwide surveillance system utilizing the network of hemophilia treatment centers and a serum bank to detect, monitor, and warn of adverse effects in blood recipients.
- Strengthening consumer-based patient outreach, including expanded support for peer- and chapter-outreach activities, for the prevention of complications of hemophilia and other bleeding disorders.
- Substantially improving the response process involving the CDC and the FDA to ensure immediate investigation of and action on any possible viral contamination in the U.S. blood supply or blood products.

*NIH.*—We recommend:

- An additional \$2.0 million to further NHLBI's research to advance a cure for hemophilia and other bleeding disorders, with accelerated research into seeking a cure for hemophilia and other bleeding disorders reliant on blood products.
- An additional \$1.0 million to provide results from its study into the effects of CJD and Parvovirus B19 on the safety of the blood supply.
- Sustained funding in support of the HIV/AIDS clinical trials program for persons with hemophilia provides access to the newly available drugs, such as protease inhibitors.

*MCHB.*—We recommend that the hemophilia treatment centers program has sufficient resources to fully participate in the collection of critical data, surveillance activities, and patient notification efforts related to adverse events in blood and blood products.

*Agency Coordination.*—It is critical that all responsible Public Health Service agencies—FDA, CDC, and NIH—work collaboratively to ensure a safe blood supply. To accomplish this goal, NHF is continuing its efforts to ensure that FDA establishes a responsive patient notification system. We once again request that the Appropriations Committee direct that a progress report be generated by the Department of Health and Human Services on the allocation of resources and actions taken in the following areas essential to protecting the U.S. blood supply:

- Research, data collection, and surveillance needed to implement an efficacious patient notification system,
- Improved viral inactivation methods, and

—Consumer-based patient outreach and involvement.

Our recommendation for a total of \$5 million represents an incremental step in sustaining efforts to ensure a safe blood supply. We hope that the Committee will act favorably on our request.

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PREPARED STATEMENT OF THE ASSOCIATION FOR HEALTH SERVICES RESEARCH

Thank you for the opportunity for the Association for Health Services Research (AHSR) to submit testimony to the Chairman and Members of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. AHSR appreciates the support that the Committee continues to provide to the Federal agencies responsible for the Government's health services research efforts.

AHSR is the only national professional association devoted to the promotion of research focused on the delivery, quality, and financing of our health care system. The Association represents more than 2,500 individuals drawn from a wide array of professional disciplines who are actively engaged in research and education. In addition, AHSR has 130 organizational members including universities, consumer groups, large employers, insurers, managed care companies, health care systems, pharmaceutical companies, and other organizations representing key components of the private sector.

Health services research encompasses research, data collection and analysis, and evaluation focused on determining what works well and cost-effectively in delivering health care. Its scope includes assessing disease interventions and their outcomes, developing better health quality measures, evaluating the impact of health programs, and providing valuable information to providers, consumers, and employers about these findings. In each case, health services research not only provides critical information, but serves as a resource to decisionmakers.

Nowhere is this resource function more important than within the Federal Government itself. As our nation wrestles with containing the growth of health costs, health services research provides essential information on health care quality, costs, and potential savings that helps to reduce the growth of the Federal Medicare and Medicaid programs while ensuring a continued commitment to quality care.

SUSTAINING THE COMMITMENT TO HEALTH SERVICES RESEARCH

*Agency for Health Care Policy and Research*

AHSR supports increased funding for the Agency for Health Care Policy and Research (AHCPR) as the focal point of leadership for the nation's health services research effort. The agency works in tandem with public and private sectors in enhancing health care quality, reducing health care costs, and making health information more readily available.

—AHCPR supports and conducts research that improves disease treatments, often at a reduced cost to the health care system, by evaluating clinical trials, comparing treatment methodologies, and assessing the outcomes and benefits of health interventions.

—AHCPR helps consumers, providers, employers, and policymakers make informed choices about their health care by increasing access to outcomes information and clinical trial results.

—AHCPR assists in the development of measurement systems that enhance the ability of providers to diagnose, treat, and monitor disease.

Further, AHCPR conducts the Medical Expenditure Panel Survey (MEPS), the only national source of information for estimating the costs and analyzing the impact of the growing enrollment in managed care. This survey yields annual data on health care costs, on quality of care—especially for the chronically ill, the disabled, and the uninsured—and on health insurance status and expenditures. MEPS is critically important to Congress and Federal and State agencies in the ongoing effort to assess the impact of health care patterns and policy changes. Without MEPS, it would be impossible to effectively monitor how much Americans spend on health care, how many Americans have health insurance, and how many Americans are receiving the care they need.

Unfortunately, AHCPR's funding has diminished over the past two years to the point that the agency now funds 50 percent fewer grants today than six years ago and its ability to continue to conduct its vitally important work is seriously threatened. This loss of support has occurred while public and private sector demand for health care information has dramatically increased.

—Health Care Professionals need AHCPR's patient outcomes and effectiveness research to determine which of the many promising health care interventions is most effective in day-to-day practice.

- Employers and Health Plans are using AHCPR's research to develop patient care quality measures that are based on scientific rigor in order to improve accountability.
- Employees, Consumers, and Patients are demanding good information so that they can make informed choices regarding health plans, health professionals, and the risks and benefits of alternative treatments.
- Policymakers need fundamental research on the costs and utilization of health care services to evaluate the impact of developments in the health care marketplace and the costs or savings of proposed changes in policy.

AHSR is recommending a funding increase for AHCPR of \$16 million in fiscal year 1998 for a total of \$160 million, which will restore agency funding to its fiscal year 1995 level. This funding correction will allow AHCPR to overcome the existing shortfall and continue its valuable research focus on health care delivery improvements and savings, particularly in the Medicare program. For example:

- The Dupont Merck Company is supporting an AHCPR trial to determine the most effective way to administer anticoagulation therapy, which could prevent 80,000 strokes a year and save the health care system over \$500 million annually.
- Four peer review organizations estimate that AHCPR research on prostatic disease and benign prostatic hypertrophy has contributed \$36.8 million in Medicare savings.
- AHCPR research found that elderly patients who receive beta blockers are rehospitalized for heart ailments 22 percent less than those who do not receive beta blockers, indicating that the Medicare program could achieve significant savings if beta blocker therapy was more widely utilized.
- AHCPR research estimates that the Medicare program could save \$47 million a year by shifting cardiac catheterization to the outpatient setting.

*Recommendation.*—AHSR strongly recommends an increase for AHCPR of \$16 million in fiscal year 1998 for a total of \$160 million, returning the agency to its fiscal year 1995 funding level.

#### *Centers for Disease Control and Prevention*

CDC's National Center for Health Statistics (NCHS) is the nation's principal vital and health statistics agency. NCHS conducts a broad-based program of ongoing and special studies to meet the nation's health information needs in the areas of statistics and data on health status—such as cancer, AIDS, obesity, blood lead levels, and low-weight births—and has been working in close collaboration with AHCPR to streamline its health data collection and analysis activities.

NCHS also provides staff support for the National Committee on Vital and Health Statistics (NCVHS) and its subcommittees, which advise the Secretary of Health and Human Services on health data and statistics concerns. NCVHS has become increasingly active in the past several years, addressing issues relating to uniform health data sets, the need for improved mental health statistics, and the data needs of state and local communities. This national committee has been particularly involved this year in examining and developing recommendations to implement the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996.

*Recommendation.*—AHSR supports the continued support of NCHS as provided for in the President's fiscal year 1998 funding request of \$89 million.

#### *Health Care Financing Administration*

As the research arm of the Health Care Financing Administration (HCFA), the Office of Research and Demonstrations (ORD) guides the development and implementation of new health care financing policies and evaluates their impact on Medicare and Medicaid beneficiaries, participating providers, and states. Through research, development, and evaluation of payment and delivery innovations, ORD significantly contributes to major program reforms and improvements, including implementation of hospital and physician payment reform, development of managed care choice options, evaluation mechanisms for accessing nursing home quality, and enhanced quality measurement techniques.

As our nation's health care system continues to change, there is a clear need for better methods to monitor and evaluate its performance. ORD plays a critical role in creating a better understanding of how well Medicare and Medicaid are performing in terms of access, quality, efficiency, costs, and beneficiary satisfaction and in how to further improve program performance. AHSR believes that HCFA and Congress will have an increasing need for the information and data available from ORD as efforts are made to modernize the Medicare and Medicaid programs, further control costs, and expand managed care enrollment.

*Recommendation.*—AHSR recommends an additional \$5 million above the President's fiscal year 1998 funding request of \$45 million for ORD to lay the groundwork for monitoring and evaluating the impact of the growth of managed care, alternative state financing mechanisms, and prospective payment on the Medicare and Medicaid programs.

NATIONAL INSTITUTES OF HEALTH

*National Institute of Alcohol Abuse and Alcoholism (NIAAA)*

NIAAA is the foremost agency supporting biomedical, behavioral, and health service research directed towards improving the prevention and treatment of alcohol abuse and alcoholism and reducing associated health, economic, and social consequences. NIAAA's health services research programs identify factors that improve the effectiveness of alcohol treatment and prevention services across regions and populations.

*National Institute on Drug Abuse (NIDA)*

NIDA supports over 85 percent of the world's research on the health aspects of drug abuse and addiction, treatment, and prevention. In addition to funding research that seeks to develop a better understanding of the biological reward patterns of drug use, NIDA's health services research programs target implementation of new findings and prevention techniques into everyday clinical practice and work within communities to develop a greater public awareness of the effects of and prevention of drug abuse.

*National Institute on Mental Health (NIMH)*

NIMH's health services research programs are the focal point for studies on the frequency of mental disorders, such as schizophrenia, depression, anxiety and eating disorders, and Alzheimer's disease, and for studies on the risk factors that define the development of mental illness. NIMH supports the development of improved methodologies for conducting mental health services research and on mental health economics, including public and private financing of mental health care, the impact of different insurance and reimbursement policies, and the cost-effectiveness of care.

*National Library of Medicine (NLM)*

NLM's National Information Center for Health Services Research and Health Care Technology serves as a central clearinghouse of information on health services research, public and private sector clinical practice guidelines, and on health care technology. The databases of information created and maintained by the Center are a starting point for nearly all clinical and health services research and greatly enhance the ability of other federal and state agencies, providers, and consumers to access medical information.

NLM also is involved in the evaluation of the use of telemedicine and computer-based patient records as part of the federal government's High Performance Computer and Communications Program. The evaluation of this program will provide a clearer picture of the benefits and appropriate uses of these promising technologies, including protecting the confidentiality of electronic health data. NLM's work in this area also makes the agency a natural choice for the evaluation and development of medical applications as part of the President's Next Generation Internet Initiative.

*Recommendation.*—AHSR supports the President's fiscal year 1998 budget requests for the National Institutes of Health and, specifically, the requests for NIAAA, NIDA, NIMH and NLM. AHSR recommends that NLM should be included as part of the President's Next Generation Internet Initiative and that funds should be directed to NLM for the purposes of evaluation of this initiative and to ensure inclusion of medical applications in the development of this new Internet infrastructure.

*Conclusion*

Health services research findings encourage cost-effective use of our nation's health care resources to provide better care, create greater access, and allow for more informed decisionmaking. A strong sustained federal commitment to health services research is essential if this critical information is to continue to be available as a resource for patients, physicians, insurers, employers, and policymakers. AHSR strongly supports an increased federal commitment to health services research as a means of reaching our nation's health cost containment goals while simultaneously improving our nation's health care delivery system.



## PREPARED STATEMENT OF WILVERIA B. ATKINSON, PH.D., THE SCIENCE AND TECHNOLOGY ADVISORY COMMITTEE

The National Association for Equal Opportunity in Higher Education (NAFEO) is the organization of Presidents and Chancellors of the Historically and Predominantly Black Colleges and Universities (HPBCUs). The committee on which I serve functions to (1) monitor participatory opportunities in science and technology for member institutions, (2) provide forums in which scientists from our institutions engage in dialogue with representatives from non-member institutions and relevant governmental and private agencies, and (3) advocate programs and processes that enhance the scientific and technological capabilities of our institutions. It is for support of two of the National Institutes of Health programs designed to increase the number of under-represented minority citizens that are engaged in biomedical research that I petition you today.

The Science and Technology Advisory Committee to NAFEO is keenly aware of, and sensitive to your efforts regarding budget controls. NAFEO understands that budget priorities must be made firmly in the best interest of the nation as a whole. The percentage of under-represented minority citizens in the nation and their participation in the biomedical research arena will increase dramatically by the year 2025. We have, therefore, looked carefully at the administration's budget request for the NIH and find no line-item budget requests for two of its programs that will have substantial impact in the 21st Century on the security and leadership role of our nation in the biomedical research arena. They are the Research Infrastructure in Minority Institutions (RIMI) Program administered by the National Center for Research Resources (NCRR) and the Minority International Research Training (MIRT) Program administered by the Fogarty International Center (FIC).

These programs are uniquely designed to be inclusive rather than exclusive by providing support for both minority and majority institutions through individual, collaborative and consortia institutional awards. In both programs, all qualified students and faculty meeting the criteria established by the particular institution are eligible to apply for and receive support for basic research or research training.

The RIMI Program is inclusive. A major feature of the program is the enhancement of biomedical research and research training capabilities of the institution. Through a novel directive, it requires and supports collaborative biomedical research projects between scientists at minority institutions and scientists at Ph.D. degree-granting majority institutions without regard to the ethnicity of the scientists. The collaborative efforts undergird substantial enhancement of the research and research training capabilities of the minority institutions while supporting research of collaborating partners at majority institutions. Through formal collaborative agreements, half of the scientists supported through RIMI awards are at majority institutions.

The MIRT Program is inclusive. Sixty-three percent of the programs are at non-HPBCUs. However, at all participating institutions, the primary focus of training is under-represented minorities. Trainees in the programs do biomedical research at premier institutions and training sites in fifty-seven different countries. While receiving invaluable biomedical research training, the academically talented, self-disciplined trainees are effective in counteracting the negative perceptions of under-represented minorities expounded for decades through the television media and the press. It is in the nation's best interest that foreign countries respect the capabilities and talents of under-represented minorities as these individuals assume greater prominence in global interactions on behalf of the United States in the 21st Century.

In this regard, in March 1996 Dr. Harold Varmus, Director of the NIH, appointed an external advisory panel, Co-Chaired by Drs. Joshua Lederberg of Rockefeller University and Barry Bloom of the Albert Einstein College of Medicine, to review the programs at the Fogarty International Center. The panel provided the Director its report in mid-December. In addition to recommendations on refocusing the functions of the Center/the panel endorsed three of the programs it administers. Second on the list of three was the Minority International Research Training (MIRT) Program.

Substantial increases to the budget of the NIH have been proposed, and the NAFEO strongly endorses those increases. However, the proposed increases do not include line-item budgets for the two programs that the NAFEO deems to be highly supportive of the nation's leadership role in the biomedical arena.

Therefore, the NAFEO respectfully requests that the following line-item budgets be included in the NIH appropriations for the fiscal year that begins October 1, 1997: For the National Center for Research Resources, NIH: Research Infrastruc-

ture in Minority Institutions—\$7,000, 000; For the Fogarty International Center, NIH: Minority International Research Training Program—\$7,000,000.

This total of fourteen million dollars for developmental research and research training added to the total NIH budget invested in biomedical research human resources within the under-represented minorities will still equal less than 1 percent of the budget of the NIH.

PREPARED STATEMENT OF THE COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL  
REHABILITATION

The Council of State Administrators of Vocational Rehabilitation (CSAVR) is comprised of the chief administrators of the public agencies providing rehabilitation services to persons with disabilities in the fifty (50) states, the District of Columbia, and the territories.

These Agencies constitute the State partners in the State-Federal Program of Rehabilitation Services for persons with mental and/or physical disabilities, as authorized by the Rehabilitation Act of 1973, Public Law 93-112, as amended.

While the Rehabilitation Act is the cornerstone of our Nation's commitment to assisting eligible people with disabilities to obtain competitive employment and to live independent and productive lives, it is severely underfunded.

When one considers that a Louis Harris and Associates study estimates that two out of every three adults with a disability are unemployed, and that the Rehabilitation Program has the resources to provide services to only one in twenty eligible people, this underfunding constitutes an unacceptable tragedy for the millions of people with disabilities who need services in order to become employed, yet are unable to receive them.

The great responsibility placed upon the Rehabilitation Program became even more acute, with the passage and implementation of the "Americans with Disabilities Act" (ADA). The ADA vastly expands opportunities for all Americans with disabilities. It is vital therefore that the Rehabilitation Program assist people with disabilities to fully realize the promise of this landmark legislation.

*Vocational rehabilitation services; basic State grants*

Fiscal year:		
1998 CSAVR recommendation .....	\$2,500,000,000	
1997 authorization .....		(1)

<sup>1</sup>Such sums.

Basic State Service Grants are the lifeblood of the Vocational Rehabilitation Program, financing the provision of vocational rehabilitation services to eligible individuals with mental and physical disabilities for placement in competitive employment.

These Federal dollars, matched with state monies, permit State Rehabilitation Agencies to provide, or to contract with private organizations and agencies to provide individualized, comprehensive services to eligible persons with mental and/or physical disabilities, for the purpose of rendering these individuals employed and independent.

Such services may include evaluation; comprehensive diagnostic services; counseling; physical restoration; rehabilitation engineering; the provision of various kinds of training and training supplies, tools and equipment; prosthetic devices; placement; transportation; post-employment services; and "any other service" necessary to rehabilitate an individual into employment.

For fiscal year 1997, the Federal Government advises that the \$2,176,038,000 appropriated for Basic State Vocational Rehabilitation provided services designed to lead to gainful employment for 1,255,142 people with disabilities of which 979,011 were severely disabled. Of this number, nearly 200,000 will be placed in competitive employment.

Despite this expenditure, there still are not sufficient funds to serve all those eligible, disabled people who have the potential and desire to work and who need rehabilitation and training services to obtain employment and self-sufficiency.

In carrying out the Congressional mandate to give priority of service to the rehabilitation of individuals who are severely disabled, State Agencies have found that the costs—in time, effort, and money for services—are much greater than the cost of rehabilitating people less severely disabled.

At the same time, it is alarming to note that the purchasing power of the resources available has remained virtually stagnant since 1980.

With these statistics in mind, the Council strongly urges that the Congress assist us in facing this challenge by providing Federal appropriations for Basic State Vocational Rehabilitation Services in the amount of \$2,500,000,000 for fiscal year 1998, an increase of \$323,962,000 over the fiscal year 1997 appropriation and \$253,112,000 over the fiscal year 1998 Administration request. With this increase in resources, the CSAVR estimates that nearly 200,000 more persons will receive services and 22,500 more will be placed in competitive employment.

The justification for higher funding levels stems from the purpose for which the money is spent—the prevention of an incalculable waste of human potential, a purpose on which no price tag can be placed.

Over the decades, Vocational Rehabilitation has more than paid for itself by helping persons with disabilities become gainfully employed; increase their earning capacity; by freeing family members to work; and/or by decreasing the amount of welfare payments, health services, and social services they might need; as well as by assisting them to become taxpayers.

Appropriating additional monies for Vocational Rehabilitation Services reduces the Federal Deficit.

Indeed, the Congressional Budget Office has stated that “a reduction of funds for rehabilitation \* \* \* would generate increases in other parts of the federal and state budgets.”

Funds appropriated for Vocational Rehabilitation are a sound investment of the Public's money.

#### OTHER PROGRAMS AUTHORIZED BY THE REHABILITATION ACT

The Rehabilitation Act is recognized as the most complete and well-balanced piece of legislation in the human services field. In addition to the Basic State Vocational Rehabilitation Services Program, the Act contains provisions for: an innovation and expansion program; a training program; a research program; a comprehensive services for independent living program; a supported employment program; and, among others, special projects and demonstration efforts. The CSAVR strongly supports adequate funding for all Sections of the Act.

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#### PREPARED STATEMENT OF DONALD W. DEW, ED.D., CRC, PROFESSOR OF COUNSELING, GEORGE WASHINGTON UNIVERSITY, ON BEHALF OF THE NATIONAL COUNCIL ON REHABILITATION EDUCATION

The National Council on Rehabilitation Education (NCRE) is an organization of over 100 colleges and universities composed of educators, researchers, human resource development specialists, and graduate students who are dedicated to quality education and training for a variety of rehabilitation professionals. The members of NCRE prepare qualified vocational rehabilitation professionals proficient in assisting individuals with disabilities to obtain meaningful employment.

I welcome the opportunity to submit testimony to this subcommittee to express the views of NCRE and to request that \$50 million be appropriated in fiscal year 1998 in order to meet the critical need for qualified rehabilitation professionals.

From its beginning in 1918, the vocational rehabilitation program in the United States has been a model of America's investment in itself. From its initial exclusive focus on veterans to its current priority on serving persons with severe disabilities, the vocational rehabilitation program has proven itself to be a cost-effective system that prepares people with disabilities for work and independence in the mainstream of society. During the majority of history, Congress wisely has augmented this investment by actively supporting the training and education of personnel to provide quality vocational rehabilitation services. Members of Congress have concluded that vocational rehabilitation services can be delivered to the 43 million Americans with disabilities in the most effective and efficient way by ensuring that the deliverers of those services are qualified professionals.

Most persons with disabilities are able to work. More importantly, like the vast majority of Americans, most of them want to work. According to the recent Lou Harris poll, 8.2 million people with disabilities looking for work at the time would immediately trade all of their disability benefits for a full-time job. Mr. Chairman, NCRE believe that these individuals deserve the opportunity to make that kind of trade-off. It is not only the right thing to do for fellow-Americans, it is a giant step toward reversing policies that have resulted in our spending over \$200 billion a year on “dependency programs” for individuals with disabilities, many of whom are highly motivated to become working taxpayers.

People with disabilities have better employment outcomes when they have received assistance from qualified rehabilitation professionals. Rehabilitation profes-

sionals work cooperatively with people with disabilities to provide counseling and guidance, evaluation, and job placement. Job placement is the primary goal of the vocational rehabilitation process. It is crucial that Congress ensure an adequate supply of qualified rehabilitation professionals through sufficient appropriations for rehabilitation education.

The Rehabilitation Services Administration has reported to Congress that for every \$1 spent on rehabilitation services to return an individual with disability to employment, \$18 in tax revenue to the Treasury is generated. Trained rehabilitation professionals provide better services for individuals with disabilities at a lower cost to the American taxpayers. In the 1992 Reauthorization of the Rehabilitation Act, Congress required states to use "qualified" rehabilitation professionals to provide vocational rehabilitation services. This change was implemented to benefit individuals with disabilities who are served by graduates of rehabilitation education programs. Federal funds supplementing state and local resources have allowed rehabilitation education programs to be responsive to changes in the field and address severe acute and chronic manpower shortages. Meeting these needs requires a nationally coordinated comprehensive educational program and graduates of these programs help improve employment outcomes for people with disabilities.

The United States Department of Education documented a critical shortage of qualified rehabilitation professionals nationwide. This shortage is exacerbated by the anticipated retirement of approximately 30 percent of rehabilitation professionals over the next five years.

Another challenge in the training of qualified rehabilitation personnel is the emphasis that RSA and rehabilitation education programs are placing on attracting students from traditionally under-represented populations. African-Americans, Hispanic Americans, Native Americans and students with disabilities are all being targeted for recruitment into the rehabilitation professions. Vocational rehabilitation agencies are serving increasingly diverse populations and it is critical that professional counselors reflect that diversity. Scholarship support serves as an extraordinarily effective tool to enhance recruitment of members of these under-represented groups.

Mr. Chairman and members of the Subcommittee, the National Council on Rehabilitation Education appreciates this opportunity to testify that \$50 million will be needed in fiscal year 1998. We are well aware of the challenge that Congress is under to reduce government costs. People with disabilities, along with many other Americans, share your frustration with the disproportionate spending on programs that promote dependence instead of that independence that comes with employment. We believe that an investment in rehabilitation education to increase the number of qualified rehabilitation professionals is the most cost-effective means to providing high quality services in the most fiscally responsible way possible.

Thank you very much for this opportunity to share our concerns and recommendations.

PREPARED STATEMENT OF THE NATIONAL AGING AND VISION NETWORK

The National Aging and Vision Network is comprised of individuals and representatives of public and private agencies that provide vision rehabilitation services to persons who are older and blind, who reside in all 50 states, the District of Columbia, and the territories. Formed in 1994, the Network's goal is to increase the availability of responsive, high quality services for older individuals who are blind or severely visually impaired through the vision-related rehabilitation system, the aging network, and the health care system. Network members collaborate on advocacy efforts, share vital information on service delivery mechanisms, work to develop outcome measures and to develop and maintain funding resources to support essential services.

*Rehabilitation services independent living services for older individuals who are blind (title VII, chapter 2)*

[In millions of dollars]

Fiscal year:		
1996 appropriation .....	8.95	
1997 appropriation .....	9.95	
1997 authorization .....	(1)	
Department of Education fiscal year 1998 request .....	9.95	
NAVN fiscal year 1998 recommendation .....	52.0	

<sup>1</sup> Formula grant.

*Justification*

There are over 4 million individuals in the country age 55 or over who are experiencing severe vision loss. This number has doubled in the last 30 years, and is expected to double again by 2030. These are not just numbers; these are our parents or grandparents who are experiencing difficulty adjusting to vision loss.

Prevalence of severe visual impairment is age-related. Prevalence of severe visual impairment is 47 per 1000 in individuals 65–74. By age 85, one in four older people cannot read a newspaper with best corrected vision. Loss of vision dramatically affects the older person's ability to do other everyday tasks as well.

