S. HRG. 106–817

Senate Hearings

Before the Committee on Appropriations

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations

Fiscal Year 2001

106*th* CONGRESS, SECOND SESSION

H.R. 4577 and 5656/S. 2553

DEPARTMENT OF EDUCATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENT OF LABOR
NONDEPARTMENTAL WITNESSES

Labor-HHS-Education Appropriations, 2001 (H.R. 4577 and 5656/S. 2553)

S. HRG. 106–817

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2001

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

ON

H.R. 4577 and 5656/S. 2553

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, 2001, AND FOR OTHER PURPOSES

Department of Education
Department of Health and Human Services
Department of Labor
Nondepartmental witnesses

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2001

TUESDAY, FEBRUARY 29, 2000

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

The subcommittee met at 9:34 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Craig, Stevens, Harkin, Reid, Murray, and Feinstein.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF ALEXIS M. HERMAN, SECRETARY

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health, Human Services, and Education will now proceed.

We have an extraordinarily distinguished panel, the three secretaries of the departments, which are funded by this subcommittee. Protocol calls for identifying the secretaries in sequence of appointment.

The Department of Labor goes back to 1913, and the Department of Health and Human Services to 1953, and the Department of Education to 1979.

The President has submitted a budget which totals $106.2 billion, which is a very substantial increase over the $95.1 billion from last year. My own view is that in a Federal budget of $1.8 trillion, that this is a reasonable figure for the departments which have the responsibilities which these three departments have.

Now I believe that when you talk about education or health or worker safety, you are talking about a capital investment in America. But my views are not widely shared on Capitol Hill. And there is already talk of a total allocation of a budget far below the $622 billion, which the President has requested.

It is my hope that we will proceed with the budget process much faster this year than last year. And I believe that the leadership in both the House and the Senate agree with that.

We really need to pass these bills and present them to the President in a timely way, so that they can be acted upon by the President long before the fiscal year ends and not have budgets submitted in October and November, bills submitted in October and November, when there is no opportunity to follow the constitutional process, which is the Congress submits the bills, and the President either signs them or vetoes.

We have come to a practice where the Executive Branch sits in on the legislative process. And it is unconstitutional on its face, and I think it is highly undesirable. And there are some significant debates. My own sense is to try to beat the President's figure illustratively on education. Last year we came out of the Senate Appropriations Committee with $500 million above the President.

There may be some disagreements on priorities. And the Congress has a role, perhaps the lead role, on what those priorities ought to be. But that cannot be debated when you are into October or November and, if there is a gridlock, the consequence is closing down the government.

This is a very, very ambitious program. The administration is moving into a great many areas which have traditionally been left to the States. Talk about classroom size and more teachers, talk about school constructions. I supported our former colleague, Carol Moseley-Braun, Senator Carol Moseley-Braun, on efforts to begin on the school construction program. But that is not a widely held view.

And my own sense is that if we make provision for those kinds of programs, there ought to be some discretion at the local level, if the local boards decide they want to do something else, because all of the districts are not the same. But we cannot have that debate in October and November. But we could have that debate in July, August or September.

If the President vetoes a bill, let us debate it. Let us see what we are going to do and how the public responds to a little difference in the point of view.

This year's budget has a very ambitious program on youth violence. And I thank the three secretaries and also the Department of Justice, and specifically Deputy Attorney General Eric Holder, for working with the subcommittee on a series of meetings last year, which resulted in the reallocation of some $893 million on 16 programs to try to focus on juvenile violence in a quiet, unpublicized way. But the at-risk children in America are an enormous concern.

I just saw these statistics today that the Senator prepared from 1992 to the present. There have been 257 school-related violent deaths, 62 of which involved multiple deaths. I sat down with Bruce Reed, the domestic counselor, and talked to him about the coordination program. And I think that really has great potential.

We are going to take a new look at the drug prevention program this year, which is a first cousin of youth violence, and try to take a look to see if we might reallocate some funds with some specific evidence on the drug issue.

The Foreign Operations Subcommittee last week heard testimony for $1.6 trillion for money for Colombia. And I am very much interested in stability in Colombia, but I have grave doubts about $1.6

trillion going after a supply, which, if it is not from Colombia, will be from Bolivia or Equador or somewhere else.

And I believe we have an imbalance with two-thirds of the money going to the so-called supply side. You have to work on interdiction. You have to work on street crime. And I spent a lot of my professional life doing that. But the demand side, I think, is much more promising, rehabilitation and education, to deal with that issue.

Well, those are just a brief overview of some of the items at the top of my mind as to where we are going to be heading. If we can hold the opening statements—your full statements will be admitted into the record—to double time, to 10 minutes, that would be great. If you need a little more time, I have never seen a cabinet officer interrupted yet.

So we will begin with our very distinguished Secretary of Labor Alexis Herman, if that is the proper name, Ms. Herman.

Ms. Herman was recently married, and she may want to correct the record, or she may not.

We have just been joined by the illustrious Senator from Iowa, Senator Tom Harkin. So I will interrupt my introduction of Secretary Herman to yield to my colleague.

Senator HARKIN. Thank you very much, Mr. Chairman. I apologize for being late. I will just ask that my statement be made a part of the record.

Senator SPECTER. And then I will proceed with the introduction.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. I would welcome the three secretaries here, in this last budget year of the Clinton administration. I particularly want to thank all three of the secretaries who are here for their great leadership.

Secretary Riley and Secretary Shalala for the entire duration over the last 7 years, your great leadership of your two departments. And what you have done to move this country forward both in education, Secretary Riley, and in covering the health needs of all of our citizens, Secretary Shalala, I compliment you and commend you for your great leadership over these several years.

And to Secretary Herman, again for your great work for the administration in your previous iterations, but also in your role in this last 4 years with the Department of Labor.

Again, I think the budget that we have, as submitted by the administration, is one that will continue the progress that we have made in all these areas to continue to move this country forward in a way that education gets to the kids that maybe are not in the highest income areas and have the best schools and the best education, and gets to middle income families for college, for sending their kids to college, and the health needs, the labor area.

PREPARED STATEMENT

I guess I just want to thank you all for what you have done over the last several years. It has been great working with you. And I commend you for this last budget of the Clinton administration, because it does keep us moving in that direction that you have so

stalwartly led over the last several years, all of you. I just thank you for it and welcome you here for this hearing.

Senator SPECTER. Thank you very much, Senator Harkin.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Mr. Chairman, it's a pleasure to welcome Secretary Herman, Secretary Shalala and Secretary Riley today to testify about the Administration's fiscal year 2001 budget.

In general, I was very pleased with the overall fiscal year 2001 budget. I think the President has balanced the need to fund important domestic programs—many of which are funded in this bill—with the need to protect Social Security and Medicare.

Secretary Herman, I was very pleased to see the large increase in funds to eliminate child labor and I look forward to working with you on that initiative this year. I also want to commend you for your request to set up an Office of Disability Policy at the Labor Department. As the chief sponsor of the Americans with Disabilities Act, I am committed to ensuring that every American with a disability has the opportunity to achieve economic self-sufficiency and independence. I am pleased that you share my commitment.

Secretary Shalala, I was glad to see that the Administration has requested a substantial increase for child care. Last year, during consideration of this bill on the Senate floor, we were able to increase funding for the Child Care and Development Block Grant to $2 billion. We lost that increase in the end but I am committed to seeing that we increase funding for child care to $2 billion in this year's bill. I am also glad to see the requested $1 billion increase for Head Start. The evidence is very clear that we need to reach children when they are very young.

I was somewhat disappointed about the budget request for NIH—an increase of $1 billion. Last year, this subcommittee was able to provide a $2.3 billion increase for NIH—maintaining a course to double NIH funding in five years. This year's request does not keep us on that course. Senator Specter and I have introduced a Sense-of-the-Senate calling on the Budget Committee to reflect an $2.7 billion increase for NIH in this year's budget resolution. The opportunities are out there, the potential is great. But we have to commit the resources to get the job done

I must add that I was disappointed in the requested cut in the Community Services Block Grant and I hope to work with Senator Specter to restore that cut during this year's appropriation process.

Secretary Riley, I was very glad to see your fiscal year 2001 budget which calls for a $4.5 billion increase for education programs. And it will come as no surprise to you that I am particularly pleased with you request of $1.3 billion for school renovations and repairs. As you well know, the GAO has found that the cost of bringing the Nation's schools into good repair is about $112 billion. Today, I will be introducing a bill to reauthorize the existing school infrastructure program and look forward to working with you on this important initiative this year.

Thank you, Mr. Chairman—and I look forward to hearing from our witnesses.

SUMMARY STATEMENT OF HON. ALEXIS M. HERMAN

Senator SPECTER. One additional note before turning to Secretary Herman. At a presidential request of $622 billion, that exceeds the $540 billion cap in the fiscal year 2001 appropriations by some $82 billion. We have not addressed that yet.

And the caps have not been followed. But that is going to have to be addressed. According to the President's figures, that will still leave a $9 billion on-budget surplus. That is somewhat speculative, but we at least ought to note that it is not in compliance with the act, and we are going to have to deal with that as we proceed.

Back to the Secretary of Labor, confirmed in May of 1997, prior to which she served as assistant to President Clinton and director of the White House Public Liaison Office. She had served as deputy director of the Presidential Transition Office.

During the administration of President Carter, she directed the Women's Bureau at the Department of Labor, a graduate of Xavier University.

And again, we congratulate you, Ms. Herman, on your recent nuptials and look forward to your testimony.

Secretary HERMAN. Thank you very, very much, Mr. Chairman. I appreciate your words, also of congratulations. And I am still known as Secretary Herman and now Mrs. Charles Franklin. And quite frankly, I see no reason why I have to choose.

I shall be known as both. But thank you very, very much.

Senator SPECTER. Ms. Herman, you have been chosen, so you do not have to choose.

Secretary HERMAN. Mr. Chairman and Senator Harkin, thank you for the opportunity to present the Department of Labor's fiscal year 2001 budget. It is a special pleasure for me to join my colleagues, Secretary Riley and Secretary Shalala, in outlining the administration's goals and priorities.

Mr. Chairman, I think that we are all aware of the strength of the American economy today. Yet despite widespread prosperity, we still face two major and related challenges. Business leaders tell me that they simply cannot find the skilled workers that they need. And at the same time, millions of Americans remain outside the mainstream of our prosperity for lack of job skills.

Yet, if we take these two problems together, I believe they constitute an historic opportunity to provide the business community with the skilled workers it urgently needs, while at the same time bringing skills, jobs and hope to individuals and communities that for too long have been left behind.

The President's budget for fiscal year 2001 requests $39.8 billion for our department, $12.4 billion in discretionary funds. This is an increase of $1.2 billion over last year.

The majority of this increase is for targeted initiatives to provide the skilled workers who can meet the needs of our economy. Our budget puts special emphasis on young Americans. The Department of Labor's new Youth Opportunity Movement is the most intensive effort to reach young people in our history.

I recently announced youth opportunity grants to address skills training and job placement in 36 of the poorest urban and rural areas and Indian reservations in America, places where the unemployment rate is more than 6 times above the national average. Our new budget includes $375 million for this initiative, an increase of $125 million over the current year.

Mr. Chairman, you and I have visited youth programs in Philadelphia, and we have seen how they change the lives of young people. I believe our Youth Opportunity Movement will create similar success stories for tens of thousands of at-risk youth from coast to coast.

Last September we discussed with this subcommittee ways to reduce violence and drug abuse among our young people. One of the administration's responses has been the Safe Schools/Healthy Students Initiatives started last year by the Departments of Justice, Education and Health and Human Services. Our new budget includes $40 million to enable the Department of Labor to join them

in supporting community-wide programs to prevent youth violence and drug abuse and to promote youth employment opportunity.

Mr. Chairman, we share your concern that too many out-of-work young people get into trouble and wind up in jail. We need to provide positive alternatives and second chances. That is why our budget builds on the youth offender projects that began under your leadership and proposes to add $61 million for a total amount of $75 million.

The youth offender program will bring young offenders into the workplace through job training and placement and new partnerships with the criminal justice system. We hope that we will now be able to work even more closely with the Department of Justice, which has a companion proposal to bring these young people back into community life.

Too often, youth unemployment is a part of an environment that also includes high dropout rates, drug abuse, gang activity, violence and crime.

Mr. Chairman, in answer to the questions you raised in your letter about drug abuse reduction and early intervention, we believe that our youth-related programs can reduce social problems. Studies show that well-designed school programs lead to better academic achievement and lower rates of drug abuse, violence and arrest.

For all of our focus, however, on young people, this cannot be our only concern. We have to reach out to other untapped pools of workers. These include 5.7 million unemployed Americans, 4.4 million who are not in the labor force but say they want a job, and an additional 3.2 million who work part time because they cannot find a full-time job.

Our budget includes $255 million for our Fathers Work/Families Win, a new two-part initiative that grows out of the successful Welfare-to-Work Program.

Fathers Work will provide jobs for non-custodial parents, mostly fathers who owe child support. Families Win will help low-income parents who are struggling to make ends meet by providing better access to community services and upgrading job skills.

We are reaching out to people with disabilities, whose unemployment rates are more than three times the national average. We took an important step last December, when President Clinton signed the Bipartisan Work Incentives Improvement Act, which makes it possible for millions of people with disabilities to take jobs without losing their health insurance.

Our budget also includes funds to establish an Office of Disability Policy, Evaluation and Technical Assistance headed by an Assistant Secretary, which will provide leadership in helping disabled Americans enter the workforce.

We are now in the second year of a 5-year effort to provide skills, counseling and other assistance to every dislocated worker who loses a job through no fault of their own. To meet our goal of Universal Re-employment, our budget includes an increase of $275 million for information, training and One-Stop Career Centers.

Our concern is not only putting Americans in jobs, but ensuring that those jobs provide an adequate living for them and for their families. That is why the President has asked Congress to increase

the minimum wage by $1 over 2 years. And I strongly endorse his request.

Our budget also includes funds to oppose the worst forms of child labor around the world and to support international labor standards. These proposals reflect the President's challenge for us to put a human face on the global economy and to ensure that every American worker can compete on a level playing field, recognizing that today what happens around the globe in fact impacts workers around the corner.

Mr. Chairman, there will never be a better time than today to put America to work and to build an even stronger, more inclusive national economy. We will work with you in every way that we can to meet these goals.

PREPARED STATEMENT

I appreciate the opportunity to appear before this subcommittee, and I look forward to answering any questions that you may have. Thank you very much.

Senator SPECTER. Thank you very much, Secretary Herman.

[The statement follows:]

PREPARED STATEMENT OF ALEXIS M. HERMAN

Mr. Chairman, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to present the Department of Labor's fiscal year 2001 Budget. I am particularly pleased to join my colleagues, Secretary Riley and Secretary Shalala, to discuss key Administration priorities.

Mr. Chairman, I am especially pleased to be here with you today because the proposals in DOL's fiscal year 2001 budget request are exciting and innovative and build on seven years of solid accomplishments.

The President's request for fiscal year 2001 reflects the Department's goal that all workers have the opportunity to find and hold jobs, with safe and healthful working conditions, good wages, secure pensions and health benefits; and that they have opportunities to improve their skills over their lifetime.

To meet this goal, the overall budget for the Department in fiscal year 2001 provides a total of $39.8 billion in budget authority. DOL's request for discretionary programs is $12.4 billion, $1.2 billion above the fiscal year 2000 level. Since 1993, President Clinton has committed to investing in today's workers in order to keep America strong in the years ahead. This budget is faithful to that commitment.

President Clinton, in his State of the Union Message, spoke of the extraordinary state of our economy the more than 20 million jobs created over the past 7 years, the lowest unemployment rate in 30 years, and low inflation. America's workers are more productive, and real wages have increased as well.

The President also recognized that our prosperity is not universally shared among all Americans. The President called for a 21st Century revolution of opportunity, responsibility, and community. This vision includes steps to reward work, strengthen families, and expand opportunities to all our citizens. DOL has an important role to play in meeting those challenges.

I believe that the Department's programs are part of those all-important investments in the workforce and workplace of the future. Our bottom line is about helping people obtain skills, jobs and opportunity. It is about ensuring that, as our Nation moves forward, no one is left behind. We acknowledge that the Government cannot accomplish this alone; we need to enter into appropriate partnerships with others who share our commitment for a better America.

HELPING WORKING FAMILIES AT A TIME OF UNPRECEDENTED PROSPERITY

The dynamic forces of technology and globalization, while providing prosperity for many, continue to change the workplace in ways that may not benefit some Americans. Those who work hard should be able to realize the American dream for their families. DOL's budget takes account of the dramatic changes that are sweeping through the Nation and the world economy, and proposes significant, realistic poli-

cies and programs to help America's working families manage change and succeed in this new century.

Today we face two major workforce challenges: one new and one old. Many businesses report difficulty in filling vacancies. At the same time, millions of Americans, including many youth, dislocated workers and people with disabilities, are having a difficult time getting jobs, even during this period of unprecedented economic expansion. As I have often said, we do not have a worker shortage, but a skills shortage. Through the initiatives in the fiscal year 2001 Budget Request, we can help provide the business community with the skilled workforce it needs while bringing prosperity to individuals and communities that have been left behind.

THREE STRATEGIC GOALS

DOL's fiscal year 2001 Budget Request provides the resources we need to continue to make substantial progress toward DOL's three strategic goals: a prepared workforce, a secure workforce, and quality workplaces. I will first briefly describe our three goals and then describe the initiatives and programs in the fiscal year 2001 Budget Request that will help us to achieve these goals.

A Prepared Workforce.—DOL's budget request reflects one of the President's top priorities: investing in education and training to help ensure that every American has the education and the skills to succeed in the increasingly competitive global economy. Among other things, we must help young people make a successful transition to the world of work and family responsibility. Because a changing economy often requires our Nation's workers—of all ages—to acquire new skills, we must also serve dislocated workers in need of assistance as the labor market changes.

A Secure Workforce.—We must ensure that all Americans are economically secure both while in the workforce and after they retire. Employment-based pension and health benefits are the foundation of family security. Yet only about one-half of all full-time workers in the private sector have pension coverage today. Three-quarters of the workers in small businesses are not covered by a pension plan at all. Increasing access to our private pension system and assuring that private pensions, health care, and other employee benefits are secure and properly administered are some of DOL's most critical priorities addressed in this budget.

Quality Workplaces.—My third goal is to help guarantee every working American a safe and healthful workplace with equal opportunity for all. I believe tough enforcement is necessary when an employer's practices threaten workers' safety and health, discriminate on the basis of gender, race, religion, color, national origin, veterans' status, or disability, endanger children, or deprive workers of fair wages. DOL's ultimate goal, however, is compliance with employment laws. There must be an appropriate balance of fair and consistent enforcement, cooperative partnerships, and compliance assistance and training. Within the context of our global economy, I am also firmly committed to improving workplaces internationally, such as by improving implementation of core labor standards internationally and by eliminating abusive child labor practices abroad.

A PREPARED WORKFORCE

We must ensure that every American has the skills, the education and the training to be ready for the challenges and opportunities of the 21st century. The funds in DOL's budget will support programs to provide skills to young Americans, to work toward the goal of Universal Reemployment, and to reach out to untapped pools of workers, such as homeless veterans and Americans with disabilities, and bring them into the mainstream of our economy.

The fiscal year 2001 Budget Request puts a special focus on helping young people gain the skills they need to start up the career ladder. Even in today's booming economy, in some areas, unemployment among young people reaches 30 percent or more, and that is simply unacceptable. We cannot afford to lose even one of these young people. There has never been a better time to invest in workforce development initiatives. That is why we have launched our Youth Opportunity Movement to give young people skills, jobs and hope.

Youth opportunity movement

I am proposing several programs under the Youth Opportunity Movement umbrella to address the opportunity gaps and reach untapped labor markets in order to advance the goal to promote a prepared workforce.

I am very pleased that President Clinton helped launch our Youth Opportunity Movement as part of his New Markets tour last July. This is the most intensive effort to reach young people in our Department's history, and it is no secret that it is a personal priority of mine. Our Labor Day 1999 report entitled "Future Work:

Trends and Challenges for Work in the 21st Century" points out that there are almost 11 million young people who are not in school and have a high school diploma or less. The four million high school dropouts are at a particular risk of being permanently disconnected and disenfranchised from our society. There are warning signs when this is about to happen—the absence of supportive and caring individuals in their lives; low academic success which often leads to diminished self-esteem and leaving school; use and abuse of drugs and alcohol; out-of-wedlock births; and contact with the criminal justice system.

Youth opportunity grants

The Department's fiscal year 2001 budget includes $375 million for Youth Opportunity Grants, an increase of $125 million above fiscal year 2000. This program is intended to provide comprehensive, longer term intervention, primarily in the lives of out-of-school youth living in inner cities and high poverty areas, to help them graduate from high school, get jobs, and progress in the workforce. On February 19, the President announced the first round of grants to 36 communities across the country—from Philadelphia to the Pine Ridge Indian Reservation. The fiscal year 2001 request includes $250 million to provide for the third year of funding of these five-year grants. An additional $125 million is requested in fiscal year 2001 to fund the first year of 12 to 15 new competitive grants to high poverty areas. The program will serve an estimated 85,000 young people next year. These grants will focus on raising the high school graduation rates and long-term employment prospects of young people living in these poor areas.

Responsible reintegration for young offenders

As you know, we have shockingly high rates of incarceration in our Nation today—and many of those in jail are young people. Too many out-of-work young people get into trouble and wind up in jail, and that is a tragic waste. We need to provide positive alternatives and second chances.

That is why our budget includes $75 million to bring young offenders into the workplace through job training, placement, and support services, and by creating new partnerships between the criminal justice system and our workforce development system. When we get young people out of trouble and into jobs, we are not just helping individuals, we are strengthening the future of our communities. Each year, approximately 500,000 people leave prison. We must do more than lock people in jail. We must lead them into hope for the future.

This initiative will build on our experience with the Youth Offenders projects begun under your leadership, Mr. Chairman. This large scale Workforce Investment Act (WIA) Pilot and Demonstration initiative will link offenders under age 35 with essential services that can help make the difference in their choices in the future, such as education, training, job placement, drug counseling, and mentoring, which are the primary tools for reintegrating this population into the mainstream economy. Through local competitive grants, this program would establish partnerships between the criminal justice system and local workforce investment systems, and will complement a related program in the Department of Justice. An estimated 19,000 offenders will be served by this initiative.

Safe schools/healthy students

When we think about the problems young people have today, we also think of the tragic outbreaks of school violence that have shocked the Nation. We must ask what we can do to reduce violence and drug abuse, and help move young people in the right direction.

One of the Administration's responses to this challenge is the Safe Schools/Healthy Students Initiative, begun in fiscal year 1999 by the Departments of Justice, Education, and Health and Human Services. DOL's budget for fiscal year 2001 includes $40 million to enable DOL to join this partnership in supporting community-wide programs to prevent youth violence and drug abuse. With DOL's participation, the activities for the next round of grants can be expanded to provide services to out-of-school youth, including connections among high schools, post-secondary schools, alternative schools, and work-based learning programs, in an effort to reduce violent behaviors.

The White House Council on Youth Violence—of which I am a member—will play an important role in coordinating both the Safe Schools/Healthy Students and young offenders initiatives.

Job Corps

The Job Corps continues to be America's biggest and most successful residential job training program for at-risk youth. The Job Corps provides intensive skills training and academic and social education for these youth. I am requesting $1.4 billion

for the Job Corps in fiscal year 2001 to allow us to serve more than 73,000 young people at 122 centers in almost every State. This request includes a net increase of $35 million above fiscal year 2000 for the Job Corps to support efforts to attract and retain top-quality staff, and for the operating costs of new centers.

Universal reemployment

For all our focus on young people, they are not and cannot be our only concern. Many other Americans need help gaining the skills demanded by today's economy. Sometimes the challenge is not first-time employment but reemployment for those who have lost jobs and need new skills. Two years ago the President set an ambitious goal for our Nation called "Universal Reemployment." We are on the path to meet the goal of providing assistance to all dislocated workers who lose a job through no fault of their own. The initiative will: provide all dislocated workers who want and need assistance the resources to train for or find new jobs; expand and improve the quality of employment services now available to all job seekers and enhance services for individuals receiving unemployment compensation; and ensure access to the One Stop System, either in person or electronically, to help workers find jobs and training.

The Department's fiscal year 2001 request includes $1.975 billion, an increase of $275 million above fiscal year 2000, for Universal Reemployment. Of this amount, $1.8 billion, an increase of $181 million, will support dislocated worker retraining and adjustment assistance activities under Workforce Investment Act. This initiative will provide State formula grants, as well as a national emergency grant account, to help 984,000 laid off workers return to work quickly. These resources are part of a phased in effort to assist all dislocated workers in need of these services.

We are requesting $154 million for new and better ways of providing employment and related information through One Stop Career Centers and America's Labor Market Information System (ALMIS)—an increase of $44 million above fiscal year 2000. ALMIS services include America's Job Bank which now lists about 1.5 million jobs, and America's Talent Bank, which lists more than 500,000 resumes. Also included in DOL's request for the Universal Reemployment initiative is an additional $50 million for the One Stop Employment Service for reemployment services grants that will provide targeted, staff-assisted services to unemployment insurance claimants identified as having a high probability of exhausting their benefits. This will speed their reentry into employment and reduce benefit duration. Finally, the request includes $10 million to implement AgNet nationally, a system that will match agricultural workers with employers.

We are also concerned about the skill levels of currently employed workers. DOL's budget proposes $30 million for a new program of employment and training assistance to incumbent workers under WIA Pilot and Demonstration authority. This effort is intended primarily to address the major job losses in the manufacturing industry where one half million jobs have been lost since March, 1998. Complementing the activities under the Universal Reemployment proposal, this initiative will boost skills and wages of non-management U.S. workers through competitive grants to States to train and upgrade the skills of about 20,000 incumbent workers and, through local partnerships, to help firms with training in order to prevent displacements.

Fathers work/families win

The Department's budget includes $255 million for Fathers Work/Families Win, a new two-part initiative that builds on the Welfare-to-Work program. Fathers Work/Families Win promotes responsible fatherhood and supports working families.

We have all heard about deadbeat dads. Well, Fathers Work is about upbeat dads. It will provide jobs for noncustodial parents—mostly fathers—who owe child support. Most of these fathers are young and unemployed. Most want to meet their obligations, and Fathers Work will help make that possible. You cannot pay child support if you do not have a job.

A complementary part of this initiative, Families Win, will help low-income parents who are struggling to make ends meet by helping them find work, obtain better access to community services and upgrade their skills so they can move up career ladders. Together, these two initiatives are an important, exciting new way to put America to work. The strong working relationship we have forged with the Department of Health and Human Services in administering the job training, Welfare-to-Work, and Temporary Assistance to Needy Families programs will serve our Fathers Work/Families Win initiative. For example, our grants will go only to entities that have established relationships with child support enforcement agencies, reinforcing linkages that have been developed under Welfare-to-Work.

These competitive grants will be awarded to State and local Workforce Investment Boards, enabling States and local communities to complement welfare reform efforts by focusing on work connections, post-employment work support activities, and skills training. The initiative helps families with incomes up to 200 percent of the poverty level.

Disability initiatives

We are also reaching out to another untapped pool of talent. Last December, the President signed the bipartisan Work Incentives Improvement Act, which makes it possible for millions of people with disabilities to take jobs without losing their health care. At a time when our economy is booming, 26 percent of persons with a severe disability are working, as compared to over 80 percent of those persons without a disability. We cannot afford to waste the talents of millions of Americans.

DOL's budget includes funds to establish an Office of Disability Policy, Evaluation, and Technical Assistance headed by an Assistant Secretary. This new office will provide leadership within the Department of Labor in helping people with disabilities enter, re-enter, and remain in the workforce. With the recent passage of the Work Incentives Improvement Act and the Workforce Investment Act, the stage is set to achieve real change in the unemployment rate of people with disabilities. In addition, DOL's budget continues the competitive grants enacted in fiscal year 2000, totaling $20 million to be awarded each year by the Department to partnerships of organizations to provide incentives for broader systems—building on efforts to coordinate service delivery through, and linkages across, the One Stop Career Center system established by the Workforce Investment Act.

HOMELESS VETERANS PROGRAMS

Homeless veterans represent another group with untapped promise. The Department's request for fiscal year 2001 includes $15 million—a 50 percent increase over the fiscal year 2000 level—to provide employment and training services to help about 15,000 homeless veterans obtain employment and progress toward self-sufficiency. We expect about 8,700 homeless veterans to find jobs as a result of the services we provide.

Economic indicators

The Department is also requesting $20 million for the Bureau of Labor Statistics, $12 million of which is for new initiatives to improve major economic indicators, which are critical for monitoring the state of the economy and implementing Federal legislation. In its Producer Price Index program, BLS will extend coverage for the first time to the construction sector of the U.S. economy, and will continue its ongoing expansion of coverage in the service sector. This budget request includes $4.3 million to develop a new timeuse survey that will provide nationally representative estimates of how Americans spend their time in an average week, weekday, and weekend. This will provide important and meaningful data in many areas such as the amount of time invested in the care of the young and the elderly in our society, variations between single and two-parent families, and time invested in skills acquisition.

A SECURE WORKFORCE

The second strategic goal is a secure workforce. It is not enough simply to have a job. The goal of a secure workforce helps attain important values, such as dignity, family and community. A job should pay a decent wage, should provide health care benefits and should lead to a quality retirement.

You cannot have security, or strong families and strong communities, if people work hard and still cannot pay their bills. That is why the President has proposed to increase the minimum wage by one dollar an hour over the next two years. This increase would help more than ten million workers—almost 70 percent of them adults and 60 percent of them women. For a minimum wage worker, a $2000 raise is enough for a family of four to pay its rent for five months or to buy groceries for seven months. Raising the minimum wage is simple economic justice.

Too many workers are also insecure because they are afraid their jobs will be sent overseas. That is why the President again proposes legislation to consolidate, reform and extend the Trade Adjustment Assistance and NAFTA Transitional Adjustment Assistance programs for workers who lose their jobs due to trade. The proposals would expand eligibility for benefits to workers who lose jobs when production shifts abroad, increase training opportunities for trade-affected workers, link training and income support, and provide needed support services.

Pension, health and other employee benefits are vital to the economic security of hard-working Americans and their families. As Secretary of Labor, I have the re-

sponsibility for protecting these job-based benefits for more than 150 million Americans.

We work diligently to make sure workers feel secure in their promised benefits. We make certain that the assets held by pension and health plans are secure and available to pay promised benefits. The Department operates a nationwide program of educational outreach and technical assistance that serves to protect the rights of workers and their families entitled to benefits under their job-based benefit plans. We provide broad-based outreach to employers, especially small employers, to assist them with their questions about the plans they sponsor for their employees and to encourage those employers who do not sponsor a plan to consider setting one up. The Department also recognizes the importance of partnerships—we work with the employee benefits community to find innovative solutions that enhance our nation's system of employee benefits.

That is why our budget request of $108 million for the Pension and Welfare Benefits Administration includes additional resources to expand our efforts to provide protection to the health care and pensions of workers and their families. These new protections will include implementing a new program (the Rapid ERISA Action Compliance Team) to better protect the rights and benefits of American workers and their families if their employer faces financial hardship and their pension and health benefits are in jeopardy. In addition, the budget request will expand the Department's Health Benefits Education Campaign and enhance our customer service efforts by developing new publications, multimedia educational products and the creation of a toll-free interactive system to provide individuals with maximum direct access to the customer service staff trained to answer their health care and pension related questions. These initiatives will build on our ongoing efforts and allow us to respond to the increasing demand from workers and their families for assistance—last year we responded to over 153,000 inquiries from workers and their families and obtained benefit recoveries of over 62 million dollars.

The Pension Benefit Guaranty Corporation (PBGC) also helps achieve the goal of a secure workforce by guaranteeing pension benefits for 42 million workers and retirees in private-sector defined benefit plans. The budget request provides increases for enhanced computer security and to speed final benefit determinations.

QUALITY WORKPLACES

Our third strategic goal is quality workplaces. By quality workplaces, we mean those that reflect such basic values as health, safety and fair play. Globalization means we must be concerned about the quality of workplaces overseas as well as at home. That is why the President has challenged us to put a human face on the global economy.

International child labor

According to the International Labor Organization, an estimated 250 million children between the ages of 5 and 14 are working in developing countries, 120 million of them full time, and tens of millions under abusive or dangerous conditions. We are committed to improving the lives of children both at home and abroad by opposing abusive child labor wherever it exists and by providing the necessary resources for its elimination. Building on our past funding of the ILO's international child labor program, and the recent ILO convention on banning the worst forms of child labor that was unanimously approved by the U. S. Senate in November and signed by the President in December, the Administration proposes $100 million to support international efforts to eliminate abusive child labor. These funds would not only permit us to increase the global efforts to remove children from abusive and dangerous conditions, but would also allow us to increase our efforts to support the educational infrastructure in areas where oppressive child labor is a pervasive and systemic problem. Education, not hard labor provides children with real opportunities and hope for a better future. I would like to thank Senator Harkin for his impressive leadership on this issue over the past several years.

International labor standards

Additionally, our budget includes $40 million for international core labor standards initiatives. The Department proposes to expand the efforts begun last year to achieve internationally-recognized core labor standards, and to build social safety nets, so American workers can be more confident that we are building a global economy with the "human face" that President Clinton has called for. This should be a race to the top—not to the bottom. In all these ways, we are working to make globalization empower workers and improve their lives, not accept a lowering of standards at a time when so much progress is possible.

When we consider quality in the international workplace, we must also consider the terrible harm being done by HIV/AIDS. When I was in Africa last year, I saw that AIDS is not only a vast human tragedy but a major economic disaster. When workers die, their skills and experience die with them. Production is down in many countries. This disease threatens not only development and progress in Africa but peace and stability.

That is why our budget includes $10 million as part of a larger, government-wide Global HIV/AIDS Initiative that will work with African leaders to use the workplace as a forum for providing health education programs to prevent the spread of AIDS. The workplace has a great, potential for providing millions of workers with information that can literally save their lives.

Domestic child labor

To continue our commitment towards reducing the more than 200,000 workplace injuries that occur among young workers in America each year, I am requesting $13 million for the Department's domestic child labor activities, including $8 million to continue to help eliminate violations of domestic child labor laws, particularly in the agricultural sector, and $5 million for demonstration programs to provide alternatives to field work for migrant youth. This request includes additional funds to implement targeted enforcement tools, including "strike teams" in the agricultural and garment industries, and to enhance education and outreach efforts undertaken as part of the "Safe Work/Safe Kids" initiative.

Family leave

Today, the Family and Medical Leave Act (FMLA) allows covered and eligible workers to take up to 12 weeks of job-protected, unpaid leave to care for a newborn or adopted child, attend to their own serious health needs, or care for a seriously ill parent, child, or spouse making it less likely that employees will have to choose between work and family. The President has again proposed to expand the FMLA to reach workers in firms with 25 or more employees, extending coverage to 12 million more workers.

For lack of money and other reasons many workers are unable to take advantage of unpaid leave. The Department is requesting $20 million to fund competitive planning grants for States and other interested entities to explore ways to make parental leave and other forms of family leave more affordable and accessible for American workers. This initiative will help identify in more detail the workers in need of financial assistance to take parental/family leave and to develop and evaluate options to aid these workers.

Equal pay

We cannot talk seriously about a quality workplace unless we also talk of equal pay for equal work. Today, the average woman who works full-time earns approximately 75 cents for each dollar that an average man earns. This gap, in part, is attributable to differing levels of experience, education and skills. However, even after accounting for these factors, a significant pay gap remains between men and women. When women are not fairly paid, their whole family suffers. We need to rid ourselves of this stubborn, lingering pay discrimination.

That is why the President has proposed an Equal Pay Initiative to expand opportunities for women and help end wage discrimination. His proposal includes $17 million for the Department to support initiatives on behalf of equal pay. The Equal Pay Initiative dedicates $10 million from the current H–1B nonimmigrant fee for DOL to train women in nontraditional occupations such as those in high-tech industries and also provides $7 million to help employers assess and improve their pay policies, to provide nontraditional apprenticeships, and to support public education efforts. The President supports the Paycheck Fairness Act, which would strengthen wage discrimination laws and provide for additional research, training, and public education efforts on this important subject.

Workplace safety

Finally, safety and health are absolutely basic to a quality workplace. We are proud that for the sixth consecutive year, workplace injury rates have come down and are now at the lowest level since we began keeping records in the 1970s. But we can still do better. Even one workplace death is too many.

Our budget includes $668 million to promote health and safety for more than one hundred million workers through programs of the Occupational Safety and Health Administration and the Mine Safety and Health Administration. Through a combination of targeted enforcement, compliance assistance and partnerships, these agencies work hard to protect workers from illness, injury and needless death.

The Department's request includes a $44 million increase for OSHA which will enable OSHA to achieve better balance between its outreach activities, such as compliance assistance and training, and its enforcement activities, which in recent years have been targeted to high hazard worksites. The increase will improve our ability to provide expertise and services to both employers and employees.

Among OSHA's efforts to provide safe and healthful workplaces is its ergonomics rulemaking. Workers suffer roughly 600,000 musculoskeletal disorders each year. The proposed standard can protect 27 million workers from the risk of incurring such injuries and illnesses. I remain committed to completing the standard this year.

The Department is requesting an increase of $14.2 million for the Mine Safety and Health Administration's (MSHA's) programs to enhance protection of miners, by providing necessary training to miners and for better auditing of accident and injury reporting. Approximately $3.2 million of this increase will augment MSHA's enforcement activities in the metal/nonmetal industries. DOL's budget also includes a request for additional funds for the State grant program to provide training assistance to miners and mine operators.

Information technology initiative

The Department's fiscal year 2001 budget establishes a permanent, centralized IT investment fund for DOL managed by the Chief Information Officer (CIO). In the past, DOL agencies have separately budgeted for and managed their own IT investments. While the investments met the immediate needs of the individual agency, a unified approach will provide more efficient and effective services.

For fiscal year 2001, the Department's request includes $60 million to fund IT investments within three crosscutting areas: (1) Information Technology Architecture and Web Services; (2) Common Office Automation Implementation; and (3) Security-Critical Infrastructure Protection. These investments will enable the Department to implement a sound information technology investment strategy, and expand our Internet capacity for the elaws program which provides the public with additional access to information on labor laws.

CONCLUSION

These are some of the ways we will work in fiscal year 2001 to achieve our Department's strategic goals. These are important, exciting initiatives, because they are not just numbers or words on paper—they are about helping real people, with real talents to develop and real challenges to overcome.

I will be happy to answer to any questions you may have about the fiscal year 2001 President's Budget for the Department of Labor.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. DONNA SHALALA, SECRETARY

Senator SPECTER. We now turn to the distinguished Secretary of Health and Human Services. As noted by Senator Harkin, Secretary Shalala has served during the full 7 years plus of the President's administration. And beyond that is the longest serving Secretary of Health and Human Services in U.S. history.

During her career, she has been a scholar, a teacher, a public administrator, chancellor at the University of Wisconsin-Madison, where she was the first woman to head a big ten university, and named by Business Week as one of the five best managers in higher education. She earned a Ph.D. from the Maxwell School of Citizenship in public affairs.

And we welcome you back, Madame Secretary.

Secretary SHALALA. Thank you very much, Senator Specter, Senator Harkin, members of the subcommittee.

I would like to begin by thanking you, Mr. Chairman, for the leadership you have shown in working to prevent youth violence. And I would like to thank Senator Harkin for his kind words, too.

When we presented our fiscal year 2001 budget, I noted the searing images that we saw last year at Columbine and other schools must never be repeated. If there was ever a bipartisan issue in this country, this is it. That is why the President worked with Congress to establish a new White House Council on Youth Violence to get all Federal agencies thinking and working together to prevent youth violence.

And that is why my colleagues, Secretary Herman and Secretary Riley, and I join you in your determination to bring to bear the resources we need to fight this problem effectively. How pleased I am to be with both of them today.

At HHS, the Surgeon General is developing a report on youth violence that we expect to be completed this year. However, this much we already know. Violence is preventable. So we intend to find out what works and what does not and then publish and disseminate a source book of the best practices. Our budget also increases the mental health block grant by $60 million, a full 17 percent. And we are budgeting another $78 million to stop youth violence.

Now let me highlight other important features of our budget and why we believe this budget is critical to the health and future of the American people.

Our fiscal year 2001 budget brings us to where we should be at the dawn of a new century, a great nation pledging allegiance to great goals. Those goals are expanded health care coverage, renewed support for children and families, greater scientific advance-

ment, and the creation of a healthier America. Our fiscal year 2001 budget brings those goals within reach without loosening our commitment to fiscal discipline or to a balanced budget.

This budget is about people. It makes a record investment in health care coverage, in access and in quality. Two years ago, with bipartisan support, we launched the State Children's Health Insurance Program. Two million children are now enrolled.

Now we want to make sure that this new program, and Medicaid, carry millions more children and their parents into the safe harbor of quality health care. The President's Family Care Program will do just that.

But even as we expand coverage to some parents through Family Care, we recognize that many low income adults work in jobs that do not offer health insurance. These workers frequently rely on local health institutions and local professionals who provide services at a reduced or no cost. Secretary Herman has married a man who does exactly that. Dr. Franklin is a family doctor.

And while he gets reimbursement from many parts of the health care system, he told me the other night that he also often has to offer reduced cost services to make sure the families he has treated over the years, who might lose their health insurance, continue to get that treatment.

This year we want to increase our support for community service networks to $125 million, five times our investment last year. We need to strengthen and modernize Medicare. First and foremost, that means dedicating more than $300 billion of the on-budget surplus over 10 years to extend the solvency of the trust fund until 2025.

We also must add a voluntary prescription drug benefit to Medicare. And I emphasize voluntary. As the President said in his State of the Union message, we would never design Medicare today without a prescription drug benefit. We cannot change the past. However, we can change the future and catch up with modern medicine. But the longer we wait, the worse the problem will become. And the more expensive it will become.

Government cannot step into the shoes of parents and communities. But government does have a role to play in helping families balance work and children. One recent study notes that in 1998 only 10 percent of the 14.7 million children eligible for Federal child care subsidies received them.

So as part of the President's Child Care Initiative, this year's budget adds another $817 million to the Child Care Development Block Grant.

Senator Specter, you will recognize that exact amount, because we talked about it during the appropriations process last year. This is part of our discretionary budget and brings the total block grant to $2 billion.

Mr. Chairman, Head Start is one of the most successful bipartisan programs our two branches of government has ever created for children. And this year we are requesting $6.3 billion for Head Start. That is $1 billion more than last year, the largest increase in the history of Head Start. We believe the program merits it.

I cannot talk, of course, about children without talking about drugs, as you have yourself, Mr. Chairman. I know that you would like to pursue this further in our question and answer period.

We know that marijuana use has leveled off among teens, but too many teens are still saying yes to drugs and alcohol. And that is why our budget includes over $3.3 billion for substance abuse treatment and prevention.

I mentioned the success we have had in cutting the death rate from AIDS, but HIV/AIDS is still a disease without a cure. And it is still the greatest public health challenge both here and around the world. So fighting HIV/AIDS remains a top priority for the department. Our total AIDS budget this year is $9.2 billion, an increase of 8.4 percent over last year. Every agency's AIDS-fighting budget is going up, in prevention, treatment and research.

On the prevention side, we have proposed to add an additional $75 million to help stop the spread of the disease. Specifically, the CDC will direct $40 million of the new funds to local communities, including prevention services to target minority communities. CDC will spend another $26 million to fight AIDS around the world.

And at the same time, the Health Resources and Services Administration will spend $1.7 billion in Ryan White funding to help people living with HIV/AIDS. This is a $125 million increase over last year.

Our budget requests for AIDS-related research at NIH is $2.1 billion, a 5.2 percent increase over last year. The total NIH budget this year is $18.8 billion, $1 billion more than last year. This subcommittee, of course, should take pride in the unprecedented investment it has made in basic and clinical research.

Our shared commitment to the National Institutes of Health, and to producing quality science and quality scientists of the next generation on both the NIH campus and at the great research universities, is an extraordinary legacy.

Years from now, I predict we will see results beyond our wildest dreams. And some of those results are certain to come from the $73 million we intend to invest over 2 years to build a National Neuroscience Research Center at the National Institutes of Health. This will put all NIH brain research under one roof. More important, the center will usher in what is certainly to be the century of the brain.

In the interest of time, let me quickly mention three other areas where we intend to increase our discretionary budget. We take very seriously the need to stop infectious diseases and bioterrorism.

Our budget increases by almost 50 percent CDC's funding for disease surveillance. As for bioterrorism, which may be the biggest threat of the 21st century, we are proposing to spend $265 million to prepare for and respond to biological attacks.

We also want to make a major investment in bricks and mortar. In addition to the Neuroscience Research Center at NIH, CDC proposes to spend $127 million, $70 million more than last year, to modernize and expand three critical laboratory sites. The remaining funds will go towards completing the Edward R. Roybal infectious disease lab and construction of a new environmental health lab.

Mr. Chairman, I want to conclude my testimony by noting that our greatest moral imperative is to close the gaps in health outcomes between minorities and the majority population. In 1998, the President set a goal of ending health disparities in six major areas. Now almost every operating division of my department is working to close these gaps.

That includes an additional $35 million for CDC for community-based research and demonstration projects to reduce disparities, money aimed at those communities themselves.

PREPARED STATEMENT

Thank you very much, Mr. Chairman and members of this committee. I would be happy to join my colleagues a little later to answer any questions you may have.

Senator SPECTER. Thank you very much, Secretary Shalala.

[The statement follows:]

PREPARED STATEMENT OF HON. DONNA SHALALA

Good morning, Chairman Specter, Senator Harkin, and members of the Subcommittee. I am pleased to appear before you today to discuss the President's fiscal year 2001 budget for the Department of Health and Human Services. At the outset, let me thank you again, Mr. Chairman, for your leadership on the prevention of youth violence and substance abuse and on the treatment of mental health—issues which I will discuss in detail later in my testimony. I am honored to be here with Secretaries Herman and Riley to continue our dialogue and coordinated efforts in these areas.

A PROUD HISTORY. . .

Mr. Chairman, before I discuss our plans for confronting the challenges that lie ahead, I think it is important first to take a look back at where we have been. Over the past seven years, we have worked together to develop innovative solutions that have improved the health and well being of all Americans. Let me note just a few of these accomplishments:

—Working together, we have expanded enrollment in Head Start from approximately 714,000 children in 1993 to an estimated 950,000 in this budget, while at the same time improving the quality of the program, thereby providing a strong foundation for success for hundreds of thousands of low-income children.

—Two years ago, the President called for an increase of almost 50 percent over five years in the NIH budget as part of his Research for America Fund. Since that time the NIH budget has increased by over $4.2 billion and, with the funding proposed by the President this year, we will be ahead of schedule in reaching our goal. In addition, we have increased the number of Research Project Grants funded by the National Institutes of Health by over 30 percent, from 23,952 in fiscal year 1993 to 31,524 in this budget. This represents a dramatic expansion of our scientific knowledge base that will pave the way for biomedical advances in the years ahead.

—We have nearly doubled the number of people receiving access to comprehensive combination drug therapy under the Ryan White Care Act AIDS Drug Assistance Program (ADAP), from almost 49,000 in 1994 to approximately 75,000 with this budget.

—We have improved the health of our seniors by increasing the number of healthy meals served to older Americans under the Administration on Aging's Nutrition programs from 240 million in fiscal year 1994 to 279 million in this budget year.

—With the enactment of the Health Insurance Portability and Accountability Act of 1996, we have helped individuals keep their insurance when they change jobs, guaranteed renewability of coverage, and helped ensure access to health insurance for small business.

—Together with the states, we have undertaken the largest health care coverage initiative since Medicare, namely the State Children's Health Insurance Program. In just the two years since its enactment, the number of children enrolled in SCHIP—now almost 2 million—has doubled. In addition, the number of

states covering children up to 200 percent of poverty has increased by more than sevenfold.

—Last year, the President signed into law the bipartisan Ticket to Work and Work Incentives Improvement Act that allows people with disabilities to maintain their Medicare and Medicaid coverage when they go to work. It also includes a new demonstration program that allows people with disabilities who are still working and are not sufficiently disabled to qualify for Medicaid to obtain coverage and reforms the training system for people with disabilities.

—We created the Vaccines for Children Program, to finance immunizations for children without private health coverage. Childhood immunization coverage rates in 1998 were the highest ever recorded. Ninety percent of toddlers in 1996, 1997 and 1998 received the most critical doses of each of the routinely recommended vaccines, surpassing the President's 1993 goal.

We also have undertaken a number of new initiatives to target emerging threats and address long-standing problems. We have launched new initiatives to promote research on disease prevention and health care quality, to improve the quality of nursing home care, to provide support for our nation's children's hospitals, and to increase the number of children adopted from our child welfare systems. To educate Medicare beneficiaries about their health care options, we have implemented the largest peacetime outreach campaign ever undertaken by the federal government. We have stepped up efforts to increase the availability of substance abuse treatment, to eliminate racial and ethnic health disparities, and to address the AIDS crisis in minority communities. And we have invested significant resources to prepare the nation to respond to the medical and public health consequences of chemical and bioterrorist attacks. We have launched new initiatives to protect the rights of Americans in managed care and protect the privacy of electronic medical records, and most recently, to improve patient safety and reduce preventable medical errors in our health care systems.

While we should be proud of past accomplishments, we must continue to address ongoing health and human services challenges. These include: expanding access to quality health care and extending protections to the uninsured and at-risk; supporting working families and bettering the lives of our nation's children; encouraging greater scientific advancement; and creating a healthier America.

Thanks to our continuing economic prosperity, we have a great opportunity to meet these challenges. In the last two years, we have recorded back-to-back surpluses for the first time since the 1950's. The combination of a strong economy, fiscal discipline, and unprecedented advances in our scientific knowledge give us the opportunity to make the investments needed to build on all of our achievements over the last seven years.

Mr. Chairman, the total HHS budget request for fiscal year 2001 is $421.4 billion (Outlays). The amount before this subcommittee totals $267 billion (BA), of which $44.8 billion is discretionary. This discretionary component represents an increase of $4.5 billion over last year. Let me now highlight the main components of our fiscal year 2001 budget request.

EXPANDED HEALTH CARE COVERAGE

We live in an age of remarkable advances in the biomedical sciences. Yet too many of our citizens are denied the benefits of these advances because they lack access to quality, affordable health care. Throughout his Administration, President Clinton has made expanding access to health care one of his most important goals. Working with the Congress, we have had some notable successes, including enactment of the State Children's Health Insurance Program, which today covers nearly 2 million children; the Health Insurance Portability and Accountability Act, which allows workers to keep health insurance coverage when they change jobs and limits the ability of insurers to deny coverage based on pre-existing conditions; and most recently, the Ticket to Work and Work Incentives Improvement Act, which allows disabled Americans to return to work without losing their Medicare and Medicaid coverage.

But even with these successes, approximately one-seventh of the population still lacks health insurance. Our budget seeks to address these problems through a number of initiatives designed not only to expand access to care but to improve the quality of health care as well.

Expanding coverage under Medicaid and SCHIP

The State Children's Health Insurance Program (SCHIP), enacted in 1997, now provides nearly two million low-income, uninsured children with access to health insurance, preventive medicine, and immunizations. While the success of the SCHIP program has greatly enhanced the health of these children, many of their parents

remain uninsured. And there still are many children who are eligible for Medicaid and SCHIP who are not currently enrolled. With the country's resources growing, the economy booming, and the SCHIP program showing great progress, it makes sense to take advantage of this opportunity to implement new options for low-income working families without health insurance. The President's budget includes proposals to create a new "FamilyCare" program that expands coverage to the parents of children eligible for Medicaid and SCHIP, increase outreach efforts, and simplify the enrollment process.

Under FamilyCare, parents would be enrolled in the same programs as their children, and states would receive the higher SCHIP matching payments for expanding coverage to parents. To ensure that the original intent of the SCHIP program is met, states would be required to expand eligibility for children up to 200 percent of poverty before accessing funds to cover parents. As is the case with children, priority in enrollment would be given to lower-income parents before covering higher-income parents.

If, after five years, some states have not expanded coverage of parents to at least 100 percent of poverty, they would then be required to do so. By 2006, all poor parents would be eligible for coverage just as their children are today. We believe that enrolling parents in Medicaid or SCHIP will not only improve their health, but will also make it easier for entire families to access insurance through one source, thereby increasing the number of children participating in the program. This FamilyCare initiative is a practical, targeted approach to encouraging greater insurance coverage. Over eighty percent of parents of uninsured children under 200 percent of poverty are themselves uninsured, while nearly two-thirds of uninsured parents (6.5 million) have children eligible for Medicaid or SCHIP. The budget proposes to extend and improve the transitional Medicaid program, which provides important health insurance coverage for families moving from welfare to work. Our proposals would use existing state administrative and delivery systems and no new bureaucracies would be needed.

In addition to covering parents, states also will be given the option to extend Medicaid coverage to young people ages 19 and 20. If they do, they will also have the option to cover kids up to age 20 under SCHIP. To further increase Medicaid and SCHIP enrollment, the President's budget supports new efforts to simplify eligibility and aggressively expand efforts to enroll eligible children identified through school lunch programs. To ensure that children are not overlooked in States that have different rules and procedures for Medicaid and SCHIP, we also propose to require that States conform certain eligibility rules between Medicaid and SCHIP. Our budget also proposes $10 million in mandatory funding for competitive grants to States that develop innovative plans for outreach to the homeless and the coordination of services across the Medicaid, SCHIP, TANF, Food Stamps, and Mental Health and Substance Abuse programs. If they do, they also will have the option to cover kids up to age 20 under SCHIP.

Finally, our budget seeks to reverse some of the inequities that have resulted from the 1996 welfare reform legislation by giving states the option to provide Medicaid or SCHIP coverage to legal immigrant children and pregnant women. The budget also proposes to restore SSI and Medicaid eligibility to legal immigrants who entered the United States after the enactment of welfare reform, become disabled and live in the U.S. for five years. Parents of legal immigrant children would also be eligible for coverage under our FamilyCare proposal. In addition, the budget seeks to restore Food Stamps eligibility to legal immigrants who were in the country before the enactment of welfare reform and either subsequently reach age 65 or have children who are eligible for Food Stamps.

In addition, the budget will take an important step to improve the health of low-income Americans by ensuring that they have access to drugs that help them quit smoking. The budget will ensure every state Medicaid program covers both prescription and non-prescription smoking cessation drugs, removing a special exclusion now in law, and requiring states to cover these drugs as they cover all other FDA-approved drugs.

Modernizing and strengthening Medicare

For the last thirty-five years, Medicare has been the cornerstone of our efforts to ensure that all seniors have access to the quality health care they need and deserve. However, since its enactment in 1965, much in the health care system has changed, not only the types of care provided and the setting in which these services are performed, but also the makeup of the population that receives Medicare. These changes have dramatically increased the financial strains on the Medicare program, and current actuarial projections show that by approximately 2015, just as the large baby-boom generation is becoming eligible, Medicare may be faced with insolvency.

The Clinton-Gore Administration budget also dedicates $432 billion over ten years to Medicare to extend the solvency of the Trust Fund until at least 2025 and to create a voluntary, affordable prescription drug benefit. It includes a new, multi-billion dollar reserve fund that can be used to add protections against catastrophic drug costs to the President's proposed drug benefit. This financing commitment is part of a comprehensive plant to modernize and strengthen Medicare to ensure that it can continue to deliver high quality, affordable care in the 21st Century. These steps include making the program more competitive; introducing private sector purchasing and management tools; and continuing our historic fight against fraud, waste, and abuse.

Over the last thirty-five years, the development of new prescription drugs to treat a variety of conditions has helped Americans to live longer and higher quality lives. The centerpiece of the President's plan to modernize Medicare is a voluntary prescription drug benefit that would be affordable and accessible to all beneficiaries. This benefit, which would rely on market competition to obtain lower prices, would have no deductible, and would pay half of all costs up to $2,000 in fiscal year 2003, increasing to $5,000 by fiscal year 2009. The plan would fully pay for costs for beneficiaries with incomes below 135 percent of the poverty level, and provide premium assistance for those with incomes between 135 and 150 percent of the poverty level, while providing financial incentives to employers to continue offering prescription drug benefits to current retirees.

The President's budget also proposes much-needed incentives to increase the utilization of preventive services by Medicare beneficiaries. Our plan would eliminate existing coinsurance and deductibles for covered preventive benefits, including colorectal and prostate cancer screenings, pelvic exams, mammographies, bone mass measurement, and diabetes self-management. The President also is planning to develop a three-year demonstration for smoking cessation services. By lowering the cost and expanding the availability of these services, we will not only save lives, but will minimize the need for more extensive, and expensive, treatments in the future.

While we work to strengthen Medicare to better serve current beneficiaries, our budget also includes proposals to expand access to Medicare to groups who face barriers to health insurance coverage. These proposals will allow Americans ages 62 to 65 to buy into Medicare by paying a premium, provide a similar buy-in option for displaced workers ages 55 to 62 who have lost employer-provided health coverage, and provide COBRA coverage to retirees between the ages of 55 and 65 whose companies have reneged on their promise to provide health benefits. To make these buy-in options more affordable, the budget includes a proposal for a tax credit, available to displaced workers over age 55 as well as all eligible persons ages 62 to 64, that would be equal to 25 percent of the buy-in premiums.

As important as our efforts to modernize the Medicare benefit package are, Medicare recipients will be able to realize the full benefits of these new services only when we give equal attention to strengthening and modernizing the management of our health programs. The President's budget continues efforts to improve the Health Care Financing Administration's (HCFA) management, building on the five-part reform plan advanced last year to increase flexibility while also increasing accountability. Our budget also maintains our commitment to fighting fraud and abuse, investing in a new Medicare contractor oversight initiative to address a number of concerns outlined in OIG and GAO reports last year. This initiative includes funding to improve evaluation of program operations, establish financial management controls at each contractor, develop an integrated general ledger accounting system that will ensure clean audit opinions into the future, and monitor and oversee these changes at all contractors.

These actions will augment the successful efforts we have undertaken in partnership with you, Mr. Chairman, and Senator Harkin to combat fraud, waste, and abuse in the Medicare and Medicaid programs. As you know, the Department of Justice recently announced that, in conjunction with HHS, it had achieved a $486 million settlement with a national health provider that had been defrauding the Medicare program. This action is in addition to results reported in latest Health Care Fraud and Abuse Control account report that indicated that $490 million had been collected as a result of successful prosecutions in 1999. Of that amount, $369 million was returned to the Medicare trust funds. In addition, the Medicare Integrity Program reported an increase of 25 percent in total overpayments prevented and identified in the first six months of fiscal year 1999 compared to the same period the year before. These successful efforts are why the latest Medicare Trustees' Report included this Administration's fraud and abuse efforts as a contributing factor in slowing the rate of growth of the Medicare program.

Increasing access to health care for uninsured individuals

Those who lack health insurance often are forced to rely on emergency rooms or ad-hoc networks of facilities and individual health professionals for whatever care they are able to receive, or to forgo any health care at all. Last year, the President's budget requested $25 million to launch a new initiative to help community health clinics, public hospitals, academic health centers, and other institutions serving the poor to create new systems of comprehensive and coordinated care that uninsured workers and their families could depend on, and Congress responded by fully funding this request. To continue this effort, this year the President is proposing to increase funding for this initiative to $125 million. This increase will allow as many as 40 to 60 additional communities to receive grants to improve the capacity of safety-net providers. The President's budget also continues to provide strong support for the nation's Community Health Centers, which provide care to nearly 10 million low-income and uninsured individuals in rural and inner city areas. Our budget requests $1.1 billion to support Community Health Centers, an increase of $50 million over last year.

Long-term care

With more Americans now living longer than ever before, one of the most pressing demands we face is the increasing need for long-term care services. Studies show that the great majority of individuals who need long-term care prefer to remain in their own homes and communities rather than receive care in institutional settings, but this places a heavy burden on the family members and friends who must provide supports for them. More than half of these caregivers are women, and one-third have full time jobs. Our budget seeks to address the pressing need for new long-term care solutions through a multi-faceted initiative designed to help both the millions of Americans who require long-term care and those who care for them.

Our budget invests $125 million to support family caregiver activities in the Administration on Aging (AoA). This initiative will provide States and local communities with the flexibility to design and provide caregiver support activities to approximately 250,000 families nationwide who are caring for elderly relatives with chronic diseases and disabilities. Services provided will include quality respite care, information about local services, counseling, and training for complex care needs.

The budget also proposes $140 million over five years to expand access to home and community-based care services under Medicaid through an option to equalize income eligibility standards for those who need institutional care but choose to live in the community. This long-term care initiative also includes a $3,000 tax credit to provide support for those with long term care needs and those who care for a disabled or elderly relative; an innovative housing initiative to integrate assisted living facilities and Medicaid home and community based care settings; and a program to provide Federal employees, annuitants and their families with the opportunity to purchase private long-term care insurance at group rates.

Nursing home quality initiative

As we begin to develop a support system for those who choose to receive long term-care in home and community-based settings, we must also continue to ensure that nursing home residents are receiving the highest quality care possible. The fiscal year 2001 budget includes $71 million for continuing quality monitoring activities in last year's budget to improve federal and state oversight of nursing homes. Now in its third year, this initiative supports the efforts of states to strengthen enforcement and oversight of nursing home quality and to crack down on those who repeatedly violate program standards. Expanding on activities already underway, funding will support increased surveys of repeat offenders, improved training for surveyors, and enhanced legal services including resolution of the backlog of appeals.

RENEWED SUPPORT FOR CHILDREN AND FAMILIES

Mr. Chairman, these investments in health care access and quality, in improving our public health system, and in broadening our scientific knowledge, all are fundamental to making sure that the new century is a time of good health and prosperity for all Americans. But just as we honor our commitments in the health arena, we also keep our commitments to improving the lives of the nation's children and families. The President's budget keeps our promise to work toward an America where every child, and every family, has the opportunity to succeed at work, at school, and at home.

HHS YOUTH VIOLENCE PREVENTION ACTIVITIES

HHS is pursuing a range of activities to assist in the prevention of youth violence, and we have requested $78 million for these activities. The Safe Schools/Healthy Students Initiative is an unprecedented collaborative effort involving this Department, along with the Departments of Education and Justice. SAMHSA is our lead agency for this important effort. Through this initiative, we are assisting 54 school districts in designing and implementing comprehensive educational, mental health, social services, law enforcement and juvenile justice services for youth. The increase in this program provided by the Congress for fiscal year 2000 will enable us to increase that number to 70–75 Safe Schools/Healthy Students grants by the end of the fiscal year. In addition to its support for this partnership, SAMHSA has developed a comprehensive set of activities to provide direct grants for exemplary practices as well as a variety of activities for developing innovative technology, technical assistance, evaluation and social marketing in the youth violence prevention arena.

The Surgeon General is developing a Report on Youth Violence that may be completed this year. Local communities, private organizations, academia, other federal departments, state and local governments, and other groups are providing information and assistance to ensure the report soundly addresses the prevention of youth violence. In addition, CDC is engaged in a variety of activities including research on school violence and suicide prevention. For example, CDC will evaluate programs for high risk youth and publish and disseminate The Best Practices to Prevent Violence by Children and Adolescents: A Sourcebook based on the input of experts from across the nation. CDC also will initiate National Centers of Excellence on Youth Violence and a National Youth Violence Prevention Resource Center. The Administration for Children and Families (ACF) is proposing to build on these efforts by focusing on the mental health needs of runaway and homeless youth.

NIH research has demonstrated behavioral interventions in the home and classroom that address violence in children with behavioral disorders and is developing and improving programs aimed at prevention, early recognition, and intervention for youth violence in various community settings. Finally, the President has convened a White House Council on Youth Violence, which includes representatives from the Departments of Treasury, Labor, Justice, and Education. The Council's duties include developing a citizens' information hub; producing reports on youth violence; expanding the Safe Schools/Healthy Student model of collaboration; providing tools for parents to deal with the issue of youth violence; coordinating the federal research agenda; and developing further policy responses.

Expanding substance abuse activities

Even with all our efforts over the last few years to expand the availability of services to those addicted to drugs and alcohol, there continues to be a significant gap between the need for substance abuse treatment and the capacity available to provide treatment. Estimates by the Office of National Drug Control Policy show that less than half of the five million individuals who need substance abuse treatment actually receive these services. To further close this gap, the President's budget includes a total of $3.3 billion in HHS for substance abuse treatment and prevention, including $2 billion to support SAMHSA's substance abuse prevention and treatment activities. Included in this request is an additional $54 million for Targeted Capacity Expansion grants to support rapid and strategic responses to emerging areas of need. The request also includes an increase of $31 million for the Substance Abuse Block Grant, which will provide funding through the states for over 10,500 community-based treatment and prevention organizations. In all, our budget request will enable more than 16,000 additional individuals to access treatment services.

Improving mental health services

The Surgeon General's Report on Mental Health, released in December 1999, has focused new attention on the plight of those who suffer from mental illness. While about one in five Americans experiences a mental disorder in the course of a year, many of them will not receive the treatment they need. To address this problem, the President's budget proposes an increase of $100 million for mental health services provided by the Substance Abuse and Mental Health Services Administration (SAMHSA). This includes an increase of $60 million for the Mental Health Block Grant, to support state efforts to create comprehensive, community based systems of care for both adults and children. It also proposes to create a new $30 million Targeted Capacity Expansion Grant program to support prevention and early intervention services, as well as local service expansion.

Improving access, affordability, and quality of child care

For the millions of American families in which parents must work to support their children, the availability of child care is often the difference between self-sufficiency and dependency. But even though funding for child care has doubled under the Clinton Administration, recent studies showed that in fiscal year 1998 only ten percent of the children potentially eligible for federal child care subsidies received them. As we have said before, no parent should be forced to choose between the job they need and the child they love. We must take steps to close this gap and help all parents find child care that is safe, reliable, and affordable.

As we close this gap, we also must continue to improve child care quality. Study after study has shown that safe, quality child care is essential to the healthy development of our children. But the lack of quality care has forced too many parents to place their children in less than desirable settings, and even low quality care can place a heavy financial burden on low-income families. The President's budget builds on our ongoing efforts to remedy these deficiencies with a comprehensive initiative designed to not only make child care more affordable but also to improve the quality of care.

Our fiscal year 2001 budget requests an additional $817 million, for a total of $2 billion, for the discretionary Child Care and Development Block Grant. This increase will provide child care subsidies to almost 150,000 additional low-income children. Also included in the $2 billion total is $223 million to improve the quality of care, of which $50 million is for infant and toddler quality care efforts; $19 million is for school-aged care and resource and referral activities; and $10 million is for ongoing research, demonstration, and evaluation programs. Our budget also proposes an increase of $3 billion in mandatory funding over five years, including $600 million in fiscal year 2001, to establish an Early Learning Fund. This fund will provide money to states to offer community level challenge grants for programs that improve childhood development and school readiness and the quality and safety of care. The President's Child Care Initiative also includes critical increases for activities in the Departments of Treasury and Education.

Enhancing head start

Since its enactment thirty-five years ago, the Head Start program has been one of our greatest success stories, ensuring that millions of low-income children start school ready to learn. In 1993, the Clinton Administration set the goal of enrolling one million children in Head Start by fiscal year 2002. The President's $6.3 billion request for fiscal year 2001, an increase of $1 billion, will keep us on track to realize this goal, increasing the number of children enrolled to nearly 950,000. A portion of these funds will be reserved for grants to unserved and under-served populations. Consistent with the focus of the 1998 reauthorization of Head Start to improve the quality of services, $418 million of the proposed increase will be targeted for reducing class size, improving facilities, staff training, and school readiness; obtaining safer and better equipment; and attracting and retaining top-quality staff. Finally, our Head Start budget request includes $564 million for the Early Head Start program, which will provide 54,000 infants and toddlers and their families with continuous and comprehensive child development and family support services.

Increasing parental responsibility through child support enforcement

One of the key underpinnings of this Administration's support for working families is the idea of encouraging personal responsibility. Nowhere is this more evident than in our actions to step up child support enforcement, which is a critical support for children and families. Child support collections have almost doubled since 1992, reaching an estimated level of $15.5 billion in fiscal year 1999. Our package of child support enforcement proposals is self-financing and it increases collections to families by more than $1.8 billion over five years. These proposals build on our success in the program through changes designed to give states new options to get more money to families and to improve enforcement tools to increase collections. These actions are part of a comprehensive Administration initiative to promote and ensure that non-custodial parents who can afford to pay child support do so, and helping low-income non-custodial parents go to work so that they can support their children through "Fathers Work" grants in the Department of Labor's budget. Under one proposal, we would match State efforts to allow families still working their way off welfare to keep a portion of the child support they are owed, increasing payments to these families by $388 million over five years. A second proposal provides States with the option to simplify their rules for distributing child support to ensure that families that have left welfare will keep all the child support paid by the non-custodial parent, resulting in increased payments to families of $815 million over five years. Both of these proposals build on our Family First distribution policies. Our

package also includes proposals for better enforcement techniques and program improvements that will save the Federal government nearly $600 million over five years while increasing payments to families by over $650 million.

Ensuring continued educational excellence in the nation's children's hospitals

As we move to increase the number of children with health insurance, we also must continue our efforts to ensure that all children receive the highest quality care. Expertly trained pediatricians are a critical ingredient in providing high quality care to children, and children's hospitals play an essential role in their education, training over 25 percent of all pediatricians and the majority of pediatric specialists. Last year, the President proposed a new $40 million program to support the vital role children's hospitals play in training physicians. This year, our budget proposes to double this amount, providing $80 million to raise support for approximately 60 free-standing children's hospitals to a level more consistent with other teaching hospitals.

Advancing innovative treatments for asthma

Approximately 5 million of our nation's children suffer with asthma, and children from low-income families are disproportionately affected. What makes this particularly disconcerting is that the number of children afflicted has doubled over the past 15 years, with the sharpest increases in rates among children under age 5. Asthma is a leading cause of school absenteeism, and children who suffer from asthma are often forced to limit their activities. To address this growing health problem, our budget proposes $100 million over two years in demonstration grants to states to test innovative asthma disease management techniques for children enrolled in Medicaid and SCHIP. Through appropriate clinical disease management, these programs will attempt to reduce asthma related incidents and keep children with asthma out of emergency rooms and in school.

Providing heating and cooling assistance to low-income families

The Nation has been severely affected by this winter's fuel oil and propane price increases which, in some cases, have doubled since last year. On February 16, the President took steps to respond to critical needs by releasing all remaining emergency Low Income Home Energy Assistance Program (LIHEAP) funds for this year, bringing the total heating assistance funds released this winter to $295 million. On February 25, the President submitted a supplemental request to Congress for an additional $600 million in contingent emergency LIHEAP funding to help as many people as possible meet the additional heating costs and to establish an emergency reserve in the event of a severe summer heat wave. It is essential that Congress act quickly on this request to help to relieve the burden of rising fuel bills. To further address this problem, I have encouraged States to take advantage of the flexibility of current law to reach families with high energy needs, including the option of raising State LIHEAP income eligibility limits. Federal law allows States to set income eligibility limits at the greater of 150 percent of the poverty level or 60 percent of State median income. I also have encouraged States to fully utilize their options under TANF to ensure low income families with children receive the assistance they need.

GREATER SCIENTIFIC ADVANCEMENT

As we enter the new millennium, we stand on the cusp of an era of that promises unprecedented scientific advances. However, these breakthroughs only will be realized if we continue to make the necessary investments in biomedical research. Our budget continues along the path we set several years ago by investing in basic biomedical research as well as in research that will lead to improvements in the quality of care, thereby moving important scientific discoveries from the laboratory into our hospitals and clinics.

Investing in biomedical research

Biomedical research has been at the center of the unprecedented gains we have made in improving the health and quality of life for all Americans. Breakthroughs that did not seem possible only a few years ago are now within our reach, but it will require a sustained investment for these endeavors to bear fruit. The President's fiscal year 2001 budget includes almost $19 billion, an increase of $1 billion over last year's funding level, for biomedical research at NIH. This increase will support research in such areas as diabetes, brain disorder, cancer, disease prevention strategies, and development of an AIDS vaccine, and eventually lead to a revolution in our ability to detect, treat, and prevent disease. This request will enable NIH to fund 31,524 research project grants, the highest total in history, and en-

hance activities in critical areas such as research on racial and ethnic health disparities, biomedical information and technology, clinical research, and genomics.

Using science to improve quality of care and reduce medical errors

As we make new breakthroughs in biomedical research, we also must work to see that these scientific advances result in better quality health care. Even with all our scientific innovations, a recent study by the National Academy of Sciences' Institute of Medicine estimated that as many as 98,000 Americans die each year due to medical errors. The Quality Interagency Coordination Task Force, which HHS leads, just released its report, Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact, which incorporates and expands on the report of the Institute of Medicine (IoM). Our report also builds on the extensive and thoughtful review of the medical errors issue that has been undertaken by this subcommittee. Our budget dedicates $20 million in the Agency for Healthcare Research and Quality (AHRQ) and $13 million in the Food and Drug Administration (FDA) for new activities to address medical errors and patient safety. In addition, HCFA will require that hospitals implement medical error reduction and patient safety programs in order to meet Medicare's conditions of participation.

Overall, our budget invests $250 million in AHRQ to support research activities that will improve quality of care, and produce better health outcomes. These resources will be used to step up research efforts on the uses and tools of health information technology; sponsor clinical prevention research and research to enhance patient safety and reduce medical errors; and expand research on issues of workers' health. These activities will help us to learn how best to translate knowledge into daily practice and improve health care for all Americans.

Our budget also invests and additional $20 million to implement a new Health Informatics Initiative designed to improve patient care and health outcomes through the efficient and effective use of data and information. This request will fund a set of cross-cutting and agency-specific investments in information systems and health data, thereby enabling HHS to assume a greater national leadership role in the establishment of health data standards while also strengthening the information base for decision-making, improving the uniformity and ease of transmission of health care data, and protecting the confidentiality of health information. In addition, our budget includes $45 million to enhance the Food and Drug Administration's postmarket activities. This includes funds to expand their adverse-event reporting system and to allow FDA to investigate, identify and prosecute those selling prescription drugs over the Internet without proper certification.

Food safety initiative

Enhancing our capabilities to conduct surveillance also will help us in our ongoing fight against the threat of food borne diseases. Estimates show that food-related hazards are responsible for as many as 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. To combat these outbreaks, the budget seeks a $10 million increase for CDC's Food Safety Initiative programs. These funds will support enhanced public education efforts and the continued expansion of the PulseNet network of health labs. This award-winning network performs DNA "fingerprinting" of disease causing bacteria, enabling public health agencies to identify and respond more rapidly to disease outbreaks. In addition, the FDA is seeking an increase of $30 million for its Food Safety Initiative activities. These funds will be used to increase inspections so that all high risk food establishments are covered, expand the number of examinations of imported foods, increase laboratory capacity, broaden efforts to work with states and the industry to make standards more consistent, and in conjunction with the Department of Agriculture and the states, begin to implement the Egg Safety Action Plan prepared by the President's Council on Food Safety.

CREATING A HEALTHIER AMERICA

Expanding access and improving the quality of health care are crucial steps toward ensuring that all Americans live long, healthy lives. But new threats to public health continue to emerge, and many long standing health problems still pose considerable risks. From AIDS prevention and treatment to food safety and the control of infectious disease, our fiscal year 2001 budget continues our work to vigorously safeguard the public health.

HIV prevention initiative

As a nation, we have made substantial progress in our fight to prevent the spread of HIV and AIDS. Thanks to the use of combination anti-retroviral therapy, the AIDS death rates in the United States continue to decline. But in some parts of the

world, and in some communities in the United States, the virus continues to spread rapidly. Domestically, the impact of HIV among certain segments of the population, especially minority communities, continues to be severe. In 1997, 45 percent of those newly diagnosed with AIDS were African American and 20 percent were Hispanic. Globally, the AIDS pandemic continues to be a major threat, particularly in developing countries. In sub-Sahara Africa, for example, it is estimated that four million people each year are newly infected with HIV. Internationally, the President's budget includes an increase of $26 million for the Centers for Disease Control and Prevention to continue the initiative undertaken last year to prevent the spread of HIV in developing countries.

Domestically, our budget request supports our ongoing initiative to reduce the spread of HIV and AIDS in minority communities. It provides an increase of $50 million (including $10 million in reallocated funding) for CDC's domestic prevention programs to encourage individuals at risk to avoid behaviors that can result in the transmission of the disease. These funds will be directed to community based interventions designed to reduce the rates of HIV infections, with special emphasis on vulnerable populations including racial and ethnic minorities, women, injection drug users and their partners, and young gay men. Internationally, the President's budget includes $61 million for Centers for Disease Control and Prevention (CDC), an increase of $26 million, to continue the initiative undertaken last year to prevent the spread of HIV in developing nations.

Ryan White

Up to one-third of the 750,000 Americans living with HIV are currently not in care. As we step up our efforts to prevent the spread of AIDS, we must also continue to help those who already suffer from this deadly disease. The President's budget keeps this commitment by providing $1.7 billion for the Ryan White Program, an increase of $125 million. These additional funds will provide primary medical care, pharmaceuticals critical to treatment, and other critical support services for those living with HIV and AIDS. This includes an increase of $26 million for the AIDS Drug Assistance Program (ADAP), which will allow a total of approximately 75,000 individuals to receive comprehensive combination drug therapy.

Reducing racial health disparities

One of the long-standing priorities of this administration has been making sure that all people receive the highest quality health care, regardless of their race or ethnicity. Unfortunately, members of minority groups, including American Indians and Alaska Natives, continue to bear a disproportionate burden of the nation's disease and illness. The President's budget continues the effort to eliminate these health disparities. A targeted response to this problem is the request of $35 million to expand CDC's program of demonstration projects in six identified areas of health disparities: infant mortality, cancer, heart disease, diabetes, HIV/AIDS, and immunizations. Funds will support the continuation of ongoing projects and the development of projects in two new communities. The budget also proposes increasing funding for the Office for Civil Rights by nine percent, including new program resources to ensure that our racial health disparities initiative has a strong civil rights nondiscrimination component. We also request an increase of $230 million for the Indian Health Service, the largest funding increase in two decades, to implement a multi-pronged effort to improve the quality of care for Native Americans.

Family planning

Support for family planning services has been a key factor in preventing over one million unintended pregnancies each year. Family Planning Clinics provide a range of valuable services including sexually transmitted disease and cancer screening and prevention; HIV prevention and education; and contraception services and counseling. As part of our strategy to prevent teen pregnancies, these services have also contributed to reducing the teen pregnancy rate to its lowest level on record (since 1976). Our fiscal year 2001 budget request continues our strong commitment to family planning services, providing an increase of $35 million over fiscal year 2000. These funds will support grants to family planning clinics which will enable approximately 5.75 million low-income clients to receive reproductive health services and clinical care.

Preventing emerging infectious diseases

Thanks to the extraordinary advances in transportation and other technologies and the expansion of international commerce, we truly live in a global community. While these advances have resulted in numerous economic and cultural benefits, they also have placed increasing strains on our public health system. Since 1970, more than 35 new infectious diseases have been identified. More recently, we have

begun to see the emergence of drug-resistant bacteria and viruses, and the spread of older diseases to areas where they were previously unseen, such as the recent outbreak of West Nile encephalitis in the New York City area. To combat these threats, our budget requests a total of $202 million to support infectious disease prevention activities at the Centers for Disease Control and Prevention. This includes an increase of $26 million to fight emerging infectious diseases, of which $20 million would be used to support the development of a national electronic disease surveillance system, which will enhance the ability of state and local health offices to respond to multi-state outbreaks of diseases and to share information, both among themselves and with CDC.

Combating bioterrorism

The recent arrests of suspected terrorists at the Canadian border has reminded us all of the serious threat that terrorism poses to the peace and prosperity of our nation. The threats posed by bioterrorism are particularly deadly because of their communicability and their ability to remain undetected for long periods of time. Continuing our efforts to prepare for and respond to the consequences of a bioterrorist event, the Department's budget includes $265 million for activities across agencies to mount a comprehensive public health effort to combat this deadly threat. This strategy includes four major components. First, our budget strengthens critical components of our public health infrastructure, including our surveillance systems, epidemiological and laboratory capacity, and communications technology. Second, it continues funds for the purchase of a stockpile of the pharmaceuticals needed to treat the most likely biological agents. Third, it provides funds for research, development, and regulatory review of new vaccines and new diagnostic screens for chemical agents. Finally, it would support the establishment of an additional 25 local area health care response systems, bringing the total number around the country to 97.

Investing in HHS laboratory and health infrastructure

To successfully overcome the public health challenges of the 21st century, we must invest now to modernize the infrastructure that provides the foundation for our public health and biomedical research systems. Many of the laboratories at CDC and FDA are overcrowded and outdated, while at the National Institutes of Health (NIH) the fragmentation of laboratory space delays the pace at which new discoveries are made. Our budget requests substantial increases to solidify this foundation and construct state-of-the-art facilities. For CDC, we are requesting a total of $127 million, an increase of $70 million, for laboratory construction at three sites. First, our budget includes $85 million in fiscal year 2001 and additional funding in fiscal year 2002 and fiscal year 2003 to construct a laboratory to handle the most highly infectious and lethal pathogens studied at CDC, as well as housing important work on antibiotic resistant diseases, AIDS, sexually transmitted diseases, and tuberculosis. Second, we request $20 million to complete and equip the Edward R. Roybal infectious disease laboratory. Third, we request $4 million to design a facility to replace our antiquated environmental health laboratory. The remainder of the request will be used for security improvements and maintenance of existing facilities.

For NIH, we are requesting $149 million for intramural buildings and facilities. Intramural projects include $73 million over two years to construct a new facility to house the new National Neuroscience Research Center, and $24 million to begin design and construction of a new centralized animal facility. Our budget also includes $20 million for new lab construction at FDA, as well as $65 million for health facilities construction in the Indian Health Service (IHS).

RIGOROUSLY EVALUATING PROGRAM PERFORMANCE

Our budget request for fiscal year 2001 presents the annual performance information required by the Government Performance and Results Act (GPRA) of 1993. Notably, this includes the first GPRA performance report of HHS and its components, which compares fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. Although GPRA reporting must mature before its full value will be realized, our performance report for this year shows improvements for critical HHS initiatives of the past few years. SAMHSA reports that retailers in more States have complied with rules prohibiting tobacco sales to youth than we had projected in our 1999 performance plan. HCFA achieved its 1999 goal for reductions in Medicare payment errors a year early, and pursues increasingly rigorous goals in fiscal year 2001 and fiscal year 2002. ACF and its program partners, including states, exceeded performance expectations when they moved 1.3 million welfare recipients into new employment. Information like this demonstrates that GPRA can be a valuable tool that will enhance our efforts to improve programs that serve the American people.

As our performance measures continue to mature and performance trends emerge, the GPRA data will serve as important program indicators to support the identification of strategies and objectives to continuously improve programs across HHS.

A ROAD MAP TO A BETTER AMERICA

Mr. Chairman, as I look back at the journey we have taken, I feel tremendous pride in what we have been able to accomplish. While there were occasional bumps in the road and we did not reach every destination we set out for, we have made great advances in improving the nation's health and well being. Today I have placed before you a road map for the destinations we have charted—improving health care access, coverage, and quality; making America a healthier and safer place; expanding our scientific knowledge, and giving all our children and families the opportunity for success—and these are destinations we all wish to reach. Thanks to the unprecedented economy, our fiscal discipline, and a new age of scientific breakthroughs, the conditions under which we set out on this road have never been more favorable.

FISCAL MANAGEMENT AT CDC

Mr. Chairman, before concluding, I would like to speak about the recent news stories regarding the management of hantavirus funding at CDC. Dr. Koplan and I are deeply concerned about CDC's failure to report these reallocations to the Congress in a timely fashion. I strongly believe that the full accountability and integrity of our budgeting and reporting efforts are central to our responsibilities, and I have zero tolerance for inaccurate reporting or inaccurate statements. We have an obligation to expend our funds consistent with congressional expectations and to report in an accurate and timely fashion.

In consultation with Dr. Koplan, I am taking what I consider to be aggressive and unprecedented actions to rectify this problem and restore the trust of this Congress. These actions, which will be coordinated by the Department and CDC, include:

—The Chief Financial Officer (CFO) of the Department of Health and Human Services (HHS) will take such actions as necessary to certify all financial obligations made by the National Center for Infectious Diseases for the remainder of the fiscal year.

—The Department's CFO also will work with Dr. Koplan to ensure that all senior decision-makers in the National Center for Infectious Diseases receive certified budget execution training.

—CDC is commissioning an external review of the agency's fiscal management practices. The review is to be completed within six months. The results of this analysis will be communicated to the Congress as soon as the review is complete.

—CDC program managers will conduct a top-to-bottom examination of CDC's 133 programs and projects to make sure there are no other areas of concern. During the 90 day period CDC managers will be able to fully and openly identify any area for which there may be a discrepancy between actual expenditures and the information provided to Congress. Dr. Koplan will share these findings with the Congress.

—CDC has commissioned Pricewaterhouse Coopers, a firm of independent auditors, to thoroughly examine our hantavirus expenditures. The results will be communicated to the Chairman immediately upon completion. When this audit is complete, CDC will expand the effort to the entire National Center for Infectious Diseases.

In addition, Dr. Koplan has for the past year put in place numerous corrective actions to respond to the Inspector General's report on Chronic Fatigue Syndrome. He has implemented new financial management systems; initiated improvements in the agency's budget displays and in the allocation of centralized agency costs. Again, let me state very clearly that neither any senior manager at HHS nor I have any tolerance for inaccurate reporting and that we are all devoted to restoring the credibility and integrity that is central to the important work done at CDC.

Chairman Specter, Senator Harkin, and members of the Subcommittee: I would like to thank each of you for all of the hard work you have done to make everything we have accomplished a reality, and I look forward to working with all of you to meet the challenges before us in this budget. I would be happy to address any questions you may have.

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

STATEMENT OF HON. RICHARD W. RILEY, SECRETARY

Senator SPECTER. We now turn to the distinguished Secretary of Education, Secretary Richard Riley, who has also served during the entire tenure of President Clinton's Administration starting in January of 1993.

Secretary Riley brought a wide breadth of experience to the position, having been governor of the State of South Carolina, a State Senator and a State representative, so that he has been in many fields, many capacities.

He had a nationally recognized effort to improve education in South Carolina, which led to his appointment as secretary. He is a graduate of Furman University and a recipient of a law degree from the University of South Carolina.

Thank you for joining us, Mr. Secretary, and we look forward to your testimony.

Secretary RILEY. Thank you so much, Mr. Chairman. I thank you and Senator Harkin and Senators Murray and Feinstein for the strong support of education that all four of you have shown us. It's clear that you really believe in the investment in young people's education and all people's education.

STATE OF AMERICAN EDUCATION

It is a great pleasure to be here with my colleagues in the Cabinet. I just have completed my annual state of American education address, which I gave down in Durham, NC, at a turn-around school, a school that was predominantly African-American and was really a school that was classified as a low-performing school. But they had a new principal, and it was a very exciting thing. It is now an exemplary school there in Durham.

I talked about higher expectations. I talked about the achievement gap between the students whose families are educated and have money and students who are minorities, and, oftentimes, limited English proficient. I talked about the digital gap and really those things that we can do about those. And we are trying to close that gap. I see good things happening. We have a lot of work to do.

The E-rate, for example, is other work that we have done in technology. We just recently had a determination that 95 percent of our schools are connected to the Internet. And we have gotten up to 63 percent of all classrooms connected. That is enormous growth, and I am very proud of it.

Increased attention to early childhood programs that my colleagues spoke about is making a real difference. Parents have an

absolute focus on keeping their children out of harm's way and school safety is a paramount issue.

Overall, the American people have made education clearly one of their top priorities. The budget reflects these priorities. Turning around failing schools, school safety, improving teacher quality, modernizing our nation's schools, technology, safe schools, helping working and middle class families pay for college.

The American people, I think, are getting into a new position when it comes to how we improve education. I think they have moved beyond the debate on Federal versus local control. I strongly believe that State and local control, in terms of control, must be there.

But it is so interesting to see that we have come to a new place. The American people want practical answers. They want to know specifics. If we are going to have national priorities, what are they? What are our expectations? And they want accountability for those.

They want local, State, and Federal interests working together to create new partnerships, partnerships that are not just government, obviously, but include business, community groups, jump old boundaries, and make things happen. The Federal Government is the junior partner in all of that, but a very important partner.

THE GOOD NEWS ABOUT EDUCATION

So where are we when it comes to education? Higher standards are now in place in all 50 States. The big job now is to get standards down in the school classroom, where they impact every child and have real accountability measures. We are also starting to see the early benefits of our sustained focus on raising standards. I think it is making a difference in every State.

And I would like to submit for the record a new release from the Center on Education Policy and the American Youth Policy Forum, entitled "Do You Know the Good News About American Education?" And it is, I think, a very good indication that across the board very interesting things are happening.

DEPARTMENT OF EDUCATION BUDGET REQUEST

But I will be the first to tell you that we still have a very long way to go. There are schools out there that should not even be called schools, and they need fixing immediately. The proposed investment in this budget, I think, moves in that direction. We are requesting $40.1 billion, an increase of $4.5 billion or 12.6 percent over the fiscal year 2000 spending.

The budget continues a strong emphasis on improving accountability in Title I, reducing class size, improving teacher quality, technology, modernizing our schools, increasing after-school opportunities to help keep children out of harm's way. And I remain very excited about the President's college opportunity tax cut proposal. It can make a real difference in giving young people the chance to go to college, and middle income families as well.

TEACHER RECRUITMENT AND RETENTION

This budget includes $1 billion to support better teaching with a strong emphasis on recruiting and retaining high-quality teach-

ers. There is no single way to get that job done, and we come at it from many angles, that have been carefully thought about.

21ST CENTURY COMMUNITY LEARNING CENTERS

One of the best ways to keep our children out of harm's way is through positive after school experiences. That is why we are proposing a $547 million increase for 21st Century Community Learning Centers, doubling the funding to the total of $1 billion, making the after-school effort very important.

SCHOOL SAFETY AND DISCIPLINE

School safety and discipline are very immediate. We do not need another Columbine. I worry about that every single day, and I know each of you do. And the other incidents that have happened, even though they are very rare, are still so terribly important. Any one of them makes it a crisis.

SMALL, SAFE AND SUCCESSFUL HIGH SCHOOLS INITIATIVE

Young people need to have a strong sense of connection. I think that is very important, when you look at school violence. We propose to scale up our Small, Safe and Successful High Schools initiative by providing $120 million to help 700 high schools create schools within schools. These are these large, often consolidated schools.

SAFE SCHOOLS/HEALTHY STUDENTS INITIATIVE

We are now in our second year of funding for our joint safety initiative with HHS and the Justice Department. There is an enormous demand for this initiative. I think there is great potential in that. It is something, Mr. Chairman, you have been interested in. Over 440 cities applied for those grants. We were able to grant 54 of them in the first year, to show you how significantly it is seen by cities. We expect another 20 to 23 to be funded this year.

CHILDREN'S HEALTH INSURANCE PROGRAM

I would mention CHIP, Mr. Chairman and members of the committee. I think all of us ought to be talking about that, how we get young people out there to get health care. That is, just like these other issues, an overlapping issue. But under eligibility of Medicaid and CHIP, really every poor young person in the country ought to be receiving health care. And that is, too, related to these issues.

SAFE AND DRUG-FREE SCHOOLS AND COMMUNITIES

But it is important to remember that our nation's schools still are basically safe. We have 53 million young people in school every day. That is an awful lot of young people. Yet less than 1 percent of the homicides among youth aged 12 to 19 occur in schools, at school functions or on the way to school, way less than 1 percent.

Drug use is falling slightly, but remains much too high. It is one of the reasons why we continue to work hard to improve the effectiveness of the Safe and Drug-Free Schools program. The budget reflects those changes. We believe that our middle school coordinators effort can play a positive role in helping parents and school of-

ficials who are on the front line, and I think our effort to support character education and civic education also help as well.

SCHOOL MODERNIZATION

I also urge the Congress to pass our school modernization legislation. Many rural and urban school districts need the help. Our modernization proposal now comes in two parts. And I want to try to urge you all to take a look at that. Both are worthy, I think, of consideration.

We are putting strong emphasis on our new $1.3 billion appropriation for school renovation, a request to help school districts renovate and repair thousands of old schools that are in urgent need of repair, often in areas that cannot float a bond issue. They really do need some special help.

Our school buildings are wearing out in many of these older cities. They are old, overcrowded in other areas. We think that that bears an awful lot of attention.

PELL GRANT MAXIMUM AWARD

Let me conclude by a comment on higher education. We are proposing increasing the maximum Pell Grant to $3,500, up from $3,300, a $200 increase, up more than 50 percent since 1994.

COLLEGE OPPORTUNITIES TAX CUT

The President's new 10-year, $30 billion College Opportunities Tax Cut—which I would be happy to discuss in detail, if you would like, will be of significant help to working class families who make under $43,000 a year. It provides special help for them, as well as middle class parents with several children going to college with special cost problems.

I thank you very much for giving me the chance to be here with my colleagues. And I, like they, welcome questions. Thank you.

PREPARED STATEMENT

Senator SPECTER. Thank you very much, Secretary Riley.

[The statement follows:]

PREPARED STATEMENT OF HON. RICHARD W. RILEY

Mr. Chairman and Members of the Committee: Thank you for this opportunity to discuss the President's fiscal year 2001 budget request for education. I want to begin by thanking you, Mr. Chairman, as well as other Members of this Subcommittee, for your strong and consistent support for education over the past several years. Working together, I believe we have made real progress in helping to expand educational opportunity for all Americans.

The American people have made education one of their top national priorities. We recognize that the Federal government is the junior partner in our education system, and that real progress in improving education depends primarily on State and local efforts. But we can play a critical role in encouraging and supporting State and local initiatives, particularly in the areas of raising standards, improving accountability for results, and helping to meet the needs of disadvantaged and limited English proficient students and students with disabilities.

The American people also see this time of peace and prosperity as a unique opportunity for the Nation to be investing in the long-term future of our great country by improving education at all levels. Some might argue that the growing Federal budget surplus should be used for broad-based tax cuts, but that's not what I hear when I talk with students, parents, and teachers across the country. What I hear

instead is a strong consensus on paying down the national debt and building for the future by investing in the education of our children.

That is why the President is requesting $40.1 billion in discretionary spending for the Department of Education, an increase of $4.5 billion or 12.6 percent. This budget reflects the transition to the second phase of the standards-based reform efforts we launched seven years ago. First, we worked with the Congress to support State and local efforts to raise standards and put accountability measures in place. Standards are now in place in all 50 States and we are working hard to improve accountability. Now we need to ensure that States and communities have the resources needed to ensure that all students can achieve to higher expectations and that teachers are prepared to teach to the new standards.

The Department's request provides significant new resources to help States and communities implement higher standards in their schools while coping with booming enrollments and the need to modernize academic facilities. The request also provides substantial new support to help prepare disadvantaged students for postsecondary education and make college more affordable for all Americans.

INCREASED ACCOUNTABILITY

The 2001 budget for education once again emphasizes accountability for results, particularly for chronically failing schools. Our purpose is not to punish the students in those schools, but to provide the right combination of incentives and support that will accelerate the changes needed to improve the quality of their education.

The President's request for Title I includes $250 million for a second year of accountability grants, an increase of $116 million over the 2000 level. These funds would enable States and school districts to provide the additional assistance needed to help failing schools—primarily those identified for corrective action under Title I—turn around and improve student achievement.

The President's proposal also recognizes that in too many schools, students and parents have waited far too long for meaningful change and improvement. For this reason, school districts participating in Title I would be required to offer students enrolled in a school identified for corrective action the choice of attending another public school not identified for corrective action. The goal here is to help ensure that no student is trapped in a truly bad school, and to reinforce the idea of serious consequences for schools that consistently fail to improve. At the same time, we are emphasizing efforts to turn around poor-performing schools, because even with a public school choice option the majority of students will continue to attend their neighborhood school.

IMPROVING LOW-PERFORMING SCHOOLS

We want to balance accountability for meeting high standards with new resources to help students meet those standards and to help school districts turn around failing schools. This is why, for example, the request includes a $547 million increase for 21st Century Community Learning Centers, for a total of $1 billion for afterschool and other extended-learning programs. These funds would support high-quality extended learning opportunities for nearly 2.5 million children, including students in low-performing schools.

We also would add $450 million to reduce class size in the early grades, for a total of $1.75 billion to help children get more personal attention, improve discipline, and learn more. There's no better way to rapidly improve student achievement than to put highly trained teachers into small classrooms where they can provide the individual attention students need to reach high standards. The request would bring the total number of teachers hired under this program to about 49,000, or almost halfway to the President's goal of hiring 100,000 teachers over seven years.

One of the best ways to bring about real change and turn around failing schools is to help communities and schools to put in place reforms based on solid research. This is why our budget includes $190 million for the Comprehensive School Reform Demonstration program to help an additional 1,900 schools develop and implement proven, comprehensive reform models. We would also increase funding for educational research by $30 million to help meet the growing need for research-based information on what works in education.

The request also expands the Small, Safe and Successful High Schools initiative to help create smaller, safer, and more disciplined and supportive learning environments in approximately 700 of the Nation's largest high schools. The President's budget would provide $120 million for such effective innovations as schools-within-schools or career academies that assign students to groups of a few hundred—helping to replace the isolation many students feel in large schools with smaller, more nurturing communities.

Another way to accelerate change is by giving parents more choices of public schools. Our budget would increase the choices available to parents and students through a $175 million request for Charter Schools. These funds would support the start-up of some 1,700 new or redesigned charter schools, which have the flexibility to offer innovative educational programs in exchange for greater accountability for student achievement. The 2001 request would bring to 2,400 the number of charter schools helped by this program, supporting the President's goal of creating 3,000 charter schools by 2002.

We also are seeking $20 million for the Opportunities to Improve our Nation's Schools initiative, or OPTIONS. This flexible new authority would support 40 grants to States and school districts to implement and test new approaches to public school choice, including inter-district programs and public schools at work sites and on college campuses.

Our budget also acknowledges the importance of recognizing success. A new, $50 million Recognition and Reward program would reward States for improving student achievement and for reducing the achievement gap between high- and low-performing students, as measured by State results on the National Assessment of Educational Progress.

MODERNIZING OUR SCHOOLS

A key priority for 2001 is to help ensure that all students have the opportunity to attend safe, modern school facilities that are equipped with up-to-date educational technology. With public school buildings averaging some 42 years of age and a backlog of more than $100 billion in repairs, it is clear that we have a lot of work to do. This is why the 2001 request includes two proposals to upgrade school facilities.

The School Renovation program, a major new $1.3 billion discretionary initiative, would help school districts repair or renovate their schools. The $1.3 billion total includes $50 million in grants to approximately 119 districts with at least 50 percent of their children residing on Indian lands, $125 million in grants to high-need school districts, and $1.125 billion that would leverage an estimated $6.5 billion in 7-year, no-interest loans.

The School Renovation initiative would complement the President's School Modernization Bonds proposal, which would provide nearly $25 billion in tax credit bonds over two years to modernize up to 6,000 schools. Tax credit bonds, which the President is proposing for the third year in a row, would provide interest-free financing to help State and local governments pay for modernizing schools and addressing overcrowding.

An additional factor driving the demand for the upgrade of school facilities is the explosion in the development and use of educational technology based on multimedia computers and access to the resources of the Internet. Computers are the "black board and chalk" of the future. A key resource for this revolution in educational technology is the E-rate, created by the Telecommunications Act of 1996, which provides nearly $2 billion annually in subsidies to help schools and libraries connect to the Internet.

The Department budget would provide $450 million for the Technology Literacy Challenge Fund, an increase of $25 million, to help schools integrate technology into the curriculum and ensure that teachers in high-poverty communities are prepared to use educational technology effectively. We also would double funding to $150 million for the Preparing Tomorrow's Teachers to Use Technology program, which helps prepare new teachers to use technology effectively to improve instructional practices and enhance student learning in the classroom.

And to help close the digital divide in our communities between those who enjoy the full benefits of computers and the Internet and those economically disadvantaged individuals and families who lack access to such technology, the budget would more than triple funding for Community Technology Centers. The $100 million request would support up to 1,000 new centers offering area residents access to extended learning opportunities before and after school, adult education, and online job databases.

MASTERING THE BASICS

The President's budget also expands support for programs that help students master the basics and close achievement gaps between disadvantaged and minority students and their more advantaged peers. The request includes $8.4 billion for Title I Grants to Local Educational Agencies and $286 million for the third year of the Reading Excellence program, which helps all children to read well and independently by the end of the third grade. We would increase funding for Special Edu-

cation Grants to States by $290 million for a total of $5.3 billion, while boosting support for Special Education Parent Information Centers by 40 percent.

Indian Education programs would receive $116 million, an increase of 50 percent, to provide larger formula grants to school districts for Indian Education programs, and to launch a new $5 million American Indian Administrator Corps that would train American Indian teachers and professionals to become school administrators.

It is difficult if not impossible to master the basics in communities and schools threatened by youth violence. I know that preventing youth violence is a priority shared by both President Clinton and the Chairman of this Subcommittee. To help expand the Youth Violence Initiative that you helped launch last year, Mr. Chairman, we are requesting a $50 million or 25 percent increase in funding for Safe and Drug-Free Schools National Programs. These funds would be used primarily to make new awards under the Safe Schools/Healthy Students initiative. This interagency initiative—funded by the Departments of Education, Health and Human Services, Justice, and Labor—would receive a total of $247 million in 2001, an increase of more than $100 million over the 2000 level.

IMPROVING TEACHER QUALITY

We need to elevate the teaching profession and expand opportunities for teachers to continually update their skills. Improving teacher quality is a major emphasis in the Educational Excellence for All Children Act, the Administration's proposal for reauthorizing the Elementary and Secondary Education Act of 1965. We need to make sure our teachers are prepared to teach to the new State standards, and we need to help States and communities deal with the projected nationwide shortage of 2 million teachers over the next 10 years. Our budget provides $1 billion for a comprehensive approach to reaching these goals, with an overall focus on preparing both new and experienced teachers to bring high standards into the classroom.

This includes $690 million for Teaching to High Standards State Grants, our TitleII reauthorization proposal to promote professional development linked to State standards and assessments. A new $75 million Hometown Teachers proposal would support comprehensive approaches to teacher recruitment and retention in high-need districts, while a $50 million Higher Standards, Higher Pay initiative would help high-poverty school districts attract and retain high-quality teachers through better pay linked to a rigorous peer-review process.

To help meet the growing demand for high-quality leadership in our school districts and schools, particularly in the area of implementing standards-based reforms, the budget includes $40 million for a School Leadership Initiative. This new program would fund consortia-based efforts to provide current and prospective superintendents and principals—particularly those serving high-poverty, low-performing districts and schools—with the professional development opportunities needed to help them serve as effective leaders.

The request also would provide $50 million to reward school districts that show the largest increases in the number of teachers who are fully certified and teaching in the field in which they are trained, $25 million to encourage career-changing professionals to enter the teaching ranks, and $30 million to train some 15,000 early childhood educators and caregivers in techniques to improve early literacy skills and prevent later reading difficulties.

In addition, the 2001 budget includes $100 million for Bilingual Education Professional Development to help address the critical national shortage of well-prepared bilingual and English-as-a-second-language (ESL) teachers.

NEW PATHWAYS TO COLLEGE

A college education remains the best guarantee of success in a rapidly changing, technology-based economy that demands critical-thinking skills and the ability to adapt to new ways of doing business. Postsecondary institutions are enjoying their own enrollment boom—climbing last fall to a record 14.9 million students—but too few disadvantaged and minority students are entering and completing college.

To help give these students and their families new pathways to college, the 2001 budget includes a $125 million increase for GEAR UP to provide 1.4 million low-income elementary and secondary school students the skills and encouragement they need to enter and succeed in college. We also are asking for $725 million for TRIO outreach and support services to more than 760,000 disadvantaged postsecondary students. The TRIO request includes $35 million for a new College Completion Challenge Grant program that would help reduce the college dropout rate, particularly among poor and minority students. Another pathway to college is Tech-Prep Education, which supports efforts by partnerships of high schools, postsecondary institutions, and employers to create comprehensive technical education pro-

grams that prepare students for both college and high-tech careers. The 2001 budget nearly triples Tech-Prep funding to $306 million.

MAKING COLLEGE MORE AFFORDABLE

Just as important as preparing for college is helping students and families pay the rising costs of a postsecondary education. Over the past six years larger Pell grants, expanded work-study opportunities, lower borrowing costs on student loans, and Hope and Lifetime Learning tax benefits have made college financially possible for all who qualify.

Paying for college is still a difficult burden, however, especially for low- and middle-income families. Our 2001 budget would help reduce that burden. For example, we are proposing a maximum Pell Grant award of $3,500, a $200 increase over the 2000 level. A $60 million increase for Supplemental Educational Opportunity Grants would provide a total of $875 million in grant assistance to an estimated 1.2 million undergraduate students, or 64,000 more than in 2000. And a $77 million increase for Work-Study would continue the President's commitment to give 1 million students the opportunity to work their way through college.

Outside the discretionary budget for postsecondary education, President Clinton would dramatically expand tax benefits for postsecondary education through a new College Opportunities Tax Cut. This proposal would build on the Lifetime Learning Tax Credit to give over 5 million families the option of taking a tax deduction or claiming a 28 percent tax credit on up to $5,000 in annual postsecondary education tuition and fees. The limit would rise to $10,000 in 2003, and the Treasury Department estimates families would save an additional $30 billion over 10 years, compared to the current Lifetime Learning tax credit.

To increase academic opportunities for minority students and increase their numbers in high-skill fields such as science and engineering, the President's budget proposes $40 million for Dual-Degree Programs for Minority-Serving Institutions. This program would provide competitive grants to partnerships between Minority-Serving Institutions (MSIs) and nationally recognized research universities. Participating students would earn two degrees in five years, one from the MSI and one from the partner institution in a field in which minorities are underrepresented.

Finally, the President's budget targets additional funds to Latinos as part of the Administration's Hispanic Education Action Plan. The 2001 request includes more than $800 million in increases intended to help expand educational opportunities and improve outcomes for Latinos. In addition to increases for programs like Title I and TRIO that serve large numbers of Latino students, the request provides an $86 million increase for Adult Education, most of which would be used to triple funding for Common Ground Partnership Grants. These grants support demonstration programs that provide immigrants and other participants with English literacy skills, coupled with civic education and basic skills that are necessary to effectively navigate key institutions of American life. The budget also includes nearly a 50 percent increase for Hispanic-Serving Institutions to support postsecondary education institutions that serve large percentages of Latino students.

I believe this budget is a fitting start to a new century—the Education Century—and would provide the resources needed to increase both quality and opportunity in our education system. The 2001 request will, as the President noted in his State of the Union address, move the Nation "a long way toward making sure every child starts school ready to learn and graduates ready to succeed."

I will be happy to answer any questions you may have about the President's 2001 budget for education.

Senator SPECTER. Before proceeding to our customary 5-minute rounds of questioning from the members, we have been joined by the chairman of the full committee, Senator Stevens.

We would be delighted to hear from you, Mr. Chairman.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Well, thank you very much. I apologize for being late. I do have a conference. I just have a very short statement I would like to make and submit some questions for the record, if that can be done.

I do welcome all three of you secretaries. I think it is a very great thing that you all would come at the same time, so we can

have everyone here with responses that are of mutual importance to all of us, I am sure.

I would like to put the full statement in the record, if I can.

Senator SPECTER. Without objection, it will be.

Senator STEVENS. Secretary Shalala, I want to thank you particularly for providing Alaska some great help, particularly in the area of combating a very high rate of fetal alcohol syndrome and fetal alcohol effect problems in our State. Fetal alcohol syndrome, as we all know, is estimated to cost over $1.4 million for each person that is born with it.

And unfortunately, we have the highest level per capita in the country. We believe it is an entirely preventable condition and appreciate what you are doing to help us work on the prevention side.

I also am grateful to you for your assistance in making PET scans available to our seniors under the Medicare program. We talked about this last week. And I understand your staff and the Health Care Financing Administration have agreed to a reasonable level of Medicare payment for PET scans under the new Outpatient Hospital Payment System that is going to go into effect in the summer. I congratulate you very much for that.

I appreciate your agency's willingness to continue working cooperatively with the PET community on getting full, broad, coverage for PET scans.

It is my understanding the PET community will be submitting revised information to HCFA in the next 45 days. We will all be following the progress on that. And hopefully we will be able to get full approval of PET coverage by this summer.

Incidentally, in flying back from California on Sunday, I read a whole series of new brochures that are out from across the country on the use of PET, how we are expanding its use into all forms of cancer, as well as the brain. I think it just an invaluable new system of imaging and diagnosis.

I am very interested in it because of my great friend, Dr. Michael Phelps of UCLA, who is the inventor of that. And I am very proud of him as a friend. It has been about 20 years ago now that I stopped off to see him at UCLA. And he gave me a rundown of the PET scan.

I told him I was supposed to make a speech to the National Convention of the American Legion that day. When he got through giving me his presentation, I asked him what time it was, and he said it was 8:00 p.m. I started at 3:00 with him, and unfortunately missed that convention altogether, I was so mesmerized by what he was doing. He has undoubtedly made a significant contribution to our medical diagnostic capability.

And I do believe that it is going to be expanding in its use, primarily because of the help you and your staff are providing.

IMPORTANCE OF TECHNOLOGY IN EDUCATION

Secretary Riley, I am also here to tell you I am particularly pleased with your recognition of the importance of technology in our classrooms and training teachers to effectively use that technology.

LONG-DISTANCE EDUCATION

I am sure you know we are going into our State with a whole new concept of education by distance, long-distance education. Telemedicine and tele-education are two very important opportunities for our State, which is, after all, one-fifth the size of the whole United States.

In the past, many opportunities were denied to our teachers and students in Alaska because of the isolation of rural communities and villages. But distance education will change that.

Alaska and Hawaii in particular, and some of the rural south 48 States will benefit tremendously from the new technologies in distance education. I am very grateful to all you for what you and your people have done working with us.

BALANCE BUDGET REQUEST WITH RESOURCES

A word of caution, however. I am disappointed in the President's budget request because it promises more than we can deliver. It includes paying out monies that theoretically come in as taxes, which have no chance of being approved.

And because of that, we are going to have a real difficulty in maintaining our commitment to a balanced budget and our position that we will not use the Social Security surplus in financing the working operations of the Federal Government.

I look forward to working with the chairman, the members of this committee, and all of you to try to come up with a realistic spending plan for the next fiscal year that will meet our needs and not return to the days of a heavy deficit.

PREPARED STATEMENT

Thank you very much. And I will submit the questions.

Senator SPECTER. Thank you, Senator Stevens.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TED STEVENS

Senator Specter, Senator Harkin, and members of the subcommittee.

I'd like to begin by thanking you, Mr. Chairman for the leadership you have shown in working to prevent youth violence.

When we presented our fiscal year 2001 budget, I noted that the searing images we saw last year at Columbine and other schools must never be repeated.

If there was ever a bi-partisan issue—this is it.

That's why the President worked with Congress to establish a new White House Council on Youth Violence to get all Federal agencies thinking and working together to prevent youth violence.

And that's why my colleagues, Secretary Herman and Secretary Riley, and I join you in your determination to bring to bear the resources we need to fight this problem effectively.

At HHS, the Surgeon General is developing a Report on Youth Violence that we hope will be completed this year.

However, this much we already know: Violence is preventable. So we intend to find out what works. What doesn't. And then publish and disseminate a sourcebook of best practices.

Our budget also increases the Mental Health Block Grant by $60 million—a full 17 percent.

And we're budgeting another $78 million to stop youth violence.

Now let me highlight other important features of our budget and why we believe this budget is critical to the health and future of the American people.

Our fiscal year 2001 budget brings us to where we should be at the dawn of a new century: A great nation pledging allegiance to great goals.

Those goals are: Expanded health care coverage; renewed support for children and families; greater scientific advancement; and the creation of a healthier America.

Our fiscal year 2001 budget brings those goals within reach—without loosening our commitment to fiscal discipline and a balanced budget.

This budget is about people.

It makes a record investment in health care coverage. In access. And in quality.

Two years ago, with bipartisan support, we launched the State Children's Health Insurance Program.

Two million children are now enrolled.

Now we want to make sure that this new program—and Medicaid—carry millions more children, and their parents, into the safe harbor of quality health care.

The President's FamilyCare program will do that.

Even as we expand coverage to some parents through FamilyCare, we recognize that many low income adults work in jobs that do not offer health insurance.

These workers frequently rely on local health institutions and professionals who provide services at a reduced or no cost.

This year we want to increase our support for these community service networks to $125 million—five times our investment last year.

We need to strengthen and modernize Medicare.

First and foremost that means dedicating about $300 billion of the on-budget surplus over 10 years to extend the solvency of the Trust Fund until 2025.

We must also add a voluntary prescription drug benefit to Medicare.

As the President said in his State of the Union, we would never design Medicare today without a prescription drug benefit.

We can't change the past. However, we can change the future.

But, the longer we wait, the worse the problem will become—and the more expensive it will become.

Government cannot step into the shoes of parents and communities, but government does have a role to play in helping families balance work and children.

One recent study notes that in 1998 only 10 percent of the 14.7 million children eligible for Federal child care subsidies received them.

So as part of the President's Child Care Initiative, this year's budget adds another $817 million to the Child Care Development Block Grant.

This is part of our discretionary budget and brings the total Block Grant to $2 billion.

Mr. Chairman, Head Start is one of the most successful bipartisan programs our two branches of government has ever created for children.

This year we're requesting $6.3 billion for Head Start.

That's $1 billion more than last year—and the largest increase in the history of Head Start.

I can't talk about children without talking about drugs. I know, Mr. Chairman, that you would like to pursue this further in our question and answer period.

We know marijuana use has leveled off among teens. But too many teens are still saying "yes" to drugs and alcohol.

That's why our budget includes over $3.3 billion for substance abuse treatment and prevention.

I mentioned the success we've had cutting the death rate from AIDS.

But HIV/AIDS is still a disease without a cure—and is still the greatest public health challenge both here and around the world.

So fighting HIV/AIDS remains a top priority for the Department.

Our total AIDS budget this year is $9.2 billion—an increase of 8.4 percent over last year.

Every agency's AIDS-fighting budget is going up in prevention, treatment and research.

On the prevention side, we propose to spend an additional $75 million to help stop the spread of this disease.

Specifically, the CDC will direct $40 million of the new funds to local communities—including prevention services targeted to minority populations.

CDC will spend another $26 million to fight AIDS around the world.

At the same time, the Health Resources and Services Administration will expend $1.7 billion in Ryan White funding to help people living with HIV/AIDS.

This is a $125 million increase over last year.

Our budget request for AIDS-related research at NIH is $2.1 billion, a 5.2 percent increase over last year.

The total NIH budget this year is $18.8 billion—$1 billion more than a year ago.

This subcommittee should take pride in the unprecedented investment we have made in basic and clinical research.

Our shared commitment to NIH, . . .

. . . and to producing quality science and scientists—on both the NIH campus and at great research universities—is an extraordinary legacy.

Years from now, we will see results beyond our wildest dreams.

Some of those results are certain to come from the $73 million we intend to invest—over 2 years—to build a National Neuroscience Research Center at NIH.

This will put all NIH brain research under one roof.

More important the Center will usher in what is certain to be The Century of the Brain.

In the interest of time—let me quickly mention three other areas where we intend to increase our discretionary budget.

We take very seriously the need to stop infectious diseases and bioterrorism.

Our budget increases by almost 50 percent CDC's funding for disease surveillance.

As for bioterrorism—which may be the biggest threat of the 21st century—we're proposing to spend $265 million to prepare for, and respond to, a biological attack.

We also want to make a major investment in bricks and mortar.

In addition to the Neuroscience Research Center at NIH, CDC proposes to spend $127 million—$70 million more than last year—to modernize and expand three laboratory sites.

The remaining funds will go toward completing the Edward R. Roybal infectious disease lab, and construction of a new environmental health lab.

Mr. Chairman, I want to conclude my testimony by noting that our greatest moral imperative is to close the gaps in health outcomes between minorities and the majority population.

In 1998, the President set a goal of ending health disparities in six major areas.

Now, almost every operating division is working to close these gaps.

That includes an additional $35 million at CDC for community-based research and demonstration projects to reduce disparities.

Thank you.

TRANSPORTATION FUNDING FOR WELFARE WORKERS

Senator SPECTER. Secretary Herman, when you talk about areas of needs, of trying to move workers from, say, the inner city, where there are no jobs, to the suburbs, where there are jobs, I think that is an area which requires special attention.

And I thank you for taking the initial steps to free $1.3 million for Philadelphia. We talked about that week before last, and you acted on it last week. But when I visited the transit system yesterday, I was told the check was in the mail. Do you know how far along the delivery route that check is?

Secretary HERMAN. I believe it will arrive on Thursday.

Senator SPECTER. OK. So I will report back to them that it is still in the mail.

That program needs a lot of additions. They transport 1,500 people in buses, and they have some 9 vans. But I am making a survey to see how many poor people need that transportation, what it would do for the lives of people giving them dignity and a job, and what it would do for the taxpayers on reducing welfare payments. So we are going to come back to you there, but I do appreciate your help.

BIOTERRORISM

Secretary Shalala, you commented specifically about the $265 million on bioterrorism. A commission just finished its work a few months ago on dealing with weapons of mass destruction. I served as vice chairman. And the commission did not move into the domestic area. And I believe that is something that we ought to be doing more on, this subcommittee, and will.

But could you give us in a general way the use of the $265 million on anti-bioterrorism?

Secretary SHALALA. Yes. Thank you, Mr. Chairman. As you well know, unlike other kinds of terrorism, bioterrorism, the response for it needs to be done on the ground in local communities.

And, much of this money is focused on building up the public health infrastructure and educating the medical community, both in terms of identifying what may turn out to be a release of some kind of disease and reporting it as quickly as possible.

So what we do on the ground level is strengthen the existing public health infrastructure and the State and community public health officials that are responsible. And, simultaneously strengthen our surveillance systems, which were set up originally for infectious diseases, but now are full reporting systems for any kind of outbreaks, which are reported from the community, State, and then to the CDC, and our response time in our laboratory capacities across the country in being able to make a diagnosis quickly.

Senator SPECTER. Could you give me your evaluation as to the adequacy of our domestic program against potential bioterrorism?

Secretary SHALALA. The current program is inadequate. And that is the reason for these substantial investments at both the local level, the State level, as well as the national level.

Senator SPECTER. I would like to work with you on the staff level. I do not want to cut you short, but I want to come to a couple more questions.

Secretary SHALALA. We would be happy to do that. The person who is coordinating it in the Department, I want to point out, is the Assistant Secretary for Planning and Evaluation, Peggy Hamburg, who is a physician and the former New York City health commissioner.

Senator SPECTER. That is a good start.

Secretary SHALALA. We particularly picked someone who actually knows what you do on the ground and how you can strengthen the system from the bottom up.

MEETING DIVERSE NEEDS OF SCHOOL DISTRICTS

Senator SPECTER. Secretary Riley, last year we had a real battle over the potential for local flexibility on the issue of providing additional teachers. And the question which I would like you to provide for the record, because I want to ask another question before my red light goes on, I intend to observe it, is what is the disadvantage of allowing a school board to go for books or computers or some other facet, instead of hiring teachers to reduce class size?

PREVENTION OF YOUTH VIOLENCE

But the question I want to get a response from all three of you secretaries on is, our program against youth violence has looked at existing resources on the National Institute of Mental Health and Center for Disease Control, the parenting initiatives, et cetera.

MASS MEDIA ENTERTAINMENT AND YOUTH VIOLENCE

But what about the role of movies and television and the computer and video games? And we do not want to point fingers, as many have, there specifically. But to what extent should we look at that? Considering the first amendment rights and freedom of

speech, how big a problem is it? And what are your suggestions as to what we ought to be doing there? May we just work through the panel?

Secretary Riley, why do you not start?

Secretary RILEY. Well, when you have the distribution system this country has, the capacity to deliver and the amount and availability of information that we have now—and we have really only scratched the surface, you then are going to have considerable issues to deal with. And that is the availability of undesirable information and so forth to youngsters.

And I emphasize the important role that parents and teachers play in that. I think no matter how many filters you have, how much you try to deal with that—I was in the mine force in the Navy, and we were always talking about measures and countermeasures. And you get a countermeasure for filtering out something, and then they develop a measure to produce it in a different way.

So I think you can have all of that, and it is a help. But really, it falls back on, I think, parents working with young people, making sure that the availability and the use of these powerful tools is supervised and managed.

And the same applies with teachers in schools. Schools can do a better job than families, because they have the constant supervision of computers and other information. So I think it is a combination of things. All of these technical things are important. But really, it falls back on quality teachers and quality parents.

Senator SPECTER. I am going to come back to this question in the second round, because we have quite a large attendance. And I do not want to exceed the 5-minute rule here.

Senator Harkin.

PENSIONS PAID VIA LUMP SUM VS. ANNUITY

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

Secretary Herman, I sent you a letter on January 28 discussing what appears to be an increasingly common, but unfortunate, practice concerning pensions. What is happening is that many major companies offer employees retiring early the option of taking their pension benefits as a lump sum. ERISA requires that all defined benefit plans must pay benefits as an annuity, must pay it as an annuity, unless the employee and his or her spouse knowingly agrees to waive the annuity form.

Although the statutes and regulations require the plan fiduciary to disclose the "relative value" of the optional forms of a benefit, a growing number of these employers not only fail to disclose, some, I think, even try to hide the fact that the lump sum has a value far less than the annuity. I think this represents a clear violation of the specific ERISA statutes and regulations, as well as an employer's general fiduciary responsibility.

Have you looked into this? And are you proposing any plans to stop this kind of an abusive practice?

Secretary HERMAN. Senator, we are looking very carefully into it. And I certainly appreciate the concern and the interest that you have taken in particular in this issue, because what it really boils down to is the ability of beneficiaries, of participants, to make in-

formed judgements and their right to know. It is not necessarily the quantity of the information, but it is about the quality of the information that is needed to make critical retirement decisions.

And we want to continue to work with you and others in efforts to advance the whole education effort to ensure, first of all, that plan participants are getting the information that they need to make informed decisions about their own retirement.

But additionally, as your letter points out, we are also working with Treasury, and the IRS, to look at what formal steps we may need to take in this area regarding the specific obligations of ERISA. And I will be sure to have a written response to your letter in the very near future.

CDC'S BUILDINGS AND FACILITIES

Senator HARKIN. I appreciate that, and I appreciate your attention to this. And one of the examples I used in my letter, the annuity option had an actuarial value 80 percent larger than the lump sum. And yet, the information that was given to the employee did not point that out at all.

And, of course, you hold out a lump sum and tell them they can invest in the stock market and they can make all this fast money and stuff. It looks very nice. But really what is happening is, basically the employer is buying back the annuity at a very reduced rate.

So I encourage you to pursue this vigorously, and I am sure that you will.

Secretary Shalala, recently I visited the Center for Disease Control in Atlanta. And I have to tell you, I was shocked at the condition of the facility at the world's premier disease control center, the one that people around the world look to for the prevention of outbreaks, the rapid response to the various diseases and viruses that are coming out. I understand just in the last 20 years 35 newly emerging diseases have been identified and are becoming virulent.

I remember when Senator Hatfield left the Senate. He spoke on the Senate floor about the fact that with the Cold War over, it is no longer the Russians are coming, but the viruses are coming. And he spoke about the need to invest more basically in NIH.

I think we have focused a lot on NIH. You have, to your great credit, we have on this committee, to the chairman's credit, focused on doubling NIH research. He has been a great leader in that. I wonder if maybe we have not somehow kind of shortchanged the Center for Disease Control. I remember the movie Outbreak with Dustin Hoffman in it. I always assumed it was filmed there.

Senator HARKIN. That is sort of what I assumed. I get down there and find out that the movie producers came down there and looked at CDC and, as I understand it, refused to film it there because no one would believe how bad it was. So they went to Hollywood and built their own set. So what you see in the movie was not the actual Center for Disease Control.

Now I know they have a proposal in for new buildings. And I must say that the time frame is too long. I think somehow we have to collapse that time frame. I am just shocked. I do not know why I had not really paid more attention to this myself in the past. I think perhaps a lot of focused on NIH and the basic research.

But when you are talking about these newly emerging viruses and diseases and outbreaks of food-borne illnesses, I mean, this is where we look worldwide for rapid intervention.

So I just—and I have to believe that it makes it more difficult to recruit scientists, too, when they go down and take a look at that place. Who wants to work there? I mean, it really is bad. I know you know that. I mean, you have been there.

But I am just wondering for your response, just a general response, on the conditions and whether you think we should be pushing a little bit harder and faster on the buildings and renovation of CDC than what we are doing.

Secretary SHALALA. Senator Harkin, I welcome the opportunity to talk to you about that. I do not disagree with your comments. In fact, this year's budget has 122-percent increase in our request for construction money. It is part of a master plan.

What I would like to do is to work with the committee and identify and show you what we have done in a master plan. If you would like to shorten the amount of time, we would certainly be prepared to talk to you. But we have now laid out a master plan.

This may be a case of a little out of sight, out of mind. And, we need to pay attention. The focus on CDC, in this budget, is my personal highest priority. As I am ending my tour of duty in government and since I spent much of my career working with State governments, we could figure out how to finance capital projects.

We have to do it out of every year's budget, as opposed to stretching it out over time. And the budget rules are just irresponsible, in my judgment, about the financing of capital projects. We have to put everything in the budget in 1 year——

Senator HARKIN. Crazy.

Secretary SHALALA [continuing]. As opposed to spreading it over time. And we need to work through these issues when we are investing in institutions as important as the CDC or the NIH or any of the other institutions where we have to build facilities.

FDA also has a proposal here. It has been just as difficult to struggle to make sure that FDA has first-class facilities, because of the way the budgeting rules work, and not our lack of interest or attention to the structures that we think are so responsible and important to the quality of work.

Senator HARKIN. Thank you.

Senator SPECTER. Thank you, Senator Harkin.

Senator Feinstein.

CLINICAL TRIALS DATA BASE

Senator FEINSTEIN. Thanks very much, Mr. Chairman.

I want to compliment the three of you on your presentations. I thought they were excellent. With your permission, Mr. Chairman, I will submit a statement for the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR DIANNE FEINSTEIN

Thank you to all of you for coming before our subcommittee today. You are responsible for addressing some of the nation's most pressing problems. Let me name a few that face my state, the largest state in the nation, 34 million people.

California's needs

Our nation's schools face huge challenges—low test scores, crowded classrooms, teacher shortages, booming enrollments, decrepit buildings.

—California has 5.8 million students, more students than 36 states have in total population and one of the highest projected enrollments in the US.

—California will need 300,000 new teachers by 2010. Eleven percent or 30,000 of our 285,000 teachers are on emergency credentials.

—California has 40 percent of nation's immigrants; we have 50 languages in some schools.

—For school construction, modernization and deferred maintenance, California needs $21 billion by 2003 or 7 new classrooms per day. Two million California children go to school today in 86,000 portable classrooms.

—California's Head Start programs serve only 13 percent of eligible children.

—For higher education, the University of California has the most diverse student body in the US. Federal programs provide nearly 55 percent of all student financial aid funding that UC students received. Our colleges and universities are facing "Tidal Wave II," the demographic bulge created by children of the baby boomers who will inundate California's colleges and universities between 2000 and 2010 because the number of high school graduates will jump 30 percent.

So our needs are huge.

Fiscal year 2001 education budget

While these needs cry out for resources, the federal share of elementary secondary education funding has declined from 14 percent in 1980 to 6 percent in 1999. Funding is so short in my state that California teachers are spending around $1,000 a year out of their own pockets to pay for books, magic markers, scissors and other school supplies, according to the San Diego Tribune, August 16, 1999.

I commend the Administration for proposing to increase education funding in fiscal year 2001 to $40.1 billion or 12.6 percent. I welcome this increase. I hope we can do better because the status quo in American public education is not enough.

I would like to share with you, Secretary Riley, some of my concerns:

Title I: For the Title I program, I have two concerns: First is the "hold harmless" provision. Thank you, Secretary Riley, for opposing the Title I "hold harmless" provision that has been included in our appropriations bills. I hope you will more actively work to prevent its enactment again.

In 1994, Congress included in the Title I law a requirement that you annually update the number of poor children so that the allocation of funds would truly reflect the most up-to-date number of poor children. This is a very important provision to growing states like mine. However, despite my opposition, the hold harmless provision has been included in annual appropriations bills, effectively overriding the census update requirement and locking in historic funding amounts for states despite the change in the number of poor children.

Secretary Riley, I whole-heartedly agree with your statement last year—which I hope you will reaffirm today—that "a basic principle in targeting should be to drive funds to where the poor children are, not to where they were a decade ago."

With 18 percent of the country's Title I students, California only receives 11.4 percent of Title I funds. Please join me in vigorously fighting the hold harmless provision. At least, 775,000 eligible Title I students are not getting services in my state.

Second, on Title I, I hope we can work together to better focus the funding on academic achievement. Title I reaches virtually every school district and can be an important force for change. I hope you will give me your thoughts on how to put more "academic teeth" into Title I.

Head Start

Head Start is one of the most important federal programs because it has the potential to reach children early in their formative years when their cognitive skills are developing. Many studies have confirmed the significance of bringing positive influences to early brain development. But we know that poor children disproportionately start school behind their peers—they are less likely to count to 10 or to recite the alphabet. Every child deserves not just a good start, but a head start.

And yet, "Head Start has only vague performance standards and no curriculum to stimulate the growth of literacy and numeracy," say Henry Aaron and Robert Reschaeur in Setting National Priorities, The 2000 Election and Beyond. Research tells us that for every dollar invested, we save $7.00 in decreased expenditures for compensatory education, crime and welfare. I hope that both you Secretary Riley

and Secretary Shalala will discuss the plight and challenges of Head Start with me. I will have some very specific questions to pose to you.

The proposed addition of $1 billion for HeadStart to enroll 1 million more children by 2002, a 19 percent increase, is good first step. California has 764,462 poor children age 5 and under in poverty, but we only serving only 13 percent of eligible children. We must do better. I want to explore with you the challenge of major reform of the Head Start program to better prepare children for school at a time when high quality preschool programs can have long lasting benefits.

Impact aid

I am disappointed in your impact aid request. You are proposing to cut Impact Aid from $906.5 million in fiscal year 2000 to $770 million in 2001.

California has 119 school districts receiving Impact Aid, helping 1 million students. In fiscal year 2000, California is receiving $57 million in Impact Aid. In California, Impact Aid funds only 23 percent of the cost of educating a federally-connected student. This is an important program in a state that has many tax-exempt federal properties.

Immigrant education

I am disappointed that your budget request proposes flat funding—no increase—for immigrant education. Appropriations were $150 million in 1998, $150 million in 1999, and $150 million in 2000 and you have requested $150 million.

California receives $180.00 for each eligible immigrant child which hardly begins to address the needs these children bring to the classroom. These are the most at-risk of all children. They speak another language; their schooling has been interrupted and they have huge adjustment challenges. Can't we do better?

Other education challenges

I commend the President's initiatives on school construction, both the tax credits for bondholders and the new school renovation grants. These are long overdue.

The continued drive to hire teachers and reduce class sizes is right on target. California started reducing class sizes in grades K–3 in the 1996–1997 school year. We had then and we still have some of the largest class sizes in the country. And every parent knows that the smaller the class the more individualized attention students receive and the more effective the teacher can be.

CHILD CARE

Secretary Shalala, I am so pleased to see that the Administration has recommended $818 million for the Child Care Development Block Grant. As you know, Senators Dodd and Jeffords offered an amendment last year to increase funding to assist working families with the costs of child care. The Dodd-Jeffords amendment doubled the discretionary funding for the CCDBG by $818 million to a total of $2 billion. The amendment passed 41–54, but was dropped in conference with the House and was not included in the final version of the bill. I understand that Senator Specter has committed to including the increased funding in his chairman's mark for fiscal year 2001 appropriations. I am hoping these funds will not be forward funded this year, as in previous years.

HEALTH CARE

Now I will turn to health care, another important concern of Californians.

California's needs

We have an uninsured rate of 24 percent (7.3 million people), far above the national rate of 17 percent. Despite a thriving economy, the number of Californians without health insurance grows by 23,000 per month, far exceeding the national rate.

California has the second highest incidence of HIV/AIDS in the US.While the AIDS death rate has declined, it is till too high; 40,000 new infections develop each year. In California, 100,000 people are living with HIV/AIDS. Nationally, half of all HIV-infected people do not receive regular medical care (Rand study, December 1998).

California ranks 37th overall among states having children immunized by the age of 18 to 24 months.