However, through the funds currently available, agencies are still only reaching 5 percent of the individuals who are older and blind who need services to continue to live productive and independent lives.

We urge you to take this opportunity through this appropriation to continue to build on a first for this country, that is, a nationwide service delivery program which delivers what it promises and which truly makes a significant difference in the lives of older individuals who are blind, and who without these services are among our nation's most vulnerable citizens.

*Background*

Under the 1992 reauthorization of the Rehabilitation Act, Congress provided the mechanism to establish a nationwide service delivery system for individuals who are older and blind. They acted to change the existing law to allow formula funding of programs for older blind persons. However, this formula will not trigger until the appropriation level reaches \$13 million. With an appropriation of \$13 million, each state would receive a minimum of \$225,000.

We have found that this appropriation will not adequately meet the needs of individuals who are older and blind. We are asking that the appropriation level be increased from the current \$9.9 million to \$52 million. With the higher figure, states with larger populations of older individuals would receive proportionate amounts. This increase would ensure that older persons who are blind, and who live in any state or territory, will have the same access to vision-related rehabilitation services.

Since its first funding in 1986, this program has been one of the most successful and cost-effective programs initiated by Congress. In 1995–96, the grantee states used the funds to deliver services to over 22,000 older individuals at an approximate cost of \$500–\$600 per person. The number of people served through this program has increased 60 percent over the last three years, since a mechanism was established for minimum funding of \$160,000 for each state.

As documented in program evaluations and countless testimonials, Chapter 2-funded services have enabled older individuals who become blind to continue to live independently in their own homes and communities. The program has helped these older individuals to regain self-confidence, self-reliance, and self-worth by providing them the opportunity to learn the skills needed to perform the most basic tasks of daily living and to remain active and contributing members of their communities for as long as possible.

The types of services provided by grantee states include: training in how to travel safely; communications skills; training in activities of daily living skills; low vision services and adaptive devices; individual counseling; counseling and supportive services to family members; and community integration. The goal of all of the services is to reduce the need for costly support services, such as in-home and community-based long-term services, and/or premature nursing home placement.

—The program serves individuals who are newly blinded and have no where else to turn to obtain vision-related rehabilitation services.

—Chapter 2 funded services are cost-effective.

Tax dollars are directed toward helping individuals maintain or regain independent functioning and productivity, rather than costly in-home services or nursing home care.

With timely and appropriate intervention, the need for such care has been averted or delayed as has been indicated in a number of states in which independent living services are provided. This intervention results in extreme cost savings to the states and federal government. Provision of support services in the home through aging network programs or home-health agencies is costly.

The cost of providing independent living services on a one-time basis averages from \$500 to \$600 per person. In these difficult financial times for long term support services we need to do everything we can to insure that people can continue to live independently.

There is no other national service delivery program for older individuals who are blind.

Funds for vision-related rehabilitation services for older people who are blind are not provided through the Older Americans Act, through Medicare, Medicaid, or any other consistent funding mechanism. State rehabilitation agencies for the blind are the most logical service providers or brokers.

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PREPARED STATEMENT OF LYNNE P. BROWN, ASSOCIATE VICE PRESIDENT FOR GOVERNMENT AND COMMUNITY RELATIONS, ON BEHALF OF NEW YORK UNIVERSITY CENTER FOR COGNITION, LEARNING, EMOTION AND MEMORY

Research into cognition, learning, emotion, and memory can help educators, physicians, and other health care givers, policymakers, and the general public by enhancing our understanding of normal brain development as well as the many disabilities, disorders, and diseases that erode our ability to learn and think, to remember, and to emote appropriately.

New York University is seeking \$10.5 million over five years to establish at its Washington Square campus a Center for Cognition, Learning, Emotion and Memory. The program will draw on existing research strengths in the fields of neural science, biology and chemistry, psychology, computer science, and linguistics to push the frontiers of our understanding of how the brain functions, and how we learn.

Such exploration into the fundamental neurobiological mechanisms of the nervous system has broad implications for human behavior and decision making as well as direct applicability to early childhood development, language acquisition, teaching methods, computer science and technology development for education, the diagnosis and treatment of mental and memory disorders, and specialized training for stressful occupation.

*Cognition, Learning, Emotion and Memory Studies at NYU (CLEM)*

New York University is poised to become a premier center for biological studies of the acquisition, storage, processing and retrieval of information in the nervous system.

To be housed at NYU's Washington Square Campus within the Center for Neural Science, the new Center will capitalize on the university's expertise in a wide range of related fields that encompass our computer scientists who use MRI imaging for research into normal and pathological mental processes in humans, our vision scientists who are exploring the input of vision to learning and memory, our physical scientists producing magnetic measurements of brain function with a focus on the decay of memories, our linguists studying the relation of language and the mind, and our psychiatrists conducting clinical studies of patients with nervous system disorders.

The New York University Program in Cognition, Learning, Emotion and Memory (CLEM) focuses on research and training in the fundamental neurobiological mechanisms that underlie learning and memory—the acquisition and storage of information in the nervous system. Current studies by the faculty at NYU are determining why fear can facilitate memory; how memory can be enhanced; what conditions facilitate long-term and short-term memory; and where in the brain all these memories are processed and stored. The research capacity of this Center capitalizes on our expertise in physiology, neuroanatomy, and behavioral studies, and builds on active studies that range from the mental coding and representation of memory to the molecular foundations of the neural processes underlying emotional memories. Our faculty use electrophysiological and neuroanatomical techniques to study the organization of memory in the medial temporal lobe. Together these researchers bring substantial strength in psychological testing, computational sophistication, advanced tissues staining and electrical probes, and humane animal conditioning. These core faculty are well recognized by their peers and have a solid track record of sustained research funding from federal agencies and private foundations: total costs awarded and committed for their research for full project periods from all sources presently total \$7 million. Additional faculty are being recruited in areas of specialization that include: the cellular and molecular mechanisms operative in neural systems that make emotional memory possible, neurophysiological studies of memory in non-human primates, computational modeling of memory, and neuropsychological and imaging research on normal and pathological human memory.

Colleagues in the Biology Department are doing related work in the molecular basis of development and learning. Given the important input of vision to learning and memory, the Center has strong links with the many vision scientists based in the Psychology Department who work on directly related topics that include form, color, and depth perception, memory and psycholinguistics. Colleagues in behavioral science study learning and motivation, memory and aging. Physical scientists ex-

plore the magnetic measurement of brain function, with a focus on the decay of memories. CLEM also shares research interests with colleagues in the Linguistics Department, who study the relation of language and the mind.

Research linkages extend to computational vision studies, now centered in NYU's Sloan Program in Theoretical Neurobiology. The Sloan Program works closely with computer scientists at our Courant Institute on Mathematical Science, with colleagues at the Medical Center in Psychiatry, who use MRI imaging for research into normal and pathological mental processes in humans, and in Neurobiology, who are conducting clinical studies of patients with nervous disorders, especially memory disorders.

What is unique and exciting about the establishment of such a comprehensive center at NYU is the opportunity to tap into and coordinate this rich multidisciplinary array of talent to conduct pioneering research into how the brain works. In this, the "Decade of the Brain," NYU is strategically positioned to be a leader.

#### *Early childhood and education*

Research into the learning process as it relates to attention and retention clearly holds important implications for early childhood development. Although most of a person's brain development is completed by birth, the first few years of life are critically important in spurring intellectual development. For example, research has already shown that in their early years, children need human stimulation, such as playing and talking, to develop the ability to learn.

With more immigrant children in schools, language development is another crucial area of study. If a child's brain were more receptive to acquiring sounds during the first few months of life, and language in the first few years of life, then students may learn a second language more quickly if taught in the lower grades instead of waiting for high school.

In the midst of a national debate on education reform, thousands of education innovations are being considered without the advantage of a fundamental understanding of the learning process. CLEM researchers, coupled with educational psychologists, can contribute to a better understanding of how parents can stimulate their children's cognitive growth, how children learn at different stages and use different styles, how educators can accommodate those styles, and how educational technology can be harnessed to increase retention and memory.

At NYU, these efforts will be enhanced by our scholars and research conducted in our School of Education and our New York State-supported Center for Advanced Technology.

#### *Computer science and technology development*

As we refine our knowledge of how the brain acquires, processes, retains and retrieves information and images, we will also be able to improve the design, development and utilization of computer science and technology. As we reach a better understanding of how children learn, we can more effectively harness computer technology in the service of education.

At NYU, this effort is enhanced by the presence of our New York State-supported Center for Digital Multimedia, Publishing and Education, which brings together educators, laboratory scientists and software designers who explore how interactive multimedia technologies enhance learning and develop prototype teaching models.

#### *Specialized training*

Research into how cognition and emotion interact can have applicability to other diverse areas of interest including retraining of adult workers, job performance and specialized training for high risk or stressful jobs such as military service and emergency rescue work.

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PREPARED STATEMENT OF DR. ANN MARCUS, DEAN, SCHOOL OF EDUCATION, NEW YORK UNIVERSITY

Strong and sustained support is needed for the healthy development of children throughout American society. Without such support, we cannot expect to meet the demands of the future or provide the opportunities that young people need to function as productive citizens.

When we speak of support, however, we know that money is not enough. It is crucial that every form of support aim at strengthening the vision, capacity, and quality of the multiple institutions helping to build the lives of young people. Governments, universities, professional organizations, business and industry, and community organizations of all kinds needs to find better ways of working together to increase the quality of services provided to young children.

New York University is firmly committed to the improvement of social services and educational opportunities for the young. The challenge can be met only by learning from past experience and bringing new knowledge and insight as well as more productive forms of collaboration and quality enhancement into the delivery of crucially needed support for early development in children's lives. Our experience in research, professional preparation, and program delivery over several decades has illuminated several ingredients required for successful efforts to assist young children through programs designed for their benefit:

- Flexible and responsive technical assistance, shaped by community and family needs while at the same time informed by the best research and professional standards, is essential for strengthening local capacity for designing and managing effective programs.
- Programs aiming to provide greater support for child development must embody built-in strategies of continuous improvement, not only in terms of quality enhancement focusing on services and outcomes, but also generating better understanding of how to activate community and institutional partnerships in support of children and families.
- University-based efforts to coordinate services for children offer special promise for integrating research and practice, clarifying professional standards while improving service delivery, utilizing the comprehensive disciplinary mix and technological resources available in an intensely collaborative and creative environment, and fostering shared vision and purpose across sectors within a framework that emphasizes a growing knowledge base along with cooperative inquiry and dialogue attuned to community needs.
- Programs focusing on early childhood development need to be well designed to provide a solid foundation for the child's transition to school, making connections between success in overcoming obstacles during the first years of cognitive, emotional and social growth, and continued success in the first years of formal schooling and beyond. Special attention needs to be given to learning problems as disabilities in the lives of many children, all of whom have the potential for sustained development and productive lives when their needs are properly addressed.

#### *New York University's Head Start Programs*

In spring 1997, the New York University School of Education will submit a renewal application to the U.S. Department of Health and Human Services, Administration for Children and Families, for two Head Start programs: the Region IIA Head Start Technical Assistance Support Center (TASC) and the Resource Access Project (RAP). New York University has held both of these contracts since their origination (TASC in the late 1960s, RAP in the late 1970s). The TASC serves Head Start programs in New York and New Jersey; the RAP serves Head Start programs in both states and in Puerto Rico and the U.S. Virgin Islands.

New York University has a long, outstanding record in managing the Region IIA Technical Assistance Support Center and the Resource Access Project and expects to succeed in renewing its contracts with the Administration for Children and Families and continue its work with the Region's Head Start Programs. Factors which support the University's excellent record include:

- A dedicated, highly trained professional staff, many of whom have been with their projects for over ten years and know thoroughly how to assess the needs of the Region's Head Start programs and respond to those needs effectively and in a timely manner.
- Well-established consultant networks, carefully recruited and selected by the NYU staff and approved by the DHHS Regional Office. The consultants, who reside throughout Region II, work during the year to provide site-specific services to Head Start program directors, staff, children and families as needed. The TASC and the RAP staffs each maintain a pool of over 120 consultants who may be called into service.

#### *A Strong Commitment to Early Childhood Development*

New York University plays a growing role in assisting agencies, organizations, communities and families to improve opportunities for child development and education. In addition to its outstanding and wide array of academic programs, the School of Education currently sponsors a number of early childhood projects and initiatives, many of which receive substantial funding from public and private sources. These initiatives include:

- An Early Childhood Faculty Workgroup, representing several departments in the School of Education and faculty members from the NYU School of Social Work and Wagner School of Public Service. Under the direction of Dr. LaRue



Allen, Professor and Chair of the Department of Applied Psychology, the faculty group meets regularly to discuss issues in early childhood development and education, including Head Start, child care programs and pre-kindergarten programs. The faculty members are currently designing several research studies and service delivery demonstration projects and will seek external funding next spring. Dr. Edward Zigler, Professor at Yale University and one of the major figures in Head Start and early childhood development, has agreed to work with the Early Childhood Faculty Workgroup as a senior consultant and will assist with project design and developing collaborations with other researchers and networks in the United States.

- An Early Intervention Faculty Workgroup, also representing several departments in the School of Education and faculty members from the Rusk Institute of Rehabilitation Medicine, NYU Medical Center. This faculty group focuses on the needs of children with disabilities (ages 0–2) and their families, and is currently conducting a research study on the effectiveness of interdisciplinary delivery of home-based services to infants with special needs and their families.
- As previously mentioned, New York University's School of Education houses two federally-funded technical assistance programs which serve the Head Start programs in federal Region II. The Region IIa Head Start Technical Assistance Support Center (TASC) provides technical assistance and training to staff in all Head Start programs in New York and New Jersey. The Resource Access Program (RAP) provides technical assistance and training to Head Start staff in all programs in New York, New Jersey, Puerto Rico and the U.S. Virgin Islands. These two programs, funded by the DHHS Administration for Children and Families, have been awarded to New York University for over twenty years.
- Faculty in the School of Education's Department of Teaching and Learning (Dr. Frances Rust and Dr. Margot Ely), in collaboration with the School's Metropolitan Center for Urban Education (Dr. LaMar Miller), are currently conducting a professional development project for staff in four large Head Start Centers in New York City. This multiyear demonstration project is funded by the Robin Hood Foundation.
- Other early childhood projects in the School of Education include a personnel training project in early childhood special education, funded by the U.S. Department of Education's Office of Special Education and Rehabilitative; a research study on the need for aloneness in infants; and a longitudinal study of relationships between the mother-infant dyad and cognitive development in infants.

In summary, this nation must strengthen its commitment to children with continuous improvement of education and services for the young. New York University intends to devote its resources—through research, teaching, training, technical assistance, and professional service—to the greatest extent possible to expanding and strengthening available opportunities for healthy development, successful learning, and productive lives for the nation's young.

As early childhood with all its promise and peril rises on the list of the nation's priorities, NYU is growing in strength and reputation in this arena. Indeed, NYU has emerged as a major center of research and training across the spectrum of fields—education, psychology, nutrition, medicine—that bear upon children from birth to the early grades. NYU's Head Start Technical Assistance Support Center (TASC) and Resource Access Project (RAP) reside at the heart of the academic enterprise—and they draw from it in highly productive ways as they connect with communities and agencies and organizations engaged in the quest for quality improvement in Head Start and other services for the young. NYU is committed to the further expansion of early childhood initiatives and looks forward to working in partnership with the federal government toward that end.

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PREPARED STATEMENT OF CHARLES L. CALKINS, NATIONAL EXECUTIVE SECRETARY,  
FLEET RESERVE ASSOCIATION

#### *Introduction*

Mr. Chairman. The Fleet Reserve Association (FRA) appreciates the opportunity to offer this distinguished Subcommittee its views on Impact Aid to school districts providing educational programs for the children of members of the Uniformed Services.

FRA is a Congressionally Chartered organization with a membership of more than 162,000 men and women of the Navy, Marine Corps, and Coast Guard. It is the only military organization exclusively representing more than 500,000 active duty enlisted personnel of the Sea Services. It is estimated that greater than 60 percent

are married and that 50 percent have school-age children. Impact Aid is one of their major concerns.

*Public Law 103-382*

Public Law 103-382, Section 8001, provides “financial assistance to local educational agencies in order to fulfill the Federal Government’s responsibility to assist with the provision of educational services to federally connected children, because certain activities of the Federal Government place a financial burden on the local education agencies.” The meaning of those words has not strayed far from the language in the statute’s predecessor, Public Law 81-874—to provide financial assistance to school districts upon which the government placed a financial burden. That burden existed then, and continues to exist in school districts experiencing heavily-impacted enrollments of military-sponsored children.

Impact Aid legislation was first enacted exclusively to assist in educating the children of military personnel and federal employees enrolled in local schools on or near military/federal installations. Over the years, other classes of children have been added, but appropriations have failed to match the increases. The result has been a strain on the amount of federal funds available for impacted school districts.

*Classes of Military-Sponsored Students*

More than 2,300 schools in nearly 400 districts are affected by the impact of 545,000-plus enrolled military-sponsored children. Due to the numbers, FRA is concerned that the quality of education provided these children may be deteriorating, not because of the declining efforts of teaching professionals, but because of reductions in annual fundings of Impact Aid for both “a” and “b” categories of students. Category “a” students have military parents living and working on a military installation. Category “b” have parents either working or living on the installation, but not both.

Repeated attempts have been made to terminate payments to category “b” students. Again this year President Clinton’s fiscal year 1998 request contains no funds for the “b” students. In her prepared statement before the applicable House subcommittee, the Department of Education’s Assistant Secretary for Elementary and Secondary Education said of Impact Aid funding: “Our request would provide school districts funding (for) two categories of federally connected children that create the greatest financial burden on school districts—children living on Indian lands and the children of members of the uniformed services who live on Federal property.” (Emphasis Added)

The reason most often cited is that the parents of “b” students are paying taxes because they reside in the civilian community. This is partially true. However, no matter how much tax revenue is gained or lost, military personnel are protected by the Soldiers’ and Sailors’ Civil Relief Act (SSCRA). Non-resident military parents are not required to pay local or state income taxes or personal property taxes. So the reduction or termination of category “b” payments robs the school districts of needed funds to provide quality education for both military and civilian-sponsored students.

*Concern for Funding*

The funds requested for fiscal year 1998 by the Administration to assist in educating military-sponsored children total \$658 million. This is not anywhere near the \$850 to \$900 million needed to get the job done. More alarming to military parents is the fact that the Administration’s request covers school districts heavily impacted with children living on Federal lands, as well as those with military-sponsored children.

For more than two decades, beginning with the Nixon Administration, one President after another attempted to decrease funds for Impact Aid to school districts educating the children of members of the Uniformed Services. Most disturbing about President Clinton’s fiscal year 1998 budget request, is that it asks for less Impact Aid funding despite his claim that education is the Administration’s number one priority. President Clinton’s “Call to Action for American Education in the 21st Century” expresses little concern for the education of military-sponsored children for the coming fiscal year.

In 1995, the Defense Science Board Task Force on Quality of Life discovered that military families “are fully aware of the Impact Aid Program and its intent. (Military) Families believe Impact Aid not only assists the (school) districts they are forced to use, but also helps to ensure that local (school) districts address the needs of the military child.” They are troubled when funds come under attack or learn that the Administration has requested less money than needed to provide the resources to educate their children.

*Military's Impact on School Districts*

Of significance is the location of a great number of Navy and some Marine Corps active duty families. They are assigned to heavily-impacted military installations such as those in San Diego and Norfolk, Virginia, this, in turn, produces heavily-impacted school districts.

San Diego is an excellent example of the impact on local school districts. Due to lack of space, only token family housing is available on military installations in and near the city. Federal housing is located off the installations so military personnel assigned to that area must use local schools for the education of their children. Minimal local taxes may be collected for the school districts because the housing could be considered federal property. School districts thus have no choice but to rely heavily on congressionally appropriated Impact Aid funds.

Some school districts, short of Impact Aid funds, have attempted to force military personnel who have children enrolled to pay tuition. This resulted in the Department of Defense filing law suits to require applicable school districts to continue educating the children regardless of the cost or shortage of funds.

The Base Realignment and Closures Commission (BRAC) actions and the "downsizing" of military personnel contribute to the misconception that there is justification to decrease funds for Impact Aid. Another misconception is that there is no rationale to commit taxpayers' money for the education of children whose military parents live off federal installations. These misunderstandings leave many impacted school districts struggling for ways to meet rising budgets.

*The Need for Increased Appropriations*

FRA firmly supports enhanced education programs for all the Nation's citizens, but not at the expense of the children of our Sailors, Marines, and Coast Guard personnel. The defense of the Nation and its citizens, and the sustainment of the freedom to live in a Country devoted to education, rests with the military students' parent-sponsors serving in the U.S. Armed Forces.

These men and women endure personal sacrifices to carry out the missions assigned by their Commander-in-Chief, the President of the United States. As the Chairman, House National Security Committee, recently stated: "Soldiers, Sailors, Airmen, and Marines are working harder and longer to execute their peacetime missions due to an inherent tension between personnel and resource shortages and an increased pace of operations. Military personnel and their families are paying an increasingly higher human price from repeatedly being asked to 'do more with less'." The current personnel tempo they are sustaining would cause the average citizen-employee to throw up his or her hands and walk off the job.

The military has reduced its troop strengths, nearly 30 percent since 1989. Still the number of operations involving military personnel have not decreased concurrently to offset the loss. Desert Shield, Desert Storm, Somalia, Haiti, Bosnia are but a few of the larger operations that have kept, or are now keeping troops on the move and away from their families over extended periods.

More than 50 percent of the Navy is at sea or deployed at any one time. Marines can expect to be deployed 50 percent of their time in the Corps, or longer if stationed in Hawaii. The Coast Guard has more operational commitments than it has personnel on the active duty roster.

The down-sizing of the military, the closing or realignment of military installations and Presidential recommendations endorsed by Congress, dictate much of the increased tempo resulting in longer family separations leaving one spouse to often act as a single parent. These actions jeopardize the morale of both parents and create anxiety and concern among their children.

One of the military's top enlisted chiefs stated that his troops could withstand the increased personnel tempo as long as they know their families are being well-cared for by the very Government sending them away from their loved ones for months at a time. FRA implores that Congress, which is Constitutionally-charged with raising an army and navy for the defense of the nation, will do its best to keep the morale of Service personnel at the highest level of readiness. It could begin here by adding to the President's Impact Aid appropriations request. A significant amount is needed to relieve the concern military parents have for their children's well-being and future education.

The Association gratefully acknowledges the interest and support of this distinguished Subcommittee in past years in correcting the shortfall-requests for Impact Aid funds.

PREPARED STATEMENT OF GEORGE A. ZITNAY, PH.D., PRESIDENT AND CEO, BRAIN INJURY ASSOCIATION, INC.

Dear Mr. Chairman and Members of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies:

Thank you for allowing me the opportunity to submit testimony on behalf of the Brain Injury Association, Inc. for the record. My name is George A. Zitnay, Ph.D., and I am the President and Chief Executive Officer of the Brain Injury Association. My testimony focuses on the Traumatic Brain Injury (TBI) Model Systems under the National Institute on Disability and Rehabilitation Research (NIDRR) with the Department of Education.

There is a strong need to expand this program from the limited number of four sites to a more appropriate number of 12 to 15. Funding of \$7 million, the same as that which is provided for Spinal Cord Injury Model Systems, is needed for this important program in fiscal year 1998. Significant advances in care have been developing as a result of the TBI Model Systems, and additional systems are urgently needed to assist more states in implementing service systems for people with TBI.

Below is background information on brain injury, the Brain Injury Association and the work of the TBI Model Systems:

*Brain injury*

Traumatic brain injury is defined as an insult to the brain, not of a degenerative or congenital nature but caused by an external physical force, that may produce a diminished or altered state of consciousness, which results in an impairment of cognitive abilities or physical functioning. It can also result in the disturbance of behavioral or emotional functioning.

Traumatic brain injury has become the number one killer and cause of disability of young people in the United States. Motor vehicle crashes, sports injuries, falls, and violence are the major causes of traumatic brain injury. Long known as the silent epidemic, TBI can strike anyone—infant, youth or elderly person—without warning and with devastating results. Traumatic brain injury affects the whole family and often results in huge medical and rehabilitation expenses over a lifetime.

An estimated 1.9 million Americans experience traumatic brain injury each year. Incidence is highest among younger adults. A major disability like TBI has a profoundly disorganizing impact on the lives of individuals and their families. Questions involving community, family, and vocational-restoration, as well as concerns about future happiness and fulfillment are common. (Banja, J. & Johnston, M. "Ethical Perspectives and Social Policy," Archives of Physical Medicine and Rehabilitation, Vol. 75, SC-19, December, 1994). Even individuals who have integrated well into society experience adverse psychosocial effects. Employment instability, isolation from friends, and increased need for support are a few of the problems encountered by individuals with TBI. Families often function as the primary support system for individuals with TBI after discharge from acute care. There is a clear and compelling need for research to develop family treatment strategies and explore their effect on outcomes for individuals with TBI.

*The Brain Injury Association*

The Brain Injury Association, is a national, non-profit advocacy organization dedicated to improving the lives of persons with brain injury, as well as promoting research, education and prevention of brain injuries. It is composed of individuals with traumatic brain injury, their families, and the professionals who serve them. What began as a small group in a mother's kitchen has blossomed into a national organization with 44 state associations, over 400 local support groups and thousands of individual members.

*The Traumatic Brain Injury Model Systems Program*

In 1987, the National Institute on Disability and Rehabilitation Research (NIDRR) provided funding to establish TBI Model Systems of Care. These research and development projects focused primarily on developing and demonstrating a comprehensive, multidisciplinary model system of rehabilitative services for individuals with TBI, and evaluating the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.

The TBI Model Systems serve a substantial number of individuals, allowing the projects to conduct clinical research and program evaluation, which maximize the potential for project replication. In addition, the TBI Model Systems have the ad-

vantage of a complex data collection and retrieval program with the capability to analyze the different system components and provide information on project cost effectiveness and benefits. Information is collected throughout the rehabilitation process, permitting long-term follow-up on the course of injury, outcomes, and changes in employment status, community integration, substance abuse and family needs. The TBI Model Systems projects serve as regional and national models for program development and as information centers for consumers, families and professionals.

On March 4, 1997, NIDRR issued a notice of proposed priorities in the Federal Register, for fiscal years 1997 and 1998 for research and demonstration projects, rehabilitation research and training centers, and a knowledge dissemination and utilization project. The TBI Model Systems project was included in NIDRR's proposed priorities. It is the Brain Injury Association's understanding that NIDRR received a record number of comments in response to this notice. Most commenters requested an increase in the number of TBI Model Systems sites and in funding for the program.

In the notice, NIDRR acknowledged that the health care costs associated with TBI are staggering, and stated "[i]n view of current scrutiny of all health care spending, which may result in pressures to constrict or deny rehabilitation care to individuals with traumatic brain injury, it is important to gather information on the efficacy and cost-effectiveness of various treatment interventions and service delivery models. Credible outcome monitoring systems are needed to establish guidelines by which fair compromises can be reached (citing Johnston, M. & Hall, I. "Outcomes Evaluation in TBI Rehabilitation," Part I: Overview and System Principles, "Archives of Physical Medicine and Rehabilitation," Vol. 75, December, 1994). NIDRR continued, "a greater emphasis on outcomes measurements and management will foster the gathering of information on efficacy and cost-effectiveness."

The TBI Model Systems Program continues to maintain a unique role by collecting essential information:

- nature and intensity of rehabilitation services (acute trauma through community integration);
- costs and benefits of rehabilitation services to persons with differing characteristics;
- circumstances and severity of injury;
- information on community integration, especially regarding vocational outcome and quality of life;
- data on multiple concussions in sports;
- annual lifetime follow-up.

The program also emphasizes widespread dissemination of findings through publications, conferences, and development of Internet resources.

In addition to addressing specific research questions, TBI Model Systems provide individualized services to those with TBI and their families especially after discharge from rehabilitation, such as community referrals, peer support and outpatient therapy.

While the incidence of severe TBI related to vehicular crashes has leveled off, interpersonal violence continues to increase and has become a primary cause of TBI, as well as the prevalence of multiple concussions in sports. Each year, an increasing number of new persons with brain injury are followed; the data collection and quality assurance resources necessary for lifetime follow-up has increased exponentially. Considering the inclusion of new persons in the data base each year, more and more resources will be necessary for long term follow up.

Additional centers are needed to speed up the accumulation of data, which is important given the impact on the health care system due to managed care. The current number of centers is small relative to the incidence of TBI in this country. Increased funding is necessary since the level of funding has not changed since the initial awards were made a decade ago, and there is an increasing burden on each center to meet goals with essentially less funding each year.

With more resources, the TBI Model Systems would be better able to accomplish the following:

- determine the effects of managed care and how reduced lengths of stay and reduced services affect outcomes and long term costs for persons with TBI;
- develop more effective employment programs to reduce the 75 percent unemployment level which exists for at least the first four years following injury. This effort would help reduce the cost of public assistance programs;
- develop and evaluate new neuromedical treatment strategies which could prevent the occurrence or impact of early and late medical complications and reduce costs;
- develop targeted interventions to accommodate unique needs of minorities, thereby reducing the social and economic costs of violent brain injury;

- establish clear decision rules to triage to traditional and alternative programs with a full analysis of costs and benefits; and
- increase access to information through the Internet—TBI Model Systems Web Site.

The Brain Injury Association is aware of numerous sites, in over 14 states, that would be interested in establishing additional TBI Model Systems, and some that might coordinate with a few of the 18 existing Spinal Cord Injury sites. The incidence of traumatic brain injury is substantially greater than that of spinal cord injury and the number of facilities to meet the needs of people with TBI should appropriately reflect this fact.

I respectfully request that you consider the needs of persons with traumatic brain injury and their families and expand the TBI Model Systems program to 12 to 15 sites, funded by \$7 million in fiscal year 1998.

Thank you for your continued support for this important program. I appreciate your time and attention in assuring that an appropriate expansion may be fully realized.

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PREPARED STATEMENT OF THE AMERICAN FOUNDATION FOR THE BLIND

*Introduction*

The mission of the American Foundation for the Blind is to enable persons who are blind or visually impaired to achieve equality of access and opportunity that will ensure freedom of choice in their lives. AFB accomplishes this mission by taking a national leadership role in the development and implementation of public policy and legislation, informational and educational programs, diversified publications, and quality services.

In light of the recent reauthorization and restructuring of the Individuals with Disabilities Education Act (IDEA) (Public Law 105-17), we felt it important to supplement our recommendations for fiscal year 1998 appropriations to the Subcommittee on Labor, Health and Human Services, Education and Related Agencies. The following recommendations particularly reflect the reorganization of the discretionary programs in IDEA and supplement the Statement for the Record previously filed by the American Foundation for the Blind on May 1, 1997 (copy attached).

As in our previous statement, this document is presented in tabular summary form to facilitate its readability. Additional information to substantiate the rationale for each of the funding recommendations will be furnished to the Subcommittee upon request.

INDIVIDUALS WITH DISABILITIES EDUCATION ACT

When IDEA was first enacted as the Education for All Handicapped Children Act (Public Law 94-142), Congress promised the states that Part B, the State Grant section, would ultimately provide 40 percent of the average per pupil expenditures. That goal has never been met. However, AFB is genuinely pleased to hear that many Members of Congress this year are interested in large increases to Part B of IDEA to bring the appropriated amount closer to that figure. We hope that, should new money become available for IDEA, increases will be made to all deserving programs under the statute rather than all increases being added to Part B. Increases to the Infants and Toddlers program (Part C), the Preschool program (Section 619), and the support programs in the new Part D are also of great importance to students who are blind or visually impaired. Technology development, personnel training to address shortages in the field, video description, and early intervention for blind or visually impaired infants and toddlers to try to avoid additional expenses at a later age are all urgently needed.

*Infants and toddlers with disabilities (part C, formerly part H)*

[In millions]

Fiscal year:	
1996 appropriation .....	\$315.8
1997 appropriation .....	315.8
1998 authorization .....	400.0
President's fiscal year 1998 request .....	<sup>1</sup> 324.0
AFB fiscal year 1998 recommendation .....	<sup>1</sup> 400.0

<sup>1</sup>The fiscal year 1996 and fiscal year 1997 appropriations numbers are based upon the previous IDEA statute, prior to reauthorization. The President's fiscal year 1998 and the AFB 1998 recommendations are based upon the newly reauthorized and restructured IDEA.

We believe that the full authorization level of \$400 million for fiscal year 1998, as found in the Individuals with Disabilities Education Act Amendments of 1997 (Section 645), should be appropriated for this program. The number of children served under the Infants and Toddlers program has increased from 150,000 to 190,000 over the last four years with no parallel increase in appropriations. The success rate of this program and its early intervention focus in enhancing the development of infants and toddlers with disabilities, including those who are blind or visually impaired, and the capacity to meet their needs has been proven. The money to expand the program is necessary and well spent.

*Preschool grants (section 619)*

[In millions]

Fiscal year:	
1996 appropriation .....	\$360.4
1997 appropriation .....	360.4
1998 authorization .....	500.0
President's fiscal year 1998 request .....	374.8
AFB fiscal year 1998 recommendation .....	500.0

We believe that the full authorization level of \$500 million for fiscal year 1998, as found in the Individuals with Disabilities Education Act Amendments of 1997 (Section 619(j)), should be appropriated for this program. The number of children served under the Preschool program has increased from 491,000 to 577,000 over the last four years with no parallel increase in appropriations. The ability of schools to provide a free appropriate public education to children ages three to five to effectively transition from Part C, Infants and Toddlers program, to Part B. State Grant program, is imperative. An increase in this appropriation is necessary to keep up with the increased demand and help states meet their obligation.

*Personnel preparation to improve services and results for children with disabilities (part d, subpart 2; section 673)*

[In millions]

Fiscal year:	
1996 appropriation .....	\$91.34
1997 appropriation .....	93.33
1998 authorization .....	( <sup>1</sup> )
President's fiscal year 1998 request .....	82.1
AFB fiscal year 1998 recommendation .....	123.76

<sup>1</sup>Such sums.

We remain seriously concerned about adequately funding personnel preparation to address the shortage of teachers who are trained to deal with the unique needs of blind or visually impaired children. First, sufficient appropriation to this section is necessary to guarantee an adequate number of qualified personnel who can instruct blind and visually impaired students in such specialized services as orientation and mobility and the use of braille. These are the very skills that Congress recently recognized in the IDEA reauthorization are important to these children's education (See Section 602(22) on orientation and mobility and Section 614(d)(3)(B)(iii) on braille). Second, Congress recognized in the recent reauthorization the importance of the federal role in low incidence personnel preparation (Section 671(a)(4)(C)) and Section 673(b)). Sufficient appropriation to support that role is imperative. We are concerned that the restructuring of the personnel preparation section and the addition of the new State Improvement Grants to address some of the personnel preparation needs in the states (and necessary appropriation for that section), may cause a diminution in the appropriation for the personnel preparation programs that remain under federal control.

*Technology development, demonstration, and utilization and media services (section d, subpart 2; section 687)*

[In millions]

Fiscal year:	
1996 appropriation .....	<sup>1</sup> \$29.1
1997 appropriation .....	30.0
1998 authorization .....	( <sup>2</sup> )
President's fiscal year 1998 request .....	30.0

AFB fiscal year 1998 recommendation ..... 41.6

<sup>1</sup>Total of the former technology and media and captioning lines.

<sup>2</sup>Such sums.

#### *Technology*

Access to adaptive technology, such as talking computer terminals, has a significant impact on the appropriate education for children who are blind or visually impaired. In addition, incentives for development and availability of new technologies as funded under this part are of crucial importance to students with low incidence disabilities, including those who are blind or visually impaired, because of the small size of potential markets.

#### *Video Description*

The reauthorization of IDEA includes language limiting, beginning in 2001, the video description or captioning that can be funded under this section. Video description provides blind or visually impaired persons with narration of visual elements of television, cinema and performing arts. Part of the rationale for the limiting language is that the transition to private funding of captioning should be well underway by that time due to the publication of the Federal Communications Commission's regulations on captioning in August 1997. (See Senate Report 105-17, page 39 or House Report 105-95, page 119). However, the FCC has not regulated on video description and hence there will be no requirement for video described programming on broadcast television as there will be with captioning. Additionally, video description is a newer technology which is not as advanced as captioning in its movement toward the development of private funding sources. This recommendation includes \$3.0 million for video description services, a \$1.5 million increase over the fiscal year 1997 appropriation in order to assure that people who are blind or visually impaired are not left behind as new technology is developed. Additionally, it allows video description to expand its markets in anticipation of the 2001 deadline.

#### *Services for deaf-blind students (section 661(i)(1)(A))*

[In millions]

Fiscal year:		
1996 appropriation .....	\$12.83	
1997 appropriation .....	12.83	
1998 authorization .....	( <sup>1</sup> )	
President's fiscal year 1998 request .....	NA	
AFB fiscal year 1998 recommendation .....	<sup>2</sup> 29.2	

<sup>1</sup>Such sums.

<sup>2</sup>Although this is no longer a line item, AFB believes that programs serving deaf-blind students should total \$29.2 million.

The discretionary programs reorganized by the IDEA Amendments of 1997 no longer provide a separate programmatic line for deaf-blind services. However, Congress recognized the importance of the federal role in providing services to this population by including services to deaf-blind students in several sections of Part D (technical assistance, regional resource centers, etc.) and by creating a floor of the current 1997 appropriation of \$12.83 million below which total funding for these students would not fall (Section 661(i)(1)(A)).

However, a \$12.83 million floor does not take into account the current needs of this population. The currently identified population of 11,000 children is at an all-time high, up from 2,500 children when the program was first authorized. Despite such a significant growth in population, the appropriation has not increased. We believe that direction from the Committee to recognize the need for increased funding to this population is imperative to assure that the floor created by the new law does not become a ceiling beyond which additional funding will not be provided. As stated in our previous appropriations statement, we believe that programs serving this population should total \$29.2 million in order to address the needs of these students.

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PREPARED STATEMENT OF THE AMERICAN FOUNDATION FOR THE BLIND, MAY 1, 1997

#### *Introduction*

The mission of the American Foundation for the Blind is to enable persons who are blind or visually impaired to achieve equality of access and opportunity to all



aspects of society. AFB accomplishes this mission, in part, by taking a national leadership role in the development and implementation of public policy and legislation.

We appreciate the opportunity to submit our appropriations recommendations for fiscal year 1998 to the Subcommittee on Labor, Health and Human Services, Education and Related Agencies. This document is presented in tabular summary form to facilitate its readability. Additional information to substantiate the rationale for each funding recommendation will be furnished to the Subcommittee upon request. Please note that the recommendations (in millions of dollars) contained herein do not reflect adjustments for inflation. Therefore, if our recommended amount for each program or activity cannot be appropriated, we urge the Subcommittee to increase the appropriation by at least a factor for inflation.

*Individuals With Disabilities Education Act—Special education personnel  
development (part D)*

Fiscal year:	
1996 appropriation .....	\$91.34
1997 appropriation .....	93.33
1998 authorization .....	( <sup>1</sup> )
President's fiscal year 1998 request .....	NA
AFB fiscal year 1998 recommendation .....	123.76

<sup>1</sup> Pending

We are seriously concerned about the shortage of teachers who are trained to deal with the unique needs of blind and visually-impaired children. Congress needs to fund these programs at the recommended level to ensure an adequate supply of qualified personnel who can instruct blind children in such skills as orientation and mobility and the use of braille. Also, this recommendation includes an appropriation to the full authorization level for grants to Historically Black Colleges and Universities which would significantly assist in achieving critically needed improvement in training persons to serve those needs in their communities.

*Technology, educational media, and materials for individuals with disabilities  
(part G)*

Fiscal year:	
1996 appropriation .....	
1997 appropriation .....	
1998 authorization .....	( <sup>1</sup> )
President's fiscal year 1998 request .....	NA
AFB fiscal year 1998 recommendation .....	\$15.0

<sup>1</sup> Pending

Access to adaptive technology, such as talking computer terminals, has a significant impact on appropriate education for children who are blind or visually impaired. Accordingly, Congress should fund Part G as recommended to assist in the development and availability of new technologies.

*Centers and services for deaf-blind children (sec. 622)*

Fiscal year:	
1996 appropriation .....	\$12.83
1997 appropriation .....	12.83
1998 authorization .....	( <sup>1</sup> )
President's fiscal year 1998 request .....	NA
AFB fiscal year 1998 recommendation .....	29.2

<sup>1</sup> Pending.

This recommendation would allow a needed increase for the Office of Special Education Programs to fund authorized projects. The currently identified population of 11,000 children is at an all-time high. Of these children, 5,000 are being educated in the local school districts which means that coordinators must provide technical assistance in very wide geographic areas. This has resulted in an increasing number of special educators and general educators who need basic training in instruction of the children who are deaf-blind.

*Media and captioned films (sec. 653)*

Fiscal year:	
1996 appropriation .....	\$19.13
1997 appropriation .....	20.03

1998 authorization .....	( <sup>1</sup> )
President's fiscal year 1998 request .....	NA
AFB fiscal year 1998 recommendation .....	26.6

<sup>1</sup> Pending.

We are particularly interested in two programs authorized by Section 653. This recommendation includes \$3.0 million for video description services which is a \$1.5 million increase over the fiscal year 1997 appropriation. Video description provides blind persons with narration of visual elements of television, cinema, and performing arts. The number of venues for video description has grown from 32 public television channels to 142 today; to open description on cable channels to featured classic films on a major cable channel. This recommended appropriation level will provide assurance that blind people are not left behind as new technology allows for the deployment of digital television and expansion of the multi-media environment in the classroom.

Also in this account, we recommend inclusion of a \$1.0 million increase over fiscal year 1997 funding for Recording for the Blind and Dyslexic (RFB&D). RFB&D is the only national source of recorded educational textbooks for blind or visually impaired students at all levels. Increased funding will allow for the expansion of digital audio tapes, a new technology which significantly enhances the utility of text book tapes.

*Rehabilitation services independent living services for older blind individuals—title VII, chapter 2*

Fiscal year:	
1996 appropriation .....	\$8.95
1997 appropriation .....	9.95
1998 authorization .....	( <sup>1</sup> )
Department of Education fiscal year 1998 request .....	9.95
AFB fiscal year 1998 recommendation .....	52.0

<sup>1</sup> Such sums.

The recommended appropriation level will move this program into a fully funded formula grant program. Between 1960 and 1990, the number of severely visually impaired persons age 65 and older, living in the community doubled to three million; the number living in nursing homes doubled to 500,000. (National Center for Health Statistics) The current appropriation allows only a very modest program in each state which works to keep these individuals independent. The recommended appropriation level would, for example, (based on an informal calculation of a formula grant) provide Illinois with a grant of nearly \$2,270,000 and Wisconsin with \$1,013,226. With the public cost of nursing home placements now averaging \$30,000 per year, it is clear that more appropriate and less expensive alternatives to institutionalized care must be found.

*Rehabilitation services rehabilitation training (sec. 302)*

Fiscal year:	
1996 appropriation .....	\$39.63
1997 appropriation .....	39.63
1998 authorization .....	( <sup>1</sup> )
Department of Education fiscal year 1998 request .....	39.63
AFB fiscal year 1998 recommendation .....	50.0

<sup>1</sup> Such sums.

Long-term grants under the Rehabilitation Act provide the only source of funding for college-based programs to train orientation and mobility instructors and rehabilitation teachers for the blind. As a result of the 1992 amendments to the Rehabilitation Act, the eligibility rate for client services has increased, creating the need for professional services in an area with already well-documented shortages.

*Rehabilitation services braille training projects (section 803, part B)*

Fiscal year:	
1996 appropriation .....	\$0.573
1997 appropriation .....	.248
1998 authorization .....	( <sup>1</sup> )
Department of Education fiscal year 1998 request .....	<sup>2</sup> NA

AFB fiscal year 1998 recommendation ..... 1.0

<sup>1</sup>Such sums.

<sup>2</sup>Funding has been provided under Title III Special Demonstrations Programs. Variation in funding is based on the number of projects in a multi-year funding cycle.

Since fiscal year 1993, approximately \$2.2 million has been allocated to the effort to increase Braille literacy. These projects provide Braille literacy training to rehabilitation professionals, parents of blind children, and family members of blind individuals in the form of instructional materials such as computer tutorials and the creation of a national network of experts in teaching Braille. Increased funding will allow for the development of future projects for the training of multiply-impaired blind persons, training for those blind persons for whom English is a second language, and more development work in the area of teaching mathematics.

*Helen Keller National Center*

Fiscal year:	
1996 appropriation .....	\$7.14
1997 appropriation .....	7.34
1998 authorization .....	( <sup>1</sup> )
Department of Education fiscal year 1998 request .....	7.53
AFB fiscal year 1998 recommendation .....	8.57

<sup>1</sup>Such sums.

Three important factors have emerged to create the need to increase the appropriation for the Helen Keller National Center (HKNC). HKNC, the American Association of the Deaf-Blind, the Rehabilitation Services Administration, and the Council of State Administrators of Vocational Rehabilitation have developed a cooperative agreement for providing state plans for deaf-blind services. However, effective implementation of this plan is based on development of a national registry which current funding levels will not support. Second, there is a great need to expand training in and development of new technology in computer hardware and software for employment training. Third, the HKNC endowment authorized by the 1992 amendments has not been initiated because federal funds required to trigger its establishment have not yet been appropriated.

*American Printing House for the Blind*

Fiscal year:	
1996 appropriation .....	\$6.68
1997 appropriation .....	6.68
1998 authorization .....	
Department of Education fiscal year 1998 request .....	6.68
AFB fiscal year 1998 recommendation .....	8.19

We recommend an increase of at least \$1.51 million for the American Printing House for the Blind (APH). The number of students served continues to grow even though the appropriation has remained fairly constant. Even the recommended appropriation level would only bring the per capita allotment to \$122.09 per student with an estimated number of registered students of 57,008. That is the same per capita allotment which was available in 1983 when the estimated number of eligible students was 38,249. This failure to keep pace with the number of eligible students results in the development of fewer specialized educational materials provided to blind students. This limits their ability to benefit from educational programs on an equal basis with their sighted peers.

PREPARED STATEMENT OF DAVID GIPP, PRESIDENT, AND RUSSELL MASON, CHAIRMAN,  
UNITED TRIBES TECHNICAL COLLEGE

RE: UNITED TRIBES TECHNICAL COLLEGE USE OF VOCATIONAL EDUCATION FUNDING IN  
MOVING FAMILIES FROM WELFARE TO WORK

United Tribes Technical College (UTTC) submits this statement on fiscal year 1998 Department of Education funding for tribally controlled postsecondary vocational education institutions as authorized under Title III, Part H of the Carl Perkins Vocational and Applied Technology Education Act.

All levels of governments in this country—tribal, federal, state, local—are searching for ways to move people from welfare to work. We want you to know that not only does UTTC have an excellent track record in this regard, but our college edu-

cates and trains persons from Indian reservations which suffer the highest chronic employment in the nation.

*Appropriations request*

Our fiscal year 1998 requests are:

- \$4 million for Tribally Controlled Postsecondary Vocational Institutions, a \$1.1 million increase over the Administration's fiscal year 1998 request and the fiscal year 1997 enacted level. Funding for this program is authorized under Title III, Part H of the Carl Perkins Act, and it supports UTTC and one other tribally controlled postsecondary vocational institution, the Crownpoint Institute of Technology. The Administration's request for \$2.9 million would maintain the same level of funding appropriated for each of the past several years; and
- We ask that the Committee Report acknowledge the important role of tribally controlled postsecondary vocational institutions in moving Indian people into economic self-sufficiency.

*Who is United Tribes Technical College?*

Established in 1969, the UTTC is a unique, inter-tribal vocational technical education institution located on a 105-acre campus in Bismarck, North Dakota. UTTC is owned and operated by five Tribes situated wholly or in part in North Dakota: the Spirit Lake Dakota Tribe, the Sisseton-Wahpeton Sioux Tribe, the Standing Rock Sioux Tribe, the Three Affiliated Tribes of the Fort Berthold Reservation, and the Turtle Mountain Band of Chippewa. Control of the institution is vested in a ten-member board of directors comprised of elected Tribal chairpersons and Tribal council members.

UTTC is a "full service" postsecondary vocational education institution—we provide vocational education services for adults, run a nursery, pre-school and elementary school for the children of our adult students, and operate a dormitory system and a health clinic. We believe that this community setting has a great deal to do with the success of our students—students who, by and large, come from impoverished homes and communities.

*Moving Indian students and their families from welfare to work*

Most of UTTC's students receive some form of public assistance. Yet, when our students graduate, we place over 80 percent of them in jobs—a job placement record sustained over the past 10 years. This is well above the job placement rates required in the welfare reform statute. Our calculations show that a UTTC graduate pays back in taxes over a 6.4 year period the costs of receiving an education at our institution.

Our 300+ students come from all over Indian country—some years we have students representing 45 tribes. Combined with family members and our pre-school and elementary students, the UTTC campus population exceeds 500. The majority of the students have never spent more than one continuous year away from their home reservations. They have also experienced chronic unemployment due to extremely depressed local economies and to education limitations which are well below the national average.

A large proportion of our students are from the 14 tribes in North Dakota and South Dakota, where the jobless rates are enormously high. BIA Labor Force data reports that the percentage of the potential Indian labor force on and near reservations in the Aberdeen Area (South Dakota, North Dakota, Nebraska) which is not employed is 75 percent—the BIA's official unemployment rate for this area is 47 percent. Of Indian people living on and near reservations in the Aberdeen area who are employed, only 16 percent earn over \$9,000.<sup>1</sup>

Thus, UTTC is committed not only to its post-secondary mission, but to the economic, social, and cultural advancement of Indian people. Our mission is to provide an environment where students and staff can preserve and transmit knowledge, values, and wisdom to ensure the survival of native people and Indian Nations along with the vocational training of native students. There is no other post-secondary vocational education institution that in a residential setting is Tribally-controlled, culturally-based, family-oriented, and focused on both Tribal economic needs and mainstream employment training.

The enactment last August of welfare reform legislation makes the work of UTTC even more critical. We want to be a full partner in moving Indian families into jobs with living wages, but as it stands now, we have to turn away students due to lack of institutional resources. We do no recruiting at UTTC, yet we have a current wait-

<sup>1</sup> Indian Service Population and Labor Force Estimates, U.S. Department of the Interior, Bureau of Indian Affairs, 1995.

ing list of over 200 students who want to attend our institution. Some persons wait for 2 to 4 years to be admitted, and some potential students do not even apply, knowing of the waiting list.

*UTTC Accredited Program Offerings and Other Services.*

We offer ten accredited certificate programs and ten accredited Associate of Applied Science degree programs.<sup>2</sup> We are in the process of integrating entrepreneurship and high technology offerings into appropriate curricula. All programs are accredited through the North Central Association of Colleges and Schools at the certificate and two-year degree granting levels.