In my state, 37 hospitals have closed since 1996 and 15 percent more may close by 2005. Over half my state's hospitals are losing money. Seismic safety requirements add more cost strains.

Health budget

National Institutes of Health

While I welcome the $1 billion or 5.6 percent increase, I am told that to keep us on the path toward doubling NIH over five years, the increase should be $2.7 billion. Even though Congress has given NIH generous increases in the last two years, NIH is 1999 could still only fund 32 percent of grant proposals.

Our investment in biomedical research has given us longer lives, healthier lives, and cures and new treatments.

This is an area of governmental activity that Americans overwhelmingly support. Fifty-five percent of Californians said they would pay more in taxes for more medical research

Cancer

The President proposed only a 5.9 percent increase for cancer research.

Cancer is a concern of virtually every American. Fifty percent of Americans have had someone close them die from cancer.

The American Cancer Society and other major cancer groups are calling for a 15 percent increase for the National Cancer Institute, raising NCI from $3.25 billion to $4.1 billion.

The Cancer March, that came to Washington in September 1999, called for increasing the National Cancer Institute budget by 20 percent each year for 4 years, to get to $10 billion by 2005. They cited the impending "cancer explosion," coming with the aging of the American population. Because of the aging of the population, the incidence of cancer will reach staggering proportions by 2010, with a 29 percent increase in incidence and a 25 percent increase in deaths, at a cost of over $200 billion per year. The cancer burden will balloon especially in the next 10 to 25 years as the country's demographics change.

Why invest more in cancer research? The Cancer March Research Task Force said we could reduce cancer deaths from 25 to 40 percent over the next 20 year period, saving 150,000 to 225,000 lives each year. Other areas that could be enhanced are bringing new cancer drugs from the laboratory to clinical trials; continuing to identify genes involved in cancer; improving our understanding of the interaction between genes and environmental exposures; finding new ways to detect cancers earlier when they are small, not invasive and more easily treated.

We must also improve participation in cancer clinical trials. Medicare beneficiaries account for more than 50 percent of all cancer diagnoses and 60 percent of all cancer deaths, but only two percent participate in clinical trials.

Along this line, I hope Secretary Shalala can tell us today that the clinical trials database that we enacted in 1997 is all ready to go. This is an important 1–800 number for patients and doctors to find out what research trials for serious and life-threatening diseases are underway.

Cancer prevention is another area that needs increased resources. The American Cancer Society says that 60 to 70 percent of all cancers are preventable. We need to do more in this area so that Americans never get cancer.

Other health programs

I welcome the President's initiatives to fill in some of the gaps in health care—new initiatives like expanding the CHIP program to children's parents; strengthening enrollment in CHIP through schools and child care centers; increasing funding for community health centers; restoring Medicaid to immigrant children who entered the U. S. after August 1996 and to legal immigrant pregnant women; increases for immunizations; for HIV/AIDs services. All of these are very important to my state.

I do have to question why the HHS budget cuts funding to train health professionals by $84 million. Almost one in five Californians lives in a health professions shortage area. We are facing a nursing shortage and will need 43,000 more nurses by 2010, which is a conservative estimate based on a projected 23 percent increase in the state's population.

Even though we have a booming economy, we are faced with many challenges to which your budgets respond. I look forward to working with you to craft a final bill that responds to these concerns that I have outlined.

I am also concerned about the delay in establishing the clinical trials database. We passed the FDA bill requiring NIH to set up a toll-free 1–800 number in 1997. We created it at the suggestion of patients and their doctors who said they need one simple place to go to find out what research trials were being conducted. I am quite concerned that, two and a half years later, this still not be set up and announced. I hope you will have good news today, Secretary Shalala.

Thank you again for coming before our subcommittee.

Senator FEINSTEIN. Secretary Shalala, it is my understanding that last night your department announced that you are implementing the clinical trials database Senator Snowe and I authored. Will it now be possible for an individual to call a 1–800 number and get information about clinical trials relating to acute diseases?

Secretary SHALALA. More important than just the 1–800 number, they will be able to go on the website, get information about individual clinical trials, and find out who to contact about that particular clinical trial. So it is a very transparent system on clinical trials. I think the first 4,000 are up and on the website.

So from our point of view, your initiative and our ability to get this up on the website so that people find out what the clinical trial is doing, how to enroll, and specifically who to call, this is a major step forward in health in this country.

Senator FEINSTEIN. Well, thank you very much.

Secretary SHALALA. And thank you for your leadership.

HEAD START

Senator FEINSTEIN. Well, Senator Snowe and I appreciate that very much. Thank you.

Let me just share with you some of my thinking about Head Start. I appreciate very much that there is an additional $1 billion to expand the program by about 17 percent. I am coming to question whether we should expand the program prior to the time we make Head Start truly a Head Start program. I am finding that many Head Start classrooms do not teach any cognitive skills whatsoever.

I am also finding that the standards are vague and that Head Start is a missed opportunity. One of the major cities in California has just told me they can only pay $22,000 a year for a Head Start teacher. You are not going to get a Head Start teacher that is going to bring about any quality education for that.

And then I took a look at the French system, looked a little bit about what the Core Knowledge Foundation is doing in setting up some model Head Start programs. I really think we are missing the boat by expanding Head Start without improving the quality of the program first.

And since this is a 100-percent federally funded program, it seems to me that not only do we miss the boat, but we have an obligation to see that standards and quality are present. I think there is enough information. Cognitive learning is quite possible in children of a Head Start age.

My questions are these, and I will just ask them, and then perhaps you can respond: What is HHS doing to move Head Start from custodial child care to a program that stresses cognitive development and learning?

Second, would HHS be opposed to changing the focus of the Head Start program so that more attention is placed on the development of cognitive skills?

Third, what kind of coordination or communication does the Department of Education have with HHS on this program?

And finally, should we not really move Head Start to the Department of Education and convert it into a strong preschool program and focus on cognitive development?

COGNITIVE SKILLS AND STANDARDS IN HEAD START

Secretary SHALALA. Let me answer those questions quickly. The answer is that Head Start is the strongest preschool program that we have in this country. Over the last 7 years this administration has invested substantially in improving not only the cognitive learning part of the program, but in raising the standards. In fact, 25 percent of all the new money going into Head Start has been invested specifically in raising the quality of the program.

So tough have we been on this program that we have closed over 150 Head Start programs that did not meet our standards. No other government program has been as effective in both raising standards and closing down programs that did not meet our standards.

Before we came into this administration, not one Head Start program had ever been closed for not meeting its standards in the history of its program.

The difference between Head Start and other kinds of custodial programs is in fact its investment in training and in specific standards. In fact, the specific rules of Head Start, are much more detailed than other programs.

I would be happy to talk to you at some length about the cognitive part of Head Start. But the genius of Head Start is that it is comprehensive. It integrates both health, social services, education and learning.

CUSTOMER SATISFACTION IN HEAD START

The evaluations of the program have concluded that it is a stronger program than any other preschool programs in this country. And parents' satisfaction of this program is the highest of any government agency or government program that we have. It is even higher than the ratings for Mercedes and BMW in customer satisfaction of the program.

SHOULD HEAD START BE TRANSFERRED FROM HHS TO ED?

Do I think it should be transferred to Education? I do not. But let me tell you specifically why. First, the history of Head Start is a history of a program that was started because of what was perceived as the weakness in the education programs in this country, a lack of parental involvement. However, we have built a series of partnerships with the Department of Education.

And increasingly there are incentives in Head Start for public schools to integrate Head Start programs with their other preschool programs, their kindergarten programs. So there is a seamless program.

But evaluations have shown something very interesting. And that is, where Head Start programs are standalone, there is more parental involvement than in these new cooperative endeavors with public schools. That is, you get less parental integration into the program when there is a cooperative agreement with a public school than you do with standalone programs.

That means we see ourselves as reformers of the role of public schools and of public education. And no one has been a stronger

supporter in HHS than I have been of public education in this country.

But it is a different kind of program of the highest quality that has played an important role, I believe, in our understanding of preschool education and its quality by any measure.

If you trotted out here the world's greatest experts on early childhood education, including the experts from the Yale Study Center, they would say to you, this program has gone through a transformation over the last 7 years, that it is strong both cognitively in terms of what it teaches and in the way it is managed and the way programs are integrated.

So we started out with an overall assessment by experts in the field. They told us what to do. We have incorporated those. We have invested this money heavily in improving the quality, teacher training, and all the other parts of the program.

But simultaneously, we have kept the heart of the program. And that is integrating parents into the learning process for these young people.

Senator SPECTER. Secretary Shalala, you are on a very big subject. Could you supplement your answer for the record?

Secretary SHALALA. I will, yes.

Senator SPECTER. Because we are pretty much over time.

Secretary SHALALA. With both the data and the research. And I would be happy to look at any California programs that my good friend, the Senator from California, thinks are weak in particular. And I would be happy to have our teams look at them very carefully.

Senator FEINSTEIN. Mr. Chairman, would it be possible to ask Secretary Riley to respond to that as well?

Senator SPECTER. Well——

Secretary RILEY. How about in writing?

Senator FEINSTEIN. In writing?

Senator SPECTER [continuing]. If you can briefly.

Senator FEINSTEIN. In writing would be fine.

Senator SPECTER. If you can briefly respond orally, and supplement it, Mr. Secretary, in writing, because we do have other Senators who are waiting.

FOCUS ON COGNITIVE SKILLS IN EARLY CHILDHOOD

Secretary RILEY. Very briefly, I want to thank Secretary Shalala for really honing in during the reauthorization of Head Start a couple years ago and all the work that has been done since in centering on standards and quality.

I think the question, Senator, is the cognitive skills for early childhood, which, as you point out and as Secretary Shalala has pointed out, have gotten more attention with all the brain research and so forth. The question is, are they provided, and not how and where.

I am not into the empire building of the Department of Education. I am interested in cognitive skills being there in Head Start. And as I read it, they are very strong. That is a very strong focus from HHS now, and they really are trying to move in that direction as rapidly as possible and are doing a grand job moving in that direction.

We are working closely with them, with the overlap of Title I. The flexibility of Title I enables school districts to use Title I for early childhood. And so we are seeing more and more of that, and we are working very well in a cooperative way.

[The information follows:]

HEAD START

Head Start is America's premiere early childhood education program, and continues to lead the way in state-of-the-art approaches to enhancing young children's development. Head Start's performance standards are, in fact, quite comprehensive and clearly delineate what programs must do in serving children and families. These standards cover the areas of Education and Early Childhood Development, Child Health, Child Mental Health, Child Nutrition, Family Partnerships, Community Partnerships and Program Governance, among others. A copy of these standards is attached. Furthermore, it should be noted that the Performance Standard on Education and Early Childhood Development clearly requires that all programs must, in collaboration with Head Start parents, implement a curriculum and goes on to discuss what this curriculum must include.

This Administration has invested heavily in improving not only the cognitive learning aspects of this program, but in raising its standards. We have paired investment in critical elements of quality such as teacher compensation and training with a tough approach to enforcement of high standards in every Head Start program. Annual salaries for Head Start teachers have increased from $14,600 in 1992 to $20,700 this year. Since 1995, more than 140 local grantees have been replaced because they have been unable to rectify deficiencies in program quality. We will continue these investments in fiscal year 2001 and will devote more than half of all new Head Start money to continued improvements in the quality of the program.

In addition, Head Start has made a commitment to measuring child outcomes, including cognitive outcomes as well as other key aspects of children's development and parental involvement. Our research shows that typical children leave Head Start with a wide range of specific knowledge and skills that prepare them for kindergarten. These practical, common sense achievements form the foundation for continued progress in learning by Head Start children in kindergarten where they show statistically significant growth in vocabulary, letter recognition, writing and other pre-reading skills.

Head Start provides top-quality early childhood education along with comprehensive services, such as health, nutrition, and family support services, to almost 900,000 low-income, preschool children and their families across the nation, including more than 81,000 children and their families in California.

Head Start currently places a strong emphasis on cognitive skills. Preliminary results from the Family and Child Experiences Survey (FACES) indicate that average program quality is in the "good" to "excellent" range and no classroom scored below the "minimal quality" range. Head Start children are ready for school, performing above the levels expected for children from low-income families who have not attended center-based programs. The survey also found that 66 percent of Head Start parents read to their child three or more times a week and that 70–90 percent of parents teach their children letters, numbers or songs.

We are building upon this progress with new initiatives, including expanded training in family literacy services, new partnerships with pre-kindergarten and child care programs, and the development of local grantee systems to track and analyze child outcome data.

The Head Start Bureau has extensive collaborative relationships and initiatives with the Department of Education, including the following:

—Recent joint sponsorship with Title I, Even Start, and HHS's Child Care Bureau of a national leadership forum of State leaders and managers of pre-kindergarten, Head Start, and child care programs to explore new opportunities to use State and Federal early childhood funding to reach more children with higher quality services and to identify ways to eliminate barriers to cross-program collaboration.

—Long-standing involvement with ED in joint efforts to serve infants, toddlers, and young children with disabilities, including participation in the Federal Interagency Coordinating Council, and public-private partnerships such as the Conrad Hilton Foundation/Head Start $15 million initiative to training community teams of Early Head Start, ED early intervention program providers, par-

ents and other community agency leaders to improve serving to infants and toddlers with disabilities.

—Collaborative efforts in research and accountability efforts, including joint sponsorship and funding of major longitudinal studies of early childhood development (including the National Center for Education Statistic's Early Childhood Longitudinal Survey, Kindergarten & Birth Cohorts) and emerging efforts in Title I and Even Start to utilize the Head Start Performance Measures outcome measures in Federal evaluations and State-level accountability efforts.

—Additional leadership efforts between Head Start and public education programs and systems occur at the State and local level through the nationwide network of Head Start-State Collaboration Offices which give priority attention to forging linkages among local Head Start agencies, family literacy initiatives, State pre-kindergarten programs, and local education agencies.

—Finally, and most importantly, every local Head Start grantee is held accountable for maintaining strong and effective partnerships with local elementary schools and districts through specific mandates covering the provision of family literacy and adult education services, services to children with disabilities, and preparing every child and family for a successful transition to kindergarten.

Senator SPECTER. Mr. Secretary, thank you for that amplification.

HEAD START STAFF SALARY LEVELS

Senator HARKIN. If I might just say one thing to my friend from California. You are not going to get good cognitive skills teaching to the point that we want in Head Start if you are going to keep paying Head Start teachers as babysitters.

Secretary RILEY. That is true.

Senator HARKIN. If you are going to pay them at the rate of babysitters, that is what you are going to get. Now if you want to start getting cognitive skills—the big scam on Head Start is what we are not paying the Head Start teachers.

Senator SPECTER. Secretary Shalala and Secretary Riley, Senator Feinstein raises a very important question. And we have been in conference on these figures, debating precisely the issues which both Senator Feinstein and Senator Harkin have raised.

If you would—I think this is something we ought to pursue at the staff level. This may even be a subject for a full blown hearing. But let us pursue it at the staff level. And if you could supplement your verbal answers in writing, we would appreciate it.

Senator Murray.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman. And thank you to all three of the cabinet members who are here today, and I just personally thank you for all the work you have done on behalf of so many children and families in this country in your service. And I really do appreciate it.

CLASS SIZE REDUCTION FUNDING

Secretary Riley, let me begin with you. The chairman asked you a question and a response in writing, but I really would like to hear your opinion on the debate that we continue to have on whether or not to focus targeted money on reducing our class sizes by hiring additional teachers or whether or not just sending that money out to schools to allow them to purchase books or pencils or paper or computers or whatever their needs are.

I do not think there is any doubt in anybody's mind that there are tremendous needs in our public schools for those kinds of things. But what are the advantages of targeting it directly to hiring additional teachers?

ROLE OF FEDERAL EDUCATION PROGRAMS

Secretary RILEY. Well, of course I look at the Federal role as being one of support of the States and local schools, but with a national identification of a priority and a targeted effort. That is how Federal programs are most effective, and that is the role as I see it.

CLASS SIZE REDUCTION—USE OF PROGRAM FUNDS

We have as a goal for this Nation to get the class size of early grades down to 15 to 18 pupils per teacher—and the research shows that that works. It works in those grades. It works in the eighth grade, in the twelfth grade, and on into college. It makes a difference in a child's education.

So by setting the national goal to do that—to reduce class size, and that is a proposal that you have strongly supported, then we have to move in that direction. If you then lump that in with a block grant kind of approach, what you do is you take your eye off the prize.

You take your eye off the focus, your eye off the national goal in this country of saying that all children will have a relatively small classroom in those early grades with a teacher well qualified to teach reading.

So I am very much in opposition to lumping national goals, national focus, in with a number of other things. You have no way for accountability. There is no way you can look at how well it is working, if people have all kinds of options.

Now I think within a program, there should be enormous flexibility. In the Federal Government, of course, under the proposal that you and I have supported, they do not pick the teachers, they do not decide what classes to do what in. It simply is a Federal priority targeted for that direction. And that is what makes a difference. And you can look at it in the future, see if it's working, or if it is not, determine why.

CLASS SIZE AND SCHOOL VIOLENCE

Senator MURRAY. Thank you very much, Mr. Secretary. And the chairman asked about this issue of school violence. In talking to the teachers who are now in classes of 15 or 16, they tell me specifically that they now can focus attention on young kids and have them have that adult-child relationship that they believe will make a difference on the issue of violence later on.

So if we do have that targeted approach, we will be able to follow that more closely. And I appreciate your response.

EDUCATIONAL TRAINING AND WELFARE RECIPIENTS

Secretary Shalala, I have a question for you. I am hearing a lot of anecdotal evidence in my State and elsewhere that many of the community college programs that typically were filled with return-

ing welfare-to-work mothers, nursing programs, things like that, are empty this year. Enrollments are way down. And a concern that because education is no longer considered a—that you need education as part of your welfare, that we have lost a lot of those moms, young moms, either back home in perhaps an abusive situation that they cannot get out of or in jobs that are going to go nowhere.

Are you hearing this at your level as well? And I really would like to hear from Secretary Herman and even Secretary Riley on this, because both of you mentioned the disparity in people who are able to go to college and in the disparity in the workforce between those who are able to get into higher paying jobs and not.

And I am worried about this component of those welfare-to-work moms, if they are not getting into programs in our colleges that will help them get into those higher paid jobs.

Secretary SHALALA. Senator Murray, when the welfare bill was written, it left to the States the decision about whether full-time college attendance could be integrated, and you would not lose the 2-year time frame. So those decisions were left to the State, as opposed to something that was automatic.

The vast majority of college students in this country are now going part time. That is, they are working and going to school. And while that is a particularly heavy burden for young moms and for people coming from welfare to work, the fact is that in their own neighborhoods, in the houses next to them, are people who are combining work and going to school.

And I just think the States have struggled with this issue. Is it fair to allow a small group of people, because they came through the welfare system, to go to school full time and be subsidized by the welfare system as an investment in their long-term earning potential versus people who live next door to them that have chosen to go directly into dead end jobs, but at the same time go to school part time to help increase their earning power over a period of time?

There are numerous programs which Secretary Herman can outline that are available for people to combine the two or that they can get into. But the States addressing the issue of fundamental fairness, some States have struggled with it and said, yes, you can go to a 2-year community college. Other States have said, well, maybe for certain people a 4-year program in nursing, for example.

I fought the State of New York, when I ran Hunter College, trying to get them to allow welfare, former welfare, recipients to stay in 4-year nursing programs because my belief was that their earning power at the end would be substantially better. But I do understand the fairness problem, because at that institution were people from the same neighborhoods, with the same socioeconomic backgrounds that were combining the two and killing themselves in the process for doing that.

Senator MURRAY. Well, if nobody——

Secretary SHALALA. So I think the States have——

Senator MURRAY [continuing]. Is in our nursing programs, then we do have a problem.

Secretary SHALALA. Right. And nursing programs are a particular problem, because it is hard to do them part time. There are

a set of programs, physical therapy, nursing, where it is a particular problem because it is hard to do those programs part time. You can do a 2-year program part time often, a certification program, but it is hard to do a 4-year program part time.

So the States can make the decision to allow someone to do it, and many of them have struggled with the decision. We do not have a national standard that we can impose. Congress specifically——

Senator SPECTER. Senator Murray, would you like that answer amplified for the record? Because we are going to have to move on.

Senator MURRAY. I would. I know Secretary Herman, if she could just comment in a 10-second time frame, I would like to hear what she has to say.

Senator SPECTER. Take 10 seconds, Secretary Herman.

Secretary HERMAN. I think Welfare-to-Work had unintended consequences in regard to educational opportunities. We did amend that last year to allow vocational education and job training for up to 6 months. And we are making further progress.

Senator SPECTER. Thank you very much.

Thank you very much, Senator Murray.

Senator Reid.

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

I am wondering if—in the audience is Dr. Koplan. I wonder if he could respond to some questions. He is head of the Centers for Disease Control.

Senator SPECTER. Well, we had planned to call him at the conclusion of this panel. But if you want to do that in your 5-minute round——

Senator REID. That would be great.

Senator SPECTER [continuing]. We would do that.

Wait just a minute, though.

We have asked Dr. Jeffrey Koplan to be present at this panel today. And I had, as I stated, planned to call him at the conclusion of this round. But to accommodate Senator Reid on his schedule, we will move to Dr. Koplan at the present time.

We have written Dr. Koplan, and he has responded. And those letters will be made a part of the record concerning expenditures made at the Center for Disease Control, which are at variance with what the congressional authorizations were, congressional appropriations.

With that, Senator Reid, you can begin your round of questioning.

DR. WILLIAM BELLINI'S STATEMENT

Senator REID. Thank you very much, Mr. Chairman. You, as usual, are right on line. I was greatly disturbed to read a quote earlier this month in newspapers all around the country, in The Washington Post particularly, when one of Dr. Koplan's staff members, a Dr. William Bellini, who is in charge of the measles program, told the inspector general, and I quote, "It's a bigger crime to follow Congress's direction than to spend money where science dictates," end of quote.

This is the basis for a very troubling thing. In the mid-1980s, Mr. Chairman, in Lake Tahoe, a series of people came down with a dis-

ease that was then known as Epstein Barr syndrome that is now is chronic fatigue syndrome. Under the good auspices of this committee, we were able to get some money to specifically study that disease.

We were very disappointed to learn that that money was spent for something else, because they thought it could be better spent on something else. If it were only Epstein Barr that money has not been spent properly for, maybe we could say that was a mistake. But now we learn that the Hanta virus, money that was set aside for that, which is also a western United States disease where people are dying as a result of this disease, who are being exposed to something, we believe, dealing with rats. We are not too sure.

And then I have been getting mail the last few days, Lyme disease, the same thing. You know, we have report language, and it is ignored on many occasions. But when we appropriate money for a specific program, that is the program it should be spent on. And words cannot describe how disappointed I am.

I have people all over the country that are writing to me that have been extremely sick. And this is not just Congress coming up with this. We have had the Inspector General look at this, and he acknowledges that they are spending money on programs other than what it was dictated for.

So, Dr. Koplan, as I say, I just think this is outlandish. And I think the excuses that we have from your department are not very good. I appreciate the apology. You in writing apologized. But the answers that we have are just very, very bad.

I recently received an employee, who, if their name were disclosed, would of course get fired. But they have sent me a batch of stuff, which I have sent on to the inspector general, where this is going on in the Centers for Disease Control.

I do not know how to say this, but a stop has to be put to this. It is very, very difficult. It took me more than 10 years to get specific money for this Epstein Barr program. And then to have your office, your department, spend it on something else, and then we learn later it is Hanta virus, it is Lyme disease, we do not know what else.

How do you respond to this? And I would also like to know how in the world can you have somebody working for you that in effect spits in Congress's face, William Bellini, who says, "It's a bigger crime to follow Congress's direction than to spend money where science dictates."

[The information follows:]

QUOTE FROM THE WASHINGTON POST

The comments at the hearing, drawn from a Washington Post article, were inaccurately attributed to Dr. William Bellini, a Centers for Disease Control and Prevention employee.

Secretary SHALALA. Senator, if I might——

Senator REID. I asked the questions, Ms. Secretary, to Dr. Koplan.

Dr. KOPLAN. Senator Reid, thanks for giving me the opportunity to respond to this. First of all, let me answer your last question first, which is that we have 8,000 employees, and the sentiments

that you just expressed, that one of them was quoted as saying, are antithetical to my own beliefs and opinion.

As Director of CDC, I can tell you that the vast majority of our staff, and all of our senior managers and decision makers believe strongly in following the directions of Congress, the budgetary directions of Congress and congressional intent. And that has been made clear to our staff top to bottom. And I strongly believe that, and I cannot emphasize it enough to you.

Individual quotes, certain individuals in the institution do not speak for the institutional as a whole.

Senator REID. Do we just let that go? Is there anything in his record? Do we let it—is he just down there drawing his merit pay with this?

Dr. KOPLAN. I do not know the individuals involved in detail.

Senator REID. But do you not think that should be flagged and take a look at this? I mean, this does not speak well of the Centers for Disease Control.

Dr. KOPLAN. All of our staff have been told by me——

Senator REID. I want to know what——

Dr. KOPLAN. Might I finish, Senator?

Senator SPECTER. Senator Reid. Senator Reid, let him finish his answer.

Dr. KOPLAN. All of our staff have been told in very clear terms what the relationship with Congress is, how I view the importance of that, and what our responsibilities and obligations are, both the Congress and the American public. And the type of attitude you just described is not tolerated in what we do.

We have put in place——

Senator REID. OK. Not tolerated. What has happened to Bellini? Nothing?

Dr. KOPLAN. I cannot describe personnel actions toward individuals, but I believe individuals are still allowed to express themselves on a wide variety of topics that I cannot necessarily tell them what to think.

That is not an attitude or an expression of opinion that is likely to encourage someone to take any more management responsibility or have any policy options within our organization.

By the same token, I have not had a chance to speak to this individual. I do not know what he was saying in general. And I do not know where the quote comes from.

Senator REID. I told you.

Senator SPECTER. Senator Reid. Senator Reid, let us come back to this. Senator Craig has been waiting.

We are going to take it up, and we will have another round in a moment or two.

Senator Craig.

Senator CRAIG. Mr. Chairman, I came here to listen. I am intrigued by what Senator Reid is saying. If you can trust the Center for Disease Control, nearly every agency—not every agency. A good many agencies I work with more dominantly than I do these——

Senator REID. If the Senator would yield, I heard the Senator dealing the Forest Service a week ago, the same situation.

Senator CRAIG. Last year it was $400 million there, and they do not come back to their authorizing committees to get reauthoriza-

tion. They just reprogram. And that is very frustrating to a Congress that oftentimes directs very specifically where the money should be spent.

Now there are ways to reprogram money. You come back to the authorizing committees, and you get the consent of Congress to do so. Somehow in this administration we have had a real problem at times. But I am not singling out any one of these secretaries. When I say that, I am saying that in a generic form.

And, you know, as a member of the Appropriations Committee, we only know how to get tougher by firewalling and straightjacketing. And that does not offer the flexibility that sometimes is necessary. But I do not blame the Senator for being frustrated. There is clear evidence of those kinds of remarks and attitudes.

Senator HARKIN. Would the Senator just yield for a second? I think the Senator may have just misspoke. Reprogramming comes to the appropriating.

Senator CRAIG. You are correct. Reprogramming comes to the appropriating committees. But oftentimes, reprogramming, if it is significant enough, the appropriating chairman also consults with the authorizing chairman, which is wise and responsible to do when it comes to significant changes in direction that have happened. That is what I am suggesting.

Mr. Chairman, thank you very much.

Senator SPECTER. Thank you, Senator Craig.

Let us proceed with Dr. Koplan, since Senator Reid has brought it up. And we will conclude this. We do have some other questions for secretaries.

Dr. Koplan, the difficulty arises in part from the fact that there had also been misstatements by the Center for Disease Control as to the chronic fatigue syndrome research program, where funds were allocated in a different way, so that it appears to be a repetitive problem.

Senator Reid has pressed you about Mr. Bellini's statement. Had you heard that before Senator Reid raised it with you this morning?

Dr. KOPLAN. I have not heard Mr. Bellini's statement before. No.

Senator SPECTER. You had not heard about it before today?

Dr. KOPLAN. We had an inspector general's report that was delivered to me in May. There were background paperwork to that report that an inspector general's office did not provide me with. And I believe some of the quotes that are being provided are from background documents that I had not seen.

Senator SPECTER. But your statement to the subcommittee is you had not heard about what Mr. Bellini had said prior to the time Senator Reid brought it up this morning.

Dr. KOPLAN. I had not heard Mr. Bellini's quote.

Senator SPECTER. All right. Well, that is—first of all, we ought to make the determination as to whether it is true that he in fact did say it. And if we make that determination, then I think there ought to be an investigation by you in the first instance, Dr. Koplan, as head of the Centers for Disease Control, to see what an explanation would be, if we determine the statement was made.

When you deal with this sort of a statement, you have a potential violation of the Penal Code Section 1001, a false official statement. And we do not want to start to deal with that. But there is a high level of concern, really anger, in the Congress about what has happened here.

Dr. KOPLAN. Chairman Specter, I share it. I share that concern. And the institution, CDC, and myself as responsible, erred in both reallocating funds and in not reporting it and not having appropriate discussions with the folks who we are dependent on for our well-being and for your trust. We have made a mistake. That mistake seems to be larger than just one unit.

And because of that, we have put in place recently I think strong measures to address it and to address it across the whole institution. We have done several of them in partnership with Secretary Shalala.

OIG REPORT

Senator SPECTER. Have you inquired of the inspector general, who made the report, what the details were, so you would be in a position to answer?

Dr. KOPLAN. The inspector general presented me with a report last May.

Senator SPECTER. You have already said that. My question is: Have you inquired of them to find out more?

Dr. KOPLAN. We met with them. They gave us a set of recommendations to put in place. We put those in place and went several steps further in putting into place recommendations.

Senator SPECTER. Let me come back to my question, which you still have not addressed. Did you inquire of them as to what other information they had? You said they submitted a report. You said you met with them, and you put more steps into play. But have you found the details of their investigation? Have you said to the inspector general, tell us all you found here, so we can deal with it?

Dr. KOPLAN. We asked for all they had found, and they gave us that set with recommendations. They did not provide us with background material, which they normally do not supply to agencies; in other words, interviews they do with everyone who they met with.

Senator SPECTER. Did you ask for that?

Dr. KOPLAN. No, we did not ask for it.

Senator SPECTER. Well, I suggest that you do that. I would suggest you make the inquiries.

What assurances are you in a position to give that this problem is going to be corrected in a forceful way?

Dr. KOPLAN. Thank you. One, we are working with the department. The Department is placing a financial officer to provide oversight for our Center for Infectious Disease expenditures. That is the larger unit in which Hantavirus and chronic fatigue syndrome sits.

Senator SPECTER. Are there any items besides those two where you have knowledge that there has been misstatements by the Centers for Disease Control?

Dr. KOPLAN. There are no items besides those two in which I believe there are misstatements. But we are putting in place a sys-

tem that is going to look broadly throughout the agency, including a management review of all of CDC's budgetary practices, to look everywhere and try to uncover it.

Senator SPECTER. Have you taken any disciplinary action against anybody who made a false report?

Dr. KOPLAN. I have reassigned a senior official in our Division of Virology and put new leadership in the Division of Virology.

Senator SPECTER. Anything beyond the reassignment?

Dr. KOPLAN. Reassignment is a pretty strong action in our institution.

Senator SPECTER. Well, sir, my question was: Anything beyond a reassignment?

Dr. KOPLAN. No.

Senator SPECTER. Just one individual, one reassignment.

Dr. KOPLAN. That is correct.

Senator SPECTER. Is that individual the only one who has been determined to have made a false statement?

Dr. KOPLAN. I am not sure that individual has made a false statement. That individual was reassigned to assume other duties to——

Senator SPECTER. OK. Why did you make a reassignment of that individual?

Dr. KOPLAN. I think there are other duties to which he is better suited. And we can make more improvements in the division for which he was responsible and——

Senator SPECTER. So that reassignment is not related to the false statements.

Dr. KOPLAN. I am not sure of the false statements you are referring to, sir.

Secretary SHALALA. Senator Specter.

Senator SPECTER. I want to finish this. I want to finish this.

Have you made a determination as to any employees at CDC who made false reports relating to these two items, chronic fatigue syndrome and Hantavirus?

Dr. KOPLAN. There have been disciplinary actions taken at CDC to personnel.

Senator SPECTER. How many for false statements made with respect to Hantavirus and chronic fatigue syndrome?

Secretary SHALALA. Senator Specter, we have a privacy issue here, if we might take a break and talk to you privately about what we can say on the record.

Senator SPECTER. Well, is there a privacy issue, Madame Secretary, if names are not named?

Secretary SHALALA. Yes.

Senator SPECTER. Why?

Secretary SHALALA. Because anything that could lead to the individuals—you are the lawyer. But I certainly would like to discuss this, not on the record, before the director of the CDC responds to that.

Senator SPECTER. Well, I do not see a privacy issue in the absence of any specified person being identified or a category which could lead to the identification. But at your request, we will take a brief recess.

Let us step into the back room, Madame Secretary, Dr. Koplan, Senator Reid.

Senator HARKIN. I think I am next. I just might say that I have looked at this issue, too. And I am equally upset about it as just about anybody else could be. And I think I have looked into it in-depth. I would just like to state for the record that I have met with Dr. Koplan both here and in Atlanta about this issue.

It goes without saying that people should follow the intent of Congress. I can somehow see how this thing transpired. I do not know that anyone made intentionally false statements.

I think the budget office responded to a question asked by Congressman Porter, I think, using what knowledge they had at the time of what was done. I do not think that the budget office—this is my own opinion—really had the information about what had happened to the funds.

I am not—I do not want to sit here and go on with this thing that somebody made false statements. I do not know that that is so. And from my look at it, I do not believe that is so. I believe statements were made based upon the best information that people had at the time when they made that statement. That is not intentionally making a false statement. I want to make that clear.

Second, I think what maybe Secretary Shalala said earlier about being out of sight, out of mind, I really do believe that whereas we have in the past continually worked with NIH as to how they are spending the money that we give them, and we do not earmark, but a lot of times we make our intentions known about where Congress wants to move, whether it is in AIDS, Ryan White type of initiatives, or whether it is in breast cancer research, a myriad of things that we give congressional intent.

We are constantly—you do it, Mr. Chairman. I did it before, when I was chairman. We constantly have them up here to tell us what they are doing and how they are proceeding. And I would say even myself, when I was ranking on this, I did not bring CDC up here to talk to them. They were down there doing their thing.

And I just think that perhaps we need a new relationship with the Centers for Disease Control and Prevention, to keep a closer working relationship on exactly how this money is going out and what they are doing and how they are operating.

I talked with Dr. Koplan about what had happened down there and the reassignment of certain individuals. I had not heard the statement before either. This is the first time I had heard that statement. And I obviously need to know more about whether it is so and how it was said and that kind of thing before we can take action on it.

But from what I have heard from Dr. Koplan, I am reasonably assured that steps have been taken on their end to correct this and make sure it does not happen again. I think what we do, what we have to do here as appropriators, I believe, is to establish a closer type of a working relationship with CDC and to have them up here more often to talk about where we are investing this money and what the intent of Congress is.

But I think this is a two-way street. You had that relationship with NIH. I just do not think we have had it with the CDC.

Senator SPECTER. Well, thank you, Senator Harkin. I do not know if there has been a false statement made either here. But when Dr. Koplan testifies that one person has been reassigned and that that is not related to a false statement, but for efficiency, that is really not—that is really beside the point of the question.

And then he said there has been disciplinary action taken. With the record of the Center for Disease Control and the very substantial sums involved here, my sense is that this subcommittee has a duty to inquire and to find out what has happened.

We are going to respect privacy. The questions asked of Dr. Koplan did not go to any individual or any category of individual, but just to find out if there had been a report of falsification and, if so, whether it was determined to be true or false and, if so, what action was taken.

But when Secretary Shalala wants a session off the record, we will do that. Let us do that promptly, because we are going to have to conclude this hearing in the course of the next 10 minutes.

Do you want to step back, Secretary Shalala, Dr. Koplan.

Senator SPECTER. The subcommittee will resume.

We had allocated 2 hours for this hearing. And I am scheduled to meet with the House leadership at 11:30 to see what the funding is going to be for this subcommittee.

We are working far in advance of the October sessions on that with my purpose being to try to see if we cannot get adequate funding for these three departments.

Secretary Shalala has raised a question about the Privacy Act, and I have grave reservations as to its applicability in this situation. But we will pursue it to see if there is a basis for it. And we will proceed to work with Secretary Shalala and Dr. Koplan on private meetings and then make a determination as to what further hearings are needed.

My sense is that on a matter of this sort, there is public interest and a right to know, and that this incident could have very substantial therapy for other branches of government. I do not know what the facts are, whether there has been any violation or whether there is any implication of 18 U.S. Code 101. We have to make that determination.

But in view of the time and in view of the request, we will do that privately. And we will report publicly what our findings are. And to repeat, if there is a necessity for a public hearing, we will reconvene.

Let me turn now to Senator Cochran.

DELTA REGIONAL AUTHORITY

Senator COCHRAN. Mr. Chairman, thank you very much. I came over to urge the secretaries to look at the Delta Regional Authority proposal the President has made. Yesterday they had a meeting at the White House with governors from the States that are involved.

And in each of these instances, I think there are significant roles that can be played by these three departments in this undertaking, without really using any of the proposed spending to establish a new Federal agency.

This authority, in my judgment, may or may not be needed in the context that is being proposed, if we use the resources that we

have and some of the existing programs, like Job Corps, where we can train people who need jobs. We have a growing economy all over the country, but it is growing much slower. And in some places, it is negative, for example in the Mississippi Delta and in the lower Mississippi River Valley region.

But in education, we have teacher training programs. Delta State University has a $1.5 million appropriation that this committee approved last year. There are more parts to this training and upgrading of skills, of teachers, recruiting people, a superintendents training program that has been proposed as a part of this program that has not been funded.

We think that if you could go back and take a look at some of the proposals that places like Delta State University, Mississippi Valley State University, Alcorn State University—those are all in my State—but the community colleges, too, can play a major role, if we give them a little extra money. They have the know-how. They know what the problems are.

And I think we are missing the bet, if we divert attention from some of the existing resources that we have, like Job Corps, teacher training programs and the rest, and in the rural health centers, to be sure that we have an infrastructure there.

RURAL HEALTH CENTERS IN THE DELTA REGION

We have introduced legislation this week to double the appropriation over the next 5 years for rural health centers. They have done a very effective, cost-effective, job. We hope the administration can support this increase in funding that Senator Bond and I and others are sponsoring here in the Senate.

So I do not have any real questions. I have some, but I am not going to ask them, because we are out of time. But I just wanted to let you know what my highest priority was this morning for discussion with you.

So we appreciate you being here and look forward to working with you on these and other issues as we go through this next fiscal year. Thank you very much.

Secretary RILEY. Mr. Chairman, if I might respond to the comment. And I thank you for it. As you know, I was in Mississippi last week and got over into the Delta Region and went to Delta State University and I also was in the Cleveland area. And I strongly support the tenor of your remarks. I was there. I talked to a lot of school people and parents, higher education people.

I did the same thing in Iowa a couple of weeks ago and saw in those rural areas—one little school district in Mississippi even told me they had 17,000 people in the district, and they had lost something like 1,000 jobs over the last couple of years.

And then we have a program that they very much want to use, like Gear Up to connect up colleges with these struggling middle schools, and yet it calls for a match, which is a very legitimate thing for it to do. But they say they have no way of participating. They do not have any money for the program match requirement.

In this school construction thing, where we do have resources for some grants in those very needy areas, they cannot support a school bond issue. And so I think it is good for all of us to get out and see the kind of thing you are talking about. Those people are

working so hard in the Delta Region, and I was very proud to be there with them.

Senator COCHRAN. Thank you very much, Mr. Secretary.

Senator SPECTER. Thank you very much, Senator Cochran.

YOUTH SAFETY AND HEALTH QUESTIONS FOR THE RECORD

There will be more questions submitted for the record. Senator Campbell and Senator Domenici made specific requests. And I would like the observations of all three of you in writing on what we ought to be looking toward on movies, television and video games, an enormously sensitive subject. And in structuring our program against youth violence, we have deliberately not moved in the direction that everybody pummels, but have treated this as a national health problem, very much as Dr. Koop suggested years ago, putting it under the Surgeon General, so he has the responsibility.

And I have asked each of you to let me know who your point persons will be, because this subcommittee intends to conduct extensive oversight, really working with you, as we started to do last year, but give our views on the subject and interact, so we can make more money available to you or make more reallocations or get the legislative branch in with our power of the purse to help out on that.

STEM CELL RESEARCH AND DIABETES

We are going to ask you some questions on stem cells. There is a report today about some phenomenal new advances on mice and diabetes. We had a postponement hearing on that subject that Senator Lott has agreed to bring that subject up as a free-standing bill, very important medical research. And we are going to do our best to come to grips with these budget issues.

Senator Stevens came and told you that the money was not there for what you have asked for. And that is a prevailing view. When you have a total budget of $622 billion, it pushes up, aside from the Balanced Budget Act and the caps, which we are going to have to act on one way or another, you do have the issue. Nobody wants to invade the Social Security surplus. So that is a limit that nobody is going to transgress.

But we are going to work with you and try to see to it that you are adequately funded. I think you were last year, and we are going to try to the good job for America this year, with your cooperation. Thank you all very much.

I will insert a statement from Senator Gorton for the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR SLADE GORTON

For decades now, Washington, D.C. has taken almost complete responsibility from local communities for how our schools should be run. Over the past few years, I've visited perhaps over 100 schools and listened to countless numbers of parents, teachers and principals, and they almost universally agree that it's time for Congress and the President to restore the authority local communities once had to make decisions for their local schools.

Last year I proposed, along with Mr. Goodling in the House, the Academic Achievement for All Act, also known as Straight A's. This bill is based on the simple premise that in exchange for a significant increase in flexibility states and school districts would be held to a higher standard of accountability. Under my proposal,

states would have the option of submitting a charter proposal that would set specific and measurable performance goals to reach by the end of five years. If approved, states would be allowed to use any of their regular Federal K–12 formula program funds for state education priorities and programs, in exchange for being held accountable for meeting their goals. States would be free to combine their federal funds from multiple programs to more effectively address the needs of students in their state. Alternatively, states would be free to administer Federal education programs the old way—Straight A's does not eliminate any program. It's the state's choice of which approach to use.

What this means for states and school districts is that they can use federal funds for any initiative that improves performance of students in your state. States that choose to participate can focus more funds on disadvantaged students, increase efforts to improve teacher quality, reduce class size or even hook up all their classes to the Internet. The one string is that these efforts must increase the achievement of all students—including the lowest performing students—over the course of five years.

If states do not substantially meet those goals, they would lose their Straight A's status, and revert to the categorical, regulated approach under current law. If states do well and significantly reduce achievement gaps between high and low performing students, they will be rewarded with additional funds.

Finally, school districts would not lose any Title I funding. If Title I, Part A ($8 billion program for educationally disadvantaged children) is included by a state, each school district in the state would be assured of receiving at least as much money as they received in the preceding fiscal year.

I've received a good deal of feedback from my constituents on my proposal, and a great deal of it has been positive. They do not shy away from being held strictly accountable for the academic success of all children if they are freed from the myriad of rules and regulations imposed on them by the federal government. Mr. Secretary, tomorrow the Senate education committee will take a closer look at reauthorizing ESEA and included in the package is Straight A's.

The very fact that Straight A's is being adopted into any ESEA reform bill sends a dramatically different message to state and local school districts across the country. For the past 35 years, we have consistently told our local educators that "D.C. is in charge of running schools across the country." Now, as the education debate gets underway, we are going against the grain by trusting our state and local education officials to do what they think is best for our children. I ask you to back me in that endeavor and put your trust behind our teachers, rather than D.C. bureaucrats.

All children can learn, and they will do so only because of the dedication and hard work of those who know their names, not because those of us in Washington, D.C., create a number of new programs with good intentions. Mr. Secretary, I urge you to seriously consider the merits of the Straight A's proposal and support funding priorities that provide those who know our children best—their parents, teachers, principals, superintendents, and school board members—with the flexibility they need to educate our children.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. 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:]

DEPARTMENT OF LABOR

QUESTION SUBMITTED BY SENATOR KAYE BAILEY HUTCHISON

BONUS INCENTIVE ACT

Question. Madam Secretary, as you know, the Senate recently passed legislation I introduced, the Bonus Incentive Act, which will allow employers to pay their hourly wage employees performance-based bonuses, without the unnecessary and burdensome need to go back and recalculate the employee's overtime pay. Typically, this results in very small changes to overtime pay, while it clearly discourages thousands of American businesses from paying their employees bonuses. One estimate

is that if my bill passed, it could mean an average increase to an hourly worker of $1,000 per year in bonus pay. Do you support this legislation, and if not, why not?

Answer. The Bonus Incentive Act was attached to a provision to increase the minimum wage in an amendment to the Bankruptcy Reform Act of 1999 and passed by the Senate in February. This measure would amend the Fair Labor Standards Act (FLSA) to exclude from the definition of "regular rate"—the basis for calculating overtime premium pay (time-and-a-half-pay)—any payments made to reward employees for meeting or exceeding productivity, quality, efficiency, or sales goals, i.e., the additional compensation provided through gainsharing plans, incentive bonuses, commissions, or other performance contingent bonus plans.

The Department strongly opposes this amendment. If enacted, it would substantially reverse the FLSA's long-standing overtime policy and drastically weaken existing protections for workers to receive true time-and-a-half overtime premium pay. These requirements, which have been in place for over 60 years, provide vital worker protections that discourage employers from working their employees excessively long hours and ensure fair compensation to those who bear the burden of working extended hours.

This bill would not guarantee workers the right to receive incentive compensation for any additional hours they work and therefore, does not ensure that workers—who may have to work excessively long hours for their employers—will ever share in any of their employer's gains. The amendment would, however, allow an employer to pay artificially low hourly wages and structure its compensation system on newly "excludable" bonus pay. Such a compensation structure would enable the employer to effectively transfer much of its business risk directly to its employees. The workers' only rights would be overtime pay at time-and-a-half a reduced hourly wage—not their true wage.

Moreover, the amendment would encourage employers to require employees to work longer hours at lower earnings, directly contrary to the statute's original intent-to limit the detrimental impact that long work hours can have on the health, efficiency and general well-being of workers and their families. The Administration's Statement of Policy on November 8, 1999 regarding the Bankruptcy Reform Act of 1999 reiterates the President's position in stating that if Congress sends him a bill "delaying the [minimum wage] increase, repealing overtime protections for certain workers, adding costly and unnecessary tax cuts . . ., he will veto it." In considering identical legislation in the House (H.R. 1381, the Rewarding Performance in Compensation Act) I advised Chairmen Ballenger and Goodling that I would recommend that the President veto the legislation because it is contrary to the best interest of this Nation's working men and women.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

NATIONAL MINE SAFETY AND HEALTH ACADEMY

Question. What amount of revenues did the Academy receive for the use of its facilities by mining officials from foreign nations for fiscal year 1998, fiscal year 1999, fiscal year 2000, and the projected amount for fiscal year 2001?

Answer. The training facilities of the National Mine Health and Safety Academy are used to promote international mine safety and health through training and exchange of information and techniques. Because of the mutual benefit of exchanging health and safety information with other nations, we have waived food and lodging fees for international groups that have been invited to participate in MSHA training programs. No change is anticipated for fiscal year 2001. The sponsoring country pays travel costs to and from the Academy.

Question. What were the staffing levels at the Academy for those same years?

Answer. Staffing levels at the Academy have remained relatively constant in recent years. For the years in question, they are:

Fiscal year 1998—63 FTE
Fiscal year 1999—65 FTE
Fiscal year 2000—66 FTE
Fiscal year 2001—66 FTE (est.)

Question. Has the training provided by the Academy to mining officials from foreign nations led to a reduced number of mine-related deaths in those countries? What countries benefitted most from this training?

Answer. Since 1998, the Academy has trained mine inspectors and mining officials from South Africa, Hungary, Poland, Peru, Malaysia, Australia, Mexico, the Ukraine, Croatia, Russia, and Thailand. In addition, the Academy has hosted a

number of international mine rescue teams, including those from Russia, Poland, and the Ukraine.

The following information reflects the actual and estimated number of mining officials from foreign nations trained or provided training guidance at the Academy during fiscal years 1998 through 2001:

Fiscal year 1998—59
Fiscal year 1999—83
Fiscal year 2000—124 (est., with 32 to date)
Fiscal year 2001—250 (est.)

Both MSHA and the visiting officials recognize the value of sharing technical expertise to reduce hazards in the mine industry. Training and materials provided to these delegations give the international delegations a basis to make improvements in health and safety conditions in their respective countries. Generally, improvements in the reduction of mining-related accidents are realized over extended periods.

At this time, there are no statistics available to indicate the degree to which this training has affected miners' health and safety in the individual countries. There is, however, anecdotal evidence that suggests that it has led to some improvements in participating countries. For example, following the March 2000 methane explosion in the Ukraine, we received a letter from the Ministry of Labor and Social Policy requesting assistance from MSHA in developing health and safety programs. Additionally, the letter stated that they attributed their improvements in mining safety during 1999 to the assistance and support provided by MSHA (letter attached).

MINISTRY OF LABOR AND SOCIAL POLICY OF UKRAINE,
March 20, 2000.

Hon. STEVEN K. PIFER,
Ambassador of the United States of America,
Vul. Yuriya Kotsyubinskoho 10, Kiev, Ukraine.

DEAR AMBASSADOR PIFER: As you are aware, the coal industry of Ukraine has recently experienced another unfortunate accident—this time at the Barakova Mine that resulted in the death of eight-one coal miners, and seven more being injured. During the past few days we have received many conveyances of sympathy and concern from various U.S. governmental organizations, individuals, and friends. All of this has been greatly appreciated.

This was the worst accident that the coal industry has experienced for over twenty years, and it came after we had achieved a positive trend during 1999 in the number of deaths and accidents in this industry. We attribute many of these positive results to the assistance and support that we have received from your Department of Labor-Mine Health and Safety Administration (MSHA) during the past two years under our Cooperative Agreement. This program has been instrumental in raising the awareness of safety at our coal mines; it has greatly enhanced the effectiveness of the Labor Safety Committee and the morale of its workers.

The purpose of my letter is humbling but very necessary under the current situation in Ukraine. The Labor Safety Committee requests your consideration and support in a program to help create a safer environment for the coal miners of Ukraine. Specifically, we would be interested in joining with MSHA in developing a program to address the following issues:

—raising awareness of coal miner safety by developing and presenting a training program designed for Ukrainian mining conditions and practices,
—develop a program to use the Barakova Mine as a test case to demonstrate the effectiveness in the utilization of rockdust to control excess underground dust. The success of this program will result in the writing of new regulations that will be implemented at all Ukrainian coal mines, and
—a method to improve communication during mine accident investigations.

We are aware that the resources of the U.S. Government are not unlimited, but believe that a jointly developed program between MSHA, the Labor Safety Committee, and the Ministry of Fuel and Energy can be a cost effective method ti improve the health and safety of our miners. Thank you for your consideration of this vital issue.

Sincerely,

P. OVCHARENKO,
First Deputy Minister.

CONVENTION 176

Question. The General Conference of the International Labor Organization adopted Convention 176 on June 21, 1995, establishing minimum mine safety and health

standards for the international community. Convention 176 was based on the Federal Mine Safety and Health Act of 1977, and if ratified, the U.S. would be in full compliance without the need for any further legislation. Would you please explain the Administration's position on Convention 176, and any externalities that could result from its ratification.

Answer. The Administration strongly supports ratification of Convention 176. The Convention recognizes the importance of preventing injuries and deaths in the mining industry throughout the world. Widespread ratification of the Convention is in our interest since it would help raise international standards to the same high level reflected in our own law. U.S. ratification would reinforce the important role of the ILO in developing effective labor standards for the global economy. The National Mining Association and the United Mine Workers of America worked with the Department of Labor in developing Convention 176, and both organizations support its ratification.

Convention 176, as you indicated, is patterned after our own Federal Mine Safety and Health Act of 1977 (Mine Act). Ratification therefore does not require any change to U.S. mine safety and health law or regulation. This conclusion was reached by the Tripartite Advisory Panel on International Labor Standards (TAPILS), which carefully examined Convention 176, including its negotiating and legislative history. TAPILS' membership includes representatives of the Departments of Labor, Commerce, and State, the U.S. Council for International Business, and the AFL–CIO.

The Mine Act is the foundation of the safety and health successes that we have achieved in this country. The Mine Act, as well as its predecessor statute, the Federal Coal Mine Health and Safety Act of 1969, are universally regarded as critical in having reduced the number and severity of mine explosions, mine fires, and other catastrophic events in the mining industry in this country. In developing Convention 176, the U.S. Government, industry and labor agreed that the adoption and enforcement of a common set of safety and health laws by the international community will help ensure safe and healthful working conditions for miners throughout the world, as well as help ensure that U.S. businesses can compete fairly in the world economic market.

In recent years, the Department of Labors' Mine Safety and Health Administration has provided mine safety and health assistance and advice to several countries. These exchanges have made us even more firm in our conviction that establishing uniform safety and health standards is essential for raising labor standards globally. Mining remains one of the most hazardous industries, both here and abroad. In part due to inadequate health and safety standards, the human toll associated with mining is particularly high in certain foreign countries. As recently as last month (March), a methane explosion in the Ukraine resulted in the death of 80 coal miners. According to reports, at least 274 miners were killed in the Ukraine in 1999, and about 360 in 1998. Reports indicate that South African mines recorded 312 work-related deaths in 1999, and that mining accidents in China killed more than 3,000 people in the first 9 months of that year.

Convention 176 has been ratified by 12 nations. The South African Parliament agreed to ratification in December 1999, and is currently processing the procedural papers needed for the International Labor Organization to officially recognize South Africa as a ratifying country. We were extremely pleased that the U.S. Senate gave its advice and consent to ratification of Convention 182, the Worst Forms of Child Labor Convention in November 1999. Like ratification of Convention 182, U.S. adoption of Convention 176 would reflect our commitment to work together with labor and business interests to raise labor standards around the world.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

WORKER ADJUSTMENT AND RETRAINING NOTIFICATION ACT

Question. Recently there have been plant closings in Wisconsin that have violated the WARN Act. This act has several loopholes in it, however, and it does not allow the Department of Labor to investigate or enforce the act. If the Department of Labor had the authority to investigate and enforce the act, how many workers could be helped and what would the possible impact be? How much funding would this effort require of the DOL?

Answer. As part of the development of our dislocated worker consolidation bill in 1993, DOL conducted consultations on the possibility of amending WARN in the areas of coverage and enforcement. No action was taken for a number of reasons, including:

—The concern that amendments might reopen issues and upset the fragile consensus that produced the original statute, and
—The belief that coverage changes would have to be accompanied by agency enforcement in order to be effective and the cost of that enforcement, in both dollars and Federal positions, would be great.

These factors have not changed. In fact, support for the Department's role in enforcing labor laws and the positions and funds comprising that enforcement has become an issue in cases where Federal law already assigns the Department these responsibilities.

Advance notice of layoff is a critical component for workers to begin the adjustment process, and for the workforce system to provide the specialized assistance needed by affected workers. The importance of early notification is recognized by the Department.

The positive impact of DOL having enforcement authority would be in the number of additional workers who receive advance notice of layoff. (This assumes that DOL enforcement authority leads to greater employer compliance with WARN.) The Department does not have data on the number of workers who should have received notice under WARN, but did not.

To promote greater employer awareness of their obligations under WARN, the Department is exploring a public information campaign and targeted outreach to employees, employers, and organized labor to (1) stress the employers' obligations under WARN, (2) encourage advance notice on a voluntary basis even when WARN may not apply, and (3) encourage even earlier notification of impending layoffs and closures than WARN requires.

Finally, WARN enforcement would require about 30 staff, including those in regional offices, in a management unit in the national office, and in the Office of the Solicitor, which would involve an estimated staffing cost of $3.3 million.

WORKFORCE INVESTMENT ACT IMPACT

Question. There is some concern that the Workforce Investment Act, which will be fully implemented in Wisconsin in July, will already face a sunset in 2003, too early to fairly judge if the new act is successful. What is the Department of Labor doing to measure the Workforce Investment Act's successes or shortcomings and will the data be enough to get a clear picture?

Answer. The Department has contracted with Social Policy Research Associates to conduct a process evaluation of WIA implementation. While there will be a lag time for the receipt and analysis of the initial WIA performance data (including customer satisfaction), the information will be instrumental in determining State and local success in achieving the WIA reforms and the core measures. Our technical assistance, discretionary grant investments, and performance incentive awards authorized by WIA are targeted at expanding partnerships in the One-Stop delivery system. In sum, our focus and resources are directed at assuring positive outcomes for the customer—increased employment, retention, and earnings, increased occupational skill attainment, while meeting the needs of American employers in staying globally competitive.

TRAVELING SALES CREW INDUSTRY

Question. As you know, I recently introduced legislation, S. 1989, to make it illegal for young people under the age of 18 to participate in the traveling sales crew industry. These sellers travel around the country and go sell products door-to-door. In my state there was a tragic accident taking the lives of several sellers, many under 18. Recently there was another accident in California that took the life of two adults. All in all almost 40 people have been killed in this industry due to negligence and criminal behavior. I believe that this is no environment for a child to be in and that it is too dangerous for minors. Does the Department of Labor agree that the traveling sales crew industry presents a workplace safety problem?

Answer. Yes. Vehicle related incidents of all types are the number one killer of young workers—accounting for 43 percent of fatalities for workers under the age of 18. When you also consider the dangers of peddling door-to-door in unfamiliar neighborhoods, working long hours in strange surroundings, this industry is clearly characterized by a number of serious occupational risks. The Senate Permanent Subcommittee on Investigations, in 1987, also documented problems of worker exploitation in the traveling door-to-door sales industry.

Question. Does the industry present an unacceptable risk for minors?

Answer. As you know, child labor is one of the Department's top priorities. When children work, they must do so safely and legally. The youth peddling industry, in general, presents special hazards for young workers. Children as young as eight-

years-old are recruited from poorer neighborhoods and transported by crew leaders to unfamiliar locations to peddle candy and other consumer goods door-to-door, at subway stops, and at shopping malls. We have been looking at the issue of commercial youth peddling and the special hazards that this industry poses for young workers. This past spring, the Department joined with the Interstate Labor Standards Association and the National Child Labor Coalition to launch a public awareness campaign to educate parents and young people about the dangers of the youth peddling industry. We are also working with our State colleagues to coordinate enforcement activities to protect children who are being exploited. And, we have sought and obtained additional resources to undertake a thorough evaluation of the hazardous occupations orders, which began last year through the National Institute for Occupational Safety and Health.

As you know, we have been and will continue to assist you and Senator Harkin in your efforts to address problems in this industry. As I have often stated, the Department is committed to doing everything possible to ensure that the early work experiences of our young workers are positive and safe, and do not interfere with their primary occupations-as students.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

JOB TRAINING HIGHLIGHTS OF THE 2001 BUDGET REQUEST

Question. The President has requested a total of $2 billion to provide effective job training assistance to those workers who are struggling to keep their skills current in our changing global economy. Can you briefly highlight some of the President's initiatives in his fiscal year 2001 budget as well as the success of a new innovative approach to job training in the 21st Century?

Answer. The 2001 budget includes $2 billion for the second year's request for the President's Universal Reemployment initiative which will ensure that by 2004: (1) all dislocated workers will have access to the training and employment services the want and need; (2) that all unemployment insurance claimants who have been profiled as unlikely to return to work quickly will get the reemployment services they need to return to work; and (3) all Americans will have access to the information and services of One-Stop Career Centers. This initiative will provide resources to train for or find new jobs, expand and increase quality of employment services, enhance services for individuals receiving unemployment compensation, and ensure availability of the One Stop System, either personally or electronically.

The programs to be funded are increased by $275.5 million, as follows:

Dislocated Workers Employment and Training:

—Second year's funding of the President's Universal Reemployment Initiative.

—The request is $1.77 billion—an increase of $181.5 million over 2000.

—984,000 dislocated workers will be assisted under this initiative.

—Included in the request is $105,100,000 for Skill Shortages grants that will be financed only if the Administration's proposal for an employer user fee on the permanent labor certification process is enacted. Upon enactment of the fee, a budget amendment will be proposed reducing budget authority.

America's Labor Market Information System (ALMIS):

—Component of the One-Stop Career Centers budget.

—ETA request is $154 millions for ALMIS, $44 million over 2000.

—The major components are: Core Employment Statistics; Universal Access for Customers/Digital Divide Initiatives; Lifelong Learning and Earning; and Measuring and Displaying Performance Information

—ALMIS Services and Products: Mobile One-Stop Vans; Nationwide Toll-Free Number; America's Job Bank, America's Talent Bank; Occupation Network (O*Net); America's Learning Exchange; Access America; Agricultural Network (AgNet).

Reemployment Services Grants to States.—ETA requests $50 million to provide reemployment services to unemployment insurance claimants to help them return to work.

I view this historic time of economic prosperity as an opportunity to address the challenge of bringing skills, jobs and hope to individuals and communities that for too long have been left behind. That is why our Budget not only proposes increases in funding for some formula-funded Workforce Investment Act programs, but also proposes several targeted initiatives for groups that we have not paid adequate attention to in the past.

We have asked for an increase of $125 million for Youth Opportunity Grants to address skills training and job placement in the poorest urban and rural areas and

Indian reservations in America. I recently announced 36 of these grants. With this first grant competition we were able to fund only about 25 percent of the eligible communities that submitted applications. Over 160 communities put together the broad partnerships and developed comprehensive plans for meeting the needs of this target population. We had far more high quality applications than we could fund. These additional dollars will allow us to reach about 20 additional communities . We know that the needs were great in all the communities that applied and these additional funds will take us a few steps closer to reaching these communities.

Responsible Reintegration for Young Offenders is a $75 million pilot and demonstration initiative that will test new approaches to bring young offenders into the workplace through job training and placement, and by creating partnerships between the criminal justice system and our workforce development system. We hope that by developing models showing how we can work effectively with the criminal justice system, we can expand services to this population through our State and local grant programs.

Safe Schools/Healthy Students is an ongoing collaboration among the Departments of Education, Health and Human Services, and Justice to promote healthy childhood development and to prevent school violence and the abuse of alcohol and other drugs. We believe the Department of Labor has something to contribute to this interagency initiative and have proposed $40 million so that we can join in this initiative to enrich the connections among secondary and post-secondary schools, alternative schools, out-of-school youth programs, and work-based learning. Some of these funds will be used to assist in building the infrastructure of youth councils under WIA.

Fathers Work/Families Win is a $255 million, two-part initiative that grows out of the successful Welfare-to-Work program. Fathers Work will provide jobs for non-custodial parents—mostly fathers—who owe child support. Families Win will help low-income parents who are struggling to make ends meet by providing better access to community services and upgrading job skills. These families often include members who have been on welfare or may be at risk of going on welfare, but because they are employed, most have not received services under JTPA.

I view these initiatives as addressing some needs and target groups that our workforce development system has not sufficiently dealt with in the past, and that would not be addressed through our formula grants. For example, the youth formula programs provide a relatively small amount of funds to every area in the country, while Youth Opportunity Grants concentrate a large amount of funds in targeted high-poverty urban, rural and Native American communities, exactly where the need is the greatest.

With respect to job training in the 21st Century, I believe the Workforce Investment Act (WIA), which we are now implementing and which becomes fully effective on July 1, 2000, offers us a new innovative approach. Under WIA, information and access to training and other services will be provided through customer-focused One-Stop Career Centers in each local area. Training will generally be provided through the use of Individual Training Accounts, and clients of the Workforce Investment System will be provided information on the past performance of training providers to help them make career choices. The new WIA system will be accountability-driven and all training providers must be certified. The Workforce Investment Act also provides the authority for a state of the art, quality information system that helps American workers and companies navigate the labor market and exercise informed choice in their workforce decisions. Together, these new tools will help us respond to the demands of the changing global economy.

PAY EQUITY

Question. In his State of the Union Address, President Clinton highlighted the issue of pay equity or pay inequity for women. We all realize this is an important issue of fairness, however, pay inequity for many women plagues them well beyond their working life. More women live in poverty after the age of 65 and single women over 65 are at a much higher risk of living in poverty. How does addressing pay equity for women during their working life impact their economic status after the age of 65? In addition, isn't pay equity really a family issue, not just a women's issue? What impact does bridging the salary gap between men and women in the workplace have on the family?

Answer. We recognize that pay inequity is not just about pay—it is also about benefits. And although the pay and pension gap between men and women has been narrowing, we know we must work hard to reduce it further—and to someday see equal employment opportunity and pension equity for all.

On average, women who work full-time earn only about 75 cents for every dollar that a man earns. Less than 40 percent of all working women in the private sector are covered by a pension (compared to 46 percent of men). Only 32 percent of current female retirees receive a pension (compared to 55 percent of men). Recent (1994) men retirees' median annual benefits were $9,600, compared with only $4,800 for women, half the benefit amount for men.

Women's economic status after age 65 often depends on what wages they received when they were working—and whether or not they have a pension from their own work. If a woman has a pension but received lower pay while working, she will face a lifetime of inequity because most pensions are based, in large part, on wages. If a woman receives lower wages while working and does not have a pension, she will face an even more difficult time making ends meet when she retires. And with or without a pension, lower wages make it harder for women to save their own money for retirement.

The pay gap is a family issue. Women's earnings are a significant source of family income. Women's earnings help support nearly three out of four working American families. Yet women tend to be concentrated in lower paying jobs. Fifty-four percent of full-time female workers earn less than $25,000 a year compared to 36 percent of full-time male workers. When women aren't paid equally or don't have equal access to high-paying jobs, the whole family pays the price.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)

Question. Over the past several months, the price of crude oil has increased from $10 to $30 a barrel, causing the subsequent increase of diesel fuel, heating oil and unleaded gas. As a result of increases in home heating fuel prices this winter, the President released all of the emergency LIHEAP funds ($300 million) on 3 dates: January 25, February 8, and February 16. The President is requesting $600 million in additional emergency funding in the supplemental. The President's fiscal year 2001 request for LIHEAP is the same as last year: $1.1 billion in regular funding and $300 million in emergency funding. How many additional families have applied for assistance? In light of the dire situation this year, does the President's request adequately reflect the funding needs?

Answer. LIHEAP is one of the 1981 block grants. As a result, ACF does not have specific current information on the number of additional families that have applied for assistance. ACF is, however, in daily contact with their State partners to keep abreast of needs and developments in the State LIHEAP programs. A number of States have modified their program eligibility requirements as a result of the large fuel oil price increases. LIHEAP funds are distributed to the States as block grants. States have used this flexibility to leverage emergency funds in a variety of ways to support the energy needs of low income households, including increasing benefit levels for emergency heating assistance for current recipients and raising eligibility limits to serve greater numbers of households. As example, Pennsylvania raised its maximum crisis payment from $250 to $300, provided a supplemental payment of $250 to households already eligible under the program (up to 110 percent of the federal poverty level), and provided a payment of $250 to households up to150 percent of poverty. The State also delayed the closing date for the State's crisis program from March 15 to April 30.

Fiscal year 2000 emergency funds served their function well, addressing the needs of low income households facing significant increases in heating costs. This year was an extraordinary situation, which we do not expect to be repeated. However, the Administration is seeking a $600 million supplemental appropriation for LIHEAP, to assist families with this winter's heating bills and provide a reserve in the event emergency summer cooling assistance is needed.

WORKER HEALTH

Question. Within the funds provided for the Agency for Healthcare Research and Quality, the President proposes to spend $10 million for "improving worker health." How does this research differ from the research being conducted by the National Institute of Occupational Safety and Health (NIOSH)?

Answer. The research focus at NIOSH is on the causes and prevention of work-related illness and injury. Two components of AHRQ's proposed worker health initiative focus on the outcomes and effectiveness of clinical treatment and the quality

of the systems in which care is provided after a worker has been injured or otherwise becomes ill. These two components have a focus on quality of patient care and return-to-work that responds to research requests we have received from the business community, labor, and major purchaser groups. The third component of this initiative focuses on the health care workplace and the impact of the ways we organize and manage the delivery of health care services on the quality of patient care. This part of the initiative builds upon past AHRQ research on the relationship between professional staffing patterns and the quality of patient care as well as research requests we have received from major health clinics and hospitals in our stakeholder outreach meetings. This area of investigation is complementary to NIOSH's work on health care worker health and safety. AHRQ and NIOSH have collaborated effectively on this issue and will continue to do so in the new initiative. This initiative will help employers ensure that injured workers receive quality health care.

HEALTH CARE ACCESS FOR THE UNINSURED

Question. The President is requesting $125 million for an initiative he calls "Health Care Access for the Uninsured." It appears that your request requires authorizing legislation before Congress can appropriate funds. Please explain how this program would work and the goals that the administration hopes to achieve.

Answer. In fiscal year 2000 Congress appropriated $25 million for the Health Care Access for the Uninsured program which we are operating under Section 330 demonstration authority of the Public Health Service Act. In order to strengthen the program the Administration provided Congress with the draft bill, "Community Access to Health Care Act of 2000" on March 22, 2000. The Community Access Program (CAP), included in our budget request as the Health Care Access for the Uninsured program, is an innovative effort to help communities build and strengthen integrated health care delivery systems for uninsured and underinsured persons. The health care services available to the uninsured can be fragmented, often with little to no coordination among providers who serve this population. Not only can patient care be compromised, but much-needed resources can be wasted as providers duplicate efforts. CAP addresses this growing problem by fostering community-based efforts to improve service integration for the uninsured. Building off the critical foundation established by providers who have traditionally provided services without regard to ability to pay, CAP will provide new resources to help communities coordinate core services more effectively. CAP grants will support the development of infrastructure, such as information systems, referral relationships, and clinical protocols, that will help providers improve access to existing services and promote the efficiency of the care that is delivered. By supplementing existing categorical programs to fund safety net services and targeting infrastructure development not currently supported through those programs, CAP will allow communities to better harness their current capabilities and resources.

CAP is designed to encourage community-wide collaboration and stimulate creative approaches to the development of coordinated, comprehensive care systems. CAP recognizes that the "safety net" of providers willing to deliver care to the uninsured can vary from community to community, resulting in a wide array of integration challenges. To accommodate this variability and to promote innovation, CAP is intended to be flexible to community needs. No single model for integration is being promoted; rather it is our goal that a diversity of models be explored. While the methods used to achieve integration may differ, all CAP grantees will represent community-wide coalitions focused on developing sustainable infrastructure for improved services integration.

FAMILY CAREGIVER PROGRAM

Question. Last year, the President requested $125 million for a "Family Caregiver Program." Congress did not appropriate funds because this program was not authorized. You are requesting the same level of funding this year. Do you believe that you can undertake this program without authorizing legislation?

Answer. Yes, Title III–D of the Older Americans Act provides existing authority to support caregivers. As we look at the needs of our older population we become more and more cognizant of the needs of their caregivers. Establishment of the National Family Caregiver Support Program, through reauthorization of the Act, has the advantage of providing the kind of visibility we would like for this program, and would probably afford a better opportunity to systematize the services we are suggesting need to be put into a package. However, Existing authority will permit us to do the work that is essential to intervene immediately. We will continue our ef-

forts to seek reauthorization of the Older Americans Act and the formal establishment of the National Family Caregiver Support Program.

MEDICAL ERRORS

Question. Last week, the President issued his recommendations for reducing medical errors, following the Institute of Medicine's report "To Err is Human: Building a Safer Health System." The President has requested $20 million to reduce medical errors. Is this investment significant enough, given the fact that medical errors cause up to 100,000 deaths annually? How long do you think it would take to accomplish your goals to truly see a reduction in the rate of medical errors?

Answer. The recommendations you refer to are much broader than HHS—they also address work needed in other agencies involved in health care and health coverage, such as the Department of Defense, The Department of Veterans Affairs, the Office of Personnel Management, and the Department of Labor. Our budget includes increases of $33 million to start this work. An increase of $20 million is requested in the Agency for Healthcare Research and Quality (AHRQ). AHRQ will create a Center for Quality Improvement and Patient Safety which will carry out a wide range of research activities to reduce medical errors. An increase of $13 million is requested in the Food and Drug Administration to reduce medical errors related to adverse events from FDA-regulated products, as well carry out a wide range of activities recommended by both the Institute of Medicine and the Quality Interagency Coordinating Task Force (QuIC), which I co-chair. In addition to activities for which dedicated funding is requested, HCFA will require that hospitals implement medical error reduction and patient safety programs to meet Medicare's conditions of participation. These activities, combined with other work recommended by the QuIC, will give us a good start on the work of reducing medical errors.

YOUTH VIOLENCE

Question. On February 25, Bruce Reed sent a letter describing the Administration's progress on instituting the youth violence prevention initiative. What specific ways will you encourage HHS agencies to coordinate with the Department of Labor and the Department of Education to ensure the coordination of efforts to reduce youth violence?

Answer. In developing the Youth Violence Prevention Initiative, our efforts extend across Department lines. A Federal Coordinating Committee on the Prevention of Youth Violence has been convened, which includes representatives from the Department of Labor, Justice and Education. This committee is assessing the cross-cutting issues in violence among youths and is exploring ways on how to synchronize and maximize our collective efforts into a meaningful blueprint of an effective initiative.

The Department of Health and Human Services is already working closely with the Departments of Education and Justice to continue coordination of the Safe Schools/Healthy Students initiative begun in fiscal year 1999. The Safe Schools/Healthy Students is an unprecedented collaborative effort to assist communities in designing and implementing comprehensive educational, mental health, social service, law enforcement and juvenile justice services for youth. Our efforts in this collaboration, through the Substance Abuse and Mental Health Services Administration's Center for Mental Health Services, have resulted in the funding of 54 grants to school districts around the country. While no increase in funding is requested for SAMHSA, the overall President's fiscal year 2001 Safe Schools/Healthy Students budget request includes funding for an additional 40 grants, and would include the Department of Labor as a new partner in this effort.

CDC, and the U.S. Department of Education, Department of Justice, and the National School Safety Center continue to examine homicides and suicides associated with schools and identified common features of school-related violent deaths. The study examines events occurring to and from school, as well as on both public or private school property, or while someone was on the way or going to an official school-sponsored event. The first study looked at deaths occurring during 1992–1994. CDC and its partners are updating and expanding the original study, examining school-associated violent deaths since July 1994.

In addition, the Office of the Surgeon General is developing a "Surgeon General's Report on Youth Violence" that will be completed this year. Information and assistance is being obtained from HHS operating divisions, other Federal Departments such as Education, Justice and Labor, communities, private organizations, academia, State and local governments, and other groups to ensure the report soundly addresses the prevention of youth violence as a collaborative intervention requiring a well-coordinated approach.

MEDICARE COVERAGE OF INJECTABLE DRUGS AND BIOLOGICS

Question. When will HCFA issue a program memorandum to carriers as required by the report language accompanying Section 219?

Answer. The program memorandum (AB–00–21) was issued on Friday, March 17, 2000.

Question. What is the status of the policy conveyed in the transmittal of August 13, 1997 of the Deputy Director of the Division of Acute Care to regional offices regarding injectable drugs?

Answer. We have directed our contractors to disregard the memorandum and all other documents based on that memorandum until further notice. Contractors are to base any determinations they make with respect to self-administered injectable drugs on policies that pre-existed that memorandum.

Question. I am concerned that some carriers may consider the August 13, 1997 transmittal to be the current Medicare policy on injectable drugs. Can you assure me that, today, it is Medicare's policy among all carriers to cover injectable drugs for program beneficiaries if the physician determines that it is inappropriate or impossible for a particular patient to self-administer the drug?

Answer. In accordance with the DHHS Appropriations Act, 2000 requirements, we have suspended the August 13, 1997 memorandum and have instructed our contractors to make determinations with respect to self-administered injectable drugs based on policy guidance that pre-existed that date. This law also effectively precludes us from clarifying our policy, since any clarification could easily be read as restrictive; therefore, our contractors are making determinations based on policies in place prior to August 13, 1997. While our contractors will be acting independently, I can say that historically they have not been inclined to provide coverage for injectable drugs that can be self-administered.

QUESTIONS SUBMITTED BY SENATOR ERNEST F. HOLLINGS

LIVER ALLOCATION POLICIES

Madam Secretary, I'm a bit confused by the Department's December 21 Federal Register notice, and was wondering if you could clarify your understanding of the moratorium imposed on the OPTN Final Rule by Section 413 of the Ticket to Work and Work Incentives Improvement Act of 1999.

The Amended Final Rule would have required the OPTN to submit revised liver allocation policies by February 15, 2000—88 days after the Rule was to become effective on November 19, 1999. But Section 413 imposed a moratorium on the effective date and all provisions contained in the Amended OPTN Final Rule Until March 16, 2000.

The Department's December 21 notice states on page 91626: "Because we do not seek to have the deadline occur during the period when the regulation is stayed, we have decided to extend the deadline to March 16, 2000"—just 30 days after the original deadline, and the first day the Rule can become effective under the moratorium.

Question. Could you please explain to me why requiring the OPTN to work on the most controversial new allocations policies required by the Rule during a period when its implementation has been stayed by Congress does not violate both the spirit and the letter of the moratorium?

Answer. The OPTN has been working on the refinement of the liver allocation policy continuously since the NPRM was published in 1994. We did not believe it was wise to interfere with their deliberations. Nor did we believe it was wise to suggest that the patients could wait for the benefits of an improved liver allocation system. The OPTN delivered a liver allocation policy proposing wider sharing for patients with the most urgent need and plan for further refining the medical distinctions among chronically ill patients on March 15, 2000. The Department is reviewing that submission. I believe it is a reflection of the OPTN's efforts to address the problem and a testament to the Department's persistence that a policy that puts patients first was delivered on time.

Question. Section 413 also requires the Department to solicit and review comments on the Rule, and to revise it appropriately in accordance with this review. How, then, can you justify your December 21 Federal Register notice, which announced a March 16, 2000 effective date for the rule, when you had not even begun to receive, much less review, comments on your October amendments? What kind of message do you think this sends to those who will be so deeply affected by the provisions of this Rule?

Answer. We were confident that our staff could review the comments and identify any new issues that would require modifications to the rule quickly. In fact, no new issues were raised by the public comments and no change was needed. A Federal Register Notice so stating was published March 21, 2000.

Question. Do you plan to revise the Rule based on public comments? If so, what is your time frame? Why wouldn't you postpone the effective date until you make the additional modifications? If you do not plan to modify the regulation, why not?

Answer. We were confident that our staff could review the comments and identify any new issues that would require modifications to the rule quickly. In fact, no new issues were raised by the public comments and no change was needed. A Federal Register Notice so stating was published March 21, 2000.

QUESTION SUBMITTED BY SENATOR DANIEL K. INOUYE

HEALTH CENTERS WAIVERS

Secretary Shalala, On April 20, 1998, HCFA sent a letter to State Medicaid Directors requiring States with Section 11 15 waivers to comply with the terms and conditions of their waiver as they relate to federally qualified health centers. In this letter, HCFA committed to review those States' compliance with the waiver and to take corrective action if necessary.

Madame Secretary, it has been nearly two years since that policy was released and it is my understanding that States with Section 11 15 waivers are still not complying with the terms and conditions specified. This has created a very serious problem in my state costing Hawaii health centers $1.2 million a year as a result of this non-compliance.

Question. What is the Department's plan to take corrective action regarding this problem and when do you plan to implement this course of action?

Answer. On July 15, 1998 HCFA sent a letter to all State Medicaid Directors with the section 1115 waiver of cost-based reimbursement for federally qualified health centers (FQHCs). This letter requested that each State submit information pertaining to the methodology used to reimburse FQHCs under their section 1115 demonstrations. The submitted information was to include an analysis of how the methodology was developed to calculate a cost-related or risk-based adjustment, as well as a description of how the methodology was implemented.

We received the State responses and on September 30, 1998 we wrote to the Primary Care Association (PCA) in each State in order to share the State response and to request that the PCA review the response. We asked each PCA to provide us with their assessment of the State response as well as any comments they wished to provide on the adequacy of the State's methodology for meeting the FQHC term and conditions.

On January 4, 1999 we sent a follow up letter to seven States, including Hawaii, requesting further information and clarification of their methodology. We received all of the State responses by May 1999. Since that time we have worked in partnership with the Health Resources and Services Administration to assess the State and PCA responses. We expect to be in contact with the Hawaii regarding this assessment shortly.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

BATTERED WOMEN AND CHILDREN

Question. I would like to focus my questions on my concerns regarding the impact of welfare restructuring on battered women and children, who are some of the most vulnerable citizens. Secretary Shalala, as you are aware, I fought to implement a "family violence option" within Federal welfare guidelines. My objective was clear—to make clear that punitive welfare restrictions did not result in more women and children becoming trapped in violent homes or relationships. I feel confident that the final regulations issued by HHS for the States to implement a family violent option will meet my objective. However, I have become increasingly concerned that States are not screening properly and are not directing services and benefits to battered women. Can you briefly outline what steps you are taking to ensure that battered women do not end up being victimized by our welfare structure and do we have any real outcome data on the number of battered women impacted? How many of those who have fallen off welfare are now trapped in violent homes or relationships?

Answer. The Department's Administration for Children and Families, Office of Family Assistance has a number of initiatives that address domestic/family violence.

In fiscal year 1997, a grant was awarded to the Anne Arundel County Department of Social Services, Maryland to develop and pilot test a domestic violence training curriculum for administrative and front line service staff. The training model developed in collaboration with the YWCA of Annapolis (Maryland) is intended to better equip staff to identify and serve clients of TANF and other public assistance programs who may be victims of domestic violence. New staff receives training on how to identify and screen for potential domestic violence situations.

Anne Arundel County was awarded a subsequent grant in fiscal year 1998 to increase its capacity to provide technical assistance to human service agencies on integration of services and organizational change. The organizational change model included strategies to assess and provide services to families at risk of domestic violence, and other barriers to self-sufficiency.

Anne Arundel County Department of Social Services like many local welfare offices places information in public restrooms about domestic prevention services and hotline telephone numbers.

ACF has funded our Regional Offices to provide targeted workshops around domestic violence issues such as identification, screening, confidentiality, and safety planning. A major conference is planned for our Northeast Hub (Regions I–III) in August of this year.

ACF's Office of Community Services funds the National Family Violence Hotline, which provides assistance to families in immediate danger of violence, and provides grants to community organizations for Family Violence Prevention Services.

The Department has an ongoing Family Violence workgroup composed of senior staff from its operating divisions who coordinate DHHS program policies and activities to provide education on domestic violence prevention and services.

With reference to outcomes, as of February 2000, we are beginning to receive detailed quarterly data from states on individuals receiving TANF assistance. We will not have outcome data on battered women, but we will know the number of women who are exempt from the work requirements based on receipt of a domestic violence waiver.

In addition to these cooperative efforts, DHHS and DOL convened a series of conferences to share with other welfare reform stakeholders, an informational "road map" on how to succeed in moving welfare families to self-sufficiency. The information presented included models of promising practices for helping families move from welfare to work. The conference objectives were to help participants:

—gain insight on how agency practitioners and the private sector have responded to challenges of moving welfare recipients to work;
—learn from practitioners how to prepare for the difficult task of moving welfare clients with multiple barriers to work;
—interact with peer practitioners from a broad cross-section of Federal, State and local agencies, community-based organizations, employers, and other disciplines; and
—gather practical information, helpful practices, and names of professional contacts to help structure programs to move families to self-sufficiency.

CHILD CARE

Question. One of the greatest challenges to meeting welfare-to-work goals is child care. I have listened to this Administration and many Governors talking about the success of welfare restructuring. However, there has been little action at the state level to increase the availability of affordable, quality child care, especially infant care. We know that early childhood development is essential, yet I am not convinced that we are targeting limited resources to implementing new, innovative child care programs. I know the President is calling for additional resources. I=d like to know B what are we doing to ensure that parents, especially those caught between work and welfare, can locate quality, affordable child care?

Answer. A recent report, *Access to Child Care for Low-Income Working Families*, found that in an average month in fiscal year 1998, only 10 percent of the 14.7 million children eligible for child care subsidies under Federal regulations received them. The fiscal year 2001 budget request includes several proposals to help low-income families find and afford quality child care. For fiscal year 2001, we are requesting $2 billion, an increase of $817 million, for the discretionary Child Care and Development Block Grant (CCDBG). These funds are critically needed to help address the gap between available funds and the child care subsidy needs that low-income working families re experiencing. This increase will provide child care subsidies to nearly 150,000 additional children. $223 million of the total funds re-

quested will support State activities that improve the quality of child care, including $50 million for infant and toddler quality activities and $19 million for school-aged care and resource and referral activities.

In addition, the budget includes $600 million in entitlement funds for an Early Learning Fund to focus on the quality of child care. The Early Learning Fund will be used to provide grants to communities to improve school readiness by fostering the cognitive, physical, social and emotional development of children under five years-old through improvements in the quality of child care settings, among other things. The President=s budget also proposes an increase in the Child Care and Dependent Care Tax Credit (DCTC) of $7.5 billion over 5 years and an expansion of the Earned Income Tax Credit (EITC) of $23.6 billion over 10 years, both of which would help low-income working families obtain quality, affordable child care.

QUESTIONS SUBMITTED BY SENATOR LARRY CRAIG

Question. Is the Federal Center for Substance Abuse Prevention part of the Substance Abuse and Mental Health Services Administration or SAMHSA?

Answer. Yes, the Center for Substance Abuse Prevention (CSAP) is part of the Substance Abuse and Mental Health Services Administration (SAMHSA).

Question. A survey was sent out to Missourian students in grades 6, 8, 10, and 12 by the State of Missouri, and funded by the Federal Center for Substance Abuse Prevention, for the purpose of participating in a study designed to "develop important information that will help combat such problems as alcohol and other drug use in our schools and communities." If the states purpose of the SAMHSA sponsored survey is to help combat alcohol and drug use problems, then why do 10 percent of the questions deal with handguns?

Answer. This survey was conducted as part of a Missouri needs assessment contract. Needs assessment provides a means for States to obtain data critical for prevention planning, resource allocation, and to establish baselines for performance measurement. States are collecting uniform data through school and community resource studies and assessing risk and protective factors in four domains—Peer/Individual, Family, School, and Community—using readily available surveys, including the CSAP Student Survey Risk and Protective Factors Instrument, the Youth Risk Behavior Assessment Survey (CDC) and/or other community-based instruments

To assist States with needs assessment, CSAP contracted with Hawkins, Catalano, and Miller to help develop a survey instrument. Hawkins et al. worked with a six state consortium (WA, OR, CO, ME, KS, and UT) to develop the Student Survey and pilot it. CSAP and ONDCP assessed the viability of the Student Survey among the first 3 cohorts (11 out of 23 states, or 48 percent) and determined that the Survey was an accurate needs assessment instrument. Discussions with the ONDCP regarding the State needs assessments determined that these assessments would be of more value if we could compare the data gathered for one State to the data of other States. Since the Student Survey is a reliable needs assessment instrument, the Survey was designated as a mandatory instrument for subsequent needs assessments. Based on this, Missouri is required to use this instrument. States that have, or are scheduled to use the Student Survey include: Washington, Florida, Kansas, New Jersey, South Carolina, Maine, Utah, Oregon, Arkansas, Delaware, Montana, Arizona, Hawaii, Missouri, Virginia, Alabama, Michigan, and Tennessee. Three states also using the survey, but not as part of the CSAP needs assessment are: Louisiana, Kentucky, and Pennsylvania. NIDA also is using the Student Survey in communities as part of a seven state consortium diffusion study.

Research has consistently shown a strong association between substance use and violence. This is reflected in studies depicting violence as a precursor to substance abuse (by victims of violence) as well as depicting substance use as a precursor to violence (by assailants). The Student Survey, in use since 1993, includes questions related to individual, peer, family, and community antisocial behavior because of this consistent relationship. Student survey results from both a CSAP six state consortium and the National Institute on Drug Abuse (NIDA) seven state consortium further support this relationship.

The handgun questions, which comprise 5.2 percent of the survey, are part of scales that measure:

—association with antisocial peers
—early initiation of problem behavior
—attitude toward antisocial behavior
—antisocial behavior
—convention involvement
—perceived availability

—community laws and norms
—family history of antisocial behavior

NIDA study data show that every one of these constructs is strongly correlated with 30-day substance use as well as with antisocial behavior. Hence, the survey scales are important for identifying risk factors that potentially should be targeted within a State program.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

STATUS OF REPORTS

Question. On December 9, 1999, I wrote to your office to inquire as to the status of certain initiatives identified in Senate Report 106–166 accompanying the fiscal year 2000 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill and/or Conference Report 106–479 accompanying the Consolidated Appropriations bill. I respectfully ask you to provide me with a status report of the following projects:

$38,500,000 and 303 full-time equivalent employees for the new National Institute for Occupational Safety and Health laboratory in Morgantown, West Virginia; (CDC)

Answer. The investment in the new National Institute for Occupational Safety and Health (NIOSH) laboratory in Morgantown, West Virginia, continues to yield significant scientific advances in understanding and preventing work-related disease, injury, and death. Activities at the new laboratory include: applied and preventive, multi-faceted laboratory-based research into the causes, mechanisms, prevention, and control of occupational disease and injuries; the development of high-tech engineering solutions for the control of occupational hazards; and basic and applied health communications research to improve the effectiveness of NIOSH communication efforts.

Highlights of the laboratory's fiscal year 1999 accomplishments include:

—*Hexavalent Chromium Research*.—NIOSH researchers developed a field-portable method for on-site determination of hexavalent chromium (a carcinogen found in structural components of buildings, as well as ink, paint, textile dyes, graphic art supplies, and wood preservatives), which is critical for assessing worker exposure and the effectiveness of control measures. Additional NIOSH basic research is examining the mechanism of hexavalent chromium-induced carcinogenesis.

—*Modeling Silica Exposure*.—NIOSH investigators performed a silica inhalation study using animal models to examine pulmonary damage, pulmonary inflammation, fibrosis, and dust retention. The study found explosive increases in lung damage and inflammation when dust burdens stabilize, and observed that inflammation progressed even in the absence of continued exposure. The data will be used to model dust deposition, clearance, and retention in rats and to compare results to models for humans.

—*Carcinogenesis Mechanisms for Cadmium*.—NIOSH studied the molecular mechanisms responsible for tumorigenic potential of cadmium. Findings suggest that genetic instability and changes in the cancer-related and novel genes may be responsible for the cell transformation and tumorigenesis induced by these metals. Identification of mechanisms for workplace-related carcinogenesis will help identify appropriate strategies for therapeutic intervention and prevention, as well as improve risk assessment for carcinogens.

—*Laboratory-based Models for Work-related Stress*.—To determine the role of acute and chronic stress as occupational risk factors or contributors to disease, NIOSH is working with external partners to use laboratory-based models to determine the biochemical, cellular, and molecular changes engendered by specific stressors alone and in conjunction with various disease models. Results from this work indicate that glucocorticoid release associated with stress enhances skin response to chemicals and can exacerbate damage in the brain areas important for cognition.

—*Silicosis Outreach for Hispanic and Latino Workers*.—NIOSH is developing an outreach project to increase the awareness of the seriousness of silica exposure among construction workers in Texas (who experience an alarming number of deaths attributed to silicosis) and to increase the use of engineering controls and respiratory protection in these workers. NIOSH assessed the workers' knowledge, beliefs, and behaviors about silicosis prevention, as well as their information seeking habits and barriers to and facilitators of prevention. NIOSH is using these data to develop a silicosis prevention program in fiscal year 2000.

—*Preventing Deaths from Tractor Overturns*.—Tractor overturns are the largest single source of agricultural fatalities, accounting for approximately 132 deaths per year. Current rollover protective structures (ROPS) do not provide adequate protection because farmers manually lower them when working in low clearance areas and may forget to raise them. NIOSH has developed a ROPS prototype that is stored normally in a compact form but automatically deploys to full dimension, without operator input, to protect the operator in the event of an overturn. The new system includes: (1) a roll bar and deployment mechanism, which were successfully tested for appropriate protective strength according to industry standards, and (2) a sensor to identify an impending overturn and trigger the roll bar deployment. A patent application is being developed for this device.

Research at the new laboratory will continue to focus on critical areas in occupational safety and health in fiscal year 2000. For example, researchers at the new laboratory are: coordinating an Institute-wide intramural initiative to study allergic and irritant dermatitis, including latex allergy, using state-of-the-art research methods; studying the genetic mapping of lung and prostate cancer to aid in the identification of at-risk worker populations; and using virtual reality technology to study the prevention of falls, which are one of three leading causes of injuries occurring in the workplace.

$3,000,000 for the construction of West Virginia University's Eye Center; and $1,1135,000 for the construction and equipment of the Harts Health Center in Harts, West Virginia

Answer. Congress provided $120 million for eighty-six specific projects in fiscal year 2000 and this amount has been reduced to $112.4 million under the fiscal year 2000 government-wide discretionary spending rescission authority. The projects at the West Virginia University's Eye Center and the Harts Health Center in Harts, West Virginia will be notified in April 2000 of the amount available for their specific project and they will be provided with an application kit and application guidelines. They will be given 60 days to submit their application and supporting documentation. Following a 75-day review period, given the large number of projects, grant awards are scheduled for the end of September 2000.

Approximately $1,000,000 for West Virginia University's Prevention Center funded through the Centers for Disease Control and Prevention; (CDC)

Answer. In fiscal year 1994, West Virginia University received a four-year Prevention Research Center (PRC) grant from CDC. Under this cooperative agreement, they received approximately $1,000,000 per year in core funding.

In fiscal year 1998, at the end of West Virginia's 4-year project period, they competed for renewal of their core PRC cooperative agreement along with the other 13 PRCs which existed at the time. In fiscal year 1998, CDC approved a 12-month extension of the project to allow the PRC time to expend their remaining funds to complete program goals and objectives.

CDC's fiscal year 1999 appropriations committee report language mandated that all "incumbent" PRCs were to be funded. Based on this language, CDC awarded West Virginia a new 5-year PRC cooperative agreement, which began on February 1, 1999. The fiscal year 1999 award amount for the first year of this new 5-year project period included $600,000 in new core funds, which was commensurate with the level of funding received by the other 13 incumbent PRCs. The award also included $133,611 in new supplemental funds, and $285,000 in funds West Virginia withheld in previous years, for a total approved amount of $1,018,611.

In fiscal year 2000, the West Virginia PRC received $650,000 in new core funds to support the second year of the current project period, which began on February 1, 2000. This increase in core funding was equal to the funding level of the other incumbent centers. They will also again have the opportunity to request funding for continuation projects and compete for new special interest project funding this year.

Current center activities include evaluating the efficacy of a new teen smoking cessation program, *Not on Tobacco*, in two Appalachian states. Other research projects focus on diabetes, cardiovascular disease, nutrition, tobacco, and mental health. The Center continues to be the Coordinating Center for the Women's Cardiovascular Health Network and participates in the Tobacco Control Network. The Center also provides participatory research training to West Virginia Bureau for Public Health funded projects and has strong relationships with the West Virginia Department of Education, the American Lung Association, other voluntary health organizations, and other community-based groups.

$687,000 for Marshall University's Autism Training Center; (CDC)

Answer. CDC will encourage Marshall University to broaden its intervention program to include secondary conditions in children with autism as well as to examine etiologic factors and conduct surveillance for the condition.

$850,000 for the Farm Resource Center through the Center for Mental Health Services of the Substance Abuse and Mental Health Services Administration

Answer. SAMHSA will announce the availability of a demonstration grant program in April 2000. The Rural Outreach Program demonstration would continue outreach activities that ameliorate stress associated with unemployment in rural communities and increase access to, and utilization of, mental health and substance abuse services for coal miners, farmers, and their families in Illinois and West Virginia and western Pennsylvania. This program, designed to result in more effective mental health and substance abuse services delivery, is intended to address the needs of adults and their families in rural areas who have or may be at risk for developing a mental illness or substance abuse problem. Needs of their children who have or may be at risk for developing emotional or other behavioral problems are addressed also.

Report language and $500,000 for the Office of the Surgeon General, in conjunction with the Public Health Policy Board and other agencies, to establish a process for selecting health priorities based on clear scientific data on emerging health threats to children

Answer. The final fiscal year 2000 appropriation did not include funding to establish a process for selecting health priorities. However, in January 2000 the Surgeon General launched Healthy People 2010, the third iteration of the Healthy People initiative first launched in 1979 with the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention*. Healthy People 2010 sets the nation's health agenda for the next decade and states a set of common goals developed through a national consultative process; it also provides a mechanism to monitor progress toward achieving those goals. The scope of the Healthy People initiative has grown over the last three decades to more than 460 objectives—about a third of which relate to children. This approach identifies important public health issues for children and families, and assesses the relevant science available on these topics, in order to stimulate public discussion and effective interventions. The multidisciplinary and broad public health expertise of the Public Health Policy Advisory Board has taken a similar approach. Dr. Louis W. Sullivan, the current Chairman & CEO of the Public Health Policy Advisory Board, was among the distinguished leaders who participated in the release of the *Healthy People 2010* Report. *Healthy People 2010*, which now includes a set of ten leading health indicators, has provided a monitoring apparatus to measure and achieve progress towards our child health goals.

Report language urging the Surgeon General to host a summit on obesity policy to develop a national strategic plan to prevent obesity and to complete the Surgeon General's Report on Nutrition and Health which was to focus on dietary fat

Answer. The Surgeon General is very concerned about the increasing health burden of obesity and overweight, and has considered how best to contribute to its alleviation. Towards this end, HHS and the U.S. Department of Agriculture (USDA) are jointly planning a National Nutrition Summit for May 30–31, 2000, that will have a major focus on overweight and obesity. This summit will highlight: accomplishments in food, nutrition, and health that have occurred since the 1969 White House Conference on this topic; the continuing challenges and emerging opportunities in this area; and nutrition and lifestyle issues across the human lifespan, especially those that we confront in solving the nation's epidemic of overweight and obesity. The summit will include policy makers, leading researchers in obesity, nutrition, physical activity and community-based prevention, and representatives of consumer, trade, business, and health professional organizations. An HHS/USDA interdepartmental steering committee is coordinating the summit, and held a public meeting in December 1999 to solicit input on the agenda. The committee will continue to solicit input and to involve other relevant government agencies in its planning efforts.

As a follow-up to the 1988 *Surgeon General's Report on Nutrition and Health*, and to fulfill the requirements of Public Law 103–183, a *Surgeon General's Report on Dietary Fats and Health* was being developed under the aegis of the Department's Nutrition Policy Board. However, it became clear to the report drafters that, while the role of dietary fats (especially saturated fats) in coronary heart disease is well established, the science related to dietary fat intake and other chronic diseases is still evolving—and has become increasingly complex and, in some cases, contentious.

There is also emerging evidence that energy balance is a key dietary factor affecting health and disease risks, independent of the effects of fats. Because dietary fats are a component of energy intake, it is difficult to parse the effects of fat or types of fat on disease risk and energy intake per se.

Therefore, in order to obtain the balanced review needed to address this issue, the Office of Public Health and Science turned to the Institute of Medicine (IOM). In the fall of 1999, IOM began a 24-month comprehensive review of macronutrients with dietary fats and health, and including energy balance as a major component. This review is part of the IOM's multi-year project to evaluate nutrient requirements and establish recommended dietary intakes. Several other significant reviews with relevance for dietary fat and health issues parallel the IOM study; these include: a National Cancer Institute-funded systematic review and synthesis of the research literature concerning diet-related behavior change interventions; a Rand Corporation study funded by the Centers for Disease Control and Prevention on healthy aging, which will include diet, nutrition, and fat; and the National Cholesterol Education Program's expert panel review of current detection, evaluation and treatment methods for high blood cholesterol. As these reports are finalized, the science related to dietary fats will be better understood, and the Department will be better able to take appropriate action to promote and protect public health.

Report language under the National Institute on Alcohol Abuse and Alcoholism regarding Fetal Alcohol Syndrome (FAS), genetics, neuroscience, medications development, alcohol and Hepatitis C, alcoholic liver disease, and "Research to Practice" Forums

Answer. Fetal Alcohol Syndrome (FAS)—FAS research at NIAAA is supported in both the intramural and extramural programs and accounted for approximately 6.7 percent of the Institute's budget in fiscal year 1999. Prevention of FAS is a high priority for the Institute. All meritorious candidates submitted in response to a recent request for applications have been funded. Research continues in a large community-based trial of comprehensive interventions to prevent FAS and other alcohol-related birth defects among four Plains Indian tribes, with two other Native American communities serving as comparison sites. A project to develop a screening tool and determine the prevalence of drinking in women in prenatal clinics in the District of Columbia also was cosponsored by the National Institute of Child Health and Human Development (NICHD). Data collection now has been completed, and data analysis is under way.

To aid the health care community in addressing the problem of FAS, the NIAAA has developed two manuals for use in clinical practice. These manuals soon will be ready for distribution. One is designed to train health practitioners who treat women of childbearing age on the assessment of risk drinking and on referral and intervention methods. The other provides a guide for pediatricians on screening children for FAS. The NIAAA plans to pilot test the effectiveness of both manuals with primary care health professionals. In addition, the NIAAA is preparing a Request for Proposals to establish a FAS clearinghouse.

The NIAAA will continue its leadership of the Interagency Coordinating Committee on Fetal Alcohol Syndrome (ICCFAS). Member organizations include seven organizations within the U.S. Department of Health and Human Services (DHHS), the Office of Special Education in the U.S. Department of Education (DoED), and the Office of Juvenile Justice and Delinquency Prevention in the U.S. Department of Justice (DOJ). To promote information exchange and to assure high quality research, the NIAAA sponsored an investigator workshop at the October 1999 ICCFAS meeting.

—Genetics—Approximately 50–60 percent of total population vulnerability to alcoholism is mediated by genetic factors. The NIAAA-funded Collaborative Study on the Genetics of Alcoholism (COGA) has found significant evidence for genetic linkages on several chromosomes. These chromosomal regions are likely to contain genes that influence alcohol-related behavior. This powerful new data set generated by COGA is now ready for release to the general scientific community. The COGA databases contain extensive clinical, diagnostic, psychological, neurophysiological, pedigree, and genetic data on thousands of individuals, who comprise hundreds of families of alcoholics under study. The neurophysiological data will be distributed by SUNY Downstate Health Sciences Center (New York, NY); all other data will be distributed by Washington University (St. Louis, MO). The companion collection of cell lines and DNA samples from individuals studied will be distributed by Rutgers University (Piscataway, NJ). The Institute plans to encourage intensive analysis of the substantial COGA data set by the broadest possible spectrum of investigators.

—Neuroscience—Approximately 25 percent of the NIAAA's resources are committed to neuroscience research. Recent neuroscience findings on the biologic mechanisms that underlie alcohol's effect represent new possibilities for development of medications for alcohol disorders. Most pharmaceuticals target specific protein sites. Scientists have identified at least one protein site on a neuroreceptor implicated in alcohol's neurodepressant actions, opening the potential for design of compounds to block such protein sites and, thus, alcohol's effects. In response to these and other findings, the Institute has solicited research grants for the study of in vivo screening models that will test new compounds for alcoholism pharmacotherapy. Another initiative solicits research that will examine how alcohol affects neurochemical changes that take place during adolescence.

—NIAAA-supported scientists are using and expanding powerful new techniques for studying specific protein areas of neuroreceptors. Site-directed mutagenesis and chimeric techniques permit researchers to examine, individually, components of neuroreceptor proteins to determine if they are involved in the brain's response to alcohol. Gene knock-out techniques eliminate the activity of specific genes and the proteins they encode. These genetic techniques thus allow scientists to test whether specific proteins, including components of neuroreceptors, mediate alcohol's effects on nervous system function. The NIAAA will issue a Request for Applications (RFA) to apply these techniquest to alcohol studies in fiscal year 2000. In addition, NIAAA-funded investigators are among the pioneers of a microdialysis technique that enables researchers to directly measure—simultaneously—neurotransmitter and neurophysiologic response in freely-behaving rats exposed to cognition-altering substances.

Based on these neuroscience finding, NIAAA-supported scientists are developing new pharmacologic compounds. Grants awarded under the pharmacotherapy-screening initiative will enhance the laboratory testing process for evaluating the therapeutic potential and likelihood of risk associated with these substances. Once this screening task has been accomplished, promising compounds will follow the usual route in the medication-development pipeline; namely, testing for efficacy and safety in animal studies, then small-scale human trials, when appropriate. Compounds shown to be safe and effective in small-scale human trials will then become candidates for large-scale human clinical trials.

—Medications Development—NIAAA-supported scientists are making rapid progress in understanding the neurobiologic mechanisms that underlie alcohol's effects. With this understanding comes the potential to design compounds that therapeutically alter these mechanisms. To channel this rapid accumulation of data toward medication development, the NIAAA is encouraging research grant applications that will result in new methods of screening promising compounds with therapeutic potential. This screening initiative also includes a component intended to stimulate research on pharmacotherapy for the sequelae of alcoholism, such as liver disease.

—Project COMBINE, a large, multi-site, clinical trial of promising alcohol-treatment medications—naltrexone and acamprosate—is ongoing. Investigators are testing the effectiveness of these medications alone and in combination. The medications are being evaluated with two behavioral interventions which are applicable to two types of treatment settings. One is applicable to primary care medical practices, and the other is suitable for addiction medicine speciality practices. Preliminary studies evaluating safety of the combination of the medications and the feasibility of the study protocol are in progress, and the main trial will begin early in year 2000.

—Alcohol and Hepatitis C—The NIAAA is an active and integral component of the research initiatives and collaborations among the NIH Institutes regarding hepatitis C virus (HCV). Heavy drinking increases the severity of hepatitis C and complicates its treatment. Recognizing the substantial increased risk for infected individuals to advance to end-stage liver disease and liver failure, the NIAAA has released a Request for Applications (RFA) in fiscal year 2000. This solicitation specifically focuses on the role of alcohol in promoting end-stage liver disease and subsequent death in HCV patients. Principal goals of this research include elucidating alcohol's impact on the course of hepatitis C, as well as exploring potential mechanisms and their exploitation in the development of successful treatment options.

In fiscal year 1999, the NIAAA also cosponsored other HCV initiatives. For examples, the NIAAA participated in the requests for Hepatitis C Research Centers, sponsored by the National Institutes of Allergy and Infectious Diseases (NIAID), that will provide a national research network blending basic research

and clinical investigations to promote translational research in HCV research—that is, bring the basic research findings into the clinic. In addition, the NIAAA co-sponsored a request for Small Business Innovation Research (SBIR) applications to establish new animal models to advance the field of alcohol and hepatitis C research. An underlying premise is that multi-disciplinary basic laboratory, animal model and clinical research is needed to advance our understanding of HCV and the liver disease and cancer it can cause. The Institute also has established a new collaboration with the American Liver foundation's (ALF's) "Hepatitis C Initiative" and is working closely with the ALF in advancing patient-related information and activities.

—Alcoholic Liver Disease—Scientists have made significant progress in understanding the biological mechanisms that lead to organ damage in alcoholic liver disease (ALD), the fourth leading cause of death among urban U.S. males and a source of costly morbidity. Among the findings are that reactive oxygen species (namely, producers of free radicals, which cause harmful changes in many molecules) and Tumor Necrosis Factor (TNF), a protein that causes an inflammatory response, play major roles in ALD, NIAAA-funded investigators are researching numerous methods to either inhibit TNF expression in liver cells directly through genetic manipulation or by specific insertion of TNF-inhibitors into liver cells. In fiscal year 1999, the Institute expanded this research area through a Program Announcement (PA), entitled "Mechanisms of Alcohol-Induced Hepatic Fibrosis," which solicits grant applications elucidating new therapeutic approaches for the fibrosis seen in alcoholic liver diseases. Since TNF is implicated in many major diseases (for example, cancer, arthritis, and multiple sclerosis), advances in discovering how to selectively express cytokines associated with organ damage will benefit a variety of disciplines.

—Research and Practice Forums—In 1997, the Director of New York's Office of Substance Abuse Services met with NIAAA Director Dr. Enoch Gordis to discuss a number of issues affecting prevention and treatment services in the State. Two ideas emerged: (1) directing research dissemination efforts specifically to clinical directors of treatment programs, and (2) developing a rigorous research demonstration project to test recommended science-based clinical practices and measure outcomes in four or six volunteer treatment programs. To fund these efforts, the Institute entered a partnership with the Center for Substance Abuse Treatment (CSAT). The first phase of the collaboration was a "research-practice forum" held in Saratoga Springs, NY, in October 1998. The research symposium was designed specifically for clinical supervisors and directors in New York who received the most cutting-edge research findings on issues affecting their work for incorporation into their programs. In turn, researchers also benefitted from input and information from the supervisors about real world barriers and difficulties encountered in their clinics.

The NIAAA and CSAT continue work with New York State, the provider's association, and clinical directors of six programs on phase II of this project. Six programs have been selected to participate in the Best Practices/Researcher in Residence Program. The program's goal is to encourage the adoption in clinical practice of recent treatment research advances by placing nationally recognized scientists in brief periods of residence at participating clinical treatment sites. Information exchange between participating researchers and clinical supervisors and staff will occur through training sessions, research seminars, presentations of recently-developed techniques, case reviews, and clinical problem solving.

This program has been expanded to the State of North Carolina where a forum was held in November 1999. Phase II of the North Carolina project is under discussion and will be implemented in year 2000. If efforts in these two states shod sufficient promise, they will be repeated elsewhere throughout the country.

INTERNATIONAL CONFERENCE ON RURAL AGING

With more than fifteen percent of the West Virginia's population being at least sixty-five years of age, a percentage that is expected to increase over the next several years, such statistics underscore the need to take a closer look at how the needs of an aging population may affect West Virginia, the United States, and nations around the world. To help address the challenges associated with aging, delegates from around the globe are slated to converge in Charleston, West Virginia, this coming June for the international "Rural Aging: A Global Challenge" conference. The rural aging conference is planned to direct special attention toward meeting the needs of the elderly residing in the some of the least developed areas of the world.

Organizers hope that the event will result in a stronger commitment to senior citizens by both the public and private sectors.

Question. Currently, West Virginia University has submitted its application to the Administration on Aging for release of the remaining $500,000 that I secured for implementation of the conference. What steps will you take to ensure the funds are released before the June 9, 2000 deadline?

Answer. The Administration on Aging has been in frequent contact with the staff from West Virginia University to assure processing of funds as quickly as possible. Extensive technical assistance has been provided to assist in the planning of the conference. The Project Officer at the Administration on Aging has helped University staff connect with representatives of the U.S. Federal Committee, State International Year of Older Persons coordinators and internationally recognized speakers. She has also developed publicity, recommend substantive program content and identified partners who are providing help in handling the details of this event. Based on all the assistance provided HHS has every confidence the funds will be released before June 9.

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OBESITY IN WEST VIRGINIA

Question. The West Virginia Department of Health and Human Resources reported in May 1999 that 4.2-percent of West Virginia's population falls into the category of being clinically obese. This alarming statistic places West Virginia first in the nation in obesity, with the percentage reportedly growing higher each year. Sadly, it is the children who are falling prey to this epidemic, making them the fastest growing portion of the obese population. What steps are you taking to create heightened obesity awareness and prevention, particularly with regard to West Virginia?

Answer. The Department sees obesity as a very serious public health problem. In fiscal year 2000, CDC received approximately $4.5 million in new funds for nutrition/obesity activities. With these funds, CDC will provide support to up to eight states to initiate nutrition and physical activity programs to prevent and control obesity and related chronic diseases. In carrying out these programs, states will (a) select one or more priority population in which to plan and initiate activities; (b) develop appropriate internal and external partnerships to carry out the plan; and develop, conduct, and evaluate nutrition and physical activity intervention programs. West Virginia is encouraged to apply for CDC funding.

Currently, CDC provides funding for State-based school health programs in West Virginia to: (1) develop a state system of support for coordinated school health programs ($225,000) and (2) expand comprehensive school health education, with a focus on physical activity, nutrition and tobacco use prevention ($212,000). West Virginia has used these funds to:

—Assist in the development and implementation of child nutrition polices. The West Virginia's Department of Education requires food served in school cafeterias to meet the dietary guidelines and prohibits the sale of high sugar and high fat foods during the school day;

—Evaluate and develop revised physical education requirements. The State Board of Education requires Physical Education requirements in grades K–8, and a full unit of Physical Education instruction as a high school graduation requirement;

—Develop physical fitness requirements. President's Physical Fitness Test is required by law for all students in grades K–9 which includes a new accreditation standard that requires schools to have a 40 percent passage rate on the test or show improvement in each of the previous 3 years;

—Develop standards in health education and physical education for the State Board of Education;

West Virginia plans to hold a Nutrition Symposium in 2001 for school health teams that will focus on obesity and being overweight; and continued physical edu-

cation summits to help physical education teachers change their focus from sports to lifetime fitness activities.

MEDICARE REIMBURSEMENT OF AMBULANCE SERVICES

Question. Earlier this year, the Health Care Financing Administration (HCFA) advised all carriers to suspend any Inherent Reasonable (IR) pricing until the Government Accounting Office (GAO) has finished their study of current IR authority as revised by the Balanced Budget Act of 1997 (BBA). Although HCFA is scheduled to implement a fee schedule reimbursement for ambulance services beginning January 1, 200 1, counties such as Doddridge and Marion are in dire need of a reassessment. What can you do to provide relief to West Virginia's ambulance services?

Answer. Since our instructions to the carriers to suspend any inherent reasonableness activities, the Congress enacted the Balance Budget Refinement Act of 1999 (BBRA). Section 223 of BBRA prohibits use of the inherent reasonableness authority by the Secretary or her contractors until (1) the General Accounting Office (GAO) reports on its inherent reasonableness study, and (2) HCFA publishes a final rule that responds to the GAO report as well as to the comments received on the January 1, 1998 Interim Final Inherent Reasonableness regulation.

Therefore, we currently have no mechanism to provide relief to ambulance suppliers in your state at this time.

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

HEAD START

Question. The President's goal is to enroll $1 million children in Head Start by 2002. Providing children with access to programs that improve cognitive and social development in their early years is important. And yet, "Head Start has only vague performance standards and no curriculum to stimulate the growth of literacy and numeracy," say Henry Aaron and Robert Reschaeur in *Setting National Priorities, The 2000 Election and Beyond*. What is HHS doing to move Head Start from custodial child care to a program that stresses cognitive development and learning?

Answer. Head Start is America's premiere early childhood education program, and continues to lead the way in state-of-the-art approaches to enhancing young children's development. Head Start's performance standards are, in fact, quite comprehensive and clearly delineate what programs must do in serving children and families. These standards cover the areas of Education and Early Childhood Development, Child Health, Child Mental Health, Child Nutrition, Family Partnerships, Community Partnerships and Program Governance, among others. A copy of these standards is attached. Furthermore, it should be noted that the Performance Standard on Education and Early Childhood Development clearly requires that all programs must, in collaboration with Head Start parents, implement a curriculum and goes on to discuss what this curriculum must include.

This Administration has invested heavily in improving not only the cognitive learning aspects of this program, but in raising its standards. We have paired investment in critical elements of quality such as teacher compensation and training with a tough approach to enforcement of high standards in every Head Start program. Annual salaries for Head Start teachers have increased from $14,600 in 1992 to $20,700 this year. Since 1995, more than 140 local grantees have been replaced because they have been unable to rectify deficiencies in program quality. We will continue these investments in fiscal year 2001 and will devote more than half of all new Head Start money to continued improvements in the quality of the program.

In addition, Head Start has made a commitment to measuring child outcomes, including cognitive outcomes as well as other key aspects of children's development and parental involvement. Our research shows that typical children leave Head Start with a wide range of specific knowledge and skills that prepare them for kindergarten. These practical, common sense achievements form the foundation for continued progress in learning by Head Start children in kindergarten where they show statistically significant growth in vocabulary, letter recognition, writing and other pre-reading skills.

Question. Would HHS be opposed to changing the focus of the Head Start program so that more attention is placed on the development of cognitive skills?

Answer. Head Start provides top-quality early childhood education along with comprehensive services, such as health, nutrition, and family support services, to almost 900,000 low-income, preschool children and their families across the nation, including more than 81,000 children and their families in California.

Head Start currently places a strong emphasis on cognitive skills. Preliminary results from the Family and Child Experiences Survey (FACES) indicate that average program quality is in the "good" to "excellent" range and no classroom scored below the "minimal quality" range. Head Start children are ready for school, performing above the levels expected for children from low-income families who have not attended center-based programs. The survey also found that 66 percent of Head Start parents read to their child three or more times a week and that 70–90 percent of parents teach their children letters, numbers or songs.

We are building upon this progress with new initiatives, including expanded training in family literacy services, new partnerships with prekindergarten and child care programs, and the development of local grantee systems to track and analyze child outcome data.

Question. What kind of coordination or communication does the Department of Education have with HHS on this program?

Answer. The Head Start Bureau has extensive collaborative relationships and initiatives with the Department of Education, including the following:

—Recent joint sponsorship with Title I, Even Start, and HHS's Child Care Bureau of a national leadership forum of State leaders and managers of prekindergarten, Head Start, and child care programs to explore new opportunities to use State and Federal early childhood funding to reach more children with higher quality services and to identify ways to eliminate barriers to cross-program collaboration.

—Long-standing involvement with ED in joint efforts to serve infants, toddlers, and young children with disabilities, including participation in the Federal Interagency Coordinating Council, and public-private partnerships such as the Conrad Hilton Foundation/Head Start $15 million initiative to training community teams of Early Head Start, ED early intervention program providers, parents and other community agency leaders to improve serving to infants and toddlers with disabilities.

—Collaborative efforts in research and accountability efforts, including joint sponsorship and funding of major longitudinal studies of early childhood development (including the National Center for Education Statistic's Early Childhood Longitudinal Survey, Kindergarten & Birth Cohorts) and emerging efforts in Title I and Even Start to utilize the Head Start Performance Measures outcome measures in Federal evaluations and State-level accountability efforts.

—Additional leadership efforts between Head Start and public education programs and systems occur at the State and local level through the nationwide network of Head Start-State Collaboration Offices which give priority attention to forging linkages among local Head Start agencies, family literacy initiatives, State prekindergarten programs, and local education agencies.

—Finally, and most importantly, every local Head Start grantee is held accountable for maintaining strong and effective partnerships with local elementary schools and districts through specific mandates covering the provision of family literacy and adult education services, services to children with disabilities, and preparing every child and family for a successful transition to kindergarten.

Question. Shouldn't we move Head Start to the Department of Education and convert it into a strong preschool program and focuses on cognitive development?

Answer. I do not believe that Head Start should be transferred to the Department of Education. While the cognitive elements of Head Start are extremely important, the genius of the program is that it is comprehensive. It integrates health, nutrition and family support services with education and learning. The American Customer Satisfaction survey found that Head Start=s composite satisfaction score of 87 is unsurpassed among all public and private entities in the survey. Head Start parents said that they would recommend Head Start to other parents and that they are confident that Head Start will continue to do a good job of providing preschool education in the future. In addition to these high levels of parent satisfaction, Head Start programs demonstrate exemplary levels of parent involvement, a key ingredient in children=s success.

We are continuing to introduce new initiatives to challenge and support Head Start's drive for excellence, including expanded training in family literacy services (in collaboration with the Department of Education's Even Start program), new partnerships with pre-kindergarten and child care programs and funding sources, and the development of local grantee systems to track and analyze child outcome data.

IMMUNIZATIONS

Question. You have told me that opening up the Federal Vaccines for Children Program to SCHIP beneficiaries would require a legislative change. Would you support legislation to make SCHIP beneficiaries eligible for the Vaccines for Children Program? If no, why not?

Answer. The Department would not oppose such legislation.

HIV/AIDS

Question. What are your plans to reinvigorate the government's focus on preventing the further spread of HIV/AIDS, particularly in communities of color?

Answer. The Centers for Disease Control and Prevention has the lead for the Department in preventing the further spread of HIV/AIDS. CDC has initiated a number of national, regional, and community-based programs designed specifically to reach racial and ethnic minorities at greatest risk of HIV infection. CDC is focusing specifically designed programs on the HIV/AIDS prevention needs of African- Americans and other disproportionately affected racial/ethnic minority communities in three broad categories: technical assistance and infrastructure support, increasing access to prevention and care services, and building stronger linkages to address the needs of specific populations.

In October 1999, CDC awarded funds to more than 100 organizations throughout the nation to expand HIV prevention efforts in African-American and other communities of color at high risk of infection, including Latinos, Native Americans and Asian Pacific Islanders communities. The 1999 awards represented a 50 percent increase in funding earmarked for HIV prevention efforts in African-American communities. Awards include 47 African American community-based organizations (CBOs) and 7 State and city health departments to develop HIV prevention programs in correctional facilities to reach high-risk minority populations, as well as, new national efforts to encourage HIV testing among African- Americans and others at high risk of HIV infection.

In addition, CDC continues to provide funds to State and local health departments for HIV prevention. Funding priorities for the health departments are determined through a community planning process. Community planning provides an approach to ensure community voices and programs to keep pace with the local epidemic, and States are strongly encouraged to direct resources towards their HIV epidemic. Funds are used to (1) address prevention needs in communities of color; (2) build capacity of grassroots organizations to deliver effective, targeted, culturally competent interventions; and (3) supplement funds for demonstration projects focusing on HIV seropositive persons, correctional activities, and perinatal prevention work. In fiscal year 2001, an increase of $40 million will fund grants allocated through the community planning process to focus on high risk populations, including minorities. An additional $10 million will also be directed towards the"Know Your Status" campaign in fiscal year 2001 to focus predominantly on minority populations.

Question. What has HHS learned during the past year about the effectiveness of the current role and structure of the CARE Act in improving access to HIV treatments among underserved communities?

Answer. Over 67 percent of Ryan White CARE Act programs provide services to minorities, based on 1997 Annual Administrative Reports from CARE Act grantees. An initial draft of a study conducted by the University of California, San Francisco, and supported by HRSA, did not find minorities disproportionately under represented in acquiring access to HIV treatments when other public funding and entitlement benefits programs (e.g., state programs and Medicaid) are taken into consideration. The study's final report is expected by the end of fiscal year 2000.

Question. Do you think the current formula used to distribute funding is effective and working? Why or why not? If not, what changes would you propose to the formula?

Answer. We do believe the current formula for distributing funds under Title I and II, which was revised when the CARE Act was reauthorized in 1996, is effective and works. In order to more fully understand and address the complex set of issues associated with the allocation formulas, the Administration supports the authorization of an Institute of Medicine study to examine the financing and delivery of HIV services to low-income, under and uninsured persons with HIV.

Question. Do you think the current formula effectively sends funds to areas where the AIDS epidemic is? Why or why not? If not, what changes would you propose to make?

Answer. We believe the current formula effectively sends funds to areas where the AIDS epidemic is. In order to more fully understand and address the complex set

of issues associated with the allocation formulas, the Administration supports the authorization of an Institute of Medicine study to examine the financing and delivery of HIV services to low-income, under and uninsured persons with HIV.

Question. What can HHS do to make certain that the funding is going to communities most impacted by the epidemic? What should Congress do?

Answer. As you already know, Congress appropriated additional funds to address the needs of minority communities through the Congressional Black Caucus initiative in both the fiscal year 1999 appropriation and the fiscal year 2000 appropriation. The Agency allocated funds to communities based on the allocation process specified in the report language accompanying the fiscal year 1999 appropriation and is assessing the impact of these funds. In allocating these funds, grantees were provided direction in the use of these funds. The fiscal year 2000 appropriation significantly increased the amount of CARE Act funding designated for minority communities.

We understand that the Senate is beginning to discuss Ryan White reauthorization. We believe that this reauthorization can strengthen the Ryan White program's ability to ensure that funding is going to communities most impacted by the epidemic. This can be accomplished by considering changes to the Act that will focus on methods for identifying and reaching HIV-positive individuals who are not currently receiving care, increasing the service capacity of providers in underserved communities, and establishing increasingly accountable service networks.

BIDIS

Question. Given the widespread availability of bidis and their harmful health effects, it is especially important that bibis be included in all anti-tobacco programs. What is HHS, FDA, and CDC doing to address the increasing use of bidis?

Answer. Research has shown that bidis are a significant health hazard to users, leading to an increased risk of coronary heart disease and cancers of the mouth, pharynx and larynx, lung, esophagus, stomach, and liver. One study found that a bidi produces more than three times the amount of carbon monoxide and nicotine and more than five times the amount of tar than a cigarette, when tested on a standard smoking machine.

In 1996, the Food and Drug Administration (FDA) published a final rule prohibiting the sale of cigarettes and smokeless tobacco products to minors. The Agency has been enforcing the provision since 1997 in an enforcement partnership with state and local governments.

Bidis are not ordinarily sold in conventional tobacco retail establishments. FDA is carrying-out research to determine the types of retail outlets that are likely to sell bidis; results are expected shortly. Once this information is available FDA can then determine whether additional unannounced inspections should be conducted in those establishments.

This is of course, contingent upon the Supreme Court's review of FDA's legal authority to regulate tobacco and tobacco related products.

Recent trends related to bidi use among youth underscore the need for a greater focus on preventing young people from ever starting to use bidis or any other tobacco product and to help young people to quit tobacco use. The Centers for Disease Control and Prevention (CDC) continues to help States address the use of bidis and other tobacco products through the implementation of comprehensive tobacco prevention and control programs. In particular, CDC is working with States to develop messages to inform the public about the health risks attributed to bidis use to refute the notion that they are safer to smoke than cigarettes, explore ways to involve young people and their families in efforts to prevent tobacco use to include bidis, and survey teens in order to determine trends in bidis use.

There is still much to be done, but we have established dialogue and provide ongoing technical assistance to the states and national organizations in their efforts to effectively address all tobacco issues, including bidi use.

Question. Shouldn't all bidis packages carry health warning labels? If so, what are you doing to make certain this happens?

Answer. The Federal Trade Commission (FTC) is working with bidis manufacturers and the U.S. Customs Department to ensure that health warning labels are properly placed and appear on bidi packages imported into the U.S. Anecdotal evidence indicates that some bidi packages imported and sold in the U.S. do not contain health warning labels. The public is encouraged to notify the FTC if they observe bidi packages not containing health warning labels. The FTC should answer further questions regarding the placement of the Surgeon General's rotating health warning labels on packs of bidis.

Question. Shouldn't they be sold with the same age restrictions as other tobacco products? If so, what are you doing to make certain this happens?

Answer. Bidis are subject to the same age restrictions as other tobacco products. Bidis are not safe and should never be considered a safe alternative to any form of tobacco product including cigarettes, spit tobacco, cigars or pipes. Therefore, concerns regarding the accessibility of bidis among youth are similar to minors' access issues for other tobacco products. Currently, bidis are available through the Internet, tobacco shops, some ethnic food and convenient stores, and in selected health stores. Anecdotally, youth (under the age of 18) have little difficulty purchasing them.

The Synar Amendment, enacted in 1992 and implemented by the Substance Abuse and Mental Health Services Administration (SAMHSA), requires States to enact and enforce laws prohibiting any manufacturer, retailer, or distributor from selling or distributing tobacco products—including bidis—to individuals under the age of 18. The goal of the amendment was to reduce the number of successful illegal purchases by minors to no more than 20 percent of attempted buys by minors in each State within a negotiated time period.

SAMHSA is working closely with the States to broaden their enforcement to include spit tobacco, cigars, bidis, etc. in addition to cigarettes. In addition SAMHSA is conducting a series of State and regional studies to measure the availability of these tobacco products to youth, and whether there are differences in retailers' willingness to sell to youth based on the type of tobacco product.

Question. How can we expand health services in underserved areas by reducing training opportunities of qualified health professionals? Why did you propose to cut funding?

Answer. The fiscal year 2001 budget will work to ensure a diverse workforce that is adequately distributed. The request is $218 million, an $84 million reduction. Within this overall funding level HRSA will focus resources on programs which will help disadvantaged students and reflects the Administration's goal to move away from broad-based categorical programs. Within this level there is a $10 million increase for the Centers of Excellence and the Health Careers Opportunity programs, both of which have success in increasing diversity by recruiting and retaining promising racial and ethnic minority students in health professions training. Also included in the total request is $80 million for the Children's Hospitals Graduate Medical Education (GME), doubling the funding available in fiscal year 2000. These funds will raise the level of GME support for approximately 60 freestanding Children's Hospitals to be more consistent with other teaching hospitals.

NIH SALARY CAP

Question. Wouldn't an increase in the NIH salary cap benefit biomedical research?

Answer. An increase in the NIH salary cap is unlikely to benefit biomedical research directly. In those instances in which an institution chooses to provide a base salary that exceeds the current statutory salary cap, an increase in the salary cap could affect the amount of their own funds that research institutions have available for the support of the government-university research enterprise. However, covering the additional costs for those grants resulting from an increase in the NIH salary cap could reduce the number of awards the NIH is able to make.

Question. Do you support an increase in the salary cap to Executive Level I?

Answer. In the fiscal year 2001 President's Budget, the Administration proposes to maintain the salary cap at Executive Level II.

STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) ENROLLMENT

Question. Why is enrollment in SCHIP so low?

Answer. In December 1999, HHS announced that enrollment in SCHIP was nearly 2 million for fiscal year 1999. This represents a doubling in enrollment since December 1998. We are pleased with States' success in finding and enrolling these eligible children.

Remember, SCHIP is still a relatively new program and now that all States have programs approved, we expect to see further increases in enrollment once the programs are fully implemented.

States continue to engage in and improve upon outreach activities that will increase the number of children enrolled in SCHIP. Furthermore, States continue to submit plan amendments to expand the eligibility levels for their programs.

Question. What are the Department's current efforts to improve enrollment and decrease obstacles to enrollment in SCHIP?

Answer. The Administration's FamilyCare coverage proposal builds on States' operating SCHIP programs by expanding SCHIP to parents. This will increase enroll-

ment of children in the program because States would be required to cover children up to 200 percent of the Federal Poverty Level before covering parents in fiscal year 2001–2005. Furthermore, we believe enrollment of children in SCHIP and Medicaid will increase because children are more likely to be enrolled in health insurance if their parents are also enrolled.

FamilyCare also permits States to pool allotments with employer contributions toward the purchase of private coverage. Thus, families that would be eligible for FamilyCare will be able to access their employers' health plan as long as the employer contributes half the family premium costs and the health plan met FamilyCare standards.

In addition to covering the parents of SCHIP and Medicaid eligible children, we expect to cover an additional 400,000 uninsured children over the next 10 years through several new tools, including:

—allowing school lunch programs to share eligibility information with Medicaid,
—expanding sites authorized to determine presumptive eligibility for SCHIP and Medicaid,
—requiring States to make their Medicaid and SCHIP enrollment processes equally simple.

Over the next 10 years, we expect to cover 4 million additional people, that is, 3.5 million new adults (parents of Medicaid-eligible children) and 500,000 new children in Medicaid and SCHIP.

Question. What are the current efforts to ensure retention in the programs?

Answer. Since the welfare reform law was enacted in 1996, the Department has issued guidance and other information to the States about how Medicaid eligibility rules and procedures have been affected by welfare reform. Perhaps the most significant was a detailed guide, released in March 1999, that sets forth the Federal requirements and proposes a range of options that can promote enrollment among eligible families, including those leaving welfare. This guidance made it clear that transitional Medicaid is available to all families that would otherwise lose their Medicaid coverage due to earnings. HCFA is working with States to ensure that eligible families continue to receive Medicaid after they leave welfare without any gap in coverage.

Through its Regional Offices, HCFA recently conducted on-site reviews in every State and territory to examine current policies and practices with regard to Medicaid applications, eligibility and enrollment in the post-welfare reform environment. One goal of this effort is to take the appropriate steps to ensure that eligible families receive and retain Medicaid, including "transitional" Medicaid.

In addition, we will be synthesizing the findings from the site visits and developing a plan for the next steps, including technical assistance, corrective action if appropriate, and best practices identified through our site visits.

On January 6, 2000 we released guidance advising States of the continued availability of Federal funds set aside in the 1996 welfare law to help States cover the costs of adapting their Medicaid policies and systems to welfare reform changes. At the end of last year, the Administration worked successfully with Congress to extend the life of this fund. Most States have a considerable amount of funds to use for these purposes.

Finally, on April 7, 2000 we released guidance to ensure that eligible low-income families are able to enroll and stay enrolled in Medicaid. The letter to State Medicaid Directors covers State responsibilities in three related areas: identifying and reinstating people terminated improperly; processes for redeterminations for eligibility; computerized eligibility systems.

REPORTS REQUESTED IN LAST YEAR'S APPROPRIATIONS LANGUAGE

Question. What is the status of these reports?

Answer. Reports will be submitted at a later date.

Question. When will we receive these reports?

Answer. Reports will be submitted at a later date.

INDIAN HEALTH SERVICE FUNDING

The budget calls for an increase of $192 million for the Indian Health Service. While the increase in funding is appreciated, I fear it will not be enough to bring Indian Health up to even minimal standards.

In 1998, the House Appropriations Subcommittee on Interior directed the Indian Health Service to work with Tribes to address the question of funding equity for Indians. That group used outside consultants with proven experience in actuarial research and analysis. Using the Federal Employee Benefit Package (FEBP) as a

model, the group analyzed funding for Indian Health in four defined Indian populations.

What the group found was that an additional $1.2 billion dollars would have been needed in fiscal year 1999 to fully provide services comparable to those in the FEBP. The average cost of providing the FEBP-like services is $2980 per American Indian per year (of which approximately $750 is available from non-IHS sources such as Medicaid, CHIP and Medicare.) The IHS currently has on average only $1,200 of the needed residual amount of $2,230 per person per year.

Question. Congress asked for this funding study, the results are in. Why, then, did the Administration not ask for more funding for the IHS?

Answer. The Administration has proposed an increase of $230 million for the Indian Health Service as a step towards eliminating the disparities in health outcomes which currently exist between Indian people and other Americans. This 10 percent increase is the largest requested for the Indian Health Service in over two decades.

Much of the disparity in health outcomes is closely linked to poverty, unemployment, and lower levels of educational attainment in much of Indian country. To address these problems, the Department's budget includes a $96 million increase in other programs targeted towards American Indians and Alaska Natives including increases in Head Start, Child Care, tribal TANF, the Administration for Native Americans and the Administration on Aging. The requested increase for the Administration for Native Americans is also the largest in over two decades. Looking at the Administration's entire budget for Native Americans, a total of $9.4 billion is requested, an increase of $1.2 billion over fiscal year 2000.

Question. What can the Administration do to help me bridge this gap between supply and demand?

Answer. The Administration has requested an increase of $1.2 billion in funds for Native Americans for a total of $9.4 billion. HHS's part of this request includes an increase of $326 million in funding targeted to American Indians and Alaska Natives for an HHS total of $3.5 billion. Funding requests for both HHS Agencies which exclusively serve Native Americans-the Indian Health Service and the Administration for Native Americans-are the largest in over two decades.

In addition to requesting increased funding, better inter-agency cooperation is an important means of bridging this gap. The Health Care Financing Administration has worked to increase Medicare and Medicaid collections at Indian Health Services facilities by 103 percent since 1995. The Indian Health Service has recently entered into collaborations with the Centers for Disease Control and Prevention, the Head Start Bureau, the Substance Abuse and Mental Health Services Administration, the National Institutes of Health, the Bureau of Indian Affairs, the Agriculture Department, the Justice Department and the Veterans Administration.

Tribal consultation is also important to ensure that we understand the problems of Indian communities and to assist these communities in accessing assistance from all parts of the Department. In May of 1999, HHS held its first Department-wide tribal budget consultation meeting, Leaders from 35 tribes and tribal organizations presented recommendations covering the entire Department. Our second Department-wide tribal budget consultation meeting is scheduled for this coming April. The Deputy Secretary has also held a series of five regional meetings with tribal leaders over the past year.

A fourth way to bridge this gap is through supporting tribal self-determination efforts allowing tribes to provide their own health services under contract with the Indian Health Service. A recent National Indian Health Board survey of tribal leaders found that contracting tribes were significantly more likely to than non-contracting tribes to believe that their health services had improved over the past three years. The share of IHS's budget going for tribally operated programs increased from 28 percent in fiscal year 1993 to 44 percent in fiscal year 1999. To support continued growth in tribal self-determination efforts, the Indian Health Service's budget includes an increase of $40 million for contract support costs.

CLINICAL TRIALS DATABASE

In 1997, Congress passed the FDA bill and included the Snowe-Feinstein bill requiring HHS to establish a database and a 1–800 number for clinical trials so that patients and doctors can find out what research trials are being conducted for serious and life-threatening diseases. It has been almost 3 years. I received a press release last night saying you announced the launch at 12:01 a.m. Thank you very much.

Question. Is it operational? Can people now call an 800 number? Can they access it via the Internet? Are all research trials on it? Federal, private, others?

Answer. The ClinicalTrials.gov database is operational and available on the Web. The strategy adopted by the NIH was first to develop, test, and implement an Internet-accessible database of clinical trials; NIH is now investigating how best to implement an 800 number. There are presently about 4,200 clinical trials in this first phase of the database. These are primarily clinical trials sponsored by the NIH. There are also several hundred privately sponsored trials in the database, primarily related to AIDS and cancer. In the second phase of ClinicalTrials.gov, we will enter many more clinical trials sponsored by other Federal agencies and private and commercial trials.

Question. When will it be completed? How often will it be updated? What took it so long?

Answer. The ClinicalTrials.gov database will continue to evolve indefinitely as new trials are added. The database is updated nightly as new data are received by the NLM from the sponsors of clinical trials. The clinical trials database was mandated by the November 1997 FDA Modernization Act. After considering various options for implementation, NIH tasked the National Library of Medicine in September 1998 to create the database. During fiscal year 1999, the NLM worked expeditiously to organize the 20-plus NIH institutes to establish standard data elements for each clinical trial and to input the data for the first 4,200 NIH-supported clinical trials into the system. The database was released to the public on February 29, 2000.

CANCER REGISTRIES

Last September, the Sacramento Bee reported under a headline, "Retreat on Cancer," that California's landmark cancer registry is "slowing falling apart." We were the leader in efforts to track cancer at one time, dating back to the 1940s. But it's budget has been flat for a decade.

Question. Admittedly the State should put more resources into our cancer registry, but your proposal for funding cancer registries is flat for fiscal year 2001, at $24 million. The American Cancer Society recommends an appropriation of $55 million. Why aren't you increasing funding for cancer registries?

Answer. As you know, developing a budget involved hard choices between deserving programs. The Department is working hard to improve cancer registries nationwide. The National Institutes of Health and the Centers for Disease Control and Prevention are working more closely than ever to provide good epidemiological information on cancer. They will pool their cancer data resources and create a national infrastructure for cancer control and surveillance activities. CDC's National Program of Cancer Registries (NPCR) and NIH's SEER together cover virtually the entire U.S. cancer patient population. CDC supports registries in 45 States, the District of Columbia, and three territories. The SEER program covers 5 States, 5 major metropolitan areas, rural areas in one State, and selected populations of American Indians.

The California Cancer Registry has participated as an enhancement state with the CDC's NPCR since 1994. On the basis of 1996 data, the California registry has been certified by the North American Association of Central Cancer Registries for its data completeness, timeliness, and quality. An example of California's accomplishments with its limited resources is that the state routinely reports cancer rates for Asian and Pacific Islanders and for Hispanics. These rates can then be compared with the more readily available rates for whites and blacks. A recent registry report suggested that the state's tobacco control program may have helped decrease incidence rates for lung cancer among women in racial and ethnic minority populations.

The California registry is one of eight registries participating in a special NPCR-supported childhood cancer project to design, implement, and evaluate a method to use data from a state population-based central registry to compute expected numbers of incident cancer cases in children. The registry will evaluate completeness of its data and of other existing pediatric cancer databases, such as the Pediatric Oncology Group/Children's Cancer Group, by performing data linkage.

CANCER AND ENVIRONMENTAL RISK FACTORS

Question. NCI, NIEHS and CDC sponsor cancer research. Should we be doing more on environmental risk factors for cancer?

Answer. The emergence of new research tools for clarifying how environmental factors and susceptibility to cancer interrelate, has opened many new possibilities for research on environmental risk factors. The NCI has identified "Genes and the Environment" as a major scientific opportunity for cancer research for fiscal year 2001. Among the research areas for emphasis at both NCI and NIEHS are: identify more fully the environmental causes of cancer using new epidemiologic and genetic

approaches; identify genes that modify (increase or decrease) cancer risk, including the risk resulting from environmental exposures; integrate information on genetic susceptibility and environmental exposure to estimate cancer risks for individuals, families, and populations; and develop new strategies for cancer prevention, early detection, and treatment, building upon new knowledge about the genetic and environmental determinants of risk.

The study of geographical variation in cancer rates has provided important clues to the role of lifestyle and other environmental factors that affect cancer risk. A new edition of the *Atlas of Cancer Mortality in the United States from 1950–1994* was recently published by the National Cancer Institute. The geographic patterns of cancer displayed in the atlas should help target further epidemiologic investigations into the causes of cancer and to set priorities for public health activities aimed at cancer prevention and control.

Epidemiology and Exposure Assessment

NCI and NIEHS have a long history of working together to explicate the role of environmental factors in geographic variations in cancer mortality patterns, especially for breast cancer. This working relationship was established with the Congressionally mandated Long Island Breast Cancer Study Project (LIBCSP) and the Northeast/Mid-Atlantic Breast Cancer Program, both of which the Institutes have co-funded. The latter program, comprised of highly productive research, focusing on exposure to pesticides and related chemicals and electromagnetic frequency radiation in relation to breast cancer risk, has been completed and a report has been submitted to me.

Investigators on the Long Island Breast Cancer Study Project have explored new ways to study the relationships between the environment and breast cancer. However, much remains to be learned about the role of environmental exposures and other risk factors and their interaction with genes in promoting the development of breast cancer. Beginning in mid-2000, a series of papers are expected to be published that will address results of biomarker analyses, analysis of environmental samples, and interview data on exposures both environmental and non-environmental (e.g., diet, medications, medical irradiation, electromagnetic field radiation).

In 1999, NCI, in collaboration with NIEHS, convened an ad hoc advisory group of experts from many disciplines to discuss the present status of environmental exposure assessments and cancer epidemiology. Considerations for advancing the field during the next five years were summarized, focusing on research needs and new research directions. NCI and NIEHS program staff are currently preparing a request for applications (RFA) on exposure assessment incorporating the discussions at that meeting. It is expected that the RFA will be issued and funded in fiscal year 2000.

An RFA issued by NCI and NIEHS, entitled "Regional Variation in Breast Cancer Rates in the United States," launched new projects in which investigative teams are using statistical and epidemiologic methods to investigate factors that may influence, contribute to, or account for the reported differences in breast cancer incidence and mortality rates across different geographic regions. Data on women residing in California, Connecticut, Georgia, Hawaii, Iowa, Massachusetts, Michigan, New Mexico, Washington, Wisconsin, and Utah will be analyzed. A supplement to an ongoing study in New York is evaluating the effect of electromagnetic field radiation (EMF) on breast cancer risk. The results of these studies will be critically assessed to help direct the future research agenda on the environment and cancer.

The NCI and CDC have worked collaboratively in several areas, including cancer surveillance. A recent Memorandum of Understanding lays out areas for future growth and development of this collaboration. NCI will support CDC's efforts to enhance state-specific use of cancer surveillance systems for cancer control and to develop appropriate risk communications tools for use with public inquiries about cancer rates and trends.

The NCI's Epidemiology and Genetics Research Program (EGRP) was a co-sponsor of four initiatives led by the National Institute of Occupational Safety and Health (NIOSH) within CDC. The NCI component supported the environmental and/or occupational exposure assessments for epidemiologic studies of cancer.

In response to two of these initiatives, entitled "Implementation of the National Occupational Research Agenda" and "Mechanistic-Based Cancer Risk Assessment Methods," four new grants were awarded to develop and/or improve methods for assessing past environmental and occupational exposures that could be associated with geographically related cancers, including breast cancer. Research of this type (called exposure assessment) is important in understanding breast cancer for two reasons. First, we must be able to link breast cancer development to a carcinogen exposure that occurred years before the diagnosis; and second, we must be able to

obtain environmental data for assessing the role of gene-environment interactions in the etiology of breast cancer.

Intramural Geographic Information System Projects

A new area that offers some promising technologic methods for assessing the impact of environment on cancer is the Geographic Information Systems (GIS). NCI has completed several intramural projects designed to develop methods to use GIS in estimating exposure to crops sprayed with pesticides, drinking water contaminants, and measures of proximity to industries that release toxic substances. Methods to identify populations potentially exposed to agricultural pesticides using remote sensing and a GIS were evaluated. Several future efforts are planned to further examine the usefulness of GIS in cancer-related studies. Researchers will evaluate the accuracy of several "address-matching algorithms" that determine the geographic location of respondents in health-related studies, and a comparison will be made of household levels of pesticides in dust with proximity measures to pesticide-treated crops, as estimated by GIS methods. A "pesticide drift model" will be incorporated into GIS estimates of pesticide exposures among persons living adjacent to crop fields sprayed with pesticides.

In studies of cancer etiology, GIS methods will be used to help evaluate geographic patterns in prostate cancer mortality in relation to nitrate levels in drinking water and pesticide use. A GIS will be used to map populations in the Platte River Valley usingpublic and private water supplies and to estimate nitrate exposure in drinking water to evaluate associations with rates of several cancers. In a study of bladder cancer, Global Positioning System measurements will be collected and locational information will be used to link residences to information on water quality in existing databases and to evaluate proximity to industries and industrial releases of toxic substances.

Environmental Genome Project and Gene Expression Technology

The many rapid advances in technologies for molecular genetics research are providing new opportunities to understand the genetic basis for individual differences in susceptibility to environmental exposure and how exposure and susceptibility interrelate to the development of diseases like cancer. The NIEHS has established a research program on genetic susceptibility to environmentally-associated diseases through its Environmental Genome Project, which is aimed at the identification of allelic variants (polymorphisms) of environmental disease susceptibility genes in the U.S. population, the development of a central database of polymorphisms for these genes, and population-based studies of gene-environment interaction in disease etiology. By identifying those genes and allelic variants that affect individual response to environmental agents, scientists can better predict health risks and assist regulatory agencies in the development of policies on environmental protection policies. As previously mentioned, NCI has identified "Genes and the Environment" as a major scientific opportunity in cancer research for fiscal year 2001. We are only beginning to amass these data, and much more work is needed.

cDNA microarrays are tools that can be used to analyze changes in patterns of gene expression that contribute to cancer development. This technology may revolutionize the way problems in environmental health are investigated. Given that exposures to different classes of toxicants result in distinct patterns of altered gene expression, microarray technology can be utilized to categorize and classify these effects through the direct comparison of gene expression patterns in control samples versus those treated with toxicants. In defined model systems, treatment with known toxic and carcinogenic agents, such as polycyclic aromatic hydrocarbons, dioxin-like compounds, peroxisome proliferators, oxidant stress, or estrogenic chemicals, may provide a gene expression "signature" on a microarray which represents the cellular response to these agents. These same systems can then be treated with unknown, agents under suspicion, to determine if one or more of these standard signatures is elicited. This approach will also help elucidate an agent's mechanism of action and may also be used to detect changes in exposed human populations, information essential for the risk assessment process. cDNA microarrays also hold promise for the determination of interactions between combinations of agents (e.g., dioxin and estrogen). It is also likely that new molecular targets of toxic or carcinogenic action will be identified, and that these new targets may be good candidates for analysis in the Environmental Genome Project. NIEHS and NCI each have established the capacity to do cDNA microarray technology. In a collaborative research project with the National Human Genome Research Institute; NIEHS is developing custom cDNA arrays or "chips" that comprise human cDNA clones oriented toward the detection of the expression of genes involved in responses to toxic insult. The initial "ToxChip" we have designed includes genes for xenobiotic metabolizing en-

zymes, cell cycle components, oncogenes, tumor suppressor genes, DNA repair genes, estrogen-responsive genes, oxidative stress genes, and genes known to be involved in apoptotic cell death. Plans call for this technology to be available eventually to both intramural and extramural scientists on a collaborative basis. NCI has been actively promoting and funding the use of DNA microarray technology into the extramural community through a variety of approaches. The NIEHS is also working to enhance capacity for cDNA microarray technology in research institutions.

By exploiting recent advances in human genetics and recombinant DNA technology, we can develop animal models and in vitro assay systems to identify carcinogens and toxicants in a matter of weeks rather than years, with considerable savings in terms of money and use of animals. Using cDNA microarray technology, for example, toxicologists may be able to expose cells or tissues to chemicals whose toxicity is unknown and match the results against the "signature," or common set of changes in gene expression, produced by a known class of toxicants. This would reduce the need for lengthy and expensive rodent bioassays and could lend itself to testing the effects of low-dose as well as long-term exposure. The use of cDNA microarray technology to assess changes in gene expression in response to specific environmental exposures is a rapidly growing research area that will have a large impact on the environmental health sciences, including molecular epidemiology, and drug discovery. It is appropriate that the development and validation of this new application to environmental health science is being led by the NIEHS since this technology could revolutionize the field. Similarly the leadership of the NCI in applying this new technology, in cancer research, will speed new discoveries of environmental factors that contribute to cancer.

Also, it is now possible to modify genes in animals thus orchestrating the carcinogenic process. For example, incorporation of a chemically inducible oncogene into the germline produces animals with multiple copies of the modified gene in all the cells of the organism. Conversely, one can delete one copy of a gene that acts as a tumor suppressor. Such so-called transgenic animals are much more responsive to carcinogenic exposures. In preliminary studies, a carcinogen can be identified in these animals in six months (rather than two years). NIEHS has taken the lead to establish a major collaborative effort involving the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the pharmaceutical and chemical manufacturing industry, and two foreign governments (Japan and the Netherlands) to validate the four transgenic mouse models currently available for their capacity to predict carcinogenicity.

The NCI is planning to augment its Mouse Models of Human Cancer Consortium to develop new experimental models that parallel human cancer related genes, pathways and processes. The use of model systems, particularly the mouse with its powerful genetics, will elucidate the genetic basis of the etiology of cancer. The NIEHS is establishing Comparative Mouse Genomic Centers which will focus on developing mouse models for studying the biological function of variants of DNA repair and control genes, found in the human population. Having identified relevant genes in the mouse, we can then assess whether the comparable human genes contribute to the cause of human cancer. Manipulating the genetics of the mouse experimentally will enable us to decipher not just the major genetic risk factors, but also those whose effects on risk are more subtle. To find these same less penetrant genetic effectors in human populations will require much more time and the accumulation of very large populations. Transgenic mice also afford the opportunity to test the contributions of nutrients and endogenous and exogenous environmental factors in cancer etiology.

Question. Isn't it well established that cancer can develop from the interaction of genes and the environment (broadly defined)?

Answer. The importance of lifestyle and other environmental exposures as causes of cancer is unquestionable. The pivotal role of environment is reflected in the substantial variation in cancer incidence around the world and in the changes in risk observed among groups that migrate and become acculturated in a new host country. Furthermore, epidemiologic research has succeeded in identifying a wide range of factors that affect cancer risk, including tobacco use, dietary components, sunlight, ionizing radiation, environmental chemicals, infectious agents, obesity, exercise, and hormones. Nevertheless, the causes of many cancers remain elusive. While improved approaches to measuring exposures will provide new insights, it is clear that the environment represents only part of the equation in determining who is susceptible to cancer. It is also important to understand cancer susceptibility. For example, why does one person with a cancer-causing exposure (such as smoking or infection with human papillomavirus) develop cancer while another does not?

Viewing such questions through the lens of genetics promises to provide insights into these apparent paradoxes. The scientific investment in cancer genetics, initially

focused on the intensive study of rare cancer-prone families, already has paid huge dividends. These studies have opened a unique window into the basic mechanisms of cancer, with benefits extending well beyond the rare families from which they were derived. This is because the genes identified by these studies are altered forms of normal genes involved in key biochemical pathways controlling fundamental cell processes. It has become clear that these same pathways contribute to the development and progression of the more common, non-hereditary forms of cancer. Despite evidence that one's genetic makeup may influence susceptibility or even resistance to cancer-causing exposures, only recently have the tools become available to systematically determine how variations in these genes combine with environmental and other factors to induce cancer in the general population.

Question. What is the right balance?

Answer. It is difficult to answer since NIH is striving to understand the causes of cancer through a comprehensive evaluation of genetic and environmental determinants as well as their interactions. In particular, by incorporating recent major advances in molecular genetics into epidemiologic studies, it will be possible to gain not only insight into genetic susceptibility but also a more complete understanding of the specific lifestyle and other environmental exposures that are mediated through genetic pathways and affect the risk of developing cancer.

QUESTIONS SUBMITTED BY SENATOR BEN NIGHTHORSE CAMPBELL

HEALTH STATUS OF AMERICAN INDIANS

Question. It is my understanding that you have made statements regarding your support of efforts to improve the health status of American Indians and Alaskan Natives and that one of your most recent public statements was made last July to a number of tribal leaders here in Washington. Could you clarify what role you see the Department of Health and Human Services, outside of the Indian Health Service, taking in these efforts?

Answer. A major goal of both the Department and the Administration is the elimination of racial disparities in health outcomes. Accomplishing this goal will require substantial improvements in health outcomes for Native Americans who suffer a greater disease burden than other Americans. The Indian Health Service has primary responsibility for improving Native American health outcomes but many other parts of HHS also have a role to play. For example, the Health Care Financing Administration has worked to increase Medicare and Medicaid collections at Indian Health Services facilities by 103 percent since 1995. The Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the National Institutes of Health all collaborate with the Indian Health Services, assist Indian communities directly, and or conduct research into diseases and health conditions affecting Native Americans. While it is not a health Agency, the Administration on Children and Families supports empowerment and economic development of Indian communities through programs such as Head Start, Child Care, Social and Economic Development Strategy grants, and support for Tribes running their own TANF and Child Support Enforcement programs.

To ensure that all parts of the Department play their part, we hosted our first annual Department-wide tribal budget consultation meeting last May. This annual meeting is called for in our policy on Consultation with American Indian/Alaska Native Tribes and Indian Organizations. Our second annual meeting is scheduled for next April.

Question. I have heard that it was a Department view that Indian health issues were the responsibility of the Indian Health Service. Can you tell me how you expect a direct health service organization to research the causes of disease among Indian people or to test new prevention efforts for Indian people when, by all accounts, it cannot even fund the services necessary to treat existing health problems that occur in American Indian and Alaskan Native people?

Answer. The Indian Health Service has primary responsibility for improving the health status of American Indians and Alaska Natives but many other parts of HHS also have a role to play. The Indian Health Service has demonstrated its ability to make significant improvements in Indian health, for example reducing maternal and infant mortality by more than two thirds since the early 1970s. In order to continue these improvements, we have requested a ten percent increase for the Indian Health Service, the largest requested increase for this Agency in over two decades. The total amount request for all Health and Human Service programs targeted to American Indians and Alaska Natives is $3.05 billion, an increase of eleven percent

over fiscal year 2000. The request for the Administration for Native Americans is also the largest increase requested for that Agency in over two decades.

The Grants for Special Diabetes Program for Indians offers a good example of the work done by other HHS Agencies to assist the Indian Health Service. The Centers for Disease Control and Prevention works with this program to ascertain the epidemiology of diabetes, provide technical assistance to tribal Diabetes Program grantees and helps to establish partnerships between grantees and State Diabetes Control Programs. Much of our information about type two diabetes and its impact of on Indian communities comes from ongoing cooperative studies between the Pima tribe and the National Institutes of Health. The National Institutes of Health and the Indian Health Services are cosponsors of a national multi-center study to determine if type two diabetes can be prevented in those at high risk for the disease. Volunteers from four Indian communities are participating in this study.

Question. Aren't there agencies located within the Department of Health and Human Services which specifically research the causes of disease and test prevention efforts that would be better able to handle those activities?

Answer. The Indian Health Service was created to carry-out the Federal Government's commitment to deliver health services to Federally recognized American Indians and Alaska Natives. It has demonstrated its ability to make significant improvements in Indian health, for example reducing maternal and infant mortality by more than two thirds since the early 1970s. Other HHS Agencies address the health care needs of all Americans but they do so by focusing on differing areas: research at the National Institutes of Health, mental health and substance abuse at the Substance Abuse and Mental Health Services Administration, disease control and prevention at the Centers for Disease Control and Prevention. Each of these agencies addresses the health care needs of Indian people as part of its overall mission and each assists the Indian Health Service in its delivery of health services to Federally recognized American Indians and Alaska Natives. For example research at the National Institutes of Health has provided much of our information about type two diabetes and its impact of on Indian communities. The National Institutes of Health and the Indian Health Services are cosponsors of a national multi-center study to determine if type two diabetes can be prevented in those at high risk for the disease. Volunteers from four Indian communities are participating in this study. In addition to its work on diabetes, the National Institutes of Health supports the study of other disease in Indian populations such as asthma and lung cancer. The Centers for Disease Control and Prevention has established the National Diabetes Prevention Center to address the epidemic of diabetes in Indian country, works with tribes and tribal organizations to reduce breast and cervical cancer mortality and is conducting studies to better control several Indian health problems including Hantavirus, Hepatitis A and Pneumococcal infections. The Substance Abuse and Mental Health Services Administration provides funds to tribes and tribal organizations to plan and evaluate systems of mental health care, prevent substance abuse, work with high risk youth, and provide substance abuse treatment services.

HANTAVIRUS

Question. I recently picked up the Washington Post and read a story alleging that the Centers for Disease Control and Prevention had diverted millions of dollars of funds slated for hantavirus research to other work. I know that several of my colleagues are concerned about the way CDC officials handled the original hantavirus outbreak, and now we hear that the same agency has been diverting millions of dollars of money it has claimed was used on hantavirus research, contrary to Congressional reports. Have you been able to determine exactly how much was diverted form the hantavirus research program?

Answer. CDC made a mistake by not informing Congress of the need to use some of the hantavirus funding for other deadly infectious diseases, including ebola, lassa fever and Nipah virus. We have commissioned an external firm, PriceWaterhouseCoopers, to conduct an audit to determine specifically how the hantavirus funds were spent in fiscal year 1999. In the fiscal year 2001 Congressional Justification, CDC has proposed changes related to the hantavirus line to more accurately reflect that these resources will be used for hantavirus and other special pathogens.

In order to prevent such a situation from reoccurring, we have established the following corrective action plan:

—The Department's Chief Financial Officer (CFO) will review and certify, along with CDC's Financial Management Office (FMO), the correctness of all of the National Center for Infectious Diseases' (NCID) financial obligations through the remainder of fiscal year 2000.

—The Department's CFO will ensure that all senior decision-makers in the NCID will receive certified budget execution and financial management training.
—CDC has initiated an external review of their fiscal management practices, similar to the review done at NIH, to be completed in six months. The results of this analysis will be communicated to Congress as soon as the review is complete.
—CDC program managers will conduct a top to bottom review of CDC's 133 programs and projects to make sure there are no other areas of concern. During a 90-day period, CDC managers will be able to fully and openly identify any area for which there may be a discrepancy between actual expenditures and the information provided to Congress. This information will be reported to Congress.
—CDC has commissioned Price Waterhouse Coopers, a firm of independent auditors, to thoroughly examine its hantavirus expenditures. The results will be communicated to Congress immediately upon completion.
—CDC has appointed a new Acting Director for the Division of Viral and Rickettsial Diseases while CDC seeks new leadership for its' viral disease programs.

INDIAN HEALTH RESEARCH

Question. The President's request unveiled an initiative to improve the lot of the "First Americans". Yet at least one proposed program in the Centers for Disease Control and Prevention which would specifically fund research benefitting American Indians/Alaskan Natives, originally proposed as $40 million program, was first slashed by 75 percent, then zeroed out as the budget process played out. Can you explain why this program was such a low priority considering this ambitious "initiative?"

Answer. Our fiscal year 2001 request includes significant budget increases, six percent for the Centers for Disease Control and Prevention and ten percent for the Indian Health Service. While a separate grant program for Tribes was not included in CDC, funding is requested for similar activities in both the Centers for Disease Control and Prevention and the Indian Health Service.

Our request for the Centers for Disease Control and Prevention includes $35 million for Racial and Ethnic Approaches to Community Health to support community demonstrations to eliminate health disparities. Of the 32 grantees who received funding to plan these demonstration, one was an Indian Tribe and two others focused on health disparities of American Indians and Alaska Natives. Our $35 million request also includes an increase of $1.5 million to fund eight to ten Core Capacity Grants for American Indian and Alaska Native organizations. The Centers for Disease Control and Prevention is also working with tribes and tribal organizations to address diseases such as diabetes and breast and cervical cancer.

Our request for the Indian Health Service, the largest requested increase in over two decades, includes $230 million in total additional funding to increase access to health care and reduce the gap in health disparities. Included in this total increase is $11.5 million for Preventive Health activities, including Public Health Nursing, Health Education, and tribal Community Health Representatives; $41 million to increase purchase of health care from the private sector, $40 million to provided contract support costs for tribes operating their own health programs, and $3 million for grants to improve the basic public health infrastructure of tribes enabling them to conduct effective community based injury prevention programs. Grants would be provided to approximately 25 tribes.

INDIAN HEALTH SERVICE BUDGET

Question. Did you consult with Tribes or Tribal representatives in the development of the Department of Health and Human Services budget, outside of the Indian Health Service? Did you consult with Tribes or Tribal representatives regarding the budget of the NIH or the CDC? Who did you consult with and what was the extent of your consultation?

Answer. In August of 1997, HHS issued its first Department-wide policy on consultation with American Indian and Alaska Native tribes and Indian organizations. Under this policy, each Operating Division-including the Indian Health Service-develops its own tribal consultation plan. Budget matters are generally considered to be critical for consultation.

In May of 1999, HHS held its first Department-wide tribal budget consultation meeting prior to developing its fiscal year 2001 budget submission. Leaders from 35 tribes and tribal organizations met with members of the HHS Budget Review Board making recommendations covering the entire Department. This coming April, we will hold our second Department-wide tribal budget consultation meeting to consider

the fiscal year 2002 budget submission. As part of our consultation process, the Deputy Secretary has held a series of five regional meetings with tribal leaders over the past year.

INDIAN HEALTH RESEARCH

Question. I see in your budget justification that there are a number of specific research initiatives for racial and ethnic groups, but I did not see any that were directed only toward a single American Indian or Alaskan Natives health issue. For example, there is a cancer research effort at the University of Hawaii which focuses on the high cancer incidence among Native Hawaiians, and a study of the excessive prevalence of high blood pressure among African Americans. Yet I did not come across a single initiative that targets a disease that uniquely affects American Indians. Can you explain?

Answer. In general, the Department does not request funds for initiatives targeting diseases which affect particular racial and ethnic groups. One exception, of course is the $230 million increase we have requested for the Indian Health Service to improve the health of Federally recognized American Indians and Alaska Natives. While funding in our other health agencies is not specifically requested for diseases uniquely affecting American Indians, these agencies do carry-out specific activities which improve the health of Native Americans. For example research at the National Institutes of Health has provided much of our information about type two diabetes and its impact on Indian communities. In addition to its work on diabetes, the National Institutes of Health supports the study of other disease in Indian populations such as asthma and lung cancer. In fiscal year 2000, NIH estimates it will spend a total of $98 million on research into diseases and health conditions affecting American Indians and Alaska Natives. The Centers for Disease Control and Prevention is also addressing a number of diseases as they affect Indian people including diabetes, breast and cervical cancer, Hantavirus, Hepatitis A and Pneumococcal infections. In fiscal year 1999, CDC spent about $21 million for American Indians and Alaska Natives. The Substance Abuse and Mental Health Services Administration provides funds to tribes and tribal organizations to plan and evaluate systems of mental health care, prevent substance abuse, work with high risk youth, and provide substance abuse treatment services. In fiscal year 2000, the Substance Abuse and Mental Health Services Administrations estimates it will provide a total of $64 million for American Indians and Alaska Natives.

QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

NATIONAL INSTITUTES OF HEALTH/DEPARTMENT OF ENERGY PARTNERSHIP

Secretary Shalala, as you are aware the fiscal year 2000 Labor-HHS Appropriations Bill contained a provision urging the Director of NIH to establish a pilot program to ensure the National Institutes of Health may benefit from technologies developed within the Department of Energy weapons programs in terms of their potential to enhance health sciences and improve medical care. The Pilot seeks to ensure that technologies developed within the nuclear weapons program, as well as other programs, of the Department of Energy are carefully evaluated for their impact on the health sciences, with the goal of achieving clinical applications and improved national health care.

Question. What is the status of the NIH/DOE Medical Technology Partnerships?

Answer. NIH is evaluating the adequacy of current interagency collaborations and the applicability of DOE laboratory technical resources and capabilities to improving human health and quality of life. In the area of biomedical engineering, the NIH research institutes and centers have been made aware of DOE laboratory capabilities and biomedical research programs to through the Bioengineering Consortium (BECON) of which DOE has been a member since 1997. A meeting was held on January 18, 2000, between the staff of the NIH Office of Extramural Research and representatives of the DOE's Office of Science to discuss specific areas of interagency cooperation in bioengineering research and training. Possible joint research funding initiatives were identified and are being pursued. Potential interagency training and personnel sharing opportunities were discussed, as were ways for DOE staff to become more familiar with and involved in NIH research programs. With regard to the weapons laboratories, a meeting of NIH Office of Extramural Research staff, NIH research institute staff, key DOE weapons laboratory technical representatives, and DOE Headquarters personnel was held on February 24, 2000, to identify areas of potential collaboration and ways to facilitate more effective interaction.

At the upcoming April 19, 2000, BECON meeting, DOE's Office of Science will make a presentation to NIH staff to provide further information on DOE's laboratory biomedical technology capabilities within its bioengineering program. NIH staff will also be attending and participating in the DOE Bioengineering Contractor's Meeting scheduled for May 16–18, 2000, in Albuquerque, New Mexico. Based on the results of these meetings and current NIH/DOE collaborative efforts, an evaluation will be made of the need for a formal interagency partnership and appropriate follow-up actions initiated.

Question. What other steps are being taken by NIH to ensure that technologies being developed by other Federal agencies are identified for possible medical/research applications?

Answer. Since 1997, the NIH's Bioengineering Consortium (BECON) has provided a link with other Federal agencies in areas associated with applications of engineering/physical science technologies and principles to biomedicine. To ensure that technologies developed by other Federal agencies are identified for possible medical applications, BECON actively facilitates interagency communication, sponsors bioengineering symposia, and coordinates NIH participation in interagency bioengineering initiatives. To directly communicate biomedical research progress and directions to NIH staff, other Federal agencies (e.g., DARPA, NSF, and DOE) are invited to provide presentations during the regular monthly BECON meetings which are open to the public. BECON also coordinates NIH participation in interagency biomedical initiatives such as the Interagency Working Group on Nanotechnology (IWGN), the Multi-Agency Tissue Engineering Science (MATES) Working Group, and the Bioengineering Materials and Applications (BEMA) Roundtable. Information on these types of activities is shared with BECON members during regular monthly meetings. To afford engineering and physical science researchers at all Federal agencies opportunities to make the biomedical community aware of technologies that could have possible biomedical applications, BECON sponsors major annual bioengineering symposia that are open to all interested participants. Finally, the BECON has developed and maintains a Web site aimed at providing information on all aspects of biomedical engineering (including technology development) to the general public, scientific community, and Consortium members.

DIABETES

Question. Diabetes contributes to approximately 200,000 deaths each year and is the leading cause of blindness, kidney failure and lower-limb amputations. The disease costs the nation $105 billion annually in direct and indirect costs. Today CDC operates only 16 comprehensive diabetes programs. Does CDC have any plan to expand this program in a phased fashion to all 50 States? What will in take in your professional judgment to reach all 50 States?

Answer. The overall financial constraints in the fiscal year 2001 budget forced many hard choices in public health and other programs. One of those hard choices was whether to increase the number of comprehensive diabetes programs, or fund other pressing needs. CDC currently provides funding for diabetes programs in 50 States; 16 comprehensive programs with average funding of $800,000 each, and 34 capacity-building programs. CDC also carries out a wide range of surveillance, applied research, and public education activities that are essential in making its partnership with the States effective. The $51 million requested in the budget will enable CDC to continue making significant progress in reducing the burden of diabetes. CDC has estimated that, absent competing needs in CDC and other agencies, its diabetes program could make good use of up to about twice that amount.

NIH BUDGET

Question. In recent years, NIH has recommended to Congress allocations that generally spread the funding increase evenly among institutes. This method of funding causes smaller institutes that also have viable research opportunities to lack the necessary monies to fund important research. Do you think that across-the-board percentage allocations every year adequately fund all new scientific opportunities? How about funding new scientific opportunities in those institutes who receive lessor funding? How do automatic across-the-board percentage allocations really reflect new discoveries?

Answer. This is a time of great productivity in the biological sciences. Many fields of medical research deserve increased financial support and could move faster with more funds. However, historical factors and the level of research funds already committed to grant recipients leave a relatively small fraction of each year's appropriation that can effect changes in funding policies. Since resources are not infinite, pro-

viding considerable funds to a particular area of emphasis limits what is available to others.

Allocations to the Institutes and Centers do vary to reflect many factors and consultations. Decisions that affect resource allocation or priorities at the NIH, including distribution of funds among the ICs; how much to devote to a certain discipline, disease, or grant mechanism; or which applicants to fund are influenced by several factors:

—An obligation to respond to public health needs, as judged by the incidence, severity, and cost of specific disorders. However, calculations of public health needs are difficult, and the results cannot be correlated with research spending in a simple manner.

—A commitment to support work of the highest scientific caliber. A basic tenet of our stewardship is the pledge to maximize the return on the public's investment in research; to do this, we demand that all requests for support pass stringent peer review in regard to scientific quality.

—A responsibility to seize the scientific opportunities that offer the best prospects to develop new knowledge and lead to better health. As administrators of science, we have learned that the most significant and rapid advances are likely to occur when new findings, often serendipitous, lead to expansion of other research opportunities.

—A need to maintain a diverse portfolio that supports work in many scientific disciplines and on a wide range of diseases. Because we cannot know when major discoveries will occur and what opportunities they will create, it is important to support ongoing research across a broad frontier.

—An obligation to insure a strong scientific infrastructure, with a high quality workforce and excellent research facilities. Productive science cannot be done without well-trained investigators and modern equipment and laboratories.

NIH BUDGET

Question. Dr. Varmus was very fond of saying "research in one area would lead to discoveries in other areas." How, then, are these promising areas being applied to those diseases that receive less funding?

Answer. Research probes and seeks to understand the unknown. The scientific insights that provide a basis for solutions usually accumulate over many years, and often are derived from the efforts of investigators from diverse disciplines with expertise in specific areas of science working on and communicating about differing facets of a problem. Medical discovery is marked by stops and starts, and a vital interplay among theories or questions (hypotheses), experimental evidence, and clinical observations. It is very hard—if not impossible—to predict the next discovery or to anticipate what advancement in prevention, treatment or diagnosis of one disease will be applicable to new knowledge about another, seemingly unrelated, disease.

NIH's medical research program is a diverse and continually evolving portfolio that reflects the agency's obligation to respond to public health needs, commitment to supporting research of the highest scientific caliber, and judgment as to the scientific opportunities that offer the best prospects for gaining new knowledge and better health. Sometimes scientists, when exploring the fundamental mysteries of the cell, know at the outset of their research that its findings will be applicable to understanding many diseases. For example, scientists hard at work determining the structure and electrochemical properties of a specialized pore, called the potassium channel, that helps regulate heart rhythm know that this information will be used in physiologic investigations of potassium channels, which are critical for many bodily functions, besides regulating the heartbeat, such as nerve signaling, digestion, and insulin release. A better understanding of potassium channels may help scientists develop drugs to treat diseases ranging form heart ailments to diabetes to epilepsy.

However, despite our best efforts to ascribe or assign research to a particular disease or condition, the serendipitous nature of science makes it hard to predict, with any real certainty, just which diseases will benefit from a particular line of investigation. Although different disease processes vary in their nature and complexity, they often have some commonalities. The progress made in understanding one disease often yields new ways of thinking about the etiology of another, seemingly unrelated, disease. Thus, new knowledge gained from one line of research may help re-frame or re-focus the entire approach being used to solve the most perplexing problems associated with understanding a totally different disease. For example, cancer is a disease which has its origin in the function, or malfunction, of the most fundamental process, cell division, and the enzymes that affect the process. New

knowledge about the function of enzymes in cancer cells can have and indeed, has had a profound effect on scientists' understanding of other diseases that may also have their origins in similar enzyme malfunctions, such as inherited metabolic diseases. Similarly, new information about how some osteoporosis drugs for osteoporosis preserve the integrity of bones, have suggested that these same drugs might be useful in reducing the spread or metastasis of prostate and colon cancers to bone.

A surprising example of this kind of cross-fertilization started in the area of cardiovascular disease. Years of research focused on the formation of new blood vessels as a means of improving circulation in patients with atherosclerosis (hardening of the arteries). Researchers now have taken this knowledge and applied it to a totally different goal—if we knew how to promote the formation of new blood vessels, could we block their formation? And would this not impede the growth of tumor cells, which, like all living cells need a blood supply to survive and grow. This effect, then set cardiovascular researchers to look at the role of blood vessel formation. They found that such formation promoted the development of plaques that blocked the flow of blood. This intersection of scientific discoveries has now set researchers on a course to identify ways to block this effect and to develop new therapies for improving circulatory diseases. These stories are not unique in the annals of innovation and scientific discovery.

In addition to basic research yielding discoveries that can be applied in many different areas, discoveries from research in one specific disease area often prove to be related to other diseases. For example, AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases. AIDS research has provided an entirely new way to design drugs and to treat viral infections. The development of the new "flu" drug, RelenzaTm (zanamivir), which directly benefitted from AIDS research. Another drug developed to treat AIDS is now the most effective therapy for chronic hepatitis B infection. Drugs developed to prevent and treat AIDS-associated opportunistic infections also provide benefit to patients undergoing cancer chemotherapy or receiving therapy to prevent rejection of transplants. AIDS research also is providing new understanding of the relationship between viruses and cancer.

One line of investigation often yields several potential and unpredicted new uses, which can be applied to the treatment or prevention of more than one disease. Thus, because scientific findings cross disease lines, so does the distinction or attribution of research investment and discovery cross Institute and Center lines.

Question. Don't automatic across-the-board increases for every institute each year actually pit one disease against another? By allowing large institutes to grow at the same rate as small institutes, aren't you actually ignoring many potential scientific opportunities in the smaller ones? Doesn't this prevent NIH from following their own stated research funding criteria meant to identify areas of greatest need and greatest potential?

Answer. Decisions that affect resource allocation or priorities at the NIH, including the distribution of funds among the ICs; how much to devote to a certain discipline, disease, or grant mechanism; or which applicants to fund are influenced by the numerous factors outlined above. Advice is solicited from and provided by a large number of individuals and groups, including the members of the scientific community, Advisory Councils, patient advocacy groups, Congress, the Administration, and NIH staff. Each Institute and Center (IC) convenes meetings of its national advisory council or board, composed of members from the public, medical, and scientific communities, to review a broad range of policies. Scientific opportunities arise with the advent of new technology and new discoveries in various diseases. As these discoveries are made, areas of greatest need and greatest potential are prioritized based on scientific opportunity and the financial resources that can be allotted to the study of these diseases so as to ensure that outstanding science is being funded and that such studies are aimed at obtaining results.

Question. Given that CDC has called diabetes "the epidemic of our time," do you think NIH devotes adequate funds to research this serious disease? If so, why? If not what can be done to increase the diabetes research portfolio at NIH?

Answer. The President's fiscal year 2001 Budget Request for diabetes research across the NIH is $561 million. The NIH are implementing many of the new and expanded initiatives in response to the scientific recommendations of the DRWG. However, there are scientific opportunities in diabetes-and indeed in most areas of research—that the NIH will not be able to pursue as rapidly or as fully as it might wish, given the NIH budgetary framework and our responsibility to support an overall national biomedical research agenda that addresses the many diseases afflicting Americans.

QUESTION SUBMITTED BY SENATOR KAY BAILEY HUTCHISON

Question. Madam Secretary, recently, there was an editorial in the Houston Chronicle by Nobel Prize winner Dr. Norman Borlaug, known as "the Father of the Green Revolution" on the benefits of agricultural biotechnology. A growing number of scientists and agriculture producers in Texas and throughout the world are realizing the tremendous potential of biotechnology in agriculture to feed a growing population with better environmental outcomes. In Texas, for example, over 60 percent of cotton grown in the Texas Panhandle is already enhanced by modern biotechnology. What measures are you and your Department taking to support, foster, and encourage this promising new technology?

Answer. As you know, FDA has authority over the safety of nearly all domestic and imported foods and food products in interstate commerce, including bioengineered foods. One of the most important roles of this Agency in supporting this technology is to ensure that the bioengineered foods that enter the marketplace are as safe as the traditionally developed products in our grocery stores, and that such foods undergo appropriate safety testing prior to marketing. We are confident that the bioengineered foods that have reached the U.S. market to date meet the standards of safety that apply to other food products.

In the fall of 1999, FDA announced an initiative to engage the public about foods made using bioengineering, and held a series of public meetings in November and December. One of the purposes of those meetings was to inform participants about FDA's policy and processes for ensuring the safety of bioengineered foods. FDA personnel shared the Agency's experience over the past five years in reviewing safety and nutritional assessments conducted on foods from more than 40 bioengineered plant varieties. FDA also solicited information from participants and the public regarding whether FDA's policy or procedures should be modified and also solicited comments on appropriate means of providing information to the public about bioengineered products in the food supply.

During those public meetings, we did not hear any evidence of food safety concerns about the products that have been marketed thus far, although some participants expressed concerns about potential safety issues with products that may be included in the next generation of bioengineered foods. Other participants suggested ways in which FDA could better inform the public about its processes and procedures. FDA is currently reviewing comments received in response to the public meetings and the agency's call for information. When we have completed that review, the agency will be in a position to develop and implement strategies for its biotechnology program and to articulate its plans for next steps.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Question. Why does the Administration fail to require background checks for all long-term care workers?

Answer. The Administration has proposed a system of abuse registry and criminal background checks for nursing home workers. Our provider agreements make these facilities clearly identifiable, our statutory and regulatory authority and annual surveys provide the means for monitoring and enforcing the proposed new requirements, and existing State nurse aide registries can provide information for the proposed national abuse registry. Our proposed system would include developing the national abuse registry, adding FBI background checks, and creating a new capacity in each State to screen and report FBI data to nursing homes. Even with start up funding and user fees, it would take some time for these systems to develop the ability to promptly respond to background checks from the nation's 17,000 nursing homes. For these reasons, it seems prudent to begin efforts on criminal background checks for long term care workers with nursing home staff.

HCFA also has regulatory and survey authority for home health agencies, hospices, and ICFs/MR. Once we have developed the systems and experience to handle background checks for nursing home employees, we would be in a better position to assess whether and how to expand such checks to these other three long term care settings that we do not regulate or survey. It would be problematic and to effectively enforce employee background check requirements in these other settings.

Question. As it appears in the HHS budget, it seems that the Administration's background check proposal will be funded by user fees within both HHS and DoJ. Unfortunately, there are few details about how these two agencies would coordinate their systems so that facilities can have one-stop shopping. Could you please elaborate on how you envision this system working? Do you have estimates on how much this would cost nursing homes annually?

Answer. For purposes of developing the President's budget, HCFA assumed that the background checks would be a two step process. First, a nursing home would request a query of the national abuse registry. If a report comes back that the prospective employee has a history of abuse, neglect, or misappropriation of resident property, the process would end there with the individual disqualified from employment with the nursing home. We estimate that nursing homes would pay HHS about $4 per query for a total of about $4.3 million for this portion of the background check in the first year of implementation.

If the abuse registry check produces no disqualifying information, the nursing home would proceed to the second step, a criminal background check request. The nursing home would obtain finger prints and other information from the prospective employee and forward them to a designated agency in their State. From that point, the designated State agency would serve as the "one-stop shop," collecting an additional fee from the nursing home for the remainder of background checks. The designated State agency would forward the finger prints and other information to appropriate law enforcement authorities in the State and in the FBI to conduct State and national criminal background checks. The designated State agency also would receive the State and FBI data it receives to identify any disqualifying information, report the results back to the nursing home, and handle disputes by prospective employees of the accuracy and relevance of disqualifying information. We estimate that the second, criminal background check phase of the process would cost nursing homes about $70 per check or about $41.1 million in the first year, with the designated State agency forwarding the appropriate portions of the fee to the FBI and State law enforcement agency.

The first step in the development of this system will be to determine the most effective and cost efficient methods for implementing a national abuse registry. HCFA plans to conduct such a study to include an assessment of current processes used by States and providers. We will be examining ways to create a "one-step shop" where all information could be accessed. The information from the study will feed into the ultimate implementation of the proposal.

Question. As you know, I have worked hard for the past several years to boost funding for nursing home inspections under the Survey and Certification program. I realized that the Administration continues to work hard on the Nursing Home Initiative to improve the quality and safety of nursing home residents. This year, you've asked for $234 million for Survey and Certification, but you've again assumed $63 million that would come from user fees, which Congress has declined to enact in the past. Assuming that trend continues, will the Administration still support the full $234 million and find money in the budget to pay for it?

Answer. The Administration strongly supports the need for the full $234.1 million amount for the State Survey and Certification program. User fees have been proposed the past three years as a means of reducing pressure due to Government-wide discretionary funding limitations. If enacted as proposed, the user fee would reduce HCFA's $234.1 million appropriation request by $63 million, to a total of $171.1 million in fiscal year 2001. Should Congress decide to not enact the user fee proposal, the Administration request the entire $234.1 million in appropriated funds to support State Survey & Certification activities.

Question. Would the Clinton Administration support, and more importantly, actively advocate for legislation to restore the SSBG's funding and transfer levels?

Answer. Under section 8401 of the Social Security Act, the authorization for the Social Services Block Grant was reduced to $1,700,000,000 for fiscal year 2001 and each year thereafter. In addition, under that same section, the limitation on the amount transferable to Title XX was reduced to 4.25 percent in the case of fiscal year 2001 and each succeeding fiscal year.

The President's Budget for fiscal year 2001 for the Social Services Block Grant includes a proposal to increase the amount provided to the Block from $1,700,000,000 to $1,775,000,000. It also is expected that states will use state funds to help offset any impact that this change might cause.

DEPARTMENT OF EDUCATION

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

CLASS SIZE REDUCTION

Question. Mr. Secretary, it is my understanding that the class size reduction funds are to be distributed to the neediest schools with the highest numbers of poor children. If the very purpose of the program is to help schools that are struggling

to resolve overcrowding in poor districts, how do you expect these schools to meet the matching funds requirement?

Answer. The Department does not believe that requiring local districts to provide a 35 percent match on any new Class Size Reduction funds they receive would be burdensome for most districts, and those districts that would have the greatest difficulty in providing such a match would be exempt from the requirement. In addition, a district would match only the amount above what it received in fiscal year 1999. At the 2001 request level, for an average district, the amount of the match would be only about $15,700.

We need to help poor schools and districts overcome the challenges they face in preparing their students to meet high standards. Research has demonstrated the benefits of reducing class size in the early elementary grades, particularly for lower-achieving, minority, low-income, and inner-city students. Class Size Reduction funds enable districts to reduce class size, particularly in the early elementary grades, so that teachers can provide students with more individualized attention, spend more time on instruction, cover more material effectively, and provide students and parents with more detailed feedback on each child's progress. The Department believes districts welcome Federal support to help them reduce class size in the early grades.

Question. Further, how is the exemption for low-income school districts realistic when 80 percent of the formula grant relies on poverty data?

Answer. All schools districts, not just districts that serve large numbers or percentages of low-income students, are eligible to receive Class Size Reduction funds. We are proposing to exempt only those districts in which at least 50 percent of the students they serve are from low-income households. We estimate that, after exempting the highest-poverty districts, the average national match provided by local districts would equal 30 percent of the Federal appropriation.

FLEXIBILITY IN CLASS SIZE REDUCTION PROGRAM

Question. Given the diversity of needs that different school districts have throughout the country—whether it is costs related to special education, books, or computer technology investments—what is the disadvantage of using class size funds to address the most pressing demands identified by local school districts?

Answer. I believe that the strong, demonstrated benefits of reduced class size in the early elementary grades justify making such an effort a national priority. Students who receive instruction in small classes make more rapid educational progress than their counterparts in larger classes. This is particularly true for lower-achieving, minority, poor, and inner-city children.

Under the appropriations language and our proposal for authorizing the Class Size Reduction program as Title VI of the Elementary and Secondary Education Act of 1965, districts that have met the target level in grades 1 through 3 may use their funds to further reduce class size in those grades, to reduce class size in additional grades, or to improve teacher quality. Also, States that can demonstrate conditions in certain districts that would make achieving the goal of 18 students per classroom in the targeted grades a hardship, such as a lack of facilities or a shortage of qualified teachers, can apply to the Department for a waiver from some of the program provisions.

SCHOOL CONSTRUCTION

Question. According to the 1999 School Planning and Management Construction Report, public school districts completed more than $15 billion worth of construction in fiscal year 1998, an increase of almost $3 billion over the fiscal year 1997 level. The latest figures indicate that almost $18 billion worth of construction was completed in fiscal year 1999 and districts are starting $23 billion in fiscal year 2000, resulting in roughly $70 billion of construction completed/planned in the last 4 years. To support its $26.1 billion proposal, the Administration cites a GAO study that estimated $112 billion was needed to bring schools into good condition.

Mr. Secretary, given the tremendous progress being made and the fact that you have stated that the Federal Government is a junior partner in the area of education, please justify the Administration's proposal to assume a significant Federal role within a State and local responsibility?

Answer. School construction is, and will remain, primarily a State and local responsibility under the Administration's school construction proposal. The vast majority of school facility needs will continue to be met with non-Federal resources, and decisions about school construction plans will continue to rest with State and local governments. However, some States and communities are not, on their own, able to meet the burden of providing adequate school facilities for all students, and the poorest communities have had the greatest difficulty meeting this need. The Ad-

ministration's proposal would provide financial assistance to school districts with substantial construction needs and a limited ability to meet those needs.

We owe it to our children to improve the condition of schools in order to improve their academic achievement and promote their physical health. Students have difficulty learning when they attend schools that are overcrowded, poorly lighted, either too hot or too cold, or unable to accommodate modern technology. In addition, students can be exposed to health hazards when they attend schools that are poorly ventilated or contain hazardous substances, such as lead paint and asbestos.

While expenditures for school construction have increased over recent years as the economy has improved, we believe that the need persists for approximately $112 billion to bring schools into adequate condition. Substantial school construction expenditures are necessary just to keep from slipping further behind as school facilities continue to depreciate and student enrollments swell. In addition, the increase in school construction funding has not likely been targeted to those communities with the greatest need for school construction funds.

FEDERAL SHARE OF SPECIAL EDUCATION COSTS

Question. Over the last 4 fiscal years, the annual increase requested by the Administration for the State grants program, under the Individuals with Disabilities Education Act (IDEA), has averaged about 5 percent per year. For fiscal year 2001, the request is once again for about a 5 percent increase. Over the same period, Congress has increased funding by over 20 percent per year. Federal funds are used to help pay for the excess cost of providing special education and related services for children with disabilities ages 3 through 21. The Administration claims that the Federal contribution toward meeting the excess cost of special education is currently 13 percent of the national average per pupil expenditure.

Given the financial burdens that the requirements of the Individuals with Disabilities Education Act (IDEA) place on States and school districts, why are you so reluctant to substantially increase spending for this program?

Answer. No State is required to participate in IDEA. However, the rights and protections embedded in IDEA are fundamental civil rights that guarantee children with disabilities access to equal educational opportunity.

IDEA authorizes a maximum Federal contribution toward meeting the excess cost of special education of 40 percent of the national average per pupil expenditure. We believe that the legislative history surrounding the enactment of Public Law 94–142 in 1975, which served as the basis for the current IDEA, indicates that members of Congress regarded the 40 percent as a goal, not a promise or commitment, and members acknowledged that the authorized amounts were not likely to be appropriated.

I support that goal. However, I also believe that the requested level of funding for Special Education Grants to States provides an appropriate level of support given the fact that States have the primary responsibility for educating all children, including children with disabilities. Our budget for the Department is designed to address a broad range of needs and a number of national priorities. We believe that our budget request for the Department reflects the best combination of programs and funding to address the needs of all children within our limited resources.

Question. How do you respond to school officials and parents who say that the Federal Government is not meeting its financial obligation with respect to special education?

Answer. There is a tendency to view the IDEA Grants to States program as the Federal program for providing assistance to States in serving children with disabilities. In fact, there are many Federal programs that assist States in serving these children, but they are not focused solely on children with disabilities. These programs include programs such as 21st Century Community Learning Centers, which provide a safe environment and expanded learning opportunities for children before and after school; and the Class Size Reduction program, which helps school districts improve education in the early elementary grades by providing funds to hire highly qualified teachers and reduce class size. Federal subsidies for school construction bonds that will be used to repair, renovate, and construct schools will help ensure that our school buildings enhance the teaching and learning of all children, including children with disabilities.

The $290 million increase requested for Special Education Grants to States would maintain the Federal contribution toward meeting the excess cost of special education at 13 percent of the national average per pupil expenditure by providing more than sufficient funds to offset the impact of inflation and the additional cost expected to result from serving more children.

TEACHER RECRUITMENT AND PROFESSIONAL DEVELOPMENT PROGRAMS

Question. Mr. Secretary, the President's 2001 budget request includes $1.4 billion for teacher recruitment and professional development programs, double the amount provided in fiscal year 2000, excluding the amount provided for the Class Size Reduction Initiative. Most of these programs are scattered throughout the Department and are unauthorized. Furthermore, a 1999 GAO report found that over $1.5 billion in Federal funds is invested in professional development programs, which span 13 agencies through 87 different programs. The report also stated that over 86 percent of the Department of Education's funding was used for professional development purposes.

Mr. Secretary, shouldn't the bulk of education dollars be delivered to the student, especially those in the greatest need?

Answer. The Administration believes that investing in high-quality professional development and teacher recruitment is one of the best ways to ensure that all students, including those most at risk of school failure, get the help they need to raise their academic performance. That is why the Administration's 2001 budget request would increase funds for teacher recruitment and professional development programs, including $1 billion for the Title II programs that are included in the Administration's proposal to reauthorize the Elementary and Secondary Education Act (ESEA). We believe that these programs, in total, will help States and school districts ensure that all students are taught by fully qualified teachers who have the training they need to teach to challenging State and local content standards.

Research indicates that high-quality professional development, especially when it is focused on academic content, can contribute to improvements in teachers' skills and practice and thereby raise student achievement. The most recent evaluation report of the Eisenhower Professional Development State Grants program (1999) indicates that teachers believe professional development contributes the most to improving their knowledge and skills if it: (1) is sustained over an extended period of time; (2) is connected to State and district standards and assessments; (3) emphasizes academic content and the way students learn that content; (4) encourages teachers from the same grade levels, departments, and schools to work in teams; and (5) offers opportunities to observe and practice the teaching techniques being introduced. The Teaching to High Standards State Grants program, the Administration's proposal to reauthorize Title II of the ESEA, would encourage school districts to implement professional development with these characteristics, so that all students can be better prepared to meet the challenges of the 21st century. In addition, provisions in our Teaching to High Standards proposal ensure that funds are targeted to those students who are most in need.

The 1999 General Accounting Office (GAO) report, *Teacher Training: Over $1.5 Billion Federal Funds Invested in Many Programs*, found that, in various Federal agencies in fiscal year 1999, over $579 million was provided by programs that focus exclusively on teacher training and that about $933 million was provided by programs that are designed to achieve purposes other than just teacher training but support a significant amount of teacher training.

DEPARTMENT OF EDUCATION TEACHER TRAINING PROGRAMS AS A PERCENTAGE OF ALL FEDERAL TEACHER TRAINING

Finally, I want to clarify findings in the GAO report. The report did not find that over 86 percent of the Department of Education's funding was used for professional development purposes. Rather, the report states that teacher training programs administered by the Department of Education accounted for over 86 percent of the $1.5 billion provided for teacher training programs across the Federal Government in fiscal year 1999.

PROFESSIONAL DEVELOPMENT PROGRAMS AND EARLY INTERVENTION ADDRESS THE ACHIEVEMENT GAP

Question. How do these programs address one of the most important components of narrowing the achievement gap, which is early intervention?

Answer. Early Childhood Educator Professional Development Grants, a new program proposed as part of the Administration's ESEA reauthorization bill, would create high-quality professional development opportunities to improve the knowledge and skills of early childhood educators and caregivers who work in communities with high concentrations of young children living in poverty. The program would promote school readiness and better learning outcomes for those children by focusing on professional development designed to further their language and literacy skills before they enter school.

The National Research Council report, *Preventing Reading Difficulties in Young Children* (1998), concluded that the majority of reading problems faced by today's adolescents and adults could have been avoided or resolved in the early years of childhood. Reading problems more often occur in children from poor families with little education, and, as more of those children enter group care settings, ongoing high-quality professional development for their preschool teachers and caregivers is a key strategy in helping cultivate children's literacy and language skills as a foundation for reading.

The *Cost, Quality and Child Outcomes* report (June 1999), partially funded by the Department, concludes that children's cognitive and social competence in the second grade can be predicted by the experiences they had 4 years previously in child care, even after taking into account kindergarten and first-grade classroom experiences. The report also found that children who have traditionally been at risk for not doing well in school are more affected by the quality of childcare experiences than are other children. Many early childhood providers have little formal education beyond high school, and preschool and other group care settings for young children, in particular those available to families with limited economic resources, often provide relatively impoverished language and literacy environments.

The Department would concentrate on funding projects that provide professional development opportunities for early childhood educators and caregivers working in high-poverty communities, including staff working in Title I preschools, Head Start, Even Start, and public day care programs.

IMPLEMENTATION OF TEACHER RECRUITMENT AND PROFESSIONAL DEVELOPMENT PROGRAMS

Question. Please explain how the Department of Education plans to, first, inform States and local educational agencies of all of these programs; and second, ensure that both the Federal and State governments implement them efficiently and effectively.

Answer. The Administration would provide information about these programs to States, school districts, and other eligible recipients through the channels that the Department has found to be most successful in disseminating information about our programs. For example, the Department would publish Federal Register notices about the availability of funds, provide information about the programs at conferences, such as the Department's annual Improving America's Schools Conference, place information about the programs on the Department's web site and in print materials, sponsor outreach meetings to alert eligible applicants about opportunities to apply for funds, and carry out other networking strategies the Department typically uses to alert the public about new programs.

Strong accountability provisions in the Administration's reauthorization proposal for the Elementary and Secondary Education Act (SEA) will help ensure that these programs are implemented efficiently and effectively, while allowing States and school districts the flexibility that they need to address local needs. For example, accountability provisions include requirements that grantees develop and report on their success against performance indicators as part of annual performance reports, and States would provide annual data about the number of teachers who are fully certified or licensed and who are teaching in their main teaching field.

EDUCATION FOR INCARCERATED YOUTH

Question. Mr. Secretary, there are over 2 million incarcerated adults in the United States, the highest incarceration rate in the world; and, according to the Department of Justice's most recent study, there were 106,000 juvenile offenders residing in correctional facilities in 1997. The National Adult Literacy Study indicates that the majority of prison inmates either are illiterate or have marginal reading, writing, and math skills. Most of these adults will return to free society in 4 years, having received little to no education, which has proven to be the key to preventing recidivism.

In light of these facts, can you justify the President's request for a $2 million reduction in the State grants to incarcerated youth offenders program, and the elimination of the Literacy Programs for Prisoners?

Answer. The President's request for 2001 would continue support for the Youth Offenders program at the fiscal year 1999 appropriation level of $12 million, which is also the amount the Administration requested in fiscal year 2000. The request, which is $2 million less than the amount provided in the fiscal year 2000 appropriations act, will provide States with a level that is consistent with the Department's general policy of targeting funding increases to other priority initiatives. At the requested level, States would have enough funds to serve approximately 6,700 youth

offenders. Through the program, States expect to improve academic and vocational achievement, increase participation in job placement programs, lower recidivism rates, and increase job retention among youth offenders.

The Department requested no funds for Literacy Programs for Prisoners in 2001 because this program's authorization ended with the enactment of the Adult Education and Family Literacy Act of 1998 (AEFLA). States may use up to 10 percent of their AEFLA local grant funds for programs for corrections education and services to institutionalized individuals.

12-MONTH WORKING YEAR FOR TEACHERS

Question. Mr. Secretary, in your recent address to the Nation on the state of American education, you proposed that teachers work a full year to improve teacher quality and raise their pay. Can you tell me specifically what steps the Department will take to establish this policy?

Answer. The annual State of American Education address gives me the opportunity to take a broad view of our education system and talk about both what is working and where we might make some improvements. With the success of the standards movement, one area we are really focused on now is improving teacher quality. Our proposal to reauthorize the Elementary and Secondary Education Act and our fiscal year 2001 budget request contain a variety of measures to strengthen teaching in our schools.

My call for elevating teaching to a year-round profession was not a proposal for a new Federal policy, but a suggestion that we need to look at the teaching profession in a new way. We need to attract highly qualified individuals to the profession, in part through better pay, and provide a working environment that lets them use all their talent and skill to teach to the new high standards. I believe one way to do this is through longer contracts that would give teachers more time to plan the curriculum and improve their teaching skills.

States and school districts, of course, are responsible for setting standards for teacher quality and determining the length of teacher contracts. I am not proposing any Federal intrusion into this area. What I said in my address is that I believe now is the time to begin a national discussion about making teaching a better-paid, year-round profession, and that governors and school boards should give serious consideration to this idea.

Question. Given the Federal role in education, how will these steps affect decisions that are made on the State and local levels?

Answer. We are not taking any specific actions to promote making teaching a year-round profession, merely putting an idea out for discussion at the State and local levels.

Question. Is this approach part of the Administration's reauthorization proposal for the Elementary and Secondary Education Act, which the Senate intends to consider in the next couple of weeks?

Answer. No. As mentioned above, we are not proposing any specific actions to promote the idea, but simply putting it out for discussion.

YOUTH VIOLENCE PREVENTION

Question. Mr. Secretary, please provide your observations of the relationship between movies, video games, and other related forms of youth entertainment and youth violence?

Answer. Each day, children are exposed to numerous examples of violence in the media—either through television, video games, music, or the Internet. A 1999 study conducted by the Kaiser Family Foundation found that on a typical day, children spend five hours and 29 minutes using the media. Children ages 8 to 18 spent almost seven hours; 2- to 7-year-olds spent nearly three hours and 34 minutes. The media have been successful in perpetuating, and even glamorizing, various images of violence aimed toward children. Norms supporting and justifying violence are seen daily in music videos, movies, and television. Yet, despite the far-reaching influence of the media and popular culture on children, there is little consensus regarding the impact that the media have on youth violence. Several studies have related violence in the media to actual violence by children, while other studies have discounted the role and influence of the media on children, since the media are only one of several sources of violent messages in our society.

However, what we do know is that more and more children are being exposed to violence in the media on a daily basis and that much of this exposure is unsupervised by parents. And while we cannot point to a direct relationship between violence in the media and violence in children, we can assume that the images por-

trayed in music and on the screen may contribute to, or reinforce, violent behavior and a lack of empathy for victims.

While it may not be possible to eliminate violence in the media, as parents and educators we can teach children how to be wise consumers of the media and the messages portrayed. Media literacy training can be useful, especially for students in the younger grades. In addition it is important for parents to monitor their children's exposure to the media. Parents need to know what types of movies, videos, television, and websites they are viewing, and what types of music lyrics they are hearing.

I have asked, and continue to ask, the leaders in the entertainment industry and our expanding Internet industry to step back and think about their responsibilities. Do we really need these violent video games to excite our children in order to gain a profit? Is that extra violent scene in a movie really needed to make a point? Does every action hero need to wear a long black coat and carry a sawed-off shotgun? The prime audience for movies in America today is the impressionable teenager, and the key word is impressionable. I urge Hollywood to help us raise our children right by ending their fixation with violence. We need their vision and creativity to help in the fight for our children's future. So my message to the entertainment industry is clear and simple—stop glamorizing the assassin and the killer and the use of guns. Stop listening to scriptwriters and start listening to parents. Stop listening to advertisers and start listening to teachers.

QUESTIONS SUBMITTED BY SENATOR KAY BAILEY HUTCHISON

VOLUNTARY SINGLE-SEX SCHOOL AND CLASSROOM PROGRAMS

Question. Mr. Secretary, as you may know, I have proposed specifically authorizing the use of Federal education funds for public, single-sex school and classroom programs, as long as the existing Department requirement is met that students of both sexes receive comparable educational opportunities. My amendment has passed overwhelmingly in the Senate, by a vote of 69 to 29. Do you believe that public schools should be able to use Federal funds for voluntary single-sex education programs, and if so, will you support my effort to include this amendment in reauthorization of the Elementary and Secondary Education Act?

Answer. The Department of Education is examining whether there is a legal basis for interpreting Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et. seq.) to permit single sex classrooms and schools where they are justified on educational grounds and do not involve stereotyping or stigmatizing students based on gender, and where equivalent educational opportunities are afforded to students of both sexes. These issues are sensitive and complex, including consideration of the constitutional implications of any change, but we have made substantial progress in our review and hope to issue proposed regulations this spring.

With regard to your specific question, we are very committed to exploring the permissibility of single sex schools and classes in public schools, but believe that this issue should be addressed under Title IX, and the answers should apply whether Federal, State, or local funds are used for that purpose. Developing a separate civil rights standard for single sex schools or classrooms under ESEA would create confusion and would be inconsistent with the Civil Rights Restoration Act. I hope that when we release our proposed regulation we will receive your comments. In the meantime, however, I cannot support your amendment because it defines the permissibility of single sex education only within the context of ESEA.

CIVILIAN-BASED "TROOPS-TO-TEACHERS" PROGRAM

Question. Mr. Secretary, while I understand your desire to hire additional teachers and reduce class size, I have an alternative or perhaps complementary proposal that I would like your reaction to and consideration of. I have introduced legislation to expand the very successful Troops to Teachers program and apply it to the civilian world, under the direction of your agency. Would you agree to consider this proposal, and wouldn't you agree that this may be a tremendous opportunity to place highly qualified, successful individuals in our classrooms?

Answer. I support expansion of the highly successful Troops to Teachers program as one strategy for helping to ensure that our Nation's classrooms have highly qualified teachers who can help all students achieve to challenging academic standards. In addition to the Administration's request of $1.75 billion for the Class Size Reduction program, the Administration has also requested $1 billion for a variety of programs to improve teacher quality, including teacher recruitment and retention.

Transition to Teaching program

One of these programs is the Transition to Teaching program, which would continue the highly successful Troops to Teachers program and provide additional funds to recruit, prepare, and support a wide range of talented career-changing professionals—such as engineers and scientists, corporate professionals, and returning Peace Corps volunteers—as teachers, particularly in high-poverty school districts and high-need subject areas. Former members of the military services would continue to be a key focus of the new program's recruitment efforts.

The Transition to Teaching program is included in the Administration's proposal to revise and reauthorize the Elementary and Secondary Education Act of 1965. Under the Administration's legislative proposal, the Secretary, before awarding any grants or contracts, would consult with the Secretaries of Defense and Transportation to determine how much funding is needed to continue the Troops to Teachers program. Once the Secretaries agree on an amount, the Secretary would transfer these funds to the Department of Defense.

Recruiting teachers for high-poverty areas

With the remaining funds, the Secretary would award grants or contracts to institutions of higher education, public agencies, and nonprofit organizations to recruit, prepare, place, and support mid-career professionals for teaching positions in high-poverty school districts. Allowable activities would include post-placement induction programs to support new teachers once they begin teaching, through mentoring and other activities that build upon their teacher preparation training.

Grantees could use program funds to provide each program participant with up to $5,000 in training stipends and other financial incentives, including moving expenses. Participants who complete training would teach in a high-poverty school district for at least 3 years; those participants who received a training stipend or other financial incentives but fail to meet their service obligation would be required to repay all or a portion of the stipend.

IMPACT AID FUNDING AND THE ADMINISTRATION'S CONSTRUCTION PROPOSAL

Question. Your budget again contains what can only be described as a paltry request for Impact Aid funding, particularly with regard to the critical construction needs at many of our coterminous and other Impact Aid school districts, the buildings of which are in many cases owned by your Department. How can you support an unprecedented and costly new role of the Federal Government in funding school construction when your Department and your Administration have completely neglected the construction needs of the school buildings you own, which are used to educate tens of thousands of children, including the children of members of the armed services and Native American children?

Answer. We believe that money can and should be spent concurrently on both schools that are federally owned and those that are not. All of the schools that are currently owned by the Department are located on military bases and are used by local school districts for educating children whose parents are typically members of the uniformed services. The Administration requested $5 million, the same amount as Congress appropriated for fiscal year 2000, for Facilities Maintenance in order to upgrade and transfer school facilities to school districts, which can manage school buildings more effectively than can the Federal Government. In addition, these funds would be used to perform emergency repairs to those school buildings that have not yet been transferred.

The Administration is also concerned about the poor condition of school facilities that are not owned by the Department but are used to educate our Nation's children, particularly American Indian children. The General Accounting Office estimates that it would cost $112 billion to bring our Nation's public schools into good overall condition. The Administration's School Renovation proposal would help meet this need by financing school renovation in communities that lack the resources to repair their schools. The proposal would reserve $50 million out of the $1.3 billion for approximately 118 Impact Aid local educational agencies (LEAs) that have 50 percent or more of their students residing on Indian lands. These LEAs lack the resources to undertake urgently needed renovations, such as roof or plumbing repairs and upgraded climate-control systems. The balance of the funds requested under the proposal would go to school districts that similarly lack the resources to meet their urgent school construction needs.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

FLEXIBILITY OF BLOCK GRANTS OVER TARGETED PROGRAMS

Question. Mr. Secretary, I want to commend you for your commitment and hard work on behalf of our Nation's public school children. Since 1994, we have made some important gains in raising the achievement of students. Unfortunately, I think we share the same concerns that academic achievement has not been raised enough, and that the gap between economically disadvantaged and more affluent students remains alarmingly and inexcusably large.

As you know, we have a full menu of Federal education programs today. Most are focused on very specific issues. I am concerned, however, that we have gotten away from what I believe is the Federal Government's central role as a partner in education: helping States and school districts lift academic achievement for all students, and eliminating the achievement gap between poor and affluent students. I am concerned that the current structure of Federal education programs—that is, to create a new program to address each and every education issue—actually results in spreading Federal dollars too thin to be useful for local educators.

For example, one school district might need more money to buy computers, but they might not have any pressing safety issues to address. Another school district might have a sufficient number of after-school programs, but they might really need more funding for school counselors. Under the current structure of ESEA, these school districts have little flexibility to move Federal money around. That means one of two things: either they get too little money to address their biggest problems, or they miss out on money from some Federal programs because those programs have no relevance for their schools.

Don't you agree that States and local school districts are in the best position to know what their education needs are and to devise ways to address them?

Answer. I absolutely agree that States and communities are in the best position to address their education needs, and that the Federal role is that of a junior partner. I also believe that Federal programs provide more flexibility than is commonly recognized. For example, the Goals 2000 State Grant program provides funds that can be used for a very wide variety of activities that support standards-based reform, from teacher training to curriculum to buying computers. Title I funds also support many different approaches to improving student achievement, including early childhood education, adoption of research-based reform models, after-school programs, and school safety efforts.

Question. Isn't it possible that consolidating many Federal education programs would actually give States and school districts even more resources to pour into their most pressing needs?

Answer. Our experience with block grants has shown that this approach is what really leads to funds being spread too thinly to have much impact. In fact, in a recent report from the General Accounting Office on the Goals 2000 program, State officials expressed concern that if Goals 2000 funds were not restricted to support of State and local standards-based reform efforts, they would be diverted to non-reform activities.

Question. Isn't it possible that allowing maximum flexibility to move Federal money around might result in some of these needs being better met?

Answer. It is possible, but in my view—and I say this as a former governor—not likely. I think it is important to remember that we are trying at the Federal level to exercise leadership and stimulate change. One reason this is so hard is that people everywhere—and not just in our schools—tend to keep doing things the same way, the way they are comfortable with. In my view, the "maximum flexibility" you are talking about would only encourage this kind of educational inertia.

The American people have made clear their support for more investment in critical national priorities—like smaller class sizes, expansion of after school programs, improving reading in the early grades, and helping students and their families get ready for college. It is precisely because our role—and our resources—are limited that we must target the Federal education investment to those areas where it can make a real difference. At the same time, we continue to work to provide the flexibility districts and schools need to raise student achievement, while ensuring accountability for the effective use of taxpayer funds.

TURNING AROUND FAILING SCHOOLS

Question. As you know, we have over 7,000 failing schools in our country. For years, regardless of the fact that they consistently fail to educate children, they continue to receive a steady stream of Federal money. In effect, we are subsidizing their failure. I believe that failing schools should be given the tools they need to

turn themselves around—and successful schools should be rewarded for their hard work. However, at some point, I believe we actually do more harm than good for children when we continue to subsidize schools that fail to educate them.

What do you believe should be done with chronically failing schools?

Answer. Greater accountability is at the core of our proposal to reauthorize the Elementary and Secondary Education Act (ESEA). The Administration's reauthorization bill would strengthen statewide accountability systems, provide new resources for States and school districts to turn around failing schools, and require tough measures for chronically failing schools. For example, schools in corrective action under Title I could be reconstituted with a new staff and curriculum or actually closed down and reopened as a new school or as a charter school.

Question. Does the Administration believe that at some point there must be real consequences for schools that can't or won't improve?

Answer. Yes, we do. In addition to our reauthorization proposals, we are implementing the new Title I Accountability Grants program, which couples additional resources for school improvement efforts with the requirement that gives students in schools identified for improvement under Title I the option to attend a better school. Our 2001 budget proposal would require all school districts participating in Title I to give students attending schools identified for corrective action the option of transferring to a school not identified for corrective action.

Question. Doesn't the Federal Government have a responsibility to taxpayers not to subsidize failure?

Answer. I believe we do, and so does President Clinton. This is why he took the lead more than a year ago to launch a broad-based accountability initiative that includes the measures described above. Other proposals to increase accountability, such as report cards for parents and tougher qualifications for teachers and paraprofessionals, have been incorporated into the President's ESEA reauthorization bill.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

CLASS SIZE REDUCTION PROGRAM—TEACHERS HIRED

Question. Mr. Secretary, the President has requested an additional $1.75 billion to maintain our goal of hiring 100,000 new teachers to address the severe problem of overcrowded classrooms. Opponents of this funding have argued that these funds may not be accessible for all school districts and may never make it to the classroom. Can you provide for us a brief status report on how many teachers have been hired to date and how many we could hire with the additional $1.75 billion?

Answer. Based on data from 55 percent of districts, we estimate that local districts have used their 1999 Class Size Reduction funds to hire more than 29,000 teachers.

We estimate that the $1.75 billion budget request for the program in 2001, along with the 35 percent local matching requirement, would support the hiring of as many as 49,000 teachers. Without the local matching requirement, the requested amount would support the hiring of as many as 43,000 teachers.

TECHNOLOGY LITERACY CHALLENGE FUND PROGRAMS AND PREPARING TOMORROW'S TEACHERS TO USE TECHNOLOGY

Question. Mr. Secretary, as you are aware, I have focused not just on class size but also working to make sure we give teachers the skills to use technology in the classroom. It does little good to wire every classroom to Internet or to provide Internet access to every school if teachers are not prepared to use these tools in the classroom. Can you provide a brief summary of the President's Technology Literacy Challenge Fund activities as requested in his fiscal year 2001 budget?

Answer. In 2001, we are requesting a total of $450 million for the Department's Technology Literacy Challenge Fund (TLCF) program, an increase of $25 million. The TLCF helps local districts put into place strategies to enable all schools to integrate technology fully into school curricula to improve teaching and learning. The Department's proposal for reauthorization of the TLCF would limit eligibility for awards to districts with high concentrations of poor children and a demonstrated need for technology, or to partnerships that include such districts. Districts would use their funds to increase the capacity of teachers in high-poverty, low-performing schools to use technology effectively in their classrooms. The amount requested would support approximately 3,400 local grants.

In addition to the TLCF, the Department's other educational technology programs help States, districts, and schools achieve the four goals of the Administration's Technology Literacy Challenge, which are to: (1) provide access to modern, multi-

media computers for all teachers and students; (2) connect every school and classroom to the Internet; (3) provide all teachers with the training and support they need to use technology effectively in their classrooms; and (4) develop effective and engaging software and on-line resources as an integral part of schools curriculum. The technology programs and the 2001 requested amounts are:

—*Next-Generation Technology Innovation*, for which we are requesting $170 million in 2001, would replace the current Technology Innovation Challenge Grants and Star Schools programs. The new program would focus on developing "cutting edge" applications of educational technology. In 2001, new awards would focus on developing advanced technology applications, supporting the development of high-quality on-line coursework, and a special initiative to help prepare middle school teachers in the Mississippi Delta region to use technology effectively and to develop challenging coursework on-line.

—*Preparing Tomorrow's Teachers To Use Technology* assists public and private entities to develop and implement teacher training programs that prepare prospective teachers to use technology to improve instructional practices and enhance student learning. The $150 million requested in 2001, a $75 million increase over 2000, would support approximately 466 awards.

—*Community Technology Centers* supports efforts to establish or expand technology centers to provide residents of impoverished rural and urban communities with access to computers and technology, particularly educational technology. The $100 million requested in 2001, a $67.5 million increase, would allow approximately 400 communities to establish or expand 1,000 technology centers.

—*Regional Technology In Education Consortia*, for which we are requesting $10 million, the same as the 2000 appropriation, supports regional centers that carry out professional development, resource and information dissemination, and technical assistance to help States, districts, and schools integrate technology effectively into classrooms.

—*Ready To Learn Digital Television*, for which we are requesting $16 million in 2001, supports the development of educational television programming and related activities aimed at cultivating a love of language, reading, and learning in young children.

—*Telecommunications Program For Professional Development*, for which we are requesting $5 million in 2001, would replace the current Telecommunications Demonstration Project for Mathematics program. This new program would support telecommunications-based projects designed to provide professional development to elementary and secondary school teachers in the core academic subjects.

STUDENT DEBT—GROWING IMBALANCE OF STUDENT EDUCATION LOANS TO GRANTS IN PAYING FOR COLLEGE

Question. Over the past 10 years, I have witnessed a disturbing trend in higher education. We have a growing number of students who must depend entirely on borrowing in order to pay for their higher education. The percentage of loans versus direct grants to students has dramatically increased. Students are graduating with huge debts and many discontinue or do not pursue a postsecondary education simply out of fear of carrying such a large debt. In addition, many students are looking at careers based on starting salary because they know they will have large loan payments. I realize this problem cannot be solved in one budget cycle, but I would welcome your thoughts on steps we can begin to take to reverse this trend.

Answer. One of the major steps we need to take is to continue increasing support for the Pell Grant program, where the maximum award has risen from $2,300 in fiscal year 1994 to $3,300 in fiscal year 2000. The maximum Pell Grant in fiscal year 2000 covers about 95 percent of the average tuition and fees at a 4-year public college, but still only about 38 percent of the total cost of attendance. This program is vital to the overall student aid picture, as is funding for campus-based programs such as Federal Work-Study where an estimated 1 million students will help earn their way through college with Federal assistance in fiscal year 2000.

We need to do a better job of counseling students up front on what amount of borrowing is appropriate to their specific situation. We also can encourage States and institutions to increase their level of assistance so that students may take advantage of available non-Federal aid as well.

Many students who are dependent on borrowing may be ineligible for grant aid due to family income levels. We, too, are concerned about the rising loan debt that numbers of these and other postsecondary students are carrying. One of our performance measures focuses on keeping median Federal debt burden below 10 per-

cent of income in the first year of repayment. While this is not entirely within the Department's control, since many outside factors play a role, there are options that we have instituted to help borrowers manage their debt.

For instance, the Administration established flexible repayment plans such as Income Contingent Repayment, which allows Direct Loan borrowers to repay based on size of debt and income. Other options include graduated, extended, and income sensitive repayment plans that can help make monthly payments more affordable and keep borrowers out of default.

EDUCATIONAL TAX INCENTIVES

In addition, we need to encourage eligible students and their families to use the variety of educational tax incentives available. For instance, taxpayers may be able to deduct up to $2,000 in student loan interest in 2000. Hope and Lifetime Learning tax credits are another possibility to lower overall postsecondary tuition and fee expenses. The Hope tax credit allows up to $1,500 annually toward tuition and fees paid in the first 2 years of postsecondary education and the Lifetime learning tax credit currently permits up to $1,000. The Administration is seeking to expand the Lifetime learning tax credit up to $2,800 annually and raise the income phase-out ranges so greater numbers of families can take advantage of it.

In combination, all of the ways mentioned above, represent positive steps that can help in alleviating the burden of student loan debt.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

BYRD SCHOLARSHIP PROGRAM

Question. Over the life of the program, how many students have received Byrd Scholarships and how many new and continuing awards have been made?

Answer. Since the program was first funded in fiscal year 1987, 76,376 students have received Byrd Scholarships and a total of 173,897 new and continuing awards have been made. In fiscal year 2000, 26,572 new and continuing scholarships will be made and in fiscal year 2001, our budget would provide an additional 7,310 new scholarships and 20,024 continuing scholarships.

DEPARTMENT OF EDUCATION EXPENDITURES FOR NEEDS-BASED STUDENT FINANCIAL ASSISTANCE

Question. In 1999, how much did the Department of Education spend on needs-based student financial assistance?

Answer. In 1999, the Department obligated nearly $7.7 billion in the Student Financial Assistance account in support of need-based student aid. Those funds, together with required matching funds under the Campus-Based and Leveraging Educational Assistance Partnership (LEAP) programs, less allowable administrative costs, provided an estimated $10.2 billion in available aid to students. With an additional $15.7 billion in need-based mandatory student loans (guaranteed and direct subsidized Stafford loans), the Department made approximately $25.9 billion in need-based aid available to students in 1999.

Obligations in the SFA Account in Fiscal Year 1999

Pell Grants	$6,043,864,720
Campus-based programs:	
SEOG	619,307,364
Work-study	875,536,832
Perkins loans:	
Federal capital contributions	101,662,353
Teacher cancellations	29,980,923
LEAP	25,000,000
Total obligations	7,695,352,192

DEPARTMENT OF EDUCATION EXPENDITURES FOR MERIT-BASED STUDENT FINANCIAL ASSISTANCE

Question. How much did the Department spend in the same year for merit-based student financial assistance?

Answer. In addition to $39.3 million in the Byrd Honors Scholarships program for merit-based financial assistance to undergraduate students, in fiscal year 1999, the

Department spent a total of $31 million in the Graduate Assistance in Areas of National Need (GAANN) and Javits Fellowships programs for merit-based assistance to graduate students studying in areas of national need and doctoral students studying in the arts, humanities, and social sciences.

REWARDING EXCELLENCE IN STUDENT FINANCIAL ASSISTANCE

Question. The purpose of the Byrd Scholarship program is to award students who work hard at their schoolwork regardless of economic factors. How does the Department of Education intend to build upon these efforts to reward excellence?

Answer. The Administration's fiscal year 2001 budget request recognizes the success of the Byrd Honors Scholarships program in helping high achieving students pay for a college education and would build on this success by moving the program closer to the maximum funding level authorized by law. In addition, the budget request would continue support for the GAANN and Javits Fellowships programs because of their critical role in rewarding excellence and encouraging continued learning.

SCHOOL CONSTRUCTION

Question. With the Elementary and Secondary Education Act due to be marked up by the Senate Health, Education, Labor, and Pensions Committee this week, I would like now to turn to those issues of importance to students, parents, and teachers in creating a stronger, more educated national population. I strongly believe that educating oneself is a lifelong journey, and the skills by which one learns to read and study are fostered at a young age, making these years of schooling extremely important in shaping one's future pursuit of education. Mr. Secretary, would you please respond to the following questions.

I have noted the Department's new efforts to increase budget spending for school construction. Specifically, how will these projections assist our small, rural schools in high poverty areas such as we find in my State of West Virginia?

Answer. The Administration's School Renovation proposal would provide $1.3 billion in grants and loan subsidies to provide support for urgent renovations in areas of high need. These funds would assist schools in high poverty areas, such as those in small, rural areas of West Virginia, because they would be targeted to school districts based on poverty rates, school repair needs, and fiscal capacity.

Question. When available construction funding requires matching funds, how does the Federal Government assist the small rural communities with high poverty levels and low tax bases to be competitive?

Answer. The Administration's School Renovation proposal would provide both grants that require no matching funds and subsidies equal to the size of interest payments on 7-year loans. The Administration intends to target both the grants and the loans to needy areas, while reserving the grants for areas with the greatest need.

TEACHER CERTIFICATION—NATIONAL BOARD FOR PROFESSIONAL TEACHING STANDARDS

Question. Are there any national efforts to encourage teachers to participate in the National Board for Professional Teaching Standards certification process?

Answer. The National Board for Professional Teaching Standards (NBPTS) itself encourages participation in the certification process in several ways. One way is through Teacher Subsidies (funded at $2.5 million of the Department's grant to the Board). The Board provides funds to each State to pay up to one half of the candidate fee. As a result of the program, staff in the departments of education in each State engage in a variety of strategies to increase the number of teachers in their States who are seeking certification. The Board also sponsors a series of national facilitator institutes for individuals interested in helping recruit candidates and providing support for candidates going through the certification process.

The Board has also partnered with national organizations such as the Council of Great City Schools, the National Council of Social Studies, the International Reading Association, and the National Alliance of Black School Educators to increase participation. The Board has exhibits at the national conferences of many major education and content associations. In addition, the Board works with the private sector to increase participation; e.g., State Farm is supporting candidates through its offices in each State.

Question. How can we assist States with very low numbers of participating teachers?

Answer. In those States with large numbers of National Board Certified Teachers (NBCT), there is significant State support through financial incentives, including fee support and salary increases, coupled with an increased awareness of the NBCT

process. The reverse is true in those States with low numbers of National Board Certified Teachers.

Through its grant to the NBPTS, the Department is helping to increase the number of candidates for National Board Certification in States with low participation by providing support to the Board:

—to increase State and local incentives through meetings with State stakeholders and legislators; and

—to increase awareness of the NBCT process through partnerships with the private sector, encouragement of candidate support groups, participation in national meetings involving teachers, and working with ED's Regional Educational Laboratories and institutions of higher education.

TEACHER SHORTAGES AND THE BUDGET PROPOSAL

Question. With the incredible predictions for teacher shortage rates growing almost daily, what efforts might we expect to see emerging to reverse this threatening crisis?

Answer. The Administration shares your concern about reports that many school districts are having difficulty hiring and retaining fully qualified teachers. According to the National Commission on Teaching and America's Future's report, *What Matters Most: Teaching for America's Future* (1996), "Much of the problem of teacher supply is a problem of distribution that could be solved with more thoughtful and coherent policies. While there are shortages of qualified candidates in particular fields (e.g., mathematics and science) and particular locations (primarily inner city and rural), the nation each year produces more teachers than it needs. . . . Thousands of teachers fail to make the transition from the places they were prepared to the places where the jobs are due to lack of information about where to apply, lack of reciprocity in licensing between States, and ridiculously cumbersome application procedures." (pp. 37–8)

In addition, the report concludes that inadequate efforts to retain teachers contribute to the teacher shortage. For example, the report states that "Of all of education's self-inflicted wounds, the continued tolerance for extraordinary turnover among new teachers is among the most remarkable. Chronic, high rates of teacher replacement—particularly for teachers in the first 2 or 3 years of their careers and particularly in urban school districts—increase the pressure on teacher recruitment and initial placement systems incessantly. . . . Turnover in the first few years is particularly high because new teachers are typically given the most challenging teaching assignments and left to sink or swim with little or no support. They are often placed in the most disadvantaged schools and assigned the most difficult-to-teach students, with the greatest number of class preparations (many of them outside their field of expertise) and a slew of extracurricular duties. With no mentoring or support for these teachers, it is little wonder that so many give up before they have really learned to teach." (p. 39)

The Administration is requesting funds for several programs to help school districts address their immediate teacher shortage concerns, including a proposed new initiative, Hometown Teachers, and the Transition to Teaching program. We believe that these and other teacher training programs, for which we are requesting a total of $1 billion, would encourage school districts to develop and implement longer-term solutions for recruiting and retaining high-quality teachers. For example, States and school districts would be able to use funds to develop strategies that could include mentoring programs for new teachers, higher teacher salaries, more desirable working conditions, better professional development opportunities for teachers and school leaders, and other efforts to improve the quality of the teaching profession.

DEPARTMENTAL RESPONSE TO TEACHER SHORTAGES

Question. What is the Department doing to specifically address these issues?

Answer. The Administration is requesting $1 billion in support of a comprehensive set of ESEA reauthorization proposals focusing on professional development and teacher recruitment. Programs that would be implemented as part of the package include Teaching to High Standards State Grants (which would replace the Eisenhower Professional Development State Grants and Goals 2000 programs), a School Leadership Initiative, National Activities for the Improvement of Teaching and School Leadership, the Eisenhower Regional Mathematics and Science Education Consortia, Teacher Quality Initiatives, Transition to Teaching: Troops to Teachers, and Early Childhood Educator Professional Development.

The Administration believes that these programs, in total, would help States and school districts address their teacher shortages both directly and indirectly by helping them to develop and implement short- and long-term solutions to teacher re-

cruitment issues and to reduce their teacher attrition rates. In addition to the programs that specifically address teacher recruitment, such as the Hometown Teachers and Transition to Teaching programs, other programs in the $1 billion request would provide high-quality professional development to both teachers and school leaders to help ensure that all students are being taught by teachers who are fully qualified and who are receiving the support they need to teach to challenging State and local standards.

For example, the Administration is requesting $690 million for the Teaching to High Standards State Grants program, which would help educators improve learning in American classrooms by supporting State and local efforts to align curricula and assessments with challenging State and local content standards and to provide teachers with sustained and intensive high-quality professional development in the core academic subjects. A $60 million set aside in this program would provide grants to colleges and universities that agree to partner with at least one school district to provide professional development in the core academic subjects. States would be required to give priority to those colleges and universities that plan to focus on induction programs for new teachers that provide mentoring and coaching by trained mentor teachers. The Administration believes that induction programs such as these can provide the support that new teachers need to help them to become more effective teachers and to improve the likelihood that they will stay in the teaching profession.

RECOGNIZING HIGHER EDUCATION INSTITUTIONS WITH EFFECTIVE ALCOHOL AND DRUG PREVENTION PROGRAMS

Question. As you recall, I authored a component of the Higher Education Act Amendments of 1998 to establish a National Recognition Awards program to identify institutions of higher education with effective alcohol and drug prevention programs. With the first year of the program complete, would you please provide me with a report on the second year's implementation status of the program, as well as any intentions the Department may have to broaden the program given the increase in funding?

Answer. Because the second year of the program is being funded under a different authority than last year (that is, under Safe and Drug-Free Schools National Programs rather than under the Fund for the Improvement of Postsecondary Education), the Department has needed to undergo rulemaking to implement the program for 2000. On February 14, 2000, the Department published in the Federal Register a notice of proposed priority, eligible applicants, and selection criteria for evaluating applications for new grants under for this program. We received very few comments from the public and expect to publish a final notice in the Federal Register in early April, at which time we will begin soliciting grant applications from institutions of higher education. The application deadline date will be May 12, 2000. The program will be operated in essentially the same manner as it was implemented in 1999.

The Department is planning to use the additional $100,000 in 2000 funds to make additional awards and to support enhanced dissemination activities by each grantee. A total of $600,000 will be available for awards (compared to $500,000 in fiscal year 1999). Once again $250,000 of the appropriation will be used to administer the peer review process, conduct a recognition ceremony, and develop and disseminate a publication describing the model programs. We plan to make grant awards in June, and anticipate making between eight and ten awards, ranging from $50,000 to $90,000 each.

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

TITLE I HOLD HARMLESS

Question. You have given important opposition to the Title I "hold harmless" provision that effectively negates the law's requirement that the Department use the most up to date child poverty data in allocating Title I funds. Hold harmless provisions freeze in amounts to States whether the number of poor children goes up or down. In fast-growing States like mine, the hold harmless hurts and we don't get our fair share. California lost $40 million in fiscal year 2000 because of the hold harmless. California received $944.9 million instead of the $984.5 million we should have received.

Will you vigorously oppose the hold harmless publicly?

Answer. I could not agree with you more on the harmful impact of the 100 percent hold-harmless on Title I allocations. This provision does indeed prevent Title I funds

from flowing, as intended by the authorizing statute, to States and school districts experiencing rapid growth in poor students. Research shows clearly that high concentrations of school poverty are directly correlated with low student achievement, and that even non-poor students tend to perform poorly in schools with high poverty levels. This is why the various Title I formulas are designed to target additional resources to high-poverty districts and schools. Unfortunately, in many cases the 100 percent hold-harmless provision undermines this targeting and dilutes the impact of the $8 billion annual investment in Title I. Our budget would eliminate this provision, and we certainly will support efforts by you and others to resist the continuation of this 100 percent hold-harmless requirement in the fiscal year 2001 appropriation.

STRENGTHENING TITLE I ACCOUNTABILITY PROVISIONS TO INCREASE ACADEMIC ACHIEVEMENT

Question. Current law has some accountability requirements for the Title I program, yet I question whether there have been real achievement gains under the current program. I know you agree that the early years—learning the basics—are critical to a student's lifetime success.

How can we strengthen Title I's accountability requirements to make sure the funds are spent on improving learning in the core academic curriculum?

Answer. As I indicated earlier, greater accountability is at the core of our proposal to reauthorize the Elementary and Secondary Education Act. We would strengthen statewide accountability systems to ensure that Title I schools are held to the same high standards as other schools, provide new resources for States and school districts to turn around failing schools, and require tough measures for chronically failing schools. We also would require tough corrective actions for chronically failing schools, including reconstituting them with a new staff and curriculum or actually closing them down and reopening them as a charter school.

REAUTHORIZATION PROPOSAL TO INCREASE TITLE I ACCOUNTABILITY

Question. What are your proposals?

Answer. The Administration's reauthorization proposal for Part A of Title I would encourage each State to develop a single, rigorous accountability system that holds all local educational agencies (LEAs) and schools, including Title I schools, accountable for making continuous and substantial gains in student performance and in the performance of the lowest-performing students. This statewide accountability system would be based on the State's content and student performance standards, and would include procedures for identifying and intervening in LEAs and schools that are not making gains in student performance, as well as recognition and rewards for successful LEAs and schools. States that do not operate such a system for all their schools would be required to develop one for their Title I schools.

The Administration's reauthorization proposal includes strong corrective actions to turn around consistently low-performing schools. Once a Title I school is designated for corrective action, the LEA would be required to carry out one of the following measures: (1) implement a new curriculum that research has shown offers substantial promise of improving student achievement; (2) redesign or reconstitute the school, which may include reopening it as a charter school; or (3) close the school and allow its students to transfer. Districts also could allow students in schools subject to corrective action the option of transferring to a new school.

The Administration's reauthorization bill also includes a proposal to provide additional resources to States and school districts to support school improvement efforts. The fiscal year 2000 Department of Education Appropriations Act jumpstarted this new initiative by providing $134 million for school improvement activities at the LEA level. These funds must be used for technical assistance and other interventions designed to improve low-performing schools and to help such schools enable all students to meet challenging State standards. In addition, Congress directed, through appropriations language, that all LEAs receiving these funds must provide students enrolled in schools identified for improvement with the option to transfer to another public school within the LEA that has not been identified for improvement.

The President's 2001 budget would expand funding for these new accountability grants to $250 million, with 30 percent of grant funds reserved for State-level accountability and school improvement activities and 70 percent allocated to LEAs. And to help ensure that no student is trapped in a chronically failing school, the Administration's 2001 budget proposal would require LEAs to give students attending corrective action schools the option of attending another public school within the LEA that has not been identified for corrective action. This requirement would

apply to all LEAs participating in Title I, whether or not they receive accountability grant funds.

IMMIGRANT EDUCATION FUNDS

Question. Under the immigrant education programs, the Department of Education awards grants to school districts based on the number of immigrant children enrolled, if the district has an immigrant population of at least 500 or 3 percent of their enrollment. Students counted are those that have been in this country for less than 3 academic years.

New immigrant students are probably the most at-risk students. In addition to language barriers, their schooling has been interrupted and they are in unfamiliar communities.

Funding for this program has been flat—at $150 million in 1998, 1999, and 2000. And you have requested $150 million for fiscal year 2001. California has 25 percent of the U.S. legal immigrants and 40 percent of the Nation's illegal immigrants. Last year California received $36.5 million to educate immigrant children.

In light of the serious needs these children bring to the classroom, shouldn't we be increasing immigrant education funds?

Answer. We strongly agree that school districts need Federal assistance in serving recent immigrant students. The Administration proposed, and Congress enacted, increased funding for this program in each of fiscal years 1996, 1997, and 1998. However, since 1995, the number of eligible immigrant students in the Nation has declined by 2 percent, and in California by 29 percent. With this decline, we believe that the proposed appropriation level is adequate. As you know, for 2001, the Administration has proposed large increases for both the Title I and Bilingual Education programs that serve large numbers of immigrant students.

FLEXIBILITY OF CLASS-SIZE REDUCTION PROGRAM

Question. The Clinton Administration's push to reduce class sizes in the lower grades is a good use of Federal education funds. California has been reducing class sizes in grades K–3 since the 1996–1997 school year. Because these efforts have largely succeeded in reducing class sizes in grades 1–3, in fiscal year 2000 California received a waiver that allowed my State to use class-size reduction funds to reduce class sizes in higher grades.

Will you accommodate States that have taken the initiative in reducing class size by making funds flexible enough to suit the specific class size reduction needs of the State?

Answer. Districts have considerable flexibility in the use of their Class Size Reduction funds. A district that has met the target level of 18 children or fewer in the early grades, or has reduced class size to a State or local class size reduction goal that was in effect prior to November 29, 1999, can use its funds to further reduce class size in those grades, to reduce class size in additional grades, or to improve teacher quality. We will work with States to provide them with flexibility in the use of the funds they receive under the Class Size Reduction program so that each State is able to address its specific class-size reduction needs.

REDUCTION IN IMPACT AID

Question. Impact Aid is an important program without which many schools in California and other States would be in severe financial straits. Currently in California, $57 million in Impact Aid is spent educating 1 million students in 119 school districts. Impact Aid is a basic obligation that the Federal Government has to school districts to compensate them for the lost revenues because of tax-exempt Federal property. More than half of the Administration's proposed $128 million cut in Impact Aid comes from the elimination of the "Payments for Heavily Impacted Districts."

Why did the Administration propose a drastic $128 million, or 15 percent, cut in Impact Aid?

Answer. In the Administration's budget, the types of Impact Aid funds that are targeted to the school districts with the clearest needs would increase. For example, Basic Support Payments on behalf of an Impact Aid "a" child would increase 7 percent on average from the 2000 level. (Impact Aid "a" children are generally those children who reside with their parents who both live and work on Federal land. Impact Aid "b" children are generally those students who reside with their parents who work or live on Federal land.) Under the Administration's proposed funding level and formula, the Department estimates that school districts in California would receive an increase of nearly 10 percent in Basic Support Payments, from $51.8 million in 2000 to $56.6 million in 2001.

The Administration's budget does not support payments on behalf of "b" children because we believe (as did previous Administrations) that "b" children do not present a real, uncompensated burden for school districts. Families that reside on private property either pay property taxes or rent property on which their landlords pay property taxes. Since local governments typically finance education using property taxes, the local cost of educating off-base children can be financed using property and other local taxes.

The Administration proposes no funding for Payments for Heavily Impacted Districts because the program no longer meets its purpose under the authorizing statute—to assist school districts with large proportions of federally connected students and a strong tax effort in reaching the per-pupil expenditures of similar school districts in their State. The appropriations for fiscal years 1999 and 2000 essentially rewrote both the eligibility criteria and the payment formula for this supplemental funding authority.

The program now functions more as a set of funding earmarks than a legitimate program meeting a genuine need. No school districts in California receive Payments for Heavily Impacted Districts.

By eliminating funding for authorities that fail to meet their intended purpose, the Administration is able to focus on funding increases for high priorities, such as a substantial increase for payments on behalf Impact Aid "a" children under the Basic Support Payments formula.

PAYMENTS FOR HEAVILY IMPACTED DISTRICTS

Question. Why, if the Department of Education believes that the funds for heavily impacted schools are not targeted effectively, does the Department not try to change the legislation rather than simply cutting the funding in its entirety?

Answer. The Administration is proposing changes to the legislation for Payments for Heavily Impacted Districts in its proposal for reauthorizing the Elementary and Secondary Education Act. However, neither the Senate nor the House committee bills to reauthorize Impact Aid include these changes.

The Administration's proposed changes would simplify the payment formula and bring this program back to its original purpose of assisting school districts with large proportions of federally connected students and a strong tax effort to increase their per-pupil expenditures so that they would be in line with similar school districts. These changes would discontinue the practice of distributing these funds to school districts that no longer have large proportions of federally connected children.

HEAD START PROGRAM

Question. Should the Head Start program be moved to the Department of Education and converted to a strong preschool program?

Answer. I see no reason to move the Head Start program to the Department of Education. Head Start, as it now exists, is a strong program that helps prepare our highest need children to succeed in school. The Department of Health and Human Services (HHS) has worked to ensure that Head Start is a comprehensive program that integrates health and social services with education and learning and is geared toward promoting both social competence and school readiness for our Nation's low-income children. With the greater focus on improving the standards and quality of all aspects of Head Start in the last reauthorization, HHS has worked hard to focus on improving quality, including the improvement of key school readiness indicators.

In 1998, the National Academy of Sciences released information about critical research on the importance of preventing reading difficulties in young children by focusing efforts on improving opportunities for young children to develop language and literacy skills in preschool in order to enter school ready to learn to read. The Department of Education has worked closely with HHS to focus Federal early childhood programs on this goal and to disseminate this research widely. These efforts have focused on improving the language and literacy skills of young children through the Head Start, Title I, Even Start, and Reading Excellence programs. I am confident that we will make great strides in helping all young children, especially those from poor families, improve their reading readiness.

Question. Would the program be a stronger program if moved to the Department of Education?

Answer. Again, I see no reason to move the program. Both of our agencies are working together to ensure that young children are able to start school ready to learn—by offering a wide range of approaches and services to reach the young children who are most at risk of school failure, by encouraging parents to become involved in their young children's development, and by stressing the importance of cognitive development in young children. We have learned some important lessons

in recent years about how to meet the range of needs of target families and how to manage our programs more effectively.

HHS AND ED COORDINATION ON HEAD START

Question. What is the coordination between HHS and ED vis-à-vis Head Start?

Answer. The Department of Education (ED) and the Department of Health and Human Services share the mission of providing services to young children in order to ensure that they are healthy, safe, and able to start school ready to learn. During the past 7 years, our agencies have worked to improve collaboration and communication in order to serve our Nation's children more effectively. While significant strides have already resulted from this increased interagency collaboration, we will continue our efforts to improve program efficiency and accountability. Some examples of ways in which ED is working with HHS, specifically in the areas of early childhood services, research, and performance measures are:

In the area of School Age Care and After School Programming, ED and HHS have collaborated on several successful programs, including the Federal Support to Communities Initiative (FSC), Safe School/Healthy Students, 21st Century Community Learning Centers, and Child Care and Development Block Grants (CCDBG). These programs address the growing need to provide stimulating out-of-school-time programs for our Nation's children.

In the area of accountability at the Federal level, Title I, Even Start, Head Start, CCDBG, and the Individuals with Disabilities Act (IDEA) programs are developing outcomes systems for use in improving program effectiveness and complying with the Government Performance and Results Act of 1993 (GPRA). As a next step toward coordinated indicators and measures, ED and HHS will conduct an assessment of the scope, quality, and frequency of measurement of the current set of ED and HHS program performance indicators for their early childhood programs. Included in this analysis will be a comparison of the GPRA indicators for the programs, as well as the studies, reporting systems and evaluations, and measures used to report on the indicators and evaluate the programs.

Even Start, Title I, and Head Start staff are coordinating programs on a number of fronts by focusing on ways to sustain coordination efforts at the Federal, State, and local levels. For example, Federal Even Start and Head Start staff are planning a joint conference for the summer of 2000 on coordinating accountability systems. This conference will include staff from Head Start State Collaboration Offices and Even Start Statewide Family Literacy Initiative grants, in addition to other key State offices involved in early care, education, and family literacy. In addition, ED and HHS will soon issue guidance on models for collaborating and blending Head Start, Special Education, Even Start, and Title I, Part A funds (i.e., models for combining funds to provide whole-day and year-round preschool services, or models with Title I paying for educational services and Head Start paying for health, nutrition, and parent involvement). Also, HHS and ED are exploring ways to provide joint family literacy technical assistance through the Head Start Family Literacy Technical Assistance Initiative.

HHS is also partnering with ED in the development of ED's Survey of Early Care and Education Programs, a nationally representative sample of child care providers and early childhood programs serving children under the age of six. This project is the first national survey in recent years to examine the supply of center-based programs and licensed home-based care.

TEACHING OF COGNITIVE SKILLS IN HEAD START PROGRAMS

Question. Are real cognitive skills being taught in the Head Start program?

Answer. Yes. Head Start has adopted the "whole child" view of school readiness that was recommended by the Goal One Technical Planning Group of the National Education Goals Panel. This view sees school readiness as comprising five developmental domains that are important to the child's readiness for school: physical well-being and motor development, social and emotional development, approaches to learning, language usage and emerging literacy, and cognition and general knowledge. Each of these domains is represented in the Head Start performance standards and measures and in the battery of assessments in the FACES study, a nationally representative longitudinal study of Head Start children that is being used to determine the effectiveness of Head Start. The FACES study, initiated in 1997, is entering its final phase in the spring of 2000. In the next year, the study should yield important information about how Head Start is succeeding in helping children achieve in the five designated development domains addressed in the study, including the cognitive domain.

HEAD START PROGRAM STAFF SALARIES

Question. What is the impact on the program of the low "teacher" salaries being paid to Head Start workers?

Answer. Head Start salaries have increased in recent years as the Administration has continued to emphasize program quality. However, I cannot speak specifically to the issue of the impact of the salaries of Head Start workers, since I do not administer the program. I do know that low salaries tend to discourage some highly qualified individuals from entering the teaching profession at the elementary and secondary education levels, and I assume that that is also true for the Head Start program.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Thursday, March 30, in room SD–124. At that time we will hear testimony from the Honorable Dr. Ruthe L. Kirschstein, Acting Director, National Institute of Health.

[Whereupon, at 11:25 a.m., Tuesday, February 29, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 30, 2000.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2001

THURSDAY, MARCH 30, 2000

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

The subcommittee met at 9:31 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Stevens, Harkin, Kohl, and Feinstein.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, ACTING DIRECTOR

ACCOMPANIED BY:

DR. YVONNE T. MADDOX, ACTING DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. RICHARD D. KLAUSNER, DIRECTOR, NATIONAL CANCER INSTITUTE
DR. CLAUDE LENFANT, DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
DR. HAROLD SLAVKIN, DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
DR. ALLEN M. SPIEGEL, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
DR. GERALD D. FISCHBACH, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
DR. MARVIN CASSMAN, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SERVICES
DR. DUANE 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 I. KATZ, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES
DR. JAMES F. BATTEY, Jr., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

DR. STEVEN E. HYMAN, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH
RICHARD MILLSTEIN, DEPUTY DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE
DR. ENOCH GORDIS, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH
DR. FRANCIS S. COLLINS, DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE
DR. JUDITH L. VAITUKAITIS, DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES
DR. STEPHEN E. STRAUS, DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
DR. SHARON HRYNKOW, Ph.D., ACTING ASSOCIATE DIRECTOR FOR PROGRAM COORDINATION, FOGARTY INTERNATIONAL CENTER
DR. DONALD A.B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE
DR. NEAL NATHANSON, DIRECTOR, OFFICE OF AIDS RESEARCH
DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen.

The hour of 9:30 having arrived, we will proceed with the hearing for the Appropriations Subcommittee on Labor, Health, Human Services and Education.

Today our hearing will focus on the National Institutes of Health, an extraordinary organization from very humble beginnings in 1887 with a budget of $300. The NIH today is comprised of 24 separate institutes and centers with 75 buildings of medical care on more than 300 acres in Bethesda, MD. The budget is somewhat more than $300 today.

And Senator Harkin and I have taken the lead on major increases, as you all know very well, with the cooperation of Congressman Porter and Congressman Obey on the House side.

The achievements of NIH have been spectacular in my opinion. And we have added funding at very substantial amounts in recent years, frankly, over the—perhaps not quite over the objections, but without the enthusiasm of as many members of Congress as we would like to see.

Three years ago, we put up a resolution to add $1 billion to NIH funding. And on a Senate vote, it was defeated 63 to 37. But we found the money, Senator Harkin, Senator Taylor and I, and the subcommittee, but candidly at the expense of other programs, because it was not budgeted. And we ended up with $907,000 million 3 years ago.

Having lost the resolution for $1 billion, we decided the next year to try for $2 billion. And we got a few more votes, but still substantially under 50. And we found $2 billion 2 years ago, as you all know.

Last year, we went again for $2 billion and got a few more votes, but still less than 50. And Congressman Porter wanted to trump the Senate's $2 billion with $300 million more. And when we had the final roundup last year on the budget negotiations, the leadership in both the House and the Senate did not like it; we were taking too much money.

But with your good work and our persistence, we put it in at $2.3 billion. And then there was the across-the-board cuts. So it came down to $2.2 billion.

And this year we have put in a resolution for $2.7 billion. And a question which I consistently get is: Is there too much money being thrown at NIH? Is NIH able to utilize the money which it has? And then there is always the issue of how well it is being spent and what is being produced and what could be produced with more. And as the funding has gone up, of course, you have more applications for grants.

So we talk about those 100 doors out there, and we are only opening 29 or 30 or 31 of them. But when the grants go up, or the appropriations go up, rather, then your grants come in with higher numbers.

But this subcommittee is dedicated to funding NIH generously, because we think you are worth it. When you have a Federal budget of $1.850 trillion, $18 billion for NIH is not really, in my judgment, too much.

Well, having said that, I think we do not need a hearing. We will just bring out the bank.

SUMMARY STATEMENT OF DR. RUTH L. KIRSHSTEIN

NIH has been blessed with very able directors. We miss Dr. Harold Varmus and we miss Dr. Bernadine Healey. And we have an outstanding acting director at the moment.

Dr. Ruth Kirschstein served as deputy director of NIH from July of 1993 until the present time. From 1974 to 1993, she served as the director of the National Institute of General Medical Sciences, the first woman to hold such a position. She came to NIH in 1956 as a medical officer in clinical pathology.

Dr. Kirschstein, that is the same year I started practicing law. So you and I are experienced.

She received her bachelor's magna cum laude from Long Island University and an M.D. from Tulane University School of Medicine.

Welcome, Director Kirschstein. And the floor is yours.

Dr. KIRSCHSTEIN. Mr. Chairman, I and my colleagues appreciate all the wonderful things you have said about NIH this morning. And we want to pledge to you that we will continue to do excellent work.

I am honored to appear before the subcommittee to present the President's budget for NIH for fiscal year 2001. As you have already said, I have been at NIH for many years. And although this is the first time I am testifying about the overall NIH budget, it has been my privilege to appear before this subcommittee annually for 19 years as the Director of the National Institute of General Medical Sciences.

As you have also said, the increases for the NIH for fiscal year 1999 and 2000, both nearly 15 percent, were dramatic and unprecedented and have allowed us to undertake many new and important programs.

And it has been the support of this subcommittee and the subcommittee in the House that has made a substantial difference in improving the public's health and well-being. And so the funds requested for fiscal year 2001 will permit us to continue our fiscal

year 1999 and 2000 initiatives and allow us to begin some new ones.

I would like to mention just two of the many, many advances that occurred during the last year: First, the completion of the first full sequence of a human chromosome, number 22. Its genes have importance for immune system function and in the development of congenital heart disease, schizophrenia, mental retardation and several cancers.

And second, the identification of the gene that causes salmonella bacteria to be deadly when ingested in food. And this should open up the possibilities for the development of new antibiotics, as well as vaccines.

In fiscal year 2001, we propose to emphasize first clinical research on diabetes, osteoporosis, heart disease, neurological diseases, cancer and a host of other serious diseases and disasters, particularly those that have a disparate effect on minority and underserved populations.

Second, the neurosciences will be emphasized; third, genetic medicine; and fourth, bioengineering, bioimaging and biomedical computing.

Finally, Mr. Chairman, we will strive to ensure that the NIH supports new initiatives that offer the most promise of expanding knowledge and improving health and to ensure the support of an appropriate number of new and young investigators of the highest caliber.

I and my colleagues will be happy to respond to your questions.

[The statements follows:]

PREPARED STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Mr. Chairman and Members of the Committee: I am Ruth Kirschstein, the Acting Director of the National Institutes of Health (NIH). I am honored to appear before the Subcommittee to present the President's budget for NIH for fiscal year 2001. Although this is the first time I have appeared before this Subcommittee to testify about the overall NIH budget, it has been my privilege to appear annually for 19 years as Director of the National Institute of General Medical Sciences. Mr. Chairman, your support and the support of the members of the Subcommittee, has made a substantial difference inimproving the public's health and well-being.

Mr. Chairman, all of us, we at NIH, Members of Congress and the citizens we serve, have similar expectations for medical research. We want better ways of diagnosing and treating, and, in the long run, preventing and curing disease. And we want the federal dollars invested in medical research to result in the fulfillment of these expectations.

In the last century, the scientific community, both public and private, worked in collaboration to cure or prevent once deadly infectious diseases that are now given no more thought than the common cold. I was fortunate enough to be at the forefront of the final development of the polio vaccine, one of the truly monumental achievements of the last century. There is not enough time today to list the astounding medical breakthroughs that followed our increased understanding of medical science. I will mention just a few: the development of antibiotics and organ transplantation, life-extending and life-saving cancer therapies, the identification of the AIDS virus and the drugs to treat AIDS, and discoveries involving the chemicals in the brain that are important in drug addiction and mental illness.

As we begin a new century, medical science stands on the threshold of research advances that were once inconceivable. We have identified the genes responsible for a large number of our normal functions and the genetic abnormalities that cause many diseases, such as Huntington's disease, cystic fibrosis, and certain forms of deafness. You will hear much more from my colleagues.

In his budget plan for fiscal year 2001, the President is requesting $18.8 billion for the NIH, an increase of $1 billion or 5.6 percent more than the fiscal year 2000 appropriation. By any measure, the amounts we received in fiscal year 1999 and 2000, both nearly 15 percent increases, were dramatic and unprecedented. These generous budgets have allowed us to undertake many new and important programs and to improve conditions throughout the medical research enterprise. The funds requested in fiscal year 2001 will permit us to continue our fiscal year 1999 and 2000 initiatives and to begin new undertakings and expand others under our Areas of Research Emphasis. I will say more about these areas later.

We are pleased that the public, the Congress, and the Administration place a high value on good health and understand the role that medical research plays in improving the health of the American public. These improvements result from new diagnostic advances, more effective treatment options, better ways to prevent some diseases, and ways to delay the onset or progression of other diseases and disabilities.

We feel confident of public support for our research enterprise, but are aware of our need to deliver to the public the two things it most wants from the NIH:

—research advances, year after year, that improve the health of all members of society;

—assurance that we spend the public's money wisely.

What the Public Wants from the NIH: Research Advances that Contribute to the Health of Everyone

In the past year alone, we have seen dramatic advances that are likely to have a direct, near-term effect on public health. The NIH will continue to emphasize clinical research in fiscal year 2001 because it is critical in improving public health:

—Scientists completed the first sequence of a human chromosome, 22, which has been implicated in immune system function, congenital heart disease, schizophrenia, mental retardation, birth defects, and several cancers, including leukemia. The 33.4 million nucleotides that make up chromosome 22 comprise the longest continuous stretch of DNA ever deciphered. The magnitude of this work is amplified by the insights it will give us into many diseases.

—A clinical trial (carried out in cooaboration with scientists and clinicians in Uganda) has demonstrated an affordable and practical strategy for preventing transmission of the HIV virus from mother to infant. A single oral dose of the antiretroviral drug nevirapine given to an HIV-infected woman during labor and another to her baby within three days of birth reduced the transmission of virus by half compared with a similar short course of AZT. This treatment might prevent some 300,000 to 400,000 newborns per year from becoming infected and eventually developing AIDS at a cost which is affordable in developing countries.

—Preeclampsia is a precursor to eclampsia, a potentially fatal complication of pregnancy. It is characterized by high blood pressure, excessive weight gain, and severe headaches. Eclampsia leads to convulsions and causes a variety of birth complications. Months before symptoms appeared, women with preeclampsia were compounds, prostacyclin and thromboxane, which control blood pressure. The discovery suggests new and early treatments for this condition for which there is currently no cure or treatment.

—An important gene that makes Salmonella a deadly bacterium was identified. Without the gene, which encodes for the enzyme called Dam, Salmonella bacteria not only did not kill the mice into which they were injected, but also serve as a vaccine against future infection by deadly Salmonella. Because Dam is found in many other dangerous bacteria, this discovery opens possibilities for a whole new generation of antibiotics and vaccines.

What the Public Wants from the NIH: Assurance that its Funding is Well Spent

It is clear that the public wants a fuller understanding of the NIH's funding allocations and how it sets priorities—that is, an assurance that the taxpayers' dollars are well spent. We believe, in fact, that the more the public knows about our processes the more it will support both what we do and how we do it. I want to touch on six principles relevant to establishing priorities:

—An obligation to respond to public health needs, judged variously by the incidence, severity, and cost of specific disorders. However, calculations cannot be correlated with research spending in a simple manner.

—A responsibility to capitalize on previous discoveries and to eize the scientific opportunities that offer the best prospects for obtaining new knowledge and better health. Not all problems are equally approachable, regardless of their impor-

tance to public health. Some only yield to a new technology or insight. We must, however, create environments that stimulate new ideas about difficult problems.
—A need to maintain a diverse portfolio on a wide range of diseases. We cannot always know in advance which discovery will be applicable to which disease.
—An obligation to insure first-rate scientific workforces and research facilities.
—A need to seek advice from many sources, including the public.
—And last, but truly foremost in our minds, a commitment to support scientific work of the highest caliber.

Peer review is the cornerstone of our efforts to fund the best science. To identify research worthy of funding, about 40,000 grant applications are peer reviewed at the NIH each year. Of these, approximately 75 percent are evaluated within the NIH Center for Scientific Review (CSR). The NIH is ensuring that CSR has sufficient resources so that its review will recognize, and capitalize on, the opportunities created by the diverse successes of the medical research enterprise, will anticipate emerging fields of research, and accommodate to the rapid pace of scientific change.

In 1998, the Congress asked the Institute of Medicine (IOM) to review the NIH's process for setting priorities. While supporting our principles, the IOM made some useful suggestions about ensuring that our programs are responsive to the public. Over the past year, NIH has responded by appointing a Council of Public Representatives (COPR). The COPR improves our accountability by bringing public views to the NIH, by looking at how the NIH carries out different aspects of its mission, and by conferring on trans-NIH issues. The COPR will be involved in many aspects of NIH programs and policies.

Following another suggestion in the IOM report, this past year the NIH Director required each Institute and Center to produce a strategic plan of research needs and opportunities over two to five years. The plans were developed with input from a wide range of NIH constituents, including patient and other health advocates, scientists, health-care providers, the Congress, the Administration, NIH staff, and other representatives of the public. These strategic plans will be available in the near future and should improve public understanding of the challenges all components of the NIH are facing.

This past year, for the first time, the NIH held a Budget Retreat in June to help develop its presentation of priorities and Areas of Research Emphasis for the President's 2001 budget. The meeting involved ten external advisors, five from COPR and five from the Advisory Committee to the Director (ACD), and created enthusiasm for new areas for collaboration across institutes.

In another major effort to bring public views to bear upon the NIH's programs, priorities, and activities, 26 individuals from outside the agency—scientists, physicians, other health-care providers, patients, and representatives of the ACD and the COPR—met in October to evaluate the scientific quality and relevance of the outcomes of NIH research, a requirement of the Government Performance and Results Act. A report of their assessment has been sent to the Congress as part of the President's budget.

Realizing the Potential of the fiscal year 2001 Budget Request

Generous increases in the last two budget cycles have allowed the NIH to begin many new programs. The funds requested for fiscal year 2001 will advance these programs and, with sound management, allow us to begin new ones. To ensure that NIH can support new initiatives that offer the most promise of expanding knowledge and improving health, and to ensure our ability to support a healthy number of new and young investigators, we will limit growth in commitments and in the size of awards to a two percent average increase for new and continuing grant awards. In addition to initiatives on mental health, cancer, and diabetes, new activities include:

Clinical Research.—To take full advantage of rapid research advances in the last five years, which have provided abundant new therapies to study, the NIH will begin a series of programs to expand clinical research. Career development programs will continue to improve the number and quality of investigators. We will start new pilot and early-phase clinical trials thereby speeding the testing of new therapies. We will develop new, and expand older, networks for multi-center studies of pediatric cardiovascular disease, diabetes, digestive diseases, and treatment for drug abuse. We will establish new multi-center clinical trials to evaluate complementary and alternative medical practices for insomnia, pain relief, and liver diseases. Moreover, the public will have greater access to new information on an expanded national clinical trials database (ClinicalTrials.gov) to be launched soon . It will carry information on the many clinical trials funded by the NIH, by other federal agencies, and by industry.

Health Disparities.—The NIH has a central role to play in eliminating persistent, even increasing, health disparities through medical research, research training, and dissemination of scientifically sound medical information. In fiscal year 2001, the NIH will continue to invest in this area, allocating $20 million to establish a new Coordinating Center for Research on Health Disparities within the Office of the NIH Director. A new trans-NIH Working Group will develop a strategic plan to eliminate or reduce health disparities among different segments of the American population. The plan, will include goals, timetables, and mechanisms for tracking budgets and accomplishments.

Genetic Medicine.—Last November, the Human Genome project finished sequencing one billion of the estimated three billion base pairs of human DNA and deposited them in GenBank, NIH's public database, thus putting us on schedule to have a working draft of the full human genome by this spring. Scientists can use this information to find the genes involved, e.g., in heart diseases, cancer, epilepsy, Alzheimer's, and psychiatric disorders. Companion activities, like developing genomic resources for organisms such as mice, rats, and fruit flies, will help speed the arrival of more precise medical interventions. We are rapidly moving to a time when diagnosis, treatment and even prevention will depend on a precise understanding of the genetic makeup of an individual.

Neurosciences.—This is a particularly exciting time for expansion of research in fields of neuroscience, such as neurogenetics and imaging. To foster collaboration and sharing of ideas among the many Institutes which support intramural research in this area, we are requesting funds for construction of a facility for the new National Neuroscience Research Center to house outstanding trans-NIH neuroscience research programs. A total of $73 million is requested over two years, with $47 advance for fiscal year 2002.

Other Sciences, Including Biomedical Computing.—Many medical advances build on the knowledge and technology of other scientific disciplines. To exploit our new understanding of biological processes, we need new teams of diverse and skilled researchers to overcome complex technological and research problems. In fiscal year 2001, NIH will establish an Office of Bioengineering and Bioimaging to help the Institutes and Centers set priorities in these areas of science and to enhance collaboration with other agencies.

Based on a report by outside experts, NIH has developed the Biomedical Information Science and Technology Initiative to work toward an intellectual fusion of biomedicine and information technology. In fiscal year 2001, the NIH plans to provide the infrastructure to train the next generation of interdisciplinary scientists, to develop new means for storing, managing, and accessing vast data collections, and to enhance basic research in biomedical computing.

Mr. Chairman, that concludes my opening statement. I will be glad to respond to any questions.

PREPARED STATEMENT OF DR. YVONNE T. MADDOX

Mr. Chairman, Members of the Committee: I am pleased to be here today to discuss the fiscal year 2001 budget request for the Office of the Director (OD). The OD provides leadership and coordination for the research activities of NIH, both extramural and intramural. The OD also is responsible for a number of special programs and for management of centralized support services essential to the operation of the entire NIH.

The President has proposed that the OD receive $262.5 million in fiscal year 2001, an increase of $25.2 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS in both years, total support proposed for the OD is $309.0 million, an increase of $27.0 million over the fiscal year 2000 appropriation. Funds for OD efforts in AIDS research are included within the Office of AIDS Research budget request.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including environmental and public safety regulations of facilities. The principal OD offices providing these activities include the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy;

Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and Management. This request contains funds to support the functions of these offices.

The OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs. I will now discuss the budget requests for each of these trans-NIH offices in greater detail.

HEALTH DISPARITIES, THE OFFICE OF RESEARCH ON MINORITY HEALTH, AND THE MINORITY HEALTH INITIATIVE

The Secretary, through the Department's Healthy People 2010 initiative, has made a major commitment to reduce health disparities affecting minorities and other medically underserved socioeconomic groups of Americans. To address these inequities, NIH has established health disparities research as a budget priority and an area of emphasis. This year, we have established the Office of Research on Minority Health (ORMH) as the Coordinating Center for developing a trans-NIH Strategic Plan for Health Disparities that will integrate the various research activities of the ICs toward the goal of significantly reducing health disparities. Additionally, in fiscal year 2001, NIH is requesting $20 million in new funding and related legislative authority for the Coordinating Center to award grants for minority health research under exceptional circumstances, when the Institutes and Centers do not fund such research that has been identified as a priority.

The Minority Health Initiative (MHI) is a comprehensive, trans-NIH program with a focus on developing and testing ways to reduce the disproportionate burden of disease among minority populations and on developing strategies to promote positive health behaviors across the life span. The MHI specifically targets the elimination of health disparities experienced by racial and ethnic minority populations in four key areas: infant mortality; breast, cervical, and prostate cancer screening and management; cardiovascular disease; and complications arising from diabetes. The MHI will also support the Minority Institution Cancer Center Partnerships designed to create collaborative relationships between institutions that primarily serve minorities and the NCI-designated cancer centers to conduct research, training, education, and outreach activities that focus on the disproportionate incidence of cancer in ethnic minority populations.

THE OFFICE OF DISEASE PREVENTION

The Office of Disease Prevention (ODP) has several specific programs/offices that strive to place new emphasis on the prevention and treatment of disease.

In fiscal year 2001, the Office of Dietary Supplements (ODS) will continue to develop the Dietary Supplements Research Centers Initiative. Currently, three such Centers are being funded in conjunction with the National Center for Complementary and Alternative Medicine (NCCAM), the National Institute of General Medical Sciences (NIGMS), the National Institute of Environmental Health Sciences (NIEHS), and the Office of Research on Women's Health (ORWH). The long-term goal of the Initiative is to fund eight Centers, four on botanicals and four on other categories of dietary supplements. The ODS will continue to support investigator-initiated research through the Research Enhancement Awards Program (REAP), and through collaborations with other Institutes and Centers at NIH.

In continuing efforts to inform the public about the benefits and risks of dietary supplements, the ODS plans to release a new computer information database on dietary supplements, and will offer, with the NIH Clinical Center, the first collection of public-oriented information pages (fact sheets) on specific dietary supplements, in print and through Internet access. ODS will follow with a series of fact sheets for botanical and herbal supplements to be released in collaboration with NCCAM.

Another component of ODP, the Office of Rare Diseases (ORD), supports research activities on rare diseases and conditions, develops and disseminates information to health care providers and patient support groups, and forges links among investigators with ongoing research activities in this area. The ORD continues to support workshops and symposia to stimulate research and to identify research opportunities related to rare diseases. The effectiveness of these workshops as a valid mechanism to stimulate research on rare diseases and conditions is now being evaluated.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

As NIH continues its efforts to improve health outcomes, there is increasing awareness that many of our most serious health concerns are related to individual behaviors and social context. In fact, four health-damaging behaviors-tobacco use, physical inactivity, dietary patterns, and alcohol abuse—are responsible for nearly 40 percent of the annual deaths in our Nation. The Office of Behavioral and Social

Sciences Research (OBSSR) works to integrate a psychological and social perspective across all research programs at NIH and to increase the support for behavioral and social science research and training.

One strategy that OBSSR uses to increase support for behavioral and social sciences research is the development of broad trans-NIH initiatives that address issues relevant to many Institutes and Centers. In order to gain a better understanding of the obstacles and facilitators to engaging in healthy behaviors, OBSSR and 16 other NIH Offices, Institutes and Centers recently specifically solicited grant proposals for research on disease prevention through behavior change which focused on tobacco use, insufficient exercise, poor diet and alcohol abuse. The OBSSR, with several ICs, also supports centers to investigate aspects of the interactions between mind and body in health and disease. In addition, OBSSR has joined with 12 Institutes to solicit grant applications addressing the problem of inadequate adherence to prescribed medications and therapies.