Because of its unique residential setting, we provide those institutional services that are fundamental to the delivery of quality vocational education programming. These services include:

- Adult education for students needing advanced basic education skills or who desire to pursue vocational programs requiring GEDs or high school diplomas;
- Academic instruction which allows our graduates who wish to pursue additional college education a sufficient background;
- Instructional supplies and equipment for all vocations;
- Student services including housing, a cafeteria, local student transportation, library, financial aid office, counseling and placement services, facilities maintenance, and overall administrative and fixed costs for UTTC's 105-acre campus base;
- Early childhood (nursery and pre-school) services for approximately 100 children, ages 8 weeks to five years. Nearly half of these children are under age two, and so the staff to child ratio of necessity is very high in order to provide proper supervision and to meet the North Dakota licensing requirements;
- The Theodore Jamerson Elementary School (K–8th grades) serving 133 American Indian students;
- Modest offerings of cultural, athletic, and recreational activities to supplement student learning experiences and campus-based family services.

*Funding History/Funding Shortfalls.*

Following are some of the financial difficulties UTTC has faced in recent years:

*Decreased buying power.*—Funding for UTTC has remained flat since fiscal year 1990. With flat funding and increased costs, we've experienced a 20 percent decrease in our operating and purchasing strength since 1990. Our indirect cost budget which provides much of the infrastructure funding (e.g. administrative and support services) is now approximately 81 percent of what it was in 1989.

*Increased utility costs.*—We have experienced a large increase in the cost of utilities, with electricity expenses rising about 20 percent per unit and the per unit gas cost increasing approximately 113 percent since 1990. Over the years the College has been able to partially offset utility rate increases by implementing stringent conservation measures such as improved weatherization and reductions in building temperatures. However, energy consumption cannot be further reduced because of the college's location and the harsh winters in the northern plains.

*Lowest Staff Salaries in the Nation.*—North Dakota salaries for higher education faculty rank 50th—the lowest in the nation—but the average faculty salaries at UTTC are lower even than those in the North Dakota state system.<sup>3</sup> The average faculty salary at UTTC is \$24,476, while the average faculty salary at the community colleges in North Dakota range from \$29,900 to \$32,800. This translates to our faculty receiving an average salary which ranges from \$5,500 to \$8,400 less than their peers at neighboring community colleges. Salaries for non-faculty staff would show a disparity at least as wide as that for faculty. Unlike institutions which are able to provide salary increases to employees based on the length of service (unrelated to cost of living increases), UTTC does not have the financial ability to provide a sound system of incremental merit salary increases based on length of employment.

We are at a critical juncture, and face an eminent risk of losing qualified, capable staff and faculty due to low salaries. The dedication of our staff cannot sustain them indefinitely.

*Deferred facility maintenance and repair.*—Lack of available resources has also meant limitations on the repair and maintenance of physical facilities. The College

<sup>2</sup>The following Certificate Programs are offered: Administrative Office Support, Automotive Service Technician, Construction Trades Technology with options in Carpentry, Electrical, Plumbing, and Welding; Early Childhood Education; Criminal Justice; Hospitality Management; Food & Beverage Specialization; Medical Secretary.

<sup>3</sup>Source: Integrated Postsecondary Education Data Systems (IPEDS) Report of the U.S. Bureau of the Census and the Department of Education Office of Education Statistics.

occupies the old Fort Lincoln Army Post. Other than the more recently constructed skills center and part of the community center, UTTC's core facilities are 80 to 90 years old. Estimates for new facilities total over \$12 million, according to a 1993 U.S. Department of Education report to Congress. Continuing a course of nonrepair will ultimately prove more costly as the repairs will be greater. This is especially true of the water and sewer systems on campus. Fire and safety reports document these needs. Neither UTTC nor other tribal colleges receive any facilities funding through the Department of Interior. Additionally, our 3.4 miles of campus roads are in a state of disrepair and require \$1.4 million in repairs or replacement. Our last major repairs were in 1988.

#### *Conclusion*

United Tribes Technical College is doing what Congress intended when enacting the welfare reform law last year—enabling people to be self-sufficient and in many cases helping them to get off and stay off public assistance. UTTC students receive a quality education in a native, family-based environment and in a cultural context familiar to and appropriate for them. We believe it is the primary reason for our success in educating and finding employment for UTTC students. We need your assistance to ensure that the unique educational opportunities offered by United Tribes Technical College will be available for what we hope will be an increasing number of Indian and Alaska Native students and their families next year and in the future. Thank you.

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#### PREPARED STATEMENT OF THE NATIONAL INDIAN IMPACTED SCHOOLS ASSOCIATION

The National Indian Impacted Schools Association—NIISA—is an association of public schools in Indian country dedicated to quality education and assuring that the United States' obligation to provide resources for educating Indian and Alaska Native students is fulfilled. Our membership consists of public school districts which receive federal Impact Aid funds because of the presence of students from Indian trust lands and Alaska Native lands. Approximately 90 percent of Indian and Alaska Native students nationwide attend public schools.

#### *Summary of Request*

We ask the Subcommittee to support the following with regard to the fiscal year 1998 Department of Education budget:

- \$667 million for Impact Aid Basic Support payments. This is the same as the request of the National Association of Federally Impacted Schools (NAFIS), and is \$51.5 million over the fiscal year 1997 enacted level for Basic Support payments;
- \$25 million under the authority of the Impact Aid statute for payments for Construction. This compares to the fiscal year 1997 enacted level of \$5 million and the President's request of \$4 million; and
- \$425 million for the Technology Literacy Challenge Fund as requested by the Administration to help schools integrate technology into school curricula. This is \$225 million over the fiscal year 1997 enacted level.

#### *Importance of the Impact Aid Program to Indian Country*

For Indian country, the Impact Aid program is a vital element of the public policy of providing every child a free public education. Signed into law in 1950, the Impact Aid program is one of the oldest federal education programs. Simply put, it provides federal funds for public school operations that would have otherwise been provided by local tax revenues but for the presence of federal property—in our case, lands held in trust by the federal government for Indian tribes. The Impact Aid program is an example of the U.S. government carrying out its trust responsibility—in this case, for education—for Indian and Alaska Native peoples. Some facts about the importance of the Impact Aid Program to Indian Country:

- There are over 600 school districts throughout the country which receive Impact Aid funds for Indian lands schools.
- Funds for Indian lands students represent nearly 50 percent of the federal Impact Aid appropriation.
- The Indian Country land base that generates Impact Aid funds consist of 53 million acres of Indian trust land in the lower 48 states and 44 million acres included in the Alaska Native Claims Settlement Act.

Additionally, the Impact Aid law provides a formal link between tribal governments and the public schools, providing for school district consultation with Indian tribes and tribal communities. This is especially important because public schools are State institutions, but located on tribal lands. School districts must consult with

tribes and the Indian community to develop Indian Policies and Procedures (IPP). Tribes and parents of Indian students are able to comment on whether Indian students are equal participants in educational programs and school activities, and to request modifications in school programs and materials. Tribes also have administrative appeal rights under the Impact Aid statute.

*Indian Lands School Facility Initiative*

NIISA is placing a high priority on the need for school facilities construction and renovation, including making facilities ready for education technology. We are working with Congress on the pending school construction initiatives in an effort to make them responsive to the needs of our schools—Indian lands schools. We realize, however, that new school construction legislation will probably not be enacted into law this year, and so we are asking for construction funding under the current authority of the Impact Aid statute. We have asked for \$25 million, but in reality we could ask for many times that amount with a straight face because the need justifies it.

Facility construction and renovation is a crucial issue for school districts in Indian country. It is common knowledge that school facilities in Indian country and elsewhere are overcrowded and crumbling, and that many students are educated in trailers and other temporary buildings. The condition of public school facilities nationally has been documented in recent General Accounting Office (GAO) surveys. But these GAO reports are based on only random surveys and do not provide Indian-lands specific information.

In October of 1996, NIISA sent a six-page questionnaire concerning school facility needs to every school district which receives Indian lands Impact Aid funding. The NIISA survey included a number of questions from the recent GAO surveys of public schools in order to compare results with the GAO findings. Officials in the US Department of Education Impact Aid Programs office were also consulted during the process of drafting the survey. The questionnaire went further than bricks and mortar. It also asked questions regarding the ability of the school district to raise revenue for facility construction—something not done by the GAO surveys. Finally, the survey contained a series of questions regarding each school district's readiness for computers, the internet and other education technology.

While we have not yet fully analyzed our survey results, the following findings are important indicators of the facility needs of public schools in Indian Country:

- 65 percent of buildings are over 20 years old, including 38.2 percent over 30 years old;
- \$6,872,000 is the average estimated costs necessary for repairs, renovations, modernization and construction to put schools in overall good condition;
- the average cost per student to make school buildings meet health and safety standards is \$1,947;
- to accommodate expected increased enrollment over the next 5 years, the schools responding to the survey will need 13.1 percent more space. Within 10 years, the space needs are expected to increase by 27.9 percent;
- 71 percent of school districts have had no school construction bond issued since 1985, and 23 percent of school districts have never had a bond issued;
- Of schools with 70 percent LOT MOD and higher, the need for construction, renovation, and repair funding is two thirds higher per pupil than in the other respondents to the NIISA survey. (Note: LOT MOD is a Department of Education measure of need of school districts affected by the presence of federal property.);
- 42 percent of respondents have unhouseed students;
- 59 percent of school buildings have inadequate laboratory science space;
- 63 percent of schools are not well served for before/after school care.

While NIISA appreciates the Administration's recognition of the need for school construction funding as reflected in President Clinton's school construction initiative, we intend to continue working with Republican and Democratic Members of the House and Senate to modify the proposed program to make it beneficial to Indian Country.

The President's school construction initiative would pay up to half of the interest on school construction bonds or similar financing mechanisms, with a target of stimulating at least \$20 billion in new construction or renovation projects. Without important modifications, however, the initiative would be of little, if any, benefit in Indian country where the ability to issue school construction bonds is very limited or not possible at all—this is particularly true in those school districts where a significant amount of the land base is Indian trust land. Any proposal which is dependent upon the ability of school districts to issue bonds will not help schools heavily impacted by the presence of Indian lands.

*Support for Education Technology*

NIISA supports the President's request for \$425 million for Technology Literacy Challenge Fund to help schools integrate technology into the curriculum.

Although there is considerable public discussion about linking schools to the internet, NIISA's survey results show that many, many schools lack the electrical, telephone and other infrastructure necessary to utilize modern educational technology. The NIISA survey responses show:

- 75 percent of school buildings need funding for infrastructure to support education technology—this compares to the 60 percent figure in the GAO surveys. Particularly high on the needs list is fiber optic cable;
- 56 percent of school buildings have significant needs for computers for instructional use;
- 61 percent of school buildings have significant needs for modems;
- 81 percent of school buildings need telephone lines for instruction areas
- 79 percent of school buildings need fiber optic cable.
- 62 percent of school buildings need for electrical wiring for computers.

It is no wonder we support increased funding for education technology in schools. Thank you for your interest in the need our public schools which educate children from Indian country. We ask you to always keep in mind the trust responsibility for the education of Indian and Alaska Native children and the federal responsibility regarding school districts which contain Indian and federal property.

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PREPARED STATEMENT OF THE AMERICAN LIBRARY ASSOCIATION

The American Library Association appreciates the opportunity to provide this statement for review and inclusion in the hearing record for fiscal year 1998 Appropriations. The 58,000 members of ALA, including public, school, state, academic and special librarians, library supporters, trustees, and friends of libraries, thank the Labor, Health and Human Services and Education and Related Agencies Subcommittee for your support in the past and request funding at the authorization level of \$150 million for this first year of the Library Services and Technology Act.

In addition, we ask that you fund the Improving America's Schools Act Title VI block grant at least at the fiscal year 1997 level of \$310 million. This Title is the only funding possibility for school libraries and the Department of Education estimated last year that at least 40 percent of the funding goes for school library materials and resources.

*Library Services and Technology Act*

The Library Services and Technology Act was passed and signed into law on September 30, 1996. The purpose of the new legislation is to consolidate Federal library programs while stimulating excellence and promoting access to learning and information resources in all types of libraries for individuals of all ages.

The provisions of the Library Services and Technology Act promote library services that provide all users access to information through State, regional, national and international electronic networks and provide electronic linkages among and between libraries. The law promotes targeted library services to people of diverse geographic, cultural and socioeconomic backgrounds, to individuals with disabilities and to people with limited functional literacy or information skills.

Most funds are allocated through state library agencies, which administer programs and develop cooperative plans for use of the funds. Four percent of the funds are to be used for national leadership purposes and 1½ percent for tribal library services.

The Library Services and Technology Act builds on the strengths of previous federal library programs but has some major advantages and differences. It retains the state-based approach, but sharpens the focus to two key priorities: information access through technology, and information empowerment through special services.

New technology and a multitude of community needs will shape the way we seek and obtain information. The Library Services and Technology Act encourages inter-library cooperation, emphasizes libraries as change agents and implementers of equity, extends libraries' reach as self-help institutions and community partners in lifelong learning and literacy, economic development, jobs information, health information, etc.

Public libraries of today are vastly different from the libraries of thirty years ago and the libraries of the next millennium will be different as well. The new LSTA gives states the flexibility to determine state needs and shape library programs to address those needs.



The following examples illustrate the kinds of innovative projects libraries are conducting with the use of federal funds to connect people to information that can help to change lives, advance education and contribute towards the productivity of the nation:

*Health Information.*—The Aurora, Illinois public libraries serve a population of 107,000 people, of which 12,535 are teens ages 12–18. This area has experienced a significant increase in youth violence, gang involvement, teen pregnancy, suicide and a variety of health problems. A partnership has been formed among the Aurora Public Library, Messenger Public Library of North Aurora, Sugar Grove Public Library and the East and West Aurora School districts, as well as the Mercy Center for Health Care Services, Aurora University, the DuPage Library System, Cities in Schools, Community Contacts, the Kane County Information and the Kane County Health Department to provide materials, information and programming on issues related to teen health. The primary focus was on materials for teens themselves though some materials and programs were geared to parents and those who work with teens. Teens were surveyed to determine their information needs. New relationships were developed among concerned librarians, teens, parents, educators and health care professionals. The health collections of all libraries were strengthened by the project. Based on a high level of participation and its initial success, the project will be continued.

*Literacy.*—At the Alameda County, California, library a bookmobile visits four schools in the San Lorenzo School District. Students speak 22 languages other than English and reading scores are low. The Learn A Lot program offers free tutoring and library services. Volunteers can be high schoolers to senior citizens who receive 16 hours of training plus observation time of the small group being tutored. Librarians present book talks and children may find the books on the bookmobile and take them home.

*Technology.*—At Baltimore, Maryland's Enoch Pratt library, federal funds were used to begin a partnership with library staff, volunteer partners and mentors and young adults at risk to introduce the young people to information through technology. Working with their mentors, students learned to use the Internet and access SAILOR, the Maryland State library network, to find information and become adept at using technology. Studies have shown that 60 percent of the jobs created by the year 2000 will require computer skills. The at risk youth in the innovative library program will have a head start.

The federal role in support of libraries helps to ensure that the existing information infrastructure of libraries is technologically equipped to perform governmental functions cost effectively, such as supporting literacy and lifelong learning, organizing and providing access to federal, state, and local government information and other community information, undergirding economic development by providing jobs information and supporting small businesses and providing access to consumer health information.

Past library funding was administered by the Department of Education library programs through the Library Services and Construction Act. With the new law, the Library Services and Technology Act, administration of the program moves to the Institute of Museum and Library Services (IMLS). Funding is passed through the Department of Education to IMLS, at an authorization level of \$150 million. Most funding goes to libraries through states; 4 percent is reserved for national leadership purposes. The Federal investment in the former Library Services and Construction Act and the new Library Services and Technology Act has acted and will act as a stimulant to local investment because of the funding match requirement.

The Administration's budget would provide level funding for library programs. In this first year of funding of the new Library Services and Technology Act, it is particularly important for Congress to fund library programs at the \$150 million authorization level.

A strong investment will connect more libraries to the Internet and support literacy and education, help libraries provide job and consumer health information, serve small business and provide information for lifelong learning.

#### *IASA Title VI*

The reauthorization of the Elementary and Secondary Education Act (the Improving America's Schools Act), included renewal of the Title VI (formerly Chapter 2) block grant. This block grant allows funding of school library resources and materials among its uses of funding. The rapid changes that have occurred in the former Soviet Union and united Germany illustrate how quickly a school's library can be filled with out-of-date material. Expensive atlases, geographies and other reference books were immediately obsolete. Our children deserve not only technological resources but the resources for in-depth research as well. We ask the Subcommittee

to fund IASA Title VI at least at the fiscal year 1997 level of \$310 million. The Administration's budget did not request funding for this Title.

*Other Initiatives*

The Administration's fiscal year 1998 budget proposed increased funding for IASA Title III Educational Technology. Secretary of Education Richard Riley in his testimony before the Subcommittee stated that the money was to be used to link rural and inner-city schools to the Internet and would help reach the goal of connecting all schools to the Information Superhighway by the year 2000. We ask the Subcommittee to fund Title III at the requested level. We also ask that you fund other programs under your jurisdiction that improve reading skills, literacy and lifelong learning and technological literacy and educational research and statistics. We also urge support of the budget request of the U.S. National Commission on Libraries and Information Science.

We thank the Subcommittee for the consideration you have shown for libraries in the past, and particularly for your part in accomplishing the reauthorization of the Library Services and Technology Act in the Fall of 1996.

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PREPARED STATEMENT OF THE INTERNATIONAL SOCIETY FOR TECHNOLOGY IN  
EDUCATION AND THE CONSORTIUM FOR SCHOOL NETWORKING

The International Society for Technology in Education (ISTE) and the Consortium for School Networking (CoSN) are pleased to submit the following testimony to the House Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Education.

ISTE is a nonprofit international membership organization devoted to promoting appropriate uses of technology to support and improve learning, teaching, and administration. As part of its mission, ISTE's goal is to provide individuals and organizations with high-quality and timely information, materials, and services that support technology in education. ISTE also develops products for students, classroom teachers, lab teachers, technology coordinators, and teacher educators, as well as for parents, administrators, policy makers, and visionaries.

CoSN is a nonprofit organization dedicated to promoting and encouraging the use of telecommunications by advocating access to the emerging national information infrastructure in K-12 classrooms. Its members represent educators, school districts, nonprofits and businesses that share an interest in advancing educational telecomputing. CoSN is committed to equal access, equity, and quality in school networking.

Future generations can only succeed if they are prepared for the information and technological age. According to the National Center for Education Statistics, 65 percent of U.S. public schools have access to the Internet, but only 14-percent of public school instructional classrooms were connected to the Internet. Among all public schools 20 percent of teachers used advanced telecommunications for teaching. Yet, by the year 2000, 6 of every 10 new jobs created will require computer skills. It is imperative for the federal government to support efforts to develop, disseminate, and evaluate educational technology through policy and resources.

Last year, Congress exhibited its leadership and support for such efforts by approving the Technology Literacy Challenge Fund. This program provides \$2 billion over five years to catalyze and leverage private and public efforts to provide K-12 students with the opportunity to develop technology skills. The Fund provides formula grants to all 50 states to help implement strategies enabling schools to fully integrate technology into their curricula. In the first year of the program, Congress appropriated \$200 million. ISTE and CoSN are dedicated to preserving this program and request that Congress maintain its commitment to fully funding it over the next five years.

Both ISTE and CoSN are working to prove the effectiveness of education technology programs and to develop more comprehensive evaluation criteria for these programs in the future. We are beginning to see the quality and effectiveness of many of the programs funded through the Technology Literacy Challenge Fund and other educational technology programs. These programs have helped to improve academic performance, as well as student prospects for post-secondary education and employment opportunities.

The Technology Literacy Challenge Fund, which provides funds to every state, has enabled all states to either begin or continue their comprehensive state planning for integrating technology into teaching and learning. Planning, as Congress understood by requiring states to develop a plan as part of the Technology Literacy Challenge Fund, is essential for states to be able to efficiently and effectively use the funds

appropriated by Congress. Now that the first year of planning is complete, states and school districts are ready to further implement their plans.

ISTE and CoSN also request the continuation of, and full funding for, the Technology Challenge Grants, Title VII Block Grants, Goals 2000, Star Schools, the Carl Perkins Vocational Education Act, the Tech-Prep Education Act, all of which can support the development, improvement, and effective use of educational technology if a state and/or local school district choose to use funds under these programs to complement and integrate technology toward achieving the goals of these programs.

Technology is an essential part of teaching and learning. It not only teaches important job skills for the future, it expands the scope of possibilities in learning and communicating. Thus it is important for students to not only learn how to use the technology but that teachers integrate the technology into the curriculum.

In recent years, many of the teaching techniques and classroom arrangements that have been shown to be effective are facilitated by technology. Computer tools such as word processors, databases and telecommunications help students to address and solve a wide range of problems. Indeed, computer-assisted learning and many computer-based adaptive environments for students with special needs have been shown to be highly effective.

Computers and networking make the classroom more open. Students and teachers can reach out to their community. Parents and administrators can better know what and how students are learning. Technology increases interactivity, allowing schools to better address diverse student needs. It empowers teachers and students and facilitates a restructuring of schools toward more student-centered learning environments.

The following are some examples of technology being used effectively in schools throughout the country. They are evidence that with a properly trained teaching staff and a supportive administration, students are excited about learning, show increased self-esteem have improved test scores, and are learning things most students do not learn in ways most teachers do not even contemplate.

The Clark County School District, Las Vegas, Nevada, in cooperation with the Clark County Public Education Foundation, has created a network in which community human service providers, businesses, and the educational system can join in a virtual "workspace" to collaborate with one another, apply their individual expertise, and meet the challenges of a fast growing, large school district. The network, called InterAct, was created by the Foundation. It is an educational learning community network where community partners can work with the school district to build a community that merges community needs and interests with teachers' needs and interests. The Clark County School District is the 10th largest school district in the nation, with approximately 180,000 students encompassing an area of approximately 8,000 square miles. The district has both rural and urban school. Because of the rapid growth and size of the school district, the implementation of technology is vital to assure the continued success of the school district. The Clark County Public Education Foundation is a non-profit organization that works with community leaders, businesses, industry, and human service organizations to implement innovative practices and creative applications of technology in the school district. The Foundation administers a series of grant programs for educators that encourages the development of innovative practices in schools. These innovative practices are then replicated throughout the school district to merge creative curriculum applications with current and emerging technologies.

In Louisville, Kentucky, the Jefferson County Public Schools created a comprehensive district-wide approach to technology integration. It involves all schools, all grades, and all programs. Students at all levels are using the technology to learn basic skills, to write, complete research projects that include developing databases, analyzing data using spreadsheets, publishing their work using desktop publishing applications, preparing presentations using interactive multimedia, telecommunication with distant locations about topics of mutual interest, and using simulations to develop skills to deal with real-world situations.

The Ralph Bunche Computer Mini-School, a school within a school for 4th-6th graders, in Harlem, has extensive access to network and software tools to support communication and research and the smaller, more coherent classes. Mini-school students move back and forth between their regular classes and the Computer Room, where they conduct research and work on assignments for their classes. Each Mini-school student has an electronic mail account to communicate with each other and with distant "pen" pals and individuals who can help them with their research. For example, students studying Ireland contacted a university student in Dublin for a first-hand report of the kinds of jobs and sports interest that are prevalent in Ireland. Classes have a computer in the room connected to the school network. Each Mini-school classroom gets two 1-hour periods to use the computer lab. These ses-

sions are planned with the teacher who integrates the technology into the ongoing curriculum.

In Flint, Michigan, a chemistry classroom at Flint Northern High School links computers to a remote super computer at the National Education Super Computer Program. The classroom technology includes microcomputer-based labs, spreadsheet data manipulation, graphing software, and word processing to prepare reports.

UtahLINK is an example of the wealth of information and resources a school has access to when connected to the Internet and teachers are trained in how to access that information. UtahLINK is a service of the Utah Education Network. It provides Utah schools with internet connectivity, software tools, comprehensive training, and online access to electronic educational materials both locally and from the Internet. Through UtahLINK, teachers have access to a searchable database of state-adopted course descriptions, standards and objectives in contact areas from applied technology to social studies. The database contains integrated curriculum units and lesson plans linked directly to core subject content areas as well as online projects and classroom collaboration listings. It also provides electronic access to full-text library journals and graphics.

Continued funding for these and other important education technology programs will greatly expand what and how today's students learn and better prepared them for tomorrow. We, therefore request your continued support for federal education technology programs so that one day soon all students will share the benefits of technology in their classrooms and all teachers will integrate technology it into their curricula.

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#### PREPARED STATEMENT OF THE NATIONAL SCHOOL BOARDS ASSOCIATION

##### *Introduction*

The National School Boards Association (NSBA) is the nationwide advocacy organization for public school governance through our federation of 53 states and territories we represent over 95,000 elected and appointed school board members. Local school board members are the representatives of parents and local communities, and are responsible for governing local public school districts across the nation. The vast majority of school board members are not paid for their service. Rather, they give their time because they care about the education of their own children and the children in their community. Just like the Congress, local school board members are accountable to and represent the communities that have elected them. School board members also balance the large public policy issues, the values of their community, and the impact of those issues on their school district.