OBSSR has long been concerned about the issue of violence in our society as a public health problem, and has worked to establish a trans-NIH Expert Panel on Youth Violence. This panel found that more research on youth violence interventions was needed. Subsequently, OBSSR developed a trans-NIH grant solicitation for interventions to prevent and reduce youth violence.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) is the focal point for women's health research at NIH and strives to ensure that research supported by NIH addresses the health concerns of women, that women are appropriately included as subjects in research protocols and clinical trials, and that women are encouraged to pursue careers in medical research. The science-based activities of ORWH are determined by the Agenda for Research on Women's Health for the 21st Century, an agenda developed following public hearings and scientific workshops involving some 1,500 representatives dedicated to improving the health of women. In fiscal year 2001, the ORWH will pursue a number of recommendations within this agenda including research on the effects on women of therapeutic agents, studies to develop gender-based treatments for kidney disease, studies that address prevention and elimination of lung cancer in women. In addition, the ORWH will support career development programs that encourage the pursuit of interdisciplinary research careers relevant to women's health and encourage patient-oriented or population-based clinical research careers. Finally, ORWH will continue to monitor compliance with established policies for the inclusion of women and minorities in clinical research.

OTHER OD ACTIVITIES

The OD also supports a number of additional NIH programs that promote research and enhance research career development.

The Office of Extramural Research (OER) coordinates the Academic Research Enhancement Award (AREA) program to provide grants to institutions that award degrees in health sciences but are not major recipients of NIH grant funds. These awards enable college students to participate in research projects and encourage them to pursue careers in medical research. OER also sponsors the Extramural Associates Research Development Award (EARDA) program to provide competitively awarded grants to institutions that have a significant enrollment of underrepresented minority students who, with their faculty, participate in medical research programs. The grants are designed to provide faculty at these institutions with skills needed to become more competitive in obtaining Federally sponsored research funds.

In May of fiscal year 2000, the Office of Bioengineering/Bioimaging (OBB) will be established within the OER to advance the fields of bioengineering and bioimaging. OBB will foster new collaborations among the biomedical and engineering/physical sciences with the goals of developing innovative technologies and novel products for improving human health.

The OBB will develop and coordinate programs for transdisciplinary training and career development, sponsor major symposia and smaller meetings aimed at enhancing communication among the biomedical and engineering/physical science communities, and focus attention on research in bioengineering and bioimaging. The OBB will also coordinate the Bioengineering Consortium (BECON), which consists of senior bioengineering representatives from all NIH research institutes and centers and other federal agencies.

The OER request will also provide funds for the new Extramural Clinical Research Loan Repayment Program. This program is designed to counter economic barriers to the pursuit of clinical research careers and to provide an incentive to en-

gage in this area of research. The program will award contracts to repay the educational costs of health professionals conducting clinical research in extramural institutions who agree to enter into two-year service contracts to pursue clinical research.

The NIH, through the Office of Intramural Research (OIR), maintains intramural loan repayment and scholarship programs as important instruments for recruiting high quality candidates in basic and clinical research positions. The request contains funds for the NIH Clinical Research Loan Repayment Program and the Undergraduate Scholarship Program, both for individuals from disadvantaged backgrounds, and for the General Research Loan Repayment Program. Each program provides for the payment of educational costs in return for specific commitments of service in NIH's intramural research facilities.

The Office of Science Policy (OSP) has a role in addressing science policy issues on behalf of NIH and in coordinating several science education activities. Specifically, the OSP has developed, with the Institutes and Centers, curriculum supplements to complement existing science curricula in grades K–12 that benefit both students and teachers and encourage students to consider careers in research.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

I will be pleased to answer questions.

PREPARED STATEMENT OF DR. RICHARD D. KLAUSNER

Mr. Chairman and Members of the Committee: I am pleased to appear before you for the fifth time to describe our progress in and hopes for the programs of the National Cancer Institute (NCI). I would also like to recognize with personal sadness that this will be the last hearing where I will have the pleasure of appearing before our remarkable Chairman, Mr. Porter.

THE BURDEN OF CANCER

Each year, I have begun this testimony by reporting one critical measure of the cancer burden, the annual statistics of cancer incidence, survival rates and mortality. We have recently begun to review the latest numbers and the decrease in overall cancer mortality rates first observed in the early 1990s are accelerating between 1995 and 1997, the latest year for which we have data. Drops continue to be seen for the four major cancer sites of lung, colorectal, breast and prostate. Cancer sites where mortality rates are still increasing include liver and non-Hodgkin's lymphoma. Overall, mortality rate drops are seen in both the black and white population. Remarkably, the magnitude of these drops are such that, for the first time, between 1996 and 1997, the total number of cancer deaths did not rise, despite a growing and aging population.

As this Subcommittee has discussed before, the burden of cancer is not equally experienced across our population. Monitoring rates and trends over time, by geography, by gender, age and racial and ethnic groups has been a priority for the NCI. We are particularly concerned about the disproportionate burden of cancer among the poor, the medically underserved and among certain ethnic minorities. In response to our planning processes, we are in the midst of a number of expansions in our programs aimed at the ability to assess, explain and affect the unequal burden of cancer. These expanded and new initiatives address the important message of last year's Institute of Medicine (IOM) report on the unequal burden of cancer.

We are in the process of expanding the Surveillance Epidemiology and End Results (SEER) program (our cancer surveillance program) to enhance coverage of rural whites and blacks, non-Mexican Hispanics and Native Americans. We are completing a new Memorandum of Understanding (MOU) with the Centers for Disease Control and Prevention (CDC) to formalize collaboration and integration of the NCI's surveillance and surveillance research programs with the CDC's National Program of Cancer Registries. This will allow a strategic integration of the NCI's more intensive surveillance and research system with the CDC-funded state registry systems, to help develop data standards and tools for pooling data.

In fiscal year 2000, we will begin to fund a new research program to create Special Population Networks (SPNs) for cancer control and research. These new consortia will be based within various communities serving different segments of our

diverse society in order to establish cancer control and research infrastructures to work within and to serve these communities. To support the activities of these SPNs, we are establishing a cancer control academy at the NCI for training and will link these community-based research networks to the full range of information and communication resources of the NCI. These SPNs, we hope, will provide the basis for a new national platform for cancer research to address the distinct cancer burdens of special populations. We are setting aside $50–60 million over five years to fund about 14 SPNs, the largest program of its kind we have ever funded.

This year, in collaboration with the NIH Office of Research on Minority Health, we began funding five research partnerships between NCI-designated cancer centers and minority institutions to create active and successful research programs linked to our most successful cancer research institutions. We plan to release a new Request for Applications (RFA) to sustain and enhance these new enterprises. A more complete description of our activities in this crucial area can be found at the NCI Office of Special Populations Research Web site (www.ospr.nci.nih.gov).

Monitoring cancer incidence and mortality trends can help us formulate questions about the distribution of cancer control and care, as well as about possible causes of cancer. This year, the NCI released, for the second time in its history, 25-year cancer mortality maps. These cover all 3,100 United States counties and state economic areas, for 40 cancer sites, by gender and race. These maps are available on the NCI Web site in a user-friendly and dynamic format. They do not tell us causes of cancer or indeed whether a geographic pattern reveals either a localized environmental factor, a behavioral pattern or a socio-economic pattern. But, by providing the starting point for addressing these issues, these maps are crucial resources. The NCI will release a Request for Application (RFA) to support two types of studies linked to these maps: epidemiologic research to search for explanations for geographic and temporal cancer patterns, and methodologic research to develop Geographic Information Systems (GIS) for evaluating environmental associations with cancer. These maps are one part of NCI's extensive ($472 million in fiscal year 1999) program in establishing environmental (exogenous) causes of cancer.

PROGRESS IN BASIC RESEARCH

Progress in our understanding of the biology of cancer continues at an astonishing pace. Let me highlight two examples. For decades, scientists have tried to define the minimum number of molecular changes and the number and nature of molecular pathways that must be perturbed to turn a normal cell into a cancer cell. This year, NCI-funded investigators identified that alterations of only three genes and four molecular pathways are sufficient to transform a normal human cell to one capable of producing a tumor. These identified pathways are already providing long-sought targets for new therapeutics. Identifying the specific molecular pathways that define each type of human cancer has allowed us to begin to replicate these changes in the genes of mice. As predicted, these mice develop cancer and for the first time, we can accurately mimic human cancer in the mouse. This is allowing us to finally test whether molecular changes associated with human cancer and its development are actually the causes of the progression and behavior of cancer. To accelerate the output of these breakthroughs and to use them to discover and test ways of preventing and curing cancer, we have established the Mouse Models of Human Cancers Consortium, an international collaboration of over 70 institutions. This consortium will support the development and validation of mouse models for human cancer. It is a new research structure that will enable the sharing of reagents and expertise, the development and dissemination of new technologies, the establishment of standards and prioritization of research questions. We hope to expand the activities of the MMHCC to support the development and utilization of these important new cancer research tools.

NEW APPROACHES TO DETECTION AND DIAGNOSIS

The knowledge that cancer cells develop by changing their molecular profile has set the stage for a new and systematic approach to both early detection and accurate diagnosis. Three years ago, the NCI set out to establish a full index of all the genes that are altered in each type of cancer. This project, called the Cancer Genome Anatomy Project or CGAP, has been extremely successful, identifying tags for the vast majority of human genes, annotating what types of cells and cancers express those genes, developing catalogues of chromosomal changes in cancer and discovering common genetic variations that will help to explain why individuals are different in their risk of getting cancer, their sensitivity to diet and the environment and their response to therapy. CGAP has become one of the most widely used

sources of information and reagents in the research world (www.ncbi.nlm.nih.gov/ncicgap/).

As we approach a complete list of all of the molecular tags associated with each cancer and its development, we can systematically search for "markers" for the early detection of cancer. To utilize the wealth of discovery coming from CGAP in the development of cancer markers, we have created a new national research infrastructure, called the Early Detection Research Network (EDRN). The EDRN is a novel and complex research structure established to discover, develop and validate markers for the early detection of cancer. Researchers from multiple institutions will work together to assure that potential markers are prioritized, developed into reliable and standardized assays and validated on readily available and well characterized clinical materials. Four components of the EDRN are now funded: (1) Marker discovery laboratories (18 institutions); (2) Marker development laboratories (2 institutions); (3) Clinical and Epidemiology Centers (8 institutions); and (4) a data and statistical center. In its first year, the EDRN will focus on markers for breast, prostate, ovarian, lung and GI cancers.

Systematic gene discovery through CGAP and other projects is about to profoundly change our approach to the classification and therefore the accurate diagnosis of cancer. To do this has required the development and dissemination of new technologies to read the complete molecular profiles of cancer. To enable this, the NCI funded the establishment of 24 "microarray" centers across the country. Next, the Institute announced a new funding initiative called the Director's Challenge whose goal is to identify new molecular classification schemes for cancer to replace the purely histologic schemes of the last century. The initial funding established 10 consortia involving 24 institutions addressing breast, prostate, ovarian, and colorectal cancers as well as lymphomas and leukemias. Already, results from these groups are revealing new types and subtypes of cancer that appear to predict which patients will respond to particular therapies. This year, we hope to expand this program to more types of cancer and to define the clinical implications of these new classes of cancers to help predict prognosis and guide the choice of therapy.

IMAGING CANCER

Four years ago, the NCI identified imaging as one of its extraordinary opportunities for investment. We have developed new funding mechanisms for exploratory, innovative grants (almost 150 grants received), the establishment of six small animal imaging centers, and the establishment of a national clinical trials network to rapidly evaluate the clinical utility of new imaging approaches. This network, called the American College of Radiology Imaging Network (ACRIN) has a number of clinical trials in preparation including a comparison of Magnetic Resonance (MR) and Computed Tomography (CT) in gynecologic malignancies, the use of Positron Emission Tomography (PET) to follow response to chemotherapy, the value of spiral CT for lung cancer screening, comparative studies of virtual colonoscopy and of digital mammography. We are also funding the development of centers to foster the new field of functional imaging, whereby we can detect not only the presence of a tumor but query its molecular characteristics and its behavior. This year, we will be able to fund 2–3 full multi-disciplinary In Vivo Cell and Molecular Imaging Centers (ICMICs). In addition, 27 institutions have applied to receive planning grants to develop such centers. This year, we created the Unconventional Innovations Program (UIP) aimed at developing truly novel detection and imaging systems by bringing revolutionary technologies of molecular sensing, nanoscale devices and microexplorers to enable the remote sensing of cancer. We have funded six consortia of investigators to be part of this program and hope to add more members in response to a second release of this Broad Agency Announcement. Over the past year, our investment in imaging research and technology has increased 30 percent.

Finally this year, the NCI organized a unique forum to bring together academics, industry (through the National Electrical Manufacturer's Association), the Food and Drug Administration (FDA) and Health Care Financing Administration (HCFA) to coordinate practices relevant to the development, testing and adoption of new imaging modalities and applications. This collaborative enterprise will be a standing forum to facilitate communication and progress in this critical area.

MOLECULAR TARGETS—NEW APPROACHES TO PREVENTION & TREATMENT

For the past three years, the NCI has been redirecting its drug discovery program to one based on the success of basic research in identifying the precise molecular targets implicated in the development (prevention targets) and behavior/survival (therapeutic targets) of cancer. The recent encouraging results of Herceptin for the treatment of advanced breast cancer, Rituximab for the treatment of non-Hodgkin's

lymphoma, STI 571 for the treatment of leukemia, tamoxifen for reducing the risk of breast cancer and a growing list of others, all point to the future face of molecularly targeted therapeutics and preventives. We have funded four new centers to develop new libraries of chemical diversity and to screen for promising molecular targets, and this year, we will fund new Centers of Excellence for drug development, each of which will focus on specific cancer pathways to speed the discovery of useful targets.

Last year, we initiated a novel program called RAID (Rapid Access to Intervention Development) that evaluates promising drug candidates in the laboratories of academic investigators and, via peer review, manages the movement of these candidate drugs from the lab to the point of clinical trial. To date, 32 novel agents have entered the RAID pipeline and in one year 4 have reached or are ready for clinical trials. We will expand this successful program in the coming year.

CLINICAL TRIALS—A CORNERSTONE OF PROGRESS FOR PATIENTS

Last year, the NCI supported over 1500 clinical trials in prevention and treatment, covering virtually all human cancers and asking a wide variety of clinical questions. We initiated the formal restructuring of our national clinical trials system, as described to the Subcommittee last year. This restructuring is aimed at improving the quality of scientific questions asked, increasing the speed and efficiency and decreasing the administrative burdens of participating in clinical trials. Furthermore, it aims to assure that all patients and all participating physicians have access to the full menu of available clinical trials. This year, we continued the development and deployment of a standard informatics system, funded a central Clinical Trials Support Unit to serve the entire national clinical trials system and began disease-specific state-of-the-science meetings to develop prioritized clinical trials questions and opportunities. This past year, 20,000 new patients were enrolled in NCI-sponsored treatment trials. Over the past three fiscal years, our investment in our national clinical trials program has increased almost 43 percent.

Clinical trials are complicated enterprises, and streamlining and improving their function while maintaining the highest standards of rigor, care and protection of human subjects requires attention to many different facets of the initiation, review, approval, funding, oversight and management of trials. This year, we have continued to expand the use of simplified and uniform informed consent documents and in the spring, in collaboration with the Office for Protection from Research Risks (OPRR), we will begin an important pilot project to test the feasibility and performance of a central Institutional Review Board (IRB) for multi-institutional trials.

This year, we unveiled a new, user-friendly clinical trials information system to enable patients and physicians to readily access information about all NCI-sponsored trials (www.cancernet.nci.nih.gov). We continue to work with the FDA and industry to expand this database to include industry and other sponsored trials.

Each year, clinical trials results help shape the course of clinical practice and set the stage for new questions that need to be addressed. This year, we saw the first, long-awaited results on the value of high dose chemotherapy with peripheral stem cell or bone marrow rescue for women with advanced breast cancer. These results did not support the significant and hoped-for benefits that this approach demonstrated in earlier, non-randomized clinical trials. These results underscored the crucial role that such clinical trials play in the type of evidence-based medicine to which we all aspire. In the past two years, the results of clinical trials have set new standards for increasing the effectiveness and reducing the toxicity of regimens for childhood cancers, leukemia, myeloma, breast cancer, ductal carcinoma in situ (DCIS), cervical cancer, head and neck cancer, lymphoma, colorectal cancer, prostate cancer and others.

QUALITY CANCER CARE—A RESEARCH AGENDA

One of the themes of NCI activities is to address gaps—gaps between what we need to know and our current state of knowledge, gaps between the burden of cancer across different segments of our population, and gaps between scientific discovery and medical breakthroughs. One of the most important gaps is between evidence-based best practice and actual practice. It is this last gap that we intend to address via a new major initiative called the Quality Cancer Care Committee (QCCC). This initiative was formulated in response to a recent report of the National Cancer Policy Board (NCPB) called "Ensuring Quality Cancer Care." The NCPB was established at my request as part of the Institute of Medicine (IOM) of the National Academy of Sciences. Its purpose is to provide a forum of independent and broad-based expertise to advise the Nation on cancer-related policy issues. The QCCC will be a trans-agency initiative led by the NCI to develop a comprehensive

research infrastructure to address the issues of quality cancer care across the cancer continuum from prevention to treatment to survivorship and end-of-life care; and to provide a mechanism whereby the health delivery and reimbursement activities of DHHS, especially HCFA, are informed by a discussion of evidence and through direct interaction with the cancer research agenda of the various research agencies of the Department. The research agenda of the QCCC will focus in four areas: 1) developing measures of cancer outcomes; 2) strengthening the methodologic and empiric base for quality assessment; 3) strengthening the national clinical trials infrastructure; and 4) improving the quality of cancer communications.

I am pleased to present the President's non-AIDS budget request for NCI for fiscal year 2001, a sum of $3.25 billion which reflects an increase of $183 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NCI is $3.505 billion an increase of $193 million over the fiscal year 2000 appropriation. Funds for the NCI efforts in AIDS research are included within the Office of AIDS Research budget request. With this, we can sustain the many new and productive programs, some of which I have tried to illustrate in this testimony.

NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

PREPARED STATEMENT OF DR. CLAUDE LENFANT

Mr. Chairman and Members of the Committee: I am pleased to address this Committee, once again, on behalf of the National Heart, Lung, and Blood Institute (NHLBI). During the latter half of the Twentieth Century, tremendous progress was made in improving the health of the American public. Research supported by the NHLBI was instrumental in enabling us to diminish, halt, and eventually reverse the epidemic of deaths from two major chronic diseases—coronary heart disease and stroke. Vital statistics indicate that, since its peak in 1963, the death rate for coronary disease has fallen 60 percent and the rate for stroke fell 66 percent during that time period. This has been a tremendous achievement.

Nonetheless, these two diseases have retained their ranking as the first and third most common causes of death in the United States and, during the past decade, mortality has not fallen as rapidly as it once did. We have, in a sense, weeded out many of the "easy" cases; those that remain are more complex and demand far more sophisticated solutions. Our challenge is twofold: first, to make maximal use of the new technologies that are rapidly becoming available and, second, to ensure that "real world" health practices reflect a rapid and thorough utilization of the knowledge that we have acquired. Both are essentially matters of closing the gap between what can be done and what is being done.

PROGRAMS FOR GENOMIC ANALYSIS

The generous increases in funding that the NIH has received in the past several years have provided extraordinary opportunities to invest in cutting-edge research programs to capitalize on the new technologies. As you know, the Human Genome Project is on the verge of producing its draft "blueprint" for the entire genetic makeup of humankind, which will be invaluable to the research community. In anticipation of this tremendous resource of data and technologies, the NHLBI is establishing Programs for Genomic Analysis in cardiovascular, lung, and blood diseases and sleep disorders. This ambitious new undertaking will call upon the expertise and collaboration of scientists from a wide variety of disciplines—and often from diverse geographical areas—to identity relevant genes, understand their function, and test hypotheses about the causes and treatments of disease. An essential requirement of the Programs is that the information and reagents generated will be made immediately and freely available to the research community, a practice that will enable a broad range of investigators to exploit the promising opportunities provided by this fast-moving field. This initiative has generated tremendous enthusiasm within the research community, and it promises to advance our knowledge of health and diseases in ways that could not have been dreamed of a decade ago.

PROGRAMS OF EXCELLENCE IN GENE THERAPY

Despite the recent troubling publicity about gene therapy, the NHLBI remains committed to pursuing this approach because of its potential usefulness for many intractable diseases. We just have to do it right. Accordingly, we are establishing comprehensive Programs of Excellence in Gene Therapy that will focus on rapid translation of findings from basic research into pilot studies in human volunteers, with appropriate attention to safeguarding the welfare of the patients. A major goal of this initiative will be to provide shared access to specialized services such as preclinical toxicology testing and the development of "vectors" to ferry therapeutic genes to their target tissues. The promise of gene therapy to cure hemophilia, cystic fibrosis, sickle cell disease, and other devastating diseases has long been recognized, but the path to its fulfillment has been fraught with many difficulties. We believe that this coordinated approach will make it a reality.

USING MRI TO DIAGNOSE HEART ATTACK

A pilot program at Suburban Hospital in Bethesda is testing a new approach to diagnosing heart attack patients who may be candidates for thrombolytic therapy. The value of this clot-dissolving treatment in limiting damage from a heart attack has been well established for some time. However, its effectiveness is highly dependent on the promptness with which it is administered, and many patients have not had the opportunity to benefit from this approach. We have been working through our National Heart Attack Alert Program to reduce delays in treatment, and data from the National Registry of Myocardial Infarction indicate that the time between arrival at the emergency room and administration of thrombolytic therapy has been reduced from 60 minutes to about 35 minutes in patients for whom an EKG is diagnostic of a heart attack. However, for many patients, diagnosis currently requires measurement of enzymes that appear in the bloodstream only hours after the heart attack has occurred—too late for effective thrombolysis. The experimental program at Suburban Hospital is using MRI (magnetic resonance imaging) technology, which can provide a diagnosis in about 35 minutes. In light of recent evidence that thrombolytic therapy may also benefit patients who experience a thrombotic stroke, we have also teamed up with the National Institute of Neurological Disorders and Stroke to use MRI in evaluating patients who come to the emergency room with stroke symptoms. We have every confidence that this program will form the basis for an entirely new approach to delivering prompt treatment to patients who are likely to benefit from it.

CLINICAL RESEARCH NETWORKS

During the past few years, the NHLBI has been an innovator in establishing clinical research networks to close the gap between what is known about the causes and mechanisms of disease and the tools that are available to treat them. These networks maintain a core structure of clinical centers and a data coordinating center that collaborate in conducting high-quality, systematic, rigorous clinical research. The advantage is that promising findings from basic research can rapidly be translated into information to assist the practicing physician in making the best possible decisions about how to treat patients. We began in 1994 with clinical research networks for adult asthma and acute respiratory distress syndrome (ARDS), and then moved on to develop such a network for pediatric asthma. This year, we are establishing a Thalassemia Clinical Research Network, which is expected to provide an invaluable resource for evaluating new therapies for patients with Cooley's anemia, who are few in number and widely scattered across the country. We have also announced plans for a similar effort in pediatric cardiovascular medicine, which will enable rigorous testing of both medical and surgical approaches to treating a variety of cardiovascular malformations in children.

Our experience with the ARDS Clinical Network illustrates the value of this approach. ARDS is a form of respiratory failure that affects about 150,000 Americans annually—many of whom were previously healthy—and kills about half of them. We have struggled with it for 30 years, but made very little headway, in part because of the daunting logistics of attempting to conduct timely and meaningful clinical trials in large numbers of critically ill patients. The ARDS Network, established in 1996, has already moved the field forward immeasurably by establishing the effectiveness of an innovative approach to mechanical ventilation. The new approach was shown to reduce mortality by 25 percent—a remarkable achievement for a disease in which mortality had remained stubbornly high despite many years of research. The results of this study are currently being implemented in intensive care units

throughout the world. It is evident that clinical research networks save time, save money, and produce results of tangible value to the patient.

FOCUS ON THE INDIVIDUAL PATIENT

One of the most promising new developments that we foresee is the increasing ability to understand individual susceptibility to a disease, or individual response to an intervention, so that we can target our treatments accordingly. We currently employ many broad—brush approaches in the expectation that at least a portion of the population will benefit. For example, we recommend that everybody limit sodium intake to prevent high blood pressure—prudent advice, in that the subset of people who are sensitive to salt will profit and no harm will come to others. All the same, it makes for a fairly "weak" public health message that has not been universally adopted. On the horizon, however, are several promising tests to identify salt sensitivity; they may enable us to more narrowly focus our dietary recommendations and, thereby, gain the attention of individuals who most need to heed them.

A second example is in the area of sudden cardiac death, a fatal arrhythmia that claims the lives of about 150,000 Americans annually. There is much recent interest in placing automatic defibrillators in public places to "rescue" victims of this malady, and we have just initiated a community-based research program on the topic. However, this is an after-the-fact approach, and it is clear that much more could be achieved in the long run if we were able to identify susceptibility to fatal arrhythmias and initiate preventive measures. In this regard, we are greatly encouraged by research that points to two possible approaches. One, called T-wave alternans, is a measure of irregular electrical activity of the heart that appears to correlate with the potential for life-threatening arrhythmia. An even simpler approach—which might someday, for instance, be used by coaches to screen young athletes—is suggested by the recent finding that a delay in the return of the heart rate to a normal pace after exercise is strongly predictive of mortality.

Of course, the hope of understanding individual response to treatment or individual variations in the course of a disease is what drives our efforts to unravel the genetic basis of disease, and we are looking at many diseases in this light. With regard to congestive heart failure, for instance, scientists have recently reported that a fairly common gene variation is associated with disease severity, and we see much potential for ultimately developing approaches targeted to patients whose disease is likely to follow a rapid downhill course. Particularly aggressive efforts are being made with respect to sickle cell disease, which has long been a puzzle because all patients have the same genetic "mis-code" yet the severity of the disease ranges from mild to life-threatening. We recently initiated a new research program to identify other aspects of a person's genetic make-up that modulate disease severity. This work has taken on particular urgency because we now have a cure for sickle cell disease in the form of stem cell transplantation, but we have been reluctant to use it in this country because it is literally a cure that can kill. If we were able to distinguish, early in life, the patients who will suffer severely from the disease, it would open the door to applying this treatment selectively in cases where the potential benefits substantially outweigh the risks.

ADDRESSING HEALTH DISPARITIES

Despite impressive strides toward our goal of disease prevention, we are acutely aware that not all segments of society have benefitted equally from this trend. Death rates from cardiovascular diseases, for example, are disproportionately high among U.S. blacks—and among blacks in Mississippi, they are the highest in the nation. The NHLBI's Jackson Heart Study is exploring the reasons for this phenomenon in a long-term study of 6,500 men and women. In addition to collecting data on conventional risk factors, the study will focus on newer areas, including early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders that are related to cardiovascular disease, such as high blood pressure, obesity, and diabetes. We have emphasized the involvement of local people in the development and support of this study, and are optimistic that it will provide new directions for disease prevention in the black community.

NEUROFIBROMATOSIS

As a final note, we have been asked by the Committee to comment on our activities with regard to neurofibromatosis, a condition that appears to be linked to certain forms of congenital heart disease. The NHLBI recently provided funding for some research in neurofibromatosis, in the expectation that it may help unravel molecular pathways that affect abnormal heart development not only in

neurofibromatosis, but also in other conditions. The NHLBI will be working with the National Institute of Neurological Disorders and Stroke and other NIH components to develop a workshop, planned for 2000, that will summarize the current status of NIH-supported neurofibromatosis research, identify needs and opportunities, and stimulate and focus future NIH research in this area.

PRESIDENT'S REQUEST

I am pleased to present the President's non-AIDS budget request for the NHLBI for fiscal year 2001, a sum of $2,069,582,000 which reflects an increase of $108,679,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NHLBI is $2,136,757,000, an increase of $110,327,000 over the fiscal year 2000 appropriation. Funds for the NHLBI efforts in AIDS research are included within the Office of AIDS Research budget request.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

I would be pleased to respond to any questions that the Committee may have.

PREPARED STATEMENT OF DR. HAROLD C. SLAVKIN

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Institute of Dental and Craniofacial Research (NIDCR) for fiscal year 2001, a sum of $263.1 million, which reflects an increase of $14.1 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIDCR is $284.2 million, an increase of $15.0 million over the fiscal year 2000 appropriation. Funds for the NIDCR efforts in AIDS research are included within the Office of AIDS Research budget request.

DISCOVERING SOLUTIONS TO COMPLEX PROBLEMS

In his classic analysis, The Structure of Scientific Revolutions, Thomas S. Kuhn puts forward the concept of science as a pursuit to solve complex problems. Solving problems can range from a chess match between grandfather and granddaughter, to the challenges of discovering fundamental principles of biological systems, finding solutions to health promotion in a diverse society, preventing disease, and designing "smarter" diagnostics and therapeutics for diseases and disorders that compromise health. By discovering solutions to the complex problems posed by craniofacial, oral and dental diseases and disorders, NIDCR-funded scientists are fulfilling the mission of the Institute to improve and promote health through research.

BURDEN OF DENTAL AND CRANIOFACIAL DISEASES AND DISORDERS

The mission of our Institute is to reduce the burden of diseases and disorders that are among the most common health problems both nationally and globally. The NIDCR supports research ranging from the prenatal developmental processes that form the human face and dentition, to the many local and systemic diseases and disorders that involve craniofacial tissues and structures throughout the lifespan. These include spontaneous preterm births possibly linked to maternal oral infections, birth defects like cleft lip and palate, trauma to the head, face and teeth, severe malocclusions, oral infectious diseases, head and neck cancers and chronic and disabling facial pain. Oral microbial infections producing dental caries, periodontal diseases, candidiasis and herpes lesions are common. Chronic and disabling facial pain is a major component of temporomandibular joint diseases (TMD), Bell's palsy, trigeminal neuralgia and fibromyalgia. Oral manifestations of systemic diseases such as AIDS, diabetes and osteoporosis are also common. Finally, oral complications from both cancer therapies and numerous therapeutic drugs often include yeast infections termed candidiasis, xerostomia (dry mouth), aggressive dental caries, and severe bone loss.

Health disparities are associated with the burden of these diseases and disorders, falling disproportionately upon children and adults from particular ethnic and racial

groups, historically underrepresented minorities, and lower socioeconomic classes. To accelerate discovery of solutions to these complex problems, we plan to link research, training and access to oral health care using innovative and collaborative Centers to Reduce Oral Health Disparities located in critical areas around the country. The emphasis is placed on the oral health needs of children and their caregivers. We envision these Centers as partnerships between academic health science institutions, state and local health and health financing agencies, community and migrant centers, Indian Health Service clinics, Centers for Disease Control and Prevention (CDC)-sponsored Prevention Research Centers, minority and minority-serving institutions, and other interested groups. Our strategy is to partner with the Health Resources and Services Administration (HRSA), CDC, the National Institute of Child Health and Human Development (NICHD), the National Institute of Nursing Research (NINR), and the NIH Offices of Behavioral and Social Sciences Research, Research on Women's Health, and Research on Minority Health, with funding to begin in fiscal year 2001.

GENE DISCOVERIES: THE RAPID RATE OF PROGRESS

NIDCR actively supports the rapid discovery of genes related to inherited dental and craniofacial diseases and disorders, head and neck cancer genes, and genes related to the pathogenicity of viral, bacterial and yeast infections in the human mouth. The rapid rate of progress in these three areas is highlighted in.

The discovery of craniofacial, oral and dental genes that are altered or mutated in more than a thousand inherited diseases, leads to smarter diagnosis and possibilities for improved treatments and new biomaterials. Of the 5,878 gene loci relevant to inherited human diseases, 1,250 of these are associated with craniofacial-oral-dental diseases and disorders. Over the last 5 years, more than several hundred mutated craniofacial regulatory and structural genes have been found to cause abnormal formation of the skull, cranial sutures, maxilla and mandible, teeth, tongue, salivary glands, bone, cartilage, cementum, dentin, enamel and periodontal ligament. Curiously, many of these genes involved in craniofacial development also have far-reaching effects, directing formation of such diverse body parts as the brain, limbs, thyroid glands, heart and kidney, and even has a role later in life with neoplastic diseases such as the role of patched mutations in Gorlin's syndrome. Furthermore, evidence is beginning to assist in solving the complexities of multiple gene networks and their collective interactions with environmental factors. For example, variant gene forms for enzymes required for folic acid metabolism are implicated in spina bifida and craniofacial malformations. We now assume that multiple gene-environment interactions produce birth defects in more than one hundred thousand babies each year. NIDCR is actively collaborating with other NIH Institutes and federal agencies to reduce the burden of craniofacial birth defects.

Discovery of the multiple and sequential gene mutations involved in the progression of oral and pharyngeal cancer will result in early diagnosis and improved treatments and therapeutics. The Head and Neck Cancer Genome Anatomy Project, a collaboration between NIDCR and the NCI Cancer Genome Anatomy Project (CGAP), was recently established. Genes expressed in squamous cell carcinoma and normal head and neck epithelial tissues are being compared. This strategy is expected to identify a specific combination of multiple gene mutations involved in the premalignant to malignant neoplastic process, and will also provide clinically useful biomarkers that can be used for diagnosis and for monitoring the progression of head and neck cancers.

A remaining complex problem is to determine how microbes living in homeostatic ecosystems or biofilms in the mouth become infectious pathogens. Discovery of microbial genes will lead to remarkable advances in early diagnosis and targeted drug development for improved treatments of oral infectious diseases. Since Antoni van Leeuwenhoek invented the microscope and discovered microbes growing in biofilm scrapings from his own teeth in the 17th Century, we have come to understand that more than 6 billion microbes live in the oral cavity, and these billions of microbes belong to a list of more than 500 different strains that continues to expand. Just 2 months ago, scientists identified 37 previously unknown strains of bacteria that reside in the biofilms on the surfaces of teeth. To address this problem, NIDCR and other NIH Institutes have accelerated efforts to decipher the genetic lexicon of 60 microbial genomes. Presently, NIDCR-funded genome projects include the following microorganisms: Candida albicans, Porphyromonas gingivalis, Streptococcus mutans, Actinobacillus actinomycetemcomitans, Treponema denticola, and Streptococcus sanguis. Genomic studies of seven additional microbial organisms with significant roles in oral infections are planned for the near future.

ORAL INFECTION LINKED TO SYSTEMIC DISEASE

There has been extraordinary progress in the understanding of periodontal disease in the last 25 to 30 years. A most significant discovery is our new appreciation for linkages between oral infection and systemic diseases, and this paradigm shift has already provided important new diagnostic, preventive, early intervention and treatment strategies for patients with periodontal diseases and beyond. The presence of oral infections has been associated with systemic diseases including spontaneous preterm births, cardiovascular and pulmonary diseases and diabetes. One example is particularly useful in conveying how investments in scientific research may result in significant human and cost savings benefits. Accumulating evidence suggests that maternal infections are a major risk factor for spontaneous preterm babies. Preliminary findings supported by NIDCR and NICHD suggest a dose-response relationship between the level of maternal oral infection and the risk of preterm low birth weight babies. The risk posed by the oral infection may prove to be amenable to treatment interventions. If successful, future intervention studies would demonstrate a cost effective approach to reduce some of the burden of spontaneous premature births.

GENES OF INFLAMMATION AND TOOTH LOSS

Molecular genetic studies have discovered genes that regulate chronic inflammation processes and tooth loss. Papillon-Lefèvre syndrome (PLS) is a genetic disorder that typically affects both skin and teeth. Two new studies have discovered gene mutations in the cathepsin C gene (CTSC) as the primary cause of PLS. Severe early onset periodontitis in PLS patients is unresponsive to traditional oral therapies and results in premature loss of both primary and permanent teeth; in some cases, all primary teeth are lost by age 4 years and all permanent teeth are lost by age 14 years. The periodontitis infection results in severe destruction of bone tissue in the jaws needed to support the teeth. This new discovery demonstrates the emerging significance of gene discovery and the availability of smarter diagnosis and future therapies for the oral manifestations of systemic inflammatory diseases and disorders.

GENETICS OF TOOTH AGENESIS

We are discovering that multiple gene networks are required to produce teeth. Mutations in several of these genes have been found to cause congenitally missing teeth. These molecular foundations will eventually provide the basis for the biomimetic design and fabrication of replacement teeth later in the 21st century. Nearly 20 percent of the U.S. population has congenitally missing teeth. The missing teeth are often third molars, but may be any of the other teeth found in the human dentition. The forms of missing teeth ranging from least to most severe, are called hypodontia, oligodontia, and anodontia, respectively. Recent studies identified multiple gene networks that control the formation of teeth. Mutations in two of these genes, in particular, MSX1 and PAX9, have been discovered to cause missing teeth.

The MSX1 gene is essential to tooth development and is found in chromosomes of multiple species including the fruit fly, the mouse, and humans. In a mouse model, deletion of the MSX1 gene resulted in animals with cleft palates and no teeth. Recently, selected families with congenitally missing teeth, known as familial tooth agenesis, were found to have a mutation in the human MSX1 gene. A second study, published last month, found that a mutation in the PAX9 gene resulted in congenitally missing molar teeth in three generations of a particular family. PAX9 is a member of a transcription factor family of genes involved in eye, primary and secondary palate, tooth, and thyroid gland formations. These discoveries are rapidly becoming gene-based diagnostics for dental anomalies, and also provide a biological basis for the future design and fabrication of tooth replacements.

The NIH budget request includes performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance material is the first NIH performance report, comparing fiscal year 1999 results to the goals in the fiscal year 1999 performance plan. As our performance measures mature and trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

Finally, I want you to know how privileged I feel to have been selected by Harold Varmus to be part of the leadership team at the NIH. It has been a unique honor to lead the world's largest sponsor of dental, oral and craniofacial research. My tenure at the NIH has been memorable, including: Government shutdowns, the blizzard of 1996, a 50th anniversary and a name change for our Institute, growth of

the NIDCR portfolio into significant new scientific areas, remarkable growth in NIH funding, development of novel funding mechanisms, and most recently, another blizzard. I especially want to thank you Mr. Porter and the Committee Members for your confidence and support over the last 5 years as I have served as the sixth director of this Institute. This coming July, my wife and I will return to our home in California and I will return to the private sector. Thank you. My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. ALLEN M. SPIEGEL

Mr. Chairman and Members of the Committee: I am pleased to testify on behalf of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). This year is the NIDDK's 50th anniversary. I have been with the Institute for nearly 27 of those 50 years—for the past 3 months as Institute Director. Throughout this time I havehad the privilege of conducting and directing basic and clinical research, often in collaboration with superb investigators at many academic centers and at NIH. The unique juxtaposition of laboratories and patient facilities in the NIH Clinical Center has afforded me a valuable perspective on the connections between basic and clinical research. As NIDDK Director, one of my main goals will be to strengthen those connections in order to accelerate progress toward relieving the burden of the many chronic and costly diseases within our mission. The challenges posed by these diseases are enormous. Significant gaps in our knowledge concerning their causes leave us as yet unable to prevent or treat them as effectively as we would wish. Yet, we are poised as never before to make dramatic progress in closing these gaps. New, powerful tools are becoming available to propel our progress. The support provided to NIH and NIDDK has been greater than ever before. Thus, it is with great scientific excitement and optimism that I have accepted the challenge, as Director of NIDDK, of leading the effort to alleviate the burden of diabetes, endocrine and metabolic diseases; digestive and nutritional disorders; and kidney, urologic and blood diseases.

POWERFUL RESEARCH TOOLS

Shortly, we will have in hand the sequence of the entire human genome. Merely knowing the sequence, however, does not allow one to utilize this powerful tool. This sequence or "book of life" is not written in English and lacks obvious punctuation marks. An NIDDK intramural scientist has recently discovered gene "insulators," a type of punctuation mark that allows a gene to be expressed without interference from surrounding regions. This discovery is already finding wide application in the biotechnology industry. Within the "book of life" are genes that either cause or contribute to many of the diseases within our mission. Our task in making full use of the human genome sequence is to identify all the genes within it, discover their function and how changes in these genes cause disease. New tools such as microarray technology allow simultaneous measurement of changes in expression of thousands of genes. Bioinformatics methods allow us to analyze vast amounts of sequence information. These tools will help us to apply new genetic knowledge to revolutionize diagnosis, prevention and treatment of many diseases.

Bioinformatics methods have revealed that many human genes have counterparts in the genomes of yeast, roundworm and fruitfly. The function of these genes can thus be studied at the cellular level in these experimentally simpler model organisms. Vertebrate models such as zebrafish and mouse, while more difficult to study than worms or flies, are closer in organ structure and genetic sequence to humans. Zebrafish mutants with disorders of red blood cell formation or of appetite regulation have been discovered. Mouse mutants expressing too much or too little of almost any gene in any organ can now be created. Such models not only help clarify the function of genes and their role in causing disease, but also provide systems for testing possible treatments and preventions in ways not feasible in humans. Powerful imaging methods are being developed that will allow detection of subtle changes at the cell and organ level, thereby helping to elucidate the causes of disease, monitor disease progression, and assess preventive or therapeutic measures not only in animal models but in humans. Bioengineering approaches to cell and organ replacement hold great promise as well.

RESEARCH ADVANCES: PKD, HEPATITIS C, AND DIABETES

Polycystic kidney disease (PKD) is one of the most common inherited disorders and the fourth leading cause of end-stage kidney failure, according to the U.S. Renal Data System. A long hunt led to identification of the gene responsible for the most

common form of PKD, and shortly thereafter, researchers found a second gene responsible for a rarer form. The molecular function of these two gene products is still incompletely understood, but the recent surprising discovery in the roundworm—that mutations in one of the corresponding genes leads to defects in the functions of sensory neurons—opens up new avenues to understand the basic defect in PKD. Studies of PKD genes in humans have established that cyst formation is an abnormal growth process, analogous to benign tumor formation. Indeed, just last month, NIDDK-supported investigators reported that treatment with an inhibitor of a cellular receptor for a growth factor in a mouse model of PKD prevents cyst formation and dramatically enhances survival. Of course, further studies are needed before human trials, but NIDDK is already supporting research to develop noninvasive imaging methods to monitor cyst growth. Such methods will be critical in evaluating the effectiveness of new treatments.

The CDC estimates that 4 million Americans are infected with the hepatitis C virus. Hepatitis C is the most common cause of chronic hepatitis and the most common reason for liver transplantation in the United States. Epidemiologic studies show that 70 to 80 percent of infected individuals fail to clear the virus and as many as 20 percent of these develop chronic liver disease. Intramural NIDDK studies first showed that interferon, an antiviral agent, is effective in treating hepatitis C, but it completely clears the virus in only a small minority of patients. Recently, NIDDK investigators reported a major advance in treatment; by combining interferon with another antiviral, ribavirin, they were able to clear the virus in up to 40 percent of patients. Developing even more effective treatments and a vaccine to prevent infection remain as major challenges.

According to data compiled by the congressionally established Diabetes Research Working Group, diabetes affects an estimated sixteen million Americans. It is a chronic and costly disease both in human and financial terms. The complications of uncontrolled elevation in blood sugar make diabetes the leading cause of end-stage kidney failure, adult blindness, and non-traumatic amputations, and a major risk factor for heart disease. Type 1 diabetes affects primarily children and young adults, with more than 13,000 new cases per year in the United States. This form of the disease is characterized by autoimmune destruction of the insulin-secreting beta cells of the pancreatic islets. Type 2 diabetes affects primarily adults, and is increasing in the United States at an alarming rate, nearly 800,000 newly diagnosed cases per year. It is caused by both reduced insulin secretion and resistance to insulin action. Genetic abnormalities contribute to both forms of diabetes, but unlike single gene disorders such as PKD, most cases of diabetes are thought to be due to subtle abnormalities in multiple genes. Even before completion of the human genome sequence and full deployment of new genetic tools, significant progress has been made in identifying genes that cause diabetes. Why is such information important?

In type 1 diabetes, knowledge of which genes predispose to the disease should allow identification of those at risk and to whom preventive measures should be targeted. Advances in understanding the immune basis for type 1 diabetes have identified candidate interventions to "re-educate" the immune system to prevent beta cell destruction. One such intervention is being tested currently in an NIDDK-supported multi-center trial. For those with type 1 diabetes in whom beta cell destruction has progressed to the point where little or no function remains, preventive measures are too late. The focus must be on maintaining excellent control of blood sugar, as the landmark Diabetes Control and Complications Trial showed clearly that intensive treatment with insulin can prevent or delay the onset of kidney, eye and other complications. Trying to maintain tight control of blood sugar with insulin treatment, however, can be difficult and frustrating, particularly in children. For this reason, NIDDK is committed to supporting research both to improve existing insulin treatment and to find innovative, new treatments that will represent a true cure for this disease. Recent improvements in glucose-sensing devices that can eliminate the need for multiple finger sticks represent a small step toward the goal of an artificial pancreas. Recent animal studies using novel methods to block the immune system have demonstrated the feasibility of pancreatic islet transplantation. These promising results are being carefully extended to studies of kidney and islet transplants in humans in a newly opened NIDDK branch in the NIH Clinical Center.

In type 2 diabetes, genetic studies have shown that rare forms of the disease with onset at younger than usual age can be caused by single gene mutations. At least five such genes, each involved in some aspect of regulation of insulin secretion, have already been identified. A striking example is the gene termed insulin promoter factor–1, in which different degrees of mutation result in different conditions. Mutation of both copies of this gene leads to failure of the entire pancreas to develop. A severe mutation in one copy of the gene is one cause of the rare forms of early onset type 2 diabetes. Recent studies have shown that more subtle mutations of the same gene

contribute to the more common form of type 2 diabetes by impairing insulin secretion. Identification of disease genes is important in providing novel targets for drug development and in enabling individualized therapy that is optimally effective for each patient.

Another recent advance illustrates how information about a drug target can be used to identify a new diabetes gene. A new class of diabetes drugs that increase insulin sensitivity was shown to act on a cell receptor protein termed PPAR-gamma. This led investigators to search for mutations in the gene for PPAR-gamma in type 2 diabetes patients. Such mutations were found in rare patients with an early onset form of diabetes characterized by insulin resistance, high blood pressure, and abnormal blood lipids. Because all of these features are frequently seen in patients with type 2 diabetes, more subtle defects in the PPAR-gamma gene may be responsible for more common forms of type 2 diabetes. Thus, understanding the genetic basis of even rare forms of type 2 diabetes is important, not only for care of patients with those forms of the disease, but also for what it can tell us about the causes of more common forms.

FUTURE RESEARCH PLANS

While these advances are indicative of the important progress we have made, clearly extraordinary challenges remain for virtually all the diseases within the NIDDK mission. Indeed, the congressionally-established Diabetes Research Working Group identified five extraordinary diabetes research opportunities: genetics, autoimmunity and the beta cell, cell signaling and regulation, obesity, and clinical research and trials. The NIDDK intends to seize each of these opportunities. To take full advantage of the soon available human genome sequence, we will bolster a consortium formed to identify type 2 diabetes genes and try to form a similar group to identify type 1 diabetes genes. We will form a diabetes trial network to do pilot studies of innovative methods to prevent type 1 diabetes, as clues emerge from studies of the mechanism of beta cell destruction. We will stimulate research using the most advanced methods to image islet beta cells, so that effectiveness of diabetes preventions can be sensitively monitored, and more rapidly tested. We will expand our support for studies of islet transplantation in humans by establishing a consortium and an islet transplant registry so that progress may be maximized. We will form a "Virtual Center" of interdisciplinary investigators whose goal will be a complete understanding of the biology of the beta cell. This will include identification of every gene expressed at every developmental stage and their regulatory interactions, so that we would ultimately know how a stem cell differentiates to become a beta cell. It would include elucidation of all the signaling pathways regulating insulin secretion, so that we would know every step at which this process can malfunction and identify new targets for correction. We will form a consortium of investigators who will create new mouse models to understand the causes and test possible treatments for the complications of diabetes. We will launch a major new trial to study whether sustained weight loss can be achieved in obese individuals with type 2 diabetes, and if it can, to determine whether this is in fact beneficial to health. We also plan an obesity prevention initiative building on recently successful pilot programs.

Health disparities pose a particular challenge for NIDDK, because minorities are disproportionately affected by many of the diseases for which we have research responsibility including type 2 diabetes, hepatitis C, and end-stage kidney failure. Our major type 2 diabetes prevention trial has enrolled nearly fifty percent of its patients from minority groups, and we will be supporting a new initiative directed at the alarming incidence of type 2 diabetes in children, especially from minority groups. We are supporting efforts to understand why certain groups such as African-Americans and Native Americans show increased susceptibility to the kidney complications of diabetes, so that we can learn how to prevent them. We are planning a clinical trial of interferon treatment in African-Americans to determine why they are less responsive to treatment. This should lead to improved therapies. In addition to these areas, NIDDK will be emphasizing basic and clinical studies of prostate disorders, such as BPH and prostatitis; bladder disorders such as interstitial cystitis; inflammatory bowel disease and irritable bowel syndrome; progressive kidney failure; food-related illnesses; and other health problems within our research mission.

In developing our future research agenda, we have the benefit of input from our National Advisory Council, from our many constituency organizations both lay and scientific, and from investigators attending the scientific workshops convened by our staff. As the new NIDDK Director, I have already met with many of these groups and will continue actively to reach out to them, so that we may effectively collabo-

rate in framing future research directions. Working together, we can take full advantage of this unique time of scientific momentum to mobilize the national biomedical research enterprise for the benefit of all the people of this country.

I am pleased to present the President's non-AIDS budget request for the NIDDK for fiscal year 2001, a sum of $1.186 billion which reflects an increase of $66.8 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NIDDK is $1.209 billion, an increase of $67.8 million over the fiscal year 2000 appropriation. Funds for the NIDDK's efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

PREPARED STATEMENT OF DR. GERALD D. FISCHBACH

Mr. Chairman and Committee Members: I am pleased to present the President's non-AIDS budget request for the NINDS for fiscal year 2001, a sum of $1,050,412,000, which reflects an increase of $54,327,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NINDS is $1,084,828,000, an increase of $55,085,000 over the fiscal year 2000 appropriation. Funds for the NINDS efforts in AIDS research are included within the Office of AIDS Research budget request.

I became Director of NINDS eighteen months ago with great enthusiasm about neuroscience research and the likelihood of significant advances in treating neurological disorders that were considered intractable only a few years ago. My enthusiasm has grown with time because new discoveries, generous public support and a widening sphere of collaborations within the NIH and with outside organizations have brought our mission of reducing the burden of neurological diseases into clearer focus.

We are now in the second year of a strategic planning process that has galvanized our research and patient communities as well as our own staff. Last year's planning document, "Neuroscience at the New Millennium," identified major targets of opportunity and laid out a strategy for approaching disease problems and for strengthening the capacity of the research community to continue the stunning advances of recent years. The momentum generated by this process, that engaged efforts of more than 100 distinguished extramural and intramural scientists, professional societies, and many patient advocates, resulted in many new initiatives. The Strategic Plan is based on the cross-cutting topics of neurodegeneration, neural repair, neurodevelopment, neurogenetics, synapses and circuits, cognition and behavior, and the neural environment. Our Plan is now in its second phase. Because the planning panels were so successful, we reorganized the extramural program staff into working clusters that track the major planning topics. This flexible, non-hierarchical structure has led to productive interactions among our program directors, senior staff, and external advisors in advancing our research agenda and in responding to the initiatives of investigators and to concerns of the lay members of the planning community.

USES OF FISCAL YEAR 2000 INCREASE

The fiscal year 2000 appropriation will allow NINDS to maintain and build on critical initiatives begun in fiscal year 1999 and to take advantage of new, extraordinary opportunities, including support of 200 more project grants and 50 more scientists in training and career development. I am pleased to report that in fiscal year 1999 we were able to fund eight new Morris K. Udall Centers of Excellence in Parkinson's Disease, instead of the five we had planned. Together with the three Centers funded in late 1998, we now have a national network of eleven Centers that includes a wide spectrum of basic and clinical research. Annual meetings of the Centers, along with ongoing informal interactions, will increase opportunities for collaboration and maximize this significant investment. Each Center has a training component, so new investigators will be introduced to Parkinson's disease and related disorders each year.

Another new initiative this year seeks to explore the promising new technology of deep brain stimulation in Parkinson's disease and other neurological disorders.

Studies of electrode design, patterns of stimulation, and clinical trials will determine if DBS can halt the progress of neurodegeneration as well as reverse disabling symptoms.

Another solicitation is concerned with the safety of the blood supply. We seek a rapid and sensitive test for the infectious agent (prion) responsible for the new variant Creutzfeldt-Jakob Disease. The public must be confident in the safety of the blood supply.

During the current year we will expand our efforts to apply sophisticated technology to map the location and timing of gene expression in the brain. This is an essential step in determining the function of normal and mutant, disease-causing genes. We will expand our successful neural prosthesis program, and we will develop innovative, high throughput screens for potential therapeutic agents. We intend to promote new approaches to spinal cord injury, and we plan a broad approach to analyze the efficacy of neural stem cells in repairing focal and generalized lesions. Building on one of our most successful innovations in fiscal year 1999, we plan to expand our support for a full range of infrastructure needed for modern neuroscience research. Finally, we plan to increase our investment in training physician-scientists who are most likely to engage in translational research and patient oriented research. Looking to the future, I would like to tell you about just a few of our major initiatives and priorities for fiscal year 2001.

A HEALTHY BRAIN FOR LIFE

We are concerned with neurological disorders over the entire lifespan. It is important to focus on developmental and degenerative disorders of children that can produce a lifetime of disability. Our efforts range from a new, exploratory grants program looking for new insights into common disorders such as autism and epilepsy, rare disorders such as Rett's Disease, Batten's Disease, and lipid storage diseases. We have emphasized gene discovery in epilepsy because it seems that even the most common forms such as febrile convulsions have a heritable component. At the same time we seek to promote better treatments, and even a cure, for the large number of people with "intractable" epilepsy. Many of these individuals are children, whose lives are disrupted by inadequately controlled seizures. Later this spring we will sponsor a White House-initiated conference, "Curing Epilepsy: Focus on the Future."

HALTING THE PROCESS OF NEURODEGENERATION

As requested by the Appropriations Committees, NINDS is working on the first phase of an effort to develop a comprehensive research agenda for Parkinson's disease. We were joined in this effort by NIH Institutes and Centers with significant programs in Parkinson's disease, by patient advocacy groups, and by distinguished intramural and extramural scientists. We are confident that the proposed research agenda will advance the fight against Parkinson's disease and point the way for similar progress in other neurodegenerative disorders.

Neurodegeneration is more widespread than previously thought. In addition to classical adult neurodegenerative disorders such as Alzheimer's, Parkinson's, Huntington's and Lou Gehrig's diseases, neurodegenerative processes are at work in a number of serious disorders of childhood. Neurodegeneration also complicates conditions as disparate as stroke, spinal cord injury, epilepsy, multiple sclerosis, and depression. A cell death program, named apoptosis, appears to be a "final common pathway" in the process of neurodegeneration. Encouraging evidence indicates that inhibition of this pathway may be a useful therapeutic strategy, regardless of the initial causes of the degeneration.

We must not lose sight of our goal of cognitive and emotional health throughout life. The study of disease is teaching us that decline in cognitive and emotional health is not an inevitable consequence of aging. For many, perhaps most of us, a healthy brain is as realistic a goal as is a healthy heart. But we cannot achieve our goal without a much better understanding of disease, particularly the risk factors and early changes that point to possible preventive or corrective measures. A new patient registry for Parkinson's disease, to be followed by a larger population-based study, will point the way to further study of neurodegenerative diseases at every stage of life. Through collaboration with other Institutes, we will expand these studies to include cognitive and emotional disorders and to define and promote cognitive and emotional health across the life span.

REPAIRING THE INJURED NERVOUS SYSTEM

Modern neuroscience is rewriting the textbooks that tell us that nerve cells cannot recover from deadly injury. Research on a number of fronts has produced tantalizing

evidence that manipulating the cells' environment—by adding factors that promote growth or interrupting processes that disrupt it—will eventually redefine the future for those who have lost function due to injury. A recent initiative is seeking additional research on interneuronal circuits to restore lost function. As in so many other areas of neuroscience, the ability to manipulate and implant stem cells from a variety of sources is particularly promising for both acute and chronic injury. Complementing these efforts are advances in our ability to design neural prostheses-devices that connect with the patient's own nerves and muscles to restore or augment function.

REDUCING HEALTH DISPARITIES

As we rejoice in the progress of modern medicine, we must not neglect those who, by virtue of biology or circumstance, bear a disproportionate share of the burden of disease. NINDS enthusiastically shares the commitment of NIH to reducing health disparities, and we will continue our leadership in this area. Stroke is a major health problem for the entire population but one that disproportionately affects minority citizens, particularly African-Americans. We support a broad program directed at the impact of stroke on minority populations, ranging from epidemiological and descriptive studies of disease patterns to specific therapies and educational approaches. The neurological complications of diabetes, another common disorder that particularly affects minority groups, is a major focus of interest.

Progress against health disparities also depends on building a diverse scientific workforce—a strategy that makes sense in general but is particularly important in working with minority populations. NINDS has a long history of leadership on this front. More recently, with support from the Office of Research on Minority Health, we initiated the first prototype of a Specialized Neuroscience Research Program (SNRP) at the Morehouse School of Medicine in Atlanta. A unique feature of the program is the establishment of collaborations and professional networks between investigators at minority institutions and those from more research intensive institutions and community-based organizations. Based on excellent results from the pilot program at Morehouse, and recognizing the work still to be done, the NINDS, in collaboration with NCRR, is now supporting additional SNRPs. This year we will expand the program to include a focus on HIV/AIDS, a particular problem in the nervous system, where the virus can cause dementia and neuropathy even when other manifestations of disease are well controlled.

WORKING TOGETHER TO FIGHT BRAIN DISEASE

Neuroscience is recognized as one of a few great unifying themes in modern science. Nowhere is this more evident than at NIH, where almost every Institute and Center is involved to some extent in brain research. Here we have a unique opportunity to break down what is increasingly recognized as an artificial barrier between mind and brain, between neurology and psychiatry. Our goal is to develop a model for collaborative neuroscience with an emphasis on translational research. The National Neuroscience Research Center, for which start-up funds are requested in the Buildings and Facilities budget, will provide an environment that will promote modern neuroscience in the form of collaboration, communication, and shared resources. It will build on the impressive progress already made by intramural science leaders and on the example being set by the National Vaccine Research Program.

The emphasis on collaboration will, in my view, stand out as the distinguishing feature of NIH in our time. NINDS is actively working with one or more Institutes and Centers on diseases including autism, Duchenne and facioscapulohumeral dystrophy, and neurofibromatosis. Our efforts against neurodegenerative disease include collaborations with the National Institute of Aging on clinical trials for Alzheimer's disease and with the National Institute of Environmental Health Sciences on Parkinson's disease, as well as plans for an innovative public-private partnership to foster future research. Our collaboration with the National Cancer Institute to map the genes involved in a deadly form of brain tumor has blossomed into the formation of a joint Progress Review Group for brain tumor research, building on a planning technique that has been highly successful for research on other forms of cancer. In stroke, we have joined forces with the National Heart, Lung, and Blood Institute and with Suburban Hospital in Bethesda to improve rapid diagnosis and treatment of both stroke and heart disease. We continue to work with the Brain Attack Coalition to raise public and professional awareness of stroke as a preventable and treatable disease.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the per-

formance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department. For NINDS, this effort will be augmented by our strategic planning process, which provides an ongoing forum for assessing progress and setting priorities, and by our strong commitment to efficient and effective management of our resources.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer questions you or the other Members may have.

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) for fiscal year 2001. The non-AIDS portion of the budget request is $935,166,000, which reflects an increase of $54,019,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIAID is $1,906,213,000, an increase of $109,582,000 over the fiscal year 2000 appropriation. Funds for NIAID efforts in AIDS research are included within the Office of AIDS Research budget request. I would note that the National Institutes of Health (NIH) budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan.

GLOBAL HEALTH

The NIAID research program is predicated on the view that we live in an interconnected, global community. Because of the enormous volume of international travel and trade, we cannot separate the health problems of the United States from those of the rest of the world. Clearly, it is folly to think that we are somehow isolated from diseases that are public health challenges elsewhere. In 1999 alone, we witnessed the first known appearance of West Nile fever in the western hemisphere (in New York City and surrounding areas), as well as alarming reports of dengue fever outbreaks in Texas and Florida. The yearly U.S. epidemic of influenza, which originates in Asia, is the prototypic example of the maxim "microbes do not recognize borders." Indeed, the memory of three recent influenza pandemics (1918, 1957 and 1968), as well as the ever-present threat of another flu pandemic is perhaps the best reminder of humanity's shared vulnerability to disease.

As a nation, our interest in global health stems both from humanitarian concerns and what has been called "enlightened self-interest." In addition to our obligation to ameliorate human suffering wherever possible, history tells us that healthy, stable countries make strong allies and trading partners. Conversely, poor health status can have a profound negative impact on social and economic development, and frequently contributes to political instability. Significantly, this year the United Nations Security Council for the first time devoted an entire session to a health issue—AIDS in Africa—recognizing the enormous threat that the disease poses to the security not only of that continent but the world.

INFECTIOUS DISEASES: CHALLENGES AND OPPORTUNITIES

The World Health Organization (WHO) estimates that 1,500 people die each hour from an infectious disease. Half of these deaths occur in children under five years of age, and most of the rest are working adults who frequently are breadwinners and parents. Virtually every year one or more newly recognized diseases add to the burden of known infectious conditions; in 1999, for example, the deadly Nipah virus emerged in Malaysia and Singapore. Because of the emergence of microbial drug resistance, many infectious diseases are increasingly difficult to treat. In addition, it is now clear that many chronic diseases have an infectious etiology: approximately 20 percent of all cancers are related to infections, and mounting evidence indicates that pathogenic organisms may be the underlying causes of chronic diseases such as coronary artery disease, diabetes, multiple sclerosis, and chronic lung diseases.

NIAID's Strategic Plan, available on the World Wide Web at http://www.niaid.nih.gov/strategicplan outlines the progress made in infectious disease research, including advances in HIV treatment, prevention and vaccine development, and delineates the scientific opportunities to strengthen our preparedness for infectious threats, known and unknown.

THE PROMISE OF PATHOGEN GENOMICS

Many of the challenges posed by infectious diseases lend themselves to research in a relatively new field: pathogen genomics, or sequencing of the genes of microbes, a central focus of the Institute. Pathogen genomics, coupled with data from the Human Genome Project, as well as the use of new tools such as microarray and DNA "chip" technologies to delineate the functional expression of these microbial genes, will likely underpin infectious diseases research for the coming decades and will be critical to the development of new vaccines, therapies and diagnostics.

In an important technical achievement, researchers have determined the complete genetic sequence of chromosomes 2 and 3 of P. falciparum, the most deadly malaria parasite. This new information will help to identify virulence factors and proteins involved in the parasite's lifecycle that may serve as targets for the development of drugs and vaccines. Researchers also have determined the complete genomic sequence of two strains of M. tuberculosis, the TB bacterium. These sequencing efforts are central to NIAID's detailed plans for the development of malaria and TB vaccines.

NIAID-supported researchers have also published complete or partial genomic sequences of the agents of the sexually transmitted diseases chlamydia and syphilis, as well as the leishmaniasis parasite Leishmania major. The Institute also supports the genetic sequencing of many other important pathogens that exact an enormous toll and are increasingly drug-resistant. Examples include important species of enterococci, streptococci, and staphylococci, including Stapyhlococcus aureus, which in some cases has become virtually untreatable because of drug resistance.

VACCINE DEVELOPMENT

Vaccination has been recognized as the greatest public health achievement of the 20th century, and vaccine research has long been a cornerstone of the NIAID research portfolio. NIAID-supported research has been instrumental in the development of many new and improved vaccines, such as those against hepatitis A and B, *Haemophilus influenzae* type b, pertussis, typhoid, varicella, and pneumococcal disease. A new vaccine against *Streptococcus pneumoniae*, the leading cause of morbidity and mortality in children worldwide, shows particular promise. Widespread use of this vaccine could greatly reduce the 1.2 million child deaths worldwide attributed to *S. pneumoniae* each year, according to WHO. The domestic potential of this new vaccine is also significant: pneumococcal disease causes 40,000 deaths, 500,000 cases of pneumonia, and 7 million middle ear infections in this country every year, according to CDC.

The rapidly evolving science base in pathogen genomics, immunology and microbiology will facilitate further progress in developing new and improved vaccines. In particular, vaccines that target mucosal surfaces such as those in the intestine or respiratory tract are of great importance, because many pathogens gain entry to the host via mucosal sites. Vaccines administered orally, nasally or transdermally are easy to administer and therefore have potentially great utility in developing countries and for mass immunization programs. The development of new adjuvants, which boost the immune response to vaccines, is another important area of research that has progressed rapidly in recent years. In addition to the development of vaccines against classic infectious diseases, vaccines are being pursued to fight potential agents of bioterrorism; chronic diseases with infectious origins; and autoimmune diseases and other immune-mediated conditions.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

AIDS, caused by the human immunodeficiency virus (HIV), is one of the greatest threats to global health and one of the most destructive scourges in human history. Since the beginning of the HIV pandemic, more than 50 million people worldwide have been infected with HIV, of whom more than 16.3 million have died, according to UNAIDS. In the United States, approximately 650,000–900,000 people are living with HIV/AIDS; an additional 420,200 people with AIDS had died as of June 30, 1999, according to the Centers for Disease Control and Prevention (CDC). UNAIDS estimates that the global HIV-infected population continues to expand: in 1999 alone, there were 5.6 million new infections worldwide, half of which occurred among people younger than 25 years of age. In the United States, the rate of new HIV infections has reached an unacceptable plateau of 40,000 per year, with minority communities disproportionately affected.

Although potent combinations of anti-HIV drugs have reduced the number of AIDS deaths and new AIDS cases in many western countries, the utility of these medications is limited by their substantial cost, toxicities, complicated and disrup-

tive dosing regimens, and the development of drug resistance. Many patients do not respond adequately to current regimens; even in patients who are successfully treated, the virus persists in sanctuaries where the drugs cannot penetrate and in a latent form on which the drugs have no effect. Therefore, the development of a new generation of therapies remains a major priority. In addition, approaches to purging the virus from its sanctuaries in certain cells and tissues are being vigorously pursued, as are methods to boost the body's immune defenses so they can better fight the virus.

In developing countries in which per capita health care spending may be only a few dollars a year, and where health care infrastructures are weak, anti-HIV therapies are invariably beyond the reach of all but the privileged few. This situation, coupled with the upward trajectory of the global HIV/AIDS epidemic, underscores the urgent need for effective and affordable tools of HIV prevention. Notable progress has been made. For example, an NIAID-supported study in Uganda found that two doses of the drug nevirapine, one given to the mother at the onset of labor and one given to the infant within 72 hours after birth, can markedly reduce perinatal HIV transmission. The entire regimen costs $4.00, making it feasible in resource-poor settings. Other methods of preventing HIV transmission, such as education and behavior modification and the social marketing and provision of condoms have also proven effective, both in the United States and in developing countries such as Uganda, Senegal and Thailand.

Approximately 46 percent of people living with HIV/AIDS are women. An important NIAID focus is developing interventions that will empower women to protect themselves in situations where they are unable to avoid sex with HIV-infected partners or cannot persuade their partners to use a condom. A critical effort is the development and testing of products for vaginal use—called topical microbicides—that may protect women (and their partners) from HIV and other sexually transmitted diseases. Promising microbicide candidates are now in various stages of testing in animal models and in humans.

The development of a safe and effective vaccine for HIV infection is a central goal of AIDS research, and a necessary tool to bring the HIV epidemic under control. In addition to the Institute's substantial commitment to pre-clinical HIV vaccine research, NIAID has conducted more than 50 clinical studies of HIV vaccines. Among these is the first HIV vaccine trial in Africa, a study initiated in Uganda last year in a growing effort to collaborate with scientists from developing countries to identify safe and effective vaccines suitable for worldwide use. Last year also marked the dedication of the Dale and Betty Bumpers Vaccine Research Center, a program within the NIH intramural research program to stimulate multidisciplinary vaccine research.

IMMUNE-MEDIATED DISEASES

The burden of immune-mediated diseases is staggering; these conditions, like infectious diseases, are important global health concerns. For example, 100 to 150 million people worldwide suffer from asthma; in this country alone, 15 million people are asthmatics. Asthma-related deaths worldwide number approximately 180,000 annually and are increasing both in the United States and abroad.

The past two decades of intense and highly productive research on the immune system have resulted in a wealth of new information and extraordinary growth in conceptual understanding. These accomplishments now provide realistic opportunities for major advances in the diagnosis, treatment, and prevention of a broad range of immunologic conditions.

Among the most exciting developments is our growing understanding of tolerance induction. By blocking only those components of the immune system that attack healthy tissues, it may be possible to prevent graft rejection in transplant patients without immunosuppressive drugs that dampen protective immune responses as well as deleterious ones. The ability to selectively block the immune response also holds great promise for treatment of many immune-mediated conditions, including autoimmune diseases such as juvenile (type 1) diabetes, rheumatoid arthritis and multiple sclerosis, as well as asthma and allergic diseases. In addition, understanding the mechanisms of immune tolerance will likely prove important for efforts to prevent unresponsiveness to vaccines, and for enhancing natural host responses and defenses to infection.

In October 1999, NIAID launched a major initiative to develop new ways of inducing immune tolerance, in partnership with the Juvenile Diabetes Foundation International and the National Institute of Diabetes and Digestive and Kidney Diseases. The Collaborative Network for Clinical Research on Immune Tolerance involves more than 40 research institutions. Network researchers will conduct clinical trials

to improve the success of kidney transplants using tolerogenic approaches and clinical trials are planned for patients receiving transplanted human islets to treat type 1 diabetes. Network investigators will test similar therapeutic approaches for other autoimmune diseases, such as systematic lupus erythematosus, rheumatoid arthritis and multiple sclerosis, and will pursue better ways to measure immune tolerance in humans. In addition, the network plans to conduct clinical trials in immune modulation to treat asthma and allergic diseases.

ADDRESSING HEALTH DISPARITIES

Virtually all of NIAID's research efforts address the health disparities that exist in our country, as well as the growing gap in health status between developed and developing countries. Perhaps the best example of this is the development of vaccines to prevent infectious diseases, which disproportionately affect the poor, both at home and abroad. Other efforts, such as HIV treatment and prevention research, hepatitis C research, asthma research, tissue typing and other transplantation research, and autoimmunity research, address conditions that exact a significant toll in minority communities. In addition, NIAID has a long-standing commitment to increasing the cadre of minority investigators involved in biomedical research.

CONCLUSION

The United Nations, in the International Declaration of Health Rights, asserted that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. It is not a privilege reserved for those with power, money or social standing." As the NIAID faces the new millennium, we anticipate that our research efforts will result in new and improved vaccines, diagnostics, and treatments that will make "the highest attainable standard of health" a global reality.

PREPARED STATEMENT OF DR. MARVIN CASSMAN

Mr. Chairman and Members of the Committee, good morning. I am pleased to present the President's non-AIDS budget request for the National Institute of General Medical Sciences (NIGMS) for fiscal year 2001, a sum of $1.389 billion, which reflects an increase of $73 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, the total support requested for NIGMS is $1.428 billion, an increase of $74 million over the fiscal year 2000 appropriation. Funds for the NIGMS efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

The mission of the National Institute of General Medical Sciences is to support basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines. The results of this research increase our understanding of life and lay the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS attempts to ensure the vitality and continued productivity of basic biomedical research, while producing the next generation of scientific breakthroughs and training the next generation of scientists. I am particularly pleased to announce that once again the current Nobel laureate in physiology or medicine, Dr. Gunter Blobel of Rockefeller University, was supported by NIGMS during the period when the work for which he was recognized was performed.

SNAPSHOT OF THE CELL'S PROTEIN FACTORY

I would like to begin by describing a major advance of the past year, the determination of the detailed structure of the ribosome. This stunning accomplishment is the result of a broad body of research, largely supported by NIGMS, over a period of several decades. The ribosome is the particle in the cell where proteins are synthesized. It is a factory, made up of many molecules, which is small by our daily measures but is a giant compared to most other elements in the cell. It carries out a central activity for life—the accurate synthesis of the proteins that form the body's

structures, such as muscle and collagen, and that catalyze the chemical reactions in living systems. Consequently, ribosomes are found everywhere in nature, and they don't appear to differ much between species. It's as if nature got it right the first time and didn't want to make many changes.

A major goal of modern biology has been to lay bare the mechanism by which the protein synthesis factory functions. To do so, it was ultimately necessary to identify, in great detail, the three-dimensional structure of the particle, using x-ray crystallography as a primary tool. The difficulties of this undertaking can be appreciated when it is understood that the ribosome is made up of two subunits of unequal size, comprised of a total of 54 individual proteins as well as three RNA strands. The determination of a single protein structure can still be a difficult process, so attempting to understand such a complex entity was an intimidating prospect.

The astonishing breakthroughs of the past year are the result of dogged effort, with contributions over many years from many sectors of science. The next figure shows the different avenues of research leading to the current achievements. It represents selected highlights, with the NIGMS-supported efforts shown in yellow. What is clear is that contributions were required from chemistry and physics, as well as genetics, biochemistry, and structural biology, to arrive at our current understanding. We are particularly pleased to have supported Dr. Ada Yonath, from the Weizmann Institute of Science in Israel, at a time when there was still great doubt that it would be possible to achieve the structure. This investment, and our subsequent support over 15 years, demonstrates the value of funding high-risk, high-payoff approaches.

Although the detail currently visible is not yet at a level sufficient to identify individual atoms, we are confident that the research teams we are supporting will arrive at this goal. This should provide unique insights into antibiotic action and resistance, since many antibiotics—including erythromycin and tetracycline—work by blocking bacterial ribosome function. Even this will only mark a new beginning, since, as with any factory, the various machines operate to absorb raw material, process it, and then release it in a form that can be used. To follow this process, it will be necessary to capture and visualize the machine at different points in the manufacturing cycle. But this is yet to come, and where we are today is exciting enough, for the new knowledge will greatly improve our understanding of a fundamental component of living systems.

MAJOR INITIATIVES

I would like to spend the rest of my time describing some of the opportunities that are being addressed with the increased funds that Congress appropriated to NIGMS. In particular, I would like to focus on three new initiatives—pharmacogenetics, structural genomics, and large-scale collaborative research—and then close with a description of the expansion in our support for minorities in research.

Pharmacogenetics is the effect of inheritance on drug action. In 1998, it was reported that adverse drug effects account for 100,000 deaths per year, as well as 5–10 percent of hospital admissions. The old joke of "take two pills and call me in the morning" may be appropriate for many people, but what works for the majority of the population may not be effective, and could even be dangerous, for some. The program we have initiated plans to systematically collect and interpret information about the inherited variations in humans that result in poor responses to drugs. The scientists we will support will coordinate their activities in a research network so that the results obtained can be maximally useful, and all will deposit their results in a shared repository. This effort will be conducted in collaboration with the National Heart, Lung, and Blood Institute; the National Human Genome Research Institute; the National Institute of Environmental Health Sciences; the National Institute of Mental Health; and the National Institute on Alcohol Abuse and Alcoholism.

As part of the pharmacogenetics initiative, we assembled an advisory group in May of 1999 to consider possible areas of misunderstanding and the ramifications of future research in pharmacogenetics. Since many identifiable differences in the response to drugs have emerged from studies of populations, it is necessary to consider issues of stereotyping and stigmatization of communities, and the possible resulting harm to individuals, such as discrimination in access to various social benefits, that might arise from membership in an identified group. The members of the advisory group, as well as participants in several follow-up focus groups, felt that the possible benefits of the pharmacogenetic research efforts outweighed the risks. However, they recommended that we provide a clear statement to the public of the goals of the research and the issues involved, and that we ensure that we have appropriate mechanisms in place to maintain privacy and confidentiality.

A second major effort is the Protein Structure Initiative, which attempts to use the information developed by the Human Genome Project and other genomic programs to identify the structures of all the proteins in nature. The benefits of understanding three-dimensional protein structure have been demonstrated many times. Applications include drug design and understanding of the molecular basis of disease. It is certain that a complete catalog of structures and their relation to function would provide insights into the operation and integration of biological systems that we cannot now fully comprehend. However, such an experimental effort directed at solving the structure of every protein in nature is not feasible. It would take decades and be extremely expensive. Fortunately, there is a shorter route to this goal. Proteins appear to fall into "families" of related structures. If the detailed structure of one or a few members of each family is known, it is possible to infer the structures of the other family members.

We have mounted a program, beginning in fiscal year 2000, to test approaches to identifying appropriate protein family targets, as well as to develop high-speed procedures to determine structures. Grant recipients will be asked to operate as an interactive team, sharing information about progress on a regular basis and depositing data in a shared repository to ensure there is no duplication of effort. This will be integrated with other such programs around the world. To this end, an international meeting to ensure coordination and collaboration is planned for the spring of 2000.

The last initiative I would like to describe attempts to address major problems in biomedical research by facilitating the collaboration of large groups of investigators. Although awards to individual investigators are the mainstay of our support for research, it has become clear that to put all the information together to understand how biological systems operate, something more may be required. We are attempting to provide that additional support through an approach which we term "glue grants." This is because we will supply the "glue" that will catalyze the interactions between already funded investigators to aim at problems that they could not pursue individually. In general, the glue grants will support large-scale, interdisciplinary approaches to significant biological problems by providing the resources for such items as core facilities, database development, and electronic media for effective collaboration. This approach is itself an experiment in the organization of scientific effort. It should provide one opportunity to see how the flood of information coming from individual laboratories can be integrated and amplified to address important problems of biology.

Finally, a major goal of the NIGMS is to establish programs that will result in a cadre of highly qualified researchers. This requires developing flexible training mechanisms that reflect the rapidly changing needs of science, as well as providing cross-disciplinary training. The NIGMS predoctoral training programs remain a benchmark for graduate training, and have evolved to incorporate new areas as science developed. Most recently, we have initiated a training program in bioinformatics—the field at the interface of biology and computer science—to address this emerging area. Bioinformatics is increasingly needed to manage and mine the vast quantities of data that biomedical scientists are generating.

Similarly, we have expanded our programs targeting underrepresented minorities to ensure that future demands for scientific personnel will be met. We have developed new programs to enhance the research environment at minority-serving institutions; to support computer infrastructure via supplements to existing grants; to provide technical assistance in grant writing; and to combine a traditional postdoctoral experience with an opportunity to develop teaching skills through mentored assignments at minority-serving institutions. At the same time, the average size of individual research budgets in our Minority Biomedical Research Support (MBRS) programs has doubled over the last 3 years, while the number of students supported in these programs has increased by 60 percent. We anticipate our increased investments to show real benefits in an increasing number of minority students going into biomedical research, and we are developing evaluation procedures to track the outcomes of our efforts.

We are particularly pleased with the results of the Bridges to the Future Program, which is cofunded by NIGMS and the NIH Office of Research on Minority Health. The results indicate that students in the program make the transition from 2-year to 4-year institutions and receive bachelor's degrees at a rate of about twice the national average. Although the part of the program that supports the transition from a master's degree to a Ph.D. has as yet only small numbers, the data available also suggest that the transfer rate of these students to Ph.D.-granting programs is also about twice the national average.

In conclusion, NIGMS remains dedicated to developing approaches to ensure that biomedical research continues to progress. The resources that we have received will permit us to take advantage of the rapidly expanding opportunities in science.

Thank you, Mr. Chairman. I would be pleased to answer any questions that you may have.

PREPARED STATEMENT OF DR. DUANE ALEXANDER

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2001 President's budget request for the National Institute of Child Health and Human Development (NICHD). The request of $810.5 million reflects an increase of $40.8 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS research, total support requested for NICHD is $904.7 million, an increase of $45.4 million over the fiscal year 2000 appropriation. Funds for the NICHD efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

The NICHD seeks to assure that every individual is born healthy and wanted, that women suffer no adverse consequence from the reproductive process, and that all children have the opportunity to fulfill their potential for a healthy and productive life unhampered by disease or disability. In pursuit of this mission, the NICHD conducts and supports laboratory, clinical, and epidemiological research on the reproductive, neurobiologic, developmental, and behavioral processes that determine and maintain the health of children, adults, families, and populations.

MENTAL RETARDATION

Since this Institute was established 37 years ago, a major portion of our research has been devoted to better understanding the causes, treatments, and prevention of mental retardation. One by one, in large part as a result of the support for research from this Committee, causes of mental retardation are being eliminated:

—phenylketonuria or PKU—eliminated;
—congenital hypothyroidism—eliminated;
—hemophilus influenzae type b meningitis or Hib—eliminated;
—measles encephalitis—nearly eliminated;
—congenital rubella syndrome—nearly eliminated;
—bilirubin encephalopathy—nearly eliminated.

Our progress toward understanding and eliminating the causes of mental retardation has continued during the last year. In a highly significant advance, Dr. Huda Zoghbi, an NICHD grantee in our Mental Retardation Research Center at Baylor, identified the gene responsible for Rett Syndrome, a mysterious condition that causes seemingly normal infant girls to lose their ability to walk and to develop symptoms of severe mental retardation. After years of exploration, researchers discovered the genetic difference between girls with Rett Syndrome and unaffected children. Girls with Rett Syndrome have a defective gene on one of their two X chromosomes. These girls have some normally functioning copies of the gene, so their symptoms are not immediately apparent at birth. However, between 6 and 18 months of age, these girls begin to exhibit the symptoms of Rett Syndrome when the function of the normal single gene is insufficient to meet the growing child's needs. [This discovery also sheds light on why only females are affected by the syndrome. Males with the Rett Syndrome gene possess only the mutant version of the gene because they have only one X chromosome. Presumably, male fetuses with the gene for Rett Syndrome die before birth or soon thereafter because they do not have a back-up copy of the normal gene.] The gene that is abnormal in Rett syndrome, called MECP 2, controls the function of several other genes, so when it is defective, multiple other genes, including some that are essential for brain development and function, operate improperly. Based on this exciting discovery, the NICHD is encouraging investigators to try to find pharmacologic agents that can substitute for the control mechanism, and thereby reverse or prevent the progression of Rett Syndrome.

Another significant finding we reported this year may provide a way to reduce the risk of mental retardation for children born to women who have hypothyroidism

during their pregnancy. We have known for many years that congenital hypothyroidism in children is associated with a lower IQ and we have eliminated that problem by screening all newborn infants. Now NICHD research has demonstrated that children born to mothers who have untreated hypothyroidism during pregnancy scored lower on IQ tests than children of healthy mothers, with 19 percent in the borderline or retarded range. However, when mothers with hypothyroidism were being treated for the condition, their children's IQ scores were virtually identical to those of children born to healthy mothers. This study suggests that screening women for hypothyroidism before or early in pregnancy may provide a way to prevent mental retardation. A protocol is in preparation to test this possibility in the 14 ob-gyn departments that are part of the NICHD Maternal-Fetal Medicine Network. This network is also studying ways to reduce the incidence of low birth weight, another significant cause of mental retardation.

NICHD has also provided important testing for a proposed new treatment of autism. In recent months a number of reports suggested a potential benefit to using secretin in the treatment of autistic children. We were intensely interested in these reports, but they contained no scientific data to assess the degree or duration of potential benefits. For this reason, NICHD launched a series of placebo-controlled studies to investigate potential benefits and risks of using secretin to treat autism. In results from the first of these studies, NICHD researchers found that treatment with the synthetic version of secretin offered no more benefit for children with autism than did treatment with placebo. Additional studies will seek to determine if secretin may be effective when given at various doses or on more than one occasion. We are also investigating whether secretin benefits autistic children with a particular group of symptoms and whether biological secretin is more effective than the synthetic version.

HEALTH DISPARITIES

Another area in which the NICHD has both a deep concern and a deep commitment is the elimination of health disparities among minority populations. The Institute is developing a comprehensive and coordinated research plan for eliminating health disparities among racial and ethnic minorities. Our plan will address infant mortality, reproductive health, medical rehabilitation, and child and adolescent health. I would like to highlight some of the initiatives which illustrate our strong commitment to eliminating health disparities.

Over the last two years, the NICHD awarded funds to 20 departments of obstetrics and gynecology to develop young investigators in the field and prepare the next generation of principal investigators. We also support 15 Reproductive Science Research Centers. In fiscal year 2001, the NICHD will enhance these programs by funding a program of Specialized Centers for Research in Reproductive Medicine in Minority Institutions that pairs minority institutions with established research centers. The goal of this program is to increase the capacity of minority institutions and investigators to conduct cutting-edge research in the field of obstetrics and gynecology, focusing on problems particularly prevalent among minorities.

The Institute's national Back to Sleep campaign, which urges caretakers to place infants on their backs to sleep, has met with significant success. In the five years since the campaign was launched, deaths due to Sudden Infant Death Syndrome (SIDS) have dropped 38 percent. Despite this overall success, both the SIDS rate and the rate of stomach sleeping among African-Americans remain more than double that of white infants. To address this marked disparity, the NICHD invited the leaders from a number of national African-American organizations, as well as officials from Federal, state, and municipal governments, to join us in developing and implementing strategies for reducing SIDS in African-Americans. The group identified the need for culturally sensitive materials and programs designed by and for African-American communities. The NICHD is committed to carrying out this strategy. As a first step, NICHD is conducting research with African-American caretakers such as parents, grandparents, relatives, and child care workers to identify more effective ways to communicate the Back to Sleep message. One component is a transit ad, which will be used first in the DC Metro system, and eventually in other cities around the country. The Institute's goal is to eliminate the racial disparity in infant back sleeping position within three years and hopefully thereby eliminate the racial disparity in SIDS rates.

We are also exploring ways to improve reading skills in populations of culturally and linguistically diverse students. Three years ago, the NICHD began a reading instruction research program with nine DC public schools. The purpose of the program was to determine whether applying what we have learned in other reading programs could be applied successfully with regular teachers in regular classrooms.

Data from the Early Intervention Project are still being collected and analyzed, but preliminary data show a pattern of remarkable improvements in reading ability. For instance, reading scores in schools that have historically been at the 10th to 15th percentile have improved to better than the 50th percentile. Moreover, the entire class in intervention schools is now performing at the national average. In a related area, the NICHD and the Department of Education this year are jointly soliciting research proposals for systematically studying the most effective ways to teach reading English to children whose primary language is Spanish.

HIV RESEARCH

In previous years, I reported on the research that led to the remarkable reduction in the rate of HIV transmission from mother to infant during pregnancy and birth. NICHD and NIAID research have made another important contribution to reducing maternal HIV transmission this past year. Grantees discovered that the amount of HIV in a pregnant woman's blood, known as maternal HIV viral load, is the prime risk factor for transmitting the virus to the baby. By focusing treatment on reducing the viral load during pregnancy, the risk of HIV transmission from mother to infant can be further decreased.

In the developing world, where logistics and the cost of multiple drug therapy for HIV are often prohibitive, research reported last year showed that administering the antiviral drug nevirapine to the mother just before delivery and to the infant just after birth can reduce HIV transmission significantly. NICHD and NIAID are now conducting studies to evaluate whether nevirapine, administered during the time a mother is breast-feeding can reduce the rate of HIV transmission through breast milk.

PEDIATRIC TRAUMA REHABILITATION

We also plan to expand research for children and teens in the area of trauma. Injury is the leading cause of death for children five to 18 years old; violence is the third leading cause of death for this age group. However, many clinical treatments for trauma are tailored exclusively to adults and fail to consider the long-term effects of these interventions on a developing child. The NICHD is planning a multidisciplinary, collaborative program to address this issue, led by the Institute's National Center for Medical Rehabilitation Research. This program will allow us to develop and assess therapies specifically targeted to the physical, emotional, and social needs of children. As part of this program, we will start a collaborative pediatric injury and trauma clinical trials network. Concurrently, we will be examining ways to actually prevent the risky behaviors that often result in injury and trauma.

In 1998, the NICHD held a consensus conference on traumatic brain injury or TBI. The panel identified specific concerns that require further study regarding the impact of TBI on children. Brain injuries can have a profound impact on new learning and future physical and mental development of children. Based on the panel's recommendations, the NICHD will establish specialized research programs on treatment tailored directly to the needs of young children with traumatic brain injury.

BEHAVIORAL RESEARCH

In the area of behavioral research, the Institute is identifying some of the major influences on the health and health behavior choices of young people. Since 1994, the Institute has supported The National Longitudinal Study of Adolescent Health, also know as the Add Health Study. The study has provided new insights into the ways that peers, families, schools and neighborhoods can influence positive health outcomes, as well as negative outcomes, such as violent behavior, smoking, drinking, illegal drug use, and sexual behavior. Data from this survey informed and will continue to inform public policy. With the increased funding provided by this Committee in fiscal year 2000, the Add Health study will collect additional data from the full original cohort. This study will help identify the major determinants of health and health behaviors during the transition from adolescence to early adulthood.

Mr. Chairman, the support from this Committee for the research of the National Institute of Child Health and Human Development has contributed to the elimination and near elimination of some of the major causes of childhood diseases and lifelong disabilities. We are proud of this progress but we know we still face many daunting yet exciting research challenges. In the years ahead, with your continued support, I am confident that we will return to this room and report back to you that we have eliminated some of the causes of learning disabilities, that we have eliminated some of the causes of infant mortality, that we have eliminated some of the life-long adverse consequences of child-bearing, and that we have contributed in a

significant way to eliminating the health disparities that separate racial and ethnic communities. I will be pleased to answer any questions you have at this time.

PREPARED STATEMENT OF DR. CARL KUPFER

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Eye Institute (NEI), for fiscal year 2001, a sum of $462.8M, which reflects an increase of $23.6M over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NEI is $474M, an increase of $23.9M over the fiscal year 2000 appropriation. Funds for the NEI efforts in AIDS research are included within the Office of AIDS Research budget request.

THIRTY YEARS OF ACCOMPLISHMENT

The NEI was formally established by Congress in 1968 and began full operations in 1970. Significant progress has been made in the last 30 years in understanding and treating many diseases of the eye and visual system, including:

—Developing highly effective treatments for severe diabetic retinopathy, a potentially blinding disease that affects half of the 16 million Americans with diabetes, according to the NIH's Diabetes in America. Thirty years ago, half of those who developed severe retinopathy were blind within five years of diagnosis, according to the British Journal of Ophthalmology. Today, because of NEI-sponsored clinical research, people with advanced retinopathy have less than a five percent chance of becoming blind when they get timely and appropriate treatment, according to the Journal of the American Medical Association.

—Finding that Black and White individuals with advanced glaucoma may respond differently to two surgical treatments for the disease, with Blacks likely to respond more favorably to one treatment, and Whites likely to respond more favorably to the other.

—Identifying a freezing treatment called cryotherapy that significantly reduces vision loss from advanced cases of retinopathy of prematurity, a potentially blinding visual disorder affecting premature infants.

—Showing that rejuvenation of the immune system of people with AIDS will prevent progression of a potentially blinding AIDS-related eye complication called CMV retinitis.

—Developing two new medical therapies—latanoprost and dorzolamide—for glaucoma. Both are given as eye drops.

—Finding that an antiviral drug—acyclovir—decreases the recurrence of herpes infection of the eye, a very painful and potentially blinding eye disorder.

—Identifying a gene that causes juvenile macular degeneration. This finding may bring researchers closer to finding the cause of age-related macular degeneration, a blinding eye disease affecting about 1.7 million older Americans, according to the NEI's Beaver Dam Study.

—Identifying several defective genes suspected of causing retinitis pigmentosa, a group of inherited, blinding diseases that slowly damage the retina and affect 100,000 Americans, according to the American Journal of Ophthalmology. Identifying these genes may lead to treatments that prevent nerve cell degeneration and visual loss.

—Discovering a more effective treatment for optic neuritis, which primarily affects women ages 15–45 and is often associated with multiple sclerosis. This treatment—a combination of intravenous and oral corticosteroids—restores vision more rapidly and decreases relapses.

—Finding a simpler, more successful treatment of an infection of the inside of the eye which, if left untreated or inadequately treated, can cause loss of vision.

—Demonstrating that a surgical procedure thought to be beneficial in treating an inflammation of the optic nerve is instead potentially harmful.

—Developing a questionnaire to assess the impact of vision loss on a person's quality of life. Called the Visual Function Questionnaire, it is being used to evaluate the effectiveness of new treatments being tested in clinical trials.

LOW VISION

NEI-supported researchers continue to focus on finding better ways to prevent, treat, and hopefully cure diseases of the eye and visual system. Despite these efforts, there are, according to The Lighthouse, about 14 million Americans—one in 20—who have low vision due to eye diseases and disorders of the visual system. We define low vision as a visual impairment, not correctable by eyeglasses, contact

lenses, medicine, or surgery, that interferes with the ability to perform everyday activities. As our population ages, it is expected that the number of people with low vision will increase dramatically.

The impact of low vision on quality of life can be devastating. It can lead to a loss of independence. It can affect people's ability to move about safely, to make decisions, and to communicate with others. It can lead to frustration and uncertainty with profound lifestyle and economic consequences.

To bring the message that information and help are available to people with low vision and their families, the NEI launched a Low Vision Education Program last October. The goal of the Program is to help improve the quality of life for people with low vision and outline steps people can take to use their remaining vision more effectively. A public awareness program that conveys positive, encouraging, and uplifting messages will alert the public and health professionals to this issue. People with low vision need to know that help exists, such as visual rehabilitation services and devices. The eye care professional should never tell his or her patient that nothing can be done about low vision. The fact is something can be done about it.

As part of the program, we have introduced a Low Vision Traveling Exhibit that increases public awareness about low vision and provides important information for people who do not see well. This exhibit, which will be displayed in shopping malls nationwide during the next few years, is now debuting in Birmingham, Alabama. The exhibit features an interactive CD–ROM touch screen program and provides first-person stories of how Americans are living successfully with the condition. The exhibit will help us reach those who need this information the most—people with low vision and their families and caregivers.

The Low Vision Education Program is part of the National Eye Health Education Program (NEHEP), the first Federally-funded eye health education program. It is coordinated by the NEI in partnership with close to 60 public and private organizations united behind a nationwide effort to educate people about the importance of good eye health. Through this network of "grass roots" organizations, the NEHEP multiplies its efforts in educating the public.

As we launch the Low Vision Education Program, the National Eye Institute is furthering progress in the area of low vision research, and is currently supporting 26 grants at a cost of about $6 million. Some of these projects involve laboratory research. Some involve research to develop low vision devices and explore emerging technologies. The auto focus binocular low-vision telescope has been improved. Research has yielded several new methods of presenting magnified text on computer screens. Another key advance is the development of new technology, such as route planning database systems and personal guidance systems, to improve way finding for people who are visually impaired. The NEI is a full partner in the NIH's bioengineering initiatives that bring together the necessary basic science, engineering, and/or clinical expertise to focus on a significant area of bioengineering research.

TRANSLATIONAL RESEARCH

Although the NEI is a clinically-oriented Institute, work performed in the laboratory is a fundamental pillar of research on visual impairment and blindness. It must be conducted before new therapies for preventing or treating disease can be developed and tested in a clinical trial setting. One of the greatest strengths of the NIH intramural program is that laboratory research can be conducted, and the findings quickly applied, to a small group of patients before large-scale testing.

An excellent example of our "lab-to-bedside" research is the discovery of a possible new treatment for uveitis, a severe eye inflammation that affects children and young adults. The current treatment for uveitis involves powerful drugs that can cause serious side effects, such as decreased kidney function, cataracts, glaucoma, and brittle bones. A collaboration between scientists at the NEI and the National Cancer Institute will result in an alternative therapy, called humanized anti-Tac monoclonal antibody, which can be given intravenously once a month. This biological substance seems to control uveitis as effectively as the standard treatment in this study, but with a marked decrease in complications and side effects. This study serves as a model for future studies.

VISUAL HEALTH DISPARITIES

The NEI is supporting a number of studies to improve understanding of eye disease and visual impairment in traditionally underserved populations. For example, among African Americans, glaucoma is the leading cause of blindness. Results from NEI-funded studies confirm the rates for blindness due to glaucoma in African-Americans are six times higher than the rates for Whites. On the other hand, age-related macular degeneration is rare for Blacks as compared to Whites.

Clinical Studies will help identify people at highest risk for glaucoma and those most likely to benefit from early medical treatment. To closely follow people who are at moderate risk of developing glaucoma, the NEI is conducting a clinical trial called the Ocular Hypertension Treatment Study. This multi-center clinical trial has enrolled 1500 patients, of which 25 percent are African-American. The high percentage of African Americans participating will enable analyses of the effectiveness of topical medications in preventing the development of glaucoma in Blacks.

Previous research has provided estimates of the prevalence of eye disease among Whites and Blacks in the US, but no published comparable data exists on the US Hispanic population. This paucity of data hampers the design of appropriate eye health services. The NEI is now supporting two large studies—The Los Angeles Latino Eye Study and the Visual Impairment Among Hispanics in Arizona Study—that will help direct manpower and resources toward the major eye health needs of the Hispanic population.

The NEI is also conducting an investigation of eye development and nearsightedness in schoolchildren. This study will compare and contrast normal eye growth and development in Hispanic, African-American, and Asian schoolchildren ages 6–14 years with what happens in Caucasian children. With this information, we hope to be able to predict nearsightedness in small children before it is clinically evident.

FUTURE DIRECTION OF VISION RESEARCH

There are eye diseases that have resisted our best efforts at improving treatment. But the NEI is exploiting new advances in molecular biology, genetics, immunology, cell biology, and other disciplines to accelerate efforts to find cures for blinding diseases.

The NEI has outlined new therapeutic strategies—such as gene replacement, tissue and cell transplantation, and growth factor therapy—that show great potential. We can produce—and directly view—abnormal blood vessels in the eyes of animal models. This allows us to determine if various treatments for diabetic retinopathy and macular degeneration are effective in eliminating these blood vessels, which lead to blurred vision.

The vision researcher has the advantage of utilizing noninvasive technology. Adaptive optics technology has recently been applied to the visual system, giving the clearest views yet of the living retina inside the eye. This may allow scientists to track the progression of a number of retinal diseases such as retinitis pigmentosa and diabetic retinopathy, and evaluate the efficacy of rescue of cell types in the retina.

To help develop genomic resources that facilitate understanding of the normal visual system and related disorders and diseases, NEI sponsored a two-day multi-disciplinary functional genomic workshop last September. The purpose of genetics studies related to the eye is not only to identify eye genes, which will be aided greatly by NIH's Human Genome Project, but also to determine what the genes do normally and what happens when the genes are mutated. Some ideas generated at the workshop included creating a visual system web site to enhance access to existing, or newly created, databases for genes expressed in the visual system; producing and characterizing expressed genes of the visual system; and encouraging programs for genomics, functional genomics, and disease. We have begun to implement many of these suggestions.

Research will continue to examine all these possibilities, guided by our goal of the past 30 years to improve the prevention, diagnosis, and treatment of all diseases of the eye and visual disorders. Much remains to be done. We understand that progress does not always occur as quickly as we would hope. But we put ahead of us this goal and vision for the new century. With the continued support of the American people and the research priorities outlined in our strategic plan, we will endeavor to protect this most precious sense of sight for all Americans and all of humanity.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

Mr. Chairman, I will be happy to answer your questions.

PREPARED STATEMENT OF DR. KENNETH OLDEN

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for NIEHS for fiscal year 2001, a sum of $460,971,000 which reflects an increase of $25,824,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIEHS is $468,649,000 an increase of $25,961,000 over the fiscal year 2000 appropriation. Funds for the NIEHS efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, this data will help identify new strategies and objectives to improve programs across NIH and the Department.

There is a paucity of information to make important environmental health regulatory decisions. When it's time for many of us to buy a car or a house, we take great pains to study the market, examining factors like reliability, safety and resale value, before committing ourselves to make such a major investment. As a nation, however, we frequently make decisions about how (or whether) to regulate chemical and physical agents to improve environmental health—moves that cost the public and private sectors hundreds of billions of dollars—without adequate information. This lack of information is becoming more evident as we move into an era when the biggest threats we face are from exposures to low doses, not the high doses we have traditionally faced and tried to control.

The most commonly used words in reference to environmental health risks are "not enough information." For example, a committee by the National Research Council recently concluded that "there is insufficient research, and therefore insufficient evidence, to say whether particular environmental contaminants known as endocrine disruptors may be dangerous to humans." This information gap is not unique to endocrine disruptors. Most experts agree that inadequate information exists regarding the toxicity of chemicals, the variation in susceptibility to toxic substances, the type, pattern, and magnitude of human exposure to chemicals through the diet, the workplace, and the environment.

In part, the current dilemma has resulted from the success of environmental remediation and pollution control and reduction efforts over the past 30 years. These efforts have dramatically reduced the human health threats posed by the thousands of new chemicals and technologies introduced into our environment. In fact, there are those who argue the environment no longer represents a serious threat to human health because the low-dose exposures currently experienced by most Americans pose no significant health threat. But the assumption that low-dose exposures do not present a potential health risk is seriously flawed. We now know that chronic low-level exposures have the capacity to accumulate and attain toxic concentrations in brain and other tissues. For example, it is well documented that ingested methylmercury can be completely absorbed from the digestive tract and easily accumulate in the brain and poison the neurons involved in learning and memory processes.

Managing today's risks will also require consideration of biological concepts that were not part of the environmental health science vernacular as recently as ten years ago. Concepts such as susceptibility, environmental genomics, high-throughput screening and transgenic technology were not among the priorities of the environmental health research enterprise. We need to develop new science, new technologies and new ways of conceptualizing and investigating threats to human health. Environmental decisions of the future will require better information and pollution prevention strategies than currently exist today. New approaches are needed to promote greater participation of local communities and public health officials in environmental health research and policy development in terms of priority setting and development of prevention strategies to protect public health. Particular emphasis should be made to include disadvantaged and minority populations in research and policy determinations. These groups often bear the greater burden of environmental hazards and, as has been clearly documented, suffer from poorer health than do more affluent groups.

Realizing the public health and economic potential of environmental health research requires a number of critical investments. I will focus on three of them—high throughput technologies, susceptibility to environmental toxicants, and exposure assessment.

HIGH THROUGHPUT TECHNOLOGIES

In my testimony before this Committee in 1997, I updated you on our efforts to develop and validate high throughput technologies for carcinogenicity and toxicity testing, including transgenic animal models. Today, I am pleased to report that because of our leadership in this area of research, transgenic animal models, as a tool to study chemical carcinogenesis, is the subject of intense research. In fact, a recent paper used one of these models to successfully assess chemical carcinogenesis in vascular tissue. The hope is that such animal models can be used in a carcinogenicity testing strategy, potentially reducing our dependence on the conventional two-year rodent bioassay. The transgenic bioassays use fewer animals, cost less, and take less time because of their increased sensitivity to carcinogens and low incidence of spontaneous tumors. While I am optimistic that transgenic animals will be validated for assessment of carcinogenic or toxic potential of chemicals, we have already initiated efforts to develop the second generation of alternative test systems based on differential gene expression. Given that gene expression is continuously modulated by environmental cues, exposure to toxic agents can be expected to elicit unique patterns of gene expression. Thus, DNA microarray technology, which can monitor gene expression, could be a sensitive tool to assess toxicity. The assumption is that toxic exposures are likely to evoke quantitative and qualitative changes in gene expression. Therefore, this technology should allow toxicologists to expose cells or tissues to chemicals whose toxicity is unknown and match the results against the "signature," or common set of changes in gene expression, produced by a known class of toxicants. This would reduce the need for lengthy and expensive rodent bioassays (conventional and transgenic) and would lend itself to testing at low doses and to automation. Today, I want to announce our intent to establish a DNA Microarray Resource Center to develop and distribute so-called "Tox-Chips" containing candidate genes—genes known to be involved in cell growth and proliferation and in the biotransformation of environmental carcinogens or toxin—derived from human, mouse and other animal sources. This approach to developing and applying this new technology to the field of toxicology will ensure that all investigators will have access to this expensive resource and that the products are the highest quality.

SUSCEPTIBILITY TO ENVIRONMENTAL TOXICANTS

It is well known that most smokers do not develop lung cancer and most women exposed in utero to diethylstilbestrol never develop vaginal and cervical cancer. A common question asked of physicians is, "Why me, Doc?" One answer to this question is that genetically-determined differences in susceptibility are at least partly responsible.

Significant advances in our understanding of human genetics have shown that specific genes play key roles in disease susceptibility. For example, mutations in BRCA1, P53, XPB, and ATM are predisposing for breast cancer, Li-Fraumeni syndrome, xeroderma pigmentosum, and ataxia telangiectasia, respectively. Thus, it is reasonable to expect that several of the genetic alterations in other genes will also have a significant influence on disease susceptibility. With rapid advances in cloning and sequencing of the human genome, it is now possible to identify the genetic alterations responsible for differences in susceptibility. The "sequence" of the entire human genome will be elucidated within the next 12 months. However, the order of the bases in the human genome is not one sequence but rather many variations of a common theme. In fact, sequence variation is ubiquitous in human populations; what differs is the frequencies of these variations.

Susceptibility also is influenced by the timing of exposure, the gender and behavior of the individual, the nutritional state and socioeconomic status. For example, exposure during rapid or critical stages of development of the various organ systems such as embryonic development, adolescence, puberty and old age, is likely to be an important factor in disease development. We currently have little information to guide decision-making with respect to these issues since most toxicologic assessments have been done in adults, both animals and humans, under otherwise optimal conditions.

To investigate the genetic basis for differences in predisposition to disease, NIEHS extended the domain of genomic mapping and sequencing to address the challenge of genetic diversity. The Environmental Genome Project, initiated two years ago, seeks to identify genetic changes that increase risk for disease development, and the results from these studies will have profound implications for the practice of medicine and environmental health risk assessment. The challenge will be to create a repository of all common variants—a diversity map—and correlate them with spe-

cific environmental exposures and disease phenotypes through functional and epidemiologic studies.

Today, I am announcing our intent to support the development of Comparative Mouse Genomics Centers that will make use of all available DNA sequence variation data to produce novel transgenic and knockout mouse models which will mirror specific variants of human environmentally responsive genes found in the general population. The Mouse Genomics Centers will bring together a team of investigators to develop mouse models of environmentally relevant human diseases, provide a comprehensive analysis of their phenotype and genotype, and validate them for their use by the research community. The new models produced by the Centers will then be used by the scientific community to study diseases resulting from specific insults, including exposure to environmental agents, viruses, nutritional factors, pharmacological drugs, and other physical and chemical stresses.

It is important to emphasize that susceptibilities modify risk rather than cause disease. This "gene-hunt" and "mouse-model" development exercise could have profound implications for risk assessment in terms of setting standards for environmental exposures. Data on the prevalence of susceptibility genes could take the guesswork out of environmental decision-making with respect to susceptible populations. These studies challenge a fundamental tenet of toxicology; that is, that the dose makes the poison. We now know that it is the host, plus the dose and the time of exposure, that makes the poison.

EXPOSURE ASSESSMENT

Exposure monitoring is a "right-to-know" issue for citizens who are involuntarily exposed to environmental pollutants. However, little is known about actual human exposure and body burdens of environmental pollutants. This knowledge gap hampers regulatory decision-making and introduces uncertainties in setting exposure limits. It also limits our capacity to develop effective prevention strategies. Exposure is typically estimated using indirect surrogates of environmental quality such as toxic release and production inventories and environmental monitoring. Individual exposure, though, is highly variable and is a function of individual uptake, metabolism, excretion and behavior. So the assumption that everyone living in the same geographic area have similar exposure is seriously flawed. What we need are direct measures of exposure based on tissue analysis or deposition. Simple monitoring of levels of chemicals in the environment does not necessarily reflect amounts taken up and deposited in tissues.

Exposure assessment is emerging as a scientific field due to the revolutionary advances in genetics, molecular imaging, molecular biology, and microenvironmental and personal measurement technology. As these technologies become more robust, sensitive and inexpensive, they will provide the scientific foundation for the quantitative assessment of human health risk. Exposure analysis provides the long-awaited connection between toxicology and epidemiology, and will provide the basis for hypothesis-driven research and examination of exposure-disease relationships.

Several public health areas will benefit from improvements in exposure assessment. The absence of adequate exposure data restricts our ability to (1) evaluate low-dose effects of exposure to chemicals encountered in the home, workplace and general environment, (2) identify at-risk populations based on age (e.g., children), genetic susceptibility and socioeconomic status, (3) design studies to efficiently evaluate exposure/response relationships, (4) make full use of the human genome effort for studying gene/environment interactions, and (5) to link exposure to human diseases.

In September 1999, the NIEHS and the American Industrial Health Council cosponsored an interagency workshop on "The Role of Human Exposure Assessment in the Prevention of Human Disease." With more than 400 participants, the three-day workshop represented experts from the various federal agencies, public interest groups, academia, and industry. Participants considered the workshop a landmark event in the field of exposure assessment in that it provided the vision and enthusiasm for moving the field of exposure assessment away from solely an applied discipline to one in which hypothesis-driven research can effectively connect technological advances to public health problems and controversies. Since the workshop, NIEHS has developed a collaborative relationship with the National Center for Health Statistics and the U.S. Geological Survey to develop a population-based geographical information system and disease prevalence maps.

In conclusion, the power of the science base for environmental health decision-making can now be transformed at a pace that could not have been foreseen a decade ago by even the most astute visionaries. The scientific opportunities presented

here develop an entirely new framework to understand how environmental exposures affect human health.

PREPARED STATEMENT OF DR. RICHARD J. HODES

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Institute on Aging (NIA) for fiscal year 2001, a sum of $721,651,000, which reflects an increase of $37,933,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the National Institute on Aging is $725,949,000, an increase of $38,088,000 over the fiscal year 2000 appropriation. Funds for NIA efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

Since the NIA's inception in 1974, tremendous strides have been made in uncovering the mysteries of the aging process, reducing disease and disability, and improving the quality of life for older Americans. The pace of scientific discovery has been impressive, and the Institute anticipates building upon these advances in the future. I am pleased to report the NIA's recent progress, in reducing disability and extending healthy active years of life for all Americans.

ALZHEIMER'S DISEASE RESEARCH

Alzheimer's disease (AD), the most common cause of dementia, is the result of abnormal changes in the brain that lead to a devastating decline in intellectual abilities and changes in behavior and personality. Tragically, as many as four million Americans [1] now suffer from Alzheimer's disease—a number that threatens to increase dramatically as the population of people most at risk for dementia, those aged 85 and older, reaches almost 20 million by the middle of the 21st century.[2] NIA, as the lead Federal agency responsible for Alzheimer's disease research, recognizes the urgency of this looming public health threat and is supporting basic, clinical, and behavioral research to improve AD diagnosis, treatment, and patient care, and to delay, and eventually prevent, the onset of this devastating disease. Advances in our understanding of AD over the last 20 years have been substantial, enabling the NIA to launch the Alzheimer's Disease Prevention Initiative. In collaboration with other Federal agencies and the private sector, the AD Prevention Initiative is invigorating discovery of new treatments, risk and preventative factors, methods of early detection and diagnosis; and strategies for improving patient care and alleviating caregiver burdens. The initiative is also accelerating movement of promising new treatments and prevention strategies into clinical trials, and is improving understanding of normal brain function.

In 1999, the NIA launched the first large-scale AD prevention clinical trial supported by the NIH, the Memory Impairment Study (MIS), being conducted at more than 65 medical research institutions in North America. In this trial, vitamin E, and donepezil (Aricept) will be evaluated over a three-year period for their effectiveness in slowing or stopping the conversion from mild cognitive impairment (MCI), a condition characterized by a memory deficit without dementia, to AD. Other ongoing or upcoming AD prevention trials will examine the effectiveness of ibuprofen (an anti-inflammatory drug) in reducing the development of AD; the effect of estrogen replacement therapy in preventing AD in women with a family history of the disease; and whether treatment with a variety of agents, such as aspirin, vitamin E, antioxidants, or combined folate/B6/B12 supplementation can prevent AD. The effects of these agents on normal age-related decline will also be evaluated. Information about ongoing clinical trials is available to the public through the NIA-supported Alzheimer's Disease Education and Referral Center web site (www.alzheimers.org) and toll-free number (1–800–438–4380).

The ability to assess the effectiveness of early treatments or interventions, such as those being tested in the AD Prevention Initiative, will be enhanced by our abil-

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[1] Small, GW, Rabine, Barry, PV, Barry, PP, et. al. *Diagnosis and Treatment of Alzheimer's Disease and Related Disorders.* JAMA 16: 1363–1371, 1997.

[2] Bureau of the Census, Middle Series Projections, 1996.

ity to visualize brain function using new imaging techniques. In a recent study, investigators used magnetic resonance imaging (MRI) to determine volume measurements of the hippocampus, the region of the brain responsible for memory function, in individuals diagnosed with mild cognitive impairment (Chart #1). Based on three years of observations, researchers found that in older people with MCI, the smaller the hippocampus at the beginning of the study, the greater the risk of developing AD later. This imaging study illustrates how abnormal cerebral function or anatomy can be detected before clinical diagnosis and how diagnostic advances can help ensure the effective application of emerging early interventions. Advances in imaging techniques also have important diagnostic implications for other neurodegenerative diseases, such as Parkinson's disease.

Developing effective treatments for AD based on advances in basic research is a major focus of NIA-supported studies. The ability of researchers to conceptualize effective treatments was enhanced by the discovery of two enzymes, beta and gamma secretase, that are involved in the clipping of a normal cell surface protein to produce the amyloid peptide that forms the senile plaques found in the brains of AD patients (Chart #2). Identifying and understanding how these two enzymes work will accelerate the development of interventions to block their action and stop the development of AD plaques. NIA will also support research to evaluate the potential of an immunization approach recently developed by researchers in the private sector, which, in mice, prevented the formation of amyloid plaques associated with AD.

A transgenic mouse strain that expresses a human tau gene and develops AD-like tau tangles has been developed. This model will help scientists understand how tau produces AD in the brain, and together with other AD models, will move researchers closer to developing effective preventive or treatment interventions. In another study, researchers demonstrated that shrinkage and dysfunction of certain brain cells that occur with age might be reversible. Researchers inserted into skin cells a gene that makes human nerve growth factor (NGF) and then injected the modified cells into the brains of experimental animals. After three months, the older animals injected with NGF-expressing cells had brains that resembled those of younger animals. Such gene transfer approaches to recovering cellular function could eventually have important implications for the treatment of AD and other chronic age-related neurodegenerative disorders in humans.

BIOLOGY OF AGING

Research on the biology of aging has led to a revolution in understanding the cellular and molecular changes that occur with aging and the abnormal changes that are risk factors for or accompany age-related diseases. Further, research is revealing genetic and other biologic factors associated with extended longevity in animal models, contributing to the development of interventions to reduce or delay age-related degenerative processes in humans. Presently, caloric restriction is the only intervention known to slow the intrinsic rate of aging in mammals. Rodents and other laboratory animals that are given a diet that includes necessary nutrients, but 30 to 40 percent fewer calories than in usual diets, live far beyond their normal life spans and have reduced rates and later onset of diseases. A recent study analyzed the gene expression profiles of cells from young and from old mice on usual or calorically restricted diets. Of the 6,347 genes surveyed by new micro-array techniques, fewer than one percent displayed a greater than twofold decrease in expression. Thus, the aging process may be associated with changes in expression of a limited subset of genes, rather than involving widespread changes in most genes. It was further observed that caloric restriction completely or partially suppressed age-associated alterations in expression of a large proportion of genes. This type of molecular assessment of mammalian aging will provide new tools to evaluate experimental interventions for age-related conditions.

Over the last ten years, numerous genes have been implicated in normal aging processes, in age-related pathologies and diseases, and in determination of longevity in several species including humans (Chart #3). Understanding the molecular genetics of aging and longevity is a rapidly advancing field; recent research advances have greatly expanded our knowledge of genes and biological pathways which play significant roles in determining longevity and health span. Recent discoveries in non-mammalian species including S. cerevisiae (yeast), C. elegans, (roundworms), and D. melanogaster, (fruit flies), have identified striking effects of mutations, either singly or in specific combinations, on lifespan, increasing life spans 2 to 3 times longer than those of (wild type) normally aged animals. These findings suggest signaling and metabolic pathways that may be critical in determining longevity. In addition, cross-species comparisons have identified homologous (similar) genes in animals and in humans that have similar or related functions. For example, mutations

that double the life span of C. elegans occur in genes that are homologous to genes associated with insulin and glucose (sugar) metabolism in humans, and may therefore be relevant to weight control and diabetes.

REDUCING DISEASE AND DISABILITY

Studies have shown that disability rates for people age 65 and older have been falling at an accelerating pace since 1982 and that the benefits of this trend extend to both men and women, and to minority groups. Initial field reports from the 1999 wave of the National Long-Term Care Survey indicate that disability rates have continued to fall. These data parallel heartening news from investigators who found that many centenarians remain functionally independent for the vast majority of their lives. More research is needed to understand the genetic and environmental factors responsible for centenarians' prolonged good health and extreme longevity. Similarly, more research is necessary to understand the causes and economic consequences of the decline in disability rates and to further accelerate these improvements.

Increasingly, researchers are understanding the benefits of exercise, especially for older people, as a key to preventing or delaying the onset of disease and disability. Specifically, studies have revealed that moderate physical activity can: reduce the risk of falls; benefit people suffering from a variety of ailments, including osteoarthritis and depression; and may enhance learning, memory and the generation of brain cells. There is also scientific evidence that exercise may be a factor related to increased life expectancy and the number of years people live free of disability. In a recent study, it was shown that becoming fit, even in later years (as measured by performance on an exercise treadmill test), is associated with lower mortality rates (Chart #4). The study, which included 9,000 men aged 20 to 82, compared death rates in physically unfit men who remained unfit over five years with physically unfit men who became fit during the same period. The study found that unfit men aged 60 and over who became fit had death rates 50 percent lower than those who remained unfit. In another clinical trial involving chronically ill older adults, aged 70 and older, researchers reported that one year of increased physical activity, combined with chronic-illness self-management resulted in fewer reported hospitalizations and total hospital days. These studies show that exercise can benefit older people and that it is never too late to start. The challenge remains to motivate more people to engage in regular physical activity—particularly older women and minorities who, according to national surveys, are consistently less active. Last year, the National Institute on Aging published a free manual, Exercise: A Guide from the National Institute on Aging, the cornerstone of the Institute's ongoing campaign to encourage older people to exercise. The Guide is based on scientific evidence and is intended to help people design their own exercise program. To date, the Institute has distributed over 230,000 copies.

REDUCING HEALTH DISPARITIES

Health disparities are associated with a broad, complex, and interrelated array of factors, including race, ethnicity, gender, socioeconomic status, age, education, occupation, and as yet unknown lifetime and lifestyle differences. Prevalence rates of specific diseases are also associated with race, ethnicity and socioeconomic status. One recent multi-ethnic epidemiologic study indicated that prevalence rates for Alzheimer's disease may be higher for African-Americans and Hispanics. In an examination of genetic risk factors for AD, although APOE4 is associated with higher risk of AD among Caucasians, African Americans and Hispanic elders with the APOE4 allele were not at higher risk than those with other APOE alleles. Understanding the genetic and environmental risk factors contributing to this difference will be crucial to developing effective interventions to reducing the disparity.

NIA has made reducing health disparities a major priority of its five-year strategic plan. Last year, with support from the NIH Office of Research on Minority Health, the NIA intramural program designed a mobile medical research vehicle to extend the opportunity to participate in the Baltimore Longitudinal Study of Aging and in other clinical research projects to minority and socioeconomically diverse subjects. The NIA, working with the National Advisory Council on Aging, also undertook a comprehensive review of its minority aging research activities and training initiatives. The NIA is developing an implementation plan to integrate the resulting recommendations into its programs, such as the Resource Centers for Minority Aging Research, which provide mentoring and training opportunities to individuals interested in studying the health of minority elders, and the Alzheimer's Disease Centers satellite clinics, which recruit minorities for research protocols conducted by the NIA's 28 AD centers.

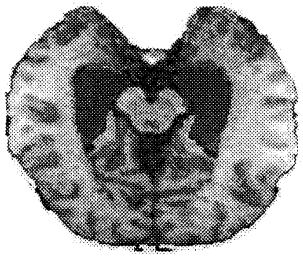
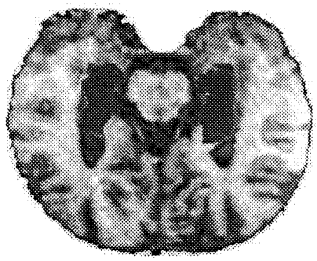
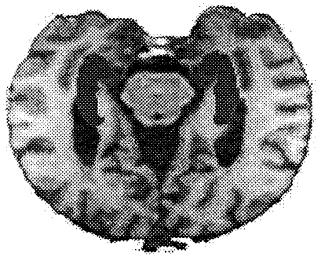
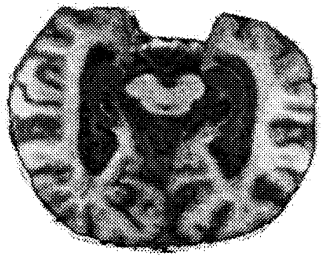
Investigators supported by the NIA continue to report exciting scientific advances that may help eliminate health disparities among groups of elders. Investigators recently published a study, which suggests that there is a difference between African-American and Caucasian women in their experience of peri-menopausal symptoms. African-American women were significantly more likely than white women (58 percent vs. 29 percent) to experience hot flashes, but fewer than 7 percent had discussed menopausal management with their physicians. Given our developing understanding of hormone replacement therapy in controlling menopausal symptoms as well as in reducing risk of problems in later life, such as osteoporosis, improved, culturally-appropriate patient education programs should be encouraged.

A decade ago, few interventions were available to address the major health concerns of older people. Entering the 21st century, the outlook has improved considerably. More interventions exist and research into treating, as well as preventing, the onset of age-related diseases is escalating. With the knowledge this research will derive, aging will be a healthier, more vigorous stage of life. I am happy to answer your questions.

Chart #1

The Anatomy of Memory

Hippocampus Size in Aging and Alzheimer's Disease

Normal	Normal	Mild Cognitive Impairment	Alzheimer's Disease
			
25 Years	75 Years	75 Years	75 Years

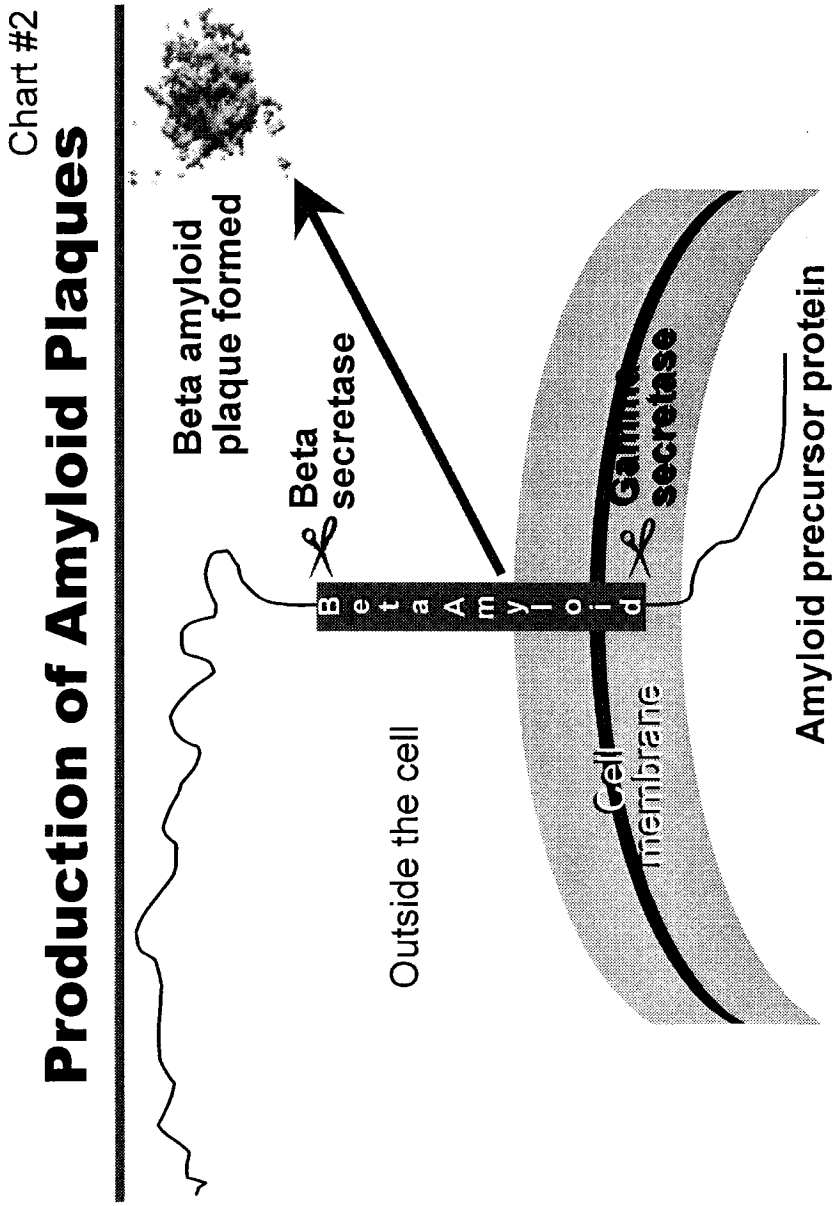


Chart #2
Production of Amyloid Plaques
Beta amyloid plaque formed
Beta secretase
Beta Amyloid
Outside the cell
Cell membrane
Gamma secretase
Amyloid precursor protein

Chart #3

Longevity Genes Across Species

Nematode	Human
catalase	catalase
age-1	PI_3-kinase (glucose metabolism)
daf-2	Insulin-like receptor (glucose metabolism)
daf-16	HNF3 (transcription factor)
WRN	WRN (Werner Syndrome)

*Known effect on aging

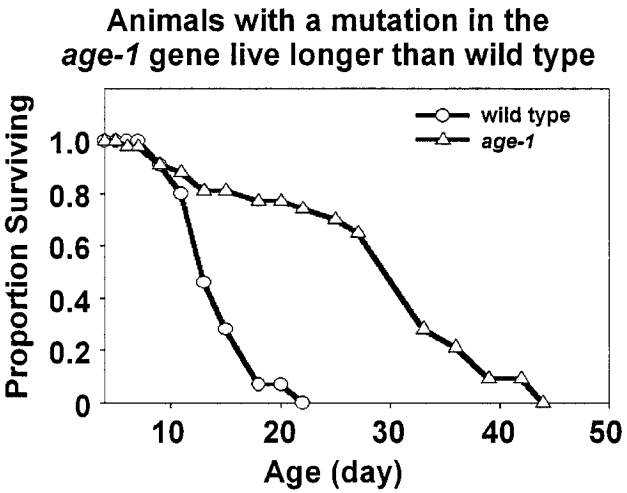
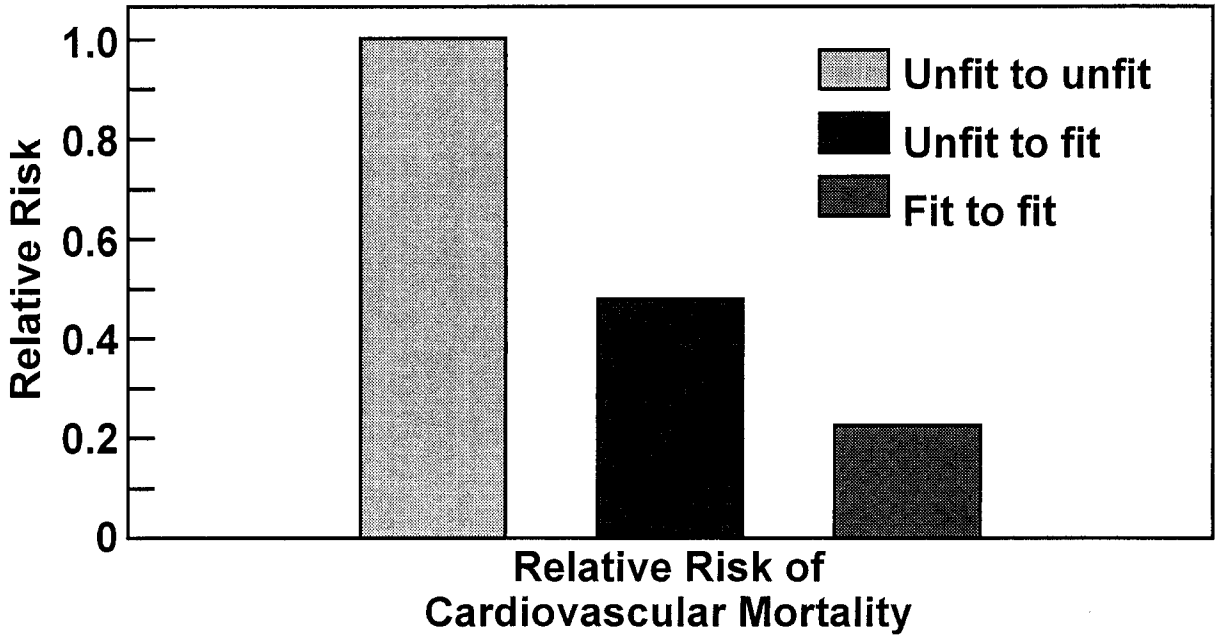


Chart #4

Becoming Physically Fit Reduces Mortality in Elderly Persons



PREPARED STATEMENT OF DR. STEPHEN I. KATZ

Mr. Chairman and Members of the Subcommittee: I am pleased to present the President's non-AIDS budget request for the NIAMS for fiscal year 2001, a sum of $363,479,000, which reflects an increase of $19,021,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NIAMS is $368,712,000, an increase of $19,232,000 over the fiscal year 2000 appropriation. Funds for the NIAMS efforts in AIDS are included within the Office of AIDS Research budget request.

I am honored to appear before this Subcommittee. I want to begin by providing a context for the research mission of our Institute. As the Director of the NIAMS, I am acutely aware that the every day life of the American people is enormously improved by the research that our Institute supports. Children on the playground, women and ethnic minorities who are disproportionately afflicted by the many diseases that affect their daily activities, adults in the work place, and elderly Americans striving to live independently—all have their lives enhanced or compromised by the health and functioning of their bones, joints, muscle, and skin. Ensuring improved quality of life and increased longevity of life for all Americans is our primary mission.

I want to express my appreciation for the fiscal year 2000 appropriation—the second year of an extraordinary budget that enabled us to invest in medical research with much more breadth and depth than ever before. I will share specific examples of ways in which we invested our budget over the last year and some of the research directions we are pursuing.

CLINICAL RESEARCH

The focus of most of my remarks today will be on clinical research. While the backbone of medical science has been and will continue to be fundamental research on how the body functions, the ultimate goal of research supported by the NIH is improving public health. In order to achieve this, we must also serve as translators—translating the basic research findings from the laboratory to improving patient care at the bedside as well as utilizing the information learned at the patient bedside to inform more focused and sophisticated basic studies. This translation is the cornerstone of the research supported by the NIAMS.

Highlights of particularly exciting and promising translational research on bones, joints, muscles and skin include the findings that lower doses of estrogen than we normally prescribe can be effective in preventing osteoporosis, that some of the new treatments for rheumatoid arthritis can be targeted directly at the disease-causing factors, that normal hair growth is controlled by genes that encode for proteins that may be excellent targets for new therapies, and that proteins that are essential for normal muscle formation can, in mouse models, be produced by injecting particular genes into the muscles that contain the defective proteins. These examples provide only a broad sample of some of the most recent findings from research studies that we have supported.

The reality is that clinical research is vitally important, but is also very costly. The significant increase in our appropriation last year enabled us to launch a number of clinical initiatives in particularly challenging areas of health, including: (1) Pilot studies in rheumatic diseases and skin diseases—These studies include expanded research on some of the most difficult public health challenges such as leg ulcers, rheumatoid arthritis, scleroderma, lupus, spondylitis and others where new treatment approaches are needed. (2) Osteoporosis in men—A major clinical trial will determine the extent to which the risk of fracture in men is related to bone mass and structure, biochemistry, lifestyle, tendency to fall, and other factors. The study will also seek to determine if bone mass can be correlated with an increased risk of prostate cancer. (3) Combination therapies for osteoporosis—It is important to determine whether combinations of drugs, often produced by different pharmaceutical companies, will be more effective and have fewer side effects than any of the drugs used alone for osteoporosis. (4) Treatment of back pain—Back pain is very common and has a serious impact on people's personal and professional lives, and results in significant costs to businesses and the American economy. We have launched a major clinical trial studying surgical versus nonsurgical treatment of three different back disorders. We anticipate that this study will have a significant effect on clinical practice and the cost of medical services for people with any of these three back disorders. (5) The Spondylitis Consortium—The NIAMS has partnered with the American Spondylitis Association in establishing the North American Spondylitis Consortium to search for genes that determine susceptibility to ankylosing spondylitis, a painful inflammatory disease of the spine, also known as arthritis of the spine. and (6) Clinical research training and career develop-

ment—Because we need to develop and maintain a pipeline of researchers who are training to plan, conduct, analyze, and disseminate the findings of clinical research, the NIAMS has enthusiastically embraced and participated in the NIH initiatives to develop and maintain careers in clinical research.

AUTOIMMUNITY

The NIAMS supports a broad and diverse portfolio of research on autoimmunity, including studies of rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, scleroderma, alopecia areata, and many blistering skin diseases—all potentially devastating chronic diseases which exact a huge toll in human suffering and economic costs. The additional funds provided by Congress for the Autoimmunity Initiative last year provided the opportunity for the NIAMS to expand its research in the following key areas: (1) pilot trials on innovative therapies for rheumatoid arthritis and scleroderma; (2) target organ damage in autoimmune diseases, also focusing on scleroderma and rheumatoid arthritis; (3) autoimmune rat repository and transgenic resource—a national resource and development center for rat models of autoimmune disorders; (4) NIAMS patient data registries—in which information will be collected on neonatal lupus and on juvenile rheumatoid arthritis, with an expansion to include genetic studies; and (5) new imaging technologies for autoimmune diseases, through a project involving in vivo imaging of tiny blood vessels in animal models of rheumatoid arthritis.

FIBROMYALGIA

The NIAMS has a firm commitment to identifying the causes of fibromyalgia and improving the daily life of people affected by this debilitating disease, and we have a broad portfolio of research in this area. Last year the NIAMS as well as the NIDCR, NINDS, and the ORWH funded fifteen new clinical and basic research studies on fibromyalgia, and we are confident that these new studies will provide much-needed information on the causes of fibromyalgia as well as new strategies for treatments.

MUSCLE DISEASES

People affected by muscle diseases face profound changes and challenges in their every day lives. We now know that many of these diseases are caused by genetic mutations, and we are supporting research to further define these mutations and to overcome the current barriers to effective gene therapy of muscle diseases. We are optimistic that genetic manipulation of skeletal muscle will improve therapy for muscle diseases such as Duchenne muscular dystrophy and Facioscapulohumeral dystrophy. The Institute, in collaboration with the National Institute of Neurological Disorders and Stroke, is sponsoring workshops in both of these areas in May 2000 and we are looking forward to hearing recommendations from experts in these fields on research directions we could pursue in fiscal year 2001.

OSTEOARTHRITIS

As many Americans are well aware, osteoarthritis is the most common disease of joints. The NIAMS continues to support a substantial amount of research across the full spectrum of scientific approaches and strategies to understand this disease and improve life for affected people. In July 1999 we sponsored a major conference on osteoarthritis with the participation of leading experts in this field and many related fields. We used this opportunity to have a tandem educational meeting for patients whose daily lives are affected by osteoarthritis. We learned a great deal about the disease from both kinds of experts—those doing research on osteoarthritis and those living with it. We are carefully considering the recommendations made from both sets of experts to strengthen our portfolio in osteoarthritis using the fiscal year 2001 appropriation, particularly in the area of prevention. The NIAMS is also partnering with our colleagues in the National Institute on Aging, the Food and Drug Administration, many pharmaceutical companies, and several professional and voluntary lay organizations to try to create a public-private partnership to identify biomarkers for osteoarthritis. Our goal is to support clinical and laboratory evaluations of biomarkers and imaging techniques as potential surrogate endpoints for clinical trials that would assess the efficacy of osteoarthritis disease-modifying interventions.

OSTEOPOROSIS

We have known for some time that osteoporosis has genetic components, but the genes that are actually associated with fractures themselves had not previously

been identified. Scientists have found that older women who have the gene for apolipoprotein E, also known as APOE*4, are at increased risk for hip and wrist fractures. We know about this gene from other studies of its association with common, late-onset forms of Alzheimer's disease and with osteoporosis in patients on dialysis. This represents a promising area for further study in patients with osteoporosis as well as those with Alzheimer's disease, who are known to have a higher risk of hip fracture.

In March 2000 the NIAMS and other NIH components will hold a Consensus Development Conference on osteoporosis to address many key questions and to bring a focus to scientific opportunities that could be pursued in this major public health problem that compromises daily activities for millions of Americans of all ages. The information that comes from this Conference will be broadly disseminated to physicians and other caregivers, as well as to the public.

SYSTEMIC LUPUS ERYTHEMATOSUS

In genetic studies of lupus, researchers have found an association between the disease and a region on chromosome 1. Fine mapping of this region has identified another candidate gene involved in immune function. Studies of the genetics of lupus may identify potential therapeutic targets and may facilitate the development of markers of disease activity. While medical research has certainly made a significant difference in the daily lives of people (primarily women) with lupus, this remains a major public health problem that compromises the quality and longevity of life for many Americans. In addition to the many systems of the body that are affected, patients with lupus also have a higher risk of neuropsychiatric manifestations and accelerated atherosclerosis. In 1999 the NIAMS sponsored workshops in both of these areas, and we intend to follow-up on the many excellent recommendations from experts who participated in these two meetings.

SKIN DISEASES

Gene therapy has potential for treating many skin diseases, diseases that significantly compromise daily life for millions of Americans both physically and psychologically. In addition, skin can also serve as a factory for the production of molecules including hormones such as insulin and human growth hormone that are used in the treatment of many systemic diseases. Skin provides a number of advantages for gene therapy approaches, including the ability to remove genetically altered skin by simple excision if problems develop. The NIAMS is supporting a scientific conference in March 2000 to increase the level of interest in gene therapy using skin and to identify scientific opportunities and needs in this area.

HEALTH DISPARITIES

While we know that disease can strike people at every age, of either gender, and in every ethic group, we also know that many diseases affect women and members of minority groups disproportionately—both in increased numbers and increased severity of the diseases. Even if variables such as socioeconomic status, access to health care, and insurance coverage are eliminated, the fact remains that diseases like lupus, scleroderma, osteoarthritis, and vitiligo all account for disparities in the health of women and minorities. We are actively seeking to understand the causes of these gender and ethnic differences, and we are expanding our commitment to better understanding of health disparities. We are also increasing our efforts to disseminate health information to minority populations and have established a toll-free line in both Spanish and English as well as produced a number of our publications in Spanish. Plans are underway for a workshop to address promising opportunities for research in this area. In addition, members of our Intramural Research Program are designing an outreach program targeted toward the minority community. While it is still in preliminary stages, it will ultimately include both local and national outreach efforts.

CONCLUSION

Bones, joints, muscles, and skin are central components of the human body. When the functions of any of these areas are affected, the daily lives of people are compromised. We are committed to continuing to support basic research as well as the many clinical studies underway, including those exploring the roles of genetics, the environment, diet, and behavior in disease. I cite our scientific achievements with pride, and I pledge to continue my commitment to support high quality science that will continue to improve the health of the American people.

The NIH budget request includes the performance information required by the Government Performance Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

I will be happy to answer any questions you may have.

PREPARED STATEMENT OF DR. JAMES F. BATTEY, JR.

Mr. Chairman and Members of the Committee, I am pleased to present the President's non-AIDS budget for the National Institute on Deafness and Other Communication Disorders (NIDCD) for fiscal year 2001, a sum of $276.4 million, which reflects an increase of $14.3 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIDCD is $278 million, an increase of $14.3 million over the fiscal year 2000 appropriation. Funds for the NIDCD efforts in AIDS research are included within the Office of AIDS Research budget request. Within the last year, we have witnessed outstanding research progress in human communication and communication disorders by NIDCD-supported scientists and clinicians, progress further accelerated by the efforts of other NIH institutes.

DEVELOPMENT

How Inner Ear Hair Cells Grow.—In humans, auditory sensory cells (hair cells) and other internal parts of the ears develop within the third month of development. These fragile, highly specialized cells, which are essential for the hearing process, are often damaged or lost as a consequence of noise, genetic mutation, drugs or other environmental insults. The resulting hearing impairment is permanent, since these cells do not regenerate in humans. NIDCD-supported scientists are examining the cellular and molecular processes that direct progenitor cells to differentiate into hair cells, leading to new approaches to stimulate hair cell regeneration after damage. These investigators have shown that in the mouse, the Math1 gene is essential for regulating the development of hair cells and progenitor cells. These findings provide novel insight into the molecular mechanisms regulating hair cell differentiation and specification.

INFANCY AND CHILDHOOD

Better Procedures to Screen Infants for Hearing Impairment.—The American Speech-Language-Hearing Association estimates that as many as 12,000 infants each year in the U.S. are born with significant hearing loss, making it a common congenital disorder. Research supported by NIDCD has shown that detection of hearing impairment and intervention within the first six months after birth is very important for optimizing language development in young children. In a five-year, multi-center study, NIDCD-supported scientists determined the optimal test procedures for neonatal hearing screening. This study was the first controlled comparison of normal hearing and hearing-impaired infants evaluating physiological responses to sound. The development of precise and timely diagnostic screening techniques for hearing impairment is the first step in providing early intervention strategies that will optimize the development of either spoken or signed language skills. The NIDCD is supporting research to develop and validate intervention strategies that are tailored to the individual with hearing impairment.

Hereditary Hearing Impairment—Gene Discovery and Implications.—Not only is hearing screening becoming available to all newborns, breakthroughs in medical genetics will enable scientists to identify the precise genetic change leading to hereditary hearing impairment. NIDCD-supported scientists have learned that about one-third of all recessive hereditary hearing impairment within the U.S. is caused by mutations in the GJB2 gene. But further studies have shown that there is significant variation in the degree and time-of-onset of hearing impairment among individuals with exactly the same mutation in both GJB2 genes. Given this variation, it would be difficult to predict onset and degree of impairment in these infants using only data from a GJB2 genetic test. The NIDCD is interested in pursuing areas of research to develop and validate diagnostic genetic tests, to assess the potential impact of genetic testing and the utilization of genetic information on attitudes and behaviors of various cultural groups and individuals.

Otitis Media—Vaccine Development and Genetic Susceptibility.—In an NIDCD-supported study, scientists have discovered that there is a strong heritable component to prolonged time with and recurrent episodes of otitis media (middle ear infection) in children. The results of this study may have future implications for primary care physicians to identify children and siblings at high risk for otitis media for careful monitoring and early intervention. In addition, with the recent emergence of antibiotic resistant bacterial isolates, it is clear that the best long-term strategy for otitis media is prevention. NIDCD scientists have developed a detoxified lipooligosaccharide-protein conjugate to be used as a possible vaccine against nontypable *Haemophilus influenzae*, a leading cause of otitis media in children for which there is no vaccine currently available. A Phase I clinical study is nearing completion in adult volunteers to evaluate the safety and potential efficacy of the investigational vaccine. Preliminary data from this study show that the vaccine is able to elicit the production of specific antibodies against the bacteria in a number of volunteer subjects. The results of this trial suggest that this investigational vaccine may be useful for preventing otitis media in children.

Cochlear Implants May Improve Language Achievement in Children.—The cochlear implant is an array of electrodes that converts sound into electrical impulses that stimulate the acoustic nerve, restoring the perception of sound. It is the only neural prosthesis in widespread clinical use with over 20,000 recipients, about one-half of whom are children. Scientists supported by the NIDCD conducted a study to measure language achievement in children with cochlear implants. The study, comparing a group of children who had received cochlear implants and a second group who were using hearing aids, showed significant differences in language achievement levels favoring the children using cochlear implants.

Improved Methods for Diagnosing Early Childhood Stuttering.—Stuttering is a disorder that typically begins between the ages of 2 and 5. When it persists, the disorder causes serious impairment in verbal communication that is often associated with significant difficulties in emotional and social adjustments. NIDCD is supporting a large-scale longitudinal investigation of children who stutter to examine various aspects of stuttering as it persists or subsides during childhood. In addition, the study is identifying risk factors that can help differentiate between children who develop persistent stuttering and those who tend to recover. The data reveal a strong genetic component to stuttering and differences in genetic liability between different subsets of children who stutter. Based on these findings, NIDCD-supported investigators have initiated a genetic association study to map and identify the genes that predispose individuals to stutter.

Defining and Identifying Specific Language Impairment in Children.—Specific Language Impairment (SLI) is a language disability observed in the absence of any other cognitive disorders, affecting as many as 8 percent of all kindergarten-age children. Research to understand and treat SLI has been hampered by the lack of uniformity in the definitions and measures that are used to identify preschool-aged and older children, adolescents or adults with SLI. NIDCD-supported researchers have developed definitional guidelines and research directions that will lead to enhanced abilities to diagnose and assess SLI, determining that a brief non-word repetition task is a powerful predictor of SLI. This test differentiates between children who will benefit from language intervention and children who will not require intervention to achieve normal language skills.

Eliminating Health Disparities in Hearing and Language Disorders.—As research moves forward to reduce the burden of disease in America, the NIDCD is committed to the idea that all segments of American people should benefit from this progress. In comparison to the general U.S. population, Native American children have one of the highest rates of otitis media. The NIDCD is continuing its support of a study on the epidemiology of this disorder and hearing loss among Native American infants, from birth to age two, at the White Earth Reservation in Minnesota. Recent assessment shows that intervention programs should focus on parental smoking as a significant risk factor for otitis media in Native American infants. The study also includes the development and implementation of prevention strategies to reduce the burden of otitis media such as promoting breastfeeding.

Treatment for Deafness Caused by Neurofibromatosis Type 2.—The NIDCD is conducting research on neurofibromatosis type 2 (NF2), a genetic disorder that often results in bilateral tumors of the acoustic nerves causing deafness in children and adults. Scientists supported by the NIDCD have determined that specific mutations in the NF2 gene result in different levels of severity of the disease. This finding will facilitate early DNA-based diagnoses that will improve disease management and increase the preservation of hearing in NF2 patients. For many individuals with NF2, surgical intervention required to remove tumors also involves resection of both acoustic nerves, so that sound perception cannot be restored with cochlear implanta-

tion. To help these individuals, NIDCD is supporting research to develop a specialized auditory prosthesis for NF2 patients. Multiple, ultraminiature microelectrodes have been implanted directly into the ventral cochlear nucleus of animals, the portion of the central auditory system where the acoustic nerve fibers once made connections. These animal studies have demonstrated the safety of this technique and deaf NF2 patients are now scheduled to be fitted with these devices within the next few years with the hope of restoring auditory perception.

ADULTHOOD

The Hazards of Noise-Induced Hearing Loss.—When an individual is exposed to sounds that are too loud, the hair cells needed to detect sound in the inner ear can be damaged, resulting in noise-induced hearing loss (NIHL). NIHL is a major health concern, but it is preventable. In a public outreach effort, the NIDCD has launched the "WISE EARS!" campaign, where a national coalition of over 60 government agencies, public organizations, businesses, industries and unions is working to inform the public about the risk of NIHL.

Molecular Mechanisms Governing Our Sense of Taste.—In humans, the loss of taste sensation can contribute to the loss of appetite and poor nutrition, a particularly common problem for older Americans. In a collaborative effort joining molecular biologists supported by the National Institute of Dental and Craniofacial Research, NIDCD, and investigators at the University of California, San Diego, candidate sweet and bitter taste receptors have been cloned and characterized. These receptors are selectively expressed in a non-overlapping subset of taste receptor cells on the tongue. This research is an important step in determining the molecular pathway activated by sweet and bitter substances, and will guide future research studies in identifying additional molecules in this poorly understood pathway.

Genetic Association and Age-Related Causes for Hearing Loss.—A recent NIDCD-supported study has demonstrated that a genetic component exists for age-related hearing loss. It is likely that different mutations in the same genes that cause profound hereditary hearing impairment in children also cause age-related hearing loss (presbycusis), a common problem for older Americans. With the ability to predict who is at increased risk, better strategies to minimize or delay hearing loss within the aging population can be developed.

NIDCD/Department of Veterans Affairs Hearing Aid Clinical Trial Yields Important Results.—The prevalence for hearing impairment significantly increases with age and hearing aids are the most common means of assistance for persons with hearing loss. The Department of Veterans Affairs and the NIDCD conducted a multi-center trial, which included elderly volunteers, to compare the efficacy of three commonly used hearing aid circuits. Data from the trial showed that performance differences among the three hearing aid circuits were minimal. Of greater importance, the trial demonstrated that each circuit improved speech recognition with improvement observed under both quiet and noisy listening conditions. NIDCD remains committed to support research leading to smaller and better hearing aids, capitalizing on bioengineering advances in microelectronics.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. STEVEN E. HYMAN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Mental Health (NIMH) for fiscal year 2001, a sum of $896,059,000, an increase of $50,083,000 (or 5.9 percent) above the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIMH is $1,031,353,000, an increase of $56,680,000 over the fiscal year 2000 appropriation. Funds for the NIMH efforts in AIDS research are included in the Office of AIDS Research budget request.

AREAS OF NEW INVESTMENT

This has been a remarkable year for the NIMH, both in our development of scientific programs and in our ability to contribute to public understanding of mental illness. Thanks to a healthy increase in our budget, we expanded our new Translational Centers program, which aims to bring basic science as rapidly as possible into the clinical arena. We built on our investment in studies of genetic risk

factors for schizophrenia, manic depressive illness, and early onset major depression, with particular emphasis on expanding our gene repository for research on autism. We initiated two major clinical trials, one on best use of new antipsychotic drugs and one on the treatment of individuals with depression who do not benefit from standard, initial treatments. We reported the findings of a multi-site collaborative study on treatment of attention deficit hyperactivity disorder, a public health problem of immense concern to parents, teachers, and health care providers, and we have initiated epidemiologic studies that will enable us to address disparities in mental health treatment outcomes with ever greater effectiveness.

HEIGHTENED PUBLIC AWARENESS OF MENTAL ILLNESS

Growing recognition that mental illnesses are real diseases of an organ, the brain; that they are diagnosable and treatable; that they represent an enormous public health burden—for example, depression is the leading cause of disability in the United States; and that current treatments can have an enormous impact on diminishing that burden spurred several important public education efforts in 1999. These included the White House Conference on Mental Health and Mental Illness, and the Surgeon General's Report on Mental Health, the first-ever on this topic. Responding to a report from the National Center for Health Statistics that 31,000 Americans committed suicide in 1996, more than half again the approximately 20,000 U.S. homicides that year, the Surgeon General issued a Call to Action to Prevent Suicide, which now is the ninth leading cause of death in the U.S. and, as the Centers for Disease Control reports, the third-leading cause of death among 15 to 24 year old Americans. NIMH has been privileged to play a critical role in providing scientific data and educational materials for all three of these activities.

We have come far in the science of mental illness and mental health, but we still have much to learn. We are thankful that the generous support of the American people, through the Congress, has made it possible to attack difficult problems at many levels. Perhaps most critical to our long-term goals of curing—and ultimately preventing—serious and disabling diseases like autism, schizophrenia, manic depressive illness, depression, anxiety disorders, and eating disorders, is our enhanced ability to expand long-term investments aimed at understanding the fundamental organization of brain and behavior. This is a time of remarkable progress in molecular and cellular biology, systems-level neurobiology, and cognitive neuroscience, and a time of unparalleled opportunity afforded by technologies ranging from gene chips to noninvasive neuroimaging. As our basic science matures, we have initiated programs aimed at speeding and enhancing the translation of that basic science into clinical applications.

CENTERS FOR TRANSLATIONAL SCIENCE

What do I mean by "translational science?" Let me describe briefly how several projects at one Center link basic and clinical research. Collaborating scientists at the University of Pittsburgh and Carnegie Mellon University are testing a hypothesis that certain abnormalities in thinking (or cognition) that are characteristic of schizophrenia reflect an impairment of functions in a particular brain region, the dorsal lateral prefrontal cortex. This disorder typically strikes in the late teen years or early twenties—just when families and, indeed, society are completing their investment in the education of a young person. Thus, this project is examining in animal models and in clinical research how the brain's circuitry changes over the course of development and, particularly during adolescence. Since both genes and environment influence brain development, one component of this study uses new gene chip technologies to examine how genes influence the circuitry of the prefrontal cortex; using the new chip technology, the investigator can determine which genes have been active and which have been suppressed in the post-mortem brains of patients with schizophrenia compared with normal controls; a similar gene analysis is being done with adolescent monkeys. Other facets of the project involve studies of a neurotransmitter, dopamine, that plays a critical role in memory functions served by the prefrontal cortex, and functional brain imaging studies of patients with schizophrenia and controls, with the aim of determining the extent to which cognitive abnormalities can be ascribed to the effects of dopamine on frontal cortex. What's exciting is that each of these discrete projects is addressing fundamental biological questions, allowing investigators to relate findings obtained from basic animal studies to clinical research with an unprecedented degree of coordination. Given the awesome complexity of the brain, we believe that team efforts like this have the best chance of understanding what goes wrong in the brain in schizophrenia.

In another Translational Center, investigators are exploring the relationship between fear and stress in animal models; a key aim is to determine whether the ef-

fects of stress on fear circuits mimic changes that occur in fear-related disorders in humans, such as post-traumatic stress disorder, anxiety and panic disorders, and paranoid schizophrenia. Investigators at NYU, Columbia University, and Rockefeller University, are using an identical behavioral paradigm—fear conditioning—to examine fear circuits from multiple perspectives, in animal and human studies. One effort that will benefit immensely from its interaction with other Center studies will follow up on findings that acute and chronic stress inhibits neurogenesis—that is, the generation of new neurons in the adult brain. This question has extraordinary ramifications for understanding mental disorders and refining treatments.

IDENTIFYING VULNERABILITY GENES FOR MENTAL DISORDERS

We have greatly augmented our investment in the genetics of schizophrenia, manic depressive illness, major depression, autism, and other mental disorders. It is now certain that these disorders have a genetic component, but solving the genetics and identifying disease vulnerability genes is extremely difficult because vulnerability to these disorders results from the effects of many genes, each contributing relatively small and interactive effects, as opposed to an illness, such as Huntington's disease, in which a single gene contributes a large effect. However, as we have learned from other central nervous system disorders, such as Alzheimer's disease, the discovery of vulnerability genes can lead to the identification and validation of exciting new targets for development of therapies. During the coming year, all of our genetics efforts will be aided by the sequencing of the human, mouse, and other animal model genomes and by ongoing projects to investigate human genetic diversity, especially as it might apply to disease risk.

TREATMENT RESEARCH ON AUTISM

Pending findings from the genetics studies that I mentioned, NIMH remains deeply committed to improving treatments currently available for autism, a brain disorder that affects between 1 to 2 of every 1,000 Americans, with often devastating, lifetime effects on thinking, feeling, and social functioning—all uniquely human attributes. A network of five NIMH-supported psychopharmacology research units are evaluating drug treatments for autism, such as risperidone and valproate. Among studies of psychosocial treatments in autism, we fund two projects evaluating parent training interventions that are tailored to the particular characteristics of child and family. Of course, we participate in the NIH Autism Coordinating Committee.

NEW CLINICAL EFFECTIVENESS TRIALS

During the last fiscal year, NIMH has initiated large-scale clinical trials on the best use of new antipsychotic medications and the treatment of individuals who failed to respond to initial antidepressant treatments. Along with our ongoing trials in adolescent depression and in bipolar disorder, which we initiated over the past two years, this thrust represents a substantial recommitment to clinical treatment studies for people with mental illness. These particular studies represent a new frontier in clinical treatment research because they will study truly representative samples of individuals with mental disorders. That is, eligibility for participating in these treatment studies no longer is limited to rarified populations within academic health centers, but is open to general populations in diverse health care settings. This new approach requires NIMH take great care to observe appropriate stewardship of the trials while our field develops the infrastructure and expertise to conduct such trials. In future years, we hope to expand this program to address such issues as depression in young children, and mood disorders that co-occur with psychotic disorders. We are also interested in cross-NIH collaborations to focus on co-occurring substance use problems with mental disorders.

RESEARCH ON YOUTH VIOLENCE

As recognition grows that violence by young people represents a public health problem, we are encouraging a new generation of studies that will attend, particularly, to the relationships between mental disorders and violence, including suicide. We know that anxiety disorders, depression, or suicidal ideation often co-occur with behavior problems, and that the combination of depression with conduct problems may be a combustible mix. Also, youth with conduct problems often exhibit inattention and impulsiveness, often coexisting with hyperactivity. We are coordinating our research involving dissemination of prevention and early intervention strategies with the Centers for Disease Control and other federal agencies, including the departments of Education and Justice. Finally, I am pleased to report that NIMH will assume a lead role in developing a Surgeon General's report on the topic of youth

violence. Dr. Satcher and, indeed, all of us have been gratified by the overwhelmingly positive response of the American public to the Surgeon General's Report on Mental Health, and we believe this follow-up report will be an effective and highly credible means of educating the public about the interaction of mental disorders and youth violence.

MULTI-MODAL TREATMENT ASSESSMENT OF ADHD

In December, NIMH and collaborating investigators reported findings from the landmark Multi-Modal Treatment Assessment Study—the MTA study—of attention deficit/hyperactivity disorder, a major public health problem that affects 3–5 percent of school children. The experiences of 600 children enrolled in the study revealed that carefully monitored medication management, with monthly followup and input from teachers, is more effective than intensive behavioral treatment. For measures such as improved academic performance and family relations, combining behavioral therapy and medication proved effective and satisfying to parents and teachers and permitted somewhat lower doses of medication. Among the important insights of the MTA study was documentation of the extent of undertreatment or inappropriate medication treatment in normal, community-based care.

RESEARCH ON HEALTH DISPARITIES

A primary goal of NIMH and NIH research is to ensure that advances in treatment benefit all Americans, including racial and ethnic minorities who experience significant disparities of outcomes with respect to many illnesses. Within the past year, NIMH conducted the first two of a projected series of State-wide conferences on mental health needs and opportunities that permit us to hear, first-hand, citizens' perspectives on health disparities. We initiated a large-scale study of the epidemiology of mental disorders among African Americans and plan on parallel studies to understand the epidemiology of mental disorder in other minority groups. These studies will complement a new, state-of-the-science epidemiologic study of mental disorders in the broader population that will be funded under a 5-year, $7.3 million dollar grant to investigators at Harvard University who will survey a representative sample of 10,000 Americans ages 15 and over. For several decades, NIMH has set the standard for modern mental health epidemiologic research, and this new study will ensure that we have data necessary to allocate resources and design policies in this era of massive change in the U.S. health care system.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will support the identification of strategies and objectives to improve programs across the NIH and the Department.

NIMH is committed to a research portfolio that stretches from molecules and genes to brain and behavior to clinical investigation to health services research and economics. This research portfolio is thriving thanks to the development of new scientific approaches ranging from genomics to neuroimaging to new clinical trial designs. In parallel, we have been able to renew our Institute structure and also the vitality of our Intramural Research Program by a combination of rigorous review and recruitment of outstanding scientists. I look forward to this new millennium with humility about the scope of the problems that we must address but great optimism about the ability of our research community to meet the challenge.

I will be pleased to answer any questions.

PREPARED STATEMENT OF DR. ALAN I. LESHNER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Institute on Drug Abuse (NIDA) for fiscal year 2001, a sum of $496.3 million, which reflects an increase of $27.1 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NIDA is $725.5, million an increase of $38.1 million over the fiscal year 2000 appropriation. Funds for the NIDA efforts in AIDS research are included within the Office of AIDS Research budget request.

BUILDING ON RECENT ACCOMPLISHMENTS

Thanks to the commitment of both the Administration and the Congress, including particularly this Committee, NIDA has been able to launch some truly significant activities in the past year. Perhaps the most noteworthy undertaking has been establishing the foundation for a vehicle that will increase dramatically the quality of drug addiction treatment throughout this country. Last year, we promised to build a National Drug Abuse Treatment Clinical Trials Network (CTN) to test and disseminate new science-based addiction treatments in real life settings. I am pleased to be able to tell you that we not only have established the first five nodes of this Network, but are about to begin implementing the first three protocols. Moreover, adding five more nodes to this infrastructure this year will take the CTN one step closer to becoming the truly national research and research dissemination network that we know it can and should be. Under NIDA's overall guidance, the CTN will foster partnerships between treatment researchers and community-based treatment providers to move well-tested science-based addiction treatments into use in diverse patient settings.

We are also building other areas of our research portfolio to better inform how this country approaches drug addiction, including looking more closely at the role genetic factors may play in determining the likelihood someone will become addicted to drugs. In the same way we are making great progress in understanding how genetics can predispose one to cancer, heart disease, or diabetes, drug abuse researchers are making similar advances in the addiction arena as well. By better understanding the factors determining an individual's vulnerability to addiction, our treatment and prevention success rates will dramatically improve.

The research community is committed to this endeavor. The response to NIDA's "Genetics of Drug Addiction Vulnerability" Initiative has been overwhelming. We were able to fund five new grants last year to examine the role of genetics in nicotine, cocaine, and heroin addiction, and we hope to support in the coming years some of the other outstanding proposals we received in response to this initiative.

LONG-TERM NEUROBEHAVIORAL EFFECTS OF DRUGS OF ABUSE

Advances within NIDA's neuroscience research portfolio also continue coming at an accelerated pace. Let me give you one example of how far our science has come since last year's appropriations hearing. You may recall that I showed you images of how drugs, such as methamphetamine and MDMA (Ecstasy), produce long-lasting changes in brain function, changes that persist even years after the individuals stopped using the drugs. Researchers have now taken those research findings one step further and have begun to unravel exactly how these brain changes dramatically affect an individual's behavior.

For example, researchers studying the residual effects of methamphetamine in users who were drug free for ten months before this study began, found that they had significantly impaired motor and memory function. When they were asked to complete a battery of tests that examined working memory and reaction times, as well as verbal memory skills, these former methamphetamine users did far worse than non-drug-using individuals. Importantly, the researchers also found that the impaired memory in the former users was clearly associated with significant reductions in the functioning of the brain's dopamine neurotransmitter systems, in this case the number of dopamine reuptake transporters. And the study showed that the greater the degree of transporter loss, the greater the memory deficits.

Researchers at NIDA's intramural program have found similar cognitive deficits with chronic cocaine abusers. Thus, these studies are clarifying how it is that illicit drugs compromise cognitive and behavioral abilities.

NIDA-supported researchers are not just using new imaging and molecular genetic technologies, they are also making significant contributions to the field by advancing the technology themselves. This is best exemplified by our efforts in the fast paced world of nanotechnology. For example, NIDA-supported researchers recently developed a biosensor system to analyze what is happening inside a single cell. These techniques are allowing us to see how important neurotransmitters like dopamine are stored and can move in and out of cells. This opens up many new avenues of research; allowing us to see with much greater resolution the impact that drugs of abuse have on the brain.

DETERMINANTS OF DRUG USE PREFERENCES AND PATTERNS

Understanding why some individuals abuse drugs while others do not and why some develop more problematic drug use than others are some of the most challenging dilemmas being probed by researchers today. As we bring new and improved

technologies and new groups of researchers into the search for answers to these questions, we are beginning to unveil some important and astonishing results. For example, using the advanced brain imaging technique of positron emission tomography (PET), researchers have found the first clues as to why some individuals are prone to use stimulant drugs and why some are not. As an example, as shown in POSTER 1, these studies have shown a dramatic association between an individual's pre-drug exposure brain dopamine receptor levels and how much the individual reports "liking" or "disliking" a psychostimulant. Here you see two individuals with different levels of dopamine D2 receptors shown before any drug exposure. (Brighter colors represent higher numbers of receptors). The individual whose brain is shown on top and who had high levels of D2 receptors reported an unpleasant response to the mild stimulant methylphenidate. On the other hand, the individual on the bottom, with low D2 receptor levels, found the stimulant quite pleasant. This suggests that differences in brain chemistry predisposes people to respond in different ways to drugs of abuse.

UNDERSTANDING THE TRANSITION FROM DRUG USER TO ADDICT

In past years, we also have shown you data clearly indicating that we know quite a bit about both the behavioral and the biological differences between addicted and non-addicted individuals. What we do not know much about, however, is the literal transition that occurs between these states. What is actually happening both behaviorally and biologically when one moves from being an occasional to a compulsive, addicted drug user? What changes an individual from a voluntary to a compulsive drug user? Understanding this transition is central, of course, to developing more effective addiction prevention and treatment strategies, and its importance has led NIDA to develop a focused "Transition to Addiction" initiative.

NIDA-supported researchers will approach these issues from many disciplinary perspectives. As just one example, they will use new molecular biology techniques, such as microarrays, to build on recent discoveries from animal studies suggesting that gradual increases in the levels of a specific brain protein, delta Fos B, are a critical part of this transition process. We know that this protein triggers the expression of other genes and the use of this technology will help identify which genes are expressed, when, and where in the brain.

RESEARCH BRINGING ABOUT SHIFTS IN NATIONAL STRATEGY

Scientific advances have not only improved our fundamental understanding of addiction, but continue to reduce many of the public health and safety consequences of this destructive disease as well. Nowhere is this better exemplified than in the philosophical shift in strategic thinking about drug abuse and its consequences that is occurring throughout many levels of society. A case in point is how advances in addiction research are leading to a blending of criminal justice and health approaches to dealing with drug abuse and criminality. NIDA-supported research has demonstrated that treating drug users while under criminal justice control dramatically reduces recidivism to both later drug use and later criminality by 50 to 70 percent. This finding is one of the reasons why NIDA and other facets of the Department of Health and Human Services have teamed with the Justice Department to work toward making drug abuse treatment more commonplace in the criminal justice environment.

ADDRESSING HEALTH DISPARITIES

Members of minority populations are disproportionately affected by the consequences of drug abuse. Accordingly, NIDA is taking extra effort to understand the causes of and contributing factors to these inequalities and working to ensure that minority issues are addressed and minority populations are adequately represented not only in NIDA's comprehensive research portfolio, but in our research communities as well. NIDA supports a wide array of programs to recruit minority populations into drug addiction research fields. In fact, NIDA has increased the number of supported minority researchers by 97 percent in the past six years. In the last few years, NIDA has also put together three new working groups representing African-American, Asian-Pacific Islander, and Hispanic researchers and scholars to help recruit and train new minority investigators and improve the quantity and quality of minority-related research.

These working groups are helping NIDA expand opportunities for working with scholars who are most knowledgeable about these populations. Minority researchers will be particularly helpful as NIDA increases its efforts to study the impact and health consequences of drug abuse in minority populations. By simultaneously in-

creasing research and research training efforts, NIDA expects to make significant improvements in racial and ethnic disparities.

RAPID AND AUTHORITATIVE RESEARCH DISSEMINATION EFFORTS

As the world's ability to exchange information expands exponentially, NIDA continues to take full advantage of these opportunities to disseminate science-based information more effectively and rapidly to a wide variety of audiences. For example, when one of our early drug warning systems, NIDA's Community Epidemiology Work Group, noted increases in the use of "club drugs" such as methamphetamine and ecstasy among adolescents and young adults, NIDA initiated a multi-element research and education campaign to stave off further growth of this problem. NIDA will increase funding for relevant research by 40 percent. In addition, the Institute has joined with an array of partners in the drug abuse professional and constituency communities to launch a multi-media education campaign as well. We developed and disseminated a community drug alert bulletin that has been sent to over 150,000 people, developed a new website (www.clubdrugs.org), and teamed with the American Academy of Child and Adolescent Psychiatry, the Community Anti-Drug Coalitions of America, Join Together, and National Families in Action to hold a national meeting to increase awareness and attention to this problem, share research findings, and identify research gaps.

We also have taken an idea from what has become a NIDA bestseller, our Prevention booklet, "Preventing Drug Use Among Children and Adolescents: A Research-Based Guide," and created a corresponding "Principles of Drug Addiction Treatment: A Research-based Guide." Since the guide debuted in October, more than 100,000 copies have been disseminated. This lay language booklet provides health care providers, patients, families, and policy makers with the latest science-based information on drug treatment. It describes the nature of addiction and the addiction treatment enterprise, and then outlines 13 overarching principles that characterize effective drug addiction treatment.

We are also taking full advantage of other dissemination opportunities. In fact, we are doing exactly what members of this Committee encouraged us to do last year. We are taking state-of-the-art brain scans showing the effects of drug abuse and addiction and using them as the core of a multi-media public education campaign. What you see here is a portion of a story board (POSTER 2) for one of our public service announcements emphasizing how drug use can damage your brain in important ways. In addition to using powerful images, we are using findings from the prevention research arena on what works and what does not work to develop persuasive, and scientifically accurate messages. We plan to send these messages to television outlets nationwide this spring.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

CONCLUSION

In conclusion, NIDA is taking advantage of emerging technologies to confront the disease of addiction head on. Our comprehensive research portfolio, our track record in sharing our research findings, and a continued commitment from the Administration and the Congress to furthering the science will serve as this Nation' s best defense against this devastating public health and safety plague. I will be pleased to answer any questions you might have.

PREPARED STATEMENT OF DR. ENOCH GORDIS

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the NIAAA for fiscal year 2001, a sum of $288,578,000, which reflects an increase of $14,587,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NIAAA is $308,661,000, an increase of $15,427,000 over the fiscal year 2000 appropriation. Funds for the NIAAA's efforts in AIDS research are included within the Office of AIDS Research budget request.

Nearly 14 million American adults meet diagnostic criteria for alcohol addiction or abuse, and 100,000 Americans die of alcohol-related causes each year, according to NIAAA epidemiology data. While death is the ultimate consequence of alcohol-use disorders, their impact on the living, in sheer numbers, is even greater. The NIAAA's epidemiology research reveals that 442,000 people occupy hospital beds each year as a result of these disorders. The financial burden that alcohol misuse imposed on the Nation in 1998 was approximately $185 billion, in direct and indirect costs, according to the Lewin Group. The sequelae of alcohol-use disorders include damage to the liver, brain, and other organs; cancer; fetal alcohol syndrome and the lifetime disabilities it produces; accidental injury to self and others; property damage; crime; broken families; and loss of productivity that deprives the Nation of valuable resources.

Biological, behavioral, and social factors converge to produce alcohol-use disorders, making them particularly complex diseases. In terms of biology, alcohol is unique among addictive substances, in that it targets not just one but many neurotransmitter systems—chemical messengers between nerve cells—resulting in unusually pervasive effects on the entire nervous system and in unique challenges for scientists. Researchers have made striking advances in identifying the molecular structures where alcohol binds to these neurotransmitter systems and in learning how variations in genes determine alcohol's actions on them.

NEUROSCIENCE

Because alcohol's effects on the nervous system are so pervasive, neuroscience is a particularly active field of research at the NIAAA. One promising area involves neuropeptide Y (NPY), a substance in the brain that increases food consumption and relieves anxiety. Studies are underway to determine the role of NPY in controlling alcohol consumption. Preliminary studies suggest that NPY may, indeed, play a role in propensity for alcohol. Surprisingly, these studies revealed that mice in which the NPY gene was inactivated (knocked out) drank more alcohol than did their normal siblings and were less sedated by alcohol. If NPY is found to play a key role in human alcohol-use disorders, NPY and its receptors—its "docking sites" on cells—become potential targets for medications to control alcohol intake.

Physical problems from long-term alcohol use do not necessarily resolve once people stop drinking. Using new MRI techniques, researchers have found persistent damage in the cerebellum, the locus of gait and balance in the brain, even in long-abstinent alcoholics. Previous anatomic measurements of cerebellar damage were difficult, because of the cerebellum's convoluted structure, resulting in less accurate data. Scientists can use these new imaging techniques to clarify the potential for reversing cerebellar damage in recovered alcoholics and to explore a new topic: the role of cerebellar damage in cognitive impairment.

These and other findings from the NIAAA's comprehensive neuroscience portfolio reflect the ubiquitous nature of alcohol's effects on the nervous system. For example, research designed to identify the protein structures where alcohol binds to nerve cells may, one day, provide groundwork for development of better medications to treat alcoholism. In another protein-related finding, NIAAA-supported scientists have found that genes in the brains of deceased human alcoholics produced less of a crucial nervous-system protein, myelin, than did those in nonalcoholics. With this information, scientists can better define changes in gene activity that result in damage to specific areas of alcoholics' brains. Other investigators are identifying alcohol-related neurobiological risks that fluctuate during adolescence and that might be related to the higher risk of adult alcoholism predicted by earlier onset of drinking in the young.

GENETICS

That genetics underlies much of the biology of alcohol-use disorders is unquestionable. Variations in genes result in variations in many components of the nervous system, and, thus, in how people's bodies handle alcohol. The way in which people's bodies' handle alcohol affects, in turn, their behaviors toward alcohol and risk for alcoholism. Evidence suggesting that alcoholism is a polygenetic disease—that many genes contribute to it—greatly complicates the search for the genes involved.

The Collaborative Studies on the Genetics of Alcoholism (COGA), a major project supported by the NIAAA, has identified several chromosomal regions likely to contain genes that influence the risk for alcoholism. The NIAAA is pleased to announce that it is making available to the general scientific community the substantial data and DNA samples generated by COGA. Scientists who take advantage of these resources can analyze them further in their own research projects, expediting the search for genes that contribute to alcoholism. The data also can be used to evaluate

new methods of statistically analyzing genetic data, not only for alcoholism, but also for other diseases.

Among the goals of the COGA project is to elucidate the genetics of alcoholism in African Americans. While COGA recruits both Caucasian and African-American subjects, the latter have not been present in numbers large enough to permit a reliable examination of whether the genetic basis of alcoholism is different in Black Americans than in White Americans. Through a NIAAA grant, Howard University Medical School will study this question and contribute its findings to the growing COGA database.

Neuropeptide Y, discussed earlier, is one of more than 20 substances that NIAAA scientists study as gene knockouts, to determine their influence on alcoholism. Some of these substances are found to increase alcohol consumption; others are found to reduce it. A recent study examined the effects of knocking out, in mice, the gene that produces protein kinase C epsilon (PKC), an enzyme involved in intracellular signaling. Absence of PKC resulted in significantly less alcohol consumption and abnormally high sensitivity to alcohol's sedating properties. Insensitivity to alcohol's sedating effects is among the factors that portend alcoholism at some point in life. Since much of the mouse genome resembles the human genome, these types of findings may lead to clues about human genetic defects related to alcoholism.

TOXICOLOGY

Alcohol is unique among abused drugs in the extent of the organ damage it causes. Animal studies by NIAAA intramural researchers have demonstrated that chronic alcohol use leads to a decrease in essential fatty acids (EFAs), nutrients that play a crucial role in brain health. The same investigators recently demonstrated that EFA-deficient rats lose nerve cells in an area of the brain involved in memory and learning, another common result of chronic alcohol use. The NIAAA continues to perform research to evaluate the potential of EFA supplementation to reduce organ damage among alcoholics.

Between 40 percent and 90 percent of U.S. deaths from cirrhosis are due to alcohol, according to NIAAA epidemiology data. These statistics underscore the importance of understanding the potential for reversing this currently irreversible disease. Scientists suspect that an immune-system protein, tumor necrosis factorα (TNFα), plays a role in alcohol-induced liver damage. NIAAA-funded researchers recently found that alcohol-fed mice in which TNFα's molecular receptor had been genetically knocked out, eliminating TNFα's actions, suffered liver pathology seven times less severe than that of alcohol-fed mice with normal TNFα levels. This finding strongly supports the assertion that TNFα is involved in alcohol-induced liver damage and is lent even more significance by the recent development of pharmaceuticals that inhibit TNFα in the treatment of inflammatory diseases, such as arthritis.

ADVANCES IN PREVENTION AND TREATMENT

Recent studies illustrate what the NIAAA's prevention research can contribute to decisions about alcohol legislation. Many states have taken the important step of lowering their legal definition of drunkenness from a blood-alcohol concentration (BAC) of 0.10 percent to 0.08 percent. However, studies of simulated merchant-ship piloting by maritime cadets revealed that even half of that concentration, a BAC of 0.04, resulted in significantly impaired performance. The cadets failed to sense their decreased judgment, underscoring the hazards of alcohol use in the context of heavy-machinery operation and the workplace. Many states still allow people to drive cars with a BAC more than twice that of the alcohol-impaired cadets.

The public also benefits from prevention findings that the NIAAA provides to alcohol-treatment practitioners. Thirty percent of Americans are subjected to domestic violence at some point in their lives, according to studies published in the *New England Journal of Medicine* and funded by the National Institute of Mental Health, the Emergency Medical Foundation, and the UCLA Southern California Injury Prevention Research Center. NIAAA-funded investigators recently concluded, in the *Journal of Studies on Alcohol*, that a combination of behavioral marital therapy and standard treatment for alcoholism resulted in a six-fold reduction in domestic violence. Of significance here is not only the magnitude of reduction in violence, but also that the reduction is sustained, as investigators determined in a 2-year follow-up study.

In the treatment arena, NIAAA-supported studies reveal that the new medication nalmefene is at least as successful in preventing relapse among recovering alcoholics as is naltrexone, the recently FDA-approved drug of choice. Nalmefene may have advantages over naltrexone, including less risk of liver toxicity, providing another

option for recovering alcoholics whose livers have been damaged by alcohol. A Finnish company plans to seek FDA approval for this new medication.

ADOLESCENT ALCOHOL USE

During last year's hearings, the NIAAA reported that initiation of drinking earlier rather than later in youth is associated with a dramatically higher risk of alcoholism at some point in life. For this and many other reasons, the NIAAA continues to make drinking among adolescents a research priority. The "hard-wiring" of the brain is vulnerable to change during adolescence, including change caused by toxic substances. Investigators supported by the NIAAA have found that adolescent animals are less sensitive than adult animals to the motor-incapacitating and sedating effects of alcohol. This suggests that adolescents have higher drinking capacities, perhaps putting them at higher risk for alcohol-related problems. Other researchers have found that human youths who engaged in heavy, protracted drinking during early and middle adolescence, when compared with nonabusing adolescents of similar demographics, score significantly more poorly on neuropsychological tests, and that these deficient scores may persist. For example, young people who have withdrawn from alcohol recently have poor visuospatial functioning, and those who have withdrawn in the past show poor retrieval of verbal and nonverbal information.

The Washington Post and CNN recently reported another NIAAA finding: An estimated one in four U.S. children is exposed to alcoholism in the family. The stressful and unpredictable environment in such families can lead to a variety of problems in these children.

OUTREACH

In addition to conducting research on adolescent alcohol abuse, the NIAAA has taken a leadership role in the Surgeon General's campaign to prevent alcohol use among youth and engages in numerous outreach activities. Recently, the NIAAA issued a pamphlet that educates parents about alcohol use among youth, and this pamphlet now is being written in Spanish. The NIAAA also is collaborating with the Robert Wood Johnson Foundation to recruit governors' spouses in a *National Leadership Initiative to Keep Children Alcohol-Free*. In January, the NIAAA and Mothers Against Drunk Driving held two press briefings, one for editors of teen magazines and the other for editors of women's magazines. The NIAAA and the Substance Abuse and Mental Health Services Administration (SAMHSA) are preparing to award a grant for public-service announcements aimed at preventing underage drinking. In addition, prominent scientists and 10 college presidents have formed a subcommittee of the NIAAA Advisory Council, to identify ways of reducing binge-drinking among college students.

Other NIAAA outreach activities include Alcohol Screening Day, the first of which was held last year. Almost 500 college campuses were among the 1,700 sites that participated. Approximately 52,000 people attended, and 29,000 of them asked to be screened. This successful event will be held again on April 6, 2000.

To ensure that its research findings reach the people to whom they matter most—people who suffer from alcohol disorders—the NIAAA, in collaboration with State agencies and SAMHSA, cosponsors a Research-to-Practice initiative. Senior clinical investigators spend several days at alcohol-treatment facilities, giving staff hands-on help in incorporating innovations from basic and clinical research into their treatment regimens.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

My colleagues and I will be happy to answer any questions you may have.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Institute of Nursing Research (NINR) for fiscal year 2001, a sum of $84,714,000, which reflects an increase of $2,672,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NINR is $92,524,000, an increase of $2,985,000 over the fiscal year 2000 appropriation. Funds for the NINR

efforts in AIDS research are included within the Office of AIDS Research budget request.

I would like to thank the Committee for your interest and support for NINR and for nursing research. In this period of rapid technological and demographic change, it is imperative that nursing research grow to help meet present and future needs and expectations of our nation's people for improved health care. More people will live longer and face chronic illness and disabilities in older age. More will be caregivers who will need to know how to live their own lives while caring for ill relatives and friends. Many will be minorities at risk for experiencing disparities in the incidence, prevalence and seriousness of disease and access to care. How people live and how they experience illness will be influenced by new technologies in the healthcare system. Increasingly, they will demand a role in managing their own health. Individuals will appreciate the value of prevention, but will still need help in achieving healthier lifestyles. And virtually everyone wants to die with dignity and a sense of control. Today I will discuss our targets for fiscal year 2001 that relate to these concerns.

CHRONIC DISEASE—A LONG-RANGE VIEW ABOUT LONG-TERM ILLNESS

Chronic illness continues to be an important NINR research emphasis. We are investigating how to both avoid complications of disease and disability and control symptoms such as pain, nausea and poor sleep. Other studies will be directed at patients who are discharged early from the hospital and still need substantial care at home. A special focus will be on family caregivers, who have varying expertise and financial and complex care demands for multiple lengthy illnesses.

In addressing early hospital discharge, recent nursing research has verified the value of a transitional care model that has been tested in several patient populations. The model uses a multidisciplinary team and involves comprehensive discharge planning, including determination of patient care needs outside the hospital, and follow-up in the home by advanced practice nurses specializing in geriatrics. As the chart shows, six months following discharge, the intervention group of older adults with common medical and surgical problems had 48 percent fewer rehospitalizations, 54 percent fewer multiple hospital readmissions, and 65 percent fewer days in the hospital at a 48 percent savings to the healthcare system when compared to controls. Widespread use of this model could save significant healthcare dollars and improve quality of care.

Early hospital discharge has placed a research spotlight on family caregivers, who often undertake the responsibility for care of their ill relatives. Caregivers of Alzheimer's patients bear special burdens. They must cope with the physical downward spiral of illness, and they also must deal with the stress of patients' behavioral problems that include agitation, depression, and wandering. Nurse researchers have developed a successful intervention that offers behavioral management skill training to caregivers. Five months after the intervention, researchers found that caregiver stress continued to be reduced when coping with disruptive behaviors of older adults in their care. The study also showed a moderate decrease in caregivers' perceptions of their burdens in providing care. Furthermore, those who were initially depressed were less depressed. These positive results may be applicable to caregivers of patients with other chronic illnesses, such as stroke or congestive heart failure.

A life-long chronic illness that often starts in childhood, Type I diabetes, represents 5 to 10 percent of the total number of people with diabetes, and can seriously impact physical health and quality of life. Our research on adolescents with this condition compared two types of recommended intensive therapies—either multiple daily injections of insulin—three or more a day—or subcutaneous infusion of insulin delivered by insulin pump—a therapy which is currently used by fewer than 5 percent of young people. Adjusting to the insulin pump has been difficult for young adults, but when they are provided with an intervention consisting of instruction and support, the outcomes have been positive. Advanced practice nurses visited the adolescents every four to six weeks and provided them with diabetes education, adjustments in managing their diabetes and clinical assessments, including measurements of hypoglycemia and adherence to dietary restrictions. Investigators found that compared to teens on multiple daily injections of insulin, those who used the insulin pump had fewer severe hypoglycemic episodes and were able to maintain their blood glucose levels within the proper range. The "pump" group scores also showed better self esteem, coping skills, and quality of life. This finding identifies the education and support that enables adolescents to use the newer pump technology effectively.

NINR is committed to expand chronic illness research in fiscal year 200l to help patients manage their conditions over time. This involves a major investment of re-

sources. We will focus on strategies to be applied broadly across chronic illnesses, including prevention of disease and its complications, self-monitoring by patients of the course of their disease, and promotion of patient success in problem solving and in maintaining a healthy lifestyle.

THE END OF LIFE—AN EMERGING RESEARCH FOCUS

Just as biomedical advances are changing the way we live with illness, they are also changing the way we eventually die. The duration of both chronic illness and the dying process has been prolonged. In fiscal year 2001, we will expand our focus on end of life to better understand at what point palliative care becomes the primary goal. We also need to know how best to facilitate communication and decision making among all involved in the end-of-life period—the patient, nurse, physician, family, and friends.

NINR is pleased that the response to last year's Request for Applications for research on end-of-life care resulted in more than 100 applications—an impressive result for a relatively new area of research. Those that were funded will form a basis upon which to build an important, growing effort.

HEALTH DISPARITIES—CLOSING THE GAP

Another area of importance to nursing research and to the nation is reduction of persistent health disparities among certain populations in our country. We must provide interventions that are more responsive to the needs of our multiethnic and multicultural society. Nursing research has long incorporated ethnic and cultural factors in designing projects and testing interventions—with the goal of tailoring care to the individual patient's needs. Yet more research is needed to identify why disparities exist and what to do about them.

Let me provide an example of nursing research that addresses an area of disparity in a growing population. For many years, there were few resources available for Hispanics with arthritis to help them manage their condition. Limited fluency in English had the effect of excluding them from most health research projects. In response to this need, nurse researchers developed and tested a successful Spanish language arthritis education program. This endeavor was not limited to translation from English to Spanish. Cultural differences within Latino communities and accurate Spanish language measurement tools were also addressed. During the program, patients learned how to exercise, communicate with health care professionals, and manage pain, fatigue and depression. Throughout a one-year period, patients experienced significant improvements in all areas. The components of this course have provided a useful model that is being tested for Hispanic populations with coronary artery disease, chronic obstructive pulmonary disease, and Type II diabetes.

NINR plans to continue its ongoing programs next year to help eradicate healthcare disparities. We will focus specifically on diabetes and its gaps in morbidity across ethnic groups. We will emphasize strategies for effective self-management of illness, and investigate the influence on health of genetics, education, poverty, diet, behavior and social support. Another goal is to increase the number of well-trained investigators to conduct minority health research. To do this, we plan to expand core research centers and career development opportunities.

CLINICAL RESEARCH

Most nursing research studies are clinical in nature, although they can also involve basic research. An example of a recent finding concerns the use of feeding tubes to provide required nutrition. Every year an estimated one million hospital patients or residents of nursing homes are fed through use of feeding tubes. Incorrect insertion or dislocation of the tube may deliver food to the respiratory system, which can be fatal to the patient. Studies have shown that current clinical methods that rely on a stethoscope rather than X-rays for tube placement are correct only 6 to 34 percent of the time. Nurse investigators have discovered that an accurate, less costly alternative to both techniques is measuring pH and bilirubin levels in aspirated contents from the feeding tube. This method has identified the misplacement of tubes in lungs with 100 percent accuracy and is less expensive and safer than repeated X-rays.

Another important innovation for clinical research and practice is telehealth—a long distance technology to reach underserved areas, such as rural communities. NINR has been active in supporting telehealth studies for treatment and monitoring of patients and for providing health information. In the next fiscal year, NINR plans to expand research to determine the effects of telehealth on various patient populations and cost savings associated with telehealth strategies. We also plan to target

patients most likely to benefit from telehealth interventions, identify barriers, and find ways to integrate telehealth into other treatment and care regimens.

BUILDING NURSING RESEARCH CAPACITY

Next year provides an opportunity to initiate new programs to increase the nursing research capacity. In the current fiscal year, we are launching the Summer Genetics Institute for extramural researchers. This new eight-week training course emphasizes genetics in clinical practice, in the research laboratory, and in nursing curricula. Other training initiatives include an intramural career transition award that combines postdoctoral training with subsequent support for beginning research at an extramural institution.

NINR continues its collaboration with the Office of Research on Minority Health in a career development program for minority nurse researchers. Studies being carried out by these minority investigators include reduction of serious developmental problems of migrant infants, suicide prevention in a population of rural Indian youth, and improving screening for prostate cancer in African-American men. NINR is also collaborating with the National Coalition of Ethnic Nursing Associations on a workshop to identify important research questions and training needs for minority nurse scientists.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Prominent in the GPRA performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

CONCLUSION

In conclusion, health research, health care, and health choices are increasingly interdependent, and nurses and nurse researchers play a vital role in all three areas. Continued growth of nursing research is critical to meet public demands and urgent national health needs. Our contributions to the scientific foundation that nourishes the work of healthcare practitioners are already making a difference in health care or have significant potential to do so. This base of knowledge merits expansion in creative new directions. NINR looks forward to the challenge.

Mr. Chairman, I am pleased to answer any questions the Committee may have.

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Human Genome Research Institute (NHGRI) for fiscal year 2001, a sum of $353.4 million, which reflects an increase of $21.8 million over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the NHGRI is $357.7 million, an increase of $21.9 million over the fiscal year 2000 appropriation. Funds for the NHGRI efforts in AIDS research are included within the Office of AIDS Research budget request. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report that compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

This is my seventh appearance before this Subcommittee. I am again pleased to report that the Human Genome Project continues to be ahead of schedule and under budget. When I appeared before you last February, Human Genome Project scientists had just completed sequencing the DNA of the worm known as C.*elegans*; laying out the entire genetic code of an animal for the first time. At that time, 405 million base pairs of human DNA sequence had been deposited in GenBank by the large scale human DNA sequencing pilot projects that were initiated in 1996. These projects tested new ways to apply sequencing strategies to the large and complex human genome.

HUMAN DNA SEQUENCING

A lot has happened in a year. Following the success of the pilot projects, the NHGRI, the Department of Energy, and our international partners (the U.K., France, Germany, Japan, and China) initiated last March full-scale production sequencing of the 3 billion bases that comprise the human genetic instruction book. The newly tested sequencing strategies, coupled with advances in sequencing technology, provided the necessary foundation to begin full-scale production.

Later this year, this international consortium will produce a "working draft" of the human genome sequence, an essential resource for the whole research community. The working draft will provide 90 percent coverage of the human genome with an accuracy of 99.9 percent. Then we will move on to complete the final, highly accurate, finished human genome sequence in 2003 or sooner, two years ahead of the original schedule

All sequence data produced by the international consortium is deposited every 24 hours in GenBank, where it is freely available to any researcher with an internet connection, without restrictions on use. The rapid public availability of the sequence is invaluable to academic scientists studying the molecular basis of human health and disease, as well as corporate researchers engaged in drug development. By November 17, 1999, the consortium had deposited the sequence of one billion bases in the human genome. Today, over half of the sequence, approximately 1.7 billion base pairs of non-redundant sequence, resides in GenBank. This marks the production of over a billion base pairs of human DNA since last year's hearing.

To reach this milestone, Human Genome Project participants actually had to sequence over 12 billion base pairs of human DNA in overlapping pieces. As project manager, I know this could not have been done without the tireless work of the hundreds of dedicated scientists and technicians at the major sequencing centers. The largest five of these are referred to as the G–5 (the Whitehead Institute at MIT, the Washington University School of Medicine in St. Louis, the Baylor College of Medicine in Houston, the DOE's Joint Genome Institute in California, and the Sanger Centre in the U.K.) and will do about 85 percent of the work.

CHROMOSOME 22

The Human Genome Project achieved another historic milestone this year when an international scientific team announced the unraveling of the genetic code of an entire human chromosome for the first time. The 33.5 million base pairs of Chromosome 22 were published in the December 2, 1999 issue of the journal Nature. Research now will focus on determining what it all means. Sequencing and mapping efforts have already revealed that genes on chromosome 22 are implicated in the workings of the immune system, congenital heart disease, schizophrenia, mental retardation, birth defects, and several cancers including leukemia, but many more secrets will be discovered in this decoded text. The results of this work give scientists insights into the way genes are arranged along the DNA molecule and pave the way for major advances in the diagnosis and treatment of disease.

Until last year, scientists were uncertain about whether an entire human chromosome could be sequenced in this manner. For example, they did not know whether insurmountable problems would prevent completing the assembly of large stretches of contiguous sequence. The work done on chromosome 22 not only answered any doubts about the ability to sequence a chromosome, it validated the strategy being pursued by the publicly supported Human Genome Project in sequencing the entire human genome.

BEYOND THE HUMAN SEQUENCE

While laying out the precise sequence of the 3 billion letters of the human genome is an awesome and audacious undertaking, it is but one of the many important objectives of the Human Genome Project. The 5-year research plan published in the October 23, 1998 issue of Science outlines seven other ambitious goals critical to the success of the Project. One such tool is a catalog of common genetic variants.

HUMAN GENETIC VARIATION

Any two human beings, regardless of ethnic or racial self-identity, are 99.9 percent the same at the genetic level. But certain changes in the sequence, some as subtle as a single letter change, contribute to disease or disease risk. Today, to find the misspelling, or misspellings, that contribute to common diseases, such as cancer, Parkinson's disease, asthma, depression, or heart disease, researchers must study pedigrees and search through large chromosome "neighborhoods" using the genetic map. But having the reference sequence, and new technologies for finding those

places in the genome that vary among us, means that assembling a catalog of common genetic variants is now possible, and will greatly speed the process of disease gene discovery.

Most variants will be single letter differences, known as SNPs or single nucleotide polymorphisms. Any SNPs found to be associated with a disease will provide targets for further study to understand the biological processes underlying health and disease and facilitate development of diagnostic tests. This understanding will in turn fuel development of improved prevention and treatment strategies. Because genetic variants can also contribute to individual differences in response to drugs, the identification and understanding of these variants will allow doctors to choose the most effective drug based on a patient's particular genetic makeup.

In fiscal year 1999, with contributions from 16 NIH institutes, the NHGRI began an initiative to discover and catalog common variants in human DNA. In the next two years, NIH-supported researchers expect to find about 100,000 SNPs. Over the past year, this initiative has been complemented by an innovative collaboration in the private sector. Last April 15, a collaborative effort of 10 large pharmaceutical companies IBM Motorola and the Wellcome Trust, announced the formation of The SNPs Consortium (TSC). The Consortium's goal is to identify an additional 310,000 SNPs. All SNPs identified by either the NIH or TSC are regularly deposited into the publicly available SNP database. This collaboration between the public and private sectors has already produced and deposited 25,000 SNP's into the public database.

SEQUENCING THE LABORATORY MOUSE

Last fall, NHGRI began sequencing of the genome of the laboratory mouse, one of The most frequently used mammals in biomedical research. Ten laboratories, now referred to as the Mouse Genome Sequencing Network (MGSN), collectively received funding. All mouse sequence produced will fall under the same data release principles adhered to for the sequencing of the human genome, i.e., assemblies greater than 2,000 base pairs will be released to public databases within 24 hours.

Mouse and humans are approximately 70 percent identical at the genetic level. Both genomes contain approximately 3 billion base pairs and encode an estimated 100,000 genes. The invaluable contribution of mouse models toward a better understanding of human disease has long been recognized in biomedical research. For example, mouse models provide scientists with unprecedented insights into the molecular basis of disease and the response to potential therapeutic agents. Intramural scientists at NHGRI are developing and utilizing mouse models to study a diverse array of human diseases. These include brain disorders such as Huntington's disease, Parkinson's disease, neural crest disorders, and blood disorders such as acute myeloid leukemia.

Sequencing the mouse is a priority for a wide spectrum of biomedical scientists. Every institute at NIH, with support of the NIH Office of the Director, made a contribution to the first year of funding. NHGRI has assumed responsibility for funding the mouse sequencing network in the second year and beyond. A significant fraction of NHGRI's fiscal year 2000 increase is dedicated to support of mouse sequencing.

FINISHING THE FLY GENOME

Looking ahead, achievement of another significant milestone is just around the comer. Publication of the complete sequence of the fruit fly, Drosophila melanogaster, is expected within a matter of weeks. The fruit fly is another useful model organism for studying genetics, with a genome of 160 million base pairs of DNA. Providing this research tool is important because understanding the role of a gene in the human body is often clarified by comparing its DNA code to that of other organisms.

NHGRI supported scientists at the University of California at Berkeley and the Baylor College of Medicine carried out the initial scaffold sequencing of the fruit fly genome. In 1998, encouraged by NHGRI, Celera Genomics began a collaboration with these groups. In order to facilitate the work in both sectors, a Memorandum of Understanding (MOU) was prepared between the publicly funded scientists and Celera Genomics to outline the respective roles of each of the partners. The MOU maintained the public sequencing effort's commitment to seeing that complete, accurate sequence for this important model organism is made freely accessible to all scientists by requiring that the annotated sequence be released to GenBank upon publication.

TOOLS FOR UNDERSTANDING THE HUMAN GENOME

Once we have the sequence of the human and key model organisms in hand, we will need the tools to allow us to explore and understand its significance in health and disease. While this exploration will take many years, it will be aided by tools now in development by the Human Genome Project; tools that enable researchers to study the entire genome and all its genes in a single experiment.

NHGRI has launched a number of initiatives to develop tools to understand gene function that will grow in coming years. One such initiative is the Mammalian Gene Collection, led jointly by NHGRI and NCL This initiative will create a complete collection of cloned and sequenced genes for humans and other mammals. In the future, scientists will be able to go to the freezer to pull out any gene they want to study. In parallel, new technologies such as microarrays are being developed, that can measure and compare the extent to which a gene is active under various conditions and in various tissues. The NHGRI intramural program is one of the world leaders in this technology. Many other clever approaches to studying gene function are being explored and the field is expanding rapidly.

Both genomic sequencing and these new functional studies generate vast amounts of data that must be organized, stored and analyzed in order to allow scientists to pursue new leads in medical research. One significant outcome of the Human Genome Project has been the transformation of biology into a field that is rich in data, which has spawned a new discipline, called computational biology. New tools for handling data to make it readily accessible to scientists, as well as new approaches for understanding the significance of the data, are urgently needed. In view of this need, NHGRI plans to place a major emphasis on funding computational genomics studies in the future. In fiscal year 2001, NHGRI will launch a new Genome Centers of Excellence program to support the development of novel technology and computational approaches for studying the function of genomes. in addition to funding innovative science, these Centers will also provide an environment in which a new generation of genomic scientists can be trained. The concept for the centers is similar to that recommended by an Advisory Committee to the NIH Director for "Programs of Excellence in Biomedical Computing." The NHGRI anticipates that these Genome Centers of Excellence will meet many of the objectives outlined in the Committee's report, known as the "BISTI" (Biomedical Information Science and Technology Initiative) report.

SAFEGUARDING THE FAIR USE OF GENETIC INFORMATION

From the outset of the Human Genome Project, the NHGRI has supported research into the ethical, legal, and social implications (ELSI) of genomic research and fostered the development of relevant policy recommendations. We have a fundamental obligation to assess and deal with concerns such as protecting the privacy and fair use of genetic information, and the integration of new genetic technologies into health care. If we do not and the public is fearful of obtaining or disclosing genetic information, or has limited access to genetic technologies, the promise of genetic medicine will not be realized and we will have achieved little.

Progress on safeguarding the fair use of genetic information was made just in the last few weeks. On February 8, 2000, President Clinton signed an Executive Order to protect federal workers from discrimination based upon their genetic information. This is built on the bedrock principle that an individual's predictive genetic information should be used for their benefit and not for harm. A variety of important organizations, such as the American Medical Association, Hadassah, the Genetic Alliance, the American College of Medical Genetics, the Biotechnology Industry Organization (BIO) and the National Society of Genetic Counselors, immediately expressed their support for the President's action.

The Executive Order, which built upon the recommendations published by the NIH-DOE ELSI Working Group and the National Action Plan on Breast Cancer, is an important step toward assuring federal workers that their genetic information will be kept private and be used against them by their employer. It also provides federal and state legislators with a useful template for extending protections to all workers. We hope to see this step built upon in 2000 by the passage of effective federal legislation barring the discriminatory use of predictive genetic information in health insurance and employment.

CONCLUSION

The dramatic progress of the Human Genome Project has exceeded the expectations of even the most optimistic just a few years ago. In a matter of months, the majority of the fundamental "Book of Life", the human sequence, will be in hand.

Having this virtual guidebook to the human genome will permit many exciting opportunities. Combining this with the catalog of human variation, and with new tools and technologies developed by the Human Genome Project, will lead to unlocking the mysteries of diseases, such as diabetes, Parkinson's, schizophrenia, and common forms of cancer. That in turn will allow new approaches to prevention based on each individual's disease risk factors. And we can, a few years hence, predict a host of new gene-based therapies specifically designed to fit an individual's genetic makeup.

Mr. Chairman, and members of the committee, it has truly been a privilege to be a part of this historic effort, known as the Human Genome Project. At the beginning of the new millennium, genetics has come to encompass nearly every aspect of health research and will surely transform how we diagnose and treat disease in the future. It will enhance our concepts of shared humanity, regardless of racial or ethnic identity.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. JUDITH L. VAITUKAITIS

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Center for Research Resources (NCRR) for fiscal year 2001, a sum of $602.7 million which reflects an increase of $33.6 million over the Fiscal Year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NCRR is $714.2 million, an increase of $39.1 million over the fiscal year 2000 appropriation. Funds for the NCRR efforts in AIDS research are included within the Office of AIDS Research.

It is a pleasure once again to have the opportunity to present the accomplishments of NCRR-supported investigators and future directions for NCRR programs. Before the recent turn of the millennium, doomsayers predicted the end of the world as we know it, and in some respects they were right. Advances in computer technology, bioengineering, imaging technologies, neuroscience and genomics will revolutionize biomedical research in the 21st century. The NCRR mission is unique among the NIH institutes and centers. While the other NIH components focus on particular diseases, organ systems, or categories of research, NCRR alone has a trans-NIH mandate—to develop and maintain the research infrastructure that enables all lines of biomedical inquiry. This effort transcends both clinical and basic research. NCRR's nationwide networks for basic and clinical research discern the molecular causes of disease, develop new preventive strategies, and assess novel therapies for diseases that affect majority as well as minority populations across this Nation. By providing scientists access to advanced technologies and sophisticated research facilities for collaborative clinical and basic research, NCRR serves as a facilitator—or catalyst—for biomedical discovery.

One of NCRR's main objectives is to utilize scarce or expensive resources to the fullest by sharing them among many investigators. This strategy is efficient and cost effective. Each year more than 20,000 investigators, supported by more than $2.5 billion in competitive grant support from the other NIH components, use NCRR-supported research resources. To meet the needs of biomedical investigators for access to costly technologies, NCRR collaborates with the Department of Energy and the National Science Foundation (NSF) to provide access for biomedical investigators to high-energy x-rays at the synchrotron facilities operated by those two agencies. In addition, NCRR provides access to advanced computing for health-related research by partnering with the NSF-supported San Diego Supercomputer Center, one of the two National Partnerships for Advanced Computational Infrastructure currently supported by the NSF.

NCRR-funded resources have been critical to numerous projects that advance biomedical science. Many NCRR-supported discoveries have immediate benefits for patients; others help basic research move forward toward this ultimate goal. For example, separate groups of scientists, using NCRR-supported beamlines for x-ray crystallography, have determined the three-dimensional structure of ribosomes—our cells' protein factories—in unprecedented detail. These studies may expedite discovery of newer, more effective antibiotics. Animal studies conducted at an NCRR-supported primate center have shown that it is possible, by gene therapy, to reverse the brain cell destruction that is characteristic of Alzheimer's disease; and NCRR-supported clinical investigators have developed methods to assess changes in particular areas of the brain of depressed patients. The identification of these specific brain areas is fundamental to designing improved treatments for depression. According to the National Institute of Mental Health, depression affects more than 19 million American adults and costs society more than $30 billion in 1990.

BIOENGINEERING, COMPUTERS, AND ADVANCED INSTRUMENTATION

The ongoing technological revolution has made it abundantly clear that biomedical science is no longer the sole province of physicians, biochemists, and biologists. Engineers, physicists, and computer scientists are essential partners for developing and adapting new instruments and technologies for health-related research. For example, improved imaging systems are needed to investigate the pathophysiology of human disease by studying patients as well as small animals and nonhuman primates as disease models. To obtain the same resolution as in humans, these imaging systems must have sensitivities that are up to 2,500 fold greater. NCRR proposes to support further technological development of high resolution imaging tools that include computed tomography, magnetic resonance imaging (MRI), and positron emission tomography.

Functional MRI imaging has provided investigators a powerful technology for studies of the human brain and has contributed significantly with other complementary technologies to a virtual revolution in neuroscience research. To further take advantage of these imaging and related technologies, NCRR proposes to support the establishment of regional MRI imaging resource centers where experts in developing and using functional MRI can work with neuroscientists to study brain disorders and also explore novel therapies, including stem cell therapy to arrest, reverse, or even cure neurodegenerative diseases. NCRR plans to functionally link those NCRR-supported Biomedical Technology Research Resource Centers equipped with sophisticated imaging capabilities with General Clinical Research Centers at the same host institution in order to accommodate patients from across this country for studies of neurodegenerative and other brain disorders, supported by NIH categoric institutes.

The use of high-level computers and advanced computer programs are essential components of today's biomedical research, but many biomedical scientists are not sufficiently familiar with bioinformatics, a key enabling technology. To help alleviate this urgent need, NCRR proposes to establish bioinformatics centers that will advance research in particular areas of biomedical investigation, as part of the Biomedical Information Science and Technology Initiative (BISTI). Those centers will create homes for interdisciplinary teams that will establish nurturing environments for exploration and research. Biomedical investigators are generating data in profuse quantities. For example, a single biomedical laboratory can produce up to 100 terabytes of information a year—about the same as the information in one million encyclopedias. In order to be useful, the data must be indexed and stored, analyzed and abstracted. To facilitate analysis of this data, NCRR proposes to establish another program that will foster development of tools to design future studies.

Synchrotron resources—which produce the high-energy x-rays used for determining the 3–D structures of molecules—have an enormous impact on structural biology and drug design. The number of NIH users at NCRR-supported synchrotron beamlines doubled between 1995 and 1997, and requests for access to these facilities are increasing at an exponential rate. NCRR proposes to alleviate the projected substantial shortfall for access to beamtime by adding more technical staff so that technical support is available around the clock. New beamlines at the Advanced Photon Source at the Argonne National Laboratory may allow investigators to address more advanced structural biology grand challenges. In addition, several new beamlines must be built at the Advanced Light Source at the Lawrence Berkeley National Laboratory and designed for high throughput studies of less complex structures to meet the anticipated high volume of need for this approach. This effort will combine new developments in beamline design, x-ray detectors, cryocrystallography, robotics, and computational software.

GENETIC MEDICINE

Manifestations of gene action are explored through phenotypic assessment of genetically altered animals and biologic characterization of macromolecules expressed by both normal and altered genes. NCRR proposes to support regionally-linked resource centers for phenotypic studies of genetically altered research animal models. These resource centers will provide a critical infrastructure for analysis of gene function in animal models of human diseases. NCRR must provide those regional resources and several other biorepositories for genetically altered biologic collections and additional funding for more technical staff to help maintain the rapidly expanding biologic collections. Additional staffing is also needed to curate and standardize the genetic databases for those important research models—including flies, fish, and worms. Without continuous updating and editing, databases quickly become useless and as a result, unnecessary duplication of research results.

HEALTH DISPARITIES

NCRR proposes to help alleviate health disparities for several diseases that disproportionately affect minority populations by competitively establishing several Comprehensive Centers on Health Disparities (CCHD). Those centers are to be hosted by medical schools located at universities that have an NCRR-supported Research Centers in Minority Institutions (RCMI) facility for clinical research. The NCRR CCHD initiative will focus on diabetes, AIDS, and infant mortality, but initially will place increased emphasis on cancer screening and management of cardiovascular disease and stroke. This effort will be in partnership with appropriate categoric NIH institutes and with nearby General Clinical Research Centers.

RESEARCH CAPACITY

NCRR proposes to continue support for construction or renovation of biomedical research facilities to assure that state-of-the-art research laboratories are available to conduct the most sophisticated research. According to a 1998 National Science Foundation survey, at least 65 percent of biomedical research laboratories are inadequate to host sophisticated research. Grant awards for construction or renovation through NCRR's Research Facilities Improvement program are not intended to be the major source for institutional funding of research laboratory construction or renovation.

NCRR proposes to expand its Animal Facility Improvement program to meet institutions' needs nationally to upgrade animal research facilities to perform genetic research with rodents, nonhuman primates and other animal models. To assist research-performing Historically Black Colleges and Universities and other minority-serving institutions in bringing their animal research facilities up to AAALAC standards, NCRR proposes a special initiative to address this problem.

CAREER DEVELOPMENT

Over the past several years, fewer young physicians have pursued research careers. To help address that problem, NCRR has initiated programs to increase the number of young physicians in the clinical research pipeline. NCRR proposes to extend that effort in fiscal year 2001. That effort includes expanded support for a year-long medical student mentored clinical research training program. The intent of this program is to serve as a catalyst for young physicians to pursue careers in patient-oriented research. The institutional GCRC or the RCMI-funded Clinical Research Center will serve as a focal point for patient-oriented research, through mentored didactic training and "hands-on" research. This new program will support up to 90 students per year. NCRR also proposes to increase the number of Mentored Patient-Oriented Research Career Development Awards to physicians and dentists at GCRC sites. This very successful program was formerly known as the Clinical Associate Physician (CAP) program.

A serious shortage exists of trained veterinary pathologists to meet the collaborative research needs of scientists to assess the phenotypic manifestations of genetically altered animal models of human disease. To enhance the pipeline, NCRR proposes to initiate a one-year program for veterinary students that will provide a mentored biomedical research experience at research-intensive institutions. In addition, NCRR proposes to increase the number of Special Emphasis Research Career Award to train veterinarians in health-related research as pathobiologists. The NCRR programs are intended to address the inadequate number of research-trained veterinarians who participate in biomedical research.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. STEPHEN E. STRAUS

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget request for the National Center for Complementary and Alternative Medicine for fiscal year 2001, a sum of $71,362,000, which reflects an increase of $3,381,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the National Center

for Complementary and Alternative Medicine is $72,392,000, an increase of $3,381,000 over the fiscal year 2000 appropriation. Funds for the National Center for Complementary and Alternative Medicine efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report that compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

At the outset, I should note that NCCAM's work reflects the growing public interest in complementary and alternative medicine (CAM) and the belief that various CAM therapies may play a role in improved public health. Approximately 42 percent of U.S. healthcare consumers spent $27 billion on CAM therapies in 1997. CAM enjoys particular popularity among baby boomers. A number of practices, once considered unorthodox, have proven safe and effective and assimilated seamlessly into current medical practice. Diet and exercise are today commonly used to prevent and control disease. Acupuncture is routinely applied to manage chronic pain and nausea associated with chemotherapy. Some of our most important drugs—digitalis, vincristine, and taxol—are of botanical origin.

Additional CAM practices have the potential to prevent and treat chronic disease, to improve understanding of how healing works and to be integrated into the routine practice of medicine. Absent definitive evidence of effectiveness, however, alternative practices may impart untoward consequences for large numbers of people.

As the NCCAM's first permanent director, I am excited by the challenge afforded me to help provide the American public the guidance it deserves. As CAM use by the American people has steadily increased, many have asked whether reports of success with these treatments are valid. It is critical that untested but widely used CAM treatments be rigorously evaluated for safety and efficacy. It is similarly important to identify promising new approaches worthy of more intensive study. The promising areas for future investments are numerous.

In order to best seize these opportunities, the NCCAM's strategy must differ from that used by other NIH Institutes and Centers. Others' projects are usually driven by basic science discoveries. In contrast, the NCCAM must focus first on definitive clinical trials of widely utilized modalities that, from evidence-based reviews, appear to be the most promising. Credible, not anecdotal, data must be provided to the public, and we must educate conventional medical practitioners about the panoply of effective CAM practices, so they can be integrated into patient care. In recognition of these needs, Congress responded in 1998 by elevating the NIH Office of Alternative Medicine (OAM), expanding its mandate, creating the NCCAM, and affording it administrative authority to design and manage its own research portfolio. The Congress continued to reflect the growing interest in CAM by further increasing funding for the Center in fiscal year 2000 to $68.4 million. We are indeed appreciative of this support. The Congress vested the NCCAM with a broad statutory mandate to conduct and support CAM research, support research training, and disseminate information on validated CAM therapies. Accordingly, the NCCAM is currently developing a strategic plan to ensure that our continued growth, development and research directions are consistent with these responsibilities. Five strategic areas have been identified as: Investing in research; training CAM investigators; expanding outreach; facilitating integration; and practicing responsible stewardship.

In seeking to fulfill its mandate, the NCCAM has undertaken a number of initiatives, established critical contacts with CAM practitioners, and begun to fashion the scientific underpinning that will enable future research discoveries.

Before describing these activities, I want to share with the Subcommittee my vision of where I expect complementary and alternative medicine to be in the years to come. As a result of rigorous scientific investigation, several therapeutic and preventative modalities currently deemed elements of CAM will prove effective. Therefore, in future years, these interventions will be integrated into conventional medical education and practice, and the term "complementary and alternative medicine" will be superseded by the concept of "integrative medicine." The field of integrative medicine will be seen as providing novel insights and tools for human health, and not as a source of tension that insinuates itself between and among practitioners of the healing arts and their patients. Advances in neurobiology will reveal more about ancient practices such as acupuncture and meditation, as well as the phenomenon of "the placebo effect" as we tap the healing power of the mind. The medical basis for effectiveness of selected herbal and nutritional supplements will be

clarified, leading to their standardization and routine use. Other modalities will be found unsafe or ineffective, and an informed public will reject them.

My vision is an optimistic one. However, I am confident that, as it is realized, the NCCAM will have not simply expanded in those ways required to meet its research mission. Rather, owing to a tradition of superb science and consumer service, the NCCAM will become the leader—and recognized as such—within a vibrant, and global, CAM research community.

Already, I have begun to recruit key experts to join me in developing our programs in intramural research, clinical research, international and traditional health studies, and traditional medicine and indigenous systems. We will continue to grow our intellectual capital and research capacity. Setting these cornerstones in place will enable us, together with our partners in CAM research, to provide definitive answers regarding CAM treatments.

CURRENT RESEARCH STUDIES

In its first year, NCCAM has developed a diverse research portfolio in partnership with the other NIH Institutes and Centers. I am pleased to highlight for you our support of some of the largest, and certainly the most definitive Phase III clinical trials ever undertaken for a range of CAM therapies.

For centuries, extracts from the leaves of the Ginkgo biloba tree have been used as Chinese herbal medicine to treat a variety of medical conditions, including age-related decline in memory. A new NCCAM study, in collaboration with the National Institute on Aging (NIA), may help resolve these questions. This study includes four clinical centers and will enroll almost 3,000 participants who will receive either Ginkgo biloba or a placebo.

Arthritis is a major public health problem for older Americans. Accordingly, in collaboration with NIAMS, NCCAM has mounted two critical clinical trials for the treatment of osteoarthritis. One is the first U.S. multi-center study to investigate the dietary supplements glucosamine and chondroitin sulfate—two natural substances, found in and around joint cartilage. The other study is an evaluation of acupuncture for the treatment of pain associated with osteoarthritis.

I am pleased to report that our study of St. John's wort for depression is nearing completion. This study, sponsored by the NCCAM, NIMH, and the NIH Office of Dietary Supplements (ODS), represents the largest and most rigorous assessment of the effectiveness and safety of St. John's wort. Investigations of St. John's wort illustrate the complex challenges afforded by some CAM modalities. A recent study reported in The British Medical Journal showed that St. John's wort is more effective than placebo in treatment of depression, and perhaps as effective as an older generation anti-depressant drug Imipramine. NCCAM's study, which is considerably larger than the European trial, compares St. John's wort with placebo and with Zoloft, currently one of the most commonly used anti-depressants. However, the therapeutic promise of St. John's wort and of botanical products like it, is accompanied by risks that the public has largely ignored. An NIH study published February 12th in the Lancet found that St. John's wort, when taken together with the important HIV protease-inhibiting drug, Indinavir, increased the rate at which Indinavir was eliminated from the bloodstream, to the extent that blood levels fell below the acceptable level for effective AIDS treatment.

NCCAM continues support for four Specialized Research Centers (cardiovascular disease, substance abuse, pediatrics and chiropractic) funded originally by the Office of Alternative Medicine. By the end of fiscal year 1999, NCCAM made five additional Specialty Research Center awards. The nine Center grants total approximately $63 million. Each focuses on one of several areas, including pediatrics, addiction, cardiovascular disease (CVD), minority aging and CVD, aging, neurological disorders, craniofacial health, arthritis, and chiropractic medicine. In addition to these nine Centers, NCCAM and ODS jointly established two Dietary Supplements Research Centers to advance the science of botanicals, including issues of their composition, safety, and biological action. Another request for Center grant applications focusing on asthma and cancer recently was released for fiscal year 2000. This, coupled with our anticipated solicitation of one more botanical center in fiscal year 2000, will likely bring our total number of NCCAM-supported centers to as many as 15.

Benign prostatic hyperplasia (BPH), or non-cancerous enlargement of the prostate, is the most common benign tumor found in men. Anecdotal reports suggested that the botanical product saw palmetto decreases prostate swelling. To determine the validity of these observations, NCCAM, in collaboration with National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK), is supporting the first rig-

orously designed, placebo-controlled study to evaluate the effect of saw palmetto extract on symptoms and quality of life in men.

FUTURE SCIENTIFIC PLANS AND PROJECTS

Because of the dearth of credible scientific evidence on CAM practices, there is unprecedented opportunity for determining the efficacy and safety of CAM modalities. We have developed the following initiatives to address them:

NCCAM has planned a collaboration on the treatment of liver disease with the NIDDK and the National Institute of Allergy and Infectious Diseases (NIAID). The project will examine the efficacy of milk thistle extract—Silybum marianum—when used to treat Hepatitis C and other hepatic diseases.

NCCAM has already begun a number of activities that will serve to facilitate the integration of validated CAM therapies into conventional medical practice. The NCCAM plans to make awards to foster incorporation of CAM information into the curricula of medical and allied health schools and continuing medical education programs. Also, the NCCAM must educate eager medical students about CAM so that they may knowledgeably guide an avid patient base toward safe and effective CAM applications. We must also work to overcome the reluctance of conventional physicians to consider validated CAM therapies and to assimilate proven ones into their practice. The Center has established a Clinical Research Curriculum Award (CRCA) to attract talented individuals to CAM research and to provide them with the critical skills that are needed.

A majority of the CAM modalities practiced in this country have arisen from the traditional healing practices of other nations. Some of the practices have "evolved" or been adapted to work within the context of our society, and often in parallel with conventional medical practices. Moreover, most of these practices are not well documented within the context of their native cultures or understood within the context of our own. Unraveling these issues will provide some important insights into how these CAM modalities are practiced and impact upon the health of U.S. minority populations—new immigrants like Hmong (from southeast Asia) and established groups like the Navajo. Likewise, the development of culturally sensitive studies will enable NCCAM to establish methodological feasibility and strengthen the scientific rationale for proceeding to full-scale, randomized, clinical trials on the application of traditional, indigenous systems. The ability to validate some of these therapies will also expand healthcare options for those who are primarily consumers of convention medicine. The international character of CAM necessitates that the NCCAM develop a broad-based international research program that reaches out to CAM practitioners across the world. Therefore, in collaboration with several other ICs, NCCAM is committed to support locally-based, traditional, indigenous research projects in countries where the opportunities for promising CAM research are greatest. That process will ensue with the forthcoming appointment of a Director for International and Traditional Medicine Studies, who will develop a long-range plan for the pursuit of studies on a global scale. Foreshadowing this appointment, I have already authorized NCCAM support, in collaboration with the NICHD, for international studies of traditional medical approaches to the health of women and children.

The NCCAM will establish an Intramural Research Program that will develop a critical mass of CAM research to stimulate collaboration in the NIH Clinical Center with other Institutes and Centers, our Federal research partners, and others. The intramural program will serve as a focus for training future CAM researchers. Last month I formed a search committee to identify the Director of this program.

INFORMATION DISSEMINATION

Specific statutory authority enables the NCCAM to disseminate information regarding the safety and effectiveness of CAM therapies to health care providers and the public. A focal point for information about NCCAM programs and research findings, the NCCAM Information Clearinghouse develops and disseminates fact sheets, information packages, and publications to enhance public understanding about CAM research supported by the NIH. Its quarterly newsletter, Complementary & Alternative Medicine at the NIH is distributed to 6,000 subscribers. The NCCAM's award winning World Wide Web site, first established two years ago, reflects the NCCAM's growth in size and stature. Averaging more than 460,000 hits per month, the site includes links to NCCAM program areas, news and events, research grants, funding opportunities, and resources. Assembled by NCCAM from the National Library of Medicine's (NLM) MEDLINE database, the CAM Citation Index (CCI) affords the public access to approximately 175,000 bibliographic citations searchable by CAM system, disease, or method. Also, in February 1999, NCCAM joined the federally

supported Combined Health Information Database (CHID), which includes a variety of health information materials not available in other government databases, including nearly 1,000 CAM citations not available elsewhere.

To facilitate our outreach to the general public, I have initiated a series of town meetings; the first will be held on March 15 in Boston, in conjunction with the Center for Alternative Medicine and Education of Beth Israel Deaconess Medical Center.

I am now happy to take your questions about these or any other of NCCAM's activities and plans.

PREPARED STATEMENT OF DR. GERALD T. KEUSCH, DIRECTOR, FOGARTY INTERNATIONAL CENTER

Mr. Chairman and Members of the Committee, I am pleased to present the President's non-AIDS budget request for the Fogarty International Center (FIC) for fiscal year 2001, a sum of $32,532,000, which reflects an increase of $3,620,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, the total support requested for the FIC is $48,011,000, which is an increase of $4,683,000 over the fiscal year 2000 appropriation. Funds for the FIC efforts in AIDS research are included within the Office of AIDS Research budget allowance.

I am delighted to relate our progress over the past year and our proposed plans for fiscal year 2001. The FIC has taken a lead role in formulating and implementing biomedical research and policy. The programs of the FIC, developed in close consultation with this Committee, reflect our Nation's enduring commitment to global health equity. But disparities in health still exist. While one-fifth of the world's population enjoys an average life expectancy approaching 80 and a life comparatively free of disability, two-thirds of the world's population, living in the least well-off countries of Africa, Asia, and Latin America, suffer overwhelmingly from the world's burden of illness and premature death. According to statistics compiled by the World Health Organization (WHO), each year in the developing world 15 million children die from infection and malnutrition—40,000 children per day—and the toll in sickness and life-long disability has even greater social, economic, and political consequences. Arguably, reversing this deepening disparity is a public health urgency in the new decade that demands increasingly creative actions from the scientific community.

Disparities in health are not limited by national boundaries. Research on conditions related to poverty in resource-poor nations have universal applications. Most recently, this has been demonstrated by the development of short-course treatment regimens for tuberculosis, field tested initially in Tanzania and now applied by public health authorities throughout the United States. Adapting research advances in biomedicine to populations at home and abroad requires a continuing commitment to basic science as well as rigorous clinical and applied studies. Our mandate at FIC is to serve as NIH's international catalyst by enabling U.S. institutions to extend the geographic scope of research and training. FIC supports over one hundred U.S. institutions that collaborate with more than ninety nations. These efforts are multidisciplinary, embracing clinical, epidemiological, basic biomedical and behavioral research. They are multisectoral, coordinated with our sister institutes at NIH and with international organizations with health and development mandates, including the World Health Organization and World Bank.

One principal strategy of the FIC is to create the human capital and institutional capabilities in developing nations necessary for a productive research enterprise. FIC places priority in four foundation disciplines: First, information science and technology, as both an analytical tool and a means to create global laboratories without walls; second, epidemiological and clinical methodologies necessary to characterize disease burdens and devise and evaluate therapeutic or preventive interventions; third, human genetics and genomics, so that developing nations may contribute to and benefit from international efforts to apply genetic discoveries to clinical practice and therapeutics; and fourth, ethical principles and practice in patient-oriented research, with the intent of ensuring the depth and transparency of the process of ethical review and the involvement of co-investigators and study volunteers as equals in accordance with international guidelines as well as local norms.

The selected examples that follow characterize several of our leading priorities in global health research and training.

DEVELOPING COST-EFFECTIVE METHODS OF PREVENTING HIV

Over ninety percent of the world's estimated 33 million persons infected with HIV live in developing countries (UNAIDS). Within the next five years, 61 of every 1,000

children born in southern Africa will not reach their first birthday due to AIDS and increasing longevity gains will be reversed. Progress in preventing future infections is dependent on rigorous scientific links with developing nations. This is the objective of FIC's AIDS International Training and Research Program, the most extensive HIV research and training network among U.S. schools of medicine and public health and counterparts in developing nations. In partnership with the National Institute of Allergy and Infectious Diseases, FIC provided training and infrastructural support for Ugandan-based trials to prevent perinatal HIV transmission through regimens of the anti-retroviral drug nevirapine. A single oral dose given to an HIV-infected women in labor and another given to her infant within three days of birth reduced the transmission rate by half at a cost of $4.00 per mother-infant pair. If implemented widely in developing nations, this intervention could prevent some 400,000 newborns per year from beginning life infected with HIV.

NOVEL APPROACHES TO TREATMENT AND CONTROL OF EMERGING INFECTIOUS DISEASES

Coupled with the AIDS crisis, parasitic and other infections continue to compound the burdens of mortality and chronic illness as well as impede economic growth in affected regions. According to WHO, malaria kills close to 2 million people each year, most are children under the age of five, and an estimated ½ to 1 billion cases of malaria occur, and this is closely associated with poor economic performance in the affected countries. Progress will require a new public health paradigm: An integrated approach to prevention and control, incorporating improvements in case management, rational drug use to limit the spread of resistance, monitoring and evaluation of control measures, and development of new diagnostic tools, drugs and vaccines. Moreover, the spread of HIV is hastened through the use of unscreened blood to treat the life-threatening anemia that often develops in malaria-infected individuals. This reinforces the need for operational strategies to ensure the safety of the blood supply and transfusion practices for the anemia of malaria, a major complication of the infection. The Multilateral Initiative on Malaria (MIM), an alliance of scientific and development agencies and African partners, was launched with major support from FIC and NIAID to address these critical needs. FIC now serves as the worldwide focal point for the MIM. To promote the agenda to reduce the burden of malaria, FIC has initiated a new research and training program to link U.S. and, in particularly, African institutions. The MIM constitutes a maturing model—a paradigm of cross-sectoral cooperation that FIC hopes to adapt to other global health urgencies.

The field of malaria and other tropical infections has reached a watershed, demonstrating the potential for application of tools of molecular and cell biology to render formerly intractable problems approachable. For example, dengue fever and its most severe form, dengue hemorrhagic fever/dengue shock syndrome, are considered among the most important and widespread reemerging infectious diseases in the developing world, including the Caribbean. Global warming impacts on mosquito vectors that makes this a threat to the U.S. mainland as well. To date, existing methods to diagnose and characterize dengue viruses have been costly and complicated to perform, particularly in developing countries with limited capabilities and resources. Under FIC support, the University of California at Berkeley and the Ministry of Health in Nicaragua have developed a new technique to rapidly, accurately, and inexpensively define the virus responsible for dengue in Central America. This method is known as restriction site-specific PCR (polymerase chain reaction). Using this new information, local health authorities now are able to track the movement of the dengue virus from Asia and Africa to the Americas, which is the start of control efforts.

Dengue is among more than thirty-five infectious diseases that have emerged or reemerged around the world in the past twenty-five years. Most recently, the outbreak of encephalitis in the New York region was attributed to the West Nile Virus, its first known introduction into the Western hemisphere. Although it is not clear how the virus migrated to the United States, this outbreak is representative of the continual challenge that newly emerging microbes present for U.S. citizens. Emerging infectious diseases are infections that are new in the population, rapidly increasing in incidence or expanding in geographic range. Most are caused by "microbial traffic"—that is, the introduction and dissemination of existing agents into human populations either from other species or from smaller populations, often precipitated by rapid ecological and environmental change. To better comprehend the consequences of changes in terrestrial and marine ecosystems on human health, the FIC, in partnership with several NIH Institutes, the National Science Foundation, and other U.S. agencies, initiated an interdisciplinary research program to elucidate the underlying biology of habitat and biodiversity changes that may lead to in-

creased disease prevalence in humans and, thus, fill an important gap in our understanding of these interrelated dynamics. With this information, we will be able to develop data and predictive models to anticipate future outbreaks and devise corrective actions before the disease strikes.

TAKING STEPS TO ADDRESS EMERGING EPIDEMICS OF NONCOMMUNICABLE DISEASE: FISCAL YEAR 2001 INITIATIVES

The classic burdens of infectious diseases in developing nations are now joined by a new class of epidemics. According to the Global Burden of Disease Study commissioned by the World Bank, over the next twenty-five years as populations age and risk exposures shift, non-communicable diseases will become the leading source of disability and premature death in developing nations. Both the pace of these changes and the sheer numbers affected will exceed the Western experience. By working in partnership with scientists in low- and middle-income nations, risk factors may be evaluated and interventions developed that will be of benefit to both industrialized and developing nations. The emerging epidemics of chronic disease in developing nations constitute FIC's major programmatic thrust for fiscal year 2001.

In cooperation with the WHO Tobacco Free Initiative and multiple NIH partners, FIC will establish a research and training program to improve international efforts to control the tobacco epidemic. Among other objectives, the program will address large gaps in our knowledge relating to the burden of death and disability associated with tobacco use in developing nations, such as behavioral determinants of smoking uptake in youth. The Center also will launch a similar effort directed at prevention and management of mental health disorders—an unseen epidemic in most developing countries. At any give time, an estimated 10 percent of the population in developing nations suffers from severe anxiety, depressive disorders and other psychosocial problems (World Mental Health: Problems and Priorities in Low-Income Nations, Oxford University press, 1995). Through international partnerships, we hope to begin to rectify the shortfall of well-trained clinical investigators and epidemiologists in mental health fields in developing nations. Moreover, we will begin to generate epidemiological data on the incidence of mental health disorders and risk factors, including sociocultural determinants of mental health in societies undergoing transition to industrialized economies.

In fiscal year 2001, the FIC also proposes to create new linkages with developing nations in the field of molecular medicine, emphasizing research and training related to the complex interplay between genes and the environment. The genetic maps, physical maps and technologies that have emerged from the human genome sequencing effort have enabled the research community to accelerate dramatically the discovery of genes underlying disease or risk factors for disease. We are now positioned to advance understanding of population genetics and dynamics for chronic conditions that affect industrial and developing nations alike, such as hypertension, type 2 diabetes, asthma, and breast cancer. FIC's long-range goals are to define some of the genes involved in multigenic disorders of global priority and then test the predictive strength of these particular polymorphisms in prospective, community-based studies. Ultimately, diagnostic, therapeutic, and prevention strategies will evolve.

Our current efforts in this field already have yielded promising leads. Scientists at the University of Washington have teamed with scientists from Tel Aviv University in Israel and Bethlehem University in the Palestinian Authority to map and clone the genes responsible for different types of inherited deafness—both progressive and early-onset. The incidence of preverbal deafness is an estimated five to ten percent in this region, among the highest in the world. Loss of hearing may be due to environmental factors or to genetic mutations in any one of a large number of genes. These genes encode proteins crucial for the proper development, structure and function of the inner ear. There may be more than 100 such genes, however only a fraction have been identified. Identifying these genes and defining the mutations that cause deafness through these novel studies will lead to a better understanding of the biology of hearing.

CONCLUSION

These programs and initiatives are representative of a broad spectrum of international research and training efforts supported by FIC. The programs of FIC recognize a deeper philosophic purpose and vision. Advances in biology over the past decades have demonstrated social and global interdependence. This is a condition of health for the biosphere as much as it is an imperative of societal well-being. There is a deepening consensus that individuals and nations share an inherited and acquired sense of social altruism—an understanding of common fate and a shared set

of social obligations. The pursuit of health through international scientific cooperation is an inherently global enterprise and one that ultimately improves the public health of this Nation as well.

The NIH budget request includes performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report, which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

Thank you, Mr. Chairman. I will be pleased to answer any questions.

PREPARED STATEMENT OF DR. DONALD A.B. LINDBERG

Mr. Chairman and Members of the Committee: I am pleased to present the President's non-AIDS budget for the National Library of Medicine for fiscal year 2001, a sum of $224,942,000, which reflects an increase of $14,806,000 over the comparable fiscal year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for NLM is $230,135,000, an increase of $16,067,000 over the appropriation for fiscal year 2000. Funds for the NLM's efforts in AIDS research are included within the Office of AIDS Research budget request.

HEALTH INFORMATION FOR THE PUBLIC

In the best tradition of American enterprise, NLM has within a few short years re-engineered its information services to benefit directly both health professionals and the public. The public has always been the ultimate beneficiary of NLM's services. But today's consumer now has the same access as doctors and scientists to the Library's immense databanks. NLM has also created new services aimed directly at the general public that are proving popular with Web users. These changes, encouraged by this Committee and supported by Congress, have been endorsed by NLM's Board of Regents.

The NLM has a two-step strategy to maximize the utility of its services. The first is to respond to the needs of the Web-using public. It is estimated that 40 to 50 percent of Americans are connected to the Internet, and health information is a popular topic for searching. In three years the Library has seen the number of searches on its MEDLINE database rise from 7 million searches a year to 250 million. The Library estimates that 30 percent are done by the members of the public for themselves and their families. That a database of 10 million references and abstracts to medical journal articles would prove to be so popular is remarkable and demonstrates an eagerness for authoritative health information by the public.

The Library has created for consumers a new service, MEDLINE*plus*, to complement its databases of scientific literature. MEDLINE*plus* has grown rapidly in little more than a year, and provides links to information on 350 diseases and medical conditions. This information, reviewed and selected by highly trained medical librarians, originates from such trusted sources as the Institutes of NIH and professional societies. NLM constantly scans these and other organizations for up-to-date information and the links are checked daily. MEDLINE*plus* contains a feature unique in the world of Web-based information for the public: carefully pre-formulated searches of the MEDLINE database that will return references and abstracts deemed especially useful for the average consumer.

A new service, ClinicalTrials.gov, was introduced by NLM on behalf of NIH in February 2000. This database, accessible through MEDLINE*plus*, contains vital information about thousands of clinical trials sponsored by the NIH and other Federal agencies. Now patients, families, and members of the public can find out about cutting-edge research being conducted around the U.S. and whether they are eligible to join a study. ClinicalTrials.gov contains a statement of purpose for each clinical research study, together with the recruiting status, the criteria for patient participation in the trial, the location of the trial, and specific contact information. The database will be expanded to include clinical trials sponsored by private industry and in other countries.

Not all Americans, however, can search the Internet. Thus, NLM's second strategy is to improve access for this group by encouraging medical libraries to work with local public libraries and other community organizations. In 1999 NLM completed a pilot project with public libraries in nine states and the District of Columbia. The purpose was to evaluate whether these libraries, using the Internet, could help meet the needs of the public for good health information. The project revealed that MEDLINE*plus* is an excellent place for consumers to begin their search and

that public librarians need training in answering health reference questions and in finding and evaluating health information on the Web. Building on what we learned in this project, the NLM made awards in February 2000 to fund 49 electronic health information projects in 34 states that will increase Internet access in many settings, from middle schools serving low income and educationally underserved students to shopping malls and senior centers. These imaginative and well-targeted projects will stimulate medical libraries, local public libraries, and other organizations to work together to provide electronic health information services for all citizens in a community. Crucial in this effort is the Regional Medical Libraries and members of the National Network of Libraries of Medicine.

HEALTH DISPARITIES

The NLM has in place a number of programs that in recent years have been directed toward remedying the disparity in health opportunities experienced by segments of the American population. One of these programs deals with toxic waste sites and other environmental and occupational hazards that are much more likely to occur near homes in poor neighborhoods than where affluent Americans live. The Library has a program to train health professionals, community leaders, and others in minority neighborhoods to use the NLM's databases of information about hazardous waste information. The Library provides minority schools with state-of-the-art equipment, software, and free access to computerized information sources, including NLM's own toxicology and environmental health information databases. Other Federal agencies have joined with NLM and the project has grown from 9 participating minority institutions to more than 60.

Similar to the program for toxicology and environmental health, the Library has been working with institutions that serve minority populations to encourage the use of NLM information services relating to HIV/AIDS. These include the databases AIDSLINE (references and abstracts), AIDSTRIALS (clinical trials), AIDSDRUGS (drugs being tested), and DIRLINE (organizations that provide health information to the public). The NLM has in place a program to train health professionals, community organizers, information professionals, and patient advocates in the use of these resources. Requests for this training have been strong and sustained, and NLM has responded to the extent its resources permit. In addition to the programs mentioned above, NLM grants and contracts have been targeted to support health information programs for African Americans, Latinos, and Native American populations in the south; rural hospitals in the Midwest; Native Americans in Alaska and the Pacific Northwest; African American and Latino populations in the Pacific Southwest; and Puerto Rico. To illustrate, telemedicine in rural Alaska is being tested as a strategy for controlling costs and for raising the quality of health care for a minority population that is scattered across a vast area.

The NLM is a key participant in the Multilateral Initiative on Malaria Research effort in Sub-Saharan Africa. Scientists in many developing countries are unable to communicate easily with other scientists, search biomedical databases, or collaborate with colleagues in industrialized countries. This results in poor coordination and monitoring of research, redundancy of effort, and a growing disparity in research productivity. The Library is supporting the implementation of high end communications hardware and software in remote malaria research sites in Mali, Kenya, Cameroon, Ghana, and Tanzania. Since Internet connections can effectively carry voice, data, and video image transmissions, the Library is helping to bring them to scientists in those countries. The Ghana sites, for example, are engaged in malaria vaccine development and testing readiness.

MEDICAL INFORMATICS

A recently released report recommends that the NIH invest heavily in computer and information technology so as to be able to manage data and model biological processes. It also observes that there is an acute need for training specialists competent in computational biology. This recommendation falls within the scope of the NLM's medical informatics training program under which the Library supports 12 programs at U.S. universities to train experts to carry out research in general informatics and in the genome-related specialty of bioinformatics. NLM plans to augment some of these training programs with additional resources so that they can make use of the advantages they already enjoy: experienced faculty, curricula, sanctioned university status, and ready access to potential candidates. NLM envisions expanding the program beyond 12 centers with the addition of training awards to new institutions.

To ensure that the Internet will continue to support the health sciences, the NLM is a strong supporter of the Next Generation Internet (NGI), a partnership of indus-

try, academia, and government agencies that seeks to provide affordable, secure information delivery at rates thousands of times faster than today. Advanced medical imaging, for example, requires more bandwidth than is currently available. Other applications require a guaranteed level of service (for example no data loss, or assured privacy protection) that today's Internet cannot provide. To help the health sciences prepare to use the capabilities the next few years will bring, the Library is supporting the development of innovative medical test-bed projects that demonstrate the application and use of the capabilities of the Next Generation Internet. Spread out over three phases, the support includes a variety of telemedicine-related projects, advanced medical imaging, and patient-controlled personal medical records systems. In the last phase there will be a scale-up of especially promising projects to regional or national level.

The Visible Human Project is an example of a program that requires both advanced computing techniques and the capability of the Next Generation Internet. The two very large datasets of anatomical data represented by the Visible Human Male and Female are being used (without charge) by 1,240 licensees in 41 countries, and at four mirror sites in Asia and Europe. In addition to the varied uses to which these licensees are applying the data (for example, recyclable cadavers, virtual colonoscopies, and brain surgery rehearsal), the Library is seeking to create a public software "toolkit" that will allow anyone to use the data to "create" any anatomical object. A collaborative project of the NLM, in partnership with several NIH Institutes and the National Science Foundation, is extending the Visible Human Project by developing an extremely detailed atlas of the head and neck.

GENETICS OF MEDICINE

As a result of the accelerating pace of research, the GenBank database of DNA sequence information maintained by NLM's National Center for Biotechnology Information is growing to gargantuan sizes. It now contains some 5 million sequences with a total of nearly 5 billion base pairs, and the NCBI Web site, where GenBank is made freely available, receives some 800,000 queries per day from 120,000 scientists and others around the world. In addition to academic institutions, major biotechnology and pharmaceutical firms are among the heaviest users of the NCBI Web site. They not only search GenBank, but use NCBI-created computational tools such as that which allows researchers to use the growing body of known 3-dimensional structures to infer approximate 3D sequence structure from similarity relationships. NCBI scientists have also collaborated with 64 colleagues from government, university, and commercial laboratories around the world to produce a new "gene map" that pinpoints the chromosomal locations of almost half of all human genes. This milestone in the Human Genome Project, available on the Internet, will expedite the discovery of human disease genes and by extension, contribute to advances in detection and treatment of illnesses.

BASIC SERVICES

Despite the NLM's extensive involvement with computer and communications technology, the staff is ever mindful of its responsibility to maintain the integrity of the world's largest collection of medical books and journals. Increasingly, this information is in digital form, and the NLM, as a national library responsible for preserving the scholarly record of biomedicine, is developing a strategy for selecting, organizing, and ensuring permanent access to digital information. Regardless of the format in which the materials are received, ensuring their availability for future generations remains the Library's highest priority. The expanding NLM collection and research and development programs continue to put pressure on current NLM storage capacity. The issue of NLM space needs will be considered as NIH revises its Master Plan. In the meantime, NIH has assigned NLM space in the Natcher Building, located adjacent to the NLM Building to address the immediate needs as longer term options are developed and evaluated.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification strategies and objectives to continuously improve programs across the NIH and the Department.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. NEAL NATHANSON

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the AIDS research programs of the National Institutes of Health for fiscal year 2001, a sum of $2,111,224,000, an increase of $105,041,000 above the comparable fiscal year 2000 appropriation. NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report which compares our fiscal year 1999 results to the goals in our fiscal year 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

The Office of AIDS Research (OAR) is responsible for setting the scientific agenda for the large and diverse NIH AIDS research program. To this end, we develop the annual AIDS research plan and budget, based on the most compelling scientific priorities that will lead to better therapies and prevention for HIV infection and AIDS. Those priorities are established through a collaborative process involving the NIH institutes and non-government experts from academia and industry as well as the full participation of the AIDS-affected community.

Mr. Chairman, at our hearings here last year initiated unprecedented attention on the international dimension of the AIDS epidemic. Your support and attention to critical global needs at those hearings were a catalyst for efforts that have increased throughout the year. In January, the United Nations Security Council declared that AIDS is now a national security issue, representing a new kind of threat to political stability. AIDS in Africa is killing ten times as many people as war, sabotaging economic development, leading to massive social breakdown, and creating a generation of orphans. Ambassador Richard Holbrooke called AIDS "a direct, cancerous growth on the political, social, and economic security of Africa."

THE UNRELENTING PANDEMIC

By every definition, AIDS is the great plague of the 20th century—an epidemic of biblical proportions. (Chart 1) AIDS already has killed more than 16 million people, surpassing tuberculosis and malaria as the leading infectious cause of death worldwide, according to recent data from the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). In 1999, a record 2.6 million people died from AIDS—more than in any prior year. UNAIDS estimates that in India between 3 and 5 million people are infected, with new infections doubling every 14 months. New epidemics are rapidly increasing in Russia, Eastern Europe, and in China. AIDS remains a serious threat in Latin America and the Caribbean. Africa (Chart 2) remains the epicenter of the pandemic, bearing the largest disease burden, with 70 percent of people living with AIDS worldwide, 83 percent of global AIDS deaths, and 95 percent of the world's AIDS orphans. HIV-infected women aged 15 to 49 outnumber infected men. In Harare, the capital of Zimbabwe, 40 percent of adults are HIV-infected. The impact of AIDS on developing nations and many former communist countries is staggering, with even greater potential disaster to come. AIDS is reversing decades of progress from important public health efforts, lowering life expectancy, and significantly affecting international businesses. Lost productivity and profitability, the cost of sickness and death benefits, and the decline in a skilled workforce in the developing world will have economic effects worldwide. AIDS is affecting the military capabilities of some countries as well as the international peacekeeping forces.

THE EVOLVING EPIDEMIC IN THE UNITED STATES

In the U.S., the incidence of new AIDS cases has declined, thanks largely to expanded use of new antiretroviral therapies that prevent progression of HIV infection to AIDS. The previous decline in death rates has now leveled off. The state of Illinois just announced a 24 percent increase in AIDS cases in 1999. Most significantly, the annual incidence of new HIV infections has not declined since 1990 (Chart 3). This means that although therapeutic interventions are delaying death, at least for a time, we have not slowed the epidemic. Chart 4 shows that HIV infection rates are continuing to climb in two major groups—women and minorities. Rates are also increasing in young homosexual men and people over 50 years of age. AIDS affects the disenfranchised in our society—the poor, the homeless, and those with addictive or mental disorders. Further, drug resistant strains of HIV present a serious public health concern.

These data forebode an epidemic of even greater magnitude ahead, and shape our most urgent research priorities. These priorities (Chart 5) address two critical populations—those living in developing countries, and the minority populations of the U.S.—with a two-pronged agenda: therapeutic research to treat those who are already infected; and prevention research to reduce HIV transmission. Our prevention agenda includes both vaccine and non-vaccine strategies, such as behavioral research, development of topical microbicides, and prevention of perinatal transmission.

PRIORITY: INTERNATIONAL RESEARCH

We are increasing our international AIDS research porfolio. As more than 90 percent of new infections occur in developing countries, where therapeutic interventions are unaffordable and undeliverable, NIH is pursuing interventions that can be implemented in these resource—and infrastructure-deprived nations. I will cite just a few examples. A recent NIAID-sponsored clinical trial in Uganda demonstrated that nevirapine, an antiretroviral drug costing less than $4, given once to the mother and once to the baby at birth, could reduce mother-to-child transmission by 50 percent. The NIH vaccine research effort underscores the crucial role of NIH in addressing prevention needs worldwide. Clinical trials within both the new NIAID Vaccine Trials Network and Prevention Trials Network are expected to involve international sites. The OAR is supporting the first international conference on microbicides to stimulate new research initiatives in this critical area. To further our efforts and enhance international collaboration, the Fogary International Center is expanding its research and training programs in many developing nations. The OAR fiscal year 2002 annual plan, which we are now developing, includes a special section for international research, and we have established an International AIDS Research Collaborating Committee to bring together all of the Departments of the U.S. government conducting AIDS research, along with international partners such as the UNAIDS and the World Bank.

PRIORITY: HEALTH DISPARITIES IN THE UNITED STATES

The disproportionate impact of the HIV/AIDS epidemic on U.S. communities of color is demonstrated graphically on Chart 6. AIDS remains the number one cause of death among young African American men. OAR established a new group, the Ad Hoc Working Group on Minority Research, to advise us on the scientific priorities in this critical research area, and we added a new section to our plan on research targeting minorities. We are directing increased resources toward new interventions that will have the greatest impact on these groups, including those that address co-occurrence of other STDs, hepatitis, drug abuse, and mental illness, and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities, and we will continue to assure the participation of minority subjects in AIDS clinical trials as well as natural history, epidemiologic, and prevention studies. In accordance with the Congressional Black Caucus initiative, the OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research. We estimate that with this budget request, NIH will devote approximately $427 million to research targeting AIDS in minority community communities.

PRIORITY: BETTER THERAPIES

The development of protease inhibitors has had a significant impact on the length and quality of life for many HIV-infected people in the U.S. But the news in this area is not good. At the recent scientific meeting on retroviruses, the overriding theme was the long and serious list of problems for patients receiving these HIV therapies, including: (1) failure to obtain a satisfactory reduction in viral load even for patients who comply with treatment regimens; (2) expensive and complicated regimens that make compliance difficult; (3) drug toxicities; (4) metabolic and cardiac complications, including diabetes; and 5) drug resistance. We must develop and test new, simpler, less toxic, and cheaper anti-HIV drugs. Chart 7 summarizes our key priorities to accomplish that goal: (1) develop new targets for the design of new antiviral drugs; (2) conduct clinical trials to answer key questions such as: At what point in the disease process should therapy be initiated and which combination of drugs should be used? At what point should the drugs be switched and to which

drugs? How can toxicities and drug resistance be prevented? How can regimens be simplified and compliance improved? and (3) translate research results into clinical practice information that is useful to caregivers and their patients, particularly in minority communities.

PRIORITY: HIV PREVENTION

NIH supports a comprehensive approach to HIV prevention research that includes contributions from the biomedical, behavioral, and social sciences. The OAR prevention science research agenda (Chart 8) targets interventions to both infected and uninfected at risk individuals to reduce HIV transmission. In addition, different strategies must be applied to each subepidemic in the US and around the world. Our biomedical prevention research priorities include areas such as the development of topical microbicides for women; perinatal prevention strategies, including understanding of breast-feeding risk; and management of sexually transmitted diseases that enhance risk of HIV transmission. NIH also supports behavioral research strategies, including prevention interventions related to drug and alcohol use. We are focusing efforts on infected individuals who may not know they are infected, but in addition, data suggest that some HIV-infected individuals successfully responding to therapy believe that they are less infectious and that they cannot be reinfected. As a result, they may re-engage in risky behaviors. Thus NIH is supporting research to develop HIV prevention interventions targeted to HIV-infected individuals.

PRIORITY: VACCINES

A safe and effective vaccine is the critical missing element in our armamentarium. In 1997, the President challenged the nation to develop an AIDS vaccine. Consistent with this challenge, NIH has moved forward aggressively to build a comprehensive vaccine research enterprise. Funds in this request represent more than a 100 percent increase in NIH vaccine research since fiscal year 1997. These funds will provide new grants to foster innovative HIV vaccine research and allow the invigoration and reorganization of the NIH vaccine clinical trials effort. The new Dale and Betty Bumpers Vaccine Research Center will be occupied this summer. Dr. David Baltimore continues to chair the AIDS Vaccine Research Committee which advises the NIH on the overall vaccine program. In February 1999, NIH-supported investigators initiated the first AIDS vaccine trial in Africa. In collaboration with industry partners, NIH has now tested 28 different HIV vaccine candidates, individually or in combinations, in over 3000 uninfected volunteers. Several new vaccines, including vaccines designed to induce mucosal immunity, novel DNA vaccines, and more complex vaccines presenting several viral proteins, have entered phase I trials. In addition, recent studies of "therapeutic vaccines" that do not prevent infection, but can prevent or delay disease progression in animal models has offered opportunities for additional vaccine strategies.

There have been significant incremental advances in the development of an AIDS vaccine. A number of candidate vaccines have been formulated for use in rhesus monkeys where they can be tested for their ability to protect against a "challenge" with a simian immunodeficiency virus that has been shown to produce AIDS in these animals. This permits the rapid testing of the potential protective efficacy of vaccine concepts. The left part of Chart 9 shows the blood levels of two groups of monkeys, one vaccinated and one given a placebo control. The vaccinated monkeys had a much reduced infection, with a much better survival than the control group. Protection of this magnitude has been seen with several candidate vaccines. The right part of the chart shows one of the most recent vaccines that has been tested in humans for its ability to produce immune responses. Both versions of the vaccine induced the production of antibodies and cellular immune responses (CTLs), but only in a proportion of immunized subjects. Although this was not a trial of effectiveness, the subjects were followed for HIV infections. There appeared to be about half as many infections in the immunized subjects, although the numbers were too small to be statistically significant. Results of this kind are encouraging and lead us to hope that full scale trials of vaccine effectiveness may begin in humans in the next few years.

BENEFITS TO OTHER DISEASE RESEARCH

AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune and metabolic diseases. AIDS research has provided an entirely new paradigm for drug design and development to treat viral infections. One example this year was the development of the new flu drug, Relenza, which directly benefited from AIDS research. The drug known as 3TC, developed to treat AIDS, is now the most effective therapy for chronic hepatitis B infection.

Drugs developed to prevent and treat AIDS-associated opportunistic infections also provide benefit to patients undergoing cancer chemotherapy or receiving anti-transplant rejection therapy. AIDS is also providing new understanding of the relationship between viruses and cancer.

SUMMARY

The transmissible nature of HIV—between individuals and across borders and populations—makes it radically different from non-transmissible diseases such as heart disease and cancer. There is the potential for unlimited spread, and also the possibility for a dramatic reduction in new infections—and thus ultimate control of the pandemic—in a way that can never be possible for noninfectious diseases. The impact of an intervention that reduces the probability of transmission, breaking the link in the epidemic chain, extends far beyond the treated or protected individual.

We have made enormous strides in our fight against this horrible disease, but these were only small skirmishes in a major global war. As this Committee clearly recognizes, our progress will be meaningless unless we can make the benefits of our research findings available to populations desperately in need both here in our own country and around the world. The worldwide human and economic toll of this insidious disease is profound, and we will never solve the problem of AIDS for our own citizens without controlling the epidemic in the rest of the global village. We cannot afford to leave anyone behind.

We are deeply grateful to the Committee for your steadfast support. I would be pleased to respond to any questions you may have.

PRESIDENT'S BUDGET

Senator SPECTER. Well, thank you very much, Dr. Kirschstein. You say you are happy to present the President's budget. You are honored to present the President's budget. Well, what was the increase he requested?

Dr. KIRSCHSTEIN. 5.6 percent.

Senator SPECTER. How much of that is in dollars?

Dr. KIRSCHSTEIN. The increase in dollars is $1 billion.

Senator SPECTER. So you are honored to present a request for an increase of $1 billion.

Dr. KIRSCHSTEIN. Yes, sir.

Senator SPECTER. I am just kidding with you a little here.

Dr. KIRSCHSTEIN. I know.

I also said I was honored to appear before you.

Senator SPECTER. Would you be more honored to receive an increase of $2.7 billion?

Dr. KIRSCHSTEIN. I certainly would.

Senator SPECTER. I mean, if it is just a question of honor, I want to get the issue straight.

RESEARCH GRANTS

What percentage of applications are recipients and grants?

Dr. KIRSCHSTEIN. We will fund the largest total of research grants we have had ever. But the percentage that we will be funding varies between institutes, but will be an overall of about 26 percent.

Senator SPECTER. Well, the percentage of grants then has not increased in the past, say, 3 years as more than $5 billion has been added to the NIH budget. Is that correct?

Dr. KIRSCHSTEIN. It has increased somewhat over the last 3 years. It was less than the level that I gave you several years ago.

Senator SPECTER. Well, I heard several years ago, 3, 4 years ago, a figure of 28 to 34 percent. And now you are saying that there are

26 percent. And of course the question is: Are you getting a lot more grant applications?

Dr. KIRSCHSTEIN. We are getting a lot more grant applications, but there are other reasons as well.

Senator SPECTER. What are those reasons?

Dr. KIRSCHSTEIN. Well, in the years during which the NIH budget was constrained, the level of funding for each individual grant was constrained as well.

And we felt, as our funds were increased, that it would be important for us to try to provide each investigator all of whom are being funded to do and are doing superb work, and that is why we are funding them, an amount of money closer to what their peers in the review process had suggested that they are able to use appropriately. And so we have tried to provide, as much as possible with the increased funds, full funding for the research grants.

In addition, we know by the way science has been changing that it is very important to begin to provide our investigators, and they have actually asked us, with certain resources that are not necessarily required in each individual grant budget: Databases; banks of nucleic acids and proteins from which they can draw from to enhance their own research; information systems; instrumentation; very large instruments which they can share.

So we have used our funds not only to provide individual investigators with the ability to do work, but provide them with the resources that are needed.

Senator SPECTER. When you say that 26 percent of the applications receive grants, can you give us an estimate, a judgment, on how many of the balance of 74 percent which do not receive grants are meritorious and, under ideal circumstances, should receive grants?

Dr. KIRSCHSTEIN. In the past, we considered that about one-third of all the grants, 33, 34, 35 percent, would be an appropriate number to strive for. However, recently the institute directors and I have discussed this. And in many cases, we feel that the number could go even higher, up to 40 or so percent, and meritorious science would continue to be funded.

Senator SPECTER. What would it take by way of NIH budget to fund, say, 40 percent of the applications?

Dr. KIRSCHSTEIN. It would take about $2 billion more, not quite.

Senator SPECTER. $2 billion on top of your current budget?

Dr. KIRSCHSTEIN. Not quite, but almost.

Senator SPECTER. So if we come in with $2 billion more——

Dr. KIRSCHSTEIN. No. $2 billion more on top of the 2000 budget.

Senator SPECTER. On top of the 2000 budget.

Dr. KIRSCHSTEIN. Yes.

Senator SPECTER. The 2000 budget is right at $17.9 billion.

Dr. KIRSCHSTEIN. Yes. The 2000 budget is $17.9 billion. You are correct.

Senator SPECTER. So if we gave you $2 billion more, you could increase grant of applications from 26 percent to 40 percent.

Dr. KIRSCHSTEIN. Closer to one-third.

Senator SPECTER. Well, OK. Now answer my 40 percent question.

Dr. KIRSCHSTEIN. I think that would take more, and I am not absolutely sure. I will try to work that out.

Senator SPECTER. Well, the subcommittee would like as precise an evaluation as you can give us on how many of those applications are meritorious. We always talk about opening up those closed doors. And then we would like to know what it would cost to do that.

My own sense is that the potential for medical research is phenomenal, life saving. The most important asset we have is our health. So we would like to know what the maximum is and see if we cannot do something about that.

Dr. KIRSCHSTEIN. Each of the institute directors has provided information to that effect. And we will ask them to provide even more for you. And we will try to provide it in total.

Senator SPECTER. Well, maybe we will just take the time to go around the room, giving you a little notice. And the questions I would like to have answered are: Current budget, what percent of the applications are granted? How many are meritorious, would you like to grant? And what would that cost?

Sometimes we do not really get the answers later in writing. And sometimes when we get the answers, we do not read them.

So let us try that this morning.

I want to yield now to my distinguished ranking member, Senator Tom Harkin.

In your absence, I was saying good things behind your back, Tom. So beware.

Senator HARKIN. I have to be careful about that now.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. And thank you for your great leadership on this committee, but especially as it deals with NIH funding. I was proud to join you last year in your great effort to secure a historic increase for NIH. And I am proud to join you again this year, hopefully for another historic increase in NIH funding.

I also want to thank Dr. Kirschstein for her leadership at NIH, for always being there when we needed someone to take the helm, especially one—as I figure, you have been there 44 years.

Dr. KIRSCHSTEIN. That is correct.

Senator HARKIN. And I want to thank you for 44 years of service to our country and beyond that, I guess, service to all humankind in terms of biomedical research. I think you are a great example, I hope, to a lot of young people today as to what research affords and what it can mean in terms of contributions they could make, if they were to stay in research.

That is one of the reasons that I hope that we can continue to increase this funding for NIH and get it doubled in 5 years, as Chairman Specter has set the course to do, and that is to let a lot of young people know today that they can have a career in research, a good career in research.

So I compliment you for that and, through you, to all of the institute directors who are here today and to thank each one of them, each one of you, for all of your work and your leadership in the area of medical research.

PREPARED STATEMENT

With that, I would just ask that my statement be made a part of the record, Mr. Chairman.

Senator SPECTER. It will be made a part of the record without objection.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Mr Chairman, I want to thank you for holding this hearing today and I want to welcome Dr. Kirschstein and her colleagues from NIH who are testifying before us today. NIH is the premier medical research institution in the world—research funded by NIH is key to maintaining the quality of our health care and key to finding preventive measures, cures and the most cost effective treatments for the major illnesses and conditions that strike Americans.

But I must say that the timing of this hearing is interesting. Yesterday, the Senate Budget Committee marked up a budget resolution that cuts nondefense discretionary spending from last year. Nondefense discretionary spending is cut by $7 billion from a freeze! Last year, this subcommittee was able to secure a $2.3 billion increase for NIH—the second year in an effort to double NIH funding over five years. Mr. Chairman, as you know, you and I introduced legislation earlier this year calling for a $2.7 billion increase for NIH in fiscal year 2001—building on last year's increase for NIH as we move to doubling funding for NIH over a five-year period.

But, it is going to be next to impossible to find that money with a cut in our allocation this year. But, Mr. Chairman, I know you will find a way—it's times like this that I'm glad you are the Chairman.

One, but certainly not the only, reason that we must continue this support for medical research at NIH is the truly awe-inspiring potential benefits of stem cell research. This Subcommittee has held a number of hearings on the issues surrounding stem cell research. At those hearings, I have had the opportunity to express my support for this research. Now it is time to move forward. Dr. Kirschstein, I understand that the comment period has closed on the stem cell research guidelines—I expect that you will keep me updated on how you intend to encourage and support quality, ethically-sound research in this area over the coming months.

I am also excited about the progress made on the Human Genome project. I see from Dr. Collins' testimony that scientists will complete the human genome sequence in 2003, two years ahead of the original schedule. I really believe that effort will results in a number of scientific breakthroughs in over the next ten years.

Thank you, Mr. Chairman—I look forward from hearing from our witnesses.

Senator HARKIN. I do have several questions. I hope we have another round, because I am not going to get them all in in 5 minutes, Mr. Chairman.

Senator SPECTER. Sure.

STEM CELL RESEARCH

Senator HARKIN. There are about three areas I want to cover. One is stem cells. I want to cover Francis Collins with the genome research. And the other one is with the National Institute of Drug Abuse, NIDA, on methamphetamine. And maybe one other question on complementary and alternative medicine. Those are basically the areas I want to cover.

Let us start with stem cells first, Dr. Kirschstein. I understand that NIH has issued draft guidelines for the funding of stem cell research. And the comment period on those guidelines ended on February 22.

Can you give us some idea of when you will be finished reviewing those comments and be ready to issue a final regulation? And do you think there will be any changes to the proposed guidelines?

Dr. KIRSCHSTEIN. Mr. Harkin, first of all, thank you for your very kind remarks.

The comment period, as you said, did close on February 22. And the staff is working very hard now to analyze all the comments—there were a considerable number—and to decide what needs to be changed about the guidelines. They will be revised. And we are working on that at the present time.

In addition, once the guidelines are published, we also want to have an oversight group in place to be able to review all the proposals related to the use of stem cells.

And so what we propose is that we put out the final guidelines at the same time as we have such an oversight group in place. And then we would be ready to go. We would anticipate doing so sometime in the early summer.

Senator HARKIN. Well, I am a little—I appreciate the time frame. Early summer, I hope that means—when does summer start, in June? June 21.

But I am a little concerned about what I thought I heard you say, and that is that there would be some revisions to the proposed guidelines. And that has raised my level of concern.

Dr. KIRSCHSTEIN. No. The revision is based on the comments and what we think are in the comments that could clarify and refine what the guidelines will say. The basic aspects of the guidelines will remain the same.

STEM CELL RESEARCH AND DIABETES

Senator HARKIN. OK. I appreciate that. Then my concern has been alleviated.

I understand that at the University of Alberta in Edmonton seven individuals with juvenile diabetes have remained free of insulin injections for close to a year after receiving transplants of insulin-producing cells.

I use that only as an example, but how does NIH plan to capitalize on this potential breakthrough? And what role might stem cells play in the future of this kind of research?

Dr. KIRSCHSTEIN. Senator Harkin, if I may, I would like to ask Dr. Spiegel, the new director of the National Institute of Diabetes, Digestive and Kidney Diseases, to answer that question.

Senator HARKIN. That would be great.

Dr. SPIEGEL. Thank you, Dr. Kirschstein.

The protocol you referred to, Mr. Harkin, the Edmonton Protocol, has indeed been successful for this period of 1 year. In collaboration with the National Institute of Allergy and Infectious Diseases' Immune Tolerance Network, that protocol will be expanded to multiple centers, which in turn hope to derive the islets that need to be produced at the NCRR harvest centers. NIDDK has also funded about $3.5 million worth of new trials on other protocols for islets transplants.

As far as stem cells are concerned, it is clear that if this is, as we hope, successful, there will be a tremendous need for additional sources of insulin-secreting beta cells.

Recent work in mice, published in Nature, indicated that one can harvest such stem cells from the pancreas and that they can cure diabetes. We will have a workshop of stem cell experts on April 10 through 11, which will explore all the possible avenues.

And we are optimistic that there will be real opportunities for breakthroughs that will bring these clinically exciting trials, as well as stem cell technology, together.

Senator HARKIN. Can you elaborate a little bit more? This has been one year that they have. Is there any indication that there is any kind of rejection or that they may have to fall back on insulin injections? What can you enlighten me about the present state of that protocol?

Dr. SPIEGEL. I would like to put it in historical perspective. Dr. Lacey at Washington University was a pioneer in this area and over 20 years ago made the first attempts at islet transplants in humans.

Unfortunately, only perhaps 1 out of 300-and-some-odd patients in the world remained insulin independent after treatment. So there were dismal failures up to now. This is why this is so promising.

And it relates both to the better methods of harvesting the islets from donor pancreases, as well as novel techniques which derive from basic immunology research. They are using a monoclonal antibody that targets a particular T-cell receptor and a drug called Rapimycin.

Now, unfortunately, this is still not what we want to achieve. We would like to achieve complete absence of immunosuppressive drugs, be able to have the patient treated during the transplant and then need no further medication. And indeed, there are studies both in mice and in nonhuman primates indicating this can be achieved.

Currently, these individuals in Edmonton have not had their medications removed. So it is too early to tell if they will be able to achieve a state of immune tolerance. But we are very optimistic that that could be the case.

Senator SPECTER. Let us return to this in just a moment, because Senator Cochran has to chair another hearing. And we want to hear from him.

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Well, thank you very much, Mr. Chairman. I want to join you in welcoming Dr. Kirschstein and the directors of the NIH who are appearing here today. It is good to see Dr. Klausner and to thank him for his trip to my State.