##### *Overview*

Horace Mann was instrumental in creating America's publicly supported education system; he saw the practical importance for our citizens, as well as business and industry, to develop a civilized society and a more productive economy. Those twin goals are as important today as they were in the 1850s. Maintaining the quality of schools to ensure an educated and productive society where everyone has the opportunity to flourish is the premise behind public education. Part of our ability to create those high-quality schools is continuing the much-needed support of the federal government. In virtually every public poll, Americans view education as their number one priority. President Clinton reflected the view of the American public in his State of the Union address when he introduced his ten-point education plan primarily focusing on elementary and secondary education.

The President's fiscal year 1998 budget touts an 11 percent increase in spending on elementary and secondary education programs. While we applaud the Administration for its effort to break education appropriations out of the small incremental increases that have been its history, the time-tested, existing programs should not receive such minimal gains, instead they need substantial funding increases. The proposed Clinton budget allots significant funds to higher education programs. Yet, the funds allocated for higher education will prove too late if our K-12 programs do not receive support to adequately prepare students for a postsecondary education.

##### *Education Investment is Critical*

The small proposed increases in the fiscal year 1998 appropriations bill for programs such as special education (4.3 percent increase) and Title 1 (4.3 percent increase) are for programs vital to school districts. Substantial funding for special education and Title 1 are necessary to keep pace with the demands for these services. After the dramatic cuts in the federal education programs in fiscal year 1995, the 15 percent increase to federal discretionary education funding in fiscal year 1997

was well appreciated, but barely restored those earlier rescissions. It is essential that the federal government's commitment for fiscal year 1998 to education spending remain consistent to that in fiscal year 1997 to address increasing enrollments generally, and in those programs specifically. The population of students with disabilities benefiting from federal funds under the Individuals with Disabilities Education Act (IDEA) is dramatically increasing—while the funding is not. According to The National Center for Education Statistics, between 1977 and 1994 there was a 46 percent increase in the number of students with disabilities. Yet, the federal government only contributes seven percent of the promised 40 percent of the “excess cost” funding for IDEA, leaving the local school districts with an overwhelming gap between need and available funds. The RAND study (Grissmer et al. 1994) concluded that students participating in Title 1 programs perform better on achievement tests than comparable students who do not receive the extra support. It is imperative that these important, specialized programs adequately provide for the wide range of students entering our schools in larger numbers.

Dramatic increases are projected for school populations within the next seven years. According to the National Center for Education Statistics, the K–12 school population will expand by seven million students, a 14-percent increase, between 1993 and 2005. The local school district budget needs to accommodate the increased number of students entering our schools to ensure each student receives a high-quality education. Without increased federal funds, it will be impossible to provide an excellent education for all of our students.

The prerequisites for a successful school that maximizes learning are expensive. David Berliner and Bruce Biddle reported in *The Manufactured Crisis: Myths, Fraud and the Attack on America's Public Schools* that increased education spending contributes to higher levels of school achievement by providing for a more talented teaching staff, smaller class sizes, and improved programs and facilities—the means necessary for a productive education experience. Further, Berliner and Biddle dispel the myth that the United States spends more on education than other industrialized countries in *The Manufactured Crisis*. In fact, they found that K–12 spending in the United States is actually less than the average industrialized nation. The United States ranks only ninth in comparison with 16 industrialized nations by spending 51 percent less on per pupil expenditure than does Switzerland, the country spending the most. The following chart offers the complete breakdown.

*K–12 per pupil expenditures for education in 16 nations in 1985*

[Based on exchange rates in 1988]

Switzerland .....	\$7,061
Sweden .....	5,932
Norway .....	5,002
Japan .....	4,927
Denmark .....	4,410
Austria .....	4,297
West Germany .....	4,016
Canada .....	3,683
United States .....	3,456
Belgium .....	3,254
Netherlands .....	3,224
France .....	3,094
United Kingdom .....	2,314
Australia .....	2,291
Italy .....	1,809
Ireland .....	1,380

Source: *Shortchanging Education* (Rasell & Mishel, 1990).

Statistical Sources: *Statistical Yearbook* (UNESCO, 1988); *Digest of Education Statistics* (National Center for Education Statistics, 1988).

*Conclusion*

A strong commitment to K–12 education programs is vital given sharp enrollment increases in elementary and secondary schools nationwide. This country must ensure that all students achieve high academic standards, and meet the demands for new educational technology. There is also the growing acknowledgment that Congress needs to pay its share of special education costs. Increased funding does make a difference in education, as it does in most areas. It contributes to higher levels of school achievement by providing a more talented teaching staff, smaller class size, and improved programs and facilities.

Establishing education as a national priority reflects the American people's continued dedication to educate its children and to create economic stability. An investment in education will secure the future of our country, our people, and our children. It pays long-term dividends. The congressional priority on education is laudatory. NSBA challenges the U.S. Congress to reflect the priority by meeting the increase for K-12 education programs established in the President's proposed fiscal year 1998 budget for the proven and effective programs, including special education and Title I, among others.

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PREPARED STATEMENT OF THE UNITED STATES CATHOLIC CONFERENCE

There are 8,250 Catholic elementary and secondary schools in the nation with more than 2.6 million students, 166,000 professional educators and millions of parents who support them. The United States Catholic Conference (USCC), urges you to provide \$41.114 million for the Title I "Capital Expenses" provision of the Improving America's School Act—Public Law 103-382, the same amount approved by Congress in its fiscal year 1997 budget and the amount proposed in the Clinton Administration's fiscal year 1998 budget. These "Capital Expense" funds are needed, as a matter of justice, to restore Title I services to large numbers of eligible students enrolled in religiously oriented schools who have been deprived of them since the Supreme Court's *Felton* decision in 1985. These funds are also needed to improve the quality of services offered to these educationally disadvantaged students.

Although The USCC's comments will be referring to Catholic schools particularly, the problem we are addressing affects students in schools throughout the religious school community. This appropriation addresses a problem affecting all religious schools enrolling eligible Title I students.

We wish to take this opportunity to thank Chairman Specter, the ranking minority member, Mr. Harkin, and each member of the Committee, for their efforts to restore full Title I services to all eligible religious school students. Since 1988, your support has secured annual appropriations for "Capital Expense" funds beginning with \$19.76 million in fiscal year 1989 to \$41.114 million in fiscal year 1997. These funds have been very critical to the task of restoring full Title I services after *Felton*.

*Chapter 1 and Catholic Schools:*

In Title I, the federal government demonstrates its determination to help students overcome the disadvantages of both lower income environment and educational ability. The extra resources Title I provides are a valued supplement to the instruction Catholic schools provide, most especially in inner city schools. It is particularly egregious when students eligible for such services, who would receive those services if enrolled in a public school, are deprived of them solely because they attend Catholic or other religious schools. Parents should not be obliged to choose between Title I services and the quality of education available in Catholic schools. Depriving students of such essential services, simply because they attend religiously affiliated schools, damages the students and our nation. This Committee, and Congress, have repeatedly shown that they share our concern.

Catholic schools are an important contributor to the educational opportunity available to American students. In numbers of schools, the Catholic school community is larger than any state system. In numbers of enrolled students, it is the third largest, after California and Texas. Almost 55 percent of all students enrolled in private and religious schools are currently enrolled in Catholic schools.

Catholic schools have demonstrated a particular success with the students Title I attempts to serve. In a number of states, Catholic schools have a higher percentage of minority students than their public school counterparts. Nationally, 24.1 percent of Catholic school students are from ethnic or racial minorities, a figure comparable to the public schools nationally. And 13.2 percent of these students are not Catholic.

Catholic schools have an enviable record for effective teaching. The drop-out rate in Catholic high schools is less than 4 percent; more than 83 percent of Catholic high school graduates go on to postsecondary education. Minority Catholic school students, in particular, have higher achievement scores than similar students in other schools in reading and math tests administered as part of the National Assessment of Academic Progress (NAEP) over the past decade. The reality is that Title I students in Catholic schools show that the program can work, even with the severe limitations that the *Felton* decision places on those students. This record of success should not be endangered by cuts in appropriations intended to help overcome these unfortunate limitations.

Catholic school Title I students are particularly concentrated in the lowest income communities. The current Title I implementation study found that 53 percent of nonpublic school students are in the most poverty-impacted quartile of school districts, compared to 45 percent of public school Title I students. Private and religious school Title I students are more likely than public school Title I students to live in the most poverty-impacted districts in the country.

*Need for Capital Expense Funds:*

In 1985, the U.S. Supreme Court held, in *Aguilar v. Felton*, that public school Title I teachers could not enter the premises of religiously affiliated schools in order to provide Title I services. Administrators quickly had to devise off-site methods of serving approximately 185,000 students. A major obstacle was the cost associated with the rent, purchase or maintenance of facilities and similar capital expenses. In about half of the cases, LEAs were able to continue Title I services to religious school students at nearby facilities, or in vans or mobile classrooms already available or provided through special state or local appropriations. The other half of students lost services, some for a few months, some longer, some permanently.

There is disagreement over the precise number of students served, or those who were eligible but lost services, or those who should have been served, but never were. But all agree that services have not recovered to the pre-*Felton* numbers or quality. The most recent reliable data available from the U.S. Department of Education shows the recovery reached approximately 177,200 in the 1993–94 school year but declined to 173,000 in the 1994–95 school year.

Congress stated that its intent with regard to the “Capital Expense” provision was “to provide sufficient funding to enable needy LEAs, to the extent possible, to restore Title I services for private school children to their pre-*Aguilar v. Felton* levels and quality”.(House Report: 100–95)

In the summary of its report on “Capital Expenses” the GAO (February 26, 1993, p. 3) concluded that only 14 of 52 SEA offices believed their states were reaching “almost all” or “all” (80 percent or more) of eligible private and religious school students. The median response was that the state was reaching about half of eligible private and religious school students.

The clearly negative impact of the *Felton* decision on the delivery of services to eligible Title I students enrolled in Catholic and other religious schools have most recently been outlined on April 15, 1997 in arguments before the United States Supreme Court as the chancellor of the New York public schools asked to be relieved from the injunction granted in the Court’s 1985 decision. We are hopeful that the Court will agree with those arguments and reverse their original decision in *Felton*. Even with a reversal of *Felton*, it is imperative to continue “Capital Expense” funding during any transitional period, so we avoid a period of disruption similar to that found after the 1985 Supreme Court decision.

*Problems With use of Capital Expense Funds:*

“Capital Expense” funds are needed to increase the degree of recovery that has been attained since 1985, and to expand that recovery to serve all the students who are eligible for Title I services. But it appears that even when funds are available, they are not necessarily being used to maximize services to students. There is a clear failure to set appropriate priorities. States are still using these funds to reimburse districts for past expenditures, Congress should end this procedure and limit expenditures to costs for needs identified in the current fiscal year. While it is true that a number of states returned unspent “Capital Expense” funds, it needs to be stated as strongly as possible that other states easily used up all of these returned funds. There are a number of states that have current needs in this area that are unmet. In addition, some LEAs, particularly small and rural districts, do not qualify for enough funds to purchase or lease adequate facilities for providing services.

The question of program quality is of equal importance. There is a serious concern, expressed in the report from the Congressionally mandated National Assessment of Chapter 1 Independent Review Panel, that in many instances the quality of services delivered is markedly inferior to what is needed for the program to succeed in making an educational difference. While some programs are very good, many are clearly troubled.

All Title I program services to students in religious schools require that the student is to be “pulled out” of the home classroom. There is common agreement among educators that this approach, even in public schools, is disruptive of sound educational progress. In such programs the student is clearly identified as a Title I student, different from the rest. In addition, the student misses instruction taking place in the regular classroom situation. Programs that take place outside the school, where students must travel, are especially disruptive and often physically

dangerous. The 1993 GAO study found parental rejection of services is another major problem. Much of this rejection is based on the parental evaluation that these “pull-out” services are viewed to be of poor quality and disruptive to the student’s overall education.

The use of computers to provide services has expanded rapidly, growing from 5 percent in 1986–87 to 32 percent in the most recent survey. The use of computers requires close evaluation. To be most effective, computers need to be integrated into the total curriculum. Unless regular classroom teachers have access to computer resources, the computer cannot become an integral part of the student’s course of study. Under current interpretation of the *Felton* decision, the placement of the computers forbids the presence of a teacher, and the teacher aide who is present may not be involved in actual instruction. The computer programs often only provide basic education, rather than providing challenging educational opportunities for the student.

Finally, Catholic and other religious school students with restored services receive assistance an average of only 3.5 days a week, compared to 5 days in the public school program. The shorter program is predictably less effective, especially when set in the context of the difficulties Title I teachers have in planning and consulting with the religious school student’s regular classroom teacher.

*Conclusion:*

We urge the Committee to recommend the full funding of the “Capital Expenses” at the same level of \$41.114 million, as appropriated by Congress when it passed its fiscal year 1997 budget and as proposed in the Clinton Administration’s fiscal year 1998 budget. We also urge that the Committee consider fully funding Title I, as well as work to improve the operation of Title I programs, in order to be better able to reach all eligible public, private and religious school students, and to provide programs and services of the highest quality possible. While we are aware of the budgetary problems that the Congress faces we urge the Committee, in an effort to provide the broadest scope of services to those most at risk, to act responsibly and provide full funding for the other Titles of Public Law 103–382, including Titles II, III, IV and VII, as well. There is a need to give special emphasis to maintaining funding for Title VI of Public Law 103–382 at its authorized level of \$370 million, since the Clinton Administration continues to “zero fund” this important program which continues to have broad support from all aspects of the education community—public, private and religious. It is a flexible program that serves the varied needs of students in almost every school in the country. Finally, we recommend that the Committee consider empowering parents to obtain supplemental services for their children, from approved tutors or specialists when other options have not been responsive to the needs of those children. We believe that this option would be effective in restoring services to students deprived of services in small school districts currently not eligible for Capital Expenses.

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PREPARED STATEMENT OF THE NATIONAL INDIAN EDUCATION ASSOCIATION

The National Indian Education Association (NIEA), the oldest national organization representing the education concerns of over 3,000 American Indian and Alaska Native educators, school administrators, teachers, parents, and students, is pleased to submit this statement on the President’s fiscal year 1998 budget as it affects Indian education. NIEA has an elected board of 12 members who represent various Indian education programs and constituencies from throughout the nation. Every year, NIEA holds an annual convention which provides our members with an opportunity to network, share information, and hear from Congressional leaders and staff as well as federal government officials on policy and legislative initiatives impacting Indian education.

We commend President Clinton for a budget that emphasizes the importance of education for all citizens of this country, including the First Americans. There are some programs such as the Office of Indian Education (OIE) in the Department of Education, Impact Aid, and higher education scholarships which deserve further consideration for increased funding and will be discussed in this testimony.

President Clinton has proposed several new education initiatives for fiscal year 1998 which will require a major investment of federal dollars. Programs like his school construction and education technology initiatives are desperately needed by schools operated and funded by the Bureau of Indian Affairs (BIA). Programs for American Indians attending the nation’s public schools will also benefit from these and other federal education initiatives. These funds will help this nation achieve



true educational equity through fulfillment of its federal education responsibility to American Indians and Alaska Natives.

THE FEDERAL RESPONSIBILITY FOR INDIAN EDUCATION

Indian education programs are not affirmative action nor race-based educational efforts but result from the historical and legal relationship between Indian nations and the United States. This government-to-government relationship is a Constitutional relationship whereby the U.S. officially recognizes some 557 Indian and Alaska Native governments as separate and distinct nations. This political relationship includes broad federal authority and special trust obligations unique only to American Indians and Alaska Natives. Tribal governments are independent of State governments even though tribal lands may lie within a state's boundaries. Many federal statutes provide for direct funding to tribal governments so that Tribes can design and administer their own programs. Among activities undertaken by tribal governments are the administration of their own police departments, courts, schools, health facilities, social service programs, the development and enforcement of environmental codes, etc. Many of these are programs formerly administered by the BIA and IHS, but are now carried out by Tribes under authority of the Indian Self-Determination and Education Assistance Act (Public Law 93-638) and the Indian Education Act of 1972 (as amended by Title IX, Public Law 103-382). Tribally chartered boards now administer more than 90 BIA-funded elementary and secondary schools and 29 tribal colleges.

Tribal governments administer an array of federal education programs—Johnson O'Malley, Head Start, Child Care and Development Block Grants, Adult Education, vocational education and scholarships. Additionally, Indian parent committees have direct input into the Indian Education Act program in public and BIA schools, and tribal governments have a statutory role in the Impact Aid program. Many tribes, with community input, have developed tribal education codes and standards. Tribes and tribal colleges are active in the development of curricula which embody Native languages, tribal history, tribal government and other courses of study specific to the unique needs of their communities.

NIEA's testimony will discuss Indian education and related programs under the authority of the Labor-HHS-Education Appropriations Subcommittee including President Clinton's proposed national school construction initiative.

DEPARTMENT OF EDUCATION

*Office of Indian Education (OIE):*

The Office of Indian Education (OIE) is authorized by the Elementary and Secondary Education Act, Title IX, of Public Law 103-382, the Improving America's Schools Act (IASA) of 1994. OIE was first authorized by the Indian Education Act of 1972 (Title IV, Public Law 92-318) after a 1969 Senate Special Subcommittee on Indian Education, chaired by Edward M. Kennedy (D-Ma) reported: "Our national policies for educating Indian children are a failure of major proportions. They have not offered Indian children—either in years past or today—an educational opportunity anywhere near to that offered the great bulk of American children."

We would venture to say that given the many accomplishments in educating American Indians since 1972, there are many deficiencies which continue to plague the long-term success of Indian education. Not the least of which is the level of academic achievement Indian people have not yet acquired as is evidenced by consistently low scores on standardized tests. Federal programs which have made the greatest positive impact, ironically, are those that have been eliminated or where funding has been drastically reduced.

For fiscal year 1998, the Department of Education has requested \$59.75 million to fund 1,219 formula grants to Local Education Agencies (LEAs) and BIA schools and \$2.9 million for program administration for OIE. NIEA supports full funding of \$83 million which, in addition to LEA grants, would include a reinstatement of certain discretionary grant programs, funding for the National Advisory Council on Indian Education (NACIE), and additional resources for the Presidential Executive Order on Tribally Controlled Community Colleges.

For the past two years, no discretionary programs have been funded in OIE. This lack of continuity has created a situation where only two programs are available to meet the post-secondary education needs of American Indians and Alaska Natives beyond high school. NIEA requests the Subcommittee's support in reinstatement of funds for programs in adult literacy, teacher training, professional development, and Indian fellowships. The BIA is the only remaining agency with an Adult Education component for American Indian adults who are striving to attain their high school equivalency. Unfortunately, this program does not reach those Indian adults in non-

reservation or urban settings. Without access to these programs that have traditionally moved American Indian and Alaska Native learners beyond high school, prospects for continued gains in academic achievement are greatly reduced.

NIEA is aware that the authority for funding of OIE programs has been transferred from Interior to the Labor-HHS-Education Appropriations Subcommittee this session. Until this recent development, OIE was the only program in the Education Department funded from a separate appropriation. As such, funding for OIE was often at odds with other priority programs of the BIA. NIEA believes that education for American Indians and Alaska Natives is a trust responsibility of the federal government no matter if these students attend public or reservation-based schools. The fact that almost ninety percent of American Indian students attend public schools does not, in our opinion, preclude the trust responsibility issue.

The following are NIEA's recommendations regarding OIE funding by category:

*Formula Grants to LEAs.*—For fiscal year 1998, the U.S. Department of Education has requested \$59.9 million to fund formula grants to LEAs and \$2.8 million for program administration of the Office of Indian Education (OIE). NIEA supports this request which will assist over 422,000 American Indian and Alaska Native students attending public and BIA schools. This base funding ensures K–12 Indian students in America's schools receive appropriate academic assistance as envisioned by the Indian Education Act of 1972.

*Discretionary Grants.*—NIEA asks the Subcommittee to support the reinstatement of discretionary grant funds which support programs in adult literacy, teacher training, Indian fellowships, and professional development on many Indian reservations. OIE's support has been critical to providing opportunities for American Indian and Alaska Native adults to obtain their General Educational Development Degrees (GEDs). Funding for Adult Education ended in fiscal year 1996 even as a \$5.4 million request was forwarded to congress. A similar situation occurred in fiscal year 1997 as well. This program is especially critical since funding for the BIA's adult education program has been steadily decreasing over the past 3 years from \$3.5 million in 1995 to the fiscal year 1998 request of \$2.3 million. The 1990 Census reported that 65.5 percent of American Indians and Alaska Natives over the age of 25 had graduated from high school compared with 75.2 percent of the general population. Of the total American Indian adults living on reservation and trust lands, only 54 percent were high school graduates or higher. Regarding approximate drop-out rates, the U.S. Department of Education NELS 88 study followed a sample group of students from 1988 to 1992 and reported that 25.4 percent of American Indian students dropped out of high school as compared with 11 percent for the total population.

*OIE Fellowship Program.*—Another major loss has been the OIE Fellowship Program, which was eliminated in fiscal year 1997. It was previously cut by \$1.3 million (over 75 percent) in fiscal year 1996 from its fiscal year 1994–95 amount of \$1.7 million. At the higher level, the program awarded more than 150 American Indian and Alaska Native students annually. When the fiscal year 1997 Indian fellowship request is added to the \$2.6 million reduction in BIA graduate student aid and to the \$2 million cut from IHS scholarships in fiscal year 1996, the result is that nearly \$8 million has been eliminated in scholarship aid for Indian students over the past two years. We are at a loss to understand why scholarship resources have suffered such a massive and seemingly inequitable cut, especially when one compares academic achievement and financial aid resources available to the general non-Indian public.

*National Advisory Council on Indian Education (NACIE).*—NIEA supports full funding for NACIE in the amount of \$400,000 in fiscal year 1998. The Department has requested only \$50,000 for the Council to hold meetings, make its report to Congress, and advise the Department on Indian education issues. In fiscal year 1996 partial-year funding in the amount of \$120,000 was made available to NACIE to close its office with no funds appropriated in fiscal year 1997. Despite this, the twelve presidentially-appointed council members are continuing to fulfill their terms since legislation mandating their duties still exists. Congress established NACIE in 1972 as a critical component of the Indian Education Act, and for over 20 years it has been the only federal advisory committee concerned with all areas of Indian education. NACIE's role is crucial to ensuring that Indian education needs are addressed at the agency and national levels. NIEA requests that its funding be restored to a level sufficient for it to continue meeting its Congressionally-mandated functions and responsibilities.

*Tribal Colleges Executive Order.*—NIEA also supports the Department's request to fund the Presidential Executive Order initiative on tribal colleges. The recommended amount of \$200,000 has been designated to come out of OIE funding. NIEA would like to see the funding level increased to \$400,000 with the entire

amount covered by a non-OIE source, perhaps from the Office of Postsecondary Education.

*Other DOE Indian Education-Related Programs:*

*Goals 2000.*—NIEA supports the fiscal year 1998 request of \$620 million, a \$129 million increase from fiscal year 1997. The BIA receive a one percent set-aside from the total Goals 2000 allotment to offer school reform planning activities, and to explore the feasibility of schools converting to contract or grant school status. The fiscal year 1998 estimate for BIA school is \$3.8 million while the Alaska Federation of Natives receive \$50,000.

*Alaska Native Education Equity.*—NIEA supports the fiscal year 1998 request of \$8 million for programs dealing exclusively with the education of Alaska Natives. Programs authorized and requested for fiscal year 1998 under this activity include: Alaska Native Educational Planning, Curriculum Development, Teacher Training and Recruitment, \$5 million; Alaska Native Home Based Education for Preschool Children, \$2 million; and Alaska Native Student Enrichment, \$1 million. Since the BIA does not fund any elementary or secondary schools, and funds only minimal educational support in Alaska, we support the department's funding request.

*School-to-Work Opportunities.*—NIEA supports the fiscal year 1998 request of \$200 million, a continuation of the fiscal year 1997 enacted amount and a \$20 million increase over the fiscal year 1996 level for the Department of Education. An additional \$200 million request covers the Department of Labor in a joint partnership. Up to one-half of one percent of funds are reserved for programs serving youths in BIA-funded schools and are an important source of the school's funding package. At this amount the set-aside for Indian programs is \$2 million, which would cover continuing grants made in 1997 serving 31 tribal community partnerships.

*Title I.*—NIEA supports the fiscal year 1998 request of \$8.077 billion, an increase of \$379 million over the fiscal year 1997 level, for grants to local educational agencies (LEAs). One percent of these funds are appropriated to support programs at BIA-funded schools. Indian students located on and near reservations come from the poorest communities in this country since most reservations can not produce enough revenue-generating activities to fund such programs. Title I funds are therefore vital to guaranteeing that Indian children receive appropriate educational services due to their disproportionately low economic situation. The BIA portion under Title I is \$47.8 million with an estimated 23,900 (42 percent) Indian students in BIA schools benefiting.

*Impact Aid.*—NIEA does not support the Administration's request of \$658 million for fiscal year 1998, which is a decrease of \$72 million from the fiscal year 1997 level of \$730 million and a decrease of \$35 million from the fiscal year 1996 level of \$693 million. We urge the Committee to support restoring the \$72 million to insure that programmatic changes intended to make the program more need-based will take place. NIEA also supports the National Indian Impacted Schools Association's (NIISA) position that Congress shall provide the necessary funding in fiscal year 1998 to implement the reforms applicable to the Impact Aid Program as set forth by Public Law 103-382.