I appreciate what Dr. Kirschstein and the NIH do for our Nation's health. The NIH has excelled in the stimulation and support of medical research. Their efforts have involved both the basic scientific research needed to understand disease and treatment, and the translational research needed to support clinical practice, and to reach the ultimate goal of improving the treatment of, and achieving the prevention of disease.

PREPARED STATEMENT

There are other comments that I have prepared as an opening statement and some questions, which I ask, Mr. Chairman, be printed in the record and submitted for answering for the record. And I apologize for having to go to chair another meeting and not being able to stay for the full period of this hearing.

Thank you all for what you do.

Senator SPECTER. Well, Senator Cochran, thank you very much for joining us. We know you are chairing another hearing. And your full statement and questions will be in the record and submitted for responses. Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I want to thank Dr. Kirschstein and the directors of the NIH's institutes for appearing here today. It is good to see Dr. Klausner and thank him for his trip to my state. I what all of you do for our nation's health. The NIH has excelled in the stimulation and support of medical research. Their efforts have involved both the basic scientific research needed to understand disease and treatment, and the translational research needed to support clinical practice, and to reach the ultimate goal of improving the treatment of and achieving the prevention of disease.

The NIH has invested in the future of our nation's health by addressing areas of need including chronic diseases and health outcome disparities among minorities, those who live in rural communities and other under served populations. Some of these initiatives have taken place in Mississippi. The NIH continues to invest in the Jackson Heart Study, one of most significant cardiovascular studies of the African-American population.

I am also very interested the ongoing efforts of NIH to increase opportunity and expand funding for projects like the Jackson Heart Study, in states such as Mississippi, that have not been traditional NIH research centers and that have lacked NIH research funding are also the areas with a high prevalence of chronic diseases.

I applaud the efforts of NIH to address not only the issues of today, but also the issues of tomorrow. Only through foresight and planning can we avert the epidemics of the future. For example, the NIH has been alert to problems such as infectious disease research and the growing problem of antimicrobial resistance.

NIH has also had the foresight to address diseases that are sometimes overlooked. One of those areas is Parkinson's Disease, a disease sometimes overshadowed by other more high profile diseases. In fact, I am hosting a briefing next week to support the National Institute of Neurological Disorders and Stroke strategic plan to develop a cure for Parkinson's.

I appreciate your efforts in each of these areas. I look forward to assisting you as you continue your important work.

Senator SPECTER. Senator Feinstein.

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

And I would like to say welcome to all of you.

Particularly for Dr. Klausner, you know this last year on the National Cancer Dialogue has been very interesting to me. And I have learned a great deal.

I have a statement, if I may, Mr. Chairman, to be entered into the record.

Senator SPECTER. Without objection, it will be made a part of the record in full.

Senator FEINSTEIN. Thanks very much.

[The statement follows:]

PREPARED STATEMENT OF SENATOR DIANNE FEINSTEIN

Thank you, Mr. Chairman, for holding this important hearing.

The American people put a great deal of hope and faith in the National Institutes of Health. NIH is truly a symbol of our national strength and the world's leading medical research institution. NIH has produced 93 Nobel Prize winners and I come from a state that has world-renowned research entities that work closely with NIH.

I have been pleased to work with NIH and this subcommittee to increase NIH funding in recent years, including the 15 percent increase we were able to provide each year for the past two years. It is a sad commentary that NIH can only fund around 32 percent of grant applications. Fortunately, that "success rate" has gone up since 1994 when it was only 25 percent, but still, the many unfunded grants

leaves a vast wealth of scientific knowledge unexplored and hundreds, if not thousands of diseases and disorders, uncured or untreated.

The challenges facing our nation are huge.

—By 2010, the incidence of cancer will reach "staggering proportions," with an increase of 29 percent in incidence and 25 percent in deaths, at a cost of over $200 billion per year.

— AIDS is now the leading cause of death among Americans ages 25 to 44.

—Rates of diabetes and asthma are rising.

—Seven to 10 percent of children are learning disabled. Forty thousand babies die each year from devastating diseases.

—Our aging population presents formidable challenges, from understanding overwhelming diseases like Alzheimers to helping people have quality of life as they have a longer life.

I am sure the decision to fund one area means not funding another and that NIH decision-makers must feel pulled in every direction.

CANCER CHALLENGES

As a co-chair of the Senate Cancer Coalition, I have been working closely with the national cancer community for several years and would like today to raise some of the concerns that are brought to my attention. I hope everyone will understand that these are not intended as criticism of NIH or any institute or individual, but are challenges for our nation as identified by experts.

The Discovery to Delivery Disconnect.—Dr. Harold Freeman, Chairman of the President's Cancer Panel, on March 8 made a presentation in which he expressed his concerns about a disconnect between the fruits of research and routine medical practice. He explained that we have made great strides in understanding disease origins, but said we must do better in incorporating research findings into routine practice. Can we do better? If so, how?

The National Cancer Institute is a research institution. It is not a HCFA or Medicare or health care delivery agency. It was never designed to be a delivery system for health care. Even so, can't we do better in connecting this disconnect?

The Unequal Burden of Cancer.—The Institute of Medicine last year issued a report on disparities in cancer care concluding, "Despite scientific gains, not all segments of the U.S. population have benefitted to the fullest extent from advances in the understanding of cancer." In October, the New England Journal of Medicine reported on a study of 11,000 lung cancer patients which found that blacks are less likely than whites to get surgery for early stages of lung cancer. The study ruled out reasons like socioeconomic status, insurance, and access to care and implied that the reason could be a breakdown in the doctor-patient relationship.

Unevenness of Cancer Care.—The Institute of Medicine also reported last year that "there is a wide gulf between what could be construed as the ideal and the reality" of cancer care, that some patients do not get care that is proven to be effective and the problem is "substantial." The study said that having health insurance improves access, but it does not guarantee good care.

The Declining Investigator "Pipeline."—The number of physician-scientists in oncology is diminishing at a time when knowledge and discovery are expanding rapidly. Funding at NCI for investigator training was only 3.1 percent of NCI's budget in 1999. The number of postdoctoral M.D. trainees in all fields funded by NIH overall has declined 51 percent of 6 years according to a study in Science. This is exacerbated by the growth in managed care plans that do not contract with academic medical centers where the bulk of research and training are conducted.

"This tragic phenomenon is jeopardizing the future of cancer research discovery and translation and the future of an America in which cancer is a treatable, beatable disease," says the National Coalition for Cancer Research.

The Salary Cap.—Since the early 1990s, Congress has placed a "salary cap" on extramural researchers, those scientists in laboratories, like the University of California. The cap is a top salary limit of $141,300, even though senior scientists on the NIH Bethesda campus can earn up to $157,000. This cap has the effect of driving talented researchers to the private sector. We should be trying to attract and retain talented researchers to our universities, not create incentives that drive them away.

Clinical Trials.—Only two percent of cancer patients are enrolled in clinical trials and of those, only 25 percent are elderly, even though cancer is disproportionately a disease of aging and the median age of cancer diagnosis is 68, according to the Cancer March of 1998. Last year, this committee asked NIH to send us a report on identifying barriers to participation in trials and recommendations for eliminating barriers. I hope you have good news for us today on that report.

The American people have said they would contribute another $1.00 per week in taxes for medical research. The public is behind NIH. This is indeed encouraging and I pledge to help NIH meet the many medical challenges that face our society.

I look forward to working with you to address these challenges to improve the health and quality of life of millions of Americans.

BENCH TO BEDSIDE APPLICATION

Senator FEINSTEIN. One of the things that I have become increasingly concerned about is the kind of disconnect that exists between discovery and application from the laboratory to the bedside. Some say it takes 5 years to get from a mouse to a human.

Somebody you know well, Dr. Helene Brown of the UCLA Cancer Center, points out that the pap smear was ready for widespread use in 1940, but was not really used until 1960. 20,000 women's lives a year were unnecessarily claimed over the 20 years of this delay.

My first question to any who care to answer is: How can we shorten this disconnect? How can we get things from the laboratory to the patient more quickly?

Dr. KIRSCHSTEIN. I think Dr. Klausner will start.

Dr. KLAUSNER. Thank you.

First of all, Senator Feinstein, I want to thank you for your leadership in the bringing together of the disparate components of the cancer community. You have been very helpful.

Senator FEINSTEIN. It has been interesting.

Dr. KLAUSNER. I think—while I can comment about some NCI programs, I think one of the characteristic changes of the last few years has been an acceleration of translation of basic research into the clinic. Now the speed with which that happens varies tremendously, depending upon what it is you are trying to translate.

For example, the discovery of a genetic alteration that predisposes an individual to a particular disease, for example cancer, can translate rapidly into a useful and useable clinical test.

In my own work with a tumor suppressor gene for predisposing an individual to kidney cancer, it took about a year from discovery for it to be widely used in clinics to help predict predisposition and to help families make decisions about surveillance and what to do about this particular predisposition syndrome.

For the development of new therapies, it often takes a long time. But I think many of the programs that have been developed with the new funding over the last few years are actually being developed to speed that transition.

Let me give you an example. We established a program about a year and a half ago called RAID for Rapid Access to Interventional Development. It is sort of a virtual national drug development system that reaches out to academic laboratories and funds new promising agents to move, we hope, within 12 months out of the laboratory into phase one clinical trials. And this is really very rapid.

We have now a little over a year's experience with the program. Thirty-two novel agents have been funded. Four of them have actually already made it out of the laboratory, basic laboratories, into clinical trials, each costing less than about $1 million per drug.

It is these sorts of programs that allow us to move things much more rapidly than we had before. And I think there are many other examples that all of us can give.

But I think it really is a characteristic of the new technologies and new programs we are all developing that are aimed specifically at speeding that transition.

STATE OF CANCER CARE

Senator FEINSTEIN. Second question—and I thank you for that. And I think you yourself pointed out the amazing extension of life that has been achieved through the pediatric model with cancer, where a child with cancer can in fact really be assured throughout the Nation of state-of-the-art cancer care. The same is not true for an adult.

And what we have found is that the state of cancer care throughout the Nation is extraordinarily erratic. The need for every cancer patient to have a quarterback physician, for example, I think preferably an oncologist, somebody who is able to go through the options with them, see that for their case they have the best possible options, there is no real state-of-the-art care for the adult cancer patient.

What is the institute doing to try to bring that about? And how might we be helpful in that regard?

Dr. KLAUSNER. Yes. I see the red light is on. Do I have time to answer this?

Senator SPECTER. Yes, Dr. Klausner.

Dr. KLAUSNER. Thank you.

Well, Senator, you are right. I think pediatric oncology, again, is one of the real success stories of NIH, of actually linking research to practice.

Sixty-five percent of children in this country who are diagnosed with cancer, regardless of their economic status or ethnicity or race, are treated on NCI-funded clinical trials. And 90-odd percent are treated on NCI-developed protocols. When I say NCI, I mean the protocols are not developed by the institute, but by our funded investigators. This is as opposed to 2 to 3 percent of adults being treated on NCI-funded clinical trials.

We believe that part of the reason there has been such progress in cure rates for childhood leukemia and childhood cancers, even without the development of major new drug advances, is due to improving protocols.

One of the things that we have been doing to try to expand this to the adult is to revamp our clinical trial system, to turn it into a truly national system with a single web-based informative structure that allows any physician to access any of the 1,500 open adult clinical trials that we have in the country. This is new and is just coming on line this summer with a new national clinical trials organizational unit.

But there is a lot that we need to do to try to open this. Funding is limited but with recent increased funding, there has been a significant increase in accrual just this past year of adult patients to clinical trials.

What does that mean? One example, in a recent adjuvant breast cancer trial, it was predicted to take 38 months just to finish the accrual. It took 14 months. That means we can ask more questions more quickly. It is a direct reflection of the funding.

There are other issues, and that is whether patients have access to clinical trials; the issue of whether, for the clinical care associated with clinical trials, patients can obtain reimbursement.

Senator FEINSTEIN. Can I just quickly——

Dr. KLAUSNER. Yes.

Senator FEINSTEIN. Are you saying then that the only way to assure that every cancer patient in the United States has state-of-the-art care is by access to clinical trials?

Dr. KLAUSNER. No. I am sorry.

Senator SPECTER. Dr. Klausner, you may answer that, but please do so briefly.

Dr. KLAUSNER. I do not think that is the only way, but I do think we need to expand the clinical trials to generate more answers more quickly.

And I think there is a variety of ways that we can make sure that the results of the clinical trials and the protocols that are generated, the expert protocols by which patients are treated on clinical trials, are more disseminated, whether it was within or without a clinical trial.

Senator FEINSTEIN. OK.

[The information follows:]

STEM CELL RESEARCH

As an introduction to the answers from the individual Institute and Center Directors, I would state that the potential scientific and medical benefits that may result from research using human pluripotent stem cells, funding and oversight of human pluripotent stem cell research by the Federal Government has become increasingly important. The participation of government in this research will help ensure that any research utilizing human pluripotent stem cells is conducted within the federal regulations and very importantly, that the results will be accessible to the public. If pluripotent stem cells are available to researchers, we expect that scientists will be able to pursue important research in the areas described below.

NATIONAL CANCER INSTITUTE

Since stem cells have the ability to divide without limit and give rise to many specialized cells in an organism, there are several reasons why may be important to cancer research and to reducing the cancer burden. First, pluripotent stem cells may be used to treat the tissue toxicity brought on by cancer therapy. Bone marrow and peripheral blood multipotent stem cells (which are more committed stem cells) are used already to restore patients' hematopoietic and immune systems after high dose chemotherapy. Pluripotent stem cells may have greater potential for returning the complete repertoire of immune response to patients undergoing bone marrow transplantation, thus contributing to the development of other treatments such as immune/vaccine therapy. Other tissues damaged by cancer therapy also may benefit by replenishing their stem cell pools, e.g., injection of pluripotent stem cells into the heart may permanently reverse cardiomyopathy caused by certain chemotherapeutic agents; injection of pluripotent stem cells that have been differentiated into neural cells may restore brain function after cancer treatment.

A second reason why stem cells may be important to cancer research is based on the finding that cancer cells may have certain stem cell properties, specifically, the ability to renew themselves. The isolation and characterization of stem cells and in depth study of their molecular and cellular biology may help scientists understand why cancer cells survive despite very aggressive treatments. Once the cancer cell's ability to renew itself is understood, scientists can develop strategies for circumventing this property.

A third and final reason for studying stem cells lies in the field of gene therapy, by which a gene that provides a missing or necessary protein is introduced into an organ for a therapeutic effect. One of the most difficult problems in gene therapy studies has been the loss of expression (or insufficient expression) following introduction of the gene into more differentiated cells.

Introduction of the gene into stem cells to achieve sufficient long term expression would be a major advance. In addition, the stem cell is clearly a more versatile target cell for gene therapy, since it can be manipulated to become theoretically any tissue. A single gene transfer into a pluripotent stem cell could enable scientists to generate stem cells for blood, skin, liver, or even brain targets. Applications to cancer might include engineering replacement cells that are resistant to chemotherapeutic assault or that express antibodies against cancer targets.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Research using human pluripotent stem cells represents an important opportunity to understand numerous processes in human biology and provides enormous potential for designing new therapies and screening candidate drugs for various diseases. Establishment of human pluripotent stem cell lines for the characterization of the biological properties and markers of stem cells will allow us to identify various stem cell populations and develop models/assays to predict successful replacement of tissue in disease or traumatic injury settings. The identification of factors that control these important processes holds great promise to ultimately treat numerous diseases that result in human suffering.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

The results from using pluripotential stem cells are enormously important towards developing innovative solutions to complex human diseases such as Parkinson's disease and a number of chronic pain syndromes. The capacity for pluripotential stem cells to differentiate into many different cell types is remarkable and has opened scientific inquiry into a number of approaches to regenerate damaged neural and muscular tissues. In addition, stem cell biology in general has opened new approaches for a number of therapeutic challenges such as soft and hard tissue regeneration. For example, mesenchymal stem cells found in bone marrow are being used to treat human bone diseases such as McCune-Albright syndrome here at the NIH.

These benefits are but a superficial glance at the possibilities for both pluripotential as well as totipotential stem cell biology. The scientific foundations are being established and we need critical support to rapidly advance our basic science of stem cell biology into preclinical and clinical trials to address the significant suffering of so many American people. Stem cell therapies could profoundly reduce the burden of many dental and craniofacial diseases and disorders such as cleft lip and cleft palate, oral and pharyngeal cancer, and a number of chronic facial pain syndromes. In addition, pluripotential and totipotential stem cell research will also produce specialized cells such as cartilage and salivary cells, which can be used as replacement for tissues damaged by disease or injury. Examples include the treatment of temporomandibular joint disorders (TMDs), the replacement of skeletal elements lacking or damaged in diseases such as fibrous dysplasia of bone, the use of cells grown in special natural or synthetic scaffolding materials, and the replacement of salivary cells damaged by autoimmune diseases (Sjögren's Syndrome) or radiation for head and neck cancer.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Human embryonic stem cells hold great promise for advances in health care because they can give rise to many different types of specialized cells that may be used to replace or repair damaged tissues and organs and for other therapeutic purposes. They can also be used to enhance the development of new medications to slow or arrest disease processes, and to aid fundamental research that can provide important insights into developmental processes important to the understanding, treatment and ultimate prevention of disease. These "pluripotent" cells have the unique capability of limitless division and self-renewal, and thus can be maintained indefinitely in cell culture.

Human embryonic stem cells offer the potential for treating a number of chronic diseases that are within the NIDDK research mission. For example:

Type 1 Diabetes.—There is an intense effort under way to understand the genetic rules by which an undifferentiated cell becomes a beta cell of the islet of the pancreas, which is capable of secreting insulin. Human embryonic pluripotent stem cells offer great hope for providing an unlimited supply of insulin-producing cells for transplantation once the rules of differentiation are known.

Liver Diseases.—Attempts at cellular therapy to replace diseased liver tissue are under way. In this case, a cell would need to differentiate along the lines of a functional liver cell. Again, a similar set of rules are necessary for this to happen, but

again the plasticity of the human pluripotent stem cell would form an excellent base for this to occur.

Kidney and Bladder Diseases.—Various forms of kidney cells or potential bladder cells also offer the potential to differentiate into highly important tissue specific cells. At the present time, there are a number of studies underway in an attempt to grow bladder cells that could be used to reconstruct a human bladder.

Developmental Biology.—There are other examples in addition to diabetes, liver failure, kidney failure, and urologic diseases in which human pluripotent stem cells may have a major therapeutic role. It would also be important to try and understand the genetic rules of development so that these important cells may be applied to important therapeutic uses.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Transplantation.—Research on embryonic stem cells could lead to cures for diseases that require treatment through transplantation, including autoimmune diseases such as multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type-1 diabetes.

The most feasible example in the short term is to treat type-1 diabetes by transplanting pancreatic islet cells or beta cells produced from autologous embryonic stem cells—that is embryonic stem cells that are removed from an individual, differentiated ex vivo to become functioning islets or beta cells, and then transplanted back into the same individual. Although there are questions about our ability to identify stem cells, obtain them in sufficient numbers from older children or adults, and produce differentiated cells, tissues or organs from such stem cells, this technique holds great promise to cure disease. Autologous transplants would obviate the need for immunosuppressive agents in transplantation, reduce the risks of transmitting infectious agents within transplanted materials, and eliminate the risks of post-transplant infection due to global immuno suppression. Moreover, such embryonic stem cells might be used to create a myriad of transplantable cells, tissues, and organs. This would address problems ranging from the supply of donor organs to the difficulty of finding acceptable matches between donors and recipients.

Primary Immunodeficiency Diseases.—Embryonic stem cells might be used to treat virtually all primary immunodeficiencies. There are more than 70 different forms of primary (congenital and inherited) deficiencies of the immune system, which are characterized by an unusual susceptibility to infection and are sometimes associated with anemia, arthritis, malabsorption and diarrhea, and certain malignancies. Almost all of these diseases are rare, and can involve considerable pain and suffering, numerous hospitalizations, high medical costs, and even death. Because these diseases are genetic, gene replacement is an important area of investigation in the search for an effective treatment. Transplanting stem cells that have been reconstituted with a normal gene might result in developing healthy cells of the types affected by the missing or damaged genetic material in the immunodeficiency disease. Based on research with animals, there is reason to believe that using embryonic stem cells as a mechanism to replace damaged or missing genes will have proliferative advantages over currently available alternatives, such as peripheral blood or bone marrow derived hematopoietic stem cells. Other hypothetical advantages include greater susceptibility to genetic transduction. Ultimately, the hope is for greater success in transplantation, long-term survival and reconstitution of normal cellular functions.

HIV/AIDS.—Research on pluripotent embryonic stem cell transplants could make restoration of immune function a viable option for treating HIV disease. Such transplants could regenerate all the components of the immune system that have been damaged by HIV infection. This includes repairing HIV-induced damage done to the cells and tissues that support immune system development, which would be a required prerequisite for T-cell repopulation. While there are many questions to be answered, experiments in animal models point to significant advantages with the use of these cells. Primarily, the embryonic stem cells are easily transduced with new genetic material, such as anti-HIV genes, so that the daughter cells are resistant to HIV infection. Thus, this combination of gene therapy and stem cell research could result in the immune reconstitution of AIDS patients with cells that are resistant to HIV.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

The logic arguing for NIH funding of embryonic stem cell research is straightforward from the perspective of nervous system disorders. Put simply: (1) Stem cells have enormous potential for treating disorders of the nervous system. (2) Research on embryonic cells is necessary to realize these possibilities.

To elaborate:

1. Stem cells have enormous potential for treating neurological disorders. The wide range of possibilities arises because these versatile cells can be used in several different ways. Plausible applications of neural stem cells include replacing lost nerve cells, replacing glial (supporting) cells, restoring complex nervous tissue, supplying cell sustaining chemicals, delivering substances widely throughout the brain, serving in tests for drug screening, and advancing fundamental studies of the brain and brain development. Although much research is needed before human trials can be safely attempted, animal experiments have already begun to demonstrate the feasibility of stem cell strategies for Parkinson's disease, spinal cord injury, demyelinating diseases such as multiple sclerosis, and enzyme deficiency disorders such as Tay-Sachs. Stem cell based strategies have also been proposed for several other neurological disorders such as stroke, epilepsy and brain tumors.

2. Embryonic stem cells are necessary to realize these possibilities. Although stem cells are present in adult brains, the adult stem cells may not have the versatility of their embryonic counterparts. There is experimental data showing that embryonic stem cells can produce not only many types of neural cells, but also muscle, blood, bone, and other tissue. There is strong evidence that embryonic cells can survive when transplanted and can migrate widely in the adult brain. Embryonic stem cells have the potential to divide for indefinite periods in culture and offer the possibility of a renewable source of replacement cells and tissue, but stem cells in the adult brain are characterized by limited availability and accessibility. Therefore, research on all types of stem cells must be done to compare their properties and find those most suitable for each of the several different potential therapeutic applications.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Studies of embryonic stem cells would speed important medical advances. For example, NIGMS has supported research devoted to the development of "artificial skin." Such a biomaterial would enjoy wide application in the field of burn therapy. Initial studies, begun in the early 1980s, has led to the development of a model for cultivating skin cells from burn patients. The method, which is being tested in patients today, consists of combining a biopolymer sponge made of collagen with actual skin cells from burn patients. Conceivably, human pluripotent stem cells could also be used as a source of "skin" to build such a graft, especially for severely burned patients with limiting amounts of remaining intact skin.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The fundamental question in biology is how a single fertilized egg develops into a complex adult organism with many different specialized cell types performing specific functions. This development follows a program directed by precisely timed turning on and off of many genes. Learning how this process works is basic to the mission of NICHD in promoting the birth of healthy offspring through research on human reproduction and development. Since pluripotent stem cells can develop into many different cell types, the study of how pluripotent stem cells can develop into many cell types may provide new knowledge of how fertilized eggs develop into organisms. Also pluripotent stem cell research will allow scientists to, among other things, direct the development of these stem cells along a certain path to become liver, blood, brain, or any type of cells which then can be used in transplantation and for other purposes. Within NICHD's area of interest, these cells could be used to replace organs or tissues that are defective as a consequence of birth defects. For example, one such condition is biliary atresia, in which part of the liver does not develop correctly. Human embryonic stem cells could potentially be directed to form liver tissue or to replace the damaged organ and save the life of the affected infant.

NATIONAL EYE INSTITUTE

Research into the treatment of retinal degenerations has demonstrated some promising results by transplanting retinal cells and tissues in an effort to "treat" animal models of retinal degeneration. However, the results have been mixed and many questions remain. The immunologic issues governing transplant survival are complex and only partially understood. Possible strategies for overcoming these problems are suggested from ongoing investigations of the development and maturation of the normal retina. Use of pluripotent stem cells could provide an additional avenue of research to overcome the immunological or other potential problems that may be encountered.

There is also a significant clinical need for improved techniques to promote conjunctival and corneal healing during disease or after injury. Conventional surgery or standard corneal transplantation procedures are not consistently successful in

treating persistent corneal ulcers, chemical or thermal injury, and other diseases that damage or scar the cornea. Recent results involving transplantation of corneal "stem" cells from the limbus region have shown some promise, but many practical and technical problems are presented by this approach. Transplantation procedures with pluripotent stem cells could provide an additional avenue of research for facilitating epithelialization of the ocular surface, reducing inflammation, vascularization, and scarring.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Human pluripotent stem cell research offers powerful new research approaches for clarifying the complex association of environmental agents with human disease processes. It also makes possible a powerful new means of conducting detailed investigations of the underlying mechanisms of the effects of environmental chemicals or mixtures of chemicals. The use of human pluripotent stem cell cultures may allow the identification of the specific early cell types at greatest risk of adverse effects from exposure to such developmental toxicants as lead, mercury, and polychlorinated biphenyls, as well as the mechanism of the toxic effect(s) and the temporal nature of future adverse effects in the subsequent cells and tissues established from these stem cells. There are often subtle effects of toxic exposures on the developing embryonic and fetal development tissue systems, yet these systems are responsible for maintaining strong post-natal health. For example, the human embryo and fetus may be very susceptible to long-terms impairments of immune or nervous system functions from the *in utero* effects of toxicant exposure.

Parkinson's disease, according to most recent findings, has a strong component related to environmental exposure component for one form of the disease. The nature of the agents and the timing of the exposure remain unknown at present. The use of human pluripotent stem cell cultures will permit screening for the subtle effects of candidate environmental toxicants and toxicant mixtures on specific cell types in the developmental stages of the cell lineage comprising the nervous system cells and tissue associated with the brain region compromised by the disease. Such explorations may yield powerful insight into the biological mechanism(s) underlying human susceptibility to the epigenetic form of this disease with onset after age 50, as well as the genetic-based "early" onset form of the disease.

It is possible that the opportunities afforded by human pluripotent stem cell research will lead to molecular markers or surrogate or combinations of both that can be utilized for population-based studies of gene-environment interaction in disease etiology. By using the toxicity screening, by human pluripotent stem cell coupled with DNA micro-array technology and gene expression profiling, it may be possible, within a decade, to construct complex data matrices of gene expression that constitute for each possibly toxic chemical a "signature" that could provide information by relating that chemical to others of known toxicity. Human pluripotent stem cell research offers great promise for use in testing the beneficial and toxic effects of biologicals, chemicals and drugs. Such studies will lead to fewer, less-costly, better-designed and more specific diagnostic procedures as well as more effective systemic therapies, not to mention the contribution of enhanced understanding to the development of strategies for prevention of disease.

NATIONAL AGING INSTITUTE

Human pluripotent embryonic stem (ES) cells hold enormous potential for cell replacement or tissue repair therapy in many degenerative diseases of aging. For disorders affecting the nervous system, such as Alzheimer's and Parkinson's diseases, amyotrophic lateral sclerosis, and spinal cord and brain injury, transplantation of neural cell types derived from human ES cells offers the potential of replacing cells lost in these conditions and of recovery of function. Human ES cells could provide a model for studying fundamental molecular and cellular processes important in the understanding of aging and age-related diseases. However, before the full medical potential of ES cells can be realized, much research needs to be done on the basic biology of human ES cells.

Pluripotential and self-renewal capacity of human ES cells.—The potential use of ES cells in human medicine hinges on the possibility that ES cells can be grown in large numbers and that they can be induced to form all human cell types. Factors controlling the self-renewing ability of human ES cells must be explored and compared to self-renewal properties of fetal and adult stem cells. Factors that control the pluripotent nature of ES cells, that is, their ability to form various cell types when grown in culture or when transplanted into human tissue must be studied. The role of telomerase and other gene-regulating proteins in self-renewal, cell fate determination, and senescence could be examined.

ES cells for transplantation and tissue repair.—Human ES cells could be used in tissue regeneration therapy in, for example, age-related neurological, cardiovascular, musculoskeletal, and immune system problems. Work in animal models of human nervous system diseases, such as demyelinating disorders and spinal cord injury, has provided evidence that mouse stem cells can survive, differentiate, and give some degree of functional recovery following transplantation to the affected region of the nervous system. The ability to use human ES cells in research would allow validation of such a cell replacement and repair strategy in animal models of human diseases. This could lead to potential transplantation of human ES cells into the brains of Alzheimer's and Parkinson's disease patients to replace lost or dysfunctional cells in the affected brain regions. ES cells also could be genetically modified to express certain proteins, such as neuronal growth factors, and then transplanted into affected brain regions in which locations they could provide local delivery of the critical therapeutic factor(s). ES cells could be used to effect bone and cartilage repair in osteoporosis and osteoarthritis, to reconstitute the immune response in age-related or genetic disorders, and to promote muscle regeneration in age-related progressive muscle wasting & strength decline. The ability of human ES cells to generate an immune response following transplantation could be assessed and compared to fetal or adult stem cells to see if they could be used to reduce the problem of rejection following cell therapy.

The ability to use human ES cells in research would allow intensive studies to be performed to understand factors leading to optimum therapeutic benefit, including determining the best type of cells (embryonic, fetal, or adult stem cells) for transplantation and what happens when cells are transplanted into hosts of different ages or into hosts with different or multiple diseases. A better understanding of the fundamental, biological properties of human ES cells could lead to their successful use in cell transplantation and tissue regeneration therapies in age-related disorders.

NATIONAL INSTITUTE OF ARTHRITIS MUSCULOSKELETAL AND SKIN DISEASES

Generation of replacement cells and tissue to treat diseases

Because stem cells constitute a self-renewing population of cells, they can be cultured to generate greater numbers of bone, cartilage, muscle and skin cells than could be obtained from a tissue sample. Equally important, if a self-renewing population of new stem cells can be established in a transplant recipient, it could effect long-term correction of many diseases and degenerative conditions in which bone, cartilage, muscle and skin cells are deficient in numbers or defective in function, such as in osteogenesis imperfecta and various chondrodysplasias.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Pluripotent stem cells research has tremendous potential for developing therapeutic strategies for regenerating selected populations of cells the degeneration or loss of which causes debilitating disease. Several clear examples include degeneration of insulin-producing cells in the pancreas which causes Type 1 diabetes mellitus, and degeneration of a subset of neurons in the brain which results in Parkinson's Disease.

By age 70, it is estimated that as many as one third of all Americans have significant hearing impairment that compromises human communication using spoken language. Many of these individuals also have problems with balance, which leads to falls and limits their mobility. The cause of this loss of hearing and balance is most often degeneration or loss of hair cells, which are the specialized cells in the inner ear that detect sound and provide sensory input needed for balance.

NATIONAL INSTITUTE OF MENTAL HEALTH

Human embryonic stem cells are a critical resource for studies of biological and disease processes, and for the creation of disease models. Human stem cells provide a model to study the factors that regulate differentiation, migration, and survival of neurons and glia in the brain. Because developmental factors are implicated in the pathophysiology of mental disorders (e.g., schizophrenia, autism, etc), it is important to understand the factors regulating critical developmental events that control stem cell fate in the central nervous system. Stem cells hold tremendous promise for the discovery and development of novel therapeutic targets such as growth factors and other signaling molecules. Stem cells also represent the most promising source of cells for use in transplantation therapy. Ultimately, stem cell research may provide important insights into the pathophysiology and treatment of mental disorders.

NATIONAL INSTITUTE ON DRUG ABUSE

Stem cells can be a valuable resource to drug abuse researchers, particularly those investigating the effects that drugs of abuse have on development. Stem cells can be potentially used to replace cells damaged by neurotoxic drugs. Using stem cells can also allow us to better determine the more subtle effects of drugs on the developing embryonic and fetal development tissue systems.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

The value of pluripotent stem cell research would be in elucidating mechanisms of cellular differentiation. With this knowledge, scientists would have the potential to selectively differentiate cells into various tissues.

Alcohol is a major source of damage to organs, such as the liver and brain, that may or may not regain function with abstinence from drinking. Development of medications that accelerate recovery in organs damaged by alcohol would be a major breakthrough. Such an advance would lessen human suffering and the economic burden associated with alcohol-induced organ damage. For cases of irreversible organ damage, stem cell research could be used to facilitate generation of new organ tissue. The following examples demonstrate the potential utility of this type of research to the alcohol field:

Reversal of cognitive deficits in alcoholics: Treatment of memory problems as a result of long-term drinking can be problematic because patients have difficulty remembering instructions from therapists. Although in less severe cases recovery is possible after 3–5 years of abstinence, initial treatment is less effective, and patients are more likely to relapse. In the case of Korsakoff's syndrome, deficits can require lifetime institutionalization of patients. Transplantation of stem cells using appropriate growth factors may reverse the neurochemical and behavioral deficits induced by chronic ethanol administration. This approach might ultimately reduce the costs of long-term care.

Organ transplantation: Alcoholic liver disease ranks second as the cause of end-stage liver disease necessitating liver transplantation. Given the scarcity of organs for transplantation, in vitro stimulation of pluripotent stem cells into liver cells and other specialized cells offers the extraordinary possibility of replacement cells and tissues for treatment.

Fetal Alcohol Syndrome (FAS) cognitive deficits: Pluripotent stem cells would provide investigators with a tool to study how alcohol disrupts cellular differentiation at various stages of embryonic development. Findings from this research would contribute to the design of potential interventions for FAS.

NATIONAL INSTITUTE OF NURSING RESEARCH

The NINR does not perform research involving embryos or stem cells. However, nursing research will benefit from the technological advances resulting from such research. When embryo or stem cell clinical applications involve patient care, nursing research studies will contribute to the science base for health care professionals, especially nurses.

NATIONAL CENTER FOR RESEARCH RESOURCES

1. Potential for stem cell cure of Type 1 Diabetes versus the present insulin injection treatment.
2. Potential cures for Parkinson's and Alzheimer's Diseases through embryonic stem cells.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

The Division of Intramural Research at the National Human Genome Research Institute is using the tools produced by the Human Genome Project, supported by the Institute's extramural research program, to study the fundamental mechanisms of development and the contributions of genetic factors to disease. NHGRI investigators have identified the following as potentially promising areas of study involving pluripotent stem cells:

Gene Expression.—The differentiation potential of pluripotent stem cells make them important candidates for studies of alterations in gene expression profiles. Being able to examine the genes that are turned on and off during the differentiation process of these cells, using newly developed microarray technology, could supply very useful information about normal and abnormal cell development. This information could have promising application to a whole host of disease areas.

Parkinson's Disease (PD).—PD is caused by degeneration of neurons in the region of the brain, the substantia nigra, leading to severe abnormalities in movement. The

cause is largely unknown, although in a few rare families with early onset disease, mutations in the gene for alpha synuclein are known to be responsible. As with other neurodegenerative disorders, replacement of damaged nerve cells with stem cells is one avenue of possible therapy. Current experiments using fetal cells for replacement have provided very mixed results, especially for the long term. One possible explanation for the less than complete replacement is that the cells being transplanted are too far along in path of development and differentiation to be able to take up residence in the substantia nigra, make all the correct connections, and replace the damaged cells. Using even less differentiated cells, such as embryonic stem cells, is a possible alternative.

Gene Therapy.—Almost any genetic disease for which cell and tissue transplantation protocols exist could potentially benefit from the application of embryonic stem cells in gene therapy. For example, patients with genetic disorders of the immune system might benefit greatly from studies involving gene transfer using specially derived pluripotent stem cells. Studies involving these cells also may be useful in immune reconstitution or in engineering immunologic resistance by HIV infected individuals.

Blood Disorders/Sickle Cell Disease.—The epsilon globin gene is expressed only in embryonic red blood cells. This gene recently has been shown to block the sickling of red blood cells by hemoglobin. Research involving embryonic stem cells could help answer questions about how to turn on the epsilon globin gene in adult blood cells and thereby halt the disease process. Stem cell research may also help produce transplantable cells that would not contain the sickle cell mutation.

Senator SPECTER. Thank you very much, Senator Feinstein.

Coming back to the stem cell issue, because that is going to be the subject of major floor debate on legislation which we have introduced to eliminate the restriction on NIH doing funding on embryos, there has been substantial resistence to eliminating that restriction on the, I think, misguided ground that we are dealing with potential human life, when in fact these are discarded human embryos. It is going to be a real battle, though. And I would like to explore it for a moment or two.

I know Senator Harkin is going to go back to Dr. Spiegel about the potential for juvenile diabetes.

But what substance is there to the argument that there are alternatives, such as umbilical cords or other avenues of approach to get adequate numbers of stem cells for research?

Who is the best person to answer that, Dr. Kirschstein?

Dr. KIRSCHSTEIN. I think many of my colleagues could, maybe Dr. Fischbach, Dr. Spiegel——

Senator SPECTER. Dr. Fischbach, we will start with you, since my red light will be on momentarily, too.

Dr. FISCHBACH. I will be brief. There are many sources of stem cells. And I am optimistic about stem cells from adult animals, but I think stem cells from embryos will also be extremely important. And I would be reluctant to rule out any source.

The devastating illnesses that are going to be treated by these stem cells demand that we explore every possibility.

Senator SPECTER. Well, Dr. Fischbach, beyond being unwilling to eliminate any source, that really does not directly answer the question as to whether there would be an adequate supply of stem cells other than from human embryos.

What is it about the embryo which requires its availability for stem cell research to get the maximum benefit, to——

Dr. FISCHBACH. At the present time, embryonic stem cells can divide and grow outside the body for an unlimited period of time. So by geometric multiplication, they can provide enormous stores of cells that can be used medically.

It is a matter of research in the future to try and transform stem cells from adults, because adult stem cells at the present time do not have that capability of unlimited growth and expansion for medical use.

Senator SPECTER. I would request that everyone submit to us a written response as to the utility of eliminating that funding limitation. We are going to have a knock-down, drag-out floor battle in the Senate.

We put into our appropriations bill last year the elimination of that prohibition in order to bring the matter to a head. But we knew that we could not get the appropriation bill through without a filibuster if that remained for floor action. So we removed it with an agreement with the majority leader to bring up a free-standing bill this year.

And I have talked to Senator Lott, and he is prepared to do it shortly. But we will need all the evidence we can get as to why that prohibition ought to be eliminated.

YOUTH VIOLENCE

Dr. Hyman, I am interested to know what progress has been made on our allocation of almost $900 million to school violence. We took that up, as you know, and you attended one of three lengthy sessions where we brought people in from various disciplines to try to treat school violence—as Dr. Koop said in 1982 as surgeon general, that it is a national health problem. And you have a very leading role in it.

Could you give the subcommittee an update as to what has been done in furtherance of your work and, perhaps to the extent you know, by the other people we met with where we had that very substantial funding allocation?

Dr. HYMAN. I will be brief, and I will give you a complete answer for the record. But I will answer in two regards. First, in regard to the research that has been initiated at NIH, including NIMH, and then in some of the cooperation across government agencies, which I think has actually been almost unique in my experience, in terms of research at NIMH, we have been focused on two areas.

One is interventions before somebody goes down the wrong road. We have recognized that children with either mood disorders or attention deficit hyperactivity disorders that are not optimally treated are at much higher risk for subsequent violent behavior and incarceration.

And we have completed several clinical trials and are initiating new clinical trials in areas to help us understand the best and safest ways to intervene early for these children.

For children who are already engaged in violent behavior, we have also initiated research on optimal ways of diverting them off this path.

And one—just to be very brief, one very important insight, although it sounds almost like common sense, is that the final common pathway for a lot of children into either violent or criminal careers has to do with aggregation of antisocial peer groups. And yet it is the practice in the United States to literally create graduate schools for delinquency by having group detentions, alternative

schools, and incarcerating young children often with hardened criminals.

There are interesting data and new clinical trials looking at something called therapeutic foster care in which foster parents are supported by professionals. And one of the linchpins of this intervention is to make sure that these youngsters do not associate with other antisocial peers. And we have evaluations from some initial trials.

And, of course, I do not have answers for you yet, because, based on new funding, we have just initiated some new replication trials.

Just to give you a flavor of the cooperation, we have been cooperating with SAMSA, especially the Center for Mental Health Services, also with the Departments of Education and Justice. We have had several meetings.

The Safe Schools/Healthy Schools Program has representation from multiple agencies and I think has some really superb demonstrations. It is too early to evaluate, but NIMH is actually supporting sort of a research evaluation to make sure that these collaborations actually do some good that we can quantify and demonstrate.

Senator SPECTER. OK. Thank you, Dr. Hyman. We will look for a more complete response in writing.

[The information follows:]

YOUTH VIOLENCE

Youth violence is a complex problem that requires complex solutions. NIMH has long supported and conducted research to generate information about risk factors, experiences, and processes that are related to the occurrence, during childhood and adolescence, of aggressive, antisocial, and violent behavior, and associated mental health problems. Broad lessons drawn from this research underscore the importance of a nurturing social environment in childhood, good early education and success in academic areas; the prominent influence of peers, whether positive or negative, on adolescent development; and the potential risks of policies that endorse or require intervention programs that house or otherwise group troubled adolescents. This overview highlights what is known about risk factors for the development of antisocial and problem behavior, and describes various early prevention and intervention strategies.

Risk Factors.—Tragic events like the shootings at Columbine High School are not typical of youth violence. Most adolescent homicides are committed in inner cities and outside of school. They most frequently involve an interpersonal dispute and a single victim. On average, six or seven youths are murdered in this country each day. Most of these are inner-city minority youths. Such acts of violence are tragic and contribute to a climate of fear in schools and communities. Many studies indicate that a single factor or a single defining situation does not cause child and adolescent antisocial behavior. Rather, multiple factors contribute to and shape antisocial behavior over the course of development. Some factors relate to characteristics within the child, but many others relate to factors within the social environment (e.g., family, peers, school, neighborhood, and community contexts) that enable, shape, and maintain aggression, antisocial behavior, and related behavior problems.

NIMH-supported research on risk for aggressive, antisocial and violent behavior encompasses multiple aspects and stages of life, beginning with interactions in the family. Weak within-family bonding, ineffective parenting (poor monitoring, ineffective, excessively harsh, or inconsistent discipline, inadequate supervision), exposure to violence in the home, and a climate that supports aggression and violence put children at risk for being violent later in life. At particular risk for violence are children who are exposed to the contributors listed above and who have mental disorders such as depression and anxiety and problem behaviors such as early conduct and attention problems, and lower cognitive and verbal abilities. Outside of the home, a major factor contributing to youth violence is peer influence. In the early school years, a good deal of mild aggression and violence is related to peer rejection and competition for status and attention. More serious behavior problems and vio-

lence are associated with smaller numbers of youths who are failing academically and who band together, often with other youth rejected by prosocial peers. Successful early adjustment at home increases the likelihood that children will overcome such individual challenges and not engage in behaviors that place them on a trajectory leading to violence. However, exposure to violent or aggressive behavior within a family or peer group may influence a child in that direction.

Longitudinal research has begun to identify broad categories of young people who progress to adolescent antisocial behavior, the multiple pathways through which such behavior develops and persists, and the multiple factors that shape this risk. Two specific life course trajectories, called life course persistent, which is viewed as a form of psychopathology, and adolescence limited, which is identified only in select social situations—offer a useful distinction both as a way of thinking about developmental knowledge and as a tool for targeting the right interventions for antisocial youth.

Life course persistent individuals begin antisocial behavior early in childhood and continue into adulthood, after their adolescence limited counterparts stop. Life course persistent behavior has been correlated with neurological deficits and pathological behaviors, (e.g., impulsivity) which are exacerbated when they are combined with stressful home situations. In one study of 13 year olds, individual differences—such as deficits in sensory, perceptual, and cognitive abilities, including the use of language—were shown to predict participation in crime five years later. One study found, for example, that boys with poorer neuropsychological functioning, especially verbal functioning at age 13, were more likely to have committed crimes at age 18 than were their counterparts with better neuropsychological functioning at age 13.

Gender Differences.—From about 4 years of age on, boys are more likely than girls to engage in both aggressive and nonaggressive antisocial behavior. Much remains to be learned about the causes of gender differences in antisocial behavior, but experts have suggested that it might be necessary to define antisocial behavior somewhat differently for boys and girls. Research has shown, for example, that girls are more likely to demonstrate social aggression by damaging peer relationships rather than by boys' overt aggression that inflicts harm through physical damage or the threat of such damage. NIMH currently is funding research on the antecedents and consequences of aggression for girls and boys as an essential step toward developing empirically-based interventions for aggressive children of both sexes.

Antisocial Behavior Co-Occurring with Child Psychopathology.—There is strong evidence for the co-occurrence of two or more syndromes or disorders among children with behavioral and emotional problems. An obviously angry adolescent has other conditions such as anxiety disorders and depression (as seen in the quiet withdrawn young person) more often than would occur by chance. Research in this area indicates that very young children with conduct problems and anxiety disorders or depression display more serious aggression than youths with only conduct problems. Although some available data suggest that conduct problems often precede problems of depression, the sequencing of these concerns is not entirely clear for youth. Whether depression precipitates acting out, whether impairments and predispositions for acting out lead to depression, or whether there are underlying causal factors that are responsible for the joint display of such problems are unresolved questions.

It is very common for youth with conduct problems to also display symptoms of attention deficit hyperactivity disorder (ADHD), the most commonly diagnosed behavioral disorder of childhood. The diagnosis is made by the presence of persistent age-inappropriate inattention and impulsivity, often coexisting with hyperactivity. This co-occurrence is often associated with an early onset of aggression and impairment in personal, interpersonal, and family functioning. Furthermore, academic underachievement is common in youth with early onset conduct problems, ADHD, and adolescents who display delinquent behavior.

Individual Liability and Genetic Factors.—Although understanding of the nature of genetic influences on antisocial behavior is incomplete, research on differences in the magnitude of genetic and environmental influences on different kinds of conduct problems will contribute to elucidating the developmental origins of antisocial behavior. Twin and adoption studies indicate that child and adolescent antisocial behavior is influenced by both genetic and environmental factors, suggesting that genetic factors directly influence cognitive and temperamental predispositions to antisocial behavior. These predisposing child factors and socializing environments, in turn, influence antisocial behavior. Research suggests that for some youth with early onset behavior problems, genetic factors strongly influence temperamental predisposition, particularly oppositional temperament, which can affect experiences negatively. When antisocial behavior emerges later in childhood or adolescence, it is suspected that genetic factors contribute less, and such youths tend to engage in

delinquent behavior primarily because of peer influences and lapses in parenting. The nature of the child's social environment regulates the degree to which heritable early predisposition results in later antisocial behavior. Highly adaptive parenting is likely to help children who may have a predisposition to antisocial behavior. Success in school and good verbal ability tend to protect against the development of antisocial behavior, pointing to the importance of academic achievement.

Parent and Family Factors.—Research has demonstrated that youths who engage in high levels of antisocial behavior are much more likely than other youths to have a biological parent who also engages in antisocial behavior. This association is believed to reflect both the genetic transmission of predisposing temperament and the maladaptive parenting of antisocial parents. The importance of some aspects of parenting varies at different ages. The impact of inadequate parental supervision, for example, tends to be more pronounced in late childhood and adolescence than in early childhood. Evidence from many studies indicates that parental use of physical punishment may play a direct role in the development of antisocial behavior in their children. Other researchers have observed that parents often do not define antisocial behavior as something that should be discouraged, including such acts as youths bullying or hitting other children or engaging in "minor" delinquent acts such as shoplifting.

Research examining the mental health outcomes of child abuse and neglect has demonstrated that childhood victimization places children at increased risk for delinquency, adult criminality, and violent criminal behavior. Findings from early research on trauma suggest that traumatic stress can result in failure of systems essential to a person's management of stress response, arousal, memory, and personal identity that can affect functioning long after acute exposure to the trauma has ended. One might expect that the consequences of trauma can be even more profound and long lasting when they influence the physiology, behavior, and mental life of a developing child or adolescent.

Peer Influences.—Antisocial children with earlier ages of onset tend to make friends with children similar to themselves. Consequently, they reinforce one another's antisocial behavior. Children who display age-inappropriate levels of impulsivity and hyperactivity (core symptoms of ADHD) are often rejected and thus are more likely to associate with other rejected and/or delinquent peers. The influence of delinquent peers on later onset antisocial behavior appears to be quite strong. Association with antisocial peers has been shown to be related to the later emergence of new antisocial behavior during adolescence among youths who had not exhibited behavior problems as children.

Socioeconomic Factors.—An inverse relationship of family income and parental education with antisocial behavior has been found in many population-based studies. Across gender and ethnicity, much of the inverse relationship between family income and antisocial behavior is accounted for by less parental monitoring at lower levels of socioeconomic status.

Studying the impact of communities and neighborhoods on children, researchers have examined three major features: (1) structural and demographic features, (2) exposure to situations or events, and (3) community-level processes and forms of social control.

In terms of structural and demographic features, research on the extent to which neighborhoods are characterized by deteriorating housing, overcrowding, greater population density, and greater numbers of female-headed households consistently shows strong correlations with neighborhood crime rates and violence.

By living in deteriorating neighborhoods with higher crime rates, children and youth are more likely to be exposed to and witness robberies, assaults, and murders. Experiencing their neighborhood as dangerous, young people are at increased risk for becoming anxious, depressed, defiant, and/or aggressive. Children who have seen or been the victim of violence are more likely to join gangs and report carrying weapons to school.

A newer line of research has begun to examine how community-level processes and forms of social control may be important factors related to youth delinquency. Studies which have examined the extent to which members of the community share collective willingness to intervene in youth misbehavior have shown these forms of collective social control to correlate with decreased rates of delinquency and problem behaviors.

Prevention and Intervention.—NIMH-supported investigators have developed and tested several effective programs and strategies to prevent youth violence at different stages of childhood, including programs for pre-school children, which are not discussed in this report. In light of the Subcommittee's interest in inter-agency collaborations, however, it is noteworthy that the Administration on Children, Youth and Families (ACYF) and the NIMH have awarded several research grants as the

core component of a new young children's mental health research initiative designed to develop and test applications of theory-based research or state-of-the-art techniques for the prevention, identification and/or treatment of children's mental health disorders within a Head Start context. Among these are projects to develop screening tools for identifying behavior problems in preschool children, to test the effectiveness of research-based classroom interventions for very young children with serious disruptive behavior problems, and to assess the mental health needs of this vulnerable population.

School-Age Children.—Research has found that between 70 and 80 percent of children with diagnosable mental disorders who receive services are served within the school system, primarily by school psychologists and guidance counselors. The NIMH has supported many projects designed to develop, establish, and improve school-based mental health service delivery systems. These projects range from broad programs intended to enhance the social and problem solving skills of all students, to highly specific programs designed to treat children already showing symptoms of mental health problems. Programs also range from those that intervene at multiple levels, including the child, parents, peers, and teachers, to those that focus solely on the child. For example, research is developing techniques for teachers to manage disruptive students.

The Families and Schools Together (FAST) Track Program is a multi-faceted, multi-year program designed for aggressive children in kindergarten, starting at age 6. A four-site study in North Carolina, Pennsylvania, Tennessee, and Washington, FAST Track involves working with the child, the family in their home, and school system, including teachers. Preschool children at high risk were identified at 55 different schools. These children were randomly assigned for intervention or no intervention. The children initially enrolled in the study are now young adolescents. An evaluation of FAST Track found that by the third grade, students who took part in the program showed less oppositional and aggressive behavior and were less likely to require special education services than students who did not take part.

The Linking the Interests of Families and Teachers (LIFT) Program is a 10-week intervention created for children and families who are at risk for the development of conduct problems due to residence in neighborhoods characterized by high rates of juvenile delinquency. The LIFT Program is a multi-component intervention that includes parent training, social skills training, a playground behavioral program, and regular communication between teachers and parents. Following program participation, students engaged in significantly fewer aggressive behaviors on the playground, parents demonstrated fewer negative behaviors during family problem-solving activities, and teachers reported improved student social behavior and peer interactions. Three years following the intervention, LIFT program students were less likely than their non-LIFT counterparts to engage in consistent alcohol use, to have troublesome friends, to have been arrested for the first time, or to demonstrate inattentive, impulsive, overactive, and disruptive behaviors in the classroom.

Research-based programs also have been initiated to enhance the skills and knowledge of all children in order to decrease their risk of future emotional and behavioral problems. NIMH has sponsored the Promoting Alternative Thinking Strategies (PATHS) Curriculum, based in Washington State, which teaches children about self-control, understanding emotions, and problem solving. The PATHS curriculum has been evaluated using students in both regular education and special education classrooms. Students who received the PATHS curriculum demonstrated better knowledge of emotions than children who did not receive the curriculum. This emotional knowledge is thought to underlie the development of necessary social skills such as friendship development and maintenance, anger management, conflict resolution, and appropriate problem solving.

The research highlighted above is, for the most part, sponsored by NIMH. In addition, numerous components of the National Institutes of Health (NIH) along with other Federal agencies have been active in responding to the Subcommittee's expressed interest in research concerned with developing and evaluating the effectiveness and sustainability of programs aimed at prevention, early recognition, and intervention for depression and youth suicide in school and community settings.

On October 28 and 29, 1999, a meeting of investigators with extensive and recognized expertise in youth violence research was held at the National Institutes of Health Neuroscience Center in Bethesda. This meeting was organized in response to a request from former NIH Director Dr. Harold Varmus to convene a trans-NIH expert panel on youth violence intervention research. It was co-sponsored by the Office of Behavioral and Social Sciences Research (OBSSR), the NIMH, the National Institute of Child Health and Human Development (NICHD), the National Institute on Drug Abuse (NIDA), the National Institute of Nursing Research (NINR), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The Expert Panel ob-

served that much research has been and continues to be devoted to identifying the multiple risk factors that contribute to antisocial behavior as well as the mechanisms by which they operate. The Panel noted that several, often co-morbid, youth behavior problems (aggression and violence, high risk sexual behavior, and drug abuse) share common risk factors in their development. They pointed out that a number of these shared risk factors reliably predict behavioral problems and can be successfully changed through interventions. The Panel also observed that many other factors have been identified as important in understanding risk for behavior problems but have not been the target of focused interventions. The meeting participants identified future research needs that are informing research activities of the Institutes.

In January, 2000, NIMH joined the OBSSR and several other NIH/IC's to co-sponsor a new RFA (OD 00–005) on developing and testing new interventions to prevent and/or reduce youth violence. In excess of 150 letters signaling intent to respond to the April 14, 2000 application due date have been received.

NIMH and the Center for Mental Health Services, Substance Abuse and Mental Health Services Administration (CMHS, SAMHSA) are issuing a joint program announcement (PA) to encourage research grant applications on services delivered to children, adolescents and their families through the CMHS's Comprehensive Community Mental Health Services for Children and Their Families Program initiative. Conducting the proposed research at one of the Children's Services Program sites is a prerequisite for funding under this PA. This PA encourages studies of the effectiveness of treatments or services delivered at these sites, the nature and impact of routine clinical practice, and factors related to successful implementation of treatments or services, including interventions targeting violent behavior and related problems.

On March 30, NIMH staff met with members of the Working Group on Youth Violence Research, a component of the White House Council on Youth Violence. Members of the Working Group include representatives from the Departments of Health and Human Services, Justice, Labor, Education, and other Federal entities. The Working Group is refining an inventory of federal activities addressing youth violence; to make information on violence prevention and other interventions available to families, teachers, administrators and others involved in designing and implementing programs; and to develop a coordinated federal research agenda on youth violence.

Staff of NIMH and the Centers for Disease Control and Prevention (CDC) are working closely to coordinate new CDC and NIMH efforts to develop new interventions and to implement effective prevention and treatment programs. This coordination has enabled NIMH and CDC to cross-reference and link research announcements issued by each agency, which already is enhancing the efficient use of federal research resources in this area of science.

Finally, NIMH, CDC, and the Substance Abuse and Mental Health Services Administration (SAMHSA) are collaborating in a major effort to develop a Surgeon General's Report on the topic of youth violence. The report, planned for release early in fiscal year 2001, will examine advances in research regarding the occurrence and prevention of violence and interventions for those who engage in violent behavior. In order to raise public awareness about the critical issues surrounding youth violence, the report will provide useful information to help parents, schools and communities by identifying potentially effective strategies for ameliorating the risk of violence among youth. In addition, attention will be given to identifying approaches to intervention that may be contributing to problems rather than reducing them. This report will be an effective and highly credible means of educating policy makers and the public about the interaction of mental disorders and youth violence.

Senator SPECTER. Senator Harkin.

TREATMENT FOR JUVENILE DIABETES

Senator HARKIN. Thank you, Mr. Chairman. I just want to get back to Dr. Spiegel one more time on juvenile diabetes and stem cells.

Again, enlighten me again on what role stem cells could play in the further progress of what has happened at the University of Alberta. And then give me some idea of maybe some time frames that we are looking at.

Just from my reading, my non-scientific reading, of it, it seems that this may be one of the earliest breakthroughs if, in fact, the data that I see from Alberta is correct, in terms of using stem cells to—and this is where my scientific expertise lacks—using the stem cells to regenerate the kind of cells that we need to replace the insulin-deficient cells in those who are suffering from juvenile diabetes. I think I am within the ballpark of scientific terminology there.

Dr. SPIEGEL. Let me try to be concise. To be clear, in the Edmonton protocol, stem cells have not been used.

Senator HARKIN. I understand that.

Dr. SPIEGEL. So they are using harvested inlets containing insulin-secreting cells from donor pancreas.

Senator HARKIN. Yes, sir.

Dr. SPIEGEL. What we are both enthusiastic and cautiously optimistic about is that we hope this will be successful, because if it is, it represents a long-sought cure for Type I diabetes, juvenile diabetes.

But it will then create an enormous demand and need for sources of insulin-secreting cells, which cannot possibly be supplied at current donor rates. And that is why stem cells are so absolutely critically important.

Because research into stem cells, both the pluripotent type of embryonic stem cells that Dr. Fischbach alluded to, as well as ones that are further along, such as stem cells from the part of the embryo that would ultimately lead to both liver and pancreas, understanding those developments are critical to be able to provide a source for these kinds of transplantation experiments.

And one final point: Basic stem cell research could also be important in teaching us ways to intervene in individuals with Type I diabetes to get regeneration of their existing stem cells. And this is potentially an important modality of treatment as well, which would be an alternative or complement to transplantation.

Senator HARKIN. I appreciate that, Dr. Spiegel. Could you—I hate to ask for more paperwork. But with regard to this area and the answer you just gave, if you could reduce that to writing for me and just get that to me, I sure would appreciate it.

Dr. SPIEGEL. I would be pleased to.

[The information follows:]

STEM CELL RESEARCH AND DIABETES

Type 1 diabetes is a disease for which stem cell research holds great promise. Research on islet cell transplantation and stem-cell biology offers compelling opportunities for the development of new, innovative approaches for treating and ultimately curing this disease. Type 1 diabetes is characterized by the inability of the body to produce insulin, a hormone necessary for glucose metabolism. It arises when the body's immune system attacks and destroys its own insulin-producing beta cells in the islets of the pancreas. The result of this "autoimmune" disease process is high levels of blood glucose, which are difficult to control with insulin injections. Moreover, although treatment with insulin sustains the patient's life, it does not prevent the devastating complications of the disease. These include kidney failure, blindness, amputation, heart attack and stroke. Clinical trials have shown that these complications can be prevented or significantly delayed by maintaining blood glucose levels as close to normal as possible. However, achievement of such intense blood glucose control requires multiple daily injections of insulin or use of an insulin pump—an extremely difficult regimen to follow, especially for children and teenagers, and one that always poses a risk of dangerously low blood sugars.

To address these problems, researchers have pursued alternative approaches to restoring insulin-producing capacity—including research to develop an artificial pan-

creas, research on whole pancreas transplantation, and studies of islet cell transplantation. Formidable bioengineering problems attend development of an artificial pancreas, and while researchers are working diligently to overcome them, a time frame for success cannot be predicted. Whole pancreas transplantation, while successful in some patients, is an extremely difficult surgery. It requires lifelong treatment with immunosuppressive drugs that can have toxic side effects. Moreover, whole pancreas transplantation does not have as high a rate of graft survival as kidney transplantation. This surgery is typically performed only in adults, often in conjunction with a needed kidney transplant for which immunosuppressive drugs would already be required.

Islet cell transplantation has several potential advantages. For example, insulin production could be restored with islets alone, which would be a much simpler procedure than pancreatic transplantation. Ideally, islet cell transplantation could be achieved with one or two infusions of cells on an outpatient basis without the need for chronic immunosuppressive drugs. Until very recently, serious technical problems have been a major impediment to rapid progress in islet transplantation research. The two key challenges have been: (1) to keep the body's immune defense system from rejecting the transplanted islets, and/or causing recurrence of autoimmune destruction of islets, and (2) to ensure that there is a sufficient supply of islet cells for transplantation. To date, only about five percent of people with diabetes who have received transplanted islets along with immunosuppressive drugs have been able to stay off insulin longer than one year. Recent scientific developments offer the potential to overcome these obstacles and have propelled researchers to focus more intense efforts on islet cell transplantation. This therapy is now viewed as a highly promising means of curing type 1 diabetes, especially for children and young adults whose disease has not yet progressed to the point of debilitating complications.

The renewed promise of islet cell transplantation derives from two complementary research opportunities that could overcome the challenges that have stymied progress in this field. The first opportunity is the development of new methods for modulating the immune system to both preserve residual insulin-producing capacity and to keep the body from rejecting transplanted islet cells. The second opportunity is the prospect that stem cell research could ensure the needed supply of islet cells for transplantation. Together, these opportunities offer unprecedented hope for curing type 1 diabetes. They are also highly consistent with major recommendations of the Strategic Plan of the congressionally directed Diabetes Research Working Group.

The first new opportunity, the development of novel immune-modulating methods, is the focus of multiple research initiatives across the NIH, including NIDDK, NIAID and NCRR. Scientists are making progress in finding ways to both halt the attack of the immune system on its own tissue and to prevent the body's rejection of transplanted organs and tissues—without the lifelong need for immunosuppression. Following promising preliminary results in experimental animals, clinical investigators are pursuing studies of novel biologic agents that offer the prospect of modulating the immune system in such a manner that transplanted organs and tissue are indefinitely accepted by human recipients. Initial clinical studies applying immune modulation therapy are being performed in patients receiving a kidney transplant for end-stage renal disease. Later this year, researchers plan to transplant insulin-producing pancreatic islet cells into patients with selected forms of type 1 diabetes.

Of particular promise are studies currently under way by a team of researchers at the Unversity of Alberta, Edmonton, Canada. These researchers have developed and are following a revolutionary protocol for islet cell transplantation in patients with type 1 diabetes. This protocol involves treatment with an antibody to a cytokine receptor; rapamyacin; and a low dose immunosuppressant. It is particularly noteworthy that this protocol did not use glucocorticoid steroids as an immunosuppressive agent. In addition to having well-known side effects, such as growth retardation and increased risk of osteoporosis, these steroids are also toxic to islets. The researchers expect to report on their results in a scientific journal in the very near future. The Juvenile Diabetes Foundation International (JDF) provided support for the initial research in Edmonton. Now, plans are under development to replicate this approach, with support from the NIAID, NIDDK and the JDF, at several transplant centers that harvest their own islets.

To the extent that islet transplantation therapy proves successful, there will be a great need for more islet cells. Currently, the NIH is working to perfect methods to increase the yield of these cells from pancreatic tissue; however, the ultimate solution will be to obtain them from other sources, such as stem cells. In this regard,

it is vitally important to pursue simultaneous research on two fronts of stem cell biology: embryonic stem cells and adult stem cells.

Embryonic stem cells offer the greatest promise of providing a limitless source of islet cells for treating and curing type 1 diabetes. Embryonic stem cells are called "pluripotent," because they have the ability to develop into most of the specialized cells or tissues in the human body. These stem cells can be derived from embryos that were intended for *in vitro* fertilization, were not used, and are donated for research purposes. Because embryonic stem cells mark the earliest stages of human development, they have not yet differentiated into specific types of organs and tissues. Thus, the possibility exists that these cells could be made to differentiate into specialized tissue needed for transplantation therapy, such as islet cells. Because embryonic stem cells have the unique property of being capable of limitless division and self-renewal, they can be maintained indefinitely in tissue culture. Thus, their potential benefits for research and medicine are enormous.

Another potential source of islet cells for transplantation are stem cells found in the tissues of adults. Although these cells do not have the same capabilities as embryonic stem cells, they could prove useful in islet cell transplantation. Adult stem cells undergo asymmetric division, with some becoming stem cells capable of replenishing the tissue in which they are located, while others are capable of specialization into different tissue. Thus, adult stem cells are at an intermediate point in the differentiation process—beyond the embryonic stage, but not irrevocably committed to a final cell or tissue type. If researchers were able to identify and isolate pancreatic stem cells from adult tissue, it might be possible to direct these cells to differentiate into islet cells. This possibility could come to fruition as more is learned about the genes regulating cellular development and differentiation.

The ability to use embryonic and adult stem cells as a means of providing islets for transplantation therapy in type 1 diabetes will be critically dependent upon a fundamental understanding of the developmental pathways that lead to the formation of pancreatic islets. A workshop on "Stem Cells and Pancreatic Development" held at NIH provided evidence of impressive progress in identifying a cascade of genes responsible for differentiation of cells from precursors in the embryonic foregut to pancreatic islet and specifically beta cells. Scientists at this workshop also reported on progress in identification, growth, and transplantation of hematopoietic, neural, muscle, liver, and pancreatic stem cells. Major recommendations for further research to permit application of stem cell technology to treatment of type 1 diabetes included:

1. Identification of molecular 'signatures' of stem cells and progenitors in the endocrine pancreas. Identifying all the genes expressed in the mouse and human pancreas throughout development is a goal of a major new NIDDK initiative on the "Functional Genomics of the Endocrine Pancreas." It is conceivable that some of the genes may regulate cellular differentiation and thus could be used to direct stem cells down the specialization pathway to become islet cells;
2. Generation of monoclonal antibodies to proteins expressed on the surface of islet beta cells and islet cell precursors to use in identification and isolation of pancreatic stem cells.
3. Identification of growth conditions that permit the proliferation and differentiation of lineage-specific stem cells both inside and outside the body;
4. Exploration of the potential use of embryonic stem cells, and tissue-specific stem cells, in the formation of pancreatic islets; and
5. Use of animal models to examine the role of stem cells in the regeneration of the endocrine pancreas.

Applying basic knowledge obtained from research in developmental and stem cell biology will enable the production of progenitor stem cells and the rational design of cellular therapies for human diseases such as diabetes. It is essential to underscore that studies of stem cells and the genes that regulate their development could be important as ways to intervene in type 1 diabetes, even beyond their use in islet cell transplantation. For example, a more precise understanding of stem cell biology could lead to methods to activate stem cells and to regenerate beta cells of the pancreas. Coupling immune modulation treatment to halt further autoimmune destruction of the islets with treatments to activate stem cells to regenerate beta cells would offer a powerful approach to prevention and treatment of patients at risk for development of type 1 diabetes.

Thus, researchers have attained a very encouraging benchmark with respect to developing new clinical approaches to type 1 diabetes. They are currently pursuing a two-pronged approach involving both immune tolerance and stem cell biology to overcome previous impediments to successful islet cell transplantation. Inducing immune tolerance can halt or reduce the autoimmune attack on the insulin-producing cells of patients and help them retain some insulin reserve. In essence, this ap-

proach provides a "shield" to block the autoimmune attack and protect the residual insulin-producing cells from further destruction. The second prong of therapy is islet transplantation-based on novel methods of immunomodulation to prevent graft rejection, coupled with research on stem cell biology to provide a limitless source of islets for transplantation.

HUMAN GENOME PROJECT

Senator HARKIN. Dr. Collins, on the human genome project, could you again enlighten me, and perhaps the press who is here and the public, there has been this big debate about Celera and you and this race to the finish and their patenting the gene and all that.

A lot of people have asked me, well, wait, if you, the human genome project, is mapping and sequencing the human gene, and it is going to be here in another 1½ years or 2——

Dr. COLLINS. We expect to have the finished sequence in 2003, but a working draft will be done in the next 2 or 3 months.

Senator HARKIN. OK. So 2003. And that is going to be available to the public?

Dr. COLLINS. Yes.

Senator HARKIN. All the knowledge, everything, all the mapping, all the sequencing you have done on the human genome.

Dr. COLLINS. Every 24 hours.

Senator HARKIN. All day long. So if a private company has already done that, and they have tried—why would a researcher then feel it necessary to go to a private company to get that kind of information, when they can go to NIH and get that information? So why do I care if Celera does whatever they are doing? As long as it is done in NIH, why should I care? I mean, it would be available to researchers all over. What is the problem?

Dr. COLLINS. Well, Senator, I appreciate the question, and I appreciate this subcommittee's support of the Human Genome Project over the last 10 years. You had the vision of this project even before some of the rest of the scientific community had caught on. That vision is clearly paying off.

We are at a very exhilarating time. Just yesterday we announced that we have crossed the 2 billion base pair mark.

Senator HARKIN. Wait a minute. I was just at the 1 billion base——

Dr. COLLINS. Well, there you go.

That is right. We appreciated your attending the ceremony in November to celebrate 1 billion. And yesterday we got to 2 billion. It was T, by the way. The second billion bases were capped off by a T.

And since the genome is only 3 billion, you can see that this working draft is coming along very quickly. It will require the course over the next 2 or 3 years to close the gaps and deal with the ambiguities that still remain in this draft version. But for many scientific applications, this will be enormously useful. And it is useful to anybody with an Internet connection.

I think the parallel that I might try to draw for you is one that is perhaps familiar to people within these halls, and that is the Thomas System for keeping track of what is going on with regards to congressional legislation and other hearing transcripts and so on.

There is this system, which citizens can go to if they are seeking information about what is happening in the U.S. Congress. And it is available for free to anybody who needs to find it out.

There are other more elaborate systems, of course, that you can pay to subscribe to, such as Lexus Nexus or Congressional Quarterly Search Service, which for the sophisticated user who has the wherewithal to pay for them, are also useful.

We think of ourselves as the Thomas System for the human genome project, where the basic information, the raw fundamental sequence of the genome, and some basic information about what it means, which our colleagues at the National Library of Medicine are putting together, is available to anybody in any country, whether in the private sector, the public sector, wherever. As long as they have an Internet contact, they can find out what we know right now, as of today.

But there will undoubtedly be uses of the genome sequence that require a sophisticated level of annotation, of melding together a lot of additional information in order to try to add value to that basic information. We see that as a golden opportunity for the private sector to set up, hopefully not one, but many different competing databases that interested subscribers can check out and decide if they think those are worth their while to pay for.

I think that is the solution to what has been a sort of tumultuous enterprise here, that we have the Thomas System, but then we have these other available, highly annotated versions that people who want to use them can subscribe to, if they find that that meets their needs.

Senator SPECTER. Let me come back to you, Senator Harkin. Senator Feinstein had some more questions.

Senator Feinstein.

AIDS VACCINE DEVELOPMENT

Senator FEINSTEIN. Thank very much, Mr. Chairman.

I would like to ask a question, if I might, about AIDS. The President's budget includes a 12-percent increase in 2001 for AIDS vaccine research. I was wondering if you could describe NIH's plan for developing the vaccine and, given this increase, if you could possibly be specific as to when a vaccine might be available.

Dr. KIRSCHSTEIN. Senator Feinstein, I am going to ask Dr. Nathanson, the Director of the Office of AIDS Research, and Dr. Fauci, the Director of the National Institute of Allergy and Infectious Diseases, to share their response to that question.

Senator FEINSTEIN. Thank you very much.

Dr. NATHANSON. Yes. So let us talk first about the way we are going about developing a vaccine, which I think was your first question. And the second was when we would expect to reach that goal.

We have a series of sequential approaches which start off with some basic laboratory work on the virus, its proteins and its genes, and then move into animal experiments. And we are particularly using a rhesus monkey model of AIDS with a simian virus, simian immunodeficiency virus, very similar to human. And that can be rapidly used to improve the speed of this translation, to test concepts much more quickly than we can do in humans.

And then we move into a further translational effort where we start first with phase one trials, which are safety trials on a small scale in humans, and then phase two, immunogenicity trials and extended safety trials, and phase three, efficacy trials.

And we are expanding at all levels and basically pursuing a number of concepts about how to make an effective and safe vaccine in parallel because of the urgent need.

We have made considerable progress with some of those concepts in animals. And at the present point in humans, there is a phase two trial that is an immunogenicity trial of a potential vaccine. It involves what is called a prime to start the immune response and a boost of an additional protein. And the results of that phase two trial will determine whether that is going to be advanced to a phase three trial.

And I think Dr. Fauci might like to comment about that and maybe add something to my comments.

Senator FEINSTEIN. As to when we might——

Dr. NATHANSON. Well, as to when we will get to the potential phase three trial, this particular product could start within about a year, if we decide to move forward. It is a product the efficacy of which is somewhat marginal. And therefore, there is some debate within the scientific community.

In fact, my council happens to be meeting today. And last night we did debate that somewhat. There are different views. And I think Dr. Fauci might like to enlarge on that.

Dr. FAUCI. The question really is twofold. When will we engage in a trial that will ask the question if a vaccine is effective? And then a much broader question that is much more difficult to answer is: When will we have an effective vaccine?

Because one of the things we need to appreciate is, particularly with HIV, in contradistinction to other vaccine studies for other microbes, it is highly unlikely that the first vaccine trial that we do will be a home run, where we will have a highly effective vaccine.

The situation is a little bit different with HIV/AIDS. When we deal with most of the vaccines that we deal with, namely for childhood diseases, we will not accept anything less than a 90 or so percent effectiveness, because we want to make sure that virtually each and every one of the children that we vaccinate will be free of getting infected with the organism in question.

With HIV/AIDS, we will probably have step-wise gradation of relatively more effective vaccines where the first one that is available might be in a range of effectiveness that would be unacceptable, for example, if it were a polio vaccine or a rubella vaccine. And those kinds of successes would probably go a long way to interrupting the kinetics of the epidemic, particularly in developing countries.

For example, if you have a 35- to 45-percent efficacy of vaccine that would be unacceptable for a vaccine that we would use for a childhood disease, whereas that might, if given to populations with a very accelerated rate of infection, might interrupt the kinetics of the epidemic to the point that we would have a major positive impact.

So it is really a complicated question and a complicated answer. We will probably within the next year or so be going into larger trials to ask a question, "Is this at least partially effective?"

But as Dr. Nathanson mentioned, while we are doing that, we will be building up a pipeline of candidates that might in 4, 5, 6, or 7 years from now be much better than the candidates that we are dealing with now.

Senator FEINSTEIN. Thank you.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Feinstein.

Senator Kohl.

Senator KOHL. Thank you, Senator Specter.

EPILEPSY RESEARCH

Dr. Fischbach, I am pleased that today NINDS is sponsoring a conference on epilepsy. I am hopeful that the discussions at the conference will lead to a clearer strategy for research into this disease. With that goal in mind, I have two questions.

Report language last year discussed curing epilepsy, not just finding new treatments for it. What is NINDS doing differently to change its focus from finding new treatments to finding a cure to stop epilepsy?

Dr. FISCHBACH. Thank you, Mr. Kohl. There is a wonderful conference which is beginning this morning and continuing for 2 days, titled "Curing Epilepsy," because the problem is that all of the drugs currently on the market merely reduce symptoms. More than a third of the patients in this country remain burdened with seizures at one time or another. There is no single therapy that completely eliminates them.

We have expanded our ADD Program, our Anti-epilepsy Drug Development Program, looking for new medications with novel targets, new ways that drugs may interfere with the epileptic process that have not been explored before.

We have developed methods for new modalities of therapies, such as brain stimulation, by stimulating outside the brain and even with electrodes placed inside of the brain, in an attempt to disrupt and cure epilepsy, defined as complete freedom from seizures and complete absence of side effects. So those are just two of the ways that we have approached it.

A third and extremely promising strategy is to make use of resources now emerging from the genomic efforts to understand the mutant genes underlying more than 50 percent of the cases of epilepsy, which should lead to new and better diagnostic and therapeutic approaches.

Senator KOHL. What is NINDS's strategy for focusing on the population with intractable epilepsy?

Dr. FISCHBACH. This is the most difficult of all. And I simply would say that the three approaches I just mentioned—new targets for medicines, electrical stimulation to manipulate circuits in the brain, and more molecular genetic approaches will be beneficial to those patients. That is our hope.

ALZHEIMER'S RESEARCH

Senator KOHL. Thank you.

Dr. Hodes, it is my understanding that some research has shown that Alzheimer's disease begins to destroy the brain cells of its victims 10 to 20 years before outward symptoms appear. Do we cur-

rently have the tools to diagnose Alzheimer's disease in its earliest stages? And if not, what research is being done to develop that capability?

Dr. HODES. Senator, you are correct in that a number of studies have shown that a combination of parameters, including imaging, have been able to identify individuals who are at high risk of developing Alzheimer's disease a decade or two later.

More recent studies, including some to be published this week, have taken a step further in refining these imaging techniques in particular, and have been extremely good at predicting which individuals are likely, over the course of a 3- to 5-year follow-up, to develop Alzheimer's disease.

This has not yet reached the stage of practicality as an intervention per se, but has an enormous impact in terms of identifying individuals at high risk. The importance of identifying individuals of high risk is particularly tied to current studies to test an intervention designed to prevent progression of disease.

So by identifying a population likely, if no intervention is used, to develop Alzheimer's, we have an opportunity to carry out the critical studies now beginning, to see if we can interfere with that process.

JUVENILE DIABETES

Senator KOHL. Thank you. Last summer, 9-year-old Lenisha Patterson of Germantown, WI, testified before this subcommittee on what it is like to live with juvenile diabetes.

I also have a short statement, which I would submit for the record and a statement from 14-year-old, Rachel Malz of Wisconsin, describing how diabetes has affected every day of her life. Both of these children have asked the subcommittee to promise to remember them and all the children who live with juvenile diabetes. I am one of 55 Senators who are trying to do just that.

[The statements follow:]

PREPARED STATEMENT OF SENATOR HERB KOHL

Thank you, Mr. Chairman. And I'd like to welcome you, Dr. Kirschstein, and all of your colleagues who have agreed to appear before the Subcommittee today.

As we all know, over the past several years, Congress has provided unprecendented funding increases for the NIH. I commend Chairman Specter and Senator Harkin for their leadership in ensuring that NIH has the resources it needs to achieve one of our nation's most important goals: curing disease and alleviating human suffering.

It is both our hope and also our expectation, that this strong investment will result in new treatments and cures for diseases. Not only will this improve the quality of life of all Americans, it will reduce the need for expensive treatments in the future by keeping our nation's health care costs down.

I strongly support biomedical research and agree that Congress should continue to provide the funds necessary to make this a reality. However, in addition to providing the dollars, Congress also has the responsibility to ensure that these funds are spent wisely. We have provided these increases as part of a balanced budget—but we must not forget that we have accomplished this by making some tough choices between other health and education programs. It is critical that these tradeoffs can be justified by ensuring that research targets our nation's most pressing health needs.

Again, I thank you, Mr. Chairman, for your support of NIH. I look forward to the question period, when we will have a chance to explore these priorities and results in more detail.

PREPARED STATEMENT OF RACHEL MALZ, MADISON, WI

Good morning. My name is Rachel Malz and I am from Madison, WI. I am fourteen years old and I was diagnosed with Juvenile Diabetes when I was only 21 months old. I do not remember even one day when diabetes was not a part of my life. My diabetes has been very difficult to control. I was placed on an insulin pump when I was ten to help control all the ups and downs. However, at the age of twelve, my kidney tests showed some problems, so my doctor started me on an Ace—Inhibitor medication. Studies have shown these drugs may help keep my kidneys working. As you can see, I am doing all I can to stay as healthy as possible until a cure is found. I need all of you in that room today to do your part and work together so it will happen soon. Thanks to you and to Senator Kohl for the opportunity to share my story.

Senator KOHL. Earlier this year we sent a letter asking you to fund more research into this area. I was pleased to learn that NIH is planning to implement the scientific recommendations of the Diabetes Research Working Group.

However, it is my understanding that doing so would cost $827 million in fiscal year 2000, while NIH projects to spend only $525 million.

I would appreciate knowing from you how NIH will be able to implement these recommendations, given the fact that the resources are presently lacking.

Dr. KIRSCHSTEIN. NIH strongly endorses the scientific recommendations of the Diabetes Research Working Group. And Dr. Spiegel and I have had many conversations about this.

Within the constraints of the President's proposal for fiscal year 2001, which was a 5.6-percent increase overall, we provided to the Diabetes Institute a 5.9-percent increase. We will work hard with the funds that are available and funds that are given to us, to do the best and most important research possible.

I think you heard from Dr. Spiegel how he is deeply involved in some of the studies on juvenile diabetes. He and I both understand the problems of that disease and feel deeply for those children. And I would like to ask him to expand on the discussion.

Senator KOHL. Thank you.

Dr. SPIEGEL. Thank you, Dr. Kirschstein.

And, Senator Kohl, I appreciate the opportunity. It brings me back to the chairman's question. The Diabetes Research Working Group suggests that NIDDK, for example, in 2001 should increase its spending by $387 million. And within the budget constraints of the President's budget, we expect to increase from $313 million to $338 million. So you see that that falls very substantially short.

Nonetheless, it is clear that there are some extraordinary opportunities, specifically in genetics, genomics and in clinical trials for Type I, Type II diabetes and obesity, all significant problems.

So we are going to do the best that we can within the constraints of the budget, but it is clear that there are extraordinary opportunities which we would seize upon, if there were additional resources.

Senator KOHL. Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Kohl.

NCI'S BUDGET

Let us try a round to see how this works on the questions that I have posed. We will start with you, Dr. Klausner. You and I have

talked about this on a number of occasions. Question one: What is the total funding for your institute?

Dr. KLAUSNER. The proposed total funding——

Senator SPECTER. No. What is the current total funding for your institute?

Dr. KLAUSNER. $3.32 billion.

Senator SPECTER. And what percent of grants do you award?

Dr. KLAUSNER. The success rate for grants will be 30 to 31 percent this year.

Senator SPECTER. And what is the total number of applications you have?

Dr. KLAUSNER. The total number of applications we have had this year is a little less than 4,000.

Senator SPECTER. And what percentage would you like to grant, or do you think are meritorious?

Dr. KLAUSNER. I think what we would shoot for is about 40 percent.

Senator SPECTER. And what would the total funding be necessary to make the grants that you would like to make?

Dr. KLAUSNER. In order to achieve that level of funding and—and I think this is important—at the same——

Senator SPECTER. You do not have to repeat the question. We would just like the answer, because I would like to go around the room.

Dr. KLAUSNER. OK. We would require about a 20-percent funding increase for the Institute to achieve the above success rate.

Senator SPECTER. OK. Would you see if you could sharpen that up a little for me on all those questions?

Dr. KLAUSNER. Yes.

Senator SPECTER. I know we are catching you sort of off guard here.

NHLBI'S BUDGET

Dr. Lenfant, Heart, Lung and Blood Institute, what is your total funding?

Dr. LENFANT. It is—including the AIDS component $2.025 billion.

Senator SPECTER. And how many grants have you made, are you making?

Dr. LENFANT. In this year, it will be 1,050.

Senator SPECTER. And what percentage is that of the applications?

Dr. LENFANT. It is 27 percent.

Senator SPECTER. And what percent grants would you like to make, if you had adequate funding?

Dr. LENFANT. I will be consistent, and I will say 35 percent is really what we should support.

Senator SPECTER. And what kind of budget would you need to do that?

Dr. LENFANT. That would require an increase of approximately 16 percent.

NIDCR'S BUDGET

Senator SPECTER. Dr. Slavkin, dental, what is your total funding?

Dr. SLAVKIN. Our current funding for fiscal year 2000 is $269 million, including the AIDS budget.

Senator SPECTER. And how many grants have you made?

Dr. SLAVKIN. We project making 157 competing awards this year. In the year that closed, our total was 131. And we anticipate next year it will be 127.

Senator SPECTER. And what percent of the applications will you be making grants to at the higher figure?

Dr. SLAVKIN. We will struggle to meet a success rate of 19 percent for fiscal year 2001. And so our——

Senator SPECTER. And what percent would you like to make?

Dr. SLAVKIN. Well, we have been hoping to reach at least a 33-percent success rate.

Senator SPECTER. And what total funding would that require?

Dr. SLAVKIN. For us, that would require an additional $41 million in funds for the competing research project grant line.

NIND'S BUDGET

Senator SPECTER. Dr. Fischbach, what is your total funding?

Dr. FISCHBACH. $1.03 billion.

Senator SPECTER. And how many grants have you awarded?

Dr. FISCHBACH. 2,000.

Senator SPECTER. And what percentage is that to the number of applications?

Dr. FISCHBACH. It is 35. We are close to 35 percent.

Senator SPECTER. And what percent would you like to award?

Dr. FISCHBACH. 40 percent.

Senator SPECTER. And how much more money would that take?

Dr. FISCHBACH. That would require approximately a 20-percent increase above the $1.03 billion.

POSSIBLE ACCOMPLISHMENTS

Senator SPECTER. What do you think you could accomplish with that extra money, Dr. Fischbach?

Dr. FISCHBACH. I think we would do a significant amount more in neuro-degenerative disorders—ALS, Huntington's disease, Parkinson's disease, and Alzheimer's disease especially. We would fund more consortial arrangements for sharing of resources.

Senator SPECTER. We heard that as to Parkinson's, the answer may be as close as 5 to 7 years. Would you confirm that?

Dr. FISCHBACH. That is the hope, and I am optimistic about that.

Senator SPECTER. How about Alzheimer's?

Dr. FISCHBACH. That is an also extremely promising area of research, as I am sure Dr. Hodes would expand on. But with new discoveries about enzymes responsible for amyloid deposition, there is renewed hope for new therapeutic targets.

Senator SPECTER. Could you give us a projection on time, if you got the extra money?

Dr. FISCHBACH. On Alzheimer's disease, I think it is difficult to project that. That is such a complex disorder involving so many dif-

ferent systems within the brain that I would hope that even prolonging useful cognitive life by 1 or 2 years in the next 10 would be an extreme advance.

Senator SPECTER. Well, would you all write down the questions and provide—I am going to observe the time signals—the total funding each of your units gets, the number of grants you are able to award with that amount of funding, what percent the awards are from the total number of applications, what percent you would like to award, and what that would cost?

[The information follows:]

INSTITUTE/CENTERS BUDGETS

The following table summarizes the total funding levels requested for each institute and center (IC) in the fiscal year 2001 President's Budget request. It also provides the number of new and competing research project grants (RPG) that each IC funds and the success rate or percent of RPG applications each IC could fund within the fiscal year 2001 President's Budget request.

The table also summarizes the success rates by IC associated with funding all new and competing RPGs in fiscal year 2001 at the professional judgment (PJ) level, as well as total costs associated with funding at the PJ level. Professional judgment budgets, which reflect each IC's best judgment of scientific opportunities available, are formulated by each IC without consideration of competing pressures or budgetary constraints or Administration priorities. NIH believes that each IC's PJ budget represents the IC's judgment of scientifically meritorious research.

As I have noted, the RPG success rate varies among ICs. This variation reflects the difficulty of predicting total numbers of applications as well as the importance of many other mechanisms in funding each IC's best judgment of scientific opportunities available for support in fiscal year 2001.

NATIONAL INSTITUTES OF HEALTH ADDITIONAL COSTS TO FUND PROFESSIONAL JUDGMENT BUDGET

[Dollars in millions]

	Fiscal year 2001					
	President's budget			Funding professional judgement		
	Total	Number of competing RPGs	Success rates (percent)	Success rates (percent)	Additional amount competing RPGs	Additional amount for IC total PJ budgets
NCI	$3,505.1	1,271	30	42	$154.5	$629.9
NHLBI	2,136.8	811	29	43	146.9	193.6
NIDCR	284.2	127	19	33	40.9	74.0
NIDDK	1,209.2	715	34	50	107.0	160.5
NINDS	1,084.8	487	25	39	115.3	151.2
NIAID	1,906.2	831	31	39	110.4	159.9
NIGMS	1,428.2	882	26	33	81.3	128.8
NICHD	904.7	332	20	35	110.3	160.1
NEI	474.0	237	34	45	41.6	69.2
NIEHS	468.6	181	23	27	12.2	59.4
NIA	725.9	315	17	33	116.5	155.0
NIAMS	368.7	216	24	35	33.4	46.1
NIDCD	278.0	140	21	37	30.3	47.3
NIMH	1031.3	485	23	33	67.0	138.3
NIDA	725.5	262	21	32	46.9	113.4
NIAAA	308.7	123	23	48	43.1	102.6
NINR	92.5	50	14	26	12.1	17.5
NHGRI	357.7	43	32	42	11.2	72.5
NCRR	714.2	57	13	22	10.0	319.3
NCCAM	72.4	18	26	40	27.6	40.2

NATIONAL INSTITUTES OF HEALTH ADDITIONAL COSTS TO FUND PROFESSIONAL JUDGMENT BUDGET—Continued

[Dollars in millions]

	Fiscal year 2001					
	President's budget			Funding professional judgement		
	Total	Number of competing RPGs	Success rates (percent)	Success rates (percent)	Additional amount competing RPGs	Additional amount for IC total PJ budgets
FIC	48.0	58	27	47	6.1	22.0
Total	18,124.7	7,641	26	38	1,324.7	2,861.0

Notes.—Because the question specifically focuses on RPGs and success rates, this table does not include information on the National Library of Medicine, the Office of the Director, and Buildings and Facilities activities.
May not add due to rounding.

Senator SPECTER. I am glad that Senator Stevens, the chairman of the full committee has—Senator, if I may have Senator Stevens' attention.

He came in just at the point where we were inquiring of this distinguished group of scientists what funding they would like to make awards on the meritorious grants. And that is a good place for the chairman of the full committee to come in.

We do not have the answers, but I will provide them to you, Senator Stevens. And I will also give you the floor at this time.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Well, thank you very much. And I am sorry to just barge in. We have a whole series of subcommittees meeting today, and I do like to stop in on each one and thank the people involved for their participation.

I do think that we have a very tight budget this year. But I also think—and I have been making speeches throughout the country on the conclusion I have reached, really.

And that is that this group, NIH, represents an investment in the future that, from a strictly conservative point of view, we ought to increase the investment now to assure that you are—that we are capable of dealing with the vast problems that will come to our country when the baby-boomer generation retires.

If we have the same degree of diseases in their generation as exist in my generation, there is going to be a skyrocketing cost that the budget just cannot absorb.

Though we are on the verge of so many breakthroughs, I think the number one and most important investment we can make this year—and I am chairman of the Defense Subcommittee—is not in defense, but is in accelerating the research and bringing about the developments and perfecting the application of some of the breakthroughs we already have.

And I am—once again, Mr. Chairman, I am still ready to do battle. We are going to continue to be on the course that we are on, and that is: We are going to try to continue our process that will, within 5 years, double the amount of money that is available for research in NIH.

Now, that is the commitment you made and, I think, we all made when we voted on that resolution. I take this resolution very seriously.

Having said that, though, I do think that we have to find some way to really make certain that this money is really going to research and not necessarily to bricks and mortar. I am a little slow about the bricks and mortar side of the budget.

I think the most important thing we can do now is accelerate this research and put it in the hands of our most competent people, and make sure that we get, to the maximum extent possible, the breakthroughs we need so we can reduce those future costs. That is the investment that I think we should make.

And I thank you, Mr. Chairman.

Senator SPECTER. See how good Senator Stevens' timing is? He came in at just the right moment. That is a pretty good commitment from the chairman.

Senator STEVENS. Thank you.

Senator SPECTER. Thank you for that, Senator Stevens.

Senator Harkin.

GENE SEQUENCING

Senator HARKIN. That is a good commitment. I appreciate that, Mr. Chairman.

Dr. Collins, I just want to wrap up this issue on the genome. I read the statement put out by Prime Minister Blair and President Clinton, statements made at the following press conference by you and Dr. Lane.

I just want to make it clear. Since I have been involved in this from the beginning, I just want to make it clear again where I think we ought to be headed in this. And I want to make it clear to the press that is here, too.

That raw fundamental data on the sequencing of the human gene or any parts thereof should never be patentable. If a private sector company wants to get patents, I believe that company should take that raw available data, conduct experiments like they would for any other drug, and if experiments prove that it has application that a certain piece of gene would produce a disease-related protein, for example, and they can prove that through experimentation, and valid experimentations, then I have no problem with a patent at that point.

But it is my belief that we have put a lot of public money into this globally, and that this raw data ought to be available to any researcher anywhere free of charge.

And if companies want to seek to try to influence the Patent Office, well, we have something to say about that here legislatively, too. The Patent Office is a creature of the U.S. Congress. I know that they have had their comment period closed on March 22. And I am hopeful that they will be issuing guidelines along that pathway.

But I have been quite upset, quite frankly, at some of the private companies who have indicated by filing thousands of patent requests, thousands of them, and they have not conducted one experiment, and they have tried to get a patent on those. I think that

is not in the public interest. And I believe that—I do not think that those patents ought to be issued.

So I just wanted to state for the record where I hope this is headed. If you have any further comments, I would welcome it. If not, you do not have to make a comment.

Dr. COLLINS. Senator, I think you have expressed the issue very clearly. NIH has taken a position on the patenting issue, which is quite close to yours, namely that sequence information in the absence of any functional data about what that particular gene does ought not to be the subject of——

Senator HARKIN. Functional data means data based upon adequate experimentation.

Dr. COLLINS. That is right. Whereas a circumstance where such data does exist and is compelling, that puts this sort of a gene patent application in the same category as other types of patent applications and ought to be seriously considered.

METHAMPHETAMINE

Senator HARKIN. I appreciate that. I said I had a couple of other questions here, but I may have to ask for those in writing. One had to do with methamphetamine because of the big problem in the Midwest. Methamphetamine, not only can we cut the supply, but the demand is a problem. And we find that this is a very addictive drug.

I just wanted to ask Mr. Millstein what the Institute is doing on research on meth and possible treatment options. I have looked at this quite a bit, and it just seems like we are not getting very far. But maybe you have some knowledge that I do not know about.

Mr. MILLSTEIN. Thank you, Senator Harkin. As you are well aware because you personally were involved in the town meeting that NIDA sponsored in 1998 in Des Moines——

Senator HARKIN. Right.

Mr. MILLSTEIN [continuing]. We used that as the kickoff for the methamphetamine initiative. Our community epidemiology work group, which is an early alert system, had shown tremendous increases in use in rural areas, including Iowa.

We had that kickoff specifically in Des Moines with your involvement, with the Governor's involvement and State health department, to talk about what we know, about public education, prevention and treatment.

Since that time, we have made methamphetamine research supplements. We have already found out more about methamphetamine and violence, methamphetamine and heart disease, methamphetamine and brain damage.

Because methamphetamine is a stimulant, we were able to pick up on some of the clinical trials that we have been conducting for cocaine in methamphetamine-using individuals, and currently are conducting clinical trials on five different potential medications, Tyrosine, Fluoxitine, Asertraline, Desipramine, and Isridapine.

We are really hopeful that because we were able to move quickly, that soon we will have some kind of answers and be able to use that knowledge to apply to treatment populations, as well as in prevention.

Senator HARKIN. I appreciate that, because it seems that—well, my time is up.

Just one last thing I would ask Dr. Kirschstein—Dr. Klausner, I wanted to talk to you about some things.

But there is a list I have here from NIH talking about the total number of dollars spent in complementary and alternative medicine, not just in NCAM but in all of the institutes. It totals about $160.7 million estimate for fiscal year 2000; NCI, $38.4 million; and others.

I would like to have a little bit further breakdown about what that all is for, what is happening in these areas, and how these different offices are correlating with NCAM on this type of research. I will not bore you, but just if you could give it to me.

Dr. KIRSCHSTEIN. We would be pleased to provide that.

[The information follows:]

FUNDING FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Each NIH Institute and Center (IC) has designated a liaison for complementary and alternative medicine (CAM) to provide scientific input to, and facilitate coordination with the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM established the Trans-Agency CAM Coordinating Committee, which serves as a forum for facilitating research collaboration and coordination, not only across the NIH, but across other major Federal health research entities as well. The committee met on May 20, 1999; November 16, 1999; and April 6, 2000. Membership of the committee includes:

—the NIH IC CAM liaisons;

—representatives of several OD Offices [Office of AIDS Research (OAR), Office of Behavioral and Social Sciences Research (OBSSR), Office of Dietary Supplements (ODS), Office of Rare Diseases (ORD), Office of Research on Minority Health (ORMH), and Office of Research on Women's Health (ORWH)]; and

—liaisons from a number of other Federal Agencies [Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Agriculture (USDA), U.S. Department of Education (ED), U.S. Department of Defense (DOD), U.S. Department of Veterans' Administration (VA), and the White House Commission on Complementary and Alternative Medicine Policy].

Prior to the establishment of NCCAM, the ICs collaborated with the NIH Office of Alternative Medicine (OAM) on a number of activities, which included administration of OAM-supported research projects. Below, each of the ICs have provided examples of their current research collaborations with NCCAM and descriptions of their own CAM research portfolios.

NATIONAL CANCER INSTITUTE

NCI's research portfolio includes diverse activities performed in many venues including: Comprehensive Cancer Centers, clinical trials performed by the Cooperative Group and Community Clinical Oncology Programs and research projects performed by scientists at a variety of other academic institutions and corporations. Following are examples of research activities supported by NCI in complementary and alternative medicine:

Examples of CAM Clinical Trials

1. Phase III randomized trial of patients with prostate cancer to study the effect of a diet low in fat and high in soy, fruits, vegetables, green tea, vitamin E and fiber on prostate-specific antigen (PSA) levels.

2. Phase II trial of patients with prostate cancer to study the effects of dietary soy on biomarkers of prostate cancer.

3. Phase I and II trials using formulations of the active components from green tea. Patient accrual began in December, 1999.

Examples of CAM Grants supported by NCI

1. Dietary Tomato Products and Experimental Prostate Cancer
2. Cohort Study of Dietary Supplements and Cancer Risk
3. Inhibition of Prostate Cancer Cell Growth by Vitamin D
4. Feasibility of Physioacoustic Therapy in Cancer Care
5. Mechanisms of Dietary Modulation of Melanoma Invasion
6. Menopausal Symptom Relief for Women with Breast Cancer

CAM Practice Assessment Program

1. Best Case Series Program—solicits and reviews case report data of complementary and alternative medicine therapies that are felt by their practitioners to be effective cancer therapies, and presents case series to the Cancer Advisory Panel for Complementary and Alternative Medicine.

2. Practice Outcomes Monitoring and Evaluation (POMES) projects—a process used to follow-up on promising Best Case Series reviews. In the pilot project, we will evaluate outcomes at the P Banerji Homeopathic Research Foundation clinics in Calcutta, India using contract support to monitor new lung cancer patients and obtain documentation and follow-up of 30–50 new lung cancer patients for 12–18 months.

CAM Citation Database.—A project to explore the feasibility of augmenting the cancer component of the existing NCCAM CAM Citation Index versus establishing an independent NCI controlled cancer CAM research database. This database will become a resource for NIH and extramural investigators interested in CAM research and will include articles and abstracts from many databases including Medline or Web of Science. The database will serve as a resource for NIH and extramural investigators interested in CAM research.

The Director of NCI's Office of Cancer Complementary and Alternative Medicine (OCCAM) meets with the Director of the NCCAM every two weeks to discuss ongoing and new collaborative projects. Also several other projects funded by the NCI (e.g. the OCCAM Website, the Practice Outcomes Monitoring and Evaluation System project in Calcutta India, the NCI's Best Case Series Program) are discussed at these meetings.

The Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) was jointly constructed by the NCCAM and the NCI to (1) review and evaluate summaries of evidence for CAM cancer claims submitted by practitioners, (2) make recommendations to the NCCAM on whether and how these evaluations should be followed up, and (3) be available to observe and provide advice about studies supported by the NCCAM and NCI, and about communication of the results of those studies. The Panel's membership is drawn from a broad range of experts from the conventional and CAM cancer research and practice communities. The organization meeting for the CAPCAM was held November 1998. The panel was subsequently chartered and is authorized to meet at least twice a year. The first meeting of the chartered panel was held July 1999. For fiscal year 2000, one CAPCAM meeting was held in December 1999 and a second one is scheduled for late summer, 2000.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

NHLBI has had a long standing interest in complementary and alternative medicine for heart, lung and blood diseases and has been collaborating with the Office and now the National Center for Complementary and Alternative Medicine since its inception. Because of the elevation of NCCAM to the Center status, most research grants initially funded by NCCAM and managed by NHLBI, have been reassigned to NCCAM. Currently, NHLBI has a few primary applications, but has secondary assignment on most new applications related to heart, lung and blood diseases. In addition to grant support, NHLBI has been involved in the following joint activities:

1. NHLBI is a co-sponsoring Institute for a PA "Acupuncture Clinical Trial Pilot Grants", issued by NCCAM in 1998. Several grants have been funded by NCCAM.

2. A workshop on the "Complementary & Alternative Medicine in Cardiovascular, Lung and Blood Research", jointly sponsored by NHLBI and NCCAM, is scheduled for June 12–13, 2000, to be held in Bethesda.

3. NHLBI and NCCAM jointly sponsor an RFA to encourage studies to assess the efficacy of CAM, including acupuncture, herbal remedies, homeopathy and magnesium supplement, in allergic disease and asthma.

4. NHLBI cosponsors an RFA on the Ginkgo Evaluation of Memory Study with NCCAM and plans to provide funding in fiscal year 2000.

5. NHLBI continues to serve on a Trans-NIH Coordinating Committee on Complementary & Alternative Medicine. This group reviewed planned activities, helped to prioritize initiatives, and offered other possible scientific directions to consider.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

In fiscal year 1999, NIDCR funded a variety of research classified as "Complementary and Alternative Medicine". The majority of this funding was associated with research projects that addressed treatment of pain associated with temporomandibular joint disorders.

NIDCR has worked with NCCAM to help develop their research portfolio. For example, Institute staff participated with NCCAM in the development of the Request for Applications for CAM Centers, which stimulated the project P50 AT/DE00076 (White/Kaiser Research Foundation-Craniofacial Complementary and Alternative Medicine Center). In addition, NIDCR staff vigorously encouraged oral health researchers to prepare CAM Center proposals, through contacting investigators, suggesting potential collaborations, and disseminating information on the CAM Center RFA at scientific meetings and in newsletters.

Similarly, NIDCR staff identified opportunities to stimulate acupuncture research within pain research activities being conducted at the University of Maryland, where several physicians and neurophysiologists originally trained in China were initiating their scientific careers under the mentorship of a world-recognized neurophysiologist-dentist. The resulting project, funded by NCCAM, used a dental (third molar extraction) pain model to compare patients' post-operative pain relief after being given standard analgesics, sham acupuncture, or real acupuncture.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

The NIDDK is supporting research on several alternative or complementary medicine strategies and has interest in their efficacy and safety and in understanding their mechanisms of action and interaction. Work on biofeedback is supported. There is close collaboration with the NIH National Center for Complementary and Alternative Medicine (NCCAM). Some specific examples include: (1) *Herbal Therapy for Benign Prostatic Hyperplasia* (BPH): The NIDDK and the NCCAM are jointly funding a clinical trial on the efficacy of saw palmetto, over the period of August 1999 through July 2002; (2) *Placebo Effect*: A trans-NIH workshop initiated by NIDDK, and jointly with the NCCAM, is planned for November 20–21, 2000. The purpose of this workshop is to develop a research agenda for placebo studies, and prepare background papers summarizing the current status; (3) *Herbal Therapy for Liver Disease*: The NIDDK and NCCAM will co-sponsor a Request for Applications (RFA) that would develop a standardized preparation of milk thistle for clinical studies of liver disease. In addition, the NIDDK held a workshop on "Complementary and Alternative Medicine in Chronic Liver Disease,"on August 22–24, 1999, with support from the NCCAM and the Office of Dietary Supplements (ODS). (4) *Chromium and Vanadium in Diabetes*: In November 1999 the NIDDK co-sponsored a meeting with the ODS on "Diabetes and Chromium: Formulating a Research Agenda." The workshop concluded that trials to assess efficacy and studies to define cellular mechanisms are needed. In 1992 the NIDDK issued an RFA to solicit research on vanadium; several laboratories are investigating its effect on glucose metabolism. (5) *Botanical Research Centers*: The Nutrition Branch of NIDDK has indicated interest in participating in a Request for Applications for Botanical Research Centers.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

NINDS funds 3 research grants in the area of complementary and alternative medicine (CAM) research. These include a clinical trial on vitamin intervention for stroke prevention and two grants on the ketogenic diet as a treatment for epilepsy.

Brief summaries of these grants follow:

Vitamin Intervention for Stroke Prevention.—This is a multi-center double-blind randomized controlled clinical trial to determine whether the administration of a multivitamin with high dose folic acid, pyridoxine, and cyanocobalamin, together with best medical management and risk factor modification, can reduce the incidence of recurrent stroke and myocardial infarction (MI) in patients with a first nondisabling stroke who also have elevated homocyst(e)ine levels. This is based on evidence that homocyst(e)ine is a risk factor for atherothrombotic disease (and may be involved in the disease etiology), and that elevated homocyst(e)ine levels can be reduced by vitamin supplementation. Such an intervention has the potential to be an inexpensive and safer alternative for preventing recurrent stroke and MI, as compared to current warfarin or ticlopidine therapy.

Efficacy of the Ketogenic Diet—A Blinded Study.—This is a blinded placebo-controlled study of the high-fat-low-carbohydrate ketogenic diet to treat children with Lennox-Gastaut Syndrome, a refractory form of epilespy characterized by atonic-myoclonic seizures. Preliminary evidence suggests that the ketogenic diet is highly effective in reducing seizure frequency. The study will test both the initial efficacy of the diet (after 5 days) and whether seizure reduction can be maintained over a longer period of time (after 6 months on the diet).

Ketogenic Diet and Brain Amino Acid Metabolism.—This study is investigating the mode of action of the ketogenic diet in a rat model. The hypothesis is that the ketone bodies produced as part of the diet reduce the rate of transamination of glutamate to aspartate. This has the effect of reducing brain concentrations of aspartate, which is excitatory, while increasing brain concentrations of GABA, which is inhibitory. This is being studied in rat pups being fed the ketogenic diet. In addition, the efficacy of the ketogenic diet to reduce seizures in a rat model of epilepsy is also being studied.

NINDS is a member of the newly formed trans-NIH CAM Coordinating Committee, which meets regularly to identify opportunities for trans-Institute collaboration on activities and initiatives related to CAM. In addition, NINDS staff have worked closely in the past with NCCAM staff on several joint initiatives, including a Request for Applications (RFA) for Centers for Mind/Body Interactions and Health, and another RFA for Centers for Complementary and Alternative Medicine Research. An NINDS staff liaison also regularly attends study section (i.e., peer review) meetings of neurology related CAM grants.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The NIAID supports complementary and alternative research efforts in areas that coincide with its own research priorities. The Institute expects to spend $8 million in this area in fiscal year 2000, and the following research examples reflect NIAID's interest in pursing research advances in its own targeted areas of research, with the help of complementary and alternative medicine.

—The NIAID is supporting research on Siberian Ginseng at the University of Iowa. Investigators are examining the use of Siberian Ginseng for the treatment of chronic fatigue syndrome, and evaluating whether subjects with idiopathic chronic fatigue will respond to Siberian Ginseng, a widely recommended herb for the treatment of fatigue.

—The NIAID is supporting research at the University of Cincinnati to determine the impact of dietary supplements on kidney graft survival and incidence and severity of post-transplant adverse events. To date, this pilot study has enrolled 20 patients and has shown a 77 percent reduction in the number of recipients having an acute rejection, leading to a 50 percent reduction in the number of biopsies for renal dysfunction. In addition, a significant reduction in the number of post-transplant infectious complications was also observed.

—An international workshop, *The Importance of Omega–3 Fatty Acids in the Attenuation of Immune-Mediated Diseases*, will be co-sponsored by the NIAID, the NIH Office of Dietary Supplements and the National Center for Complementary and Alternative Medicine, and will be held in fiscal year 2000. The primary goal of this workshop is to establish research plans for definitive, mechanisms-based, preclinical studies and clinical trials to elucidate the mechanisms whereby omega–3 fatty acids attenuate immune-mediated diseases. Fish and other marine life are rich sources of a special class of polyunsaturated fatty acids known as the omega–3 or n–3 fatty acids. Reports suggest that dietary omega–3 fatty acids may have potent anti-inflammatory activities in inflammatory disorders such as transplant rejection, autoimmune and allergic diseases. The workshop will include investigators from the United States and other countries, who will participate in the discussions to review the current knowledge and clinical trial results. Further discussions will focus on setting research priorities and formulating research plans to accelerate focused studies in this area. The workshop proceedings will be published, and proposed initiatives for new preclinical studies and clinical trials will be developed for funding consideration by NIH Institutes and Centers.

—The NIAID is providing funds to the University of California, Davis, to develop the Asthma-Alternative Medicine Center. The Center will serve as a U.S. and international resource to assist alternative medicine practitioners and researchers in identifying potential treatments and for developing protocols to evaluate the efficacy of unconventional medical practices using nutrition, ethnomedicine, and immunopharmacology for the treatment of asthma. The Center will include studies on: the effect of vitamin C on pulmonary function and quality of life on

patients with mild asthma; oral immunotherapy of grass pollen allergy using wheatgrass juice; and the influence of botanical and glandular extracts on cytokine biosynthesis and cytotoxicity.

It is customary for staff at the NIAID to interact with staff at the NCCAM on complementary and alternative medicine disciplines. For example, the NIAID program staff will consult with the NCCAM program staff about grant applications that cut across both the Institute and the Center.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The National Institute of Child Health and Human Development (NICHD) sponsors a variety of research projects to study complementary and alternative medicine (CAM). These span the life cycle, and include studies to: investigate the use of yoga to improve the pulmonary function in asthmatic women during pregnancy; evaluate the use of supportive birth companions and soft infant carriers to foster parenting skills and maternal/infant attachment; and test the hypothesis that muscle strength improvement in the elderly depends more on mental effort than training intensity. The latter has implications in rehabilitation of stroke victims. Other studies focus on pain management. One such study evaluates cognitive-behavioral treatments for pain reduction (relaxation training, parent education, stress management and thermal biofeedback) in children with recurrent migraines or abdominal pain. Another looks at the effects of manual therapies combined with specific exercises to treat chronic back pain. A third studies the effects of antioxidants (Vitamins C and E) on the pathogenesis of endometriosis, a disorder that inflicts pain and may cause infertility in women.

The NICHD has a representative on the NCCAM Trans-Agency Coordinating Committee, who attends NCCAM's regular meetings, participates in discussions of joint initiatives, strategic planning and collaborative workshops. In addition, the NICHD staff administers several large center grants in collaboration with NCCAM to evaluate the effectiveness of CAM therapies, for conditions within the mission of the NICHD, and teach research methods and provide clinical research training and mentoring programs to clinicians who employ CAM.

NATIONAL EYE INSTITUTE

In fiscal year 1999 NEI-supported complementary and alternative medicine research that was principally focused on the role of nutrition and dietary supplements on prevention and treatment of progressive blinding eye diseases such as macular degeneration and cataract. Specifically, researchers are investigating the role glutathione, an antioxidant, has for protecting the retinal pigment epithelium from oxidative stress. This research may advance our understanding of the pathogenesis of Age-Related Macular Degeneration (ARMD) and provide information for the development of treatments for ARMD. Researchers supported by the NEI are also conducting an epidemiological study to evaluate the relationship between nutritional factors and ARMD in the United States, and the results of this research will be useful for the development of future clinical trials on nutritional intervention of this blinding disease. The NEI also supported research on the biochemistry and pharmacology of macular carotenoids. This research will investigate the biochemical processes responsible for the specific deposition of lutein and zeazanthin in the macula with special emphasis on the search for potential carotenoid-binding proteins. The results of this study will provide new insights on the uptake of lutein and zeazanthin into the macula, and may lead to the development of therapies that take advantage of these uptake systems to retard or prevent blindness resulting from macular and other retinal degenerative diseases. The NEI also funded research on the use of antioxidant supplements on the prevention of cataract progression. Additionally, the NEI reports to NCCAM on studies of the impact of dietary supplements on vision and visual disorders. NEI staff participate in NCCAM workshops.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) has several objectives regarding complementary and alternative medicine:

—Assess toxicity of common herbal preparations, particularly their ability to cause reproductive, neurological and immunological toxicity

—Assess the health consequence of long-term, chronic use of herbal preparations.

—Define herb/herb and herb/drug interactions, particularly in sensitive subpopulations.

—Identify the molecular basis of herbal efficacy and toxicity.

Furthermore, the NIEHS, in conjunction with the National Toxicology Program (NTP), will design and initiate studies to identify and characterize possible adverse

health effects that may be associated with prolonged use or higher doses of some of the most popular medicinal herbs, including aloe vera, comfrey tea, androstenedione, Ginkgo biloba, echinacea, and Panax quinquefolius (American ginseng).

The NIEHS sponsored a workshop called *International Workshop to Evaluate Research Needs on the Use and Safety of Medicinal Herbs* with the NTP; NIH's Office of Dietary Supplements and its Office of Research on Women's Health; the Department of Health and Human Services' Office of Disease Prevention and Health Promotion; the Food and Drug Administration's Office of Special Nutrition; and the Society for the Advancement of Women's Health Research.

Currently, medicinal herbs are not subject to testing requirements for effectiveness or safety. This workshop succeeded in bringing together an international panel of experts to discuss necessary research to address public health concerns related to their use. In follow-up to this workshop, the NIEHS and NTP are working with NCCAM, the NIH Office of Dietary Supplements, FDA, the academic community, and others to further define and implement research that addresses deficiencies in our knowledge about herbal medicines and their potential toxicities.

NATIONAL INSTITUTE ON AGING

In fiscal year 1999, NIA funded a variety of areas related to complementary and alternative medicine including: investigations of the effects of culture and ethnicity on health care practices and treatment choices for diseases such as cancer and HIV infection; the use of phytoestrogens instead of estrogen replacement therapy for the prevention of menopausal symptoms and bone loss; the use of vitamin E to prevent atherosclerosis, cognitive decline in women, and infection; the effects of religion on health; and the use of tai chi to prevent falls.

The Director, NCCAM has met with the Director, NIA, individually, and with NIA senior scientific program staff at a special meeting to discuss areas of potential scientific collaboration. An NIA staff person serves as an official NIA liaison to NCCAM to work on collaborative activities including the development of a conference on the placebo effect. Other specific areas of collaboration that are being pursued in fiscal year 2000 include the addition of a set of questions on the use of complementary and alternative medicine to the NIA Health and Retirement Survey; an ongoing program announcement on medication use by the elderly; and a randomized, controlled trial of ginkgo biloba in preventing Alzheimer's disease.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

There is substantial interest on the part of the American public in alternative therapies, particularly for people with chronic diseases of bones, muscles, joints and skin. For example, scientists have reported that green tea products show anti-inflammatory activity in mouse models. Rheumatoid arthritis is an example of an inflammatory condition affecting joints, resulting in pain and, over time, destruction of joints. Results of recent research suggest that identification of common dietary substances, such as green tea products, capable of affording protection or modulating the onset and severity of arthritis, may be used in the future to treat or prevent rheumatoid arthritis. Another promising area of alternative medicine being pursued by NIAMS-funded scientists is an evaluation of the effects of acupuncture on carpal tunnel syndrome.

NIAMS has enjoyed substantial collaboration with NCCAM since the inception of the OAM at NIH in 1992. For example, NIAMS co-funded with OAM three of the original Centers on Alternative Medicine—the Center of Alternative Medicine for Pain Research and Evaluation at the University of Maryland, the Center to Assess Alternative Therapy for Chronic Illness at Beth Israel Hospital, and the Complementary and Alternative Medicine Research Center at Stanford University. In addition, the NIAMS and OAM jointly established the Chiropractic Consortium at the Palmer College of Chiropractic in Iowa. Furthermore, we have teamed with our colleagues in alternative medicine to fund several conferences in this area, including the NIH Consensus Development Conference on Acupuncture in November 1997, and the NIH Pain Consortium symposium "New Directions in Pain Research" in November 1997. Finally, the NCCAM and NIAMS have jointly issued a number of solicitations to stimulate research in alternative medicine. These include an RFA on Acupuncture Treatment for Osteoarthritis; and very recently, a solicitation and contract award to study the efficacy of glucosamine and chondroitin sulfate in osteoarthritis. This is a significant area of interest and concern for the American public, and the NIAMS and NCCAM staff have launched a study to provide a solid scientific basis in determining the value of these widely-used compounds in people with osteoarthritis.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

The NIDCD is currently supporting one research project involving alternative and complementary approaches to communication and sensory disorders. The long term goals of this study are to understand the epidemiology of otitis media (OM) and hearing loss among Native Americans from birth to age two and to define the relative importance of known and new risk factors in this population. Native Americans have a high prevalence of chronic otitis media, but prospective studies of OM among infants and young children, of this group are sparse. The risk factors under study include both environmental factors such as smoking by parents as well as genetic factors that may be specific to Native Americans.

Questionnaires are one mechanisms used in the study to collect information. The questionnaires ask if pregnant mothers are taking "traditional" Native American medicines. Such medicines include: sage, tea from medicine man, swamp tea; sweet grass; cedar tea; bear root; blue spruce; pregnancy tea; sumac; echinacea tea; and raspberry leaf tea. Mothers are also asked whether their children have been given any "traditional" Native American medicines, but the specific types are not asked for in the questionnaire. The answers on the questionnaire will eventually be used to determine if there is any correlation between the frequency of otitis media and the use of "traditional" Native American medicines. Approximately 5 percent of the project is devoted to the determination of possible effects of Native American traditional medicines.

The NIDCD is currently planning a workshop with the National Center of Complementary and Alternative Medicine (NCCAM) for fiscal year 2001 to explore the use of T'ai Chi (TC) and other alternative therapeutic modalities (e.g., Chi Kung, yoga, dance therapy) in the treatment of balance disorders. The collaboration of other Institutes, including the National Center of Medical Rehabilitation Research (NCMRR) of NICHD and the NIA has also been sought. There are reports in the literature suggesting that TC is effective in maintaining or improving balance in unstable individuals and in improving falls in the elderly. This workshop will explore the promise of such approaches as efficacious and low-cost alternatives to conventional physical rehabilitation and sensory substitution programs, the latter oftened termed, "vestibular rehabilitation." It will shed light on a long-standing question in the balance rehabilitation field: Should balance be trained as an isolated function or within the context of "acts of daily living."

The NIDCD has a representative serving on the Trans-agency Complementary and Alternative Medicine Coordinating Committee (TCAMCC).

NATIONAL INSTITUTE OF MENTAL HEALTH

The National Institute of Mental Health (NIMH) supports research that explores the potential usefulness of complementary and alternative medicine approaches to the treatment of mental disorders and to mental and behavioral aspects of other serious illnesses. In fiscal year 1999, NIMH CAM research included:

CAM approaches to treatment of depression

Saint John's Wort (SJW), or hypericum, a popular naturotherapy for depression in Germany, is being widely used in the UnitedStates. Previous controlled trials have indicated SJW does reduce symptoms of depression in adults, although definitive data on its efficacy are lacking and there are no scientific reports of the effectiveness, safety, and tolerability of SJW in children or adolescents. NIMH is collaborating with the NCCAM in the conduct of a three-arm, placebo-controlled, clinical efficacy study of a standardized extract of hypericum in major depression. This trial is designed to test the acute efficacy and safety of hypericum compared to placebo. In another pilot study, NIMH-supported researchers are exploring the benefits of SJW as a possible non-pharmaceutical treatment for depression in youths ages 6–16.

Exposure to light appears to offer promise for the treatment of winter depression (Seasonal Affective Disorder, or SAD), although the mechanism of the effect or the optimal scheduling of light exposure with respect to an individual's circadian phase has not been determined. NIMH-supported researchers are studying the mechanisms and timing of light therapy for best results. Other investigators funded by NIMH are determining if therapeutic sleep deprivation (TSD) can accelerate the response of depressed geriatric patients to an antidepressant (paroxetine). In other work, investigators are examining the relationship of exercise to depression in a general population, and the efficacy of exercise as a treatment for people with mild-to-moderate depressive disorder.

CAM approaches to other mental and medical disorders

For mental disorders other than depression, NIMH-supported researchers are assessing the efficacy of Eye Movement Desensitization and Reprocessing (EMDR) for treatment of post-traumatic stress disorder (PTSD) and the efficacy of hypnosis as an adjunct to traditional forms of psychotherapy. NIMH-supported ethnographic research aims to understand the therapeutic change processes in three forms of religious healing in Navajo society. For serious medical disorders, researchers are exploring the ability of peer support to enhance adherence to treatment for HIV/AIDS and the ability of cognitive-behavioral stress management (CBSM) to reduce acute stress responses in HIV-positive individuals, focusing on low socioeconomic status minority and substance-abusing individuals. Additional research evaluates the benefits of psychosocial and psychoeducational interventions to cancer patients both for pre-surgical stress reduction for men undergoing surgical treatment of prostate cancer and on survival for women recovering from metastatic breast cancer.

NIMH collaborates closely and actively with NCCAM on those CAM studies of interest to the Center, such as the Saint John's Wort clinical trial. For more exploratory CAM studies focused on limited-scope aspects of mental health research, communication with NCCAM is encouraged by NIMH at all times.

NATIONAL INSTITUTE ON DRUG ABUSE

The National Institute on Drug Abuse estimates that it spent $0.4 million on complementary and alternative medicine grants in fiscal year 1999. NIDA plans to encourage more research on this important and often cross-cutting topic area. NIDA is interested in determining the efficacy of treatments for substance abuse, including those that take on a more "complementary or alternative" approach to treating the complex problem of addiction. Currently NIDA has two research grants that focus on alternative therapies, specifically the role that acupuncture plays in treating addiction. One of NIDA's grantees is looking at the role that auricular acupuncture can play in reducing cocaine use among HIV-positive patients in methadone-maintenance programs. The other grant is researching the role that electro-acupuncture can play in alleviating pain.

NIDA has had a relationship with the staff from the former NIH Office of Alternative Medicine for several years. In fact, NIDA was one of the co-sponsors for the NIH Consensus Development Conference on Acupuncture that was held in November 1997. NIDA staff continues to collaborate with NCCAM staff in a variety of formal and informal ways including through NIDA representation on the NCCAM Trans-agency CAM Coordinating Committee. NIDA is also collaborating with the National Center for Complementary and Alternative Medicine (NCCAM) and the Office of Dietary Supplements (ODS) to sponsor a meeting later this summer to examine intervention modalities (chemo and alternative) in drug abuse and HIV/AIDS.

NATIONAL INSTITUTE OF NURSING RESEARCH

The National Institute of Nursing Research (NINR) funds a number of research studies in the area of complementary or alternative medicine. Two studies are co-funded with NCCAM. One addresses the use of melatonin for sleep disorders in patients with Parkinson's disease. The other study addresses whether the setting of a breast cancer support group for African-American women can trigger self-transcendence to enhance quality of life.

Other studies supported by NINR include a model of wellness circles for Native American Indian families to promote prevention of disease; the effects of relaxation therapy on the immune system and quality of life of caregivers of patients with Alzheimer's disease; the effects of relaxation and music on postoperative pain; the benefits of acupuncture, massage therapy, vitamins, herbs and nutritional supplements, in addition to traditional care, on those at the end of life; and the effects of cancer pain interventions that include guided imagery, attention diversion, and relaxation.

NINR research initiatives for fiscal year 2001 include self-management strategies and end-of-life palliative care. Future CAM areas of interest could involve evaluation of mind-body interventions for patients with chronic illness or who are at the end of life stage.

In addition to collaborations with NCCAM on research projects, NINR serves on the NCCAM Trans-Agency CAM Coordinating Committee, which meets three times a year to discuss initiatives and projects of mutual interest.

NATIONAL CENTER FOR RESEARCH RESOURCES

The NCRR creates, develops, and provides a comprehensive range of human, animal, technological, and other resources to enable biomedical research advances. The

NCRR serves as a "catalyst for discovery" for NIH-supported investigators by supporting resources in four areas: Biomedical Technology, Clinical Research, Comparative Medicine, and Research Infrastructure. Three of these areas currently support research resources that enable multidisciplinary collaborations and discoveries in many areas of health relating to CAM.

Clinical Research

The Clinical Research area, through its national network of 77 General Clinical Research Centers (GCRCs), supports CAM related clinical investigations such as biofeedback in advanced heart failure (Ohio State University); effects of melatonin in human sleep behavior (Massachusetts Institute of Technology); and, soybean diets and breast cancer prevention in women (University of Texas at Galveston). Other studies include the use of hypnosis as an adjunct to periodontal therapy, acupuncture for the treatment of HIV associated diarrhea and the effect of therapeutic back massage on the immune function of cancer patients.

The GCRC Program encourages funded investigators from NCCAM supported Centers such as the CAM Centers at the University of Michigan and the Addictions Center at Minneapolis to utilize the resources of the GCRCs. Many other NCCAM funded investigators are co-located with, or nearby, GCRCs such as the GCRCs at the University of Virginia, University of Washington Seattle, Brigham Women's Hospital, University of California San Diego, and the University of Indiana, just to name a few.

Biomedical Technology

The Biomedical Technology area of NCRR supports state of the art technologies and methodologies that create, develop, and provide a wide range of complex technological capabilities. Examples are studies of acupuncture in humans using magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) at the University of Pennsylvania and the characteristics of antioxidant compounds from natural products at Michigan State University. NCCAM currently supports an Intramural fellow (Dr. Joannie Shen) to study the effects of acupuncture for the treatment of alcoholism using functional MRI. This topic, or others similar to it, could potentially be supported by the regional imaging centers funded by Biomedical Technology and the GCRC Program. Dr. Shen is now performing her studies at the NIH Clinical Center.

Research Infrastructure

The Research Infrastructure area, through its Research Centers in Minority Institutions (RCMI) Program, supports research at the University of Hawaii in the use of energy healing in very low birth-weight infants as well as the use of distant healing in breast and prostate cancer patients receiving radiation. The University of Hawaii, as well as some other RCMI institutions, such as Drew and the University of Puerto Rico have been applicants to NCCAM for a variety of grants including Center support.

FOGARTY INTERNATIONAL CENTER

FIC's longstanding Biodiversity and AIDS programs support complementary and alternative medicine in the form of research on herbal therapies utilized by indigenous peoples in several nations, including Nigeria, Mexico, Chile, and Laos. Herbal medicines used for a variety of indications relevant to infectious diseases, cancer, pain, and Alzheimer's disease are explored for efficacy and safety in laboratory studies in developing countries and in the United States, including those of industrial pharmaceutical partners.

Given that CAM is used extensively abroad as well as in the United States, the FIC Director (who also serves as the NIH Associate Director for International Research) and the Director of NCCAM have discussed on several occasions common interests and the possibility of future joint initiatives examining the international role and resources available for study of CAM. In addition, FIC staff work to facilitate international dialogue between NCCAM and foreign counterparts, including those in China. Also, the FIC program director for Biodiversity works with the staff of NCCAM to ensure that relevant information is shared among interested groups.

Senator HARKIN. Thanks.

Senator SPECTER. On the questions which I have asked, I would like two additional answers in writing. One is what you have been able to accomplish with the increases in funding over the last 3

years, which for the total number of institutes, aggregate more than $5 billion. Of course, it breaks down to different figures.

I would like to have the increase actually for each of the institutes over the 3 years, what you have been able to accomplish with that extra, and what you would look forward to accomplishing if you got your wishes on the funding to have the total number of grants that you would like to see.

[The information follows:]

PAST AND FUTURE ACCOMPLISHMENTS

The following table reflects each institute and center budget increases over the last three years, to include fiscal years 1998–2001.

NATIONAL INSTITUTES OF HEALTH FUNDING BY INSTITUTE AND CENTER

[In thousands of dollars]

Institute	Fiscal year							
	1998		1999		2000		2001	
	Actual	Change	Actual	Change	Estimate	Change	Estimate	Change
NCI	2,551,281	162,240	2,891,570	340,289	3,311,687	420,117	3,505,072	193,385
NHLBI	1,526,276	94,455	1,774,827	248,551	2,026,430	251,603	2,136,757	110,327
NIDCR	210,172	13,109	238,001	27,829	269,185	31,184	284,175	14,990
NIDDK	896,686	83,622	1,021,006	12,4,320	1,141,415	120,409	1,2D9,173	67,758
NINDS	778,432	49,183	896,921	118,489	1,029,743	132,822	1,084,828	55,085
NIAID	1,352,119	94,326	1,570,530	218,411	1,796,631	226,101	1,906,213	109,582
NIGMS	1,061,505	66,116	1,202,800	141,295	1,353,943	151,143	1,428,188	74,245
NICHD	672,073	40,811	752,179	80,106	859,258	107,079	904,705	45,447
NEI	354,153	22,566	395,604	41,451	450,101	54,497	473,952	23,851
NIEHS	328,711	21,156	387,640	58,929	442,688	55,048	468,649	25,961
NIA	517,082	32,764	599,720	82,638	687,861	88,141	725,949	38,088
NIAMS	273,879	17,687	305,976	32,097	349,480	43,504	368,712	19,232
NIDCD	199,786	11,569	230,803	31,017	263,661	32,858	278,009	14,348
NIMH	748,329	47,572	854,184	105,855	974,673	120,489	1,031,353	56,680
NIDA	536,852	37,539	617,409	80,557	687,376	69,967	725,467	38,091
NIAAA	226,224	15,031	259,258	33,034	293,234	33,976	308,661	15,427
NINR	63,340	3,789	69,851	6,511	89,539	19,688	92,524	2,985
NHGRI	218,340	29,431	283,638	65,298	335,862	52,224	357,740	21,878
NCRR	452,193	38,144	560,716	108,523	675,054	114,338	714,192	39,138
NCCAM	.....	.....	50,531	50,531	69,011	18,480	72,392	3,381
FIC	28,190	1,690	35,164	6,974	43,328	8,164	48,011	4,683
NLM	161,606	11,499	181,770	20,164	215,199	33,429	230,135	14,936
OD	295,194	9,331	255,635	(39,559)	282,000	26,365	308,978	26,978
Subtotal	13,452,423	903,630	15,435,733	1,983,310	17,647,359	2,211,626	18,663,835	1,016,476
B&F	234,436	12,458	197,456	(36,980)	165,376	(32,080)	148,900	(16,476)
Total	13,686,859	916,088	15,633,189	1,946,330	17,812,735	2,179,546	18,812,735	1,000,000

In response to the second part of your question, listed below are descriptions of Institutes and Centers current accomplishments and what could be accomplished with with additional resources.

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) conducts, coordinates and funds cancer research, and provides vision and leadership for the cancer research community both in the United States and abroad.

Accomplishments

The incidence and death rates for all cancers combined declined between 1990 and 1996, reversing an almost 20-year trend of increasing cancer cases and deaths in the U.S.

To date, we have catalogued approximately 70,000 genes that are expressed in the development of cancers; of these, about 30,000 are previously unknown genes.

Scientists uncovered evidence, using the new science of cancer genomics, that diffuse large B-cell lymphoma is actually two distinct diseases. This has important implications for their treatment.

Tamoxifen, a drug long used to treat breast cancer, led to a 49 percent reduction in the incidence of primary breast cancer during the treatment period in women at high risk for the disease.

Last year, NCI supported over 1,500 clinical trials in prevention and treatment, covering virtually all human cancers. The results of clinical trials over the past two years have set new standards for regimens to treat childhood cancers, leukemia, myeloma, breast cancer, and others.

What Could Be Accomplished With Additional Funds

Priority for new resources would be given to developing cancer prevention interventions for children under 10 years of age, when they are most receptive to parental and adult influences. Opportunities for prevention of cancer include tobacco use, sun exposure, and diet and nutrition.

Additional funding will greatly enhance NCI plans to increase the number of clinical trials and the number of patients who enroll in trials.

NCI's Tumor Gene Index will catalog the genetic characteristics of tumors at each stage of growth. NCI also hopes to change the system of tumor classification from a visual to a molecular basis.

Today, NCI can support approximately only the top 30 percent of grants in the research project grant pool. More support for all types of investigator-initiated research remains a fundamental need.

Additional resources are needed to expand NCI's Surveillance, Epidemiology, and End Results (SEER) database to enhance coverage of rural whites and blacks, non-Mexican Hispanics and Native Americans.

New initiatives are aimed at training scientists that cross disciplinary boundaries to meet the complex challenge of cancer, at training physicians in the skills of clinical research, and at attracting increased numbers of minority students and young scientists into all aspects of cancer research.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Accomplishments

A newly developed procedure called cardiac magnetic resonance imaging will allow cardiologists in hospital emergency rooms to make faster and more accurate assessments that could mean the difference between life and death when a person comes into the hospital with symptoms of a heart attack.

Recently, the first totally implantable, mechanical heart-assist device was successfully placed in a patient who was no longer eligible to receive an organ transplant due to the advanced stage of his heart disease.

A recent study showed the benefits of teaching children early about eating a healthy diet and getting plenty of physical exercise. Three years afterward, children in the study continued to eat healthier food and get more exercise than their peers. The researchers concluded that giving the children occasional, positive reinforcement will help them maintain their healthy lifestyles throughout junior high, high school, and beyond.

A recent technological leap in blood testing called Nucleic Acid Testing, or NAT, screens donated blood to detect the presence of genes for the hepatitis and AIDS viruses. NAT detects even minute levels of virus, making the safest blood supply ever even safer.

A breakthrough in ventilator management offers both better survival in patients with acute respiratory distress syndrome (ARDS) and substantial monetary savings due to faster recovery and less time spent in costly intensive care units.

Two new ways have been found to determine who is at high risk for sudden cardiac death (SCD), which kills 300,000 Americans annually, often striking without warning in young, seemingly healthy people. The screening techniques can easily be incorporated into routine physical exams. Once a person is found to be at risk for SCD, appropriate preventive therapy can be prescribed.

What Could Be Accomplished With Additional Funds

Three phase I clinical trials are in progress to test the safety of using gene therapy to treat hemophilia, which affects 20,000 Americans.

A new treatment can stimulate the development and growth of new blood vessels for the heart. This treatment may one day eliminate the need for the more invasive,

risky, and costly angioplasty and bypass procedures currently used to treat heart disease.

The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial aims to gain a better understanding of how to reduce risks of heart attack and stroke in patients with type 2 diabetes. The goal is to find the most effective ways to normalize blood sugar and improve blood pressure and cholesterol levels, thereby helping diabetics enjoy longer, healthier lives.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

The National Institute of Dental and Craniofacial Research (NIDCR) seeks to improve and promote craniofacial, oral, and dental health through research.

Accomplishments

A recent NIDCR-sponsored study has revealed a mutation in the PAX9 gene that results in the absence of molar teeth. This discovery brings scientists a step closer to understanding human tooth development.

New studies sponsored by the NIDCR showed that the hormone estrogen can reverse problems associated with wound healing in the elderly.

New studies have found mutations in the cathepsin C gene that cause Papillon-Lefèvre syndrome, a genetic disorder that typically affects both the skin and teeth. In some cases, all primary teeth are lost by age 4 and all permanent teeth are lost by age 14. This research suggests possible future therapies.

What Could Be Accomplished With Additional Funds

What Could Be Accomplished With Additional FundsNIDCR recently issued a Request for Applications for Centers for Research to Reduce Oral Health Disparities for fiscal year 2001 funding. The centers will support research to investigate dental, oral, and craniofacial health disparities and design interventions to reduce them.

Scientists have already identified a large number of genes associated with craniofacial-oral-dental diseases and disorders. NIDCR is poised to pursue the next phase of genetic research, which deals with the complex gene-gene and gene-environment interactions that control craniofacial development.

NIDCR is exploring the suggested link between periodontal disease and the birth of preterm, low birth weight babies. It is also evaluating the benefits of periodontal disease treatment in women at high risk for delivering prematurely.

NIDCR will support statewide models of oral cancer prevention and early detection, and collect the knowledge and opinions of health care professionals and the public about the disease. NIDCR will support statewide models of oral cancer prevention and early detection, and collect the knowledge and opinions of the public and health care professionals about the disease.

In the future, testing saliva may be a simple way of obtaining medical diagnostic information. NIDCR scientists are investigating new ways to analyze saliva and incorporate saliva testing into trials and other clinical settings.

The NIDCR biomimetics program aims to mimic biological processes to repair body parts and help fight infectious diseases and inherited disorders. It will promote new research into restoring oral, dental, and craniofacial structures, and into molecular technologies to deliver drugs and genes to combat infectious diseases, cancers, and craniofacial disorders.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Accomplishments

Replacement of insulin-producing beta cells through regeneration or transplantation could offer lifelong treatment for type 1 diabetes. Recent studies in animals demonstrated a drug that led to long-term acceptance of these cell transplants, opening the possibility of new treatments for type 1 diabetes in humans.

Genetic studies of type 2 diabetes have found single gene mutations that cause rare forms of the disease in the young.

An NIDDK intramural scientist has recently discovered gene "insulators", which allow genes to be expressed without interference from surrounding genetic material. This discovery is of particular importance to the biotechnology industry.

An obese child with a congenital leptin deficiency was treated successfully with leptin therapy, resulting in decreased appetite, increased physical activity, and significant weight loss.

Scientists reported a treatment in an animal model of Polycystic Kidney Disease (PKD) that prevents cyst formation and dramatically enhances survival. This new finding has clear implications for treating human PKD, the fourth leading cause of end-stage renal disease.

Scientists successfully demonstrated a genetically-engineered treatment called infliximab for Crohn's disease, an inflammatory bowel disease.

What Could Be Accomplished in the Future with Additional Funds

NIDDK is co-sponsoring a number of initiatives to develop new transplantation strategies to treat type 1 diabetes and improve the success of liver and kidney transplantation.

NIDDK will support research to understand the differences in type 2 diabetes and obesity among racial and ethnic groups, with a view toward developing interventions.

Rates of hepatitis C infection are two to three times higher in African Americans than in Caucasians, and the response rate among African Americans to interferon therapy is far less than among Caucasians. NIDDK plans to expand research to address the causes of this "resistant pattern".

NIDDK will encourage research into cell and tissue development, and into the use of stem cells to combat disease.

NIDDK will expand its research on autoimmune diseases, including type 1 diabetes, autoimmune renal disease, autoimmune hepatitis, autoimmune thyroid disease, and inflammatory bowel disease.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

The National Institute of Neurological Disorders and Stroke (NINDS) seeks to reduce the burden of neurological disorders through research.

Accomplishments

Scientists identified a gene that causes narcolepsy in dogs, one of the few species besides humans susceptible to narcolepsy. This discovery may make it possible to design a drug to treat the condition.

Scientists showed that reducing corticosteroid hormone levels in aged rats restored the rate of nerve cell growth in the brain's hippocampus region to nearly the same level as in young animals. This work suggests new avenues for preventing memory loss in aging.

A study into the factors that influence the likelihood that an aneurysm will burst will allow some patients to avoid possibly dangerous surgical intervention.

Scientists have found a chemical signal that helps brain cells tolerate ischemia, a loss of adequate blood supply to the brain that causes strokes. This chemical, ceramide, presents a new strategy to reduce the damage caused by stroke.

Scientists gained new insights into a structure called the M channel, revealing the cause of one form of epilepsy. This finding opens the door for developing new epilepsy treatments.

What Could Be Accomplished With Additional Funds

A National Neuroscience Center will bring basic research findings to clinical application by promoting collaboration, communication, and shared resources.

NINDS is developing initiatives to exploit new understanding of the nerve cell circuits in the spinal cord and of the cellular mechanisms that promote spinal regeneration.

Tests must be developed to detect prions, which cause Creutzfeldt-Jakob disease and other neurodegenerative diseases, in the blood supply.

Therapies using neural stem cells have shown tremendous promise in animal models of such human diseases as Tay-Sachs, Parkinson's, and spinal cord injury.

Efforts to reduce health disparities will focus on HIV/AIDS and on preventing and treating stroke in minority populations. Supporting Specialized Centers for Neuroscience Programs at minority institutions will be vital in this endeavor.

A multi-institute study of cognitive and emotional health over the life span will improve our ability to identify people who may benefit from early intervention or preventive measures to improve brain function and delay or prevent disease.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Institute of Allergy and Infectious Diseases (NIAID) supports research to develop better ways to diagnose, treat and prevent infectious, immunologic and allergic diseases.

Accomplishments

A single oral dose of the relatively inexpensive ($4) drug nevirapine given to an HIV-infected woman at the onset of labor and another to her baby within three days of birth can reduce the transmission rate by half compared with AZT.

NIAID is spearheading a $144 million initiative to develop new ways of controlling the human immune system to improve the success of organ transplants and develop treatments for autoimmune diseases such as lupus and rheumatoid arthritis.

NIAID-supported investigators created, for the first time, live, replicating influenza A virus starting with its genetic blueprint. This research has far-ranging implications for understanding the way flu strains mutate and spread.

Scientists found that highly active antiretroviral therapy (HAART) can help adult patients infected with HIV rally and produce new immune cells.

An NIAID-led effort produced the first high-resolution genetic map of *Plasmodium falciparum*, the deadliest malaria parasite.

The genome sequence of *Chlamydia trachomatis* has been completed. This bacterium can cause blindness, genital tract infections, infant pneumonia, and other diseases.

What Could Be Accomplished With Additional Funds

Research into preventing and controlling the global spread of AIDS, tuberculosis, malaria, influenza, and hepatitis are all in need of expansion.

Future studies will focus on whole-genome approaches to emerging pathogen research, including large-scale sequencing, bio-informatics, and functional genomics.

Mounting evidence suggests that infectious agents may be the underlying causes of chronic diseases such as coronary artery disease, diabetes, multiple sclerosis, autism, and chronic lung diseases. New studies will focus on identifying the infectious agents involved in these diseases.

Increases in training funds would ensure that a sufficient number of talented investigators from diverse backgrounds enter immunology and infectious diseases research.

There are unprecedented opportunities to expand vaccine discovery and development in a variety of areas within the next five years.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

The National Institute of General Medical Sciences (NIGMS) supports basic biomedical research that is not targeted to specific diseases.

Accomplishments

New work explained how one of the B vitamins called folic acid lowers levels of homocysteine—a risk factor for heart attacks and strokes—by converting it to a harmless molecule the body needs to fuel essential chemical reactions.

Scientists discovered structural details of a protein that helps regulate heart rhythm. The work may shed light on long QT syndrome, a genetic heart condition.

Scientists gained new insight into how a molecule called a copper chaperone delivers copper to an enzyme that is defective in some cases of Lou Gehrig's disease. The work may offer insight into how to block this delivery in people with the disease.

Test tube experiments revealed an enzyme that may reverse the damage seen in the brains of people with Alzheimer's disease. The enzyme untangled "tau" protein clumps, which are associated with memory loss and dementia.

The discovery of molecular signals that prompt embryonic cells to become liver cells suggests ways to rebuild damaged organs or tissues, or make new ones from scratch.

Scientists determined the three-dimensional structure of ribosomes, the cellular factories that manufacture all of the proteins required for life. Many antibiotic drugs target bacterial ribosomes, so this work may help scientists in antibiotic development.

Scientists hunted down the molecule that triggers the body's response to painful heat. The discovery should help researchers find ways to treat pain.

What Could Be Accomplished With Additional Funds

NIGMS has launched two new initiatives to support pharmacogenetics, the study of individual differences in drug responses based on genetic variation.

NIGMS initiated a program to support structural genomics, which will develop new, faster techniques to determine protein structures from their gene sequences.

NIGMS has initiated a new program to train the next generation of scientists to develop computational approaches and associated databases for biology.

NIGMS supports genomic studies of animals that include mice and zebrafish.

NIGMS seeks to expand programs to increase the participation of under-represented minorities in the biomedical sciences.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

National Institute of Child Health and Human Development (NICHD) fosters research on reproduction, development, and behavior to maintain the health of children and adults.

Accomplishments

NICHD-funded investigators discovered the gene responsible for Rett syndrome, a heartbreaking disease that robs healthy infant girls of their language, mental abilities, and ability to walk.

Children born to mothers with hypothyroidism during pregnancy scored lower on IQ tests than children born to healthy mothers. When mothers were treated for the condition, their children scored almost the same.

For certain types of infertility, induced ovulation combined with artificial intrauterine insemination is more successful and less expensive than many other infertility treatments.

Computer imaging of the brain showed that estrogen, commonly prescribed to treat the symptoms of menopause, may also boost memory in postmenopausal women.

High doses of vitamin A reduced chronic lung disease in extremely low birth weight infants.

Researchers discovered that the absence of a protein called CC10 in premature infants placed the infants at risk for lung disease. Efforts are underway to manufacture the protein for further testing.

What Could Be Accomplished With Additional Funds

The rate of Sudden Infant Death Syndrome (SIDS) among African Americans is still more than twice that of whites. NICHD is intensifying the campaign to stress the importance of placing infants to sleep on their backs.

NICHD-funded researchers will explore how children learn and how best to help them when they have learning difficulties. Research initiatives will also focus on overcoming reading disabilities, improving mathematics skills, and on how Spanish-speaking children best learn English.

An NICHD initiative seeks to improve therapies for childhood trauma victims.

An NICHD initiative will investigate the causes of childhood violence.

NICHD will launch an array of initiatives focusing on early human development.

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) supports research, training, and other programs to address diseases of the eye and disorders of vision.

Accomplishments

A new drug called PKC 412 may be important in preventing vision loss in humans from diabetic retinopathy or macular degeneration.

Scientists detected estrogen receptors in eye tissue from young women, but not from men or postmenopausal women, that may account for gender-based differences in some eye diseases and may offer a therapeutic target for the treatment of dry eye syndromes.

Scientists have recently found that animals with induced detached retinas experienced less damage when given oxygen treatment. Further research in this area may lead to a new approach to minimizing retinal damage in humans with retinal detachment.

Scientists have shown a connection between the molecule nitric oxide (NO) and damage to retinal nerve cells in the eye. Research is now being aimed at exploiting this knowledge to develop a new class of neuroprotective glaucoma drugs.

NEI recently launched studies to determine the extent of eye disease among Latinos and a clinical trial to determine whether low intensity laser treatment can prevent the advanced complications of age-related macular degeneration, the leading cause of severe vision loss in those over 65.

What Could Be Accomplished With Additional Funds

Nerve cells in the retina can now be purified and grown in the laboratory. This provides an opportunity to study the mechanisms of cell survival and injury response.

A number of promising approaches—using growth factors, transplantation, and molecular and genetic technologies—aim to prevent or slow down degenerative eye diseases.

Identifying and sequencing genes in the visual system will lead to a better understanding of the molecular and genetic bases for visual disorders and diseases, and will ultimately lead to improved treatment or prevention.

The NEI will continue to fund the Ocular Hypertension Treatment Study (OHTS), a clinical trial of medications designed to prevent vision loss from glaucoma. Because glaucoma is the number one cause of blindness in African Americans, a high percentage of African Americans are participating in this study.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Accomplishments

NIEHS found that some fatty acids may prevent heart attacks, strokes: Using mouse models and cultured human cells from the lining of the arteries, NIEHS-supported scientists have shown that some naturally occurring fatty acid compounds called epoxyeicosatrienoic acids (EETs) and their metabolites suppress inflammation, a critical step in the development of atherosclerosis. This work offers a new therapeutic approach for preventing the arterial build-up that leads to heart attacks and strokes.

Liver carcinogen blocked: An NIEHS study in China strongly suggests that administration of oltipraz would help reduce the risk of subsequent liver cancers in high risk populations exposed to aflatoxin and represents an important chemoprevention regimen in the avoidance of an environmentally-induced cancer.

Learning how cells respond to stress, infection, injury: In times of stress, such as an infection or injury, the body's cells often respond with an inflammation. This phenomenon can lead to heart disease, autoimmunity, asthma, arthritis, neuronal degradation, and cancer. In a series of cutting-edge studies, NIEHS researchers have followed the molecular events which occur inside the cell—discovering molecular targets for potential treatments for these major human diseases.

What Could Be Accomplished With Additional Funds

The Sister Study Can Clarify Causes of Breast Cancer: NIEHS seeks to speed a study of the unaffected sisters of breast cancer cases . . . using questionnaires and a blood and urine samples to clarify the joint effects of environmental and genetic factors in the etiology of breast cancer . . . such factors as hormonally active environmental agents, growth factors, environmental contaminants of general public concern such as pesticides and solvents, as well as the role of with genes involved in their metabolic activation. With CDC, NIEHS has developed the capacity to measure biological markers for 70 new hormonally active agents, which can be used to analyze the samples.

Children's Environmental Health Centers to Focus on Learning, Behavior: Following an initial emphasis on asthma and other respiratory diseases, NIEHS would plan a new phase that will concentrate on two other key areas in pediatric environmental health: learning and behavior, and growth and development. New research opportunities include the investigation of environmental effects on such outcomes as attention deficit hyperactivity disorder.

Biomarkers for Safety: NIEHS can make important contributions, in collaboration with the NIH Office of Science Policy and Planning, in developing biomarkers for drug safety, and thus advancing not only drug safety but timely drug development.

Comparative Mouse Genomics Center (Expansion of the Environmental Genome Project): NIEHS would support development of trans-NIH Comparative Mouse Genomics Centers resource centers that produce transgenic and knockout mice which will have variants of human environmental responsive genes found in the general human population, such as the genes controlling the metabolism of toxicants, for DNA repair pathways, for the cell cycle control system, for cell death and for the cell signaling or communication. The Centers' research will be used by the scientific community to learn the importance of these human variations, in order to better predict health risks and to develop environmental policies to protect the most susceptible of us. What is learned will advance not only the protection of people from environmental factors but from viruses, nutritional shortcomings, drug side-effects, and physical and chemical stresses.

Linking Exposure to Human Disease: Using new computer imaging and computational advances, coupled with sensitive tools of analytic chemistry and gene expression/function, NIEHS proposes to dramatically enhance exposure assessment and its use to prevent human disease. In cooperation with CDC and EPA, NIEHS seeks to address issues of children's health, of low-dose chemical exposure risks, of environment-related health disparities, and of gene/environment interactions, as well as to prioritize chemicals for safety study by the NTP, and finally, with other agencies,

to evaluate of the effectiveness of regulatory decisions and get the most bang from the buck.

Advanced Research Cooperation in Environmental Health: NIEHS recently developed a new program called Advanced Research Cooperation in Environmental Health (ARCH), to link historically black colleges and universities in research partnerships with research intensive academic institution—thus expanding the Nation's base of scientists. NIEHS proposes to expand ARCH to include Hispanic serving institutions and tribal colleges and thereby establish groups of investigators at these institutions who can successfully compete for other NIEHS and other NIH grants.

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) leads a scientific effort to uncover the mechanisms of the aging process and to extend the healthy, active years of life for all Americans.

Accomplishments

NIA has launched a nationwide treatment study to assess the effectiveness of Vitamin E and donepezil (Aricept) in preventing Alzheimer's disease. Other clinical studies will look at using nonsteroidal anti-inflammatory drugs (NSAIDS) to treat Alzheimer's disease.

Studies of the brain using magnetic resonance imaging (MRI) were able to predict the development of Alzheimer's disease (AD) within a three-year period, raising the hope of developing treatments to stop brain changes before clinical deterioration begins.

Physical activity was found to increase nerve cell growth and survival in the region of the mouse brain involved in learning and memory. This study suggests that behavior modification might help alleviate the age-related decline in brain function.

Transgenic mice without the ability to rebuild telomeres, the structures at the tips of chromosomes that become progressively shorter with age, had a shortened life span. When older, they also had an increased number of spontaneous cancers.

In a long-term study of more than 6500 middle-aged men, low blood pressure, low blood sugar levels, and avoiding cigarette smoking and obesity were shown to predict healthy aging. The study also found that healthy habits or therapeutic interventions can have beneficial health effects when begun later in life.

What Could Be Accomplished With Additional Funds

Studies will help determine the genetic and environmental factors that allow centenarians to live to such an old age. Understanding the genetic, molecular and biochemical basis of aging will help us to combat aging problems and age-related disease.

NIA will lead the trans-NIH Alzheimer's Disease Prevention Initiative to make a concerted assault on this disease's development and progression.

Potential causes of disparities in adult health across race, gender, and socioeconomic status will be studied in order to reduce health inequalities.

Carefully designed national studies will examine the prevalence of elder abuse and the risk factors for elder abuse.

More research is needed into stem cells, which hold enormous potential for therapy in many degenerative diseases of aging, including Alzheimer's disease, Parkinson's disease, stroke, myocardial infarction, mascula-skeletal disorders, immune system dysfunction, and diabetes.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Accomplishments

Improved hormone replacement therapy for older women at risk for osteoporosis includes lower doses of estrogen and progesterone, in combination with calcium and vitamin D.

Researchers reported on a transcription factor that is required to establish the barrier function of the skin. These findings provide insights into how the skin performs its critical environmental protective function.

Researchers have successfully used the antibiotic gentamicin to restore the function of the gene that encodes for the protein dystrophin in mouse models of Duchenne muscular dystrophy (DMD).

Gene therapy to treat limb girdle muscular dystrophy in animals made muscles five fold less likely to be damaged during forceful contractions than untreated muscles.

Optical coherence tomography (OCT) is an advanced new method of imaging capable of detecting small structural changes in tissues during the earliest stages of disease.

Researchers found that people who did more than 4 hours of heavy physical activity per day were 7 times more likely (13 times, if obese) to develop knee osteoarthritis than people who did no heavy physical activity. Walking and light physical activities did not increase the risk.

An international research team showed that the obesity gene leptin, which helps maintain body weight, also plays a role in controlling bone density by telling the brain to slow down the rate of bone formation. This study suggests a new strategy to increase bone density and treat or prevent osteoporosis.

What Could Be Accomplished With Additional Funds

A public-private partnership is being explored to identify biomarkers, biological warning signs, for osteoarthritis that would allow earlier intervention therapies.

A recent workshop identified research opportunities into treatment approaches for osteogenesis imperfecta, a disease that typically strikes young children whose bones are very brittle and vulnerable to many fractures.

NIAMS is planning an initiative with NHLBI to explore promising research into the roles of vascular calcification and bone cell regulation in osteoporosis.

Members of the NIAMS intramural research program are designing an outreach program targeted toward minority communities.

NIAMS is enthusiastically participating in the new NIH K23 and K24 initiatives to stimulate careers in clinical research.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

The National Institute on Deafness and Other Communication Disorders (NIDCD) supports and conducts research into diseases and disorders of human communication.

Accomplishments

A study of twins and triplets revealed a possible genetic component to prolonged and recurrent episodes of middle ear infections. Once the genes are identified, doctors may be able to recognize which children and siblings are at risk and improve treatment.

An investigational vaccine that targets bacteria causing middle ear infections was shown to be safe and to provide protection against infection in animals, which may lead to use in humans.

Scientists have located more than 50 genes that can cause hearing impairment. Ten have been cloned and the nature of the problems causing the hearing loss discovered. With the ability to predict who is at increased risk, better strategies can be developed to minimize or delay hearing loss.

More than 10,000 children have received cochlear implants, a prosthesis that converts sound into electrical impulses that can be interpreted much like sound. Scientists found that children with cochlear implants had better language skills than children who used hearing aids.

A large study of children who stutter showed a strong genetic component to the condition. NIDCD has begun a study to identify the genes that predispose an individual to stutter.

Dramatic findings this year demonstrated that individual odor receptors are not dedicated to specific odors. An odor is distinguished by the unique combination of receptors that respond to it.

What Could Be Accomplished With Additional Funds

NIDCD hopes to identify with precision the early, sensitive periods for developing speech and language skills.

More research is needed to identify the molecular pathways that may lead to regeneration of auditory hair cells, a possible strategy for reversing hearing loss.

A working group will examine studies of the molecular mechanisms of middle ear infections in the hope of developing novel therapies.

Based on promising recent research advances, NIDCD will aggressively continue its investigations into the hereditary basis of hearing impairment.

NATIONAL INSTITUTE OF MENTAL HEALTH

The mission of the National Institute of Mental Health (NIMH) is to diminish the burden of mental illness through research.

Accomplishments

A White House Conference on Mental Health, the release of the first-ever Surgeon General's Report on Mental Health and the Surgeon General's Call to Action on Suicide Prevention this past year were all made possible by advances in science. There is no longer doubt that mental illnesses such as schizophrenia, depression, bipolar disorder and anxiety disorders are disorders of the brain, and that they are diagnosable and treatable.

The largest and longest study ever of children with attention deficit hyperactivity disorder (ADHD) found that methylphenidate (Ritalin) was safe and effective, particularly when coupled with intensive behavioral treatments.

Scientists showed that primate brains make new cells for the brain region involved in higher cognitive function. This research gives new hope for the repair of brain injuries.

NIMH has initiated large-scale clinical trials to learn the best treatments for bipolar disorder, depression in adolescents, depression that is unresponsive to initial treatment, schizophrenia, and Alzheimer's disease.

NIMH research has found that many people have seen their doctors the month, day, or even hours before they commit suicide, and that many suffer from depression. This knowledge raises the hope that one day the majority of these deaths may be prevented.

NIMH research has shown that many risk factors for violence occur early in a child's life, including child abuse and neglect.

What Could Be Accomplished With Additional Funds

Ongoing clinical trials in neuroscience, behavioral science, genetics, and clinical investigation will provide solid information about the best treatments for many mental illnesses including schizophrenia, depression and bipolar disorder.

Several new clinical trials will focus on children's mental disorders.

Research on school safety to be initiated this year will improve our understanding of the social and emotional factors involved in violent behavior by children.

NIMH is using a broad array of scientific approaches to examine the patterns of use of psychotropic drugs in young children.

NATIONAL INSTITUTE ON DRUG ABUSE

The National Institute on Drug Abuse (NIDA) conducts and supports over 85 percent of the world's research on the health aspects of drug abuse and addiction.

Accomplishments

NIDA launched the National Drug Abuse Treatment Clinical Trials Network (CTN), which will include not only a wide array of research centers but also some 250 community-based treatment programs.

NIDA-supported research has demonstrated a potentially powerful new treatment approach for heroin addiction known as Bup-Nx. FDA approval is expected soon.

Scientists are finding that abuse of some drugs such as methamphetamine and MDMA, or ecstasy, can cause long-lasting damage to the brain.

Using neuroimaging techniques, scientists have discovered that the amount of dopamine D2 receptors an individual has may predict whether they will find a drug pleasant.

In animal tests, a new compound, DIPP-NH2 , was found to be three times more potent at reducing pain than morphine and did not show signs of physical dependence.

What Could Be Accomplished With Additional Funds

NIDA would increase its research portfolio investigating the link between drug abuse and various diseases that predominantly affect minority populations.

NIDA has launched an initiative to understand the role of genetic and environmental factors in addiction, but it has only been able to fund half of the excellent proposals received.

Given the increasing use of "club drugs" such as ecstasy, GHB, ketamine, and others, NIDA will increase its efforts to develop effective new treatments.

Little is known about the short- and long-term effects of chronic drug abuse on the body. NIDA hopes to increase its efforts to understand these consequences, especially as drug-using populations continue to age.

NIDA would launch a Neurobiology of Development Initiative to determine the effects of drugs on brain development at all ages, especially those prenatally exposed.

State-of-the-art technologies such as functional magnetic resonance imaging (fMRI) scanners enable scientists to pose a whole new series of questions and pro-

vide analyses at an even more sophisticated level. Expanding access to and refining these costly technologies is a high priority for NIDA.

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

The National Center for Complementary and Alternative Medicine (NCCAM) is playing a key role in validating unconventional approaches to health care by supporting rigorous scientific research.

Accomplishments

NCCAM supports the largest, most definitive Phase III clinical trials ever undertaken for a range of unconventional therapies, including studies of:

—*Ginkgo biloba* to prevent dementia (with NIA).
—acupuncture for osteoarthritis pain (with NIAMS).
—glucosamine and chondroitin sulfate for osteoarthritis (with NIAMS).
—shark cartilage for lung cancer treatment (with NCI).
—saw palmetto extract for enlargement of the prostate (with NIDDK).
—St. John's Wort for treatment of depression (with NIMH).

Five new Specialty Research Center bring the number of research centers supported by NCCAM to 11. The new centers focus on aging and women's health, arthritis, craniofacial disorders, neurological disorders, and cardiovascular disease in African Americans.

What Could Be Accomplished With Additional Funds

The Clinical Research Curriculum Award (CRCA) would support instruction in complementary and alternative medicine (CAM) clinical research. NCCAM plans to make awards that help incorporate CAM information into medical and allied health school curricula.

NCCAM has formed a search committee to recruit a recognized authority in clinical research to develop an intramural research program. NCCAM intramural research will be primarily clinical in focus.

NCCAM would like to support studies examining the use of:

—echinacea to treat upper respiratory infections and ear infections.
—massage to speed the development of preterm infants.
—feverfew as a treatment for migraine.
—valerian root for the treatment of insomnia.
—milk thistle extract to treat Hepatitis C and other liver diseases.

NCCAM hopes to support studies of indigenous health systems, exploring promising traditional therapies for their potential applicability in the U.S. Examples include Native American medicine and traditional Chinese medicine.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Approximately 14 million American adults are dependent on alcohol or abuse it. The direct and indirect costs to the nation are almost $185 billion annually.

Accomplishments

NIAAA-supported scientists found that the brains of human alcoholics produced less of a crucial nervous-system protein, myelin, than those of non-alcoholics. This new finding will help scientists to pinpoint gene activity that results in damage to alcoholics' brains.

NIAAA's Collaborative Studies on the Genetics of Alcoholism (COGA) has found the likely chromosomal locations of several genes involved in alcoholism.

NIAAA-supported studies showed that the new medication nalmefene is at least as successful in preventing relapse among recovering alcoholics as naltrexone, the recently FDA-approved drug of choice. Nalmefene may have advantages over naltrexone, including less liver toxicity. A Finnish company plans to seek FDA approval.

NIAAA-supported researchers have found that people who drank heavily during early and middle adolescence score significantly lower on neuropsychological tests. Heavy drinking in the young may inflict unique and potentially lasting damage.

What Could Be Accomplished With Additional Funds

NIAAA proposes to establish an Integrative Neuroscience Initiative on Alcoholism (INIA) that would incorporate the efforts and findings from various scientific disciplines.

Microarray technology, a recently developed genetics technique, will give alcohol researchers a clearer picture of the changes in the brain caused by chronic alcohol exposure and reveal potential therapeutic targets.

At least nine promising medications for alcoholism treatment await further testing, but require a faster mechanism for moving from the laboratory to clinical trial.

NIAAA could conduct the first national, representative sample of drinking among adolescents and college-age youth. This study is crucial to estimate treatment needs.

Research is needed to identify the biological, genetic, and sociocultural factors that contribute to increased risk of fetal alcohol syndrome in some minority populations.

Recovery rates among alcoholics need to be improved. Clinical trials that identify biological factors influencing recovery will enable scientists to work toward this goal.

Researchers could better address the public health threat from hepatitis C by investigating how alcoholic liver disease and hepatitis C interact to cause unexpectedly high damage.

NATIONAL CENTER FOR RESEARCH RESOURCES

The National Center for Research Resources (NCRR) provides the critical research tools and infrastructure necessary for scientists to conduct top-notch health-related research.

Accomplishments

Scientists used powerful high-field nuclear magnetic resonance (NMR) spectrometers to identify the crucial parts of the prion protein that can change and cause degenerative brain conditions such as mad cow disease, scrapie in sheep and goats, and Creutzfeldt-Jakob disease and kuru in humans.

Postmenopausal women with hip fracture were found to show signs of vitamin D deficiency, which can be prevented with proper nutrition and vitamin supplements.

Researchers uncovered the three-dimensional structure of the cell's tiny protein factories known as ribosomes in unprecedented detail using high-energy x-rays.

Scientists have found that most babies with severe combined immunodeficiency (SCID), a rare and sometimes fatal syndrome marked by a lack of immune system cells, can survive if given a bone marrow transplant from a family member within 14 weeks of birth.

By evaluating monkeys with a specially made contact lens over one eye, scientists discovered that visual development in one eye could be significantly altered by modifying vision in the other. These findings may point to new avenues for treating and preventing visual problems in infants and young children.

What Could Be Accomplished With Additional Funds

Improved imaging systems are needed to investigate the cause, progression and treatment of brain pathologies.

NCRR proposes to establish informatics centers that will facilitate research in areas such as genomics that generate very large data sets requiring high-end computation.

NCRR proposes to establish state-of-the-art resource centers for analyzing gene expression, which will in turn facilitate defining gene function.

NCRR proposes to increase support for synchrotron facilities, which produce the world's most brilliant x-rays and are crucial to structural biology and drug design studies.

NCRR proposes to help alleviate health disparities among racial and ethnic minorities by establishing several Comprehensive Centers on Health Disparities at minority medical schools. The centers will focus on cancer screening and management, cardiovascular disease, and stroke.

NATIONAL INSTITUTE OF NURSING RESEARCH

The National Institute of Nursing Research (NINR) supports clinical and basic research to establish a scientific basis for the care of individuals.

Accomplishments

The transitional care model, with follow-up in the home by advanced practice nurses, was shown to improve the health of older adults with common medical and surgical problems at a 48 percent savings to the healthcare system. Widespread use of this model could improve the quality of patient care and save significant healthcare dollars.

NINR has tested the effectiveness of a 6-week arthritis self-management course in Spanish to help Hispanics control this widespread, painful condition. Four months after the course was completed, participants showed notable improvements in their arthritis and better overall health.

Very low birthweight infants require procedures that are probably painful to them. To avoid the use of drugs and their possible side effects, investigators tested

three non-medication interventions in an effort to ease pain in these tiny babies. Pacifiers with sucrose or sterile water were found to significantly reduce pain.

Researchers have found that a carefully designed educational program for teens who select to use the insulin infusion pump rather than multiple insulin injections enables them to achieve excellent control of their diabetes.

What Could Be Accomplished With Additional Funds

More funds would allow an intensive focus on research for improving end-of-life symptom management of pain, nausea, and weight loss.

Increased resources would focus on helping minorities, who have a high rate of diabetes, manage their condition effectively.

A new initiative would support in-depth research on promising self-management strategies for patients with such chronic illnesses as diabetes, arthritis, and congestive heart failure.

Research would be undertaken to investigate the effectiveness of a wide range of telehealth interventions, especially in rural and other underserved areas.

NINR would support multidisciplinary clinical trials to improve adherence to treatment, help patients make decisions about therapy, and manage the symptoms of chronic illness.

NINR would broaden the training opportunities for nurse researchers in the field of genetics, including an expansion of the new Summer Genetics Institute.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

The National Human Genome Research Institute (NHGRI) aims to characterize the genomes of human and selected model organisms through complete mapping and sequencing of their DNA.

Accomplishments

Human Genome Project scientists have deciphered 2.25 billion of the 3 billion chemical units of human DNA. Planners expect to complete a working draft of 90 percent of the genome by this spring and to finish the human sequence by 2003.

NHGRI-supported scientists deciphered an entire human chromosome, Chromosome 22, for the first time.

The public database GenBank has accumulated over 3.8 billion base pairs of DNA sequence. Scientists find this information invaluable—there are approximately 5 million searches of the GenBank data daily.

What Could Be Accomplished With Additional Funds

The roles of human genes are often discovered by comparing their DNA sequences to that of other organisms. Publication of the complete sequence of the fruit fly Drosophila melanogaster is expected in early 2000. Having the genome sequences of other organisms will be critical for improving the speed and accuracy of understanding gene function and disease.

A catalogue of the places in the genome where the DNA sequence differs among individuals will help in the effort to discern the genetic factors associated with many common diseases. Alterations in our genes are responsible for an estimated 3,000 to 4,000 hereditary diseases, including Huntington's disease, cystic fibrosis, and polycystic kidney disease. Genetic factors also interact with lifestyle and environmental factors like diet and cigarette smoking to influence the development of many common illnesses. In the future, an individual might be screened for hereditary predispositions to diseases and counseled on steps to prevent these diseases or delay their onset.

Supporting the fundamental research needed to develop new sequencing technology will continue to be important, even after the reference human genome sequence is finished. Faster and cheaper sequencing machines are vital to the identification of sequence variations associated with disease, to understanding gene function, and to the incorporation of new genetic technologies into patient care.

In the future, an individual may be able to take a credit card size DNA "chip" containing his or her personal DNA profile, along with a drug prescription, to a pharmacy, where the medication will be tailored to the individual's genes. The result will be fewer side effects and more effective treatment.

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center (FIC) supports research and research training to address global health challenges.

Accomplishments

Fogarty collaborators in Uganda have helped show that single doses of the antiretroviral drug nevirapine prevent mother-to-infant transmission of HIV, and are more effective and much cheaper than AZT.

FIC-supported researchers have developed a new technique to more easily identify the virus that causes dengue fever, a reemerging infectious disease in the developing world.

FIC has developed a collaborative program to combat tuberculosis (TB) with NIAID, CDC and USAID. Early results show progress with two drugs: prednisone and isoniazid.

An FIC-supported health survey shows that people exposed to unprocessed cooking fuels in their homes are at a substantially increased risk of having active tuberculosis.

FIC supports an International Training in Medical Informatics Program to train people from the developing world to apply state-of-the-art information and communication technologies to research and health surveillance activities.

What Could Be Accomplished With Additional Funds

FIC would establish an international research and training program to address tobacco prevention and control as well as research capacity in developing countries.

FIC would develop a cadre of mental health experts in low- and middle-income nations by promoting programs to provide researchers with relevant scientific training.

Efforts would be devoted to train scientists in molecular biology and molecular epidemiology techniques of relevance to developing countries.

FIC would expand its clinical research and training programs to support professionals from developing nations. Clinical trials of drugs and vaccines of mutual benefit to the United States and host countries will form a major part of this activity.

FIC would establish a program designed to reduce malnutrition and to support research to prevent and treat diseases through nutritional intervention.

FIC would establish a program designed to strengthen epidemiology research and clinical trials capacity to evaluate candidate vaccines for parasitic, bacterial, and viral disease in low- and middle-income nations.

NATIONAL LIBRARY OF MEDICINE

The National Library of Medicine (NLM), the world's largest medical library, uses computer and communication technologies to improve the organization and use of biomedical information.

Accomplishments

ClinicalTrials.gov, a new database developed by NLM, has just been made public. It is an easy-to-use system that provides the public with information on more than 4,000 federal and private scientific studies involving human subjects.

MEDLINEplus, the Web-based consumer-oriented health information service, is now delivering more than a million documents each month. The service links users to extensive data about 350 diseases and conditions, and most recently to the NIH ClinicalTrials.gov database.

NLM made awards to fund 49 electronic health information "outreach" projects in 34 states that will increase Internet access in a variety of community-based settings.

Another new information resource developed by NLM is "PubMed Central," the just-released Web-based repository that provides barrier-free access to primary reports in the life sciences.

What Could Be Accomplished With Additional Funds

ClinicalTrials.gov plans to expand to include studies not funded by the Federal Government. With additional support, PubMed Central eventually will contain peer-reviewed reports from journals and reports that have been screened but not formally peer reviewed.

NLM is planning to provide access to extensive information about prescription drugs as the next major improvement to MEDLINEplus.

Additional resources would be needed to expand the current outreach campaign through public libraries and other community organizations.

Additional support will allow NLM to augment the medical informatics training programs at its 12 centers and to make training awards to new institutions.

NLM is supporting the development of the Next Generation Internet. Additional funds will support a projected Phase III.

NLM's National Center for Biotechnology Information (NCBI) collects, analyzes, and distributes molecular biology data related to genomic analysis. NCBI manages the GenBank database. These sophisticated information tools and resources must be improved, expanded, and made even more widely available.

Senator SPECTER. We have given you a fair amount of work to do, but we are going to have a lot of work to do on this end in trying to get this funding.

This will be the third round and I think our concluding round. I will call now for the final question.

Senator Feinstein.

BUDGET INCREASES

Senator FEINSTEIN. Thanks very much, Mr. Chairman.

I was wondering if you could tell me how the various institutes apply an increase in budget across the board. And what I mean by this, in the past 2 years, there has been a 15-percent increase. But apparently these increases are not applied equally across the board, for example, in lupus or diabetes. Could you tell me how this figure gets applied across the board, or if it does?

Dr. KIRSCHSTEIN. It gets applied based on a number of factors that the institute directors use to make decisions. Each institute has a mission statement and has developed a strategic plan to relate to all the diseases, dysfunctions, organ systems that are under the purview of that institute.

In addition, the institutes seek advice very, very broadly from the statutorily mandated advisory councils, as well as other review groups of experts in the various fields. And over that large assemblage of advice and over a period of time and in discussion with their colleagues and with the Director of NIH, Dr. Varmus over the past years, final decisions are made as to what might be possible to do in a particular field.

Certain scientific areas, certain diseases are more ready for a great expansion in funds to move them forward than are others. Others need nurturing in a different way, small workshops or large conferences, to prepare the field to be able to do more research. And then the institutes make decisions as to what types of allocations go to each area.

The decisions also include how burdensome the disease can be, the quality of life with the disease, whether it affects one population, a majority population, a minority population, whether it affects women versus men. And all those factors are taken into consideration along with the scientific judgments of all these outstanding directors, to make the final decisions.

And I would offer my colleagues, any one who might wish to, to add to the answer.

Senator FEINSTEIN. Could I just follow up on that? Are you saying effectively that money goes based on how ready the science community is to advance the ball up the field, or are you saying the money goes based on the presence of viable projects? Your answer was unclear in this area.

Dr. KIRSCHSTEIN. The answer is that it is both, and many other factors, as well. There is not one way, I do not think, that any institute or any entity decides, "I shall spend," or "We shall spend' X' amount on a particular disease."

It is indeed projects that are ongoing that can be expanded because new developments have occurred. There may be an emergency situation.

Recently, for example, over the last several years, as tuberculosis reemerged as a disease that had not been of as much significance in the previous years, it was felt that it was an emergency of such a nature that a considerable amount of money had to be put into it.

So there are varying reasons to do this. And each institute director uses the best expertise from the community, from outstanding scientists, from the advisory and advocacy groups, and then comes to the best decisions possible.

Senator FEINSTEIN. Thank you very much, Doctor.

Senator SPECTER. Thank you very much, Senator Feinstein.

Well, we very much appreciate you all coming in today. As I have said in the past, we are reluctant to interrupt your research to have you come to these hearings, but it is a very impressive group. And we will be working hard to provide the funding which will enable you to continue to serve America and the world.

CANCER GROUP LETTERS

That concludes the hearing.

Senator FEINSTEIN. Mr. Chairman, before you adjourn, I have some letters from major cancer groups that deserve a response. May I ask that they be submitted for response?

Senator SPECTER. They will be made a part of the record for response.

Senator FEINSTEIN. Thank you very much.

[The information follows:]

LETTER FROM MARIN BREAST CANCER WATCH

MARIN BREAST CANCER WATCH,
San Rafael, CA, February 22, 2000.

DEAR SENATOR FEINSTEIN: I am very appreciative of your continuing efforts on behalf of the breast cancer stamp. As I told you in our phone conversation, we love the stamp and feel it has helped heighten awareness of the epidemic. However, we do want to know exactly where the money is going, and if it is not going into researching the causes, we would like to know why not.

Donna Shalala said in her letter to you that the Insight Awards program received 400 applications, with 20 percent related to environmental causes of breast cancer. How much money would it cost to fund all 80 applications related to environmental causes?

We would also like to know who is on the panel of scientists and who are the patient/advocate representatives? Who is on the presidentially appointed National Cancer Advisory Board? How can we influence the awards decision? To whom can Marin Breast Cancer Watch members write? Call? E-mail?

Shalala's letter says "Environmental factors have long been suspected as playing a causal role in breast cancer, and both NCI and the National Institute of Environmental Health Sciences already support many studies specifically addressing the role of the environment in breast cancer." We are unaware of these studies. How can we get more information on them?

I, personally, am delighted to have you as an ally in this struggle to stop the epidemic of breast cancer. I believe, with all of us working together it will happen.

Sincerely,

FRACINE LEVIEN,
Founder/Executive Director.

LETTER FROM THE BREAST CANER FUND

THE BREAST CANCER FUND,
San Francisco, CA, March 7, 2000.

Re Request to redirect Breast Cancer Stamp Funds to NIEHS.

Senator DIANNE FEINSTEIN,
Washington, DC.

Attn: Glenda Booth

DEAR SENATOR FEINSTEIN: As you know, The Breast Cancer Fund (TBCF) is very concerned about the dearth of funding for research that investigates linkages between environmental factors and breast cancer. I am therefore writing to request that you consider redirecting the funds raised by the Breast Cancer Stamp to the NIEHS in the re-authorization bill scheduled for this summer.

In Secretary Donna Shalala's letter to you dated February 14, 2000, she stated that of the 400 grant applications for breast cancer stamp revenues, 20 percent are related to environmental causes of breast cancer, "an area of major concern to many breast cancer advocates." The 20 percent number is low and most likely will result in less than 20 percent of the awards. However, an even greater problem exists with the definition of environmental factors.

Advocates use environmental research to mean studies about the effect of chemicals and radiation on the development of breast cancer, while Federal agencies like the NCI include in the concept diet, exercise, genetics, alcohol use, pharmaceuticals and hormones, as well as chemicals and radiation. With this expanded definition, NCI always appears to be doing more than it actually is with regard to research into the effect of environmental toxins, including pesticides, industrial chemicals and pollutants, and radiation.

TBCF has done extensive oversight to determine how much funding from two other important allocations for "environmental research" actually went to studies into the connections between breast cancer and environmental toxins. We report as follows:

(1) 1997 EMERGENCY SUPPLEMENTAL BUDGET

The first incident occurred in 1997, in the Emergency Supplemental Budget to which Representative Nancy Pelosi added a $15 million appropriation to study breast cancer and environmental toxins in areas of high breast cancer incidence. TBCF worked closely with Congresswoman Pelosi to draft the appropriation language and waited patiently to learn about the allocation of these funds. No action or reporting from the NIH was forthcoming, until, finally, in 1998, TBCF filed a Freedom of Information Act (FOIA) to find out whether all the groups named in the legislation were consulted and what the disposition of the funding was.

TBCF has compiled a chronology of events that the FOIA disclosed, which we are enclosing with this letter. As you will see, first, $3 million was allocated for air pollution research, and the remaining $12 million appears to have ended up in three RFAs. However, it is difficult to determine exactly what funds were related to the original appropriation, as the addition of all funding amounted to $8.25 million out of the original $12 million allocation.

As a follow-up, Representative Pelosi wrote a letter Dr. Harold Varmus at the NIH (12/99) requesting clarification on the RFAs and their relationship to the study of environmental toxins and breast cancer risk factors in the high incidence areas enumerated in the legislation. No reply has come as yet.

(2) NCI EXTRAMURAL RESEARCH ON BREAST CANCER AND ENVIRONMENTAL FACTORS

For several years, TBCF and other advocates wrote to Dr. Varmus requesting that the NIEHS budget be doubled since the mandate of that agency is to investigate the connections between environmental factors and disease. In the initial correspondence with Dr. Varmus, we were told that there were 40 extramural projects in 1997–98 that related to "Breast Cancer and the Environment." Once again, our analysis reveals that Dr. Varmus and the NCI were including topics like exercise and diet in their interpretation of "environment."

Of the 40 cited projects, TBCF looked for those related to environmental chemicals, radiation and EMFs. Our use of the term "environmental factors" was done in the most generous way. For example, we included as environmental research the creation of the New York Cancer Registry which is necessary for any future study of environmental factors. With numbers rounded to the nearest thousand, our analysis revealed the following results:

Total funding for all projects: $11,967,000

Total environmental projects: 12

Total funding for environmental projects: $4,228,000 or 35 percent of total funding.

It should also be noted that the funding for environmental research cited by Dr. Varmus represents a pittance of the total NIH budget of $15.6 billion and that the NIEHS budget was $382 million or 2.4 percent of the NIH budget for the period in question.

As a next step, TBCF plans to obtain a detailed description of total intramural breast cancer research funding at NCI for the 1997–98 period to determine what percentage of those funds went to research on breast cancer and environmental factors, as we define them. We hope you will consider the two incidents described above as you consider whether we will actually get research into the environmental causes of breast cancer by allowing the NCI to continue using the Breast Cancer Stamp funds as described by Secretary Shalala.

As you know, The Breast Cancer Fund has been and will continue to be a major supporter of the Breast Cancer Stamp. Not only is the funding raised by the stamp vital, but it gives the public a welcome opportunity to contribute to much needed research into a disease about which we are all concerned. We believe that the stamp revenues can have an even greater impact, however, if they are specifically directed to research into the causes of the disease. Identifying environmental toxins that are contributing to the disease and that can be reduced or eliminated would give us the first step toward real prevention.

Thank you for considering this request, and please do not hesitate to contact us if we may be of further assistance in this matter.

Sincerely,

ANDREA R. MARTIN,
Founder and Executive Director.

Enclosure.

CHRONOLOGY OF FREEDOM OF INFORMATION ACT (FOIA) REQUEST REGARDING $15 MILLION EMERGENCY APPROPRIATION FOR BREAST CANCER AND ENVIRONMENTAL FACTORS RESEARCH

(By the Breast Cancer Fund)

Congresswoman Nancy Pelosi inserted a section in the FY 1997 Emergency Supplemental Budget that called for a special $15 million appropriation, as follows:

". . . for the purpose of supporting multicenter research studies on environmental risk factors associated with breast cancer and factors related to regional variations in breast cancer incidence and mortality. The Committee understands that there may be a significant link between toxics and other chemical substances present in the environment and the high rate of breast cancer among women in certain areas of the country."

Several States were listed, including California, where high breast cancer incidence and mortality has been recorded. In line 12, Chapter 7, language was included mandating "consultation" with other agencies in the distribution of the funds:

"These funds will be made available on a competitive basis and through mechanisms determined by the Secretary, in consultation with the Directors of the National Institutes of Health, the National Cancer Institute, the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the Deputy Assistant Secretary for Women's Health."

The Breast Cancer Fund (TBCF) has a copy of a letter from Secretary Shalala to Senator Tom Harkin (12/19/97) which explained that the Emergency Supplemental Budget bill had passed and of the $15 million appropriated, $3 million was to be spent on air pollution studies that related to cancer and respiratory diseases. This proposal was puzzling since the funds were slated for breast cancer studies.

One year after this emergency budget bill was law (Public Law 105–18), no information or requests for proposals had come forth from the National Institute of Health. TBCF has taken the following steps to determine the disposition of the $12 million and which agencies.were consulted in the disposition.

10/14/98.—TBCF sent a FOIA to the Department of Health and Human Services (DHHS) Secretary Shalala requesting written proof that all the groups listed in the consultation mandate had been involved.

10/21/98.—A postcard was received by TBCF from the DHHS with a note that consideration of our request was underway and that all future contact should refer to case number 99–54W.

10/29/98.—A postcard was also received by TBCF from the Centers for Disease Control and Prevention (CDC) that consideration of our request was underway and in the future to refer to case number 99–151.

01/21/98.—Rosario Cirrincione from the DHHS Office of Public Affairs, on behalf of the Executive Secretariat, sent 62 pages of records to TBCF in response to our FOIA request.

03/31/98.—Ioana Petrou, Esq., TBCF General Counsel and Board member sent Rosario Cirrincione a letter indicating that none of the 62 pages related to the disposition of the $12 million in Public Law 105–18. The request for appropriate records was repeated.

06/28/99.—A letter was sent to TBCF from Beatriz Flores, FOI Clerk at the Public Health Service of DHHS, accompanied by a half inch of documentation [1] which answered our consultation questions and some issues about how the requests for research proposals were drafted. The Flores cover letter stated clearly that CDC had no records regarding this appropriation, which means CDC was not consulted. No evidence was submitted that the Office of Women's Health was consulted either. The additional documentation concerned the specifies of the Request for Proposal Applications (RFA) as follows:

(1) Regional Variation in Breast Cancer Rates in the U.S. RFA: CA–98–017 Application Receipt Date: 8/25/98

(2) Interdisciplinary Studies in the Genetic Epidemiology of Cancer RFA: CA–98–018 Application Receipt Date: 11/17/98

(3) Implementation of the National Occupational Research Agenda RFA: OH–99–002 Application Receipt Date: 6/10/99

LETTER FROM BREAST CANCER ACTION

BREAST CANCER ACTION,
San Francisco, CA, March 10, 2000.

Re Breast Cancer Stamp Re-authorization.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: We write on behalf of the undersigned organizations and the thousands of people we represent to urge you to consider changing the language of the bill to re-authorize the breast cancer stamp.

While we think this is a creative and important program, we strongly believe that the funds generated need to be spent in a way that might make a significant difference in the breast cancer epidemic. That will not happen if the current structure of the stamp program is maintained. The 70 percent of stamp proceeds that are allocated to the National Institutes of Health (NIH) should be directed by law to the National Institute of Environmental Health Sciences (NIEHS). Leaving the allocation of funds to the discretion of the NIH means more of the same kind of research that has done little to uncover the causes of breast cancer.

We know that you share our concern about how the portion of the stamp funds that are directed to the National Institutes of Health are spent. Your office has shared with us the letter dated February 14 in which Secretary Shalala responds to your questions regarding expenditure of the funds. That letter reveals precisely why it is important to change the structure of the stamp program. Secretary Shalala states that the stamp funds have been allocated by the NIH to the National Cancer Institute (NCI), which, in turn, has created a new awards program for the funds. The letter states that, of the 400 grant applications received, twenty percent relate to environmental causes of breast cancer. Notably, the letter does not indicate how many of those grants the NCI expects to fund. And, based on the NCI report, "Charting the Course: Priorities for Breast Cancer Research," which is the impetus for the grant program, it is unlikely that many of those applications will be funded.

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[1] Document Summary: The $12 million allocation was spread over a four-year period which would have resulted in a maximum of $3 million per year. However, $0.5 million of these funds was taken away to do occupational research and another $0.25 million was applied to some risk exposure work, neither of which allocations appears to relate directly to breast cancer and environmental toxins. In addition, funds were allocated to the NCI/NIEHS "Exposure Assessment in Cancer Epidemiology" amounting to $2.5 million a year for 3 years. The total funds to be awarded amounts to $8.25 million out of a $12 million allocation.

However, an even greater problem is the definition of "environmental factors." When advocates use this phrase. they mean chemicals and radiation, while the NIH and NCI mean diet, exercise, alcohol use, hormones, as well as chemicals and radiation. By using this expanded definition, the NCI always appears to be doing more than it actually does with regard to research on "the environment" and cancer.

As even a brief review of the "Charting the Course" report reveals, the NCI continues to focus its attention primarily on the molecular biology of breast cancer and on so-called "chemoprevention" strategies. The work being done to identify what in the environment might be causing the increased incidence of breast and other cancers is not being done at the NCI. If that work is being done at NIH, it is being done at the NIEHS.

As you know, the funds generated by the stamp are small in the scheme of what is directed toward and needed to solve the breast cancer problem. In light of that, it is all the more important to make sure that the funds are spent in a way that at least has a chance of addressing some aspect of true prevention. If we are ever to truly solve the problem of breast cancer by preventing the disease, we will need to discover and eradicate the causes of the disease.

We look forward to working with you to make the breast cancer stamp program as effective as it can possibly be, and we believe that this will occur by making the NIEHS the designated recipient of the stamp funds allocated to the NIH. We also believe that the stamp will gain even more popular support when the public is made aware that the funds will be directed into research on possible preventable causes of the disease.

Thank you for attention to these concerns, and for all you do to address the concerns of the growing population of people touched by breast cancer.

Sincerely,

Barbara A. Brenner, Executive Director, Breast Cancer Action, and on behalf of Francine Levien, Executive Director, Marin Breast Cancer Watch; Catherine Porter, Esq., Legal Services and Public Policy Coordinator, Women's Cancer Resource Center; Andrea R. Martin, Founder and Executive Director, The Breast Cancer Fund; Sharon Batt, Breast Cancer Action Montreal; Nora Cody, DES Action; Judy Norsigian, Boston Women's Health Book Collective.

CANCER GROUP LETTER

The importance of lifestyle and other environmental exposures as contributing factors of cancer is unquestionable. The pivotal role of the environment is reflected in the substantial variation in cancer incidence around the world. Furthermore, epidemiologic research has succeeded in identifying a wide range of cancer-causing exposures, including tobacco use, dietary components, sunlight, ionizing radiation, environmental chemicals, infectious agents, obesity, exercise, hormones, and reproductive factors. Indeed, the largest source of variability in cancer risk is due to behavior. Nevertheless, the causes of many cancers remain elusive. While better approaches to measuring exposures will provide new insights, it is clear that the environment represents only part of the equation in determining who will get cancer.

NCI, as the Nation's leading institute in supporting and conducting cancer research, has placed a special focus on breast cancer research. NCI has a portfolio of over 1400 individual NCI-funded projects having relevance to breast cancer. In fiscal year 1999, NCI expended over $387 million in research related to breast cancer, and for fiscal years 2000 and 2001, this figure is expected to be about $425 million and $450 million respectively.

To support the full range of research activities necessary to conquer cancer, including breast cancer, NCI uses a complex and dynamic process to set our scientific and funding priorities. This process is driven by several principles:

—Strive for a balanced portfolio of research in behavior, epidemiology, control, etiology, prevention, detection, diagnosis, treatment, survivorship, rehabilitation, and end of life issues;

—Link all pieces of the cancer research enterprise through translational research;

—Rely on our diverse constituencies—including scientific, medical, advocacy and other public communities—to help us identify new opportunities, gaps, and barriers to progress, create new programs, and improve existing ones.

From a strategic level, we integrate priority setting into all of our strategic planning activities. For breast cancer research planning, NCI established a Progress Review Group (PRG) in 1997 to assess the status of breast cancer research and to provide recommendations on direction and priority to speed the progress. The Breast Cancer PRG was composed of prominent members of the scientific, medical and ad-

vocacy communities and their report, published in August 1998 and entitled, "Charting the Course: Priorities for Breast Cancer Research," is the framework NCI uses to support a balanced portfolio of breast cancer research (http://wwwosp.nci.nih.gov/planning/prg/bprgtableofcontents.htm).

From the research application level, we integrate priority setting into the funding of individual research applications based on scientific merit. NCI, like the rest of NIH, uses scientific peer review panels to competitively determine the technical validity, soundness and ranking of the individual grant applications. However, NCI has increasingly used lay reviewers/consumer advocates in our scientific review panels to provide a consumer perspective. These consumer advocates actively participate in discussions, present the patient perspective, and vote on the applications. During the last 18 months, consumers have participated in almost 60 reviews, including the panel currently reviewing the applications for the program announcement "Insight Awards To Stamp Out Breast Cancer," the program that will use the funds contributed by consumers in support of the 1997 Stamp Out Breast Cancer Act.

The Insight Awards are a new initiative designed to support innovative pilot studies that are likely to generate new understanding about breast cancer and to advance underdeveloped areas of research as identified by the Breast Cancer PRG's 1998 report. The focus of this initiative is to support innovative high risk/high payoff research that would not be funded under normal circumstances. Over 400 applications have been received and are being competitively reviewed by a peer review panel for the available funds. The role of the peer review process is to judge the likelihood that the proposed research will have a substantial impact on the pursuit of the initiative's goals. The applications are being judged solely on the basis of scientific merit, with attention given to a balanced research portfolio as articulated in the Breast Cancer PRG's report. To preserve the integrity of the peer review process, names of individuals participating on review panels must remain confidential until the selection of awardees is made.

Finally, in regard to the question on the status of the breast cancer research funds provided by the 1997 Emergency Supplemental Appropriations Act (Public Law 105–18), I am submitting a letter sent to The Honorable Nancy Pelosi, dated 15 March 2000, along with the enclosures that describe the disposition of the funds and the vital research it is supporting.

LETTER FROM DR. RICHARD D. KLAUSNER

DEPARTMENT OF HEALTH & HUMAN SERVICES,
NATIONAL INSTITUTES OF HEALTH, NATIONAL CANCER INSTITUTE,
Bethesda, MD, March 15, 2000.

Hon. NANCY PELOSI,
House of Representatives,
Washington, DC.

DEAR MS. PELOSI: Thank you for your letter of December 2, 1999, to the Director of the National Institutes of Health. It has been forwarded to the National Cancer Institute (NCI) for reply. Your letter addressed the disposition of the funds designated for the Department of Health and Human Services (DHHS) Office of the Secretary, and subsequently to the NCI, in the 1997 Emergency Supplemental Appropriations Act (Public Law 105–18, enclosed). I appreciate this opportunity to provide for you descriptions of our activities relating to this appropriation and the vital research it is supporting.

The language contained in the Act directed the Secretary to use the funds appropriated "For expenses necessary to support high-priority health research" and the Conference Report (105–119, enclosed), which superseded the original Senate Report, provided the further direction that the Secretary consult with the Directors of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the Deputy Assistant Secretary for Women's Health to determine the most appropriate mechanisms for distribution of the funds. The conferees stipulated that the funds should be competitively awarded and further requested that the Secretary consider dedicating the funds to cancer research, "especially research investigating the environmental factors that may be associated with breast cancer in communities with high incidence of the disease," and asked for a report on the Secretary's plan for allocating the funds.

After designing a strategy to invest in the best opportunities for advancement, several initiatives were identified that reflected the vision of the conferees about the disposition of these funds. Dr. Harold Varmus, Director of the National Institutes of Health (NIH) sent a report (enclosed) to Congress describing the plan. The appro-

priation was divided into two parts: NCI is coordinating the disposition of $12 million allotted for the study of the role of environmental factors in cancer; and National Heart, Lung, and Blood Institute (NHLBI) is coordinating the disposition of $3 million for the study of health effects of air pollution. Air pollution studies were included in the research package at the request of the Secretary of the Department of Health and Human Services in response to the President's call for more research on the health effects of air pollution exposure as part of his implementation plan for the Environmental Protection Agency's (EPA) revised regulation on air quality standards. To date two projects have been identified for funding.

To administer the cancer research portion of the funds, the NCI, in collaboration with National Institute of Environmental Health Sciences (NIEHS), National Institute on Aging (NIA), National Institute for Occupational Safety and Health (NIOSH) at CDC and the National Center for Environmental Research and Quality Assurance at EPA, prepared and issued Requests for Application (RFA) to solicit proposals from interested investigators. Proposals were reviewed and selected for funding based on a rigorous evaluation of scientific merit. This peer review process is arduous, but necessary to ensure that money the Congress and the American people have entrusted to us is used wisely. The initiatives envisioned in the plan and their subsequent implementation, including the funding allotted to each project, are outlined in Table 1 (enclosed).

The RFA entitled "Regional Variation in Breast Cancer Rates in the United States" launched 5 new projects in which investigative teams are using statistical and epidemiologic methods to investigate factors that may influence, contribute to, or account for the reported differences in breast cancer incidence and mortality rates across different geographic regions. Data on women residing in California, Connecticut, Georgia, Hawaii, Iowa, Massachusetts, Michigan, New Mexico, Washington, Wisconsin, and Utah will be analyzed. An additional award supplemented an ongoing study in New York that is evaluating the effect of electromagnetic field radiation (EMF) on breast cancer risk.

Five new grants were awarded under the RFA entitled "Interdisciplinary Studies in the Genetic Epidemiology of Cancer". These projects, operated together as a consortium with three related NCI-funded projects, will be working to understand the way genes interact with environmental factors in cancer development. Although only one of these projects addresses breast cancer specifically, each of them promises to contribute knowledge about the impact of the relationship between genetic and environmental elements in cancer incidence and survival, an extremely important area of cancer research. Since research on environmental exposures alone cannot bring us all the information we need, we must also address the synergistic effects of genes and environmental factors to understand how a normal cell becomes cancerous.

In response to the RFAs entitled "Implementation of the National Occupational Research Agenda" and "Mechanistic-Based Cancer Risk Assessment Methods" four new grants were awarded to develop and/or improve methods for assessing past environmental and occupational exposures that could be associated with geographic patterns for some cancers including breast cancer. Research of this type (called exposure assessment) is important in understanding breast cancer for two reasons: First, we must be able to link breast cancer development to a carcinogen exposure that occurred years before the diagnosis; and second, we must be able to obtain environmental data for assessing the role of gene-environment interactions in the etiology of breast cancer.

In May 1999, NCI awarded a $4.87 million 5-year contract ($2 million from the fiscal year 1997 supplemental funds) to develop and implement the prototype geographic information system for health (GIS–H) for breast cancer studies on Long Island. The GIS–H, the first of its type, will provide a new tool for researchers to investigate relationships between breast cancer and the environment, and to estimate exposures to environmental contamination. The GIS–H data layers will include geographic data for general mapping purposes and demographic data. Data on health care facilities, health care surveys, breast cancer, and the environment will also be included. The environmental data will include information on contaminated drinking water, sources of indoor and ambient air pollution, including emissions from aircraft; EMFs; pesticides and other toxic chemicals; hazardous and municipal waste; and radiation. The system will rely chiefly on existing databases obtained from Federal, State, and local governments, as well as private sources, with emphasis placed on high-quality data. It is expected to be available for pilot studies in mid-2001. A Web site is available where the public and researchers can follow the GIS–H's progress and obtain summary information about the databases: http://www.healthgisli.com.

The important work supported by the Public Law 105–18 funds is part of our continuing commitment to a broad research agenda that promotes discovery of the ways that environmental exposures to carcinogens lead to the development of cancer. A new RFA will be issued this year to direct the remaining funds toward promising studies of this nature (see Table 1) and NCI sponsors many other projects in this research area. In accordance with our own strategic plan and the intentions of the conferees, the funds are being used to capitalize on scientific opportunities that continue to provide significant new information and that will advance our knowledge of cancer processes.

I hope this information is useful for you and your constituents. Please feel free to contact me if you have additional questions or concerns.

Sincerely,

RICHARD D. KLAUSNER, M.D.,
Director, National Cancer Institute.

Enclosures.

PUBLIC LAW 105–18

CHAPTER 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

For expenses necessary to support high priority health research, $15,000,000, to remain available until expended: Provided, That the Secretary shall award such funds on a competitive basis.

CONFERENCE REPORT 105–119

LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

OFFICE OF THE SECRETARY

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

The conference agreement modifies language proposed by the Senate which would have appropriated $15,000,000 to the Public Health and Social Services Emergency Fund within the Office of the Secretary for competitively awarded research on the environmental links to breast cancer. The Senate language designated the funding as an emergency appropriation. The House bill had no similar provision.

The conferees agree that $15,000,000 is appropriated to support high priority biomedical research. These funds will be made available on a competitive basis and through mechanisms to be determined by the Secretary, in consultation with the Directors of the National Institutes of Health and the Centers for Disease Control and Prevention, and the Deputy Assistant Secretary for Women's Health. The conferees request that the Secretary provide a report to both Committees on the research plan and allocation methodology accompanying these additional funds by July 1, 1997. Among the priorities the conferees encourage the Secretary to consider is cancer research, especially research investigating the environmental factors that may be associated with breast cancer in communities with high incidence of the disease. The conferees have removed the emergency designation for these funds, offsetting the cost elsewhere within the bill.

DEPARTMENT OF HEALTH & HUMAN SERVICES,
PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH,
Bethesda, MD, February 23, 1998.

Hon. JOHN EDWARD PORTER,
Chairman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives, Washington, DC.

DEAR MR. PORTER: On December 19, 1997, in response to the Conference Report accompanying the Fiscal Year 1997 Emergency Supplemental Appropriations Act

(Public Law 105–18), the Secretary of Health and Human Services submitted to you our research plan for using the $15 million appropriated in the Act for high-priority health research. However, after further internal discussion, we have notified the Secretary and are now notifying you that we believe we can improve upon our original project design for the $12 million we intend to use to study gene-environment interactions in the cause of breast cancer in high-risk areas of the United States. Our updated research plan is enclosed. Please note that this revision still conforms with the legislative requirement that all of these funds be awarded on a competitive basis.

Instead of a single, multi-year, multi-center, case-control study as originally envisioned, we have determined it would be more appropriate to break out the funds into four types of projects, with most of these funds awarded in fiscal year 1998. The first project would be a contract for a Geographic Information System for the Long Island Breast Cancer Study to identify potential environmental risk factors for breast cancer. The National Cancer Institute (NCI) plans to issue a Request for Proposals for this contract in late winter or early spring of 1998 for award in fiscal year 1998. The second and third projects would include research grants in the specific areas of "Addressing Environmental Factors and Breast Cancer in High-Risk Areas" and "Interdisciplinary Collaborative Studies of Gene-Gene and Gene-Environment Interactions in Breast and Other Cancers." Requests for Applications (RFAs) for grants in these two areas are expected to be issued in the spring of 1998 and awarded in fiscal year 1998. A third RFA for research grants on developing and testing accurate exposure assessments for breast cancer epidemiology is still being developed and will be advertised and awarded in fiscal year 1999. We expect to find many different research grants with a multiplicity of study designs through each of these RFAs. Both NCI and the National Institute of Environmental Health Sciences will contribute the expertise of their staffs to these projects, with NCI to have the lead responsibility for oversight of the project.

The portion of the original research plan related to spending $3 million for research on the adverse health effects of exposure to air pollutants, such as ground level ozone and particulate matter, has not been revised in this update. Specific announcements regarding the award of funds for this project are still under development.

Thank you for your continuing strong support for medical research.

Sincerely,

HAROLD VARMUS, M.D.,
Director.

Enclosure.

A STUDY OF GENE-ENVIRONMENT INTERACTION IN THE ETIOLOGY OF BREAST CANCER, IN HIGH-RISK AREAS OF THE UNITED STATES

[February 23, 1998]

The special legislation (Fiscal Year 1997 Emergency Supplemental Appropriations Act) directing research on the environmental causes of breast cancer provides a remarkable opportunity to better understand the determinants of that disease through an innovative, interdisciplinary initiative that encompasses the expertise of the National Cancer Institute (NCI) and the National Institute of Environmental Health Sciences (NIEHS). Decades of research have established that the causes of breast cancer may involve environmental factors and genetic elements that are also likely to be highly interactive in producing the disease. However, the identification of the specific exposures and array of genes involved has proven elusive. Recent profound innovations in assessment of exposure to environmental contamination and molecular genetic technology have raised the expectation that we now have the tools to gain major new insights into potentially preventable causes of many diseases such as cancer, and into breast cancer in particular. It is clear that the time is ripe for studies focused on gene-environment interactions in the risk of breast cancer. Identification of environmental influences on genetic effects should clarify the biologic mechanisms involved, and discovery of genes that modify such effects should help identify the specific environmental agents and host factors responsible for breast cancer.

All of the studies funded through this initiative will be accomplished via extramural competitive research funding. These studies will expand the existing portfolios of both Institutes in environmental causes of breast cancer. Studies will be funded for a variety of scientific approaches, including the development and application of geographic information systems for the identification of potential environmental risk factors for breast cancer, the development and testing of accurate expo-

sure assessment in breast cancer epidemiology, the study of environmental factors for breast cancer in high risk areas, as well as molecular and genetic epidemiology studies of gene-environment interaction in breast cancer. A multiplicity of study designs is envisioned. Such a breadth of approaches will provide truly new and innovative opportunities not only to clarify genetic and environmental determinants that are currently under suspicion as causative of cancer, but also to establish bio-specimen resources within epidemiologic infrastructures which can be revisited to evaluate etiologic questions as they will arise in the future. The selection of meritorious projects through the peer review process will assure that the most scientifically excellent programs, totaling $12M, will be selected, thus assuring that such studies will provide an important, productive and efficient way to exploit our rapidly expanding scientific and biotechnology knowledge base to identify preventable causes of breast cancer. Investment in new approaches to studying gene-environment interactions as they relate to breast cancer, if successful, will provide a paradigm for new programs of interdisciplinary studies into the origins of other cancers, as well as many chronic diseases.

Total project cost: $12 million

A Study of the Adverse Health Effects of Air Pollutants, Particulate Matter and Ozone

[February 23, 1998]

The Fiscal Year 1997 Emergency Supplemental Appropriations Act also provides an opportunity to elucidate further the adverse heath effects of exposure to air pollutants and particulates and the role of such exposure in the causation of diseases such as asthma, lung cancer and respiratory distress syndrome. The National Heart, Lung and Blood Institute (NHLBI), the National Institute of Environmental Health Sciences (NIEHS), the National Cancer Institute (NCI), and the National Institute of Allergy and Infectious Diseases (NIAID) all have portfolios of competitively awarded grants which study the underlying causes of asthma, emphysema, hyperresponsiveness of the airways and the premalignant and malignant changes in the cells of the lining of the airways. Building on this knowledge base, new awards will focus on the roles of a single exposure or multiple exposures to ground level ozone, of exposure to particulate matter, and the combination of such exposures along with other predisposing factors to respiratory problems. After a national competition and peer review of applications, awards will be made to the most scientifically meritorious applications and will place emphasis on new molecular diagnostic and therapeutic techniques which clarify the influence of these environmental pollutants on genetic factors and other biologic mechanisms which predispose the population of this country, particularly the young, and the socio-economically disadvantaged to diseases such as asthma, lung cancer, emphysema and other respiratory distresses. These awards will maintain a separate identification so that they can be tracked to this initiative.

Total Project Cost: $3 million to be shared by NCI, NHLBI, NIEHS, and NIAID dependent on the number and size of individual grant awards.

DISPOSITION OF 1997 EMERGENCY SUPPLEMENTAL APPROPRIATIONS

[Dollars in millions]

Plan initiative	Actual initiative	Resulting projects	Funding	Fiscal year
Geographic Information System.	Geographic Information System NO2–PC–95074.	Contract awarded to Averstar, Vienna, VA.	$2	1999
Addressing Environmental Factors and Breast Cancer in High Risk Areas (RTA).	Regional Variation in Breast Cancer Rates in the United States RFA: CA–98–017 (reissue of CA–93–024) (with NIEHS).	5 new grants (U01)	1.6	1999
		EMF study /LIBCSP (supplemental funds for U01).	.4	1999

DISPOSITION OF 1997 EMERGENCY SUPPLEMENTAL APPROPRIATIONS—Continued

[Dollars in millions]

Plan initiative	Actual initiative	Resulting projects	Funding	Fiscal year
Interdisciplinary Collaborative Studies of Gene-Gene and Gene-Environment Interactions in Breast and Other Cancers (RIA).	Interdisciplinary Studies in the Genetic Epidemiology of Cancer RFA: CA–98–018 (with NIA).	5 grants (U0I)	5	1999
Exposure Assessment Techniques (RIA).	Implementation of the National Occupational Research Agenda KRA: OH–99–002 (with NIOSH/CDC and NIEHS).	3 grants (R01)	.6	1999
	Mechanistic-Based Cancer Risk Assessment Methods RFA: OH–99–003 (with NIOSH/CDC, NIEHS, and EPA).	1 grant (ROI)	.2	1999
	New RFA for 2000 (with NIEHS).		[1] 2.2	2000

[1] Estimate.

Environmental Factors and Cancer—$12 million set aside (Coordinated by NCI).
Adverse Health Effects of Air Pollutants—$3 million set aside (Coordinated by NHLBI).

Senator SPECTER. Thank you.
Dr. KIRSCHSTEIN. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. 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:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

NIH DOUBLING: FUTURE IMPLICATIONS

Question. What happens after doubling? What are NIH's plans to maintain the "doubled" NIH after the 5th year—how will we avoid large cuts in the number of new grants, and even the total number of grants, as NIH funding moves to a maintenance level of some sort? Can you prepare some grant-funding scenarios for us so we can see what the implications would be of maintaining NIH at biomedical inflation, as well as some higher levels, in the years beyond 2003?

Answer. We recognize that Congress has stated its intention to double NIH's budget by fiscal year 2003 and appreciate the support the Congress has provided in the past three years. For responsible management, we have begun to consider the impact of similar increases in fiscal years 2002 and 2003 on NIH activities and biomedical research in general, and to consider scenarios for support of research in the years beyond fiscal year 2003. Any specific proposals for future NIH budgets, whether for overall budget requests or specific grant-funding, would be determined through the normal Executive branch budget process that considers overall fiscal constraints and competing priorities. Although at this time we cannot outline any specific proposals for NIH's future activities, for the purposes of answering this question, below are some preliminary grant funding scenarios.

For the purposes of answering this question, we have assumed increases of 15.2 percent in fiscal year 2001 over fiscal year 2000, and increases of 15.4 percent each

in fiscal year 2002 and fiscal year 2003 that would complete a five-year doubling effort begun in fiscal year 1999.

Using these assumptions, NIH estimates that by fiscal year 2003, we would fund nearly 12,000 competing RPGs, with average cost increases of 5 percent provided each year for these awards. In answering this question, NIH assumed that Research Centers, Other Research, and Research and Development (R&D) Contracts would increase by 16 and 18 percent in fiscal year 2002 and fiscal year 2003. NIH would maintain full-time training positions (FTTPs) at a level of 16,446, with inflationary increases provided for stipends, tuition allowances, etc.

NIH funding would need to continue to increase in real terms if the number of competing RPGs were to be maintained at the fiscal year 2003 level. For the three years following fiscal year 2003, if the NIH budget in total were maintained with increases equal to the Biomedical Research and Development Price Index, currently estimated at approximately 3.6 percent, then the number of competing RPGs NIH could fund would likely decrease by over 20 percent, or approximately 2,500 grants, from nearly 12,000 in fiscal year 2003 to 9,500 in fiscal year 2004. With the exception of those mechanisms requiring payraises, other mechanisms would be held flat. In fiscal year 2005, numbers of grants would continue to decrease, dropping by over a thousand to 8,200. This would be nearly 3,800 and 32 percent fewer competing RPGs than in fiscal year 2003. In fiscal year 2006, numbers of competing RPGs would increase by 1,400 to 9,600, still well below the fiscal year 2003 level of 12,000 competing RPGs.

Alternatively, if NIH were to receive total increases ranging from 8 percent in fiscal year 2004, to 10 percent in fiscal year 2005, and 7 percent in fiscal year 2006, we could maintain the number of competing awards at the fiscal year 2003 level and avoid the increases and decreases described above. Inflationary average cost increases are assumed for RPGs and all other mechanisms.

If, under a third scenario, NIH were to receive increases of approximately 10 percent, 11 percent, and 9 percent, respectively, between fiscal years 2004–2006, the number of competing RPGs could be maintained at the fiscal year 2003 level of nearly 12,000 and small increases above inflation would be provided in both competing RPGs and other research mechanisms. Average cost increases greater than inflation for competing RPGs would recognize that future investigators will increasingly use scientific databases, sources of specialized animals and sophisticated instrumentation to achieve scientific advances. NIH believes that sustained, stable support is vital to optimize the benefits of the long-term investment needed for progress in biomedical research.

More and more, we find that multidisciplinary teams are needed to solve big problems in research. The laboratory of the future will almost assuredly be driven by computer applications and technologies. While recognizing the importance of RPGs, we see that other mechanisms offer unique opportunities to bring together multiple disciplines and centers to pursue research questions, and this scenario also provides modest program growth for these other mechanisms. Under this approach, we have also assumed continued expansion of clinical research programs in all mechanisms, including the Clinical Research Career Development programs, Clinical Research Centers, Cooperative Clinical Groups, and intramural clinical research in order to speed medical breakthroughs at the bedside that will lead to improvements in treatments and interventions to decrease mortality and morbidity, and improve the quality of life. In addition, we have assumed in the third scenario the same number of FTTPs in our research training program as in fiscal year 2003, with inflationary increases for stipends.

Modern facilities are required for molecular medicine and genetic research. Continuing support of such infrastructure elements would also be a key component of our overall strategy for sustaining capacity for world class medical research. Furthermore, it will be important for NIH to have sufficient capacity to manage research portfolios and to ensure appropriate stewardship of funds. Consequently, NIH's Research Management and Support activity and the Office of the Director would receive adequate increases to enable NIH to continue to assure the public that its trust is well founded.

The fiscal year 2001 President's Budget proposed a strategy of providing average cost increases of 2 percent over fiscal year 2000 for RPGs, to control the growth of continuing commitments and support planned new and expanded initiatives. If NIH continues on the doubling path, then we can consider different approaches for managing funding increases in the best interest of scientific progress and long-term budgetary discipline.

The pace of new discoveries in the biomedical sciences is now occurring at a breathtaking rate. The explosion of new knowledge that has resulted from our explorations of the human genome and the biology of the cell is providing new opportuni-

ties to further understand disease, as well as new and innovative ways of treating, diagnosing, and preventing illness. Untapped resources for developing and testing new ideas—in other words, unused capacity—will remain available in the research enterprise in the future. The more new ideas that are explored and the more rapid the effort, the sooner these findings will be available for translation into medical practice.

NIH looks forward to working with Congress to ensure that NIH's funding increases support the highest quality research in a fiscally manageable and responsible manner.

STEM CELLS

Question. When will you begin funding research grants involving embryonic stem cells provided they meet peer review?

Answer. NIH will consider requests for new funds, supplemental funds or use of ongoing grant or intramural funds as soon as the NIH Guidelines are finalized and there is an oversight process in place.

Question. What do you think has been the negative impact on stem cell research from the year and half long delay we have had waiting for the NIH guidelines to be put in place?

Answer. As soon as it is possible to use federal funds for this research, more researchers will be able to participate and contribute to this new arena of biomedical investigation. As more people are involved, it is conceivable that progress may proceed more quickly.

Question. Some have raised concerns about fetal tissue research and possible violations of the law concerning profiting from the sale of fetal tissue research. Do NIH funded scientists spend more than the appropriate funds charged for fetal tissue? Or do they pay a flat fee that simply covers the cost of processing and transporting the tissue?

Answer. All NIH funded researchers are required to follow the local, state and Federal laws governing fetal tissue research. There is a Federal law that prohibits an individual or entity from profiting from sale of human fetal tissue. It also prohibits any individual or entity from knowingly acquiring fetal tissue from another entity for "valuable consideration." According to this law, "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. Violation of this statute carries criminal penalties. There is no evidence that NIH funded researchers spend more than appropriate charges. Appropriate charges for processing and transportation of fetal tissue may or may not take the form of a "flat fee."

Question. How would stem cell research be impacted if fetal tissue research were restricted?

Answer. If Federally funded researchers were no longer permitted to conduct research using fetal tissue, they would not be able to either derive human pluripotent stem cells from fetal tissue or conduct research using human pluripotent stem cells derived from fetal tissue.

GRANTS REVIEW PROCESS

Question. This Subcommittee receives many complaints from advocacy groups that certain fields of research are underfunded because of the current structure of the grant review system. What are you doing to address the concerns of researchers and advocates in those underfunded fields?

Answer. The Center for Scientific Review (CSR) conducts the review of approximately three-fourths of the grant applications submitted to NIH, including almost all investigator-initiated applications. The study sections that review these applications were established over a period of many years. Although the content of the science reviewed in CSR's study sections has evolved as the research enterprise developed, there had never been a systematic assessment of whether the current study sections are appropriate for the review of today's (and tomorrow's) scientific opportunities in the health-related research areas.

In 1998, CSR convened a distinguished panel (the Panel on Scientific Boundaries for Review) of scientific leaders from diverse fields of biomedicine to conduct an overall assessment of the structure and functions of its peer review system, and to propose changes needed to better align the system with the current research landscape and scientific opportunities. The Panel engaged in extensive outreach to the broad research community so as to solicit input and encourage dialogue. The Phase 1 recommendations were posted on the web for several months, and over 800 comments from professional societies and individual researchers were received and con-

sidered. Numerous meetings and teleconference calls were held among Panel members, the director of CSR and her staff and concerned representatives from advocacy groups and professional societies. A revised Phase 1 report was presented and accepted by the CSR Advisory Committee in January, 2000. The thrust of the proposed reorganization involves the distribution of research grant applications for review to a group of committees that form a cluster focused on a particular disease or organ systems, in order to stimulate the identification of the best scientific approaches to such a unit.

The second phase of the Panel's activity has just begun and will define the boundaries of the individual study sections that will populate the new clusters of review groups. Again, this will be accomplished with extensive participation by the relevant research communities, which will ensure that new directions and newly-emerging scientific areas will be accommodated and that all types of research approaches will receive a fair and appropriate review. An implementation plan for Phase 2 has been developed and posted on the NIH website, and CSR is currently beginning work on the first new cluster of study sections.

In addition to the major re-structuring of CSR, individual Institutes have responded to advocacy groups by (1) organizing workshops to identify potential research opportunities for the development or refinement of diagnoses, and therapies and the further understanding of specific diseases, and (2) issuing specific requests for applications (RFAs) that address areas that are recognized to require stimulation. Responses to these RFAs are reviewed by special review committees convened specifically for that purpose by the funding Institutes.

Question. Some institutes are taking steps to involve members of the public on certain scientific peer review panels. How are these efforts working out? What contributions can lay reviewers make to the process?

Answer. The National Cancer Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health, and the National Institute on Drug Abuse involve members of the public on their peer review panels. A description of their involvement follows:

National Cancer Institute

The NCI has increasingly involved consumers on Institute-based scientific peer review panels for grant applications and contracts proposing clinical trials of new cancer treatments. NCI has expanded the involvement of members of the public to include lay reviewers/consumers on all NCI scientific peer review panels for clinical and population based research. This includes review panels for Cancer Centers, Cooperative Clinical Trials Groups, Specialized Programs of Research Excellence (SPOREs), clinically oriented Program Projects, and projects submitted in response to Requests for Applications (RFAs). Most Cancer Center, Cooperative Group, and Program Project applications require a site visit to the applicant institution prior to the formal review committee meeting, and consumers participate in the site visit as well as in the subsequent review committee for these applications. NCI review staff worked with the NCI Office of Liaison Activities (OLA) and the NCI Director's Consumer Liaison Group (DCLG) to develop criteria for selecting consumer reviewers. In response to input from consumers, NCI developed a Consumer's Guide to Peer Review and a Consumer's Cancer Dictionary for Peer Review to facilitate participation of lay members on review panels. Consumers have been used in almost 60 reviews during the past 18 months.

Consumers participate actively in discussions, present the patient perspective in discussion, and vote on the applications. Consumers provide an important additional perspective on the proposed research in the following areas: factors that may affect study design; feasibility of plans for patient recruitment, retention and follow up of subjects; feasibility of protocols in regard to specific populations (e.g., complexity, compliance); clarity and patient acceptability of protocols; feasibility of protocols in the context of total patient care; cultural and socioeconomic aspects of protocol implementation; outreach and special challenges (e.g., need for multi-cultural research staff, composition and role of the Community Advisory Board, etc); and ethical issues, including human subject protection, adequacy of informed consent forms and inclusion of women, minorities, and children in clinical research. In addition, as they review applications, they may consider whether the proposed research is applicable to cancer in terms of prevention, cause, detection, treatment, care, quality of life, and/or other pertinent issues. Feedback to NCI from both consumers and scientific reviewers is obtained and indicates that the system is working very well.

One striking effect of use of consumers in the peer review process has been its effects on applicants. There has been a noticeable increase in documented consumer input in research proposals as evidenced by the participation of consumers in various structural and advisory capacities within applicant organizations.

National Institute of Allergy and Infectious Diseases

The use of members of the public on NIAID review committees, where they can contribute essential insights to the overall evaluation, is a thoroughly considered and well-precedented practice that NIAID considers to be an important component of the responsible conduct of the peer review of patient oriented research. Public members make important contributions and can bridge the communication and knowledge gap between scientists and the patient base they serve. The NIAID has been actively involving members of the public on certain scientific peer review panels over the last ten years, and the following data summarize some of the experiences:

—Public members bring very unique multi-faceted perspectives of the disease/condition/subject to the review group resulting in better decisions.

—They have a very high interest in the research and the process of thorough evaluation of applications to determine which have the best scientific merit.

—Their knowledge of certain diseases and the people affected by those diseases enables the public members to provide valuable input and expertise as reviewers and to raise important questions in several aspects of the research, for example, clarity of protocols, consent forms, and the feasibility of complicated protocols for certain patients.

—Since at least 1991, the NIAID special review committees have included patient and lay representatives of the target populations for selected large clinical efforts including: the AIDS Clinical Trials Groups (ACTG), the Pediatric ACTG, the Women's Interagency HIV Study, the Multi-center AIDS Cohort Study, and the AIDS Vaccine Evaluation Group. However, the NIAID does not include members of the public on committees in which patient recruitment and retention is not an issue, for example, basic science initiatives.

—The NIAID believes that proposed research efforts, the overall success of which depends upon the successful recruitment and retention of patient populations, must be evaluated on the quality, appropriateness, and feasibility of the proposed plans for recruitment and retention. So important is this aspect of the plans that the review criteria specifically include recruitment, retention, and related community outreach issues.

—As with selection of any reviewer, special care needs to be taken to select individuals with the appropriate expertise.

The NIAID also believes the review committees need to include all types of expertise relevant to making an informed assessment of the merit of the applications, and that patients or members of the public provide insights regarding the quality, appropriateness, and feasibility of plans for recruitment, retention, and community outreach. This is viewed as one of the essential types of expertise that should be brought to bear upon the overall judgement.

Public members of the NIAID review committees have review assignments in which they are asked to comment on the recruitment, retention and outreach aspects of the proposals. Their contributions are generally valued and appreciated by other (scientific) reviewers. They are full-scoring participants in the review meeting and constitute a small percentage of the voting members of any of these review committees.

Like all reviewers, the public members are asked to comment on aspects of the applications related to their personal expertise, and to score the applications on overall merit as best they can, having listened to the discussion of all other reviewers. In our experience, the scores assigned by the public members have been remarkably consistent with scores assigned by other reviewers.

In summary, the NIAID applauds the efforts of members of the public on peer review committees, and recognizes that additional members may contribute a perspective that is perhaps sometimes difficult for a scientific specialist to appreciate.

National Institute of Mental Health

Public participant reviewers have successfully served for a year on the NIMH's service and interventions review committees. Public reviewers included individuals who have suffered from mental disorders, family members of those suffering from mental disorders, policymakers in the mental health care arena, and mental health care providers. All committee members were asked for their assessment of how well the process worked. The most common feedback was that the inclusion of public reviewers was useful and that the public reviewers had done an excellent job. The public reviewers, many of whom experienced the committee process for the first time, were impressed with the efforts of the committee members and the serious and objective nature of the deliberations. NIMH will continue to request feedback from all reviewers to help inform and improve the process of public participation in its review meetings. Future plans are to help public reviewers focus on the review

issues to which they can best contribute such as determining public health importance and human protection issues, and to continue adding and training new public reviewers to ensure a broad diversity of opinions and experiences.

National Institute on Drug Abuse

NIDA is in the process of planning the recruitment and training of public consumers to act as reviewers for the treatment and services review panels. These public members will provide an important point of view, commenting on issues such as feasibility of the research, practicality of the proposed intervention, and appropriateness of human subjects protections.

NIH BUILDINGS AND FACILITIES

Question. Dr. Fischbach and Dr. Hyman, the Budget requests funding for a new National Neurosicence Research Center, at a cost of $73.3 million. How will this "integrated neuroscience program" enhance neuroscience research at the NIH? Will the broader research community benefit from this?

Answer. The most significant feature of the integrated neuroscience program is that it will speed the translation of scientific discoveries into new, clinically useful strategies for disease prevention and treatment. Sustained interactions between basic and clinical scientists are needed so that each group can be better informed about the opportunities offered by the other. In the more typical academic model, basic neuroscientists are segregated in one or more preclinical departments, quite removed from colleagues in clinical departments of neurology, psychiatry, neurosurgery, medicine, and anesthesiology. Input from the engineering, mathematics and physical sciences is minimal. This new integrated neuroscience program has a rare opportunity to set a high standard for the entire nation by "putting the brain back together" without regard to the artificial boundaries of Institute or medical school organization. Beyond the obvious medical disciplines, we will integrate bioengineering, computational science and bioinformatics as more equal partners in research in the neurosciences. In so doing, we will support and enhance the patient-oriented research that will be conducted in the new Mark Hatfield Clinical Research Center.

Each of the Institutes that will participate in this program was created with a distinct patient population in mind, and they fund research that is of special interest to their different constituencies. However, they share many areas of neuroscience research. For example common mechanisms of nerve cell degeneration probably underlie Alzheimer's disease, vascular dementia, blindness, hearing loss, and stroke. Common alterations in the actions of neurotransmitters, such as dopamine, probably underlie thought disorders such as schizophrenia, movement disorders such as Parkinson's disease, substance abuse problems including alcoholism, and the suffering due to chronic pain. Thus, the mission of each Institute would be better served by a coordinated effort on the NIH campus.

We plan to bring together, under one roof, NIH scientists who are now isolated from one another simply because of outdated historical precedents. Research will be organized, and resources allocated, according to scientific themes, not Institute identity. We will also cooperate in filling gaps in our research programs by recruiting the very best new scientists to the NIH campus.

The broader research community will benefit in many ways. One of the most exciting elements of this plan is the opportunity to attract and train the most talented young scientists, many of whom will return to the extramural community. We also envision enhanced opportunities for intramural-extramural collaboration, both on specific projects and through mechanisms that will allow the appointment of academic scientists to short-term positions at NIH. In addition to bringing individuals and teams of scientists together, the program will provide unprecedented opportunities for extramural scientists to take advantage of resources such as animal models, genetic tools, and state-of-the-art imaging devices. Perhaps most importantly, our program will serve both as a model to reinforce similar efforts in the broader community and as a template for developing strong neuroscience research programs in institutions that do not presently have them.

Question. Is this $73 million the total cost of the entire project, or is there another phase to come later, and if so, how much is the total cost?

Answer. The B&F request includes $47.3 million in fiscal year 2001 and requests advance appropriations of $26 million in fiscal year 2002 for the initial phase of construction to replace Building 35. In fiscal year 2000 the NIH plans to request a reprogramming of $5 million from other B&F projects to fund the design/construction documents for the initial phase of construction. We are considering a second phase to the NNRC project. A decision on the scope and cost of any potential phase will be made through the normal Executive branch budget formulation process.

Question. What types of research will you be able to conduct in the new center that you are unable to do with your present facilities?

Answer. As noted earlier, we believe the planned center will provide an optimal environment for translational research. However, its distinguishing feature will not be research on specific topics so much as an innovative process and environment for conducting interdisciplinary, collaborative research without regard to organizational boundaries. The importance of this can hardly be overstated in the context of what modern neuroscience is teaching us about the brain and its disorders.

Question. Are other important activities needing B&F funds being put on hold in order to undertake this project?

Answer. The fiscal year 2001 B&F request provides a level of funding to initiate or continue support for three of the highest priority projects of the National Institutes of Health (NIH): the National Neuroscience Research Center (NNRC), the Central Vivarium, and the Modernization of Building 6. The remaining funds in the request are sufficient to maintain continuity of essential and enabling projects in support of the research facilities infrastructure of the NIH.

NATIONAL CANCER INSTITUTE

Question. Dr. Klausner, shortly after you became NCI Director, you began a new research initiative called the Cancer Genome Anatomy Project to identify all of the genes involved in cancer. Can you tell us whether that project has produced any results?

Answer. This project has been extremely successful, identifying tags for the vast number of human genes, annotating what types of cells and cancers express those genes, developing catalogues of chromosomal changes in cancer and discovering common genetic variations that will help to explain why individuals are different in their risk of getting cancer, their sensitivity to diet and the environment and their responses to therapy. CGAP has become one of the most widely used sources of information and reagents in the research world (www.ncbi.nlm.nih.gov/ncicgap/).

In the past three years, the CGAP Tumor Gene Index has discovered more than 40,000 previously unknown expressed human genes, representing about one-half of all known human genes and has produced more than 900,000 DNA sequences. CGAP has discovered approximately 3,800 previously unknown genes expressed in the breast, colon, lung, ovary, and prostate and has now extended this analysis to all major forms of cancer. These new genes are already the subject of follow-up studies to assess their potential for defining molecular signatures for normal, precancer, and cancerous tissue.

We expect that having these molecular signatures of cancer will afford new opportunities to catalyze all areas of cancer research including cancer predisposition, development, prevention, detection, prognosis, and therapy. For example, CGAP discoveries may provide the platform for molecular signatures of the earliest stages of cancer development, thereby facilitating prevention research.

In the area of therapy, understanding the molecular nature of cancer will spur efforts to develop new drugs with improved effectiveness and reduced side effects because the drug design will be based the precise molecular profiles of tumors and the patients. In addition, identifying early molecular events in cancer will afford new opportunities to therapeutically target earlier stages of cancer development. NCI is working actively to build a strong interface of CGAP with the basic and clinical research communities in academia and industry to assure that these new resources are effectively utilized.

In addition, the NCI will continue to build additional infrastructure (data, technology, informatics tools) to assure that maximal value is obtained from the CGAP project. Toward that end, the NCI has implemented several CGAP inter-related components designed to provide an information and technology infrastructure for the biomedical research community. One of these components, the human tumor gene index (TGI), was fully implemented in May 1997 with the initial goal of identifying genes expressed during development of tumors in five major cancer sites—breast, colon, lung, ovary, and prostate. For breast cancer, the TGI has produced more than 17,000 DNA sequences from 11 cDNA libraries derived from human breast tissue and tumors, resulting in the categorizing of about 5,700 genes expressed in human breast cancer.

Active efforts in the research community are being directed at assessing the potential value of these newly discovered genes as markers for cancer development. These projects include laboratory studies of how environmentally-induced genetic alterations leading to altered function of a mutant protein contribute to the abnormal growth pattern which characterizes tumors. Epidemiologic studies too are focusing on the role of genetic variations possibly induced by environmental agents. Of par-

ticular interest are studies of the enzymes which metabolize environmental agents or steroid hormones, and alterations in the genes which code for these enzymes.

Question. What is NCI's/NIH's role in international cancer research? Please describe for the committee what NCI's role has been in the development of the historic All-Ireland Cancer Center.

Answer. NCI, in cooperation with extramural institutions and the Fogarty International Center of the NIH, supports international health research through bilateral agreements, grants, and contracts. The Institute supports some 1,000 Visiting Scientists and Exchange Scientists. The work of outstanding scientists throughout the world is supported through fellowships, cooperative projects, exchanges of personnel and materials, and workshops. During fiscal year 1999, NCI obligated approximately $45 million for foreign grants and contracts, the NIH Visiting Program, bilateral scientist exchanges, workshops, and international dissemination of cancer information. NCI's international effort, coordinated by the Office of International Affairs (OIA) within the Office of the NCI Director, works in conjunction with programs within NCI's divisions, at other NIH Institutes and the Fogarty International Center.

The All Ireland—National Cancer Institute Cancer Consortium

The NCI has recently embarked on an international partnership with the developing Cancer Programs on the Island of Ireland (Northern Ireland and the Republic of Ireland) in an attempt to improve the quality and range of cancer services available for patients in Ireland. This Transatlantic Partnership, called the All Ireland-NCI Cancer Consortium seeks to strengthen cancer treatment, education and research programs as the cancer communities from both the Republic of Ireland and Northern Ireland prepare to join in a unique agreement with the US National Cancer Institute. I and several members of my staff had worked closely with Chief Medical Officers of both Irish governments and other key Ireland officials to develop this concept, and we were greatly facilitated in this endeavor by our Irish ex-colleagues at the NCI.

Cancer is a significant cause of mortality and morbidity on the Island of Ireland with Northern Ireland and the Republic of Ireland having one of the highest incidence and mortality rates for cancer in the Western World. Currently there are approximately 28,000 new cases and approximately 11,000 deaths from cancer each year. Therefore, the development/improvement of services for cancer patients has been a top priority for both Northern Ireland and the Republic of Ireland. Given the NCI's leadership in the cancer field, the leadership of Northern Ireland and the Republic of Ireland felt it was timely to bring international expertise such as the NCI on board as partners in an effort to fuel the further development of cancer services in Ireland. The major components of the NCI Ireland Agreement include the following:

Education and exchange of scholars

Education forms one of the major platforms of this Agreement through the support of educational programs for Medical, Nursing and Scientific Staff. These programs will include the exchange of scholars, including Ph.D., M.D., and nursing students. Particular emphasis will be given to the exchange of medical and nursing trainees focused on clinical research. This will have an immediate clinical impact and will naturally extend the support that has already been given to the training of medical and scientific trainees from the Island of Ireland. Further exchanges would include Ph.D. students, laboratory based M.D.s in training, clinical visiting professors and investigators from the US wishing to extend their studies in Ireland.

Clinical Trials

Another major area for partnership will be the enhancement of clinical trials infrastructure and clinical trial development. Modernization of cancer care requires placing cancer delivery in the context of evidence based medicine. This requires a vigorous and contemporary clinical trials infrastructure that will center around the clinical trials infrastructure already established at the Northern Ireland Cancer Center and also the Clinical Trials organization in the Republic of Ireland. The NCI has already commissioned the development of a new Clinical Trials Information System (CTIS) which seeks as its goal to implement international standards in institutionally based clinical trials processes and has already committed significant resources to its implementation. The outcome of this element of partnership will be that clinical trials performed in these institutions will immediately be compatible for collation, analysis and presentation with studies performed in the United States. Moreover, this system will allow participating centers to immediately conform to international standards. This proposal therefore permits participating institutions in

Northern Ireland and the Republic of Ireland to quickly achieve data management standards, which will exceed that of many institutions.

Teleconferencing

Some teleconferencing capabilities and linkages are already established between both partners in Ireland and the NCI. The further investment in this infrastructure will facilitate cooperative clinical trial development, education programs, patient services development and exchange of clinical and scientific ideas. Communications will be essential to the success of this partnership.

Tumor Registries

Another area for major collaboration and partnership will be in the use of the Cancer Tumour Registries in both Northern Ireland and the Republic of Ireland. The monitoring of improvements in cancer care can only be a success with a reliable tumor registry that tracks population based cancer incidence and mortality. These registries are now available in both Northern Ireland and the Republic of Ireland, and both Governments recognize their importance. The NCI will assist both tumor registries by developing a common data base that can assist in consultation, informatic tools and quality control. The consolidation of the Registries in both the North and South will improve the overall quality of data collection and provide information on a genetically stable population. This will also act as a major tool for major epidemiological investigations and development.

Developments in Cancer Clinical Services

The NCI Ireland partnership assists in the further development of cancer clinical services programs on the Island of Ireland. This includes the improvement and standardization of Radiation Oncology practice and the development of a consolidated Radiation Oncology program for research. There are a limited number of radiation facilities on the Island of Ireland and there are significant needs in terms of linking practice elements and the implement of uniform standards of practice. The assistance in standardizing and driving the development of clinical services will also extend to elements of Medical and Surgical Oncology Practice as well as Palliative Care. The development of Palliative Care Services is already at a very advanced stage on the Island of Ireland and is one that the National Cancer Institute will benefit from in terms of its own developing programs.

The NCI-All Ireland Cancer Conference

The NCI-All Ireland Cancer Conference held in Belfast in October 1999 was an important event that highlighted the commencement of this special relationship. This Conference touched on clinical, laboratory, epidemiological, and political issues that are pertinent to the care of cancer patients. It highlighted important work by Irish, American and European Scientists coupled with input from well-known international academic and biotechnology investigators from across the world. This international expertise was asked to discuss their areas of expertise and comment on clinical and scientific programs that may help improve North and South interaction and Transatlantic collaboration. All NCI investigators were invited to participate in this conference.

Finally, the Conference punctuated the start of a very special interaction on the Island of Ireland focused on the overall development of cancer services for patients and also signaled the start of an important partnership between the NCI and the practicing cancer community in Ireland.

Question. What process does NCI use to set priorities? How does this relate to the Bypass Budget initiatives?

Answer. To support the full range of research activities necessary to conquer cancer, NCI uses a complex and dynamic process to set our scientific and funding priorities. This process is driven by several principles. Support the full range of research activities necessary to conquer cancer:

—Strive for a balanced portfolio of research in behavior, epidemiology, control, prevention, detection, diagnosis, treatment, survivorship, rehabilitation, and end of life issues;

—Give attention to the spectrum of distinct diseases we collectively refer to as cancer and the various populations that experience these diseases differently;

—Link all pieces of the cancer research enterprise through translational research;

—Rely on our diverse constituencies to help us identify new opportunities, gaps, and barriers to progress, create new programs, and improve existing ones.

We integrate priority setting into all of our strategic planning activities. These activities include identifying high priority scientific opportunities, determining what is needed to build and maintain our research infrastructure, and examining what is being done and what needs to be done to tailor broadly applicable research to spe-

cific cancers. All planning activities involve significant participation from our advisory groups and the advocacy community.

Extraordinary Opportunities for Investment—Identifying Extraordinary Scientific Opportunities

"Extraordinary Opportunities" are areas where focused efforts and increased resources could produce dramatic progress toward reducing the burden of cancer. NCI identifies and prioritizes, with formal input from cancer scientists, educators, advocates, and other cancer community leaders, opportunities that:

—Respond to important recent developments in knowledge and technology;
—Offer approaches that go beyond the size, scope, and funding of our current research activities;
—Can be implemented with specific, defined investments;
—Can be described in terms of achievable milestones, with clear consequences for investing; and
—Promise advances and progress against all cancers.

NCI Challenges—Building Critical Research Infrastructure

NCI plans for and supports research through a variety of mechanisms, many of which provide funds tailored to specific research processes. As part of an ongoing process of review and revitalization, NCI has instituted a series of external reviews to guide us in strengthening our major research support programs. In the past few years, we have completed in-depth reviews of several programs: Cancer Centers, Cancer Control, Clinical Trials, Cancer Prevention, and the Development Therapeutics Program. We prioritize and plan to ensure a research infrastructure that:

—Provides the vision, creative environments, and diverse resources needed to increase the number of discoveries and advances in cancer research and the scientific community's ability to apply these findings to prevent and treat the many forms of cancer;
—Promotes and rewards innovative thinking, cross-fertilization of ideas, and enhanced collaborations among government, academia, and industry; and
—Develops and maintains the cadre of scientists required to undertake the cancer research challenges of the future.

Tailoring to specific cancers

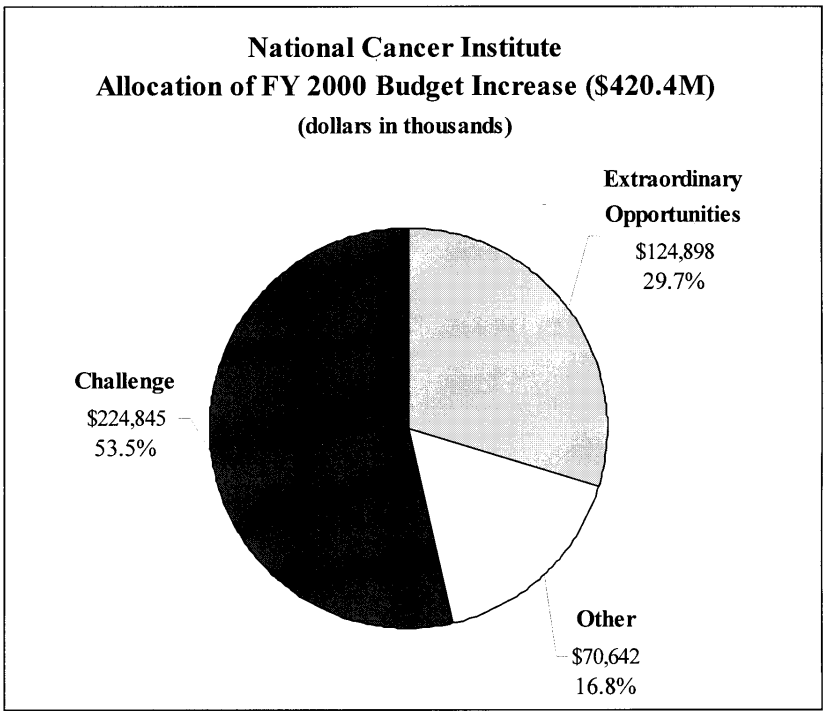
NCI must apply new discoveries and advances to specific forms of cancer. The primary mechanism for cancer site-specific research planning at the NCI is the Progress Review Group (PRG). Each Progress Review Group is composed of prominent members of the scientific, medical, and advocacy communities who know the state of the science intimately and can provide a thoughtful, considered assessment of our portfolio and recommend activities that will speed our progress. PRG recommendations give the NCI a framework to determine whether or not existing initiatives and programs are sufficient to aid the research community in addressing priority areas. Where gaps are identified, NCI modifies its plans to address unmet needs and encourages the research community to undertake projects in key areas by clearly indicating where NCI's priorities lie.

Participation from advisory groups and the advocacy community

NCI actively seeks out expert advice from a variety of advisory bodies both within and outside the Institute. Scientific experts and consumer advocates on the Presidentially appointed National Cancer Advisory Board advise NCI's Director on issues related to the National Cancer Program. The Board of Scientific Counselors and Board of Scientific Advisors provide advice to NCI leadership on the progress and future direction of NCI's Intramural and Extramural Research Programs respectively. The NCI Executive Committee, which includes NCI Division directors and other key advisors to the Director, meets regularly to make major policy and operating decisions. The Director's Consumer Liaison Group (DCLG) serves as a primary forum for discussing issues and concerns and exchanging viewpoints important to the broad development of NCI program and research priorities. The DCLG also helps develop and establish processes, mechanisms, and criteria for identifying appropriate consumer advocates to serve on NCI program and policy committees; and establishes and maintains strong collaborations between NCI and the advocacy community.

The annual Bypass Budget request is a key tool that NCI uses to articulate the results of our on-going planning and prioritizing process. Due to new scientific discoveries, advances in technology, and the related changes in scientific thought, the Bypass Budget request represents a snapshot, good for a relatively short time, of where NCI's planning and prioritizing process indicates we need to go to take advantage of new scientific opportunities in cancer research. As a result, the Extraor-

dinary Opportunities and NCI Challenge initiatives outlined in the fiscal year 2001 Bypass Budget request represents the focus of where NCI would put available funds. For example, with the $420.4 million increased funding NCI received for fiscal year 2000, we seized the opportunity to implement many of the initiatives identified in the Bypass Budget request. 83 percent of the funding increase, or $349.7 million of the $420.4 million increase, directly supported initiatives in the Bypass—$124.9 million supported Extraordinary Opportunities initiatives and $224.8 million supported NCI Challenges initiatives (see figure below).



CLINTON/BLAIR JOINT STATEMENT

Question. What was the significance of the joint statement issued by the President and Prime Minister Tony Blair? Was this statement intended to undermine research efforts in the private sector?

Answer. The President and Prime Minister Tony Blair agreed that it was important to take notice, at the the highest levels of their governments, of the progress the two countries have made in human genomics and of the era of new opportunities unfolding before us. For that reason, they issued a joint statement of position to help ensure that human genomic discoveries are used as effectively as possible for the advancement of human health throughout the world. The statement consisted of two equally important, complementary principles, designed to maximize scientific opportunities to understand the human genome, as well as medical and economic opportunities for the development of health care products.

—First, the statement reiterated the principle that raw fundamental sequence data from the human genome—the ordering of the A's, T's, C's, and G's that make up DNA—should be distributed as broadly as possible, in an unencumbered manner, for use by scientists around the world. This principle has been a condition of funding by the Human Genome Project, which makes genomic sequence data freely available over the Internet in a public database called GenBank. New sequence data are deposited daily by Human Genome Project participants.

—Second, the statement makes clear that intellectual property protection for gene-based inventions will play an important role in stimulating the development of health care products, which will in turn allow the public to realize the

full medical benefits of the fundamental scientific discoveries. As a new generation of medical discoveries begins to rely on gene-based technologies, it is essential that we afford these technologies the kind of intellectual property protection that has enabled the development of every other wave of medical innovations.

No. The complementary principles described in the statement are beneficial to both the private sector and the public. They reinforce the public-private partnership that has fueled the genomics and biotechnology enterprises, by enabling fundamental biological discoveries as well as the entrepreneurship that can capitalize on those discoveries and bring innovations to market. Key companies involved in genomics were quick to issue statements endorsing the joint statement.

HUMAN GENOME PROJECT

Question. Why did talks breakdown between the public Human Genome Project negotiators and Celera Genomics? Do you see any way the public Human Genome Project can maximize research dollars through collaborating with private sector companies?

Answer. Representatives of The Human Genome Project, Doctors Martin Bobrow, Francis Collins, Harold Varmus and Robert Waterston, met with representatives of Celera Genomics Corporation on December 29, 1999, to discuss a possible collaboration to sequence the human genome. At that meeting Celera and Human Genome Project (HGP) representatives presented quite divergent terms for such a collaboration. In a February 28, 2000, letter to Celera, HGP representatives summarized the December 29, 1999 discussion and described how specific terms for collaboration presented by Celera would conflict with the underlying principles of the Human Genome Project to make sequence data rapidly and freely available to all. On March 7, 2000 Celera Genomics President, J. Craig Venter responded that Celera Genomics continues to be interested in pursuing good faith discussions toward collaboration. On March 9, Dr. Collins sent a letter to Celera indicating that he had received its letter and would discuss possible next steps with the other HGP representatives.

HUMAN GENOME

Question. What are the likely developments in medicine over the next 10 years that will result from unraveling the human genome?

Answer. The Human Genome Project will reveal all the human genes and many of the variations in DNA that make individuals unique and affect our susceptibility to disease. Scientists will understand the genetic factors that influence the development of complex diseases—like heart disease, diabetes, Alzheimer's disease, and cancer—that are caused by several genes in interaction with each other and environmental influences. Detailed understanding of the molecular causes of disease will suggest new treatments.

In the next decade, predictive genetic tests will become available for a few dozen complex diseases. If you find you are at high risk for various ailments you will be able to adopt strategies (like changes in diet, lifestyle, medical surveillance, and treatment with drug therapy) to reduce your risk of becoming ill.

If you fall through that preventive medicine safety net and get sick anyway, new treatments will begin to be available. Some likely will be gene therapies. Others will be drug therapies designed on the basis of an understanding of gene function. These therapies will be more precisely tuned for the problem that you have and, because of early diagnosis, will be available at an earlier stage in the disease process. This new generation of preventive and therapeutic interventions based upon your genetic information, which likely will come along first for cancer, will revolutionize medicine and improve our ability to prevent, diagnose, and treat the diseases that afflict us and our families.

While both parties are open to continued discussions about the terms of a possible collaboration, it remains unclear whether the specific terms that meet the distinct goals of each of the two sectors are possible.

Several productive public-private collaborations have marked the Human Genome Project during its short history. For example, several years ago, Merck & Company, Inc. decided to fund the generation of a public collection of human EST (Expressed Sequence Tag or gene snippet) sequences. More recently, on January 19, 1999 a memorandum of understanding (MOU) was signed between Celera Genomics and the Berkeley Drosophila Genome Project Group, a consortium of research groups working at the University of California at Berkeley, Lawrence Berkeley National Laboratory, Baylor College of Medicine and Carnegie Institution of Washington. The group is funded by the NIH, the Department of Energy and the Howard Hughes Medical Institute. The MOU's stated purpose was to produce a complete, annotated, and publicly accessible sequence of the Drosophila genome at a reduced cost and an

accelerated pace. The DNA sequence of the fruitfly, Drosophila melanogaster was published in Science on March 24, 2000.

Presently, the National Human Genome Research Institute (NHGRI) is working with a consortium of groups to develop a plan to identify an estimated 700,000 single nucleotide polymorphisms (SNPs) (common areas in the human genome where the sequence varies by a single letter) over the next two years. The SNP Consortium (TSC) is a unique group of 10 pharmaceutical companies, IBM, Motorola and the Wellcome Trust of the United Kingdom, in partnership with leading HGP academic centers. Variant SNPs, that are identified, will be placed in the public domain for all to use. Many of the variants will be responsible for traits that distinguish one person from another. Others will be found to contribute to an individual's risk of developing complex diseases such as cancer, heart disease, and diabetes. The NIH and TSC have been coordinating efforts since TSC's inception. For example, efforts by both the NIH and TSC to discover SNPs are using DNA samples from the NIH SNPs resource so that data from the two efforts will be comparable. In addition, the SNP data generated from both projects are deposited in the public database, dbSNP. Finally, NIH and TSC investigators participate in joint scientific and technical meetings to share information and coordinate strategies.

Each of these collaborations combine public and private resources to generate genomic information that is freely accessible, without restriction, to both public and private sector scientists. As a result, more information has been available to the scientific community more rapidly than expected. The NIH welcomes these opportunities by which workable models for collaboration between the public and private sectors can be achieved.

MOUSE GENOME

Question. Why is it important to sequence the mouse genome if you already have the human genome?

Answer. The human genome is a very complex structure that will take decades or even centuries to understand fully. One of the best tools for understanding it is to compare it with other genomes. For example, if a certain region in the mouse genome is almost identical to the same region in the human genome, this is a clue that the region codes for an important function. If the function of such a region of the mouse genome is known, it can be deduced that the function of the human region is the same or is similar. Because we have been studying on mice for many years, we know a great deal about the biology of mice and mouse genes, an area that is difficult to study in humans. As a result, the ability to compare mouse and human sequence is expected to provide a tremendous boost for understanding human genetics. For this reason, having the sequence of the mouse is critically important.

SEQUENCING OF THE HUMAN GENOME

Question. A working draft is useful, but what are your plans for finishing the sequence of the human genome to high accuracy?

Answer. The Human Genome Project is committed to finishing the human sequence to a level of high accuracy. This has been the goal from the beginning of the project and it has not changed. The current plan is for each group to finish those sections that it has sequenced to the working draft status. An international working group has been discussing the details of strategy for finishing the sequence over the last few months and has come up with a plan that all have endorsed. The goal is to complete this by 2003, but it may well be possible to finish earlier.

HUMAN GENOME

Question. What plans does your institute have to encourage research on understanding the genome, once the sequence is in hand? What role will computers play in this next phase?

Answer. NHGRI has been supporting technology development for research on functional genomics for some time. Recently we have intensified our efforts by supporting two new initiatives. The first is the Mammalian Gene Collection in collaboration with the NCI. This project will assemble a catalogue of cloned and sequenced human genes and make them available to researchers. This collection will be a critical tool for understanding the human genome. In addition, NHGRI will shortly issue a request for applications for Centers of Excellence in Genomic Science. These centers will focus on novel approaches to studying genomic questions. We expect that they will become centers for technology development and computational biology, whereby new methodologies are created that assist scientists in understanding the human genome sequence and how it functions.

Databases, using computers, will store the information on DNA sequence, DNA variants, and a large amount of information on gene structure and function. Researchers will be able to access this information from their lab computers. Using computers, they will be able to analyze the data to discover more about how genes work, for example, by comparing human with mouse sequence to find genome regions important for gene regulation. They will also be able to use computers to make discoveries by combining the genomic information with their own research results, such as mapping genes for diseases.

CHILDREN AND DEPRESSION

Question. Children and depression—Dr. Hyman, you have often said that a depressed child is at quite a disadvantage in terms of ability to learn, form relationships, and develop overall in a healthy way. It is critical that each child in distress have the best possible chance of being noticed and evaluated in a thorough, competent way. What effect might failure to do this have on the apparently increasing incidence of violence among children and adolescents?

Answer. We can only speculate on this, as studies which would unravel the effects of untreated depression in children, for ethical reasons, have not been undertaken. We agree that children who are depressed can be identified, that valid assessment approaches are available, and that some treatments and preventive strategies, including school-based programs specifically for these children, have been rigorously tested. A major problem is that too often these treatments and preventive approaches are not available to children who need them. Instead unevaluated programs are offered under the guise of providing a "service."

There have been several longitudinal studies of children with different patterns of risk, and these studies indicate that there is a cumulative and negative effect to ignoring such risks. Children with certain patterns of risks may go on to exhibit serious behavior problems in adolescence. Many of these behavior problems can be avoided by early detection, careful assessment, and implementation of well-established intervention programs.

Question. Suicide—To what do you attribute rising suicide rates among young people? What can we do about this?

Answer. In addition to a possible increase in the likelihood of reporting youth suicides, the rising youth suicide rates have been linked to increased substance use among the nation's youth. For example, an association between lower state drinking age and higher youth suicide rates has been shown.

So far there are no proven prevention efforts shown to reduce youth suicide rates, and some school-based awareness programs have actually caused distress in vulnerable youth. NIMH and NIDA just released a program announcement encouraging researchers to submit applications that test various approaches to preventing youth suicidal behavior.

Question. Dr. Hyman, can you tell us what you are doing to address the legal and ethical issues that may interfere with the need to do critical research on depression and suicide? Should people who are (or who may be) suicidal be allowed to participate?

Answer. NIMH staff, and experts in (1) clinical research with suicidal patients, (2) bioethics, and (3) legal issues pertaining to liability risks with suicidal patients have developed a draft document, Safety and Ethical Issues to Consider for Persons at High Risk for Suicidal Behavior in Intervention Trials. Its purpose is to propose ways to minimize risk and consider the ethical issues unique to conducting research on suicidal behavior, in order to promote more research on effective interventions to reduce suicidal behaviors. Currently, the draft is being circulated to OPRR staff, representatives from the National Advisory Mental Health Council, professional and lay advocacy communities, Institutional Review Boards (IRB) and Data Safety Monitoring Boards (DSMB) members, and former research participants, for comment.

As the draft was being developed, the audience in mind included researchers conducting clinical trials designed to reduce the rate of suicidal behaviors, and the IRBs and DSMBs that must review and monitor them. However, the document is also intended to be useful for researchers conducting any type of treatment trials aimed at reducing symptomatology in disorders known to carry a high risk for suicidal behavior. The adequate incorporation of plans to increase safety, minimize risk, and consider the ethical issues pertaining to individuals who may become suicidal in treatment trials, could allow more individuals who are at risk for becoming suicidal to participate in a greater number of treatment trials.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Question. Dr. Fischbach, your Institute recently undertook a major effort to produce a five-year research plan for Parkinson's disease research. How can this kind of initiative advance the research into Parkinson's disease and should this kind of process be duplicated for other disease research areas?

Answer. The Parkinson's disease research agenda proposes a comprehensive approach—understanding the disease, developing treatments, creating research capabilities, and enhancing the research process. We are optimistic that such an approach will result in significant progress against Parkinson's and other neurodegenerative disorders. It may prove to be a good model for many diseases. We were particularly pleased by the enthusiastic participation of leaders from the Parkinson's research community, from other fields that can contribute to the effort, and from the patient advocacy groups.

NINDS embarked on a strategic planning process last year, and we continue to refine it in terms of next steps and procedures for implementation. The strategic plan is based on broad, cross-cutting themes (such as neurodegeneration), each one of which touches on many disorders. The plan has already produced many initiatives that address both basic neuroscience and specific disease problems. We plan to complement this approach with additional plans focused on specific disorders, and began with Parkinson's disease. Using a slightly different approach, we are collaborating with the National Cancer Institute to develop a plan for brain tumor research. We plan to proceed with other disease-specific plans at the rate of two or three per year.

Our view is that there are several useful models that can be employed (including the more traditional but highly effective approach of sponsoring workshops), depending on specific disease issues and the state of the science. In general, however, we do not favor the inclusion of funding proposals in long-range plans. We are concerned that a proliferation of such budget-oriented plans would decrease our ability to take advantage of new, unexpected opportunities, both in terms of the specific disease being reviewed and more broadly in other disease areas of interest.

CONSENSUS CONFERENCE ON OSTEOPOROSIS

Question. Dr. Katz, I understand that a Consensus Development Conference on Osteoporosis will be held at the NIH. What are the specific issues that this conference will examine?

Answer. NIH held a Consensus Development Conference on Osteoporosis Prevention, Diagnosis, and Therapy on March 27–29, 2000. The NIAMS was the primary organizer of this conference. Fellow sponsors included the NIH Office of Medical Applications of Research, nine other NIH Institutes and Offices, and the Agency for Healthcare Research and Quality. Well over 1,000 people attended presentations during the 3-day conference.

Osteoporosis occurs in all populations and at all ages. About 10 million people in the United States have osteoporosis, and an additional 18 million individuals are at increased risk for the disorder.

The consensus panel was charged with addressing the following five questions: (1) What is osteoporosis and what are its consequences? (2) How do risks vary among different segments of the population? (3) What factors are involved in building and maintaining skeletal health throughout life? (4) What is the optimal evaluation and treatment of osteoporosis and fractures? (5) What are the directions for future research?

In general, the panel found that nutrition, exercise, and medicines can play important roles in the prevention and treatment of osteoporosis. The panel noted that maintaining optimal bone health is a lifelong process that should begin in childhood. Bone mass attained during childhood is perhaps the most important determinant of life-long skeletal health. At all ages, physical activity and good nutrition, particularly adequate calcium and vitamin intakes, aid in developing and maintaining strong bones. Exercise can also reduce the risk of falls, a major cause of fractures in people with osteoporosis.

While hormone replacement therapy remains a common treatment and prevention option; the panel suggested that more information is needed as to how estrogen reduces the incidence of fractures. There are new medicines for preventing and treating osteoporosis, such as bisphosphonates and selective estrogen receptor modulators. New technologies have improved the detection of loss of bone mineral, a key predictor of osteoporotic fracture, although the panel recognized that no standard exists for comparing different screening devices.

The panel's recommendations for future research included identifying and intervening in disorders that can impede the achievement of peak bone mass in children

of ethnic diversity; improving diagnosis and treatment of secondary causes of osteoporosis, such as that resulting from the use of glucocorticoids (for example, prednisone); collecting data necessary to establish testing guidelines for osteoporosis; developing quality-of-life measurement tools that incorporate gender, age, and race/ethnicity; conducting randomized clinical trials of combination therapies to prevent or treat osteoporosis; and developing a paradigm for the management of fractures.

SCREENING AND TREATING OSTEOPOROSIS

Question. Do we have good screening mechanisms for osteoporosis? And once we diagnose an individual with osteoporosis are there adequate treatment protocols?

Answer. Fortunately, research over the last decade has led to some very reliable methods for assessing bone mass/bone mineral density. Dual energy x-ray absorptiometry (DXA) has been developed and used in some large studies that confirm the association of low bone mineral density with high fracture risk. This technology can assess the bone mineral density of two important sites of fracture in the body—the hip and the spine. The results of this test can be used to identify individuals at high risk of fracture who may profit from interventions designed to slow bone loss.

There are several medications available to treat osteoporosis. Estrogen has the longest history in the prevention/treatment of osteoporosis. Two newer medications called bisphosphonates are approved by the FDA for osteoporosis—alendronate and risedronate. These medications are bone-specific and have been shown to reduce fractures in clinical trials. Another approach to osteoporosis has been the development of Selective Estrogen Receptor Modulators (SERMs). These drugs mimic the positive effects of estrogen in the bone but have been modified to diminish some of the deleterious effects of estrogen on the breast and the uterus. Currently, there is one SERM that has been approved by the FDA for osteoporosis—raloxifene. However, this is an active area of research. NIH is sponsoring a workshop on Selective Estrogen Receptor Modulators April 26–28, 2000, to develop a research agenda in this important area.

OSTEOGENESIS IMPERFECTA

Question. I understand that in 1999 you supported a workshop on the development of new strategies for Osteogenesis Imperfecta, also known as brittle bone diseases. Can you summarize the outcome of that workshop? And please tell us how your 2001 budget reflects these recommendations?

Answer. In September of 1999 the NIAMS partnered with the Osteogenesis Imperfecta Foundation, the Children's Brittle Bone Foundation, and the NIH Office of Rare Diseases to sponsor a meeting on Osteogenesis Imperfecta (OI). The goal was to stimulate new clinical approaches to OI by calling attention to recent findings in several areas of basic biology and model systems. These areas include stem cell manipulation and gene therapy strategies, cell-matrix interactions, and the role of growth factors and cytokines in bone turnover. The workshop also assessed recent advances toward the ultimate goal of developing techniques for correcting the underlying genetic defects in OI. In addition, recent observations suggest that the metabolic consequences of collagen defects, such as effects on the activities of osteoblasts and osteoclasts, play an important role in the pathogenesis of OI. Exploring these new findings could lead to therapeutic approaches, such as pharmacological interventions, that could have an significant impact on the clinical management of OI. A number of research recommendations resulted from the workshop, and the NIAMS is currently assessing future research directions.

The opportunities for basic research advances to move the field forward seem to be particularly promising. NIAMS is planning an initiative in fiscal year 2001 to capitalize on the opportunity to better understand how the bone cells in patients with osteogenesis imperfecta are programmed and can be re-programmed by therapeutic intervention.

OSTEOPOROSIS

Question. With the aging of the population is osteoporosis becoming a problem for men, as well as women? And if so, do you recommend that men over 65 take advantage of bone density screening?

Answer. Although American women are four times as likely to develop osteoporosis as men, an estimated one-third of hip fractures worldwide occur in men. Studies have shown that men tend to develop osteoporosis about 10 years later in life than women. This difference has been attributed to a higher peak bone mass in men at maturity and to a more gradual reduction in sex steroid influence in

aging men. The lifetime risk of older men for fractures of the hip, spine, or wrist is considerable, and the Institute is committed to providing a particular focus on osteoporosis in men, in addition to its extensive portfolio of research on osteoporosis in women. In fiscal year 1999, the NIAMS launched a major study of osteoporosis in men. This is a 7-year study that will enroll and then follow 5,700 men 65 years and older for an average of 4 to 5 years, and will determine the extent to which the risk of fracture in men is related to bone mass and structure, biochemistry, lifestyle, tendency to fall, and other factors. The study, which is supported in part by the National Institute on Aging and the National Cancer Institute, will also try to determine if bone mass is associated with an increased risk of prostate cancer.

As mentioned above, men tend to develop osteoporosis somewhat later than women. It is not clear that it would be advantageous to screen all men over 65. Rather physicians should be aware of some of the factors that place men at high risk of an osteoporotic fracture such as previous low impact fractures, especially spine fractures that may be manifest by a loss of height, the use of certain drugs like prednisone, and the diagnosis of primary hyperthyroidism. In addition, low body weight and diseases that lead to malabsorption of food, or a family history of low impact fractures, may raise suspicion of low bone mass.

MEDICARE AND OSTEOPOROSIS

Question. Given the aging of our population, do you see the problems of treating bone diseases, which is paid for by the Medicare program, as one that will consume a large portion of the Medicare money in the next 20 years?

Answer. The aging of the American population will certainly add to the number of individuals at risk of fractures. It is estimated that one out of two women will develop an osteoporotic fracture in her lifetime. Men have a lower risk but are increasingly living to an age when their fracture risk is also high. Serious efforts at the prevention of bone loss need to be directed to reducing the number of individuals affected. Efforts directed at the young can be particularly important as the development of an adequate bone mass at maturity is important protection against fractures later in life. These efforts need to be focused on increasing physical activity, maintaining a healthy body weight and adequate calcium intake. The recent Consensus Development Conference on Osteoporosis estimated that only about 25 percent of boys and 10 percent of girls ages 9 to 17 meet the calcium intake recommendations of the Institute of Medicine.

However, the seniors of the next few decades are already adults and there is a great deal that can be done to prevent bone loss in adults. In fact, some of the same preventive measures that are effective in building bone mass in adolescence are effective in maintaining bone mass later in life. Low physical activity in older populations is a significant factor in bone loss but also affects the balance and coordination that protect against falls. Active seniors have fewer falls and less serious ones. Calcium and vitamin D can also prevent bone loss, and their intake in senior adults are seriously below the recommended levels. In some individuals at high risk of fracture, medications directed to slowing bone loss can be a cost-effective strategy.

OSTEOPOROSIS

Question. If the treatment of bone diseases is going to be a major expense to the Medicare program, do you think you and your fellow institute directors are investing enough money in bone research in order to improve the quality of life for our seniors and to reduce the cost to Medicare?

Answer. I am pleased to tell you that bone research is indeed a major priority for the NIH. A number of NIH components plus representatives from other agencies participate in the Federal Working Group on Bone Diseases—a collaboration that helps to coordinate research activities across the Federal government and provide recommendations for future research efforts. NIAMS supports bone research across the full spectrum from basic studies on how bone is normally built up and how bone breaks down in disease to clinical studies to improve our diagnostic and therapeutic abilities; and to prevention studies, especially those that target young people in their prime years for building strong bones. We also support major clinical trials that are looking at the value of combining some of the available drugs for treating osteoporosis, to determine the enhanced value that combinations of drugs may have against osteoporosis. In addition, we have recently supported a Consensus Development Conference at the NIH on osteoporosis, and experts identified a number of promising avenues for the NIH to consider and pursue. Finally, in the area of information dissemination, the NIAMS and other ICs fund the NIH Osteoporosis and Related Bone Diseases National Resource Center that provides comprehensive and timely information to patients, their families, and their health care providers. While

there are always opportunities for funding additional research, I believe that the NIH research efforts in bone—those already underway as well as those planned for the future—reflect the major priority we give to this area of research.

MUSCULAR DYSTROPHY

Question. Why has NIAMS been unable to provide as many muscular dystrophy related single investigator grants as other institutes?