Over 2,000 LEAs enrolling over 20 million children are provided assistance under this program. Impact Aid provides basic program dollars to ensure that the educational needs of federally-connected children are guaranteed. The fiscal year 1996 estimate of the number of Indian children whose school districts benefit from Impact Aid's basic support payments is 116,000. An additional 14,000 Indian children with disabilities also generate funds due to the added school district costs of educating them. In fiscal year 1996 both categories generated approximately \$338 million for public school districts nationwide.

*Education for Homeless Children and Youth.*—NIEA supports the fiscal year 1998 request of \$27 million, a \$2 million increase above the fiscal year 1997 level. Of the funds appropriated, an amount representing one percent is to be provided to the BIA for Indian students served by BIA-funded schools. The fiscal year 1998 budget request includes \$100,000 for BIA programs to provide services to homeless Indian children and youth to attend school. The most recent BIA estimate of the number of homeless American Indian students reached by this program is 540.

*Bilingual Education.*—NIEA supports the Administration's request for \$160 million for Instructional Services, \$14 million for Support Services, and \$25 million for Professional Development. For purposes of this Act, BIA-funded schools, tribes, and tribally-sanctioned educational authorities are considered LEAs. They are therefore eligible for discretionary grants to implement and improve instructional programs and professional development designed to help limited-English-proficient students master the English language and challenging curriculum geared to high standards.

The fiscal year 1998 estimate of Bilingual funds going to BIA schools is over \$712,000.

*State Special Education Grants.*—NIEA supports the Administration's request of \$3.9 billion for fiscal year 1998, a \$141.3 million increase over the fiscal year 1997 level. One percent of these funds go to BIA-funded schools to educate students with disabilities, and an additional one-quarter of one percent of funds go to tribes with BIA-funded schools for services to children ages 3–5. This funding usually represents 60 percent of the funding spent on education and related services for disabled Indian students. It is critical because of the increasing number of Indian children with disabilities—approximately 7,400 students for the current school year. The total Education Department estimate for State Special Education Grants for BIA schools is \$39.7 million.

*State Special Education Infants and Families Grants.*—NIEA supports the Administration's request of \$324 million for fiscal year 1998, an \$8.2 million increase over the fiscal year 1997 level. A quarter of one percent of these funds go to tribes with BIA-funded schools for coordinating the provision of early intervention services to children with disabilities ages 0–2 years and their families. The estimated amount going to BIA schools in fiscal year 1998 is \$4 million and will serve approximately 1,600 Indian students.

*Technology Literacy Challenge Fund.*—NIEA supports the Administration's request of \$425 million for fiscal year 1998. This program, which targets schools with the greatest need, provides grants to states to implement strategies enabling their schools to fully integrate technology into their curricula in order to help students become technology literate. The BIA is a 51st state under this program receiving about two-thirds of one percent of the program's funds. It received \$1 million in fiscal year 1997 to fund grant applications from BIA-funded schools. The fiscal year 1998 amount going to BIA schools is \$2.1 million. In order to create technology-literate environments in all BIA-funded schools, however, funding in the area of \$9.5 million to \$22.5 million would be needed—based on a recent Rand Corporation estimate of \$450 per student to create technology-rich schools. American Indian and Alaska Native students must not be left out of any initiatives that can provide them with the skills necessary to navigate the Information Superhighway, and which prepare them for academic and employment success. We urge the Subcommittee to support increased funding to the BIA for this program.

*Vocational Rehabilitation State Grants.*—NIEA supports the Administration's request of \$2.25 billion for fiscal year 1998, a \$71 million increase above the fiscal year 1997 level. One-half of one percent of these funds, or approximately \$12.4 million, are set-aside for grants to tribes to provide vocational rehabilitation services.

*Vocational Education.*—NIEA supports the Administration's request of \$1.2 billion for vocational education programs nationally. Of that amount at least \$16 million should go to the tribal projects allocation, and another \$2.9 million would continue to be earmarked for two tribally-controlled institutions. NIEA also supports the tribal colleges' recommendations on the reauthorization of the Carl D. Perkins Vocational Education Act: that the resources continue for the Indian vocational education program as provided under Title I, Section 103, and that any changes to this section require tribal consultation; that funding continue for the Indian vocational post-secondary education program as provided for under Title III, Section 385; that a new Tribally-Controlled Community College program is needed; and that a national center for American Indian vocational education research and data collection be established and funded.

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### *Administration for Children & Families:*

NIEA echoes and supports the National Congress of American Indians' (NCAI) recommendations to give the newly-formed Tribal Services Division of the Department's Office of Community Services the funding necessary to carry out its mission of making Public Law 104–193, the "Personal Responsibility and Work Opportunity Reconciliation Act of 1996," workable in Indian Country under the government-to-government relationship.

##### *Indian Health Service (IHS):*

*Indian Health Professions Scholarships.*—The Indian Health Professions sections 103, 104, and 114 under Title I of the "Indian Health Care Improvement Act" provides authorizations to support scholarship recipients, loan repayment to health professionals, and temporary employment during non-academic periods. The Administration's fiscal year 1998 request for this program is \$28.3 million, a \$1.5 million

increase over the fiscal year 1997 enacted level. NIEA, however, supports the National Indian Health Board's (NIHB) recommended level of \$29.7 million.

*School-Based Health Education Programs (IHS and BIA).*—NIEA successfully advocated in 1992 to obtain a new authorization in the Indian Health Care Improvement Act (IHCA) to establish school-based health education programs. NIEA's fiscal year 1998 request is \$5 million for both programs (\$3 million for IHS and \$1 million for BIA). Under Section 215 of the IHCA, the Secretary of DHHS is authorized to award up to \$15 million in grants to tribes to develop comprehensive school health education programs for children on reservations enrolled in grades K–12. The programs could be established in public, contract, grant and private schools.

The area of school health education receives minimal support from both the BIA and IHS. Through an intra-agency agreement, IHS receives \$230,000 annually from the Centers for Disease Control and Prevention (CDC) for school health education programs, which is the entire budget for this effort. On the other hand, BIA has no specific funds for this purpose.

We ask the Committee to recommend a funding level for this authorization of at least \$3.5 million for grants to tribes, and that \$1.5 million be provided to the BIA to fulfill its requirements under Section 215 of the IHCA to institute health education programs in its schools.

*HIV/AIDS Prevention.*—According to the CDC, there were 1,434 reported and verified diagnosed cases of AIDS among Native Americans as of June 1996, approximately a 12 percent increase over the amount CDC reported in October 1995 (1,283). Although CDC's announcement on February 27, 1997 that the number of deaths nationally from AIDS had declined, including a 32 percent drop among American Indians and Alaska Natives, it did not address the issue of individuals with AIDS living longer and needing long-term care.

We note there is no line item for AIDS medication in IHS's budget, and that the President's budget does not cover the cost of drugs to treat Indian and Alaska Native people infected with HIV. The fact remains, however, that for these individuals, IHS is the only source for their medical care. Despite recent improvements in the treatment of HIV/AIDS, such as the development of more effective drugs, far too many of our people are being denied this type of care because IHS is not being funded to provide it. NIEA supports the National Congress of American Indians' (NCAI) recommendation that a restricted line item be included in IHS's budget to cover the cost of AIDS-related treatment.

Furthermore, while NIEA supports the fiscal year 1998 request of \$3.8 million for HIV/AIDS Prevention, which is only a slight increase from fiscal year 1997, we cannot impress strongly enough upon the Committee the need for additional funding to be made available to combat this dreaded disease.

NIEA recommends a significant increase in actual funding to all HIV/AIDS education and prevention programs within IHS. NIEA also urges the Committee to impress upon the Department to implement the final recommendations of the President's Advisory Council on AIDS Services Committee regarding Native American AIDS Care Issues.

*Other DHHS Indian Education-Related Programs:*

*Administrative for Native Americans (ANA).*—NIEA supports a funding level of at least \$36 million for ANA for fiscal year 1998, an amount \$1.1 million higher than the President's request. Although the Administration for Native Americans (ANA) is a relatively small agency of the Department of Health and Human Services, its impact on Indian Country is immense. ANA provides funding for tribes and non-profit Indian organizations to encourage economic development strategies, environmental management, and language retention and preservation projects. Its mandate makes this agency uniquely situated to help Indian and Alaska Native people address their economic and social needs.

*Native American Languages Act Grants.*—NIEA supports continued and increased funding for Native language grants in fiscal year 1998. In fiscal year 1996, ANA awarded approximately \$1.8 million for these grants, yet the real need approaches \$10 million. Although the "Native Language Act of 1992" authorized a funding level of \$2 million in fiscal year 1993, such an amount has been never been appropriated. We urge the Subcommittee's support for funding at \$2 million so that tribes may have the resources to implement language preservation and enhancement projects.

*Head Start.*—NIEA supports the fiscal year 1998 request of \$4.3 billion, an increase of \$324 million over the fiscal year 1997 level. In fiscal year 1997 nearly \$99 million was available for Indian Head Start, although the estimated need is over \$400 million. We applaud the Administration's efforts over the past two years to enhance Head Start programs. NIEA believes that there is a real need to reach out to tribal entities that are not currently being served by the Head Start Bureau. Out

of 557 federally-recognized American Indian/Alaska Native tribes only 130 are Head Start grantees. These tribes provided services to 18,870 children in fiscal year 1997. Efforts should be made to expand the program in Indian Country. This is critical given the increasing population of Indian and Alaska Native children between 0–5 years of age.

*Child Care and Development Block Grant (CCDBG).*—NIEA supports an fiscal year 1998 request of not less than \$59 million for Indian tribes and tribal consortia. This was the amount appropriated in fiscal year 1997. The total fiscal year 1998 budget for the CCDBG program is \$1 billion. We commend the Administration's commitment to providing low income families with access to child care services since most Indian reservations and rural Native communities, lack child care facilities and services. There are currently 237 tribal entities and consortia which in total serve over 500 Indian tribes and Alaska Native villages.

NIEA supports the efforts of the National Indian Child Care Association in trying to expand child care resources to Indian Country and their efforts to secure at least a three percent set-aside to American Indian and Alaska Native grantees. We understand that the fiscal year 1998 funding formula is based on a 2 percent set-aside, down one per cent from fiscal year 1997. However, due to a new program components and expanded legislation there may be a larger appropriation amount to pull Indian dollars from according to CCDBG officials. NIEA supports continuation of the current funding mechanism for childcare block grants whereby funds flow from the central office to the regions directly to tribes.

#### DEPARTMENT OF LABOR

##### *DOL Indian Education-Related Programs:*

*Job Training Partnership Act.*—The Administration's request of \$52.5 million is a sharp decrease of \$14.1 million from Program Year 1995 for the Job Training Partnership Act (JTPA) Section 401 Native American Program. This program is designed to improve the economic well-being of Native Americans through the provisions of training, work experience, and other employment-related services and opportunities that are intended to aid the participants to secure permanent, unsubsidized jobs. This program is critical to both reservation and urban grantees who are largely unskilled, poorly educated, and living in poverty. We therefore request the Congress to support funding of this important program at its fiscal year 1995 enacted level of \$65 million.

*Summer Youth Employment.*—NIEA supports the fiscal year 1998 request of \$871 million for the Summer Youth Employment Program, an increase of \$236 million from the fiscal year 1996 level. The Indian set-aside is approximately \$15.8 million. On most Indian reservations this program provides the only means of employing young Indian men and women who are vulnerable to a myriad of economic and social ills such as drug and alcohol abuse, teen pregnancy and fatherhood, and unemployment due to little or no job skills. Additionally these young people are at a higher risk of dropping out of school or attempting suicide due to the lack of positive environmental influences.

#### PROPOSED NATIONAL SCHOOL CONSTRUCTION INITIATIVE

President Clinton has proposed a \$5 billion school construction initiative which would leverage \$20 billion over five years for nationwide school construction and renovation. The proposed \$5 billion would help pay for up to half the interest that local school districts incur on school construction bonds, or for other forms of assistance that will spur new state and local infrastructure investment. Interior Secretary Bruce Babbitt has asked the Office of Management and Budget to include a 10 percent set-aside for BIA-funded schools. Currently the amount designated for the BIA and Trust Territories is 2 percent or \$100 million. BIA's amount is 60 percent of the total and equals \$60 million. Unlike public schools however, the BIA will be unable to leverage additional funds through issuance of school bonds as will some of the larger territories.

An increase of the set-aside amount to ten percent would allow the BIA to address its backlog of school repair projects, including school replacements and ensure schools, that don't have the option to issues construction bonds, are equitably considered. The estimated backlog of BIA schools needing repair and renovation is \$670 million. NIEA wholeheartedly supports the Secretary's request for a 10 percent set-aside for BIA-funded schools if the President's school construction initiative is enacted.

In conclusion, we want to thank the Subcommittee for continuing to give its attention to the issues and concerns we have raised in our testimony. In light of the federal government's trust responsibility for the education all American Indians and

Alaska Natives, and on behalf of our members, we urge the Subcommittee's support for maintaining or increasing funding for the Indian education and related programs discussed herein at the levels we have recommended.

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PREPARED STATEMENT OF LYNDA JOHNSON ROBB, CHAIRMAN OF THE BOARD,  
READING IS FUNDAMENTAL, INC.

Thank you for the opportunity to offer recommendations on the Inexpensive Book Distribution Program, Improving America's Schools Act, Title X Part E, Sec. 10501. Reading Is Fundamental, Inc. (RIF) operates this program under contract to the U.S. Department of Education.

Last year Congress allocated \$10.3 million of the Education appropriation for the Book Program. We respectfully urge you to appropriate for Fiscal 1998 the \$12 million requested by the Administration.

The additional funding would allow RIF to reach 300,000 more children who most need our reading services.

Although the Book Program costs the taxpayer little, it plays a unique and unduplicated role in helping America's children acquire reading skills. Its reach and popularity extends throughout the 50 states, Washington, D.C., and the U.S. off-shore possessions.

Last year 3.3 million children participated in activities to encourage reading and learning, and selected more than 10 million free books to keep—all at a cost to the government of only \$3.19 per child for the entire year.

More than 195,000 unpaid community volunteers—37 percent of them parents of the children served—stepped forward to bring these services to the children in their communities. Local RIF projects receive Federal money only for books, none for administration or other program costs. And RIF provides no Federal dollars at all to any group that can operate the Book Program without them. Thus the program involves a major citizen commitment. I know, for I have personally volunteered for RIF for 30 years.

As a further service to children's literacy, for every Federal dollar invested, RIF and the local programs last year leveraged an additional \$5.06 in private funds, goods, and services. For example, RIF was able to secure private funding to increase the RIF services throughout northern Mississippi.

Yet for all our efforts, there remains a huge, unmet demand for the highly acclaimed Book Program. Right now RIF cannot fund its waiting list of 2,290 Federal Book fund applications to serve 1.3 million children, 83 percent of whom are educationally at risk.

SUITED TO EVERY COMMUNITY

Reading Is Fundamental and the Book Program are an American success story—an exemplary model of a Federally funded program that helps citizens help themselves to invest in children's capacity to learn. There is no other agency or institution—private, state, or Federal—that provides a comparable literacy service.

The Book Program is distinctive in additional ways: it draws local and national corporations, foundations, and service organizations into the cause of children's literacy. Among those joining forces with RIF are such major entities as Chrysler Corporation, J.C. Penney, Ameritech, Mazda, General Electric, Kiwanis International, PTO's & PTA's, Lions Clubs, Jaycees, Rotary Clubs, and numerous sororities, fraternities, and local businesses.

The Book Program has the unique ability to go to places where you would expect it to—such as schools and libraries—but also where you wouldn't: health centers, housing projects, migrant farm worker camps, crisis shelters, hospitals, juvenile detention centers, community centers, Native American Reservations, Even Start, Head Start, and other early childhood and family literacy centers. RIF goes wherever children go.

The Book Program honors local wisdom. With general guidance and technical assistance from RIF, local citizens make all the major program decisions: which children to serve, what reading activities to use, which books to place before the children. Their projects reflect the needs of their communities' children and enhance other services they provide. RIF has often been praised for its avoidance of red tape, lack of intervening bureaucracies, and its responsiveness to local volunteers. By respecting community choices, the RIF program strikes a successful balance between the national and the local, the Federal government and the private citizen.

## A NATIONAL PRIORITY

RIF and the Book Program decidedly address a demonstrated national need and priority: to ensure that American children grow up literate. From the White House, to the school house—in family living rooms and corporate board rooms—Americans have recognized just how critical it is to provide the tools to get children reading more and reading better. Yet the RIF/Book Program can reach but a fraction of the young people who need its valuable reading services.

Throughout the country there is growing alarm about the deteriorating reading ability of our young people and what that bodes for the nation.

Federal studies tell us that 40 percent of fourth grade students cannot read at even the most basic level. Of American high school seniors, 60 percent cannot read at the level they should to interpret correctly and apply what they've read.

Meanwhile, business leaders lament that young people are arriving for work unable to read instruction manuals, fill out forms, or write a well-constructed paragraph.

Employers increasingly test job applicants' reading abilities. The American Management Association reported that since 1990 more than a third of those tested were found wanting. Meanwhile, 89 percent of the jobs being created require high levels of literacy. Yet less than half our nation's students have achieved those levels.

Reading skills translate into earnings: an adult who reads better earns more—about \$400 more per week than one with poor literacy skills. Poor reading has another cost: one to the U.S. economy of about \$225 billion a year in lost productivity alone.

Literacy is a national heritage of strength. Americans' literacy skills continue to fuel the nation's triumphs.

Low literacy contributes to school drop-out rates; adolescent pregnancy; unemployment; poverty; and homelessness. Reading skills are arguably the most important tool our children need for navigating through life's challenges toward independence, opportunity and achievement. But as the studies show, we are only too often failing our children.

## A SUCCESS STORY

However, the reading studies of the past decade or so have also pointed toward solutions. Almost universally high on the list is that students at all levels who read best are those who read for fun during their own time, have reading materials at home, and whose parents encourage their reading and learning.

The Book Program clearly is part of the solution, for its key elements are access to books, incentive to read them, books in the home, parent/family involvement, and reaching children early.

Only too frequently, the Reading Is Fundamental/Book Program provides the only books in a child's home and their first exposure to the pleasure and importance of reading. And the program often provides the first comfortable avenue for parents to become involved with their children's reading.

Competent readers are made, not born.

The Book Program succeeds because it provides:

- Customized, enjoyable reading activities for children and families.
- New books that children want to read, can choose, take home to keep and read at no cost to them or their families.
- Materials and how-to guidance to help parents encourage children's reading.
- Encouragement from adults who share the pleasure and benefits of regular reading.

The Book Program also makes possible the nationwide network of local projects that attracts private support to enhance the Federally-supported services. These privately-funded initiatives include programs: to train Head Start parents to operate RIF projects and encourage reading at home; to teach young parents how to bring up their children as readers; for family literacy training for low-literacy parents in adult learner programs; to provide an intensive reading challenge for first graders that encourages and rewards children's reading while enlisting parents, teachers and local volunteers to build community-wide support for launching lifelong readers; for a program that promotes book sharing and reading between fifth and sixth graders with kindergarten and first grade students; for an at-home reading and poster contest to motivate young readers across the country; for reading corners for children in homeless shelters; for guidance booklets for parents; and a supplemental curriculum that brings together science, technology, reading and other disciplines to enhance children's enthusiasm for each.



## COST-EFFECTIVE AND CREDIBLE

RIF's operation of the Federal Book Program and all it leverages has earned many awards and widespread acclaim for accountability, efficiency and success in getting children to read.

- RIF earned one of only seven A+ ratings for U.S. Charities from the American Institute of Philanthropy.
- RIF ranked as one of the 20 most credible charities in the nation in a Chronicle of Philanthropy survey.
- RIF was named one of the nation's 10 "Charities that Make a Difference in the Lives of Children and Families" by Parenting magazine.

*RIF is Fiscally Accountable:*

RIF is independently audited each year, sometimes twice a year. In all its years of operating the Book Program, not so much as one penny has been misused or gone unaccounted for.

*RIF is Programmatically Accountable:*

Each year RIF provides to the Congress, the Department of Education, and the public a detailed accounting of programs it has funded, where they operate, the children they serve, the books that have been placed in children's hands, and what the program has accomplished overall.

*RIF and the Book Program Get Results:*

Studies, surveys, reports, assessments, and unsolicited comments most frequently cite the following results of the RIF/Book Program:

*Children Read More.*—parents, teachers, and the children report that the children spend more time reading books, such as these comments from a Raytown, Missouri parent: "Our children cherish their RIF books. They all seemed to have 'their nose in a book' after RIF."

*From an Anchorage, Alaska program:*

"RIF has undoubtedly created an enthusiasm for reading. Students are excited about the distributions and proud of their new books."

*Children—and Their Families—Use Libraries More.*—Both school and public librarians report increased library use as a result of the RIF/Book Program. RIF students in schools ask for particular authors, titles and themes. And public librarians report that more families use the libraries when their children are involved in RIF.

*A New Cumberland, Pennsylvania librarian wrote:*

"Since starting the RIF program, I have noticed an increase in library circulation, and added knowledge and awareness of authors. Parents indicate student reading increased, and the parents themselves gained an understanding of appropriate reading materials."

*In Stephens, Arkansas:*

"RIF is making a difference. Our students enjoy the 'silent reading time' at school more. They trade their books with each other. They look forward to Library Day and going to the library in between RIF distributions."

*Reading Abilities Improve.*—RIF receives many reports from teachers and school administrators that the Book Program increases reading abilities.

*Like this one from Seattle, Washington:*

"Our students continue to make positive gains in the Reading Comprehension section of the California Test of Basic Skills (CTBS). We are convinced that having RIF books in their possession encourages them to read and contributes to these gains."

*From Arnold, Missouri:*

"Our reading scores in the lower grades are soaring. On the Missouri Mastery Achievement Test (MMAT) the vocabulary and reading comprehension scores of the children served in the RIF program have increased."

*From Dunmore, Pennsylvania:*

"A number of factors are indicative of how the RIF program is contributing to our educational goals for our children. Among the most notable are our improved reading scores, increased library circulation, and a willingness to share books with classmates."

*Children's Attitude Toward Learning Improves.*—As children become better readers, they become better learners.

*Such as the Even Start teacher in El Paso, Texas, who reports that:*

“Without a doubt, the books made available by RIF have given the children and parents the resource needed to spend quality time together, reading and talking about a favorite story. This type of interaction creates various opportunities for further learning.”

*A Migrant Education teacher in Davenport, Iowa tells us:*

“Our student population is very mobile, and RIF is an educational program they can count on. We know that RIF not only helps build reading skills but also a positive attitude about school.”

*And in Elko, Nevada, we hear:*

“When students talk among themselves about a good book they got at RIF, or inquire about more books by that author at the library, you know that reading is happening, and that your RIF day was a success. It inspires discussion of ideas between students and their teachers, also, which improves interaction between all ages of people.”

*Parents Become More Involved With Their Children’s Reading and Learning.—*Parent volunteers get involved in all aspects of operating their RIF/Book program.

*The program in Norristown, Pennsylvania reports:*

“RIF has certainly made a difference in the parent volunteer programs at the elementary schools. Volunteer efforts have increased at each school. RIF has provided parents the means to enter schools, and to realize that there is nothing to fear. Many parents now routinely volunteer for classroom activities.”

*From Longview, Washington we hear:*

“We know we are making a positive impact on parents. Many share stories of how RIF has changed their own attitudes toward reading. Others have told us that volunteering for children and keeping up with their children’s education have encouraged them to return to school.”

In sum, the RIF/Book Program has amassed a demonstrable record of results in getting young people to read.

It is a locally-driven program that attracts the services and contributions of the community and citizen volunteers from all walks of life, and:

- It gets books into homes, and homes into reading.
- It is greatly in demand, and widely acclaimed.
- It is lowcost, accountable, and cost-effective.

The Inexpensive Book Program as operated by Reading Is Fundamental contributes to the reading progress of America’s children in tangible ways that draw rare applause for Federal spending:

*From a parent in Owen, Wisconsin:*

“RIF contributes a positive attitude toward government spending. Parents enjoy seeing their taxes put to good use and returned to their children.”

*From a teacher in Louisville, Kentucky:*

“This program is not a program that wastes money.”

*An Oregon school administrator for whom the Book Program has the smallest budget of the many programs he oversees:*

“I strongly feel it is the best and most effective expenditure of educational funds I have seen.”

This program achieves—dollar for dollar, child by child—far more than it costs. It is a time-tested, sound program that gets young people to read and develops their interest in learning. It meets a critical need as we approach the 21st century.

For these reasons, we respectfully urge the Congress to appropriate \$12 million for fiscal 1998 for the Inexpensive Book Distribution Program.

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PREPARED STATEMENT OF CORNELIUS J. PINGS, PRESIDENT, ASSOCIATION OF  
AMERICAN UNIVERSITIES

The Association of American Universities, on behalf of the National Association of State Universities and Land-Grant Colleges, the American Council on Education, and the Council of Graduate Schools, appreciates this opportunity to submit for the record testimony in support of the fiscal year 1998 budget for the National Institutes of Health (NIH) and the Department of Education’s graduate education programs. These associations represent all of the public and private research universities across the country. We want to note that we, along with other higher edu-

cation associations, have separately submitted testimony to the Subcommittee regarding the Department of Education's important student aid programs.

NATIONAL INSTITUTES OF HEALTH

First, we wish to express our deep appreciation for this subcommittee's efforts last year to provide a 6.9-percent increase in funding for the NIH, and for all of this subcommittee's efforts over the years to make funding for biomedical research a top priority. Your unwavering commitment to federal investment in biomedical research has resulted in a level of support for the NIH that clearly reflects widespread bipartisan support for this vital federal role.

NIH-supported research has made enormous contributions to the health and quality of life of all Americans and for many people around the world. Indeed, the partnership that has been forged between research universities and the federal government through the NIH is the envy of the world. Last year a group of business leaders wrote that the partnership of "research and educational assets of American universities, the financial support of the federal government and the real-world product development of industry has been a critical factor in maintaining the nation's technological leadership through much of the 20th century."

AAU, NASULGC, ACE and CGS all support the Ad Hoc Group for Medical Research Funding's endorsement of the NIH fiscal year 1998 professional judgment budget as the best and most reliable estimate of the level of funding needed by NIH to sustain its high standard of scientific achievement. As you know, the NIH professional judgment budget for fiscal year 1998 calls for a 9 percent increase over fiscal year 1997. This funding level would increase the number of top-quality, peer-reviewed research grants to over 8,000 and would allow the NIH to take advantage of new and emerging opportunities in biomedical science, as well as to increase the size of these grants to keep pace with inflation.

In addition to adequate funding of research project grants, we believe that research training is a critical element in maintaining a strong biomedical research enterprise, and we urge careful consideration of the research training portion of the NIH budget. The AAU and others have worked closely with officials at the NIH to develop an agency-wide policy on funding for training grants that emphasizes quality but also recognizes the importance of maintaining a robust and diverse base of scientific talent critical to ensuring the future success of our nation's research efforts. There are other mechanisms, such as research assistantships funded through NIH research grants, for maintaining our base of scientific talent, and we are concerned about the federal erosion of support for a number of these mechanisms and federal programs. The AAU has convened a Committee on Graduate Education that is looking at a whole host of graduate education issues, including mechanisms for federal support, and we will keep the Subcommittee apprised of any recommendations the AAU Committee may make.

The research university community has traditionally been an advocate for the programs included in the National Center for Research Resources (NCRR), and this year is no exception. NCRR programs have been extremely valuable to research institutions and cost-effective to the government. For example, in an era of limited resources, the Shared Instrumentation Grant Program (SIG) offers a mechanism for leveraging scarce federal dollars to ensure the availability of sophisticated, expensive scientific equipment. SIG grants make it possible to purchase the kind of equipment that cannot be funded through the RO1 grant mechanism but is nonetheless essential to the ability of our scientists to move forward in many important research areas. NCRR also administers the limited amount of funding that is provided for the highly competitive extramural construction and renovation funds. And the university-based General Clinical Research Centers (GCRCs) provide the state-of-the-art instrumentation, skilled laboratory technicians, research nurses, and specialized laboratory and computer facilities essential to conducting much of the clinical research underway today.

Finally, we are aware that this subcommittee has held an interest in the costs of research and the federal policies that govern federal reimbursement of them, and has raised some concerns about them in the past. The research community continues to examine the current system of cost reimbursement to ensure that the system is accountable and efficient. The AAU has convened a committee of university presidents and chancellors to explore these issues, as well as a technical advisory group composed of faculty and administrative representatives from a number of both public and private universities, to assist the AAU committee in its efforts. Over the years we have worked closely with OMB and OSTP on a variety of issues related to the costs of research, and we urge that these issues continue to be addressed

through the Executive Branch regulatory process where they may be considered as part of an overall government-wide policy.

These are challenging times for research universities. For those with academic health centers, they are particularly challenging given the enormous changes we are experiencing in the managed-care environment and the impact that possible changes in Medicare and Medicaid funding will have on our teaching hospitals and training programs. But these are also some of the most exciting times for new discoveries and breakthroughs in basic and clinical biomedical and behavioral research. The federal investment in biomedical research has made possible the pioneering innovations that have improved so dramatically our health, economic well-being, and quality of life. The members of this subcommittee have fought long and hard to provide the funding levels needed to support this research. In this difficult budgetary time we ask that you continue this fight and maintain your support for the NIH and the millions of people who benefit from the federal government's investment in medical research, and for those who will depend on it in the future.

#### DEPARTMENT OF EDUCATION GRADUATE EDUCATION PROGRAMS

Education at all levels will be key to sustaining and enhancing the competitive position of the United States in the global economy. Graduate education will play a particularly critical role in this country's capacity to discover and develop new knowledge, producing the scientists, engineers, and scholars responsible for expanding the frontiers of knowledge and the preservation of our intellectual and cultural heritage for succeeding generations of students and citizens.

Much of the work of doctorate recipients will be conducted outside of colleges and universities: almost 50 percent of 1995 PhD recipients had employment commitments outside the academic sector. Physical science and engineering PhDs are particularly important to industry: of 1995 PhD recipients, 44 percent of physical science PhDs and 62 percent of engineering PhDs had employment commitments in industry.

Master's degree recipients may go on to pursue doctoral degrees; more often they are educated to begin state-of-the-art careers in industry, strengthening our nation's economic performance in global competition.

It is important to the nation that a sufficient portion of our most talented college graduates pursue graduate education. Those students with the talent and motivation to succeed in graduate study are also likely to be those students with the broadest array of competing employment options. To complete a doctoral program, students must commit typically to five years or more of additional study, not only foregoing employment income but often incurring substantial additional debt beyond that carried from their undergraduate education.

Providing incentives to pursue graduate education and reducing the financial costs of that education are critical to assuring that our graduate programs continue to attract some of the nation's best talent. The federal government needs to play a central role in attracting talented students into graduate programs. Because the students who receive graduate degrees are a national resource whose employment prospects are not bounded geographically, states are reluctant to invest substantially in graduate education. Similarly, industry investment in graduate education is as likely to benefit a given company's competitors as itself. Financially strapped universities invest what they can, particularly in underfunded areas such as the humanities and social sciences. Graduate students themselves are likely to have accumulated substantial debt to finance their undergraduate education and incur the additional cost of foregone income to pursue graduate education. But federal investment in graduate education and academic research has richly repaid this nation, providing a strong base of knowledge and talent on which government, industry, and educational institutions have drawn.

The Department of Education's Title IX graduate fellowship programs are an important part of the federal government's investment in graduate education. The provision of competitively awarded, multiyear fellowships to graduate students bestows an honor on their recipients and provides a level of predictable financial support that offsets the considerable sacrifices required by graduate study.

#### *Reauthorization of the Higher Education Act: A Proposal for Consolidation*

We understand that the current pressures of the federal budget make it difficult to fund many important federal programs. Therefore, the higher education community has developed a proposal for consolidating the Department's Title IX programs to preserve their most critical elements while reducing the number of programs and reducing the federal cost in dollars and personnel of administering them.

Our proposal would consolidate the Title IX programs into a single National Graduate Fellowship Program with three complementary components:

- Traineeships in areas of national need: block grants to strong academic departments and programs in areas of national need, to be used by those programs to recruit and support talented students to pursue the highest graduate degree offered in those areas.
- Portable fellowships in humanities, social sciences, and the arts: fellowships awarded directly to students to pursue graduate study at the institution and program of their choice; awarded in the humanities, social sciences, and the arts, such a program would provide the most effective means of allocating resources in these broad disciplines, where student choice provides the best match of student interest and academic program quality.
- Grants to increase participation of students from underrepresented groups: grants to institutions to increase the number of students receiving graduate degrees from groups underrepresented in graduate education, with awards based on academic quality of programs and the institution's track record of recruiting and graduating students from underrepresented groups and placing them in academic positions.

All three components would be competitively allocated on the basis of merit. Students would receive a need-based stipend and a tuition waiver; institutions would receive an educational allowance in lieu of tuition and fees. All grants would be for three years.

The administration of the program would be contracted out to nongovernmental, not-for-profit organizations for program administration, particularly the merit review components of the program. The contracting provision would reduce the demand for federal employees to manage the program and would allocate program administration to organizations and personnel with strong records of quality administration of such programs.

We are aware that this new approach would require authorizing legislation. We have already sent our proposal to the Congressional education authorizing committees, and are committed to working for the enactment of such legislation as part of this year's Higher Education Act reauthorization. In the meantime, we request that the Subcommittee continue to fund new and continuing fellows and trainees from the existing Title IX programs in fiscal year 1998 in order to ensure that sufficient resources and programmatic functions are available for the consolidated approach. Our specific fiscal year 1998 funding request is outlined below.

#### *Fiscal Year 1998 Recommendation*

We request a total of \$42.7 million for the fiscal year 1998 appropriation for Title IX programs as follows:

- Graduate Assistance in Areas of National Need: A \$26.8 million appropriation, the amount requested in the Administration's budget, would allow the GAANN program to fund existing programs and award new traineeships in areas of national need.
- Javits Fellowships: A \$5.9 million appropriation, the amount awarded in fiscal year 1997, would allow the Javits program to fund continuing fellows and hold a new competition.
- Harris Graduate Fellowships: A \$10 million appropriation would provide funding for new competitions for both master's and doctoral Harris fellows and preserve this critical program as we head into the reauthorization of the Higher Education Act.

#### *Conclusion*

For many years, Congress has recognized the need for federal investments in graduate education and biomedical research and has provided sufficient resources to maintain these important programs. We very much appreciate the Subcommittee's long-standing bipartisan support for both graduate education and biomedical research.

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PREPARED STATEMENT OF STEPHEN A. JANGER, PRESIDENT, CLOSE UP FOUNDATION

Mr. Chairman, distinguished members of this Subcommittee, my name is Stephen A. Janger and I am President of the Close Up Foundation. I am grateful for the opportunity to submit this testimony in support of the Allen J. Ellender Fellowship Program administered by the Close Up Foundation. The past support of this Subcommittee has made it possible for thousands of students and educators to take part in a unique civic education program that benefits not only the participants but their communities and eventually society as a whole. We sincerely thank you for your support.

Educating youth about their responsibility for being informed civic participants should continue as a major effort. As you know, there is a precipitous decline of confidence in all of our institutions. We hear that people fear that the problems facing our society will not be adequately addressed. There is increasing polarization among citizens, lack of trust, and lack of civility. Our youngest citizens can be part of the solution if they are given access to the kinds of educational opportunities Close Up provides. The need is more urgent than ever before. To continue Close Up's efforts to reach students, we respectfully request \$3.0 million from the fiscal year 1998 Labor, Health and Human Services, Education and Related Agencies Appropriations bill.

As we begin our twenty-sixth year of providing our civic education program to students and educators, we have an opportunity to reflect on the accomplishments of the past quarter century. Of the many things we have accomplished, there are perhaps three things of which we are proudest. First and foremost is the fact we have stayed true to our mission of outreach to "all kinds of students."

And, we have succeeded by reaching students from low-income families, whether they are in urban, rural, or suburban settings, disabled students, students from "at-risk" schools, students who are children of migrant workers, students from remote, isolated parts of the country, and others who make up the ignored or underserved student populations of this country.

This outreach to "all kinds of students" has allowed us to involve underserved student constituencies, as well as accomplish a second goal of producing a program with a diversity of participants unparalleled by any other civic education organization's program. In addition to income and geographic diversity, we have students who are the academic elite, the class leaders, and students who struggle to stay in school. We know that these students benefit from meeting each other sharing Close Up's experiential learning program.

A third Close Up theme that has remained constant throughout our twenty-five years is our message. We strive to teach all of our participants that regardless of where they are from, they share the common responsibility of being informed citizens who participate responsibly at every level of civic involvement. This message may be one reason that so many of our student and teacher participants return to their communities to conduct and participate in Close Up Local Programs.

During the last twenty-five years, there have been an estimated 760,000 participants in Close Up Local Programs. These programs have taken many forms, but generally they mirror the Close Up Washington Program with a focus on local issues and concerns rather than national ones. Some of the local programs are multi-generational. Many involve diverse segments of the community. In these state and local programs, the message of informed citizenship is multiplied to tens of thousands of citizens at relatively no cost to the federal government. Best of all, perhaps, is that citizens of all ages participate, and students who did not have the opportunity to come to Washington can still be involved in a program that develops civic literacy and competence.

Close Up Local Programs, outreach to underserved constituencies, and diversity of participants are only a few of the many factors that make Close Up different from other civic education organizations, something that seems to be lost on the Department of Education's budget office. Last year in response to report language included by the House Subcommittee in House Report 104-659, we worked with the Department of Education's budget and program offices to produce the report that this Subcommittee received a copy of on December 30, 1996. For ease of reference, I will refer to this report as the Report in this testimony. Despite our strong protests and the objections of the Department's own program officer, the Department's cover letter to the Report included a reference to Close Up conducting a program similar to other civic education organizations that do not receive federal funds. Such misinformation has been included for the last four years in the Department of Education's (DED) budget justification material.

While it is not my intent to disparage any other organization, it is unfair and misleading of the DED to compare us in this way. This is not a simple emotional boast. There are factual assertions that serve to support the important distinction between Close Up and other civic education organizations. For example, Close Up is the only civic education organization that includes disabled students in its programs; Close Up is the only organization that encourages and provides technical support for local programs, thereby expanding the reach of our work many times over; Close Up is the only organization that offers focus programs for new American students; Close Up is the only organization that offers separate teacher programs; Close Up is the only organization that offers fellowships to students based only on economic need; and, most importantly, Close Up is the only organization that offers fellowships to every participating school.

The DED mentions that another civic education organization offers scholarships to its participants, and that that organization does not receive federal funds. Again, I would not denigrate any other organization; however, if other organizations offer scholarships to their students at all it is on an extremely limited basis, and the scholarships have academic and/or geographic criteria placed on them. I do not know the intricacies of any other civic education organization, but I do know that no other organization has provided more than 95,000 fellowships, to “all kinds of kids” from every state in America and from every background imaginable.

A great deal of what I point to with great pride would not have been possible without the support of this Subcommittee through the years. The Allen J. Ellender Fellowship funding provided by this Subcommittee has served as the seed element that has allowed the Foundation to expand the reach of the fellowship program to thousands of students annually. These students would not have been able to participate without the help of an Ellender Fellowship. For Close Up program year 1995–96, the average family income for a family with four dependents receiving fellowship assistance was \$17,826. Obviously, any program participation from students with such limited economic means would be almost impossible without Ellender Fellowship assistance.

As we stated in the Report, the Close Up Foundation will continue without Ellender Fellowships; but, the composition of the program will not be the same. The vital mix, the blend of constituencies, will diminish and participation will be for those who are able to pay for it. From the very inception of the Ellender Fellowship program, the legislative intent has been to provide economically disadvantaged students (and their teachers) the same opportunity to participate in Close Up’s program as their more affluent peers—those who are able to pay.

The Ellender Fellowships have provided to all students the opportunity to learn about responsible citizenship; the opportunity to really connect with their representatives and governmental institutions; and the opportunity to try to become effective contributors in our society. Ellender Fellowships are the equalizer and the multiplier that have enabled tens of thousands of students to participate in Close Up’s unique program.

We have used our Ellender Fellowships wisely and well. Furthermore, no one should think that the Foundation has sat back and depended entirely on federal funding. In fact, although it is a vital component of our revenue stream, the Ellender Fellowships comprise a relatively small percentage of our total revenue. This is another fact that distinguishes Close Up from many other federal grantees—we have not relied solely on the federal government for the vast majority of our revenue.

If simple cost-effectiveness and the multiplier effect of Ellender Fellowship dollars are not sufficient justification for continuation of funding, the simple fact that the Ellender Fellowships are used, as they were intended, for a program that works and works well should justify their continuation. In this time of increasing public distrust of government, and the erosion of trust in our most basic institutions, Close Up programming is designed to help to break down the negative stereotyping of Congress and the government and, at the same time, expose students to the realities and the difficulties of forming public policy. By visiting Washington, meeting with their elected representatives, and participating in workshops and seminars, the students learn first hand the multiplicity of issues and the time demands that face every Member of Congress. Educators continue to emphasize that there is no textbook that can communicate these messages as effectively as Close Up’s experiential learning program. There are many groups calling for more initiatives to revitalize America and renew our civic purpose. There can, unfortunately, be no renewal and revitalization until our young people become fully engaged and understand their role as citizens.

From the very beginning, Close Up has spent an extraordinary amount of time and energy raising private donations for the Foundation. There have been years when we have been more successful than others, but there has never been any portion of any year in which we have not been out there trying to secure support for civic education programming.

Unfortunately, even our most successful years have not always produced the results we wanted for the fellowship program, because some donations are “donor directed” to other areas of the Foundation’s work. Donations are like the “uncontrollables” in the federal budget. Donors dictate which program is to receive their donation; and, the choice for the Foundation has been either to accept the funds for specific civic education initiatives or to leave it. Obviously, there is no choice but to take the donation and use it to further civic education overall, even though we would have preferred to use it for fellowships.

It is the uncontrollable aspect of private funding that makes Ellender Fellowships so critical. The Ellender Fellowships enable us to go to an “at risk” school and provide the seed money to ensure that students who have severely limited economic means can participate in the program. Ellender Fellowships provide us with the entry to get into schools to explain and discuss the program and thus provide students with the opportunity to participate in a program that has been demonstrated to have a positive, life-transforming effect.

We know this not only from anecdotal data we have received through the years, but from present-day information. We have alumni in every walk of life, a remarkable number of whom hold positions in local, state, and regional governments, as well as in the federal government. One of our alumni is a United States Senator. We have many, many alumni who work on the Hill. Some of the Members of this Subcommittee likely have staff who are past Close Up participants. Although we know we cannot take total credit for their interest and success, a consistent message we receive from our alumni is that their participation in the Close Up program is what sparked their interest in becoming involved in the area of politics and public policy service.

We have alumni, as well, who are now in the business sector—young leaders who say their understanding of public policy making has made them more effective in their fields. Many of our “alumni” are volunteers, work on boards, and continue their participation in bettering their communities.

During the last year, Close Up has begun an effort to create an active alumni program. We have explored the creation of such a program in the past, but the estimated return on the investment of very scarce resources did not seem to justify going forward. This is another area in which we sharply disagree with the DEd. In its cover letter to the Report, the DEd stated that it believed the alumni effort was particularly noteworthy as a development task. While we are committed to developing an alumni program and are hopeful it will produce some financial benefit to the Foundation, we do not expect significant results for several years and in all likelihood the financial contribution to the Foundation will be modest.

Developing an alumni program pits us directly against colleges, universities, and professional schools, all of which have long standing, high profile development efforts. Although we believe that our almost 480,000 alumni remain loyal and interested in our welfare, most are still students or in their budding professional career stage. It would appear unrealistic for us to expect to be able to compete effectively against institutions that were part of a person’s life for four years or more for the dwindling dollars of private individual giving.

As we noted in the Report, private giving, by individuals and corporate entities to secular, nonprofit education organizations, has been on a downward trend. According to several recent studies, charities—especially those serving the disadvantaged—will not receive enough in private donations to offset scheduled reductions in federal programs. In fact, Julian Wolpert, professor of urban affairs at Princeton University, has found that the most optimistic estimates predict that contributions to charities might make up for only five percent of the total of lost federal funding.

The combination of these factors and others relative to the realities of raising private donations present a very bleak picture for the Foundation’s efforts to reach underserved student populations. Termination of the Ellender Fellowship program is likely to result in the severe reduction or possible elimination of participation of “at-risk” schools and economically disadvantaged students.

Despite this, the Foundation is continuing its effort to secure support, financial and otherwise, from the private sector. The partnership among business, philanthropy, government, and educators that has worked so well in the past to serve our young people needs to remain in tact, however. Should the government withdraw its modest support, it will be much more difficult to convince other members of the partnership to maintain their efforts.

Mr. Chairman, all of us at the Close Up Foundation are aware that the support of this Subcommittee has been a critical element for Ellender Fellowship funding; and, we are very grateful. I realize that these are very difficult budgetary times. I believe, however, that the relatively small amount of \$3,0 million we are requesting for Ellender Fellowships is money well spent because of the return it makes not only in the numbers of students affected but in the long-term contribution made to America’s civic literacy.

I will be glad to answer any questions or to provide any information. Thank you very much.



## RELATED AGENCIES

## PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony on behalf of the National Federation of Community Broadcasters, or NFCB, which is the sole national organization of community oriented non-commercial radio stations.

Community radio fully supports \$325 million in funding for the Corporation for Public Broadcasting in fiscal year 2000. Federal support distributed through the CPB is an unreplaceable resource for rural stations and for those stations serving minority communities. In the case of the rural and minority stations, CPB support may not ever be replaced and the goal of universal, local, non-commercial radio service will never be achieved.

In larger towns and cities, sustaining grants from CPB enable community radio stations to provide a reliable source of noncommercial programming—about the communities themselves. Local programming is an increasingly rare commodity in a nation that can hear and view news from around in the world every thirty minutes.

The NFCB respectfully submits two requests to the Subcommittee. First, we ask that the Subcommittee recommend to the CPB to continue the funding priority for rural radio, especially sole service providers, stations with minimal donor bases or service areas with limited programming alternatives, and community radio stations. Second, we recommend that existing mandates on CPB funding remain in place until there a full analysis of CPB's mission for public broadcasting and, if necessary, programs are developed to achieve that mission.

*Maintain funding to sole service, rural, and stations reaching underserved audiences.*

The NFCB requests that the Subcommittee include with its fiscal year 2000 CPB appropriation report a recommendation that CPB give funding priority to public radio stations that serve rural and unserved areas, sole service stations and stations reaching underserved audiences. Our request echoes language included in reports from House and Senate subcommittees on CPB appropriations in recent years.

Beginning in fiscal year 1992, the Corporation of Public Broadcasting established grant programs to support public radio stations serving extremely rural communities and underserved audiences. In fiscal year 1997, grants to the most rural stations totaled \$754,715 for support to 23 stations; the average grant was \$32,814 per station. In 1997, grants to other rural stations and those serving underserved audiences totaled \$7,970,236 for support to 65 stations; the average grant was \$122,619 per station.

With Congressional direction such as given above, these critical grant programs for especially important stations will continue. Without such language these grant programs, which represent only 15 percent of the \$59,650,000 direct radio share of the CPB appropriation, are at risk of being significantly reduced or even eliminated.

In Senate Report 104-145, these grant programs are encouraged with the language: The Committee directs CPB in allocating reduced funding to consider the impact on rural radio and TV studios, especially sole service providers, stations with minimal donor bases or service areas with limited video programming alternatives, and community radio stations. The Committee directs the CPB to give priority to stations which serve rural, underserved, and unserved areas and sole service providers.

Similar language has been included House reports on the CPB appropriations. We are asking that the Subcommittee consider including such a recommendation with the fiscal year 2000 appropriation report.

*Maintain Current CPB Mandates Pending Review*

Our second request is to maintain current mandates on CPB funding pending a full review which will take place during the coming reauthorization hearings. The mandates are the result of past Congressional actions following oversight hearings during the reauthorization process. One of the mandates that the NFCB fully supports is the requirement for CPB to support public radio stations which are the sole source of broadcasting in the areas they serve. Until that mandate was imposed, extremely rural, and extremely important community radio stations were denied funding support from CPB. While there may be some mandates that are out of date and no longer in the best interests of public broadcasting, without a full discussion and comprehensive analysis, there is no feasible way to decide which mandates should be lifted.

Thank you for your consideration of our testimony.

The NFCB is a twenty year old grassroots organization which was established by, and continues to be supported by our member stations. Large and small, rural and urban, the NFCB member stations are distinguished by their commitment to local

programming and community participation and support. NFCB's 90 Participant members and 136 Associates come from across the United States, from Alaska to Florida; from every major market to the smallest Native American reservation. While the urban member stations serve communities that include New York, Minneapolis, San Francisco and other major markets, the rural members are often the sole source of local and national daily news and information in their communities. NFCB's membership reflects the true diversity of the American population: 40 percent of the members serve rural communities and 34 percent are minority radio services.

On community radio stations' airwaves examples of localism abound: on KILI in Porcupine, South Dakota you will hear morning drive programs in their Native Lakota language; throughout the California farming areas around Fresno, Radio Bilingue programs five stations targeting low-income farm workers; in Barrow Alaska, on KBRW you will hear the local news and fishing reports in English, and Yupik Eskimo; in Dunmore, West Virginia, you will hear coverage of the local school board and county commission meetings; KABR in Alamo New Mexico serves its small isolated Native American population with programming almost exclusively in Navajo; and on WWOZ you can hear the sounds and culture of New Orleans throughout the day.

In 1949 the first community radio station went on the air. From that day forward, community radio stations were reliant on their local community for support through listener contributions. Today, many stations are partially funded through the Corporation for Public Broadcasting grant programs. CPB funds represent about 15 percent of the larger stations' budgets, but often can represent up to 40 percent of the budget of the smallest rural stations.

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PREPARED STATEMENT OF MARTHA MCSTEEN, PRESIDENT, NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE

The National Committee to Preserve Social Security and Medicare appreciates the opportunity to comment on the value of an increased federal investment in medical research through the National Institutes of Health (NIH) to save lives and reduce health care costs. As a grassroots advocacy organization representing millions of senior Americans, we strongly support a substantial and growing investment in basic biomedical research.

The members of the National Committee thank this Subcommittee for making the NIH one of your highest priorities in the past few years. Research conducted through the National Institutes of Health (NIH) has had a long tradition of strong bipartisan support and is responsible for dramatic improvements in the health and quality of life for all Americans. In the 105th Congress, several Senators have called for significant increases in NIH funding. Senators Connie Mack, Phil Gramm, Bill Frist, Alphonse D'Amato, and Subcommittee Chairman Arlen Specter introduced a Senate resolution recommending a doubling of the NIH budget over the next five years. Senators Gramm, Mack, and Kay Bailey Hutchison also have introduced a proposal to double the amount authorized for basic science and medical research for a number of research agencies, including the NIH, over a 10-year period.