Answer. The NIAMS, together with the National Institute of Neurological Disorders and Stroke (NINDS), considers research on the muscular dystrophies to be a priority area. We will continue to work with the extramural muscular dystrophy research community, as well as interested patient organizations, to stimulate and support promising studies in this area. In fiscal year 1999, the NIAMS invested nearly $5.4 million in muscular dystrophy projects, an increase of over 40 percent from the previous fiscal year.

A number of exciting studies with implications for our understanding of the muscular dystrophies have been supported by the NIAMS in recent years. One such investigation used gene therapy to restore muscle function in a hamster model of limb-girdle muscular dystrophy (LGMD). In another NIAMS-funded study, researchers successfully used the common antibiotic gentamicin to restore the function of the gene that encodes for the protein dystrophin in mouse models of Duchenne muscular dystrophy (DMD). In a third project, NIAMS-supported researchers used gene therapy in mice to give the body a boost in fighting the effects of aging on muscle, and to help repair the damage caused by injury and muscle-wasting disorders such as muscular dystrophy. These projects underscore the potential of treating human forms of LGMD, DMD and other muscular dystrophies with gene therapy approaches.

Another area of excitement relates to a new protocol developed with support from the NIAMS that makes it possible to obtain an almost unlimited number of a special class of adult stem cells from a small sample of bone marrow. These adult stem cells have the ability to develop into cells of muscle, nerve, bone, cartilage and fat. Because of their vast potential for differentiation, they may be excellent therapy vectors for a number of skeletal diseases, including muscular dystrophy.

Next month, the NIAMS—in partnership with the NINDS and the NIH Office of Rare Diseases—will support two research meetings on muscular dystrophy. The first is an international scientific conference centered on clinical and molecular studies of facioscapulohumeral dystrophy (FSHD). The meeting will bring together researchers who are already involved in FSHD projects, as well as scientists who are working in related fields and may be able to contribute to progress on FSHD. The second meeting will focus on therapeutic approaches for DMD. This workshop is aimed at addressing key questions in improving treatments for DMD, identifying areas of needed scientific knowledge, and the critical next steps to promote effective therapy. The NIH expects to build on the insights from these two meetings to develop new program initiatives related to the muscular dystrophies. Such initiatives would complement on-going efforts to stimulate research in this area, including the currently active program announcement on the pathogenesis and therapies of the muscular dystrophies.

Question. Why is there no separate study section for muscle biology? Would a separate study section enhance research and integrate efforts?

Answer. The NIH Center for Scientific Review (CSR), which conducts the peer review process, is currently involved in a comprehensive assessment of its study section structure, led by Dr. Bruce Alberts, the President of the National Academy of Sciences. The purpose of this assessment is to ensure that CSR provides a rigorous, unbiased review system that facilitates the advance of all areas of biomedical research, including muscle biology. Indeed, muscle disease review issues are being considered as part of the assessment. CSR will also be meeting with scientists at the Duchenne muscular dystrophy workshop in May to discuss this and other review concerns. The outcome of these discussions will help guide future decisions about the review of muscle-related research grant applications.

There is no simple answer to the question of whether a dedicated study section would enhance the success of muscular dystrophy research applications or otherwise improve coordination of muscle-related research. It is important to consider that the NIH receives a broad range of research applications on muscle functioning and disease, and diverse areas of scientific expertise are required to review those applications. Whether it is desirable—or, indeed, even feasible—to cluster all muscle research proposals into a single study section is one of the questions being explored by the CSR assessment described above.

MAGNETIC THERAPY

Question. Has the use of magnets been proven scientifically?

Answer. Todate, there have been only a few, rigorous, double-blinded, randomized trials investigating the efficacy of magnet therapy (e.g. Vallbona et al., 1997, Weintraub, 1998; Taylor et al, In press). Although the results of these trials suggest that magnet therapy is more effective than placebo for pain management, a definitive statement on magnet therapy's efficacy awaits completion of a large, multi-site randomized controlled trial. The research portfolio of the National Center for Complementary and Alternative Medicine (NCCAM) includes rigorous studies of magnet therapy.

Question. Are there any dangers in using magnets like sleeping on a magnetic pad or magnets in your shoes? I heard somewhere that they are not recommended for people with heart problems—they cause problems with electrical currents.

Answer. Static magnetic fields appear to be safe. In 1987, the World Health Organization reported that "the available evidence indicates the absence of any adverse effects on human health due to exposure to static magnetic fields up to two Tesla." Given that the typical static magnet used to treat disease produces a magnetic field of only a few thousands of a Tesla in strength, there is little intrinsic danger to using magnet therapy. Supporting this contention, the few well-designed clinical trials investigating static magnets have not reported any severe adverse events associated wit the intervention (e.g. Vallbona et al., 1997, Weintraub, 1998; Taylor et al, In press). Although no cause and effect was established, there has been one case report of a person who developed a myeloma after sleeping on a magnetic mattress for five years (Burns 1994). Concerning the use of static magnets by individuals with heart disease, there is conflict evidence whether low level electromagnetic fields produce changes in heart rate (Cook et al., 1994; Korpinen and Partanen, 1994) and blood pressure (Korpinen and Partanen, 1996). Until these issues are addressed for static magnetic fields, caution might be suggested for individuals suffering from severe hypertension. Caution may also be advised for individuals with cardiac pacemakers or wearing cardiac infusion pumps.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

INFECTIOUS DISEASE

Question. The NIH has invested heavily in infectious disease research. We have done a good job of developing vaccines to combat many infectious diseases, including HIV. However, one area that is of concern to me is that of drug resistance in infectious diseases. We now have bacteria that are becoming resistant to our last lines of antibiotic treatment.

What is the NIH doing to insure appropriate use of antibiotics? What is the NIH doing to stimulate the development of new antibiotics to combat drug resistant bacteria?

Answer. The NIH co-chairs with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) an Interagency Task Force on Antimicrobial Resistance. The initial public activities of this Task Force were announced in the Federal Register, Vol. 64, No. 123, Monday, June 28, 1999. This was in conjunction with a July 1999 public meeting organized by ten Federal agencies (the CDC, the FDA, the NIH, the Health Care Financing Administration, the Health Resources and Services Administration, the Agency for Health Care Research and Quality, the Environmental Protection Agency, the Department of Defense, the U.S. Department of Agriculture, and the Department of Veterans' Affairs) to coordinate Federal programs relating to antimicrobial resistance. The purpose stated in the preceding notice was "To solicit input from invited consultants regarding items to be included in a Public Health Action Plan that, when published, will serve as a blueprint for activities of Federal agencies to combat antimicrobial resistance. The Plan is being developed by a Task Force composed of Federal personnel from several Federal agencies and departments, co-chaired by the CDC, the FDA, and the NIH." It should also be noted that the fiscal year 2000 appropriations report language for CDC mentions this existing Task Force and the recommendation that a report be done within a year of enactment of the legislation—the above mentioned Public Health Action Plan is in response to this report language. Accordingly, four focus areas were selected for grouping the discussions and outcome: Surveillance, Prevention and Control, Research, and Product Development. The issue of appropriate use of antimicrobials, including antibiotics, is within the purview of Prevention and Control, and is addressed in the connotation of "judicious use." The NIH is collaborating in the overall development of the Action Plan in the role of Co-Chair, and also plans

to collaborate with the appropriate agencies coordinating any resulting actions relating to judicious use of antimicrobials, principally the CDC and the FDA, for any action items that fall within the scope of the NIH mission.

The NIH funds a diverse portfolio of grants and contracts to study antimicrobial resistance in major viral, bacterial, fungal, and parasitic pathogens. The National Institute of Allergy and Infectious Disease (NIAID) has a lead role in many of these activities, but numerous other Institutes and Centers at the NIH also support and participate in research related to antibiotic resistance.

The NIH-funded projects include basic research on the disease-causing mechanisms of pathogens, host-pathogen interactions, and the molecular mechanisms responsible for drug resistance, as well as applied research to develop and evaluate new or improved products for disease diagnosis, intervention, and prevention. Numerous genome projects seek to identify new gene targets for the development of drugs and vaccines. Other NIH-sponsored activities with relevance to antimicrobial resistance include physician and researcher training and education. In addition, the NIAID supports a number of clinical trials networks with the capacity to assess new antimicrobials and vaccines with relevance to drug-resistant infections. Among these are the AIDS Clinical Trials Groups, the Mycoses Study Group, the Collaborative Antiviral Study Group, the Vaccine and Treatment Evaluation Units, and the Tuberculosis Research Unit. The NIAID supports contracts that screen for novel antituberculosis drugs by testing in vitro and in animal models. The candidate drugs are selected for screening from submissions by academic and private sector researchers worldwide and from the National Cancer Institute's (NCI) chemical repository.

With regard to other NIAID-specific projects, the Institute funds a diverse portfolio of grants examining antimicrobial resistance among the major nosocomial bacterial pathogens, for example, multi-drug resistant Staphylococcus aureus, enterococci, and Escherishia coli. Current research support is aimed at:

—Identifying new diagnostic techniques, novel therapeutics, and preventive measures to minimize infection with resistant pathogens, prevent the acquisition of resistance traits, and control the spread of resistance factors and resistant pathogens in hospital settings;

—Understanding the molecular biology and genetics of resistance gene acquisition, maintenance, and transmission;

—Exploring novel approaches to combat resistance through passive or active immunization;

—Identifying natural antimicrobial peptides that may prove useful as new classes of antibiotic-like drugs; and

—Through the use of molecular characterization, continuing efforts to determine the degree of spread of multi-resistant international clones of Streptococcus pneumoniae in the United States and the rest of the world.

The NIAID is also creating a Bacteriology and Mycology Study Group to design and conduct multi-center clinical studies of interventions for serious fungal and healthcare-associated resistant bacterial infections. Key aspects of the effort will be to: formulate and implement a scientific research agenda; establish a multi-center clinical studies group; establish a clinical studies coordinating unit; provide leadership and organization of the study group; and conduct, complete, and report the results of the clinical studies. This project will be funded in the spring of 2001.

Finally, the NIAID recently released a Request for Applications (RFA), "Challenge Grants: Joint Ventures in Biomedicine and Biotechnology." The purpose of this initiative is to support research and development efforts whose outcomes could significantly reduce the impact of infectious diseases nationally and worldwide. The RFA was issued in response to the fiscal year 2000 Public Health and Social Services Emergency Fund appropriation of $20,000,000 designated for "NIH Challenge Grants and Partnerships." This new initiative is intended "to promote joint ventures between the National Institutes of Health and the biotechnology, pharmaceutical, and medical device industries" and involves a "one-on-one matching of federal dollars by qualified organizations that are conducting R&D activities in biomedical research or biotechnology with commercializable potential or conducting research in promising therapies."

The NIAID has identified areas of high importance where it believes successful product research and development combined with existing infrastructures and federal challenge grant funding could significantly impact a major health or medical problem. Bacterial drug resistance is an evident area of focus in this solicitation in two specific areas: tuberculosis (TB), and emerging and resistant infections, including drug resistant staphylococci and enterococci.

It is the intention of these challenge grants to encourage the private sector to develop new TB drugs, including: identification of potential new drug targets and

novel classes of drugs (making use, where appropriate, of the Mycobacterium tuberculosis genome sequence and high throughput approaches); preclinical development of novel classes of drugs and optimization of lead compounds; and clinical testing of potential new therapies. The NIAID also seeks to encourage the private sector to increase its commitment to TB vaccine development through these challenge grants. In particular, it encourages the use of whole genome approaches for the identification of promising protective antigens, and the development of both pre-exposure and post-infection candidate vaccines from pre-clinical through clinical testing.

Similarly, through the challenge grants mechanism, the NIAID seeks to interest the private sector in pursuing preclinical and clinical studies of passive or active immunization candidates to protect against resistant staphylococcal infection, first in the most vulnerable populations such as severely-ill hospitalized patients and patients facing major surgery and at risk for infection, and then also for potentially broader application to community situations. Novel therapies, such as bacteriophage therapy, will be considered as candidates for study for enterococci.

PARKINSON'S DISEASE

Question. The committee just received the Parkinson's Disease Research Agenda from your office.

Do you agree with the report that a cure for Parkinson's is now a comprehensive goal if a comprehensive approach is pursued?

Answer. A cure for Parkinson's is a realistic goal, given what is known about the disease and the research tools now available to us. The research agenda proposes a comprehensive approach—understanding the disease, developing treatments, creating research capabilities, and enhancing the research process. We are optimistic that such an approach will result in significant progress against Parkinson's and other neurodegenerative disorders.

Question. Is the NINDS sufficiently staffed to implement such a plan?

Answer. The plan reflects our best professional judgment as to what could be accomplished if funding were available to implement all aspects of the research agenda, but without taking into account fiscal constraints or other competing priorities of NIH and the rest of the Federal government. In order to do this, more staff would be required to develop the necessary initiatives and work collaboratively with the research and patient communities.

DIABETES

Question. One of NIH's initiatives for 2001 deals with genetics research and exploiting genomic discoveries. One area where genetics research could be essential is in the area of diabetes, especially juvenile diabetes.

Do genomic discoveries show promise in the area of juvenile diabetes and is funding sufficient to do this?

Answer. Type 1 diabetes has a strong genetic determinant, in which more than one gene is believed to play a role. These genes make some individuals more susceptible to developing diabetes than others. In addition, genetic factors may cause some individuals with diabetes to be more prone to developing the serious and life-threatening complications associated with type 1 diabetes. Knowledge of the genetic defects underlying diabetes will be critical not only for identifying individuals at risk for diabetes and its complications, but also for identifying targets for effective treatment and prevention.

The NIDDK is attempting to provide cutting-edge genetics and genomics resources to our investigators. We have already begun to move in this direction, with a biotechnology initiative on microarray technology that will be useful to diabetes researchers and other NIDDK investigators, and with a major effort planned for a Diabetes Genome Anatomy Project (DGAP) to locate and analyze the function of genes in all the various types of tissue relevant to diabetes. Start up of the DGAP initiative is currently slated for fiscal year 2001.

The NIDDK envisions DGAP as a trans-NIH effort involving several Institutes with a research interest in diabetes and its complications. This project would collect genomic information on the spectrum of genes expressed in all tissues relevant to diabetes and its complications. It would build upon an ongoing NIDDK initiative on the functional genomics of the developing pancreas. While our ongoing effort supports the production and sequencing of complementary DNA libraries based on multiple stages of pancreatic development, the DGAP would be much broader. Objectives would be to obtain full length cDNAs from tissues relevant to diabetes; to discover novel genes in tissues affected by diabetes; to conduct expression profiling to determine patterns of gene expression in disease; and to perform functional

phenotyping of expressed products in tissues affected by diabetes. More importantly, this initiative—if undertaken at a full-scale level—would allow for the cataloging of all information obtained in a diabetes relational database with automated data mining and query support. This database would be developed and offered as a resource for all diabetes investigators and could be used in the development of new assays, identification of potential therapeutic agents, and points of departure for new studies into diabetes and its complications. Information obtained through an initiative such as this has the potential to further our understanding of the causes and mechanisms of diabetes, to identify targets for effective treatment and prevention, and to serve as a springboard for the development of future investigator-initiated, hypothesis-driven research. The degree to which we can undertake all components of this initiative and the timeline for implementation will be dependent on resource availability.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

MENTAL HEALTH RESEARCH

Question. In several recent Mental Health Advisory Council reports you have recommended improving the relevance of prevention research into early interventions, clinical research to actual practice, and of behavioral research to serious mental illnesses. Could you please discuss some of the difficulties you've encountered in your efforts to change the institute's course toward the greatest public health needs? Where does NIMH stand relative to other NIH institutes on the rate of grants submitted and funded? Is the relative quality of the science in the grant submissions and proposals received NIMH rising or declining?

Answer. Mental disorders and suicide together account for over 15 percent of the burden of disease in established market economies such as the United States. The mission of the National Institute of Mental Health is to reduce the burden of mental disorders. NIMH also takes the lead in understanding the impact of behavior on HIV transmission and pathogenesis, and in developing effective behavior preventive interventions in areas such as violence. These collectively constitute an enormous area of responsibility. Over the past several years, NIMH has systematically examined its overall research portfolio and conducted even more in-depth reviews of selected programs, areas of science, and disorders, all with the objective of refocusing programs to bring the best science to bear on areas of greatest disease burden: depression; schizophrenia, bipolar disorder, obsessive compulsive disorder, and childhood autism, to name a few. In particular we have tried to ensure that knowledge gained is relevant to the full range of patients: from children to the aged; both sexes; all genders, races, ethnic groups; and to individuals with co-occurring conditions. This refocusing process has encountered significant challenges. One has been the need for extensive reorganization of programs within the Institute's intramural and extramural research programs. On the intramural side, certain laboratories and clinical units have been phased down or terminated in order to permit new growth and initiatives. Extramural staff and program realignments have been even more extensive and, often, difficult. It also has been quite challenging to shift the direction of the larger extramural community—for example, to motivate basic behavioral researchers to examine and revise many time-tested research paradigms in order to make research more relevant to clinical questions, or to encourage investigators to take a potentially risky step outside a given area of expertise into uncharted areas such as translational research. Although we have encountered some resistance and doubts about the need for change, these efforts are paying off.

Since we rejoined the NIH in 1993, the ratio between competing research project grant applications submitted and awards funded, or success rates, has been consistently lower by 3–5 percent from the aggregated average for all NIH Institutes and Centers. The functional consequence of this differential for scientists is that an application for funding to the NIMH had a 16 percent lower chance of success than for NIH in the aggregate. This was also true for the most recent 1999 fiscal year when the success rate for NIMH was 27 percent in comparison to the aggregate NIH success rate of 32 percent. Most NIMH applications are reviewed in committees with applications from several different NIH Institutes, and NIMH applications have been consistently judged somewhat better than average by those committees.

Although precise data is not available, it is my opinion that since joining NIH, NIMH science is stronger than it has ever been. The science has been kept sharp by strong competition within NIH review committees and the new seriousness of scientific review within the intramural research program. As indicated in the para-

graph above, NIMH scientists have performed well in review comparisons with scientists of other institutes.

RESEARCH ON CHILDREN'S MENTAL HEALTH DISORDERS

Question. As I understand it, research on children's mental disorders at NIMH still lags behind so much other research, with few treatments available that work for obsessive-compulsive disorder (which often begins in childhood) and bipolar disorder (which increasingly is seen as beginning in childhood and adolescence). What is NIMH's plan for strengthening this research and assuring the development of more effective treatments for children?

Answer. NIMH is actively planning a series of projects. A new program announcement is being crafted that will focus specifically on children with serious mental illnesses, including obsessive-compulsive disorders, bipolar disorders, eating disorders, schizophrenia, among others. The object of the announcement is to encourage a broad range of studies on the onset, course, risk processes, and treatments for serious mental illnesses in children and associated disabling impairments. In addition, next week NIMH is hosting a meeting to identify key research gaps in identification and treatments for children with bipolar illnesses, with the aim to further advance studies in these areas. Also, NIMH is currently supporting seven Research Units of Pediatric Psychopharmacology, several of which focus on bipolar illnesses in children.

RESEARCH ON MINORITY MENTAL HEALTH

Question. The landmark 1998 Schizophrenia PORT study, found that the gap between science and accessible treatment has never been wider. Moreover, this lack of "translation" was at its worst in the African American community, leading to significant health disparities. African Americans with schizophrenia were more likely to experience overmedication with anti-psychotic medications, increased side-effects, and under-treatment of depression to a higher degree than other racial/ethnic groups. What is NIMH doing to improve the translation of scientific advances into real world treatment, in general, and especially in the African American community?

Answer. Since the completion of the Schizophrenia PORT study, NIMH has funded additional studies to look, in depth, into reasons for the disparities in treatment. One study is designed to determine if adherence to treatment recommendations will lead to improved outcomes and whether minority status has an impact on what treatments are provided. In addition, the NIMH has issued a report, Bridging Science and Service, that calls for more research on improving the delivery of treatments in community populations, especially those who are traditionally underserved. NIMH also recently launched four new major clinical treatment studies that will provide data on how to treat some of the most severe mental illnesses in real-world settings. These studies are required to include minority populations so the results will be relevant to them.

Currently, the NIMH Committee on Health Disparities is drafting a document delineating the specific research priorities for the next 5 years. The report will focus on what the state of disparities is; why they exist and approaches to remedy the situation. In addition, the National Advisory Mental Health Council just issued a new report, Translating Behavioral Science into Action, which calls for research that takes into account the importance of individual, sociocultural, and organizational factors on the differences in help seeking, treatment, and outcomes from treatment.

In the past, studies of treatment in schizophrenia tended to be small scale, industry sponsored, and focused on safety and short term efficacy. The data gathered were useful in obtaining regulatory (FDA) approval, but provided little guidance for practitioners on how best to treat patients in the community. Moreover, for a number of reasons, African Americans tended to be underrepresented in these treatment trials. The net result was that clinicians had to base many treatment decisions, particularly in minority patients, on prior experience, opinion, and their own experiences, rather than objective data. To remedy this situation, NIMH recently initiated a multie-year, multi-site, multi-million dollar project to study new antipsychotic drugs in people with schizophrenia (Clinical Antipsychotic Trials of Intervention Effectiveness, CATIE). One of the project's highest priorities is to include a representative sampling of patients with adequate representation of minorities and not be limited to middle class or upper class patients. There will be considerable outreach efforts to African Americans with schizophrenia, including recruitment of study sites in African American communities. Important characteristics of the trial are that all subjects participating in the trial will receive state-of-the-art care, and clinicians involved in the trial will be guided on best clinical practice and will have world-class

experts available for consultation. While the number of patients treated in this trial will represent an insignificant fraction of the totality of people with schizophrenia, NIMH anticipates that the experience with patients and clinicians in African American communities gained through CATIE will greatly facilitate subsequent translation of CATIE's findings into that community as well as aid in dissemination of optimal clinical practices to mental health professionals providing care to African American people with schizophrenia.

NIMH RESEARCH AGENDA

Question. A recent National Advisory Mental Health Council report notes that the behavioral science portfolio at NIMH has not been well-focussed on the areas of greatest public health need and makes a number of recommendations to improve the relevance of this portfolio. Could you discuss some of the factors which contributed to this lack of attention to many of our serious mental illnesses, what you think behavioral research can contribute, and how you can redirect existing research resources to develop more relevant behavioral research?

Answer. Until recently, NIMH has focused relatively little organized effort to bridge basic behavioral science and severe mental illness. In part this has reflected the Institute's encouragement of investigator-initiated research, which, in turn, reflects academic traditions within psychiatry and psychology that often place a higher value on basic research than on clinically oriented (or applied) research. In addition, clinical and basic behavioral scientists have traditionally operated in separate academic departments unfamiliar with the language, concepts and problems of each other's disciplines. Because clinical populations have not been accessible to basic researchers, they have often focused on normal or less ill populations. Academic incentive systems and the segmentation of funding and outlets for publication have not promoted cross-disciplinary studies. Training programs in basic behavioral science often discourage exposure to clinical problems and clinical settings so that behavioral scientists may be unaware of basic research issues and opportunities posed by research on mental illness.

Finally, when NIMH has attempted to encourage targeted research that can bridge between basic behavioral research and severe mental illness, relatively few researchers have responded. This lack of interest in certain types of behaviorally oriented translational research indicates the necessity for more specific targeted efforts to stimulate interest in these areas.

Basic behavioral science will contribute to understanding and solving otherwise intractable public health problems related to serious mental illness in a number of areas:

Understanding Symptoms of Illness

The symptoms of serious mental illness involve attention, abstract thinking, social interaction, motivation, and emotion. Behavioral science should offer new ways of assessing these behavioral processes that will: (1) help link them to underlying neurobiologic processes; (2) allow their evaluation as indicators of risk prior to the development of full-blown illness; and (3) facilitate the objective assessment of response to targeted treatment interventions.

Encouraging Behavior Change

Theory-driven behavior-change interventions are highly successful in HIV/AIDS, yet remarkably, behavioral theory has rarely focused on health behaviors related to serious mental illness. More than half of all schizophrenia relapses can be attributed to lack of adherence with treatment recommendations. The application of theory-based behavior-change principles to the problem of adherence should result in effective approaches to substantially reduce morbidity in schizophrenia and other serious mental illness.

Improving Treatments

Learning theory should guide new treatment development for mental illness as well as treatment dissemination. Despite advances in psychopharmacology, patients with serious mental illness must learn ways of adapting to deficits and disabilities; learning theory should inform the development of new cognitive-behavioral interventions for skills training and illness self-management. At the same time, because research advances are very slow to influence everyday care, we need a better understanding of physician and provider behavior as related to the diffusion of innovations.

Encouraging Help-Seeking

Evidence indicates that delay in seeking treatment contributes to morbidity at the onset of serious mental illnesses including major depression, bipolar disorder and schizophrenia. Behavioral science should contribute to our understanding of the psychological and social processes, including the influence of social norms and stigma, that impede timely symptom recognition and help-seeking for serious mental illness.

Helping Families Cope with Mental Illness

Mental illness in a child or spouse can have a profound effect on family relationships, which in turn influence both the ill individual and other family members. Relationship research should explicate the adaptive responses of families that influence treatment outcome for the ill family member, including adherence to treatment recommendations. At the same time, better ways of characterizing and alleviating the family burden created by serious mental illness must be developed. The presence and severity of symptoms alone cannot account for the disabilities associated with mental illnesses. Behavioral science should contribute to a better understanding of the multidimensional nature of social, vocational and instrumental functioning to refine the choice of rehabilitation interventions. It should also aid in identifying the different treatment needs of individuals who are grouped within a single diagnostic category.

Understanding the Inheritance of Mental Disorders

Evidence indicates that defining mental disorders in terms of behavioral dimensions rather than specific diagnoses may more closely approximate inherited phenotypes. Behavioral science may aid in finer characterization and measurement of these behavioral phenotypes to facilitate the linkage of behavioral diseases to specific sets of risk genes.

"Translating Behavioral Science into Action," the report of the National Advisory Mental Health Council's Behavioral Science Workgroup, provides a wealth of specific recommendations for redirecting existing research resources. Measures commenced or soon to begin include:

—A Request for Applications (RFA) with set-aside funds that focuses on basic behavioral processes in mental illness is under development to jump start cross-disciplinary collaborations between basic behavioral researchers and clinical investigators.

—Simultaneously, a new Program Announcement (PA) will outline a trajectory of research support to include both developing and mature translational research centers to provide an infrastructure for new research, speed the translation of findings, and encourage interaction across basic, clinical and services research. These efforts will signal a serious and ongoing commitment on the part of NIMH to apply behavioral science methods to the problems of mental illness.

—An ancillary study PA encourages behavioral scientists to access the patient populations and infrastructure developed as part of the NIMH clinical trial initiatives.

—Workshops bringing together behavioral and clinical scientists have been initiated in the areas of (1) adherence in serious mental illness; (2) informed consent and clinical research; (3) research ethics; and (4) integrating behavioral science with public health.

—Staff have worked with current behavioral scientist grantees to encourage redirection into areas more closely dealing with mental disorders.

—Training activities are being examined to identify ways to overcome barriers to cross-disciplinary training experiences that are required to facilitate translational research.

SCHIZOPHRENIA

Question. Given the many changes underway at NIMH in terms of the funding of clinical research and the clinical research centers, how are you moving to assure that the research base studying schizophrenia is strengthened and expanded?

Answer. NIMH is strengthening and expanding its research base with regard to schizophrenia in the following ways: (1) initiating a large, sustained effort in the area of clinical trials of typical and atypical antipsychotics for treatment of schizophrenia, and supporting Centers and other grants addressing a large number of schizophrenia treatment issues; (2) bolstering our program for the Silvio O. Conte Centers for the Neuroscience of Mental Disorders in the area of schizophrenia (2 Centers to date); (3) undertaking major, innovative new efforts to investigate genetic contributions to schizophrenia; these efforts include a centralized, international respository for genetic samples and for services to genetics investigators; (4) funding a large number of R01-type grants focused on the neurobiology of schizophrenia,

using methods such as brain imaging, electrophysiology, electromagneto-encephalography, etc.; (5) funding an extensive portfolio of basic neuroscience research relevant to schizophrenia and other mental disorders, (6) initiating new epidemiological and other efforts to understand non-genetic risk factors for schizophrenia and to characterize, in more insightful ways, the very early stages of the disorder; (7) continuing to support a large intramural research program targeting a number of aspects of schizophrenia.

ADVOCATES ON COMITTEES

Question. NIMH was a leader in asking members of the general public—often consumers with severe mental illnesses or their family members—to serve on scientific peer review committees looking at treatment research. As you know, there was a good deal of skepticism about the wisdom of including non-scientists on the committees. Could you provide us with your assessment of how that innovative project has turned out?

Answer. Public participant reviewers have successfully served for a year on the NIMH's service and interventions review committees. Public reviewers included individuals who have suffered from mental disorders, family members of those suffering from mental disorders, mental health care policymakers, and mental health care providers. All committee members were asked for their assessment of how well the process worked. The most common feedback was that the inclusion of public reviewers was useful and that the public reviewers had done an excellent job. The public reviewers, many of whom experienced the committee process for the first time, were impressed with the efforts of the committee members and the serious and objective nature of the deliberations. NIMH will continue to request feedback from all reviewers to help inform and improve the process of public participation in its review meetings. Future plans are to help public reviewers focus on the review issues about which they can best contribute such as determining public health importance and human protection issues, and to continue adding and training new public reviewers to ensure a broad diversity of opinions and experiences.

HUMAN SUBJECT PROTECTION

Question. NIMH has been dealing with ethical issues in research on mental illnesses for a number of years and has instituted a new Mental Health Advisory Council review process to examine human subjects protections before grant approval. Has this new review process been useful? Is it helpful to have non-scientists on the review panel?

Answer. The NIMH Human Subject Research Council Workgroup has been in existence for a year and will meet next on May 3, 2000. It has helped assure that applications considered for funding meet the highest scientific and ethical standards, and that proper protections for human research volunteers are in place. Having bioethicists and consumers on this group has been particularly useful in considering research risks, benefits, alternatives, and informed consent issues.

CO-OCCURRING DISORDERS

Question. NIAAA's strategic plan hardly mentions the problem of co-occurring disorders. What plans does NIAAA have to address co-occurring disorders—and in particular, is the institute sponsoring any research to help establish the most effective treatment approaches when alcoholism and a mental disorder occur together?

Answer. The strategic plan of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is a blueprint of the Institute's major goals and objectives and the strategies for achieving them. Many elements of this plan were developed with input from the National Advisory Council, with significant input from scientists in alcohol-related areas as well as other research areas. The plan also reflects advice from a broad spectrum of sources—researchers, health care providers, over 250 liaison organizations, policymakers, people recovering from alcoholism and their families, and others. It is a "live" document that the Institute will be updating periodically. While researchers interested in the causes of disease will differ on whether studying the patient with co-occurring disease is a promising research strategy, the NIAAA is addressing the issue of co-occurring disorders throughout the strategic plan and the research portfolio.

Alcohol's effects on the human body are ubiquitous,both physically and psychologically. For example, chronic alcohol use is associated with a range of diseases, from liver damage to depression. In terms of psychological comorbidity, the challenge for alcohol investigators is to determine whether specific diseases occur regardless of alcoholism, are the result of alcoholism, or contribute to the development of alcoholism. Numerous studies in this regard are underway. For example, topics

of studies on depression range from delivery of services for depressed substance abusers to observing the outcome of treating depressed alcoholics for depression alone, alcoholism alone, or both conditions. The Institute's research on co-occurring psychiatric disorders also includes studies of alcoholics with post-traumatic stress syndrome and bipolar disorder and clinical trials of alcoholics with social phobia and depression. Neuroscience contributes vital information to studies of treatment for alcoholism and co-occurring disorders, since they identify the biological mechanisms that underlie these conditions. The NIAAA conducts numerous neuroscience studies on mental health, from research on alcoholism and schizophrenia to research on development of alcohol use and abuse in adolescents with attention-deficit hyperactivity disorder.

TREATMENT OPTIONS FOR DUALLY DIAGNOSED INDIVIDUALS

Question. Drug abuse and psychiatric disorders frequently occur together and these "dually-diagnosed" individuals pose special treatment problems. I understand that NIDA's ambitious Clinical Trials Network will address this issue. Could you please review for us what the existing research says about the most effective treatment approaches for these dually-diagnosed individuals and discuss why these approaches have generally not been adopted by the drug abuse and mental health treatment communities?

Answer. Data from the Epidemiological Catchment Area Study showed that 53 percent of individuals with substance use disorders met criteria for one or more mental disorder, and that about one-third of individuals who have a mental disorder also experience alcohol and other drug abuse disorders in their life. In the National Comorbidity Study, 47 percent of individuals with a past year substance use disorder diagnosis had a comorbid mental disorder. Affective, anxiety, personality and psychotic disorders were most commonly comorbid with substance abuse or addiction disorders.

Among treatment-seeking substance abusers and addicts, psychiatric comorbidity has been found to be commonplace. In a recent study in Baltimore, psychiatric comorbidity was detected in 47 percent of heroin addicts one month after stabilization on methadone. Antisocial personality disorder (25 percent) and major depression (16 percent) were the most common diagnoses. Psychiatric comorbidity was associated with increased severity of drug use and severity of associated social problems. In other studies increased psychiatric symptoms have been associated with increased HIV risk behaviors.

Clinical studies have shown that people who have comorbid mental and addictive disorders tend to have poorer treatment outcomes, to relapse more frequently, and are less responsive to psychiatric medications during continued use. Furthermore, studies have demonstrated that treatment of a comorbid mental disorder with appropriate psychiatric and drug addiction medications and psychotherapy and drug addiction counseling is important to the effective treatment of the addictive disorder and results in better outcomes and reduced relapse rates.

Several studies have now shown that integrated treatment programs, which combine mental health and substance abuse interventions, offer much greater promise than the totally separate programmatic approaches found in many communities. In addition to a comprehensive integration of services, successful programs include assessment, assertive case management, motivational interventions for patients who do not recognize the need for substance abuse treatment, behavioral interventions for those who are trying to attain or maintain abstinence, family interventions, housing, rehabilitation, and pharmacotherapy.

Since the late 1980's new models of treatment for the dually diagnosed—with a primary aim of integrating services——have been evolving. This integration is accomplished through the use of multidisciplinary teams that include both mental health and substance abuse professionals who are cross-trained. However, despite the encouraging research findings regarding the effectiveness of integrated treatment for this population, implementation continues to be slow because of problems related to the organization and financing of programs. Organizational guidelines have been developed for dual diagnosis programs, but few large systems have successfully integrated services.

It appears that more research needs to be done on the organization and financing of integrated treatment programs (health services research). In addition, many of the basic components of integrated treatment (family psychoeducation; motivational interventions; behavioral treatments for substance abuse; integrating pharmacotherapies, etc.) are still being developed and refined. Research is needed to address the effectiveness of the appropriate combination of these components.

Of course, another major barrier to successful implementation of this integrated approach is the lack of cross-training for health substance abuse and mental health professionals.

In summary, research has informed us that it is important to diagnose both substance abuse and mental disorders when they are comorbid and provide fully effective treatments for both disorders. Several studies have demonstrated the significant benefits of integrated substance abuse and psychiatric services in the same treatment setting rather than separate and parallel treatment. Benefits included increased engagement and retention in treatment, decreased addiction severity and decreased psychiatric symptomatology. For the most psychiatrically severe patients, these integrated interventions must include Assertive Community Outreach, which fosters continuous engagement and re-engagement in treatment, provides crisis intervention and other community-based services, and supports medication compliance and attendance at both psychiatric and drug treatment services. Research is continuing on the refinement of the components of treatment services and their effectiveness in combination therapy.

NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) will also serve as a potential vehicle for treating dually diagnosed patients. Since the CTN will be testing efficacious therapies in real life settings with diverse patient populations, dually-diagnosed patients will be included in some treatment protocols with appropriate analyses of these patients conducted to improve the treatment strategy even more. Additionally, the CTN will develop protocols to test therapies specifically targeted to co-morbid patients. For example, this may include using antidepressants as an adjunct to behavior therapies for depressed drug addicts.

AUTOIMMUNE DISEASE

Question. What is the status of the NIH's report on autoimmune disease research? What is the timing on submission of that report?

Answer. The Report of the NIH Autoimmune Diseases Coordinating Committee summarizes recent basic and clinical research programs supported by NIH and non-Federal organizations, highlighting coordination and collaborative activities in ten thematic areas; recent and ongoing activities of the NIH Autoimmune Diseases Coordinating Committee; and emerging opportunities to improve treatment and develop preventive approaches for autoimmune diseases. Twenty-two NIH Institutes, Centers, and Offices; the U.S. Food and Drug Administration; the Centers for Disease Control and Prevention; the Veterans' Administration; and ten private organizations with an interest in autoimmune diseases are represented on the Committee. The research programs supported by these groups comprise a broad range of basic, pre-clinical, and clinical endeavors addressing many different diseases, organ systems, and aspects of autoimmune disease.

The Committee will submit the report to the Office of the Director, NIH, for clearance and hopes to release the report in the very near future.

Question. What is the total amount that NIH is spending for research on all autoimmune diseases?

Answer. The NIH spent $393.2 million on autoimmune disease research in fiscal year 1999, and expects to spend $434.6 million in fiscal year 2000, and $456.9 million in fiscal year 2001.

Question. What are some research initiatives NIH is funding to develop better treatments for these diseases?

Answer. Autoimmune diseases are immune-mediated disorders in which the immune system attacks the body's own tissues. Treatment of these diseases depends largely on immunosuppressive agents that have many side effects, for example, steroids and cytotoxic therapies. However, more specific and less toxic immune therapies have shown efficacy in animal studies. As highlighted below, the NIAID, in collaboration with many other federal and private organizations, has developed new programs to assist in moving these promising therapies to clinical practice.

Immune Tolerance.—The induction of immune tolerance is a major therapeutic goal for the treatment of many immune-mediated diseases, as it will eliminate or reduce the life-long dependence of many patients on costly and toxic immunosuppressive drugs. Tolerance induction strategies seek to modify or block deleterious immune responses, such as those responses that cause the body to attack its own organs and tissues in autoimmune disorders, or the immune responses that result in the rejection of transplanted organs, tissues, and cells. A number of promising reagents for the induction of immune tolerance are being developed and can now be tested in clinical trials.

In September 1998, the NIAID published a long-term plan, now available on the web (http://www.niaid.nih.gov/publications/immune/bookcover.htm) to accelerate re-

search on immune tolerance, particularly in the clinical setting. In September 1999, the NIAID, with co-sponsorship of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Juvenile Diabetes Foundation International (JDFI), established one of the major research programs emanating from this plan, the Immune Tolerance Network (http://paramount.bsd.uchicago.edu/frameset.html). Leading investigators from more than 40 institutions in the U.S., Canada, Western Europe, and Australia are participating in the design and evaluation of clinical trials of tolerance induction therapies for autoimmune diseases, asthma and allergic diseases, kidney transplantation, and islet transplantation for type 1 diabetes. In the six months since the inception of this major clinical research program, the Network has initiated the development of clinical trials for a variety of immune-mediated disorders, including islet transplantation for systemic lupus erythematosus, and multiple sclerosis. The Network is also implementing a study to assess the immune status of kidney transplant recipients who have voluntarily discontinued immunosuppressive therapy yet maintained a functioning transplant over long periods of time. Network-supported scientists are also designing studies of several approaches to measure the induction, maintenance, and loss of tolerance in humans in conjunction with these clinical trials. Examples include the use of new biotechnologies, such as the complementary "gene chip" microarray technology, which will profile changes in gene expression associated with tolerance induction therapies, and the ELISPOTR assay that will enable scientists to analyze the expression of immunomodulatory proteins during treatment with tolerogenic therapies. In order to stimulate new insights that will lead to wider application of tolerogenic approaches, all Network-supported clinical trials will include studies of the underlying mechanisms of immune regulation as an integral part of the protocols.

The NIDDK, with the NIAID and the National Institute of Child Health and Human Development (NICHD), is cosponsoring a clinical trial to test the ability of subcutaneous or oral insulin by inducing immune tolerance to prevent or delay the development of type 1 diabetes in relatives of patients with the disease who are at risk for development of the disease in the next five years. The JDFI and the American Diabetes Association are also sponsoring this multi-center, nationwide trial.

The program, Human Islet Transplantation into Humans, will support clinical studies using new methods to induce immune tolerance, to prevent reoccurrence of the autoimmune destruction of beta cells in the islet, and to prevent transplant rejection. The NIDDK, the NIAID, and the JDFI support this program.

Immune Modulation.—Traditional immunosuppressive and cytotoxic therapies used to treat autoimmune diseases have many serious side effects, including a decreased ability to fight infection, tissue and bone fragility, and malignancy. In contrast, immunomodulatory approaches seek to modify immune injurious responses without the need for global immunosuppression. Examples include recently approved drugs that target the tumor necrosis factor, an important mediator of inflammation in rheumatoid arthritis and inflammatory bowel disease. This targeted approach appears to be more potent and less toxic than the use of cytotoxic agents or cortocosteroids in treating these disorders.

In fiscal year 1999, the NIAID, with co-sponsorship of the NIDDK, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the Office of Research on Women's Health (ORWH) of the National Institutes of Health, established the Autoimmunity Centers of Excellence to design and conduct pilot clinical trials of the safety and potential efficacy of new strategies for immune modulation in multiple autoimmune diseases. Three clinical trials of promising approaches are under development: prevention of kidney damage in systemic lupus erythematosus through interruption of a specific immune pathway, the complement pathway; induction of remissions in systemic lupus erythematosus through removal of a specific immune cell, the B cell; and prevention of the development of autoantibodies in children at risk for type 1 diabetes through the use of insulin. These Centers will also conduct pilot clinical trials of tolerance induction strategies and provide important safety and efficacy data for further evaluation by the Immune Tolerance Network.

Another new research program will focus, in part, on the development of novel treatments for the many rare immune-mediated diseases, some of which affect less than 200,000 people. NIH support in this area is particularly important due to limited industrial interest in diseases with a small market potential. A fiscal year 2000 NIAID research initiative, Clinical Trials and Clinical Markers of Immune System Diseases, will support the testing of new therapeutic approaches for certain rare immune-mediated disorders, including primary immunodeficiency diseases and autoimmune diseases. Under this initiative, the development of new biological markers and surrogate endpoints to measure disease risk, activity, stage, and therapeutic re-

sponse will be encouraged. The availability of specific and easily measured biological markers will facilitate the design and evaluation of new therapeutic strategies.

In fiscal year 1998, the NIAID initiated a program called the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials to support investigator-initiated research applications for mechanistic studies to be conducted in conjunction with clinical trials for immune-mediated diseases. The applications focus on utilization of patient samples to define: mechanisms of disease pathogenesis; immunological mechanisms underlying the clinical intervention; and surrogate/biomarkers markers of disease activity and therapeutic effect. The "parent" or "core" clinical trial must have independent financial support, either from industry, private foundations, or a federal agency. This program, cosponsored by the National Institute on Aging (NIA), NIAMS, NIDDK, the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Neurological Disorders and Stroke (NINDS), and the ORWH, has been highly successful. In the 18 months since its inception, the NIH has received 29 applications and funded eight projects in autoimmune diseases, allergy and asthma, and transplantation in collaboration with six industry partners. Through a number of steps to expedite peer review and award, applications are accepted monthly and awards are made within 13 weeks of receipt.

In fiscal year 2000, the NIDDK, the NIAID, and the NICHD will begin a new program, New Strategies for the Treatment of Type 1 Diabetes, supporting clinical studies to test new approaches to treat type 1 diabetes, including studies of immunomodulation.

Other Therapeutic Approaches—Another approach to the treatment of immune-mediated diseases involves "replacing" the immune system through transplantation of hematopoietic stem cells. In many cases, the patient's own stem cells are used to ensure that the transplanted cells do not react against the body's own tissues. Stem cell transplantation is currently being used for the treatment of several autoimmune diseases, and anecdotal reports suggest that this approach holds promise for inducing remission or decreasing disease severity. However, well-controlled clinical trials of efficacy have not yet been conducted. Therefore, in fiscal year 1999, the NIAID implemented a research initiative, Stem Cell Transplantation for Autoimmune Diseases, to design and conduct rigorous clinical trials of the safety and efficacy of this new therapeutic strategy.

In fiscal year 1999, the research initiative, Pilot Clinical Trials on Innovative Therapies for Rheumatic and Skin Diseases, was implemented under the leadership of the NIAMS to develop innovative therapies for the treatment of rheumatic and skin diseases. Awards were made for research on Wegener's granulomatosis, rheumatoid arthritis, scleroderma, systemic lupus erythematosus, and ankylosing spondylitis.

In fiscal year 1999, the NHLBI began an investigator-initiated clinical trial of Cyclophosphamide in the treatment of the pulmonary fibrosis associated with systemic sclerosis. In systemic sclerosis, interstitial pulmonary fibrosis is frequent (80 percent) and is now the leading cause of death. The mortality rate of patients with impaired pulmonary function is 40–45 percent within 10 years of onset. Uncontrolled studies suggest that cyclophosphamide may stabilize or improve lung function in systemic sclerosis patients. The study is a five-year, 13-center, parallel-group, double-blind, randomized, controlled, phase III clinical trial of oral cyclophosphamide versus placebo to assess the efficacy of cyclophosphamide in stabilizing or improving the course of pulmonary disease in scleroderma. NIAMS also contributes to the support of this study.

In fiscal year 2000, the NIDDK with the NIAID and the JDFI will sponsor new Diabetes Centers of Excellence to support basic research into the pathogenesis of type 1 diabetes and to develop new therapeutic approaches to this autoimmune disease.

Question. How does NIH intend to increase coordination of research on the family of autoimmune diseases?

Answer. In fiscal year 1998, both the Senate and the House Appropriations Committee Reports addressed the importance of coordination of NIH-supported research activities relating to autoimmune diseases. The NIH recognized the need for coordination and collaboration in this area and in fiscal year 1998 established the Autoimmune Diseases Coordinating Committee under the direction of the NIAID. Twenty-two NIH Institutes, Centers, and Offices, the U.S. Food and Drug Administration, the Veterans Administration, the Centers for Disease Control and Prevention, and private organizations that sponsor research in this area are represented on the Committee. Some of the private organizations include the Juvenile Diabetes Foundation International, the Arthritis Foundation, the National Multiple Sclerosis Society, the Systemic Lupus Erythematosus Foundation, the Sjogren's Foundation, and the American Autoimmune Related Diseases Association.

Since its initial meeting in June 1998, the Committee has collected and analyzed information on current research activities and funding levels and established multi-Institute collaborative working groups in areas of common interest and relevance to multiple autoimmune diseases. In addition, the Committee's efforts have facilitated a variety of other activities to further enhance coordination of research and increase partnerships between public and private organizations. Examples include:

—Extensive collaboration among many NIH Institutes, Centers, and Offices in planning and cosponsoring several new research initiatives in fiscal year 1999;
—Establishment of public-private research partnerships between the NIH and the Juvenile Diabetes Foundation International, the Arthritis Foundation, and the Crohn's and Colitis Foundation of America;
—Cosponsorship of workshops and scientific symposia by the NIH, the Juvenile Diabetes Foundation International, the Arthritis Foundation, and the Crohn's and Colitis Foundation of America;
—Participation of NIH staff in scientific planning activities of non-Federal organizations, such as the National Multiple Sclerosis Society, the Alliance for Lupus Research, and the Juvenile Diabetes Foundation International.

The Autoimmune Diseases Coordinating Committee was instrumental in the development, coordination, and implementation of several new initiatives in fiscal year 1999. The guiding principles of this planning process included an emphasis on: cross-disciplinary research addressing multiple autoimmune diseases; support for a mechanism-based approach, encompassing fundamental investigations of disease pathogenesis and clinical trials involving new diagnostic and therapeutic approaches; and selected research programs focusing on specific diseases, new technologies, and/or extraordinary scientific opportunities.

Several new trans-NIH initiatives emerged from this process, and nine previously planned activities in later stages of development received increased support. Support was provided for the following initiatives, the majority of which involved joint sponsorship by multiple NIH components:

—New Imaging Technologies in Autoimmune Diseases
—Environment/Infection/Gene Interaction in Autoimmune Diseases
—Autoimmunity Centers of Excellence
—Multiple Autoimmune Disease Genetics Consortium
—Target Organ Damage in Autoimmune Disease
—Stem Cell Transplantation for Treatment of Autoimmune Diseases
—Immune Tolerance Network
—Non-human Primate Transplantation Tolerance Cooperative Study Group
—Human Immunology Centers of Excellence
—Clinical Trials and Clinical Markers for Immunologic Diseases
—Rat Autoimmune Disease Genetic Resource
—Rat Autoimmune Model Repository
—Pilot Trials on Innovative Therapies for Rheumatic and Skin Diseases
—Immunological Phenotyping of Mouse Mutants
—Human Rheumatic Diseases Registries
—Hyperaccelerated Award/Mechanisms in Immune Disease Trials
—Rheumatic Diseases Registries

In November 1999, the Autoimmune Diseases Coordinating Committee established Collaborative Working Groups to encourage NIH, other federal agencies, and private organizations to prospectively develop jointly sponsored initiatives in areas of overlapping interest. Several initiatives are likely to be published in the coming year from this collaborative process.

The major challenges facing autoimmune diseases research today are the: development of a mechanism-based, conceptual understanding of autoimmune disease; translation of this knowledge into new, broadly applicable strategies for treatment and prevention of multiple diseases; and development of sensitive tools for early and definitive diagnosis, disease staging, and identification of at-risk individuals. Through the collaborative programs outlined above, NIH-supported scientists are vigorously pursuing these goals.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

EPILEPSY

Question. Dr. Fischbach, I am very pleased that today NINDS is sponsoring a conference on curing epilepsy. I am hopeful that the discussions at the conference will lead to a clearer strategy for research into this debilitating disease. With that goal in mind, I have several questions:

—Report language last year discussed curing epilepsy, not just finding new treatments for it. What is NINDS doing differently to change its focus from finding new treatments to finding a cure to stop epilepsy dead in its tracks?

—What is NINDS's strategy for focusing on the population with intractable epilepsy?

Answer. Our approach to curing epilepsy is reflected in the title of a major, White House-initiated conference we sponsored last month—"Curing Epilepsy: Focus on the Future." In light of recent science advances, and with the enthusiastic support of the research and patient communities, we are defining "cure" as the prevention of epilepsy before it occurs in people at risk, and the total elimination of seizures without treatment side effects in those who develop the disease. Our approach is threefold. We want to pursue innovative approaches to medical treatment, including the identification of new targets for drugs and new methods such as high throughput screening to identify useful medicines. We want to improve existing surgical treatments and develop new ones aimed at modifying the circuitry of the brain and take advantage of new methods such as various types of stimulation to prevent or interrupt the destructive cascade of seizure activity. And we want to harness the power of genomic information to understand how the mutant genes responsible for many forms of epilepsy lead to disease so that we can identify ways to prevent or reverse that process.

"Intractable epilepsy" is a term that we hope will become obsolete as our research strategies bear additional fruit. The approach I have just outlined for epilepsy in general is really the same we hope to apply to those for whom existing treatments have failed—better drugs, more effective surgery, and application of what we already know and expect to learn about the role of genes in epilepsy.

ALZHEIMER'S DISEASE

Question. It is my understanding that some research has shown that Alzheimer's Disease begins to destroy the brain cells of its victims 10 to 20 years before outward symptoms appear. Do we currently have the tools to diagnose Alzheimer's Disease in its earliest stages and, if not, what research is being done to develop that capability?

Answer. Alzheimer's disease (AD) is a degenerative disorder of the central nervous system where neuropathological changes may begin several decades before the disease is recognized clinically. Therefore, the most cost-effective therapies will prevent the onset of AD before it ever manifests itself clinically. These preventative therapies can only be developed if we can understand and predict the initial stages and events in the brain that lead to the development of AD.

Targeting early pathological processes necessitates development of biochemical, neuropsychological, neuroimaging and genetic markers that are sufficiently sensitive and accurate to identify at-risk individuals along the spectrum from normal aging through mild cognitive impairment (MCI) (a condition characterized by memory deficit without dementia) to AD. Most recently, diagnostic research has focused on people with MCI. These people are at increased risk of developing AD since 15–20 percent annually convert to AD versus 1–2 percent in the general population over the age of 65. A number of ongoing imaging studies are evaluating persons who exhibit early pre-clinical or clinical signs of AD and comparing their neuroimaging and biochemical measures to those of older individuals who are not cognitively impaired in an attempt to identify the earliest biochemical and imaging markers that distinguish AD from normal age-related changes.

Current neuroimaging studies are assessing whether it is possible to measure aspects of brain function and/or structure to identify individuals who are at-risk for AD before they develop the symptoms of the disease. Structural and functional imaging have been shown to be useful in identifying diagnostic markers of AD; however, in the past, most imaging studies have been cross-sectional and designed to demonstrate differences between older controls and patients who were already demented. Recently published research has conducted magnetic resonance imaging (MRI) studies in longitudinally followed individuals diagnosed with MCI who were at increased risk of AD. The studies measured two areas of the temporal lobe of the brain, the hippocampus and the entorhinal cortex, because these brain structures play a central role in memory function and are the sites of the earliest pathology in AD. The studies found that in older individuals with MCI, hippocampal and entorhinal cortex atrophy were predictive of an increased risk of subsequent conversion to AD; that is, the smaller the brain volumes, the greater the risk. The implication of these studies is that it may be possible to identify people who are beginning to develop the brain structural changes associated with the disease prior to the clinical diagnosis of AD.

Recognition and characterization of brain changes prior to the clinical symptoms or diagnosis of AD has important implications for improving the timing and effectiveness of interventions. If diagnostic procedures can be developed to detect early changes in the brain, it may be possible to develop treatments that will stop the neuropathological and biochemical lesions of AD before clinical deterioration begins.

Improved diagnosis of AD could also improve the design of drug trials. Focusing drug trials on persons at highest risk for disease is more efficient and less costly, and, among highest risk persons with minimal or no clinical symptoms, has the added benefit of testing the effectiveness of preventing progression of symptoms to a clinical diagnosis of AD. Finally, earlier and more accurate diagnosis provides patients and families important information allowing them to better plan for future care needs and management of their personal affairs.

DUCHENNE MUSCULAR DYSTROPHY

Question. As you know, 1 in 3,500 boys worldwide will be stricken with Duchenne Muscular Dystrophy, the most common fatal childhood genetic disease. There is no treatment. Each day, two boys in the United States die from this disease. After hearing the stories of these boys, I am very concerned about the lack of research being done at NIH on Duchenne and Becker Muscular Dystrophy—as well as on neuromuscular disorders generally. The dystrophin gene was discovered through NINDS-sponsored research in 1987; yet no new treatments have emerged. In 1999, less than 1 percent of NIH funds were spent on over 40 different forms of neuromuscular disorders.

It is my understanding that there are currently only 17 active research grants for muscular dystrophy research. Do you believe that is sufficient? What is NIAMS doing to encourage and fund more research grants in this area?

Answer. The NIAMS, together with the National Institute of Neurological Disorders and Stroke (NINDS), considers research on the muscular dystrophies to be a priority area. We will continue to work with the extramural muscular dystrophy research community, as well as interested patient organizations, to stimulate and support promising studies in this area. In fiscal year 1999, the NIAMS invested nearly $5.4 million in muscular dystrophy projects, an increase of over 40 percent from the previous fiscal year.

A number of exciting studies with implications for our understanding of the muscular dystrophies have been supported by the NIAMS in recent years. One such investigation used gene therapy to restore muscle function in a hamster model of limb-girdle muscular dystrophy (LGMD). In another NIAMS-funded study, researchers successfully used the common antibiotic gentamicin to restore the function of the gene that encodes for the protein dystrophin in mouse models of Duchenne muscular dystrophy (DMD). In a third project, NIAMS-supported researchers used gene therapy in mice to give the body a boost in fighting the effects of aging on muscle, and to help repair the damage caused by injury and muscle-wasting disorders such as muscular dystrophy. These projects underscore the potential of treating human forms of LGMD, DMD and other muscular dystrophies with gene therapy approaches.

Another area of excitement relates to a new protocol developed with support from the NIAMS that makes it possible to obtain an almost unlimited number of a special class of adult stem cells from a small sample of bone marrow. These adult stem cells have the ability to develop into cells of muscle, nerve, bone, cartilage and fat. Because of their vast potential for differentiation, they may be excellent therapy vectors for a number of skeletal diseases, including muscular dystrophy.

Next month, the NIAMS—in partnership with the NINDS and the NIH Office of Rare Diseases—will support two research meetings on muscular dystrophy. The first is an international scientific conference centered on clinical and molecular studies of facioscapulohumeral dystrophy (FSHD). The meeting will bring together researchers who are already involved in FSHD projects, as well as scientists who are working in related fields and may be able to contribute to progress on FSHD. The second meeting will focus on therapeutic approaches for DMD. This workshop is aimed at addressing key questions in improving treatments for DMD, identifying areas of needed scientific knowledge, and critical next steps to promote effective therapy. The NIH expects to build on the insights from these two meetings to develop new program initiatives related to the muscular dystrophies. Such initiatives would complement on-going efforts to stimulate research in this area, including the currently active program announcement on the pathogenesis and therapies of the muscular dystrophies.

Question. What, if any, coordinated strategy exists between NIAMS and NINDS to focus research on Duchenne and integrate scientific discoveries from related re-

search? Would a consensus conference on Duchenne/Becker Dystrophies be beneficial in creating that focus?

Answer. NIAMS and NINDS share the lead for Duchenne/Becker muscular dystrophy research. NIAMS brings to this role a perspective as the lead institute for basic studies of muscle biology and most muscle diseases. NINDS leads in the study of the many neurological disorders that affect neuromuscular control. Since the discovery of the muscular dystrophies, neurologists have played a major role in diagnosis and care of children and in research on these disorders. Interactions among medical professionals from several disciplines are increasingly important in studying and treating the muscular dystrophies, and the involvement of several components of NIH in muscular dystrophy research reflects this.

Some have expressed concern that no single component of NIH is responsible for all muscular dystrophy research. The division of responsibilities for muscular dystrophy research among components of NIH reflects the biological complexities of the disease, and there are substantial benefits from bringing a coordinated approach from multiple perspectives focused on muscular dystrophy. This issue in general is an important one for NIH. Biology does not abide by administrative divisions. Most disorders, including the muscular dystrophies, affect many aspects of physiology, benefit from a wide range of fundamental biological research, and require that we explore diverse strategies for treatment. It is therefore essential to bring to bear expertise and resources from all parts of NIH, as appropriate. The need for coordination is very real, and we must be vigilant. For muscular dystrophy, NIAMS and NINDS together take the lead and have initiated joint solicitations, scientific workshops and other activities, involving other components of NIH.

As noted earlier, the NIAMS and NINDS are presently partnering with the NIH Office of Rare Diseases to sponsor a workshop on therapeutic approaches for DMD. A number of scientific questions will be explored at this meeting with the goal of moving currently studied therapies toward human trials. Institute staff have worked closely with the DMD research community, as well as patient advocates, to develop the agenda for this workshop. At present, an NIH consensus conference on DMD may be premature—as the primary goal of such conferences is to develop a report evaluating state-of-the-art scientific information on a given biomedical technology with the purpose of resolving a particular controversial issue in clinical practice. However, it is our expectation that the meeting we are sponsoring this spring on DMD will provide an important focus for new approaches to this disorder, and will serve as the basis for future programmatic efforts.

Question. Concerns have been raised that there is no separate study section for muscle biology within any of the institutes of NIH. Why is this the case? Do you believe the NIH is properly organized to evaluate and coordinate muscle biology-related research—specifically related to Duchenne/Becker Muscular Dystrophy?

Answer. The NIH Center for Scientific Review (CSR), which conducts the peer review process, is currently involved in a comprehensive assessment of its study section structure, led by Dr. Bruce Alberts, the President of the National Academy of Sciences. The purpose of this assessment is to ensure that CSR provides a rigorous, unbiased review system that facilitates the advance of all areas of biomedical research, including muscle biology. Indeed, muscle disease review issues are being considered as part of the assessment. CSR will also be meeting with scientists at the Duchenne muscular dystrophy workshop in May to discuss this and other review concerns. The outcome of these discussions will help guide future decisions about the review of muscle-related research grant applications.

There is no simple answer to the question of whether a dedicated study section would enhance the success of muscular dystrophy research applications or otherwise improve coordination of muscle-related research. It is important to consider that the NIH receives a broad range of research applications on muscle functioning and disease, and diverse areas of scientific expertise are required to review those applications. Whether it is desirable—or, indeed, even feasible—to cluster all muscle research proposals into a single study section is one of the questions being explored by the CSR assessment described above.

DIABETES RESEARCH

Question. Over 175,000 adults in Wisconsin were diagnosed with diabetes in 1996. In addition to the physical and life-threatening complications diabetes sufferers face, the costs of diabetes in Wisconsin total nearly $2.3 billion annually.

I realize that funds for trans-NIH diabetes research are estimated to increase by 15.7 percent in fiscal year 2000, with a 14.7 percent increase for NIH overall. In recent years, NIH has recommended to Congress allocations among institutes that generally spread the funding increase evenly among Institutes.

Do you think that across-the-board allocations adequately fund all new scientific opportunities equally? How does this across-the-board approach square with the assertion by NIH that allocations should be made on the basis of scientific opportunity, the greatest need, and the greatest potential for breakthroughs?

Answer. NIH recommendations to Congress regarding allocations to the Institutes and Centers (ICs) vary each year to reflect many factors and consultations. The NIH solicits advice from a large number of individuals and groups, including the members of the scientific community, patient advocacy groups, Congress, the Administration, and NIH staff. Each IC convenes meetings of its national advisory council or board to review a broad range of policies and sponsors many workshops and conferences to gather opinions on specific areas of science. The efforts of the ICs to seek external advice are further augmented by those of the NIH Director through meetings of the Advisory Committee to the Director and the Council of Public Representatives.

Also, last year, for the first time, the NIH held a Budget Retreat to develop its research priorities and to establish areas of research emphasis in preparation of the President's 2001 budget. Retreat participants included ten external advisors in addition to the NIH and IC leadership. As reflected in the fiscal year 2001 budget request, proposed increases by IC range from 10.8 percent for the Fogarty International Center to 3.3 percent for the National Institute on Nursing Research.

The final fiscal year 2000 appropriation, incorporating NIH recommendations, also provided a range of funding levels across the NIH. Increases ranged from 36.6 percent for the newly-established National Center for Alternative Medicine, to 14.4 percent for the National Institute of Diabetes and Digestive and Kidney Diseases, with other ICs receiving an increase in the range of 12–13 percent. By any measure, the amount the NIDDK received in fiscal year 2000 was substantial and unprecedented and will allow a major commitment of resources to new diabetes initiatives. We will increase our diabetes research efforts by over 17 percent—more than two percentage points over the fiscal year 2000 increase provided to the NIDDK as a whole. This increase will permit new and significantly expanded research on type 1 and type 2 diabetes and diabetes complications. Some examples include: expanded support for studies of islet transplantation in humans, including support of six new research projects and the establishment of an islet transplant registry; increased support of the type 2 diabetes genetic linkage consortium; identifying and characterizing the genes involved in pancreatic endocrine development and function; funding of two new Diabetes Endocrinology Research Centers; novel approaches to imaging functional islet beta cells; understanding and combating the increase of type 2 diabetes in children, especially from minority groups; approaches to diabetic foot complications—a major cause of amputations particularly affecting minority populations; studies of the cause and treatment of diabetic neurologic complications; and, together with the NHLBI, support of two major clinical trials relating to cardiovascular complications of diabetes.

Question. Can you tell us how you plan to allocate the increases you have been receiving as a result of Congress' commitment to doubling NIH spending overall? For example, what will be the breakdown of expenditures applied to existing programs and research projects, compared to money provided to exciting new research initiatives identified by the Diabetes Research Working Group (DRWG)?

Answer. Over 70 percent of our approximate $150 million increase over fiscal year 1999 will be used to meet commitments for non-competing continuations in fiscal year 2000. Much of the remaining fiscal year 2000 increase will be directed toward congressional emphases in diabetes and prostate disease. We are making a major commitment of resources to new diabetes initiatives, by increasing our diabetes research efforts by over 17 percent—more than two percentage points over the 15 percent increase provided to the NIDDK as a whole.

The increase provided to NIDDK in fiscal year 2000 will permit new and significantly expanded research on type 1 and type 2 diabetes and on diabetes complications. Some examples include: expanded support for studies of islet transplantation in humans, including support of six new research projects and the establishment of an islet transplant registry; increased support of the type 2 diabetes genetic linkage consortium; identifying and characterizing the genes involved in pancreatic endocrine development and function; funding of two new Diabetes Endocrinology Research Centers; novel approaches to imaging functional islet beta cells; understanding and combating the increase of type 2 diabetes in children, especially from minority groups; approaches to diabetic foot complications—a major cause of amputations particularly affecting minority populations; studies of the cause and treatment of diabetic neurologic complications; and, together with the NHLBI, support of two major clinical trials relating to cardiovascular complications of diabetes.

Question. What amount of funds would it take for the NIDDK to fully implement its share of the recommendations of the DRWG? Can you find the money to meet the DRWG recommendations in the context of a doubling of the overall NIH budget if NIDDK is generally increased by the same percent as the overall NIH increase each year, give or take a percent?

Answer. The DRWG Strategic Plan made both scientific and funding recommendations for fiscal year 2000 through fiscal year 2004 for each Institute and Center of the NIH, as well as for the NIH as a whole. For the NIDDK specifically, the DRWG recommended that diabetes research funding reach $501.1 million in fiscal year 2000; $654.8 million in fiscal year 2001; and continue to rise to $989.7 million in fiscal year 2004. For the entire NIH, the DRWG recommended that diabetes research funding reach $827 million in fiscal year 2000; $1.074 billion in fiscal year 2001; and continue to rise to $1.6 billion by fiscal year 2004.

Diabetes research is receiving significant funding increases across the NIH—rising from a funding level of $457.6 million in fiscal year 1999, to an estimated $525.1 million in fiscal year 2000 and an estimated $561 million for fiscal year 2001. However, the NIDDK cannot fully implement all of the recommendations of the DRWG, even in the context of a doubling of the NIH budget, assuming that its percentage funding increase generally matches the overall percentage increase for the NIH proper. In fiscal year 2000, for example, even if the NIDDK had been able to apply the entirety of its funding increase of $150 million to diabetes research, it would still have fallen substantially short of the target funding level of $501.1 million set for it by the DRWG.

The five-year funding trajectory recommended by the DRWG for NIDDK and NIH diabetes research, respectively, would represent an increase in excess of 3.5 times fiscal year 1999 funding levels. Thus, even if its budget doubled in five years, it would not be possible for the NIDDK to implement all of the DRWG recommendations in the time frame specified without seriously harming research programs on other diseases of national concern that are within the NIDDK's research responsibilities—and the DRWG itself recommended against the diversion of funds from other programs.

Question. Can you give us your opinion of the DRWG report? To what extent do you agree that it provides a serious outline for the direction in which our diabetes research portfolio ought to go?

Answer. The Diabetes Research Working Group (DRWG) Strategic Plan serves as an important guidepost which the NIH is using to help frame its diabetes research agenda. The Strategic Plan represents a year-long deliberative planning process conducted by twelve eminent scientific leaders in diabetes research and four lay representatives, including representatives from both the Juvenile Diabetes Foundation International and the American Diabetes Association. The DRWG also solicited advice from many ad hoc scientific experts and public commentary. The Working Group evaluated all aspects of diabetes health issues, as well as the state-of-the-science, in an effort to develop a comprehensive plan. Thus, the recommendations of the DRWG Strategic Plan reflect the consensus of many talented scientists and concerned patients about the most promising avenues we can pursue to achieve greater understanding and more effective treatments for diabetes and to realize means to prevent and cure both forms of the disease and its complications. The NIH has already undertaken many new initiatives related to the extraordinary opportunities and special needs identified by the DRWG and will continue to use the DRWG Strategic Plan as a scientific framework for additional new initiatives in the years ahead, along with advice from our National Advisory Council and emerging scientific leads from conferences, workshops and other sources of external advice.

MULTIPLE MYELOMA

Question. As you well know, this committee and our colleagues in the House both addressed research for multiple myeloma in our respective reports last year. I especially want to thank the chairman of this committee, Senator Specter for his leadership on this issue.

It is my understanding that you decided to include multiple myeloma in next month's scheduled Progress Review Group (PRG) for leukemia and lymphoma. Will this, in your opinion, fulfill the intent of the report language requesting a consensus conference or scientific workshop on multiple myeloma? Do you think the PRG will fundamentally change the NCI's multiple myeloma research program?

Answer. The Leukemia, Lymphoma and Myeloma (LLM) PRG will be an excellent way to address the report language requesting a consensus conference/scientific workshop on multiple myeloma. It will undoubtedly have an impact on the direction

of NCI's myeloma research program. There are nevertheless some issues that need explanation:

The PRG process may be a more useful approach for scientific planning than either a consensus conference or a scientific workshop. Like a consensus conference, a PRG identifies a set of recommendations upon which all group members agree. However, a PRG goes well beyond a consensus conference by identifying research needs and opportunities that experts in the field agree are the most important. PRG participants do this by reviewing many research needs and opportunities and then prioritizing them. Consequently, a PRG also goes well beyond a scientific workshop, which also can involve a large number of participants but rarely results in a list of research priorities and recommendations.

In order that each of the three cancers receives sufficient attention during the PRG process, NCI has named three co-chairs, one for each cancer type. This arrangement will provide leadership for each cancer being reviewed by the PRG. In addition, NCI is committed to sufficient advocate participation throughout the PRG process. Clinical and scientific experts, however, will often have interests in more than one of these diseases, and therefore it makes sense to combine these cancers within one PRG .NCI is confidant that a combined PRG will have a great impact on the direction of the Institute's myeloma research program, since prior PRGs have resulted in substantial adjustments to the Institute's breast cancer and prostate cancer programs. It is likely that there will be some recommendations/actions that serve all three groups of cancers as well as some recommendations/actions that serve the unique needs of each disease and community.

The Leukemia, Lymphoma, Myeloma PRG is already well underway. The PRG leadership team will meet in June 2000 to select the PRG membership and to begin planning the PRG's agenda.

Question. Although multiple myeloma is a hematological cancer—according to NCI SEER data, it is the second fastest growing hematologic cancer in the United States—it's most obvious effects are in the bone destruction caused by the plasma tumors. Are there any plans to increase collaboration between NCI and NIAMS on the issue of bone disease and multiple myeloma?

Answer. NCI is currently collaborating with NIAMS in a multi-center epidemiologic study, entitled "Osteoporotic Fractures in Men (MR.OS)." A major goal of this study is to assess the relationships among risk factors of osteoporotic fractures and prostate cancer in older men (>65 years old). A total of 5,700 men will be recruited in six diverse geographical areas and will be followed for seven years. MR. OS will provide a unique perspective on prostate cancer occurrence influenced by the skeletal, hormonal, and lifestyle determinants associated with osteoporosis. Findings could provide avenues for additional research leading to preventive strategies for prostate cancer.

Another NCI-NIAMS collaboration involving studies of bone disease is the long-term support of the "Rochester Epidemiology Project" at the Mayo Foundation. Data have been collected during the past 34 years on the population of Rochester and Olmsted Counties, Minnesota, and several studies within the Project have published results on bone fractures associated with chronic disease and osteoporosis in the elderly. Investigators have also reported the incidence and trends in rates of multiple myeloma in Olmsted County during 1978 through 1990.

As scientific advances and new technologies increase research capabilities to explore associations between bone disease and multiple myeloma, the NCI and NIAMS look forward to collaborating in this endeavor.

Question. Does the NCI have any plans, or would it consider, establishing a working relationship with the CDC to develop more comprehensive epidemiological and occupational health statistics to support myeloma research activities?

Answer. NCI investigators currently collaborate with several investigators at the CDC on epidemiologic and surveillance studies of multiple myeloma and other hematopoietic malignancies. One study with CDC's National Center for Environmental Health, includes multiple myeloma and collects biological specimens needed to analyze occupational and environmental exposures in the general population. In another study, NCI investigators found a relationship between risk of multiple myeloma and exposure to solvents among workers at a U.S. Air Force base. NCI supports the continuation and expansion of collaborative activities with the CDC to explore and develop new methods and approaches to better understand the origins of multiple myeloma and the reasons for the unusually high rates in certain populations such as African-Americans.

NCI and the CDC have recently established a Memorandum of Understanding (MOU) for implementing an enhanced and more coordinated national cancer surveillance effort. NCI and CDC share a vision for a federally integrated comprehensive national cancer surveillance system. This system will build upon and strengthen the

existing infrastructure, improve the availability of high quality data used to measure the nation's cancer burden, and advance the capacity for surveillance research. The scope of this coordinated cancer surveillance system includes coverage of the entire U.S. population using high quality data to measure cancer risk and health behaviors, incidence, treatment, morbidity, mortality, and other outcomes. As leaders and catalysts in federal cancer control activities, NCI and CDC enter into this agreement to enhance cancer surveillance at national, state and regional levels. This includes developing ways of looking at each cancer site nationally. Geographic Information Systems (GIS) methodologies will enable researchers to link environmental exposures with unusually high occurrences of cancer on a geographic basis. The SEER registry and the CDC Cancer Surveillance System, especially working in collaboration, can help identify new hypotheses for causal studies in multiple myeloma.

In addition, the NCI coordinates and supports many epidemiological studies conducted intramurally and extramurally, on multiple myeloma and other lymphoproliferative diseases. Intramural investigators are collaborating with investigators participating in the SEER program in a large case-control study of non-Hodgkin's lymphoma to which a multiple myeloma component has recently been added. Under analysis is a multi-centered case-control study of multiple myeloma in blacks and whites in the United States. It is designed to identify the risk factors for this tumor. A new study linking total population registries, cancer registries, and hospitalizations for auto-immune diseases is in the planning phase in an effort to clarify the risk of familial occurrences of multiple myeloma and other hematopoietic malignancies. Also, analyses of existing case-control data are being conducted as novel occupational, geographic, and environmental hypotheses arise.

QUESTIONS SUBMITTED BY SENATOR BARBARA A. MIKULSKI

WORKPLACE ENVIRONMENT OF NIH'S OEO

Question. What is Acting NIH Director Dr. Ruth Kirschstein personally doing to address concerns about the workplace environment of the NIH Office of Equal Opportunity (OEO) and the OEO Director's treatment of OEO employees?

Answer. Dr. Kirschstein has been deeply concerned and personally involved in the issues related to the workplace environment of the NIH Office of Equal Opportunity (OEO). She has discussed these issues with all the persons involved and after such discussions did not appear to improve matters, she assigned the NIH Ombudsman the task of resolving the issue. The Ombudsman with the services of a mediator, experienced in this area, developed a process of a series of meetings, some separately with individual or groups of employees, at which they have had the opportunity to raise specific concerns privately and some separately with the Director, OEO. In addition, the two mediators have held joint meetings between the employees and the Director, OEO, at which views were exchanged. It has become clear that the issues of which you are aware, raised by some OEO employees do not represent those of all OEO employees. Nevertheless, it is clear that the issues are real and must be and are being settled.

A good deal of progress has been made. The Director, OEO has been responsive to the concerns raised by the employees, and has undertaken certain necessary steps to address the most pressing matters. In addition, the NIH has resolved the specific concerns of two OEO employees, and has entered into agreements with them that fully satisfy their concerns. Other actions are in progress and we are optimistic that a satisfactory outcome will result.

MINORITY REPRESENTATION

Question. Please specify what specific steps NIH is taking to address the following items, providing specific timetables for actions that NIH will take to:

—ensure that NIH has sufficient representation at all levels of African Americans, Native Americans, Latinos/Hispanics, Asian Pacific Americans and how NIH Institute and Center Directors will be held accountable for meeting established goals (OEO)

—retain African Americans at NIH (OEO)

—improve the tenure rate of African American scientists at NIH (OIR)

Answer. While no Federal agency can legally assure that its actions will result in complete representation of all minority groups based on their availability in the work force, including persons with disabilities, many proactive steps are underway by the NIH to achieve a diverse organization. Under the auspices of the NIH Affirmative Action Planning Program (AAP), each Institute and Center (IC) has the flexibility to set annual hiring goals. Based on an annual analysis of underrepresenta-

tion that is conducted of the various occupational series, goals are then established, based upon projections of anticipated hiring need. Individually tailored recruitment strategies, necessary to address the specific underrepresented EEO groups within its organization, are targeted for each vacancy. At the end of each fiscal year, the ICs report their accomplishments.

IC recruitment strategies vary, according to the targeted audience and the vacancies under consideration. They may include the use of: Career Opportunity Training Agreements, the Student Temporary Employment Program, advertising of vacancies on the Internet, exhibits at conferences such as those of the Association of American Indian Physicians (AAIP), the American Council on Education, the American Indian Science and Engineering Society (AISES), the National Hispanic Medical Association, the Student National Medical Association, the Hispanic Association of Colleges and Universities (HACU), and the Society for the Advancement of Chicanos and Native Americans (SACNAS). Additional recruitment activities are held at other professional meetings as well, including those of the Mexican-American Engineers and Scientists (MAES), the Association of Minority Health Professions Symposium (AMHPS) on Careers in Biomedical Professions, the League of United Latin American Citizens, the National Council of LaRaza, and the National Black Nurses Association. Additionally, EEO Officers attend local career fairs at George Washington University, Morgan State University, University of Maryland-Baltimore Campus, and Bowie State University.

Responsibilities for Equal Employment Opportunity Programs are included as an integral part of managerial performance elements to establish accountability. The OEO guidance to IC Directors on specific areas for inclusion in their annual accomplishment reports, as required for SES managers, serves to maintain consistency across IC lines. All SES managers have a separate element which is reviewed by their respective IC Director. All IC Directors' annual accomplishments and accompanying proposed ratings are reviewed by a subgroup of the NIH Performance Review Board. The Director, OEO, is a voting member of that group. Additionally, the NIH requires a performance appraisal covering EEO Program accomplishments for supervisors and managers through the use of either the stand alone critical EEO performance element or an overall supervisory or management element that incorporates EEO responsibilities. An EEO Program element is also part of the annual Commissioned Corps performance review mechanism and is one of 18 critical elements that comprise an officer's annual rating.

In June 1999, the NIH established a Corporate Recruitment Task Force designed to develop global trans-NIH recruitment strategies including those needed to address barriers to minority representation in the NIH work force. Its members include IC EEO and Personnel Officers as well as Office of Equal Opportunity(OEO) staff members. Common goals include the development of a unified corporate approach to recruitment and related issues such as relocation matters, recruitment techniques, and targeted occupations common to all or most ICs. Implementation of the Task Force's objectives is scheduled to begin in fiscal year 2001.

The recruitment of minority and women scientists is extremely competitive both within the Federal government and private enterprise. NIH continues to use the pay flexibility provisions of Title 42 and Title 38 to attract candidates to the NIH campus. Additionally, the NIH AIDS Research, Clinical Research, and General Research Loan Repayment Programs are used as recruitment incentives for minority and women scientists. The NIH Undergraduate Scholarship Program offers competitive scholarships to students from disadvantaged backgrounds who are committed to careers in biomedical research. In 1999, 10 scholarships were awarded to African American (1), non-minority (4), Asian/Pacific Islander (1), and Hispanic (4) students.

To foster an environment that attracts and retains minority employees, the OEO sponsors Workforce Diversity Initiative (WDI) activities. These activities promote equal opportunity goals, engender respect for the similarities and differences that employees bring to the workplace and assist managers and supervisors in learning how to capitalize on those similarities and differences while promoting quality, fairness and efficiency. For example, the OEO sponsored an educational project entitled the "NIH Diversity Book Bridge Project." This project took a fresh approach of using literature as a tool to discuss diversity issues. Guidance is regularly provided to the IC Diversity Catalysts to supplement the Catalysts Implementation Manual which was designed to identify specific duties for the newly appointed Catalysts in the ICs. The OEO staff provided a second document, "Guidelines for OEO Diversity Program Managers" (DPMs), for the OEO staff in their role as consultants to the ICs in the implementation of the WDI. Sharing the guidelines on DPM roles with the ICs was meant to reinforce the value of developing long term strategies and processes to promote the WDI throughout the NIH. In November of 1999, Vice President Gore's Special Diversity Task Force recognized the NIH diversity process as a best practice,

referencing in particular, the unique appointing of Diversity Catalysts in each of the ICs. Some of the ICs have incorporated the Quality of Work Life Plans into their diversity initiatives as a method of creating a healthy work environment for employees.

The NIH is also deeply involved in several ongoing Departmental Minority Initiatives. For example, the employment aspects of the Departmental Hispanic Agenda for Action and other minority initiatives related to annual recruitment activities are addressed. During fiscal year 1999, there was a significant increase in the number of HACU interns as compared to the participation rate of 10 during the previous fiscal year. Total participation during fiscal year 1999 numbered 21: 7 during the Spring Semester and 14 during the Summer. There were 7 students enrolled in the Washington Internship for Native American Students (WINS) Program, and 10 African American interns from the National Association for Equal Opportunity in Higher Education (NAFEO) Program.

Data shows that NIH needs to continue its efforts to address the retention of African Americans, particularly African American males in the scientific occupations. Several years ago, an exit interview program was established and a questionnaire was administered to all employees leaving the Agency. Based on the low response rate to the questionnaire, however, the program was discontinued. Lacking the ability to clearly identify a pattern of the reasons employees left the NIH, other actions have been taken to try to improve the NIH work climate as much as possible. For example, the Center for Cooperative Resolution has been shown as an effective alternative to the traditional methods of conflict management. Headed by an Ombudsman, the Center regularly evaluates new approaches to conflict resolution and encourages employees to develop new and more effective ways to deal with issues they face in the workplace. The Center has addressed more than 400 cases with a resolution rate of better than 80 percent. The Center offers a variety of alternative dispute resolution processes, including facilitation, mediation, shuttle diplomacy, and systems change. Within the past year, the Center has begun other initiatives such as the implementation of a seminar series on conflict for executives, utilization of Peer Panels, as well as preparation of preliminary plans for partnering agreements for scientific collaborations. More and more employees are becoming informed of the availability of the Center from briefings, publicity, and its reputation for efficiency, confidentiality, and neutrality. At the same time, the Federal discrimination complaint processing mechanism is communicated to all employees who may wish to utilize its provisions in seeking redress of employment related concerns.

As reflected above, the objectives of the NIH AAP have served to identify and recruit minority members, women, and persons with disabilities into the work force. Once recruited, additional initiatives mentioned above, such as the WDI, have been taken to create and maintain a healthy work environment for employees.

Tenure at the NIH is granted to outstanding scientists who have made major contributions to biomedical research and includes both salary support and commitment of research resources subject to rigorous review every fouryears. Tenure differs from permanent appointment in a civil service position since it includes research support as well as salary. Tenure policy and procedures at NIH were completely revamped in 1993 with additional modifications made in 1996. A major intent of the new tenure policy was to provide equality of access and opportunity for all individuals qualified for tenure-track positions. Tenure-track positions are the principal point of entry for investigators to achieve tenure at the NIH. The specifics of the policy and procedures may be viewed at the following websites:

The Tenure-Track Program at http://www1.od.nih.gov/oir/sourcebook/irp-policy/tenure-track.htm

Tenure in the NIH Intramural Research Program—Modifications to Policy at http://www1.od.nih.gov/oir/sourcebook/irp-policy/tenure.htm

Search Process for Tenure and Tenure-Track Investigators at http://www1.od.nih.gov/oir/sourcebook/irp-policy/search.htm

All tenure-track positions are advertised nationally using an advertisement that must be approved by the Deputy Director for Intramural Research (DDIR). A Search Committee must be established for every tenure-track position that becomes available. The composition of the Search Committee must also be approved by the DDIR and each committee must have as voting members a scientist who is an under-represented minority, a woman scientist and a scientist selected by the DDIR to serve as his representative.

Despite these efforts to attract and recruit to NIH under-represented minority scientists, from January 1999 through March 2000, NIH hired a total of 34 tenure-track investigators, of whom 1 (2.9 percent) is African American. From January 1999 through March 2000, 34 total investigators successfully achieved tenure, of

whom 2 (5.9 percent) are African Americans. This number represents 100 percent of African American candidates considered for tenure.

To increase the pool of qualified candidates for tenure-track and tenured positions at the NIH, the NIH intramural program continues to increase efforts to attract under-represented minorities into research training programs early in their biomedical research careers, to provide training in biomedical research and to acquaint trainees with the career opportunities available at NIH. It is expected that research training opportunities such as the Summer Internship Program for high school, college and graduate students (http://www.training.nih.gov/student/internship/internship.asp), the Undergraduate Scholarship Program (UGSP) for undergraduate students from a disadvantaged background (http://ugsp.info.nih.gov/), the Postbaccalaureate Intramural Research Training Award for students that have obtained their Bachelor's degree and fully intend to pursue doctoral degrees in the biomedical sciences (http://www.training.nih.gov/student/Pre-IRTA/previewpostbac.asp), and the newly created NIH Academy for postbaccalaureates interested in domestic health disparities (http://www.training.nih.gov/student/Pre-IRTA/irtamanualpostbacAcademy.asp) will help increase the pipeline of under-represented minorities who can successfully compete for tenure-track and tenure positions at the NIH.

CONCLUSION OF HEARINGS

Senator SPECTER. Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 10:53 a.m., Thursday, March 30, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2001

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 HEALTH AND HUMAN SERVICES

GENERAL HEALTHCARE

PREPARED STATEMENT OF PERSONS UNITED LIMITING SUBSTANDARDS & ERRORS IN HEALTHCARE OF COLORADO

Mr. Chairman and Members of the Committee: Thank you for allowing me this opportunity to submit written testimony to request funding for public education to help reduce Medical Errors. As a consumer advocate, I feel that it is imperative to budget funding for public education, consumer Hotlines and an Federal agency that will oversee all state medical boards and create national standards of care that will be communicated to the consumer. It is ludicrous to believe that the many problems in the present system will be remedied anytime soon. Therefore, the consumer must know exactly what their responsibility is as an informed and savvy patient to reduce the incidence of medical errors.

I lost my mother in February of 1995 under similar circumstances to those that Debra Malone lost her father, Dr. Karl Shipman. A combination of inexperienced and overworked hospital nurses, an inept and arrogant physician, misdiagnosis and medication errors caused my mother to suffer a myocardial infarction as an inpatient. She was in a coma for seven weeks before she died. Had she presented at an emergency room with the same symptoms that were ignored on the floor, emergency protocol would have taken the necessary tests to determine what was going on and may have saved her life. I found it nearly impossible to get any answers, and was appalled to learn that what my mother experienced was common. Nothing was reported by anyone but myself and by my own perseverance. I did not sue, had I gone forward with a civil suit, Colorado tort reform laws would have limited any award or settlement to less than the cost of pursuing the case. I filed complaints with the medical and nursing boards. Both agencies initially dismissed my complaints. The nursing board dismissed the original complaints at a lunch. Several local nurses assisted me in preparing the original complaints. After the luncheon dismissal, I spoke with the nursing board administrator. She indicated that if one of the nurses who helped me write the complaints would simply write her a letter and sign it, she would reopen the complaints process. I asked the nurses to do this, they all refused. Having become an advocate and networking with other states advocacy groups, I found two out of state nurses with impeccable credentials willing to review the records. I did not know either of them, but they were both sympathetic to the cause and reviewed the records for free. Paying for the review would have hurt the credibility with the regulatory agency. Both nurse's letters said precisely what the local

nurses told me to include in the original complaints. The administrator did keep her word, an investigation was opened that resulted in disciplinary action for two of the three nurses I filed complaints on. It is disturbing that the outcome was based on the two out of state letters, not my original complaints. The medical board told me that they would reevaluate the physician complaint if I had a physician review the records. Unfortunately, I could not find one anywhere in the United States willing to do this for free.

Peer review should be reporting these things to the regulatory agencies, they are not. The regulatory agencies investigate nearly 100 percent of all peer review complaints filed. Sadly, the regulatory agencies dismiss the majority of all consumer complaints, without checking their validity. This is not due to lazy medical boards, it is another facet of the present ailing system of healthcare delivery.

In our society, most of us see our doctors as family. We seem to have a parent child like relationship with them. We hear stories of medical errors or problems, yet we feel that our own private physician has our care under total control and nothing like that could ever happen to us. We regard our doctor as a child regards a parent, the all knowing, all seeing omnipotent super hero who protects us from all adversity. Most medical errors that occur are far from the control of our private doctors. When we are exposed to the adversities, we become confused and angry. The present system as it now exists does not allow our personal physicians to communicate the entire story to us. We then lose faith, hope and trust, we search for answers and find none. It is then, and only then, that we seek out legal counsel, searching for answers, truth and justice. I cannot imagine how difficult it must be for our personal physicians to know that something went wrong, yet not be able to comfort us, nor have a place to report the incident without fearing the consequences of doing so. What agony it must be for our doctors. These physicians, like us, are victims of a severely impaired system that must change.

Medicine is not an exact science, yet we expect perfection, when we don't get perfection, we expect compensation. How puzzling it is that less than 2 percent of all victims of medical errors seek legal counsel, yet the fear of lawsuits barricades voluntary reporting of errors in medical care. Those who work inside of medicine are bound by this code of silence. The present system has the consumer under a false sense of security. The public must be told the absolute truth, yes, some will do without surgical procedures that they would have had not knowing the full risks. The public must be told when they are being treated by doctors in training, and that the risks of this lack of experience may be harmful to them. Yes, some will refrain. The public must be told at once when an error occurs, most victims would walk away with this simple explanation. But, it does not work that way. The threat of litigation prevents medical boards from doing their jobs effectively because they fear that their hard work will become free discovery for less then 2 percent of all incidents. It is a vicious cycle that leads to nowhere.

Imagine how plaintiffs feel years after the incident when their own attorney tells them to accept a modest out of court settlement, and sign a document prohibiting them from discussing the case indefinitely. Imagine how consumers feel when they read the release that they must sign that states that the defendants admit no guilt. These settlements are reported to the NPDB, but what good does it do for the peace of mind of the plaintiff? What good does it now do for future victims of the same incident when nothing is admitted?

Both the medical profession and the consumers are programmed to believe a lie, we have been sold a bill of goods that simply is not true. It is a no win situation for everyone involved. In Colorado, there have been only 63 plaintiff verdicts in medical malpractice cases in our courts in seventeen years. The odds of going to trial and winning are not in the favor of the plaintiff. Why?, because, when all is said and done, and the truth is finally forced, it is usually in favor of the provider, because, "Medicine is not an exact science, there will be adverse outcomes, and when a physician uses due care, diligence and does make a mistake, he or she is not accountable for it in civil court". Now, if this simple truth were told from the beginning, think of how much grief, anguish and suffering could be avoided, on all sides. That is what is wrong with the present system. It does not work, and as long as we allow this sham to go on, we are doing a grave injustice to society.

One member of our organization who lost her child because of poor medical care found out there was a previous board action against the doctor involved for using poor judgment in another death of a child. This physician was grossly overworked, seeing too many patients per day. She had taken her child to see this doctor several times a week before he died. At one point she took him to an emergency room and the other doctors "did not want to get involved". The doctor in question also missed important signs of trouble with several other patients. However, this physician also did a great deal of good for other patients. Our town, and our organization were

heavily spilt over the Medical Board's decision to suspend his license. This doctor was a victim too, a victim of a savage system that, even though local peer review knew of adverse outcomes that were preventable, they were silent and did not report them to the medical board, nor did anyone help this doctor with his patient load. The controversy and rumors surrounding this doctor was that he truly loved the children he was treating, he and his partner were the only ones in town who wanted to provide care for Medicaid children, other doctors sent Medicaid children to him. The local medical community made no effort to bring in other doctors interested in Medicaid reimbursements. Knowing that this doctor would be up all night at local hospitals with families of sick children, the local medical community did nothing when this doctor would barely have time to shave before returning to his office the following morning to see other children. How can someone deprived of sleep use good judgment? Yet, when the medical board suspended this man's license based on evidence that they had gathered from many consumer complaints, the medical community remained silent, some other doctors rallied around this doctor and encouraged him to not take responsibility for his mistakes. They allowed this to go on for so long and finally when the state attempted to intercede, the local medical community closed ranks, cried sour grapes, got political and told the state to stay out of local affairs. This made it very difficult for the board, the nurses and consumers who were brave enough to act. The doctor and the board came to an agreement where he will retire early, and of course, have a clean record. How will this effect future care by this provider in another state?

Why is it that only 2 percent of all consumers affected by medical errors seek legal counsel? Could it be that the rest of us tirelessly go from one attorney to another with our tales of grief but none seem interested in our cases? Not because we were attempting to file frivolous lawsuits but because the attorneys know the usual outcome of a trial. They know the high percentage of verdicts are found for the defendant, not the plaintiff. They know most settlements would barely cover court costs and fees, expert testimony etc.. The reason for this needless heartache for those who believe that they have already been violated or betrayed by medicine is this code of silence, the lack of an honest explanation when something goes terribly wrong. The time has come for the secrets of medicine to be shared with the consumer, in easy to understand language. All too often the elusive "standard of care" for a particular malady is virtually untouchable by the consumer until the case gets to trial in civil court. At that time "expert witnesses" explain to the non medical people of the jury what happened to the patient in plain terms. These explanations are why most doctors are found not guilty of medical malpractice in our nations courts. Only at this time are the errors or mistakes made public, yet most consumers know little about researching court documents. These errors again go unreported, instead of being addressed, usually get lost in the shuffle. Admitting the error from the beginning would have avoided the costly ordeal for both the plaintiff and the defendant.

If there were a National Patient Safety Board, designed much like the National Transportation Safety board, Federal standards would then be in place and any deviation from such standards would be addressed and dealt with for the sake of public safety.

Medical errors are at an all time high, people from all walks of life are affected. Things have gotten so out of control that medical errors resulting in preventable deaths now even touch the lives of physicians themselves. Inefficient health care delivery has become a way of life and must no longer be tolerated. Many providers ask how have things gotten this bad? In every other consumer related industry, there are standard safety guidelines, this is not true in medicine. It appears that if there are no real standards to follow, no consequences due to lackadaisical behavior, and no rewards for creating accountability and dealing with problems, why strive for excellence? We must then depend on pure conscience of the brave insiders who blow the whistle risking all, or others who learn through personal loss that things must change. Unfortunately, it is unrealistic to believe that this very small inside minority can police this huge and affluent industry.

Most of us are under a false blanket of security that civil justice and government agencies are our protectors. Nothing could be further from the truth. Colorado recently made it illegal for a physician to lie to the medical board in his confidential response to a complaint. Civil justice no longer exists, instead the remnants of what once may have once been civil justice, have been replaced by a great theatrical and costly fiasco that sucks everything from both sides of the case at hand. The medical industry does not own up freely to mistakes nor does it do anything to correct them, thus leaving the American people with the shadows of a long gone system of honor, truth and justice. Voluntary reporting of medical errors already exists, it has for a long time. Voluntary reporting of errors was the reason the National Practitioners

Data Bank was created. Why then did the IOM study reveal such startling results? Why do we want to reinvent the wheel? We must have mandatory reporting and public education to seek excellence.

Public education is the only way to help consumers be better patients and take more responsibility for our own healthcare. As is being pursued in other areas, there must be a national media campaign to educate consumers on taking more responsibility and not being so dependent on the healthcare system to take care of them. As early as in middle school, public education programs must begin, teaching individuals responsible receivership of healthcare. Monthly meetings for senior citizens could be taught in public places by volunteer health care providers. Consumers would be encouraged to learn from information already available on the illness or disease that they have been diagnosed with. All would be encouraged to ask questions. Hotlines would be established for questions and answers. All information on credentials will be available and providers would encourage consumers to use these resources. Public Service announcements on television would provide consumers with a toll free number and web site information for many rich resources already available for those of us of seek them out. All informed consent forms would be given to all scheduled surgical candidates a minimum of one week before surgery for review to insure the consumer knows exactly what they are signing. There would be a consumer advocate employed by the hospital or out patient facility to explain the consent form to anyone having questions. Consumers must do their part to insure safety in medicine. Providers must allow consumers to do this without offense.

Consumers must be taught how to better communicate with all providers. They must know more than they presently do about their own bodies, conditions, and illnesses. Consumers must know how to recognize an error in the making and personal physicians must be permitted to advocate for their patients when the patient is in a hospital situation. Consumers who are elderly or mentally impaired must have someone else available to advocate for them at all times. Excellence in medicine will come about only after crossing into a new frontier where physicians and consumers work together as a real team.

Thank you for allowing me to submit written testimony. I am available to testify before the committee if need be. I can supply you with additional documents and information upon request.

PREPARED STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION

On behalf of its 300,000 physician and medical student members, the American Medical Association (AMA) would like to share three of its most pressing concerns with the Administration's fiscal year 2001 budget proposal submitted to Congress on February 7, 2000. We hope that you will take our concerns into account and look forward to working with you as the Committee begins the appropriations process for the fiscal year 2001 budget.

USER FEES

Through its budget proposal, the Administration has once again proposed user fees for physicians who submit claims on behalf of their patients. As background, several years ago, Congress enacted legislation requiring that physicians treating Medicare patients submit these claims to the Medicare program on behalf of their patients. Congress has repeatedly rejected the Administration's attempts to shift Medicare program costs onto physicians through user fees. These user fees are nothing but a tax on the physician/provider community, and we urge you to again reject them once again.

First, the budget proposal would also tax physicians $1 for each paper claim submission. The Administration admitted last year that this would have impacted 21 percent of all Part B Medicare claims and 4 percent of Part A Medicare claims at a cost of $495 million over five years. This would be an extraordinary cost for physicians to bear simply because their offices have not been linked to an electronic network. This tax is especially unwarranted since many physicians may feel more comfortable submitting hard copies of claims to their carriers given the negative experiences that some physicians have had with their carriers and the issues surrounding confidentiality of patient records.

Second, the budget proposal would penalize physicians for resubmitting claims even when payment was seriously overdue or when the contractor had rejected the claim for trivial or inappropriate reasons. The AMA strongly objects to requiring a physician to pay to resubmit claims to the Medicare program.

The AMA believes that physicians are already bearing an extremely heavy regulatory burden, which increases exponentially as the Health Care Financing Admin-

istration (HCFA) issues each new Medicare billing requirement. Physicians should not have to bear the additional cost of administering the Medicare program through new and unjustified user fees.

PHYSICIAN EDUCATION EFFORTS

Several weeks ago, the Department of Health and Human Services Office of the Inspector General (OIG) released the latest version of the Chief Financial Officer (CFO) audit. The audit and its resulting rhetoric refocused attention on billing and alleged fraudulent activities in the Medicare program. However, by OIG's own admission, auditors have not been able to separate inadvertent billing errors from fraud. The CFO audit includes all types of improper payments including inadvertent billing errors, which may involve subjective decisions open to honest disagreement. According to the OIG's own spokesperson, "We don't know how much Medicare fraud there is." (Washington Times, 3/11/00) The AMA has been asking since the inception of the audit for details regarding types of billing problems uncovered related to specialty, geographic region, and particular coding issues so that we could educate our members on the issues uncovered. The AMA has never been able to obtain such information.

We urge the federal government and the Congress to stop using such a broad-brush approach and to start being more precise with its language and its responses to these numbers. Since the advent of the first CFO audit, Congress and the Administration have emphasized enforcement as the way to eliminate inadvertent billing errors from the Medicare program. The AMA urges policymakers to begin to focus on prevention and to start implementing effective and innovative education programs for physicians. Physicians want to comply with Medicare billing regulations, and the AMA believes that federal resources should be devoted to supporting extensive education efforts for physicians.

The AMA has advocated to implement systematic reforms in situations when a carrier identifies a widespread billing problem in a physician community. The AMA has asked HCFA to require the carriers to work with the appropriate medical state and specialty societies to educate physicians about a billing problem and to help them understand how to address it in the future. We would also like to see HCFA implement education efforts for individual physicians when the carrier identifies that a physician has a billing problem. Physicians overwhelmingly agree that physician-specific education in the field is not occurring.

The AMA believes that HCFA's current education efforts present overly general directions that fail to aid individual physicians in learning specific Medicare coding and billing requirements. The AMA strongly urges the Appropriations Committee to specify that HCFA and its carriers will conduct general physician education and provide education specific to coding and billing procedures that are encountered during pre and post payment audits. The AMA also believes that the Committee should require HCFA to use the billing errors identified in the most recent CFO audit to carry out billing and coding education efforts.

The Administration has proposed in its fiscal year 2001 budget to allocate $15.8 million in funding for Provider Education and Training out of a total Medicare contractor budget of $1.3 billion. The funding level for provider education and training in fiscal year 2000 was also $15.8 million. This funding level, which represents approximately one percent of the carriers' budget, is woefully inadequate to ensure that physicians and health care providers learn about new changes to Medicare laws and billing and coding requirements. The AMA urges the Committee to significantly increase funding for physician/provider education to ensure that fewer widespread and physician specific billing errors occur and that the relationship between HCFA and physicians becomes less adversarial.

TOLL FREE LINES

The Administration has eliminated funding for two types of toll-free lines during the past several years. The first type of toll-free lines allowed physicians to call their local carrier for answers to billing and coding questions regarding Medicare claims submissions. This "penny-wise pound-foolish" approach to the Medicare contractor budget process eliminated a ready source of information and advice that physicians depended upon when billing the Medicare program. The AMA is pleased that the Administrator has now indicated that she intends to restore that capability, and we urge the Committee to ensure that this funding is continued for fiscal year 2001.

The second type of toll-free lines were used by physicians who submitted electronic claims to their Medicare carriers. Instead of proposing to tax physicians for not submitting electronic claims, the AMA believes that HCFA should provide proper incentives for those physicians who employ this preferred method of claims sub-

mission. As such, the AMA requests that the Appropriations Committee instruct HCFA to reinstitute these toll-free lines to encourage electronic claim submissions.

OVERWHELMING REGULATORY BURDENS FOR PHYSICIANS

The AMA believes that the Congress should recognize that Medicare regulations are complicated, burdensome and are in need of simplification. Princeton Professor Uwe Reinhardt described the situation in a January 21, 2000, Wall Street Journal editorial, stating that Medicare "regulations have become just too complicated to understand." There are more than 100,000 pages of Medicare rules and guidances with which a physician must comply—more than the Internal Revenue Code. Furthermore, Medicare billing frequently involves understandable differences of opinion in clinical judgments or the level of service provided. Much of Medicare billing is subjective and honest people can, and do, disagree. In fact, a 1995 OIG report found that even carriers had difficulty selecting codes.

HCFA has also acknowledged that Medicare is complex. However, the AMA believes that the agency's commitment to reducing administrative burdens is questionable. More than a year ago, HCFA assembled an internal committee named the Physicians Regulatory Initiative Team (PRIT) to review the multitude of rules, regulations and instructions with which physicians must comply in order to treat Medicare patients. Ultimately, PRIT was to make recommendations about how to streamline existing regulations. More than a year and a half has passed, and PRIT has still not finished its work.

The AMA has had some positive discussions with HCFA regarding physician education. However, Congress has not dedicated sufficient resources to education, and the AMA remains concerned that education for physicians will not be a priority. For instance, in recent years, the federal government has been holding physicians to a zero tolerance for errors standard, while not even providing a mechanism to answer physicians' questions. There have been numerous discussions during MedPAC meetings regarding Medicare's complexity, and the AMA was heartened that Congress has asked MedPAC to study the issues surrounding Medicare regulatory reform. Regulatory reform in the Medicare program is long overdue.

OIG/CARRIER ACTIVITY

When there is true fraud, the AMA supports federal efforts to prosecute such acts. However, the AMA implores the Congress to distinguish between inadvertent billing errors and fraudulent activity. In addition, we urge Congress to consider a proactive approach to ensure compliance by simplifying regulations and significantly increasing funding for physician and provider education.

Placing OIG agents in carriers' offices would only further compound the problems faced by the nations' physicians. Carriers already understand the message coming from Washington and are working diligently to recoup Medicare program money. Spending federal funds to check the checkers does not add up, but rather, would serve only to construct additional bureaucracies. These funds should be directed towards HCFA's efforts to simplify the Medicare program and towards carriers for direct physician education.

We stand ready to assist your Committee during the appropriations process and look forward to working with you on these and other issues. Thank you for the opportunity to submit this testimony.

PREPARED STATEMENT OF SANTA ROSA MEMORIAL HOSPITAL

Mr. Chairman, and Members of the Subcommittee, thank you for the opportunity to submit testimony to the hearing record regarding the proposed Northern California Telemedicine Network. This network will consist of a hub located at Santa Rosa Memorial Hospital in Santa Rosa, California and will serve over 11 hospitals, health centers and clinics in Sonoma, Napa, Mendocino, and Humbolt counties.

Santa Rosa Memorial Hospital is moving aggressively to build a permanent telemedicine infrastructure to expand health care services, as well as education and prevention programs into these currently underserved areas. The core of this initiative will be located at the Santa Rosa Memorial Hospital Emergency Department that will serve as the "hub," for this regional telemedicine network, providing access to primary, specialty and trauma care services.

The Northern California Telemedicine Network will work with other institutions to develop twelve "spoke" sites throughout northern California during the initial years of the project including:

—St. Joseph's Hospital, Eureka, California

—Redwood Memorial Hospital, Fortuna, California
—Mendocino Coast District Hospital
—Petaluma Valley Hospital
—Rohnert Park Healthcare Center
—Redwood Coast Medical Services
—Anderson Valley Health Clinic
—Mendocino Coast Clinics
—Potter valley Community Health Center
—Long Valley Health and Dental Center
—Mendocino Community Health Clinic

The growth of this network will enable a telemedicine program to achieve maximum cost effectiveness by serving multiple spoke sites from a single hub. In addition, it is anticipated that the spoke sites will develop some synergies as a result of their telemedicine technology that will allow them to communicate more effectively with each other and, importantly, with the communities most urgently in need of those services through the use of telemedicine technologies.

As I am sure that you are aware, rural America is experiencing a shortage of primary care physicians and specialist care providers. Primary care physicians are the keys to meeting the basic health care needs of patients in these areas because they are able to provide a wide variety of basic health services and identify medical problems needing further attention. Twenty-nine percent of rural residents live in Health Professional Shortage Areas (HPSA) compared to only nine percent of urban residents. Statistics from the Office of Statewide Health Planning and Development in California show that in northern California alone, all of Del Norte county and portions of Sonoma, Mendocino, Lake and Humboldt Counties are all experiencing Primary Care Health Professional Shortages.

People living in remote areas struggle to access timely, quality medical care. Residents of these areas often have substandard access to specialty health care, primarily because specialist physicians are more likely to be located in areas of concentrated population. Because of innovations in computing and telecommunications technology, many elements of medical practice can be accomplished when the patient and health care provider are geographically separated. This separation could be as small as across town, across a state, or even across the world.

Many areas in California, specifically Northern California are medically underserved areas. The United States Department of Health and Human Services has classified portions of Sonoma, Mendocino, Humboldt, Del Norte counties and all of Lake county as federally designated medically underserved areas. Access to medical care, especially specialty and trauma care is limited and episodic at best.

Often, these communities have been medically underserved due to the concentration of specialty care and health education in urban and suburban neighborhoods. The use of Telemedicine serves to provide California's underserved patients with the medical services they need. Instead of the patient being forced to travel long distances to reach a specialized provider, the patient, instead, could see their local provider and receive specialized care via telemedicine saving time, improving safety and providing a much needed service for the patient. Additionally, the need for emergency transport of patients would be significantly decreased due to the ability of telemedicine to assist in the diagnosis of a trauma patient on site. California could significantly benefit from the development of telemedicine due to its large geographical area with a population located in big cities, smaller towns and isolated rural regions.

Telemedicine has the potential to improve the delivery of health care in America by bringing a wider range of services to underserved communities and individuals in both urban and rural areas. In addition, telemedicine can help attract and retain health professionals in rural areas by providing ongoing training and collaboration with other health professionals.

Santa Rosa Memorial Hospital is grateful for the initial funding that your subcommittee provided in fiscal year 2000. This funding will enable us to establish the first like. We look forward to working with you to secure additional funds which will enable us to link the remaining 10 sites throughout California's north coast.

Mr. Chairman, we believe that Santa Rosa Memorial Hospital's Northern California Telemedicine Network creates a national model for providing access to primary, specialty and trauma care services for remote and at-risk populations. Our desire is to provide a much needed service—primary and specialty care—to these underserved communities. Therefore, Santa Rosa Memorial Hospital is seeking $2 million in continued federal support in fiscal year 2001 for the implementation of the final phases of its Northern California Telemedicine Network. The federal investment will enhance our nation's commitment to protecting the health of our citi-

zens. Your support for this effort will improve the quality of health care and contribute to the saving of lives for thousands of individuals in Northern California.

Thank you for your interest.

PREPARED STATEMENT OF THE CONDELL MEDICAL CENTER

Mr. Chairman, thank you for the opportunity to present this testimony for the record regarding the proposed Regional Center for Cardiac Health Services at Condell Medical Center, in Libertyville, Illinois.

As you may know, in the United States today, cardiac diseases are the number one killer of men and women. Everyday, more than 2,600 Americans die of cardiovascular disease, an average of one death every 33 seconds. Among both men and women, and across all racial and ethnic groups, cardiovascular disease is the number one killer in the United States. More than 960,000 Americans die of cardiovascular disease each year, accounting for more than 40 percent of all deaths nationally. In 1998, cardiovascular diseases cost the nation an estimated $274 billion in medical expenses and lost productivity, including more than $50 billion in direct Medicare and Medicaid expenditures. It is expected that that figure has increased to $286.5 billion in 1999.

Over the last 20 years there has been a dramatic increase in the indicators of prevalence of heart disease and stroke, particularly among Americans over age 65—an age group that is now about 13 percent of the U.S. population and will constitute over 20 percent by year 2010. Currently, almost 10 million Americans aged 65 years and older report disabilities caused by heart disease. Of the nearly 5 million patients afflicted with heart failure, 75 percent are older than 65 years of age.

Cardiovascular diseases are the most common cause of death in Illinois, accounting for an even higher mortality rate than on the national level. According to the National Center for Health Statistics, Illinois had the 10th highest 1995 death rate for heart attacks, stroke and other cardiovascular diseases in the nation, accounting for 101.7 deaths per 100,000 population. Illinois also had the 12th highest rate of total cardiovascular diseases in the nation, at 203.7 deaths per 100,000 population.

In Lake County, IL, these statistics have even more profound implications. Today, the County has a higher incidences of heart disease, cardiovascular disease and chronic obstructive pulmonary disease than the State of Illinois as a whole. In fact, Lake County had 4.6 deaths per 100,000 population from congenital anomalies versus Illinois' 4.2 deaths per 100,000.

With a total population of 640,000, Lake County has a potential for 5,312 cardiac catheterizations annually. Currently, there are four institutions with catheterization labs in Lake County with a combined total volume of only 1,700 or 32 percent of the potential volume, leaving a distinct cardiac health service need in the region. A primary reason for this discrepancy is that many patients are referred out of Lake County for interventional services currently unavailable anywhere in the County. In fact, some patients are forced to travel 90 minutes and more to obtain appropriate cardiac care.

With the region experiencing a 35 percent population growth through 2010, the need for an expanded primary and specialty health services infrastructure, including comprehensive cardiac care, is evident.

We here at CMC are taking steps to do identify the risk factors and implement a comprehensive program that will provide, education, prevention, diagnosis, specialty care, surgical care and rehabilitative cardiac care for our patients.

Since 1927, Condell Medical Center (CMC) has been a highly respected comprehensive community health care, prevention and education resource for Lake County, Illinois. The Medical Center has grown from its origins as a 12-bed country hospital to a technologically sophisticated 190-bed acute care medical center with affiliated health care and educational service facilities strategically located throughout Lake County.

Condell Medical Center was the first institution in Lake County to establish a cardiac rehabilitation program in 1978. Since then, the Medical Center has run a basic cardiology program including diagnostic and rehabilitative services at its main campus in Libertyville, IL. It has also provided emergency cardiac care at its main campus and its affiliated acute care centers located throughout the northwestern Lake County region. Currently, acute care centers are located in Buffalo Grove, Vernon Hills, Gurnee and Round Lake Beach. Condell affiliated medical offices are located in these centers in addition to other medical office buildings located in Lake Villa, Grays Lake and Mundelein. A focus on primary care physicians has enabled CMC to manage the medical needs of a large population of patients which has contributed to the success of its entire cardiovascular program.

Condell offers comprehensive care to area residents from the initial onset of the disease through recovery and return to daily routine, including:

Diagnostic Care.—Opened in 1996, Condell's new centralized Cardiology Department began to offer diagnostic cardiac catheterization services to area residents. One of the first fully-digital cardiac catheterization facilities in the nation, the laboratory aids Condell cardiologists in making a more thorough diagnosis of a patient's heart status. This permits faster clinical decisions, increased continuity of care and less patient stress.

Intensive Cardiac Care Center.—CMC currently operates an Intensive Care Unit with staff trained to provide optimal patient care to those with life-threatening illnesses. Monitoring equipment links patients with nursing staff. The Total Care Team, through its interdisciplinary cooperative efforts, handles the most critical situations in an efficient, well-organized manner to produce the most effective results for the patients.

In the cardiac care program at CMC is primarily comprised of non-invasive diagnostic and rehabilitative care. The Medical Center referred patients in its primary and secondary service areas to other outlying hospitals for specialty cardiac surgical services. In 1997, 1998 and 1999 a total of 240, 343 and 376 patients respectively were referred directly from Condell for interventional cardiac procedures.

The practice of referring patients for care interrupted the continuity of care, increased the health risk to the CMC patient, inconvenienced the patients and their families and broke the chain of care between the patient and their primary care physician. Additionally, the cost of care for those patients who are referred increases significantly due to transport costs, repetition of certain diagnostic tests, physician and nursing assessment during the patient admission to the tertiary hospital.

In 1996, CMC established its Cardiac Catheterization Lab providing diagnostic cardiac catheterization services as the first step in the establishment of a regional center for cardiac health services. The catheterization lab established a quality care program with comprehensive peer review process and outcomes measurements.

With the establishment of the catheterization lab in 1996 and the resulting increases in demand for services in 1997, 1998 and 1999, it became very apparent that the patients of Lake County have chosen CMC as the hospital-of-choice for their cardiac care.

Today, cardiovascular disease represents 20 percent of all CMC's hospital admissions. In 1998, CMC ended the year with 697 catheterizations, the largest market share in Lake County. In addition, the Medical Center referred 191 patients to other facilities for open-heart surgery in 1998. When the proposed cardiac care center opens, it is expected that the number of cardiac care patients will increase significantly placing additional stress on Condell's ICU, surgical and ED infrastructure.

The addition of a comprehensive cardiac health program including an open-heart surgery and angioplasty program will enable CMC to fulfill its mission of providing a full spectrum of cardiac care.

THE REGIONAL CENTER FOR CARDIAC HEALTH SERVICES AT CONDELL MEDICAL CENTER

In response to the critical need for comprehensive cardiac health services in Lake County, Illinois and the surrounding region, Condell Medical Center has established the "Regional Center for Cardiac Health Services" (RCCHS).

The Regional Center for Cardiac Health Services at Condell Medical Center is being developed as a dynamic, multi-faceted facility designed to bolster the Lake County region's ability to deal with the numerous faces of the cardiac threat in an innovative and integrated fashion. The RCCHS will provide a full suite of cardiovascular services including emergency, surgical, diagnostic, education, prevention and rehabilitation.

This Center, which is part of Condell Medical Center's planned institution wide expansion project, will build upon existing cardiac expertise at the Medical Center and create a full service regional center that will include:

—Cardiac Catheterization Lab (diagnostic and interventional cardiac cath)
—Echocardiography
—Stress Testing
—Cardiac Rehabilitation
—Cardiac outpatient monitoring
—EKG
—Pediatric Cardiology
—Cardiac ICU
—Surgical
—Prevention and Education
—Rehabilitation

The new Center will accommodate increased volume expected from the expanded cardiac programs, the Emergency Department and the primary and secondary service areas.

The proposed program will:

—Be clinically effective, using an interdisciplinary approach with input from surgeons, cardiologists, ancillary professionals, nurses, administration and importantly, patients.

—Facilitate continuity of care from admission through discharge and after-care in the home and rehabilitation.

—Enable cardiologists to maximize patient care through decreased morbidity and mortality through the use of interventional cardiac procedures and on-site open-heart surgery services.

—Provide additional suites for use in open-heart surgeries.

—Reduce referrals out of CMC and Lake County, allowing closer "home care."

—Provide comprehensive cardiac care 7 days a week, 24 hours per day.

—Locate all cardiac services adjacent to one another for increased patient convenience and improved medical efficiency.

Key components of the proposed Regional Center for Cardiac Health Services include:

SURGICAL

Condell Medical Center will provide for the first time in Lake County open heart surgery capability. It will provide suites for use solely as open heart surgery suites which will co-exist within the expanded surgical center.

EDUCATION & PREVENTION

Another aspect of the proposed Regional Center for Cardiac Health Services at Condell Medical Center will be the education and prevention programs. This will entail expansion of the existing Health Promotions Program and Cardiac Rehabilitation Program. In addition, opportunities for the development of specialty services will be evaluated and implemented.

REHABILITATIVE CARE

A key element of the Regional Center for Cardiac Health Services at CMC will be an expanded Cardiac Rehabilitation Program, conducted at Centre Club. The Centre Club is the on-campus health and fitness facility at CMC. This program helps cardiovascular patients return to a safe, healthy and active lifestyle. This two-phase program combines education with individualized exercise prescriptions, which are closely monitored by highly trained staff members.

As a key part of this initiative, CMC is also in the process of adding a second rehabilitation program off campus at its Gurnee facility.

The establishment of this center is also a critical component in the Medical Center's goal to become the County's first tertiary care center. Other components of that goal will be becoming a level I emergency department, becoming a level I intensive care unit (ICU), and becoming a level III OB/GYN facility.

Condell Medical Center is seeking $5.5 million in fiscal year 2001 two years for the final phase of its Regional Center for Cardiac Health Services. This proposed federal partnership in conjunction with the CMC financial commitment of $72.8 million will provide significant returns on the federal investment through faster and more effective treatment while helping to reduce the significant costs associated with cardiac related illnesses in the area.

The proposed Regional Center for Cardiac Health Services will serve as a national model for the provision and effective management of comprehensive cardiac care in a single location for an at-risk population. This partnership, supported by CMC's financial commitment of $72.8 million, will provide significant returns on the federal investment through faster and more effective treatment while helping to reduce the significant costs associated with cardiac related illnesses in the area. It will also help to reduce the very real costs associated with cardiac related illnesses in the region.

Again, Mr. Chairman thank you for the opportunity to submit this testimony for the record. We look forward to working with the subcommittee as it strives to implement an effective system for addressing the complex issue of cardiac care.

PREPARED STATEMENT OF THE NATIONAL TREASURY EMPLOYEES UNION

Chairman Specter, Members of the Subcommittee: My name is Colleen M. Kelley and I am the National President of the National Treasury Employees Union (NTEU). On behalf of the more than 140,000 federal employees represented by NTEU throughout the Federal Government, thank you very much for this opportunity to share our views concerning the fiscal year 2001 budget.

NTEU represents employees in many HHS agencies who will be directly affected by funding decisions made by your Subcommittee. NTEU represents employees in the Health Resources and Services Administration, Indian Health Service, Substance Abuse and Mental Health Services Administration, Agency for Healthcare Research and Quality, Administration for Children and Families, Administration on Aging, Office of the Secretary, Office for Civil Rights, Program Support Center and the National Center for Health Statistics. In addition, NTEU represents employees in the Social Security Administration's Office of Hearings and Appeals.

As the Chairman knows, spending has been severely constrained at most federal agencies over the past several years. These funding shortfalls have resulted in hiring restrictions and delayed and canceled employee training which have made it difficult for employees to do their best. With the deficit finally behind us and surpluses predicted for the immediate future, we have an opportunity to provide adequate resources to federal agencies. Doing so will enable federal employees to carry out their agencies' missions to the best of their abilities and provide first class service to agency customers.

The Administration's fiscal year 2001 budget request for program management at the Health Resources and Services Administration (HRSA) is $131 million. HRSA's goal is to bring health care services to some of our most neediest populations, including those in underserved rural communities, people living with HIV/AIDS, and those who are uninsured. There is little question that HRSA provides essential services that are desperately in need of expansion. This agency can truly no longer do more with less.

The employees represented by NTEU at the Agency for Healthcare Research and Quality (AHRQ) are committed to improving the quality of patient care in our health care system. This agency's goal is to both cut the number of medical errors and explore ways to better use research to improve medical care in our country. The Administration's budget proposal includes $3 million for program support at the AHRQ, an increase over the prior fiscal year which reflects the important work accomplished by this agency.

President Clinton's budget proposes $60 million in funding for program management at the Substance Abuse and Mental Health Services Administration (SAMHSA). This agency is at the forefront of efforts to provide early intervention programs designed to discourage young people from trying drugs as well as playing a critical role in insuring that mental health and drug abuse services are widely available. The Office of National Drug Control Policy estimates that as many as 5 million Americans need substance abuse treatment, yet, they report, less than half actually receive services. If SAMHSA is to adequately respond to the substance abuse and mental health needs in this country, the President's budget recommendation is the minimum that must be approved.

The Indian Health Service (IHS) is slated to receive $2.7 billion for its health services programs in fiscal year 2001 under the President's budget. This budget request reflects the Administration's continuing commitment to improve health care for the millions of American Indians and Alaska Natives that belong to federally recognized Tribes. These additional funds will permit the employees of IHS to continue to make a difference in the health status of the groups served by the IHS.

The fiscal year 2001 budget request for federal administration at the Administration for Children and Families (ACF) is $165 million. As the Chairman knows, ACF is one of the government's premiere agencies for promoting the health and welfare of America's children. Programs under its jurisdiction include Head Start as well as projects that promote and support child care, foster care and adoption efforts. The budget request will permit ACF to hire additional staff in key areas such as monitoring child welfare, expanding access to quality child care and overseeing the critical Head Start Program. Funding restrictions in past years have hampered ACF's ability to fulfill its mission and on behalf of the dedicated employees of this agency, I urge the Subcommittee to fully fund this request.

For fiscal year 2001, the budget request for program administration at the Administration on Aging (AoA) is $17 million. Since the turn of the last century in 1900, it is estimated that the population of Americans age sixty-five and older has grown from 3 million individuals to more than 34 million. Helping older Americans remain independent and productive is one of the key goals of AoA. The employees of AoA

operate nutrition programs, disseminate information and are active in the Alzheimer's programs. The budget recommendation for AoA is the minimum that should be approved for this important agency.

NTEU also represents employees in the Office of the Secretary of HHS. The President's budget request for departmental management is $330 million for fiscal year 2001. As you know, the employees in the Office of the Secretary help support those activities associated with the overall operation of the department. In addition, the fiscal year 2001 budget request includes funding to support research on significant policy issues including welfare reform, at-risk children and youth and improved access to health care being conducted in the Office of the Secretary.

The President's budget request for the Office for Civil Rights (OCR) for Fiscal 2001 is $24 million. The important work of OCR includes enforcing the Nation's civil rights statutes that prohibit discrimination in health and social service programs. Moreover, OCR plays a central role in efforts to prohibit discrimination against individuals with disabilities in programs under HHS's purview. In the past several years, the funding levels OCR has received have not reflected OCR's critical mission and we urge this Committee to carefully consider the President's fiscal year 2001 request.

For the National Center for Health Statistics (NCHS), the Administration has requested $110 million for program support in fiscal year 2001. This budget request is intended to support NCHS's health survey and data collection activities. One of NCHS's primary responsibilities is to follow changes in health and health care, assess the effectiveness of health care programs and identify health and disease patterns and risk factors in our country. The budget request reflects the critical work done by this agency.

As the name implies, the Department's Program Support Center (PSC) provides support services to HHS as well as to other agencies. These services include efforts in three areas, including human resources, financial management and administrative operations. For fiscal year 2001, the Administration has recommended a funding level of $326 million for PSC, a small increase over the division's fiscal year 2000 budget.

NTEU also represents employees in the Office of Hearings and Appeals (OHA) of the Social Security Administration. As I have brought to this Committee's attention in past years, OHA is once again the subject of reorganization efforts. NTEU has several concerns regarding the latest reorganization effort called the Hearing Process Improvement (HPI) plan.

As the Chairman knows, the process at OHA is judicial in nature and is focused around the due process hearing. Disability claimants who have not been found eligible for disability are entitled to a timely and fair adjudication at the hearing office level. The OHA hearing procedure permits the dissatisfied claimant to personally interact, to personally argue his/her position directly to the decision maker. The decision he/she receives is comprehensive and specific; it deals with his/her situation in great detail.

One particularly innovative and successful program stands to be eliminated if HPI is implemented. The Senior Attorney Program as originally operated, involved approximately 475 of OHA's experienced Staff Attorneys who in addition to drafting ALJ decisions, reviewed those disability cases most likely to result in a fully favorable decision before they were assigned to the disability que for an ALJ hearing. If the evidence indicated that the case was likely to result in a finding of disability, the Senior Attorney would complete development of the case, including securing additional medical evidence and appropriate medical and vocational expertise. If after such development the case was not likely to be favorably decided without a hearing, the case was forwarded to an ALJ for a hearing. However, if the record established that the claimant was in fact disabled, the Senior Attorney would draft and issue under his/her authority a fully favorable decision.

The average processing time for Senior Attorney decisions was just over 100 days. This was at a time when processing time at the OHA hearing level was 386 days—more than an entire year. As a result of the Senior Attorney Program, disabled claimants received their benefits nearly 9 months earlier than otherwise would have been the case. From its inception until the Program was sharply curtailed in 1999, the Senior Attorney Program resulted in approximately 50,000 fully favorable decisions per year.

In every respect the Senior Attorney Program has been a resounding success. It materially improved the quality of service provided to the public, especially those individuals who are disabled and entitled to timely granting of their benefits. Despite its success, the Senior Attorney as an independent adjudicator is being eliminated as part of the HPI Plan.

NTEU is profoundly skeptical that the Hearings Process Improvement Plan will materially improve disability adjudication at the hearings level. In fact, the failure to retain the decisional authority of Senior Attorneys would seem to doom HPI to failure. NTEU urges this Subcommittee to carefully review the Hearing Process Improvement initiative and urges the Chairman to carefully review the shortsighted plan to eliminate the Senior Attorney Program. Without this program, and the additional 50,000 to 75,000 decisions it will help generate each year, there is little question that a serious degradation of in the quality of service will result.

Mr. Chairman, thank you again for this opportunity to share our views on the fiscal year 2001 needs of the agencies within the jurisdiction of your Subcommittee.

PREPARED STATEMENT OF THE 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 Children's Hospital at Montefiore that we are developing.

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. Thirty 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 sixty percent have annual incomes below $30,000.

The Bronx population is largely composed of historically underserved and uninsured minorities. Three-quarters of the Bronx population are non-white—28 percent African American and 50 percent Hispanic. The Bronx is among the nation's most underserved urban areas with sociodemographic and health status indicators that underscore its need for health services. Those health and social indicators include:

—An infant mortality rate which is among the highest in the nation;

—Rates of teenage pregnancy and low birth weights that are higher than the proportions for the City and nation;

—The incidence of asthma is six times greater than the national average;

—Bronx children living with AIDS in 1996 represented 28.5 percent of all New York City pediatric AIDS cases, and 5.5 percent nationwide.

—The lack of industry and a 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 Medical Center has become a critical resource in addressing the health and social needs of the residents of the Bronx. MMC was the first hospital to create a community-oriented care program in the late 1960s and early 1970s to meet the needs of underserved residents in the Bronx. This comprehensive 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.

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 some of the City's highest rates of low birth weight, infant mortality, HIV infections and other reportable diseases. 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 are not well housed, and primary and specialty ambulatory services 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 multisite 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 embarked on a comprehensive initiative to tackle the daunting task of consolidating all of our children's services into a central location—the Children's Hospital at Montefiore. The new Children's Hospital will serve as a "hub" of our child 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 MONTEFIORE CHILD HEALTH INITIATIVE

The traditional model of children's hospitals is designed for and focuses 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 Montefiore Child Health Initiative, comprised of both the child health services within the existing Ambulatory Care Network and the Children's Hospital, is a unique example of a modern and aggressive approach to the provision of comprehensive children's primary and specialized health care services.

The Montefiore Child Health Initiative proposes a unique model of care that 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:

An Integrated 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 Montefiore Child Health Initiative will ensure that the Integrated 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 spectrum of child health and related services; and access to the secondary and tertiary services at the Children's Hospital so that children and families will have the option of receiving care in an organized, cost effective and accountable system of care.

The Montefiore Child Health Initiative will provide the consolidation and coordination necessary to effectively and efficiently provide a full range of services for the children and families of the Bronx.

The network aspects of the Initiative will play a key role in ensuring that a full continuum is and remains available for children and their families through the existing array of services throughout the Bronx, including:

—3 hospital outpatient departments, providing primary care, 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 program for homeless children providing care to over 6,300 children annually;

—An extensive base of privately practicing pediatricians throughout the Bronx and Westchester County.

The "front door" to the planned Children's Hospital, the core of the Montefiore Child 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 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 Hospital or in the community.

The network currently offers specialty services specifically geared to meet the unique 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 also address 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;
—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.

Pediatric Asthma Center

A dedicated center for the diagnosis and treatment of childhood asthma is a major focus of the Montefiore Child Health Initiative. The concept of the Pediatric Asthma Center stemmed from the disturbing statistics about childhood asthma in the Bronx:

—Almost 15 percent of children in the South Bronx have asthma (6 percent nationally).
—African American children are three times more likely than white children to be hospitalized for asthma, and four to six times more likely to die from it. Rates for Latino children are also higher than those for white children.
—More than five times as many children in the Bronx are hospitalized for asthma compared with national rates.
—In the South Bronx, the rate is 7.5 times the national rate, and more than twice the rate of New York City overall.

The Pediatric Asthma Center will establish a state-of-the-art clinical and educational resource center as well as a community-wide network of services for children and families linked directly with schools and day care programs. The Center's services will provide school-based education and pediatric care for children with asthma, and will serve as a hub for a network of diagnostic and clinical services located in Montefiore's Integrated Child Health Network. Schools and day care centers will be linked to the Pediatric Asthma Center as well as a local network primary care site for services, training and educational programs. State-of-the-art technology, including diagnostic equipment and computer links for clinical evaluation, and support for school-based health care and education, will be key components of the Pediatric Asthma Center.

A New Children's Hospital

The 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 Montefiore Child 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, with specialized activities such as dialysis and transplant technologies, designed with adequate space for parents to stay with their child;
—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 specially designed to meet the needs of each age group;
—Liaison child psychiatry services;
—Medical information stations on each unit.

CONCLUSION

The implementation of the Montefiore Child 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 Montefiore Child 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.

FUNDING/BUDGET SOURCES

The new Children's Hospital and related facilities will cost $116 million for capital construction. The Medical Center is seeking $5 million in fiscal year 2001 for this critical children's hospital and child health initiative. In fiscal year 1999 and fiscal year 2000 respectively, Montefiore received $2 million and $500,000 respectively for this initiative. 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.

Thank you for your consideration.

PREPARED STATEMENT OF ST. JOSEPH'S HOSPITAL HEALTH CENTER

Mr. Chairman, thank you for the opportunity to submit this testimony and for the support that this Subcommittee gave to St. Joseph's Hospital Health Center last year. St. Joseph's, located in downtown Syracuse, New York, is a non-profit 431-bed hospital and health care network providing services to Onondaga County and to patients from 15 surrounding counties. St. Joseph's is best known for its ranking as the #1 hospital in New York State for open-heart surgery in terms of lowest overall mortality rate. We are very proud of this ranking, which we have held for four consecutive years. What many people do not know is that we are also the largest hemodialysis center outside metropolitan New York. My statement is focused on these two areas of expertise at St. Joseph's and how we plan to initiate a chronic disease management model that will benefit our current patients with heart and kidney disease and enhance the quality of life for at-risk patients in the region. We see this initiative as one with not only health enhancement benefits but also with significant positive economic implications for the community and the region.

St. Joseph's provides over $7 million in bad debt and charity care to our service region. This comes to about 4 percent of our operating budget. This number has steadily risen over the years and we feel it will continue to do so unless some dramatic steps are taken. In order to increase access to patients who are underserved and at-risk for disease, we have implemented a program of "patient-centered care." We believe we achieved our #1 ranking for cardiac care through this process, which employs a secondary prevention model for disease management. By applying a multidisciplinary team approach to heart disease and preparing patients before surgery and rehabilitating them after, we have reduced mortality rates as well as the number of second hospitalizations. We have done this to improve the overall health of an underserved and underinsured patient base, but also for practical financial reasons. While our rehabilitation and education programs for our cardiac patients are largely unreimbursed, we are rewarded by having to perform less expensive charity