Moreover, Senators Harkin and Specter have introduced legislation, S. 441, to establish a national fund for health research to significantly expand the nation's investment in medical research, over and above funding provided to the NIH in the appropriations process. We commend the leadership demonstrated by these Senators in support of NIH funding, as well as the exploration of alternative methods of providing additional funding to supplement the NIH appropriation.

While we acknowledge the difficult choices that must be made, we urge the Subcommittee to continue to view NIH as a high priority and increase the nation's investment in basic research in fiscal year 1998. In the professional judgement of the NIH, a 9 percent increase over fiscal year 1997 is the minimum level of funding needed to sustain its high standard of scientific achievement in the coming fiscal year. We urge you to appropriate this increase to allow the NIH to continue its research efforts that permit Americans to overcome serious illness, prevent the onset or progression of disease, and prepare those suffering from disease or disability to live independently.

Investment in medical research returns manyfold in improved health and lower health care costs and improves the quality of life for individuals and their families. Hundreds of millions of health care dollars can be saved annually if ways are found to delay or prevent the onset of disorders such as Alzheimer's disease, heart disease, cancer, stroke and diabetes and to treat these conditions. Aging research in particu-

lar is a sound investment as the largest segment of our population faces retirement age, and as we are living longer.

A strategy for preventing age-related disabilities has been noticeably absent from the current debate over Medicare's future. At present, seventy percent of the cost of Medicare is generated by only ten percent of the Medicare population—the chronically ill and disabled. As Congress grapples with the rising cost of health care and the long term solvency of the Medicare program, they should look for answers from research funded through the NIH.

The best way to reduce the staggering costs of devastating diseases that afflict older persons is through basic and clinical research. In a 1995 NIH report, the annual costs of heart disease alone are estimated to be \$128 billion. The costs of Alzheimer's disease are estimated to be some \$100 billion a year. The costs of arthritis are some \$65 billion annually, and the annual costs of diabetes are estimated to be \$138 billion. Delaying the onset of chronic illnesses such as these would result in a significant reduction in nursing home admissions, reducing the costs of nursing home care by as much as \$35 billion a year.

A recent study by the Center for Demographic Studies at Duke University has found that from 1982 to 1994 the chronic disability rates for people 65 and older in the United States has decreased almost 15 percent, due in large measure to medical research. This study proves that our nation's investment in medical research is paying off in terms of human suffering prevented and economic savings. We must continue to build on this success.

Approximately 4 million Americans suffer from Alzheimer's disease, a degenerative disorder that destroys the brain, depriving victims of memory and judgement and leaving the patients unable to care for themselves. While there is still no cure or effective treatment for Alzheimer's disease, NIH-funded researchers have identified a genetic marker for Alzheimer's disease that may lead to improved diagnosis and treatment. New genetic discoveries related to a protein known as apoE4 may lead to an effective, inexpensive means of diagnosing Alzheimer's disease. Unless a cure or treatment is found, 14 million people will be stricken by the middle of the next century. A five-year delay in the onset of Alzheimer's disease could reduce this number and save some \$50 billion dollars annually.

Osteoporosis affects an estimated 25 million Americans (over 80 percent women) and leads to 1.5 million fractures a year, including 300,000 broken hips. Fifty percent of hip fracture victims lose the ability to walk independently following the break and 12 to 30 percent—or more than 50,000 individuals—die from complications within one year. The direct and indirect costs of osteoporosis are estimated to be as much as \$20 billion annually. NIH-funded researchers have isolated a gene that may help identify individuals at high risk for osteoporosis and are using this new knowledge to enhance their understanding of the cellular causes of the disease. In addition, NIH-funded scientists recently reported on a "targeted intervention" strategy that focuses on a variety of risk factors for falls, such a multiple medication use. The intervention reduces the rate of falls among older, frail individuals by at least 30 percent.

Arthritis is ranked the number one health problem of people over age 45. Half of all Americans age 65 and older will suffer from some form of arthritis by the year 2000. In recent years, researchers have gained significant knowledge about how enzymes break down cartilage and bone in osteoarthritis, the most common form of the disease. Efforts to translate these findings into clinical applications are now on the horizon, and success in this area should reduce the future burden that this disease places on older persons. Osteoarthritis costs to our nation are in excess of \$8 billion annually. By delaying the onset of this crippling disease by five years, the U.S. could save at least \$4 billion in direct and indirect costs.

These are just some of the exciting research developments that have taken place that hold promise for the treatment of aging-related diseases. Unless better ways are discovered to treat, prevent, or postpone these diseases, the costs to the nation will grow exponentially in the future. The National Committee is aware of the funding constraints under which Congress must operate and the difficult choices that must be made. However, we urge Congress to continue the NIH as a high priority in fiscal year 1998. In recent years, NIH-sponsored research has produced major advances in the treatment of cancer, heart disease, diabetes and many more disorders that have helped save many thousands of lives. Much of the medical research funded through the NIH simply would not be conducted with a diminished federal commitment.

On behalf of the National Committee to Preserve Social Security and Medicare's five and one-half million members and supporters, we thank you for the opportunity to provide comments on this important issue.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICA'S PUBLIC TELEVISION STATIONS

This testimony is submitted by the Association of America's Public Television Stations, which represents the 179 public television licensees across the country that provide high quality noncommercial educational programming and services to the American people. America's public television stations are much more than broadcasters; they are vital community institutions operating successful public private partnerships for more than 40 years.

The Association of America's Public Television Stations (APTS) and its member stations support the Administration's request of \$325 million for the Corporation for Public Broadcasting (CPB) in fiscal year 2000. CPB provides financial support to local public television and radio stations through Community Service Grants (CSGs) that are key to the stations' stability. Every year since 1968, the federal government has renewed its commitment to a strong, noncommercial educational broadcast operation in this country and we are grateful to this committee for its continued support. Without the financial backing of Congress, millions of Americans would not be able to avail themselves of the valuable services that public television stations provide.

CPB receives the federal money, which is appropriated two years in advance of actual spending, and directly distributes 75 percent of it to local public television and radio stations for operations and programming. The CSGs are the single most important source of funding for local stations, and provide, on average, one-sixth of the revenue for a public television station. This figure varies widely, however. Many small rural stations depend on federal support for up to 30 percent of their operating budgets.

Two years ago, at the beginning of the 104th Congress, many newly elected officials asked whether financial support of public broadcasting was an appropriate role for American taxpayers. The American people responded with an overwhelming "yes" in a 1995 Roper poll they ranked public television third, behind national defense and law enforcement, as best value for their tax dollar. Congressional offices reported over and over that they had never seen such an outpouring of support. Public broadcasting continues to hear this message today.

The American people have effectively communicated that a noncommercial, educational public broadcasting system should be preserved. Public broadcasters continue to have discussions with congressional policy makers to examine ways to plan for long-term financial support. Throughout our many discussions we have agreed that the core principles of the nation's public telecommunications must be preserved. They are:

- noncommercial character and educational mission
- creation and delivery of programming of unequalled quality and excellence
- editorial integrity and independence
- adaptation of new technologies to educational and public service purposes
- universal access to our services
- local ownership, control and focus of public television stations

The public broadcasting reauthorization bill that was proposed in the 104th Congress focused on a trust fund, that when fully capitalized would generate enough income to replace the annual federal appropriation. APTS continues to support the concept of a trust fund. We are now working with new leadership on the House and Senate Commerce committees to develop a reauthorization vehicle that will assure the American people continue to receive the services of public broadcasting without regard to location or ability to pay. Until an alternative funding sources is in place and fully operational, local stations will continue to require funding through the annual appropriations process.

Since fiscal year 1995, federal support for public broadcasting has been declining. While this year's request of \$325 million may appear to be a large increase over fiscal year 1999's \$250 million appropriation, in reality it is only a modest 2.7 percent increase in real dollars from fiscal year 1990. The events of 1995 and 1996 accelerated the internal review of how public television does business. Public television stations have formed new partnerships with colleagues and with other private and public entities to streamline operations and expand methods of financing our programs both on-and off-air. Public broadcasting is more efficient and will continue to work smarter.

In Florida, for example, public television stations have pooled their resources to consolidate some of their operations. Six of the public television stations there now share a programming staff. Other Florida collaborations have merged multimarket underwriting sales and membership operations.

Despite all efforts at efficiency—and public broadcasting has always provided good return on investment—valuable programs and services offered by local television

stations cannot be preserved under the present declining funding curve. Unfortunately, education, educational children's programs and outreach services are the first to suffer when funds run short because they are the services that the marketplace will not support.

#### *Education*

GED-ON-TV is an excellent example of a public television educational endeavor that also incorporates local outreach. This educational series, produced by The Kentucky Network, has enabled nearly 2 million adults to acquire a high school equivalency certificate. Recent figures from the Bureau of Labor Statistics indicate that citizens with high school diploma or equivalency contribute \$4,980 more per year to their state's economy than do high school dropouts. That's almost \$10 billion added to our nation's economy annually. Multiplied by the 30 or more years Americans spend in the workforce and the impact is significant.

Since its inception in Kentucky in 1975, KET's GED-ON-TV program has enrolled over 35,000 students. The number of adults who have taken and passed the GED test after viewing the series is approximately 15,000. The cumulative economic impact for Kentucky alone, based on a conservative estimate of only 70 percent of those passing the GED and earning an additional \$4,000 per year, equals about \$900 million added to Kentucky's economy over the past 22 years.

Nationwide, 88,000 students are currently enrolled in this program through their local public television stations. These adults are able to obtain their diplomas while at home, many while caring for an elderly parent, or a disabled child. Others are able to maintain a regular job and do their coursework at home without taking more time away from their families, especially those who live in rural areas. Public television's GED program is also used at adult learning centers, federal and state correctional systems and on armed services bases worldwide.

Public television is very proud of its children's educational programming. Research does prove that children raised on Sesame Street and other public television programs do perform better in school. The Ready to Learn project undertaken by public television is centered around a daytime block of children's programming. APTS wants to thank this committee for the additional support of Ready to Learn through the Department of Education. Local stations have expanded the value of these programs by providing outreach services to children and their parents and caregivers to help them use public television as an effective learning tool. Between November of 1995 and March 1996 public TV stations conducted 474 workshops for parents and caregivers.

Critics of public broadcasting often cite cable and network television as alternatives to public television's quality children's programming. Some programs offered there are excellent, and we welcome them as partners in our efforts to teach children. But, the kind of local outreach activities mentioned above are not offered by cable programmers. Plus, many of our nation's neediest children do not have cable in their homes. Most American households now have access to cable TV. But more than 35 percent cannot afford, or must choose more basic needs rather than spend the \$300 to \$600 per year that cable costs.

Public television programs remain the first choice of teachers and are the most frequently used in the classroom for good reason. They are 100 percent devoted to quality programs for children. Public television's objective has always been to educate, not to sell. Public broadcasting does seek support from its viewers, but a financial contribution is not a prerequisite for watching public television programs. Most of our preschool viewers are from homes where the average income is below \$30,000. More than half of the regular viewers of public television (59 percent) are from households with an income of less than \$40,000 a year.

Public television stations work directly with local schools. They broadcast an average of five and a half hours per day of instructional programming for classroom use, enabling 1.8 million teachers to use quality instructional programming to reach 29.5 million students in 70,000 schools. Local stations broadcast overnight so that teachers can record and build a library of programs. Stations encourage this and many publish special guides for teachers as well as supplementary materials to facilitate the use of public television programs in the classroom. Public television stations work with teachers to enable them to use video most effectively, and also offer access to program information on the World Wide Web.

Public television has been a pioneer in new broadcast technologies and is working with schools and teachers to enable them to participate fully in the information revolution. For example, WSBE in Rhode Island recently announced a new project that will connect schools in the state to a high speed Internet connection. The project teams the station, the state department of education, a private university, and the US Department of Commerce in funding the program. Contributions from a private

individual will ensure the service is available to every teacher and school in the state at no cost to them.

With this committee's support local public television stations can help to ensure that students of all ages and abilities have access to high quality noncommercial educational and cultural content through the best technologies.

Public television stations have gone beyond what have become almost traditional distance learning opportunities, where high school students take live, interactive, satellite-delivered courses in advanced math and science, social studies and foreign language, arts and humanities. Students now take live, interactive field trips through their local public TV stations. This February, students had an opportunity to participate in Maryland Public Television's third electronic field trip to the South Pole. As part of Black History Month, students were able to look at African American colonial life in our series of Colonial Williamsburg field trips. KET's electronic field trip to a coal mine involved over 12,000 students. In addition to field trips, students have an opportunity to talk with nationally known writers and Nobel Laureates.

Since the beginning of education reform public television has supported massive teacher training efforts. Partnerships have been developed not only with state departments of education and universities but also with a wide variety of educational organizations. Stations continue to provide professional development tied to standards-based education and focused on improving instruction. A wide diversity of topics has been covered over the years and delivered via satellite and with print and on-line support.

Nationally, public broadcasting has worked closely with the National Council of Teachers of Mathematics in developing MathLine, a professional development program of training and peer support for junior high math teachers to implement the NCTM standards. The program has expanded to K-5, and will include senior high math teachers this September. MathLine is now available to any teacher with Internet access. The Department of Education has been a valuable partner in helping to expand MathLine to reach more teachers in more schools and APTS wants to again thank this committee for its support of this program.

In 1998, public television will launch ScienceLine. Social StudiesLine and Language ArtsLine are in the pipeline for 1999. The science teachers' national association will be a full partner in the ScienceLine effort. In each case, public television is working with the appropriate professional organization to implement the national standards in the respective subject area.

Two-thirds of the nation's colleges have used public television's Adult Learning Service (ALS). Local public television stations enable 400,000 tuition-paying students a chance to earn a college degree through television. In the last 15 years, over 3.5 million adults have participated in public television's ALS. These generally older students often live off campus, are employed and have adult responsibilities. Public television helps them move ahead by making a college degree accessible.

A new program, "Going the Distance," is the first stage of the Ready to Earn project, which will enable adults to receive an Associate of Arts degree totally through public broadcasting telecourses. There are 135 colleges now involved with "Going the Distance."

#### *Outreach*

Public television stations are very proud of another non-broadcast service that centers on programs that explore local social, educational and community issues. These "outreach" programs, coordinated through the Public Television Outreach Alliance (PTOA), provide viewers with examples of concrete actions they can take to improve their lives and participate in local action for constructive change.

Public television has dedicated major resources to programming, support materials and activities around the topic of literacy, the family, and women's health. Recently, a two year campaign to curb youth violence was completed. Later this spring results of these efforts will be compiled and presented to Congress.

#### *Conclusion*

Congress has made a very wise investment in public broadcasting. It has helped improve millions of Americans lives every day. APTS hopes that the committee agrees with those who benefit from public television's services that it as a cost-effective way to reach people on critical issues of the day, not as luxury.

On behalf of the nation's public television stations, APTS looks forward to working with Congress to ensure that we have the financial resources to continue to provide the American people free access to quality, noncommercial educational television.

PREPARED STATEMENT OF ROBERT M. TOBIAS, NATIONAL PRESIDENT, NATIONAL  
TREASURY EMPLOYEES UNION

Chairman Specter, Members of the Subcommittee: My name is Robert M. Tobias, and I am the National President of the National Treasury Employees Union (NTEU). Thank you for the opportunity to present NTEU's views concerning the fiscal year 1998 funding for the U.S. Department of Health and Human Services (HHS), and the Social Security Administration (SSA).

The National Treasury Employees Union (NTEU) represents over 160,000 federal workers, including employees in HHS's Office of the Secretary, the Office for Civil Rights, the Administration on Aging, the Administration for Children and Families, the Food and Drug Administration, the Health Resources and Services Administration, and other HHS operating divisions as well. NTEU also represents the Attorney-Advisors at SSA's Office of Hearings and Appeals.

NTEU is pleased to comment on the budget request President Clinton has submitted for the Social Security Administration and Department of Health and Human Services for fiscal year 1998. If there is one concern on our part, it is that fiscal year 1997 is more than half over and little progress has been made regarding agency appropriations for the new fiscal year which will begin the first of October.

As we all know, the Labor-HHS Appropriations measure has proven to be one of the most difficult funding bills to enact into law in recent years. For fiscal year 1997, the Labor-HHS measure was included in a Continuing Resolution. Up until the very end of September, federal employees at the agencies funded through this appropriations measure remained unsure as to whether or not they were facing another federal government shutdown. It has been estimated that during the 1995-1996 shutdowns, 3.5 million hours of work was lost at HHS alone. The many programs administered by SSA and HHS have a wide impact on our nation's citizens. It is critical that adequate funding be provided and that funding be provided in as timely a manner as possible. That is NTEU's goal and it is the goal of the dedicated federal employees we represent at the Social Security Administration and Department of Health and Human Services as well.

The President's fiscal year 1998 budget recommends an appropriation of \$143.1 million for administration of HHS's Administration for Children and Families (ACF). This is the same as the fiscal year 1997 funding level. The ACF oversees an array of important federal initiatives including the successful Head Start program, child abuse prevention and treatment programs and a host of other critical child, youth and family programs. While we believe this division's workload demands at least the level of funding provided in the current fiscal year, it is critical that ACF funding levels not be reduced below current levels. Cuts in this agency's funding level in past years have hampered the employees' abilities to fulfill the agency's mission and I urge Congress to be mindful of the important role ACF plays as funding decisions are made.

For the Administration on Aging (AOA), the President's budget requests a \$37,000 increase in program administration funding. As the lead agency within HHS on aging issues, the recommended increase in appropriations is both reasonable and necessary. Adequate program administration funding is critical to insuring that AOA can effectively deliver the services it is charged with providing.

Few agencies play a more pivotal role in Americans' daily lives than the Food and Drug Administration (FDA). Charged with protecting the health of the nation against impure and unsafe foods, drugs, cosmetics and other potential hazards, the President's budget request includes a \$66 million increase in salary and expense accounts at the FDA. I would urge Congress to provide at least the level of funding prescribed in the President's budget for this critically important agency.

For the equally important Health Resources and Services Administration (HRSA), the Administration budget recommends a decrease of almost \$2 million below the fiscal year 1997 level. HRSA plays a central role in ensuring that quality health care is available to millions of Americans and I urge Congress to carefully review this agency's needs and appropriate sufficient funds to ensure that HRSA will be able to continue its important federal role.

The mission of HHS's Office for Civil Rights (OCR) is to ensure that recipients of federal funding through HHS do not discriminate against program beneficiaries. OCR has an enormous responsibility, yet past appropriations levels have not kept pace with this division's workload and staffing requirements. I am pleased that the President's budget request includes a \$1 million increase in funding above the 1997 level. At a minimum, the Administration's budget request for OCR should be adopted.

HHS's Program Support Center (PSC) first began operating during fiscal year 1996. This division was the outgrowth of departmental streamlining and efforts to combine similar operations. PSC provides a number of key functions including financial management and administrative operations for HHS. The President's budget request for PSC is the same as the fiscal year 1997 level. I would urge the Congress to, at a minimum, insure that funding does not drop below the 1997 level.

The Social Security Administration (SSA) continues to have two areas of concern with its disability system, Continuing Disability Reviews (CDR) and the backlog at the Office of Hearings and Appeals (OHA). NTEU believes that the current level of funding for the CDR program will permit significant progress to be made in that area. However, the OHA backlog problem continues because substantial funds are being expended in the Disability Process Redesign (DPR) toward the goal of decreasing the backlog, but without appreciable results. NTEU believes that SSA could make a significant reduction of that backlog with a much smaller expenditure by suspending or terminating the Adjudication Officer Initiative of the DPR and continuing the highly successful and relatively inexpensive Senior Attorney Program (also known as the Short Term Disability Project Action No. 7).

The massive increase in the disability backlog that OHA experienced from 1992 to 1996 has been contained; there has been no significant change in the OHA backlog since July 1996. While no one at OHA is satisfied with the status quo, it is at last moving in the right direction. This stabilization of the backlog is due in great part to the Senior Attorney Program, which if continued, will permit a significant reduction in the case backlog, in processing times, and even in the reversal rate thereby providing greatly improved service to the public.

#### *Senior Attorney Program*

The Senior Attorney Program, also known as Short Term Disability Project Action No. 7, is a sharply focused plan with a well defined target, the disability backlog at the Social Security Administration's Office of Hearings and Appeals, which for the most part uses existing agency assets. This program does not require restructuring the Agency; a massive infusion of expensive technology; revising the decisional methodology; extensive employee dislocations; comprehensive, lengthy and expensive training of substantial numbers of employees; and nearly four years of planning without tangible results. In short, the Senior Attorney Program has been relatively inexpensive and very effective providing greatly improved service to the public primarily through redirecting current assets.

Senior Attorneys spend approximately 25–50 percent of their time performing Action No.7 work and most of the remaining 50–75 percent of their time drafting ALJ decisions. The ability of Senior Attorneys to perform both tasks significantly increases managerial flexibility allowing human assets to be directed to the highest priority tasks thereby maximizing OHA productivity. Action No. 7 was hindered by a variety of "start-up" problems and fierce resistance from Administrative Law Judges, including many Hearing Office Chief Administrative Law Judges. Despite this resistance, nearly 47,000 Action No. 7 decisions were produced in fiscal year 1996. However, recent management initiatives have significantly improved the operational efficiency of Action No. 7 resulting in a significant increase in production. During the first three calendar months of 1997 nearly 16,000 Action No. 7 decisions were issued; this is an annual rate of over 62,000 cases. Quality Assurance studies have demonstrated that the accuracy rate of Senior Attorney decisions significantly exceeds that of Disability Process Redesign's Adjudication Officers and is somewhat higher than that of on-the-record ALJs decisions. The accuracy of the Senior Attorney decisions combined with the significantly lower payment rate of Senior Attorneys (approximately 22 percent) than the payment rate of ALJs on the Senior Attorney cases that were not paid by Senior Attorneys (approximately 57.1 percent), demonstrate that Action No. 7 is not an effort to "pay down the backlog". During the course of the Senior Attorney Program, the overall payment rate at OHA has significantly declined thereby incurring a substantial savings in program costs. Additionally, the implementation of Action No. 7 has not resulted in an unacceptable increase in the number of ALJ decisions awaiting drafting. Action No. 7 has resulted in deserving claimants receiving a favorable decision with an average processing time of approximately 120 days as compared to the over 1 year average processing time for a case requiring an ALJ hearing. Finally, Action No. 7 has caused a decrease of nearly a month and a half in processing time even for those Action No. 7 cases which were not paid by Senior Attorneys and which still required an ALJ hearing as compared with non-Action No. 7 cases.



*The Adjudication Officer Initiative of the Disability Process Redesign*

The primary Long-Term Initiative purporting to improve the OHA workload situation is the Redesigning Disability Process (DPR). However, at the outset of DPR, SSA admitted that it was not intended to deal with the two largest problems plaguing the Social Security disability system: The lack of an effective Continuing Disability Review (CDR) and the backlog at OHA. SSA subsequently claimed that one goal of the Adjudication Officer Initiative was to reduce the OHA backlog. The DPR consists of 83 separate initiatives of which GAO recently noted none had been completed. SSA is currently involved in an extensive review of its customer service program. To that end, a Customer Service Executive Team (CSET) has been charged with the responsibility of reviewing the current plan and suggesting improvements. In a meeting on April 16, 1997 the CSET proposed that the Agency conduct focus groups and surveys of its "disability customers" to update its understanding of the service desired by these customers. At that time a senior SSA executive informed the CSET that such activities would make those managing the DPR uneasy if customers indicate desires not consistent with the Agency's current plans. This has heightened concerns the driving force behind the implementation of portions of the DPR, such as the AO initiative, is not improved service to the public, but advantage in the ongoing power struggle at the upper echelon of SSA management.

The initiative that SSA indicates will provide relief to the workload situation of OHA is the Adjudication Officer (AO) Initiative which began testing in November 1995. Despite the highest level of priority, carefully selected personnel, a priority on data processing equipment, and the establishment of closely controlled, ideal test conditions, AO productivity remains at less than half the level predicted by the DPR model. SSA recently admitted that the DPR model upon which implementation of DPR is predicated is flawed. At the outset of the AO test SSA was so confident in the reliability of the model that it questioned the need for testing at all, and even when forced to conduct a test, publicly stated that the test was not a test of the concept, only a test of fine tuning of the implementation of the Program. SSA also stated that no decision had been made regarding implementation. Through February 21, 1997, despite the resources consumed, the AO test had produced only 5,689 decisions. Further, the quality of those decisions, based on Agency quality assurance evaluations, is less than that of similar ALJ and Senior Attorney decisions. By any objective measure, the AO test has been a nearly complete failure and demonstrates the inability of the AO concept to efficiently process disability appeals. The DPR, particularly the AO test, has had no measurable effect upon the workload of OHA except consuming resources, both human and material, that could have been put to much better use.

*Recommendations*

The Senior Attorney program has significantly reduced the delay in granting deserving disabled people their disability benefits, stabilized the OHA workload, and reduced the overall payment rate at OHA, thereby contributing to a savings in program costs with a relatively small outlay in funds. NTEU recommends that funding for this program continue.

The Adjudication Officer Initiative of the Disability Process Redesign should be immediately suspended or terminated and at least some of the funds scheduled for that project should be redirected to effective efforts at reducing the OHA backlog.

Thank you again for this opportunity to share our views concerning the fiscal year 1998 funding levels for SSA and HHS. The downsizing and budget cuts of recent years have taken their toll on the ability of the dedicated federal employees who work at these agencies to perform their jobs. I urge Congress to carefully review the needs of these agencies as work gets underway to establish funding levels for the coming fiscal year.

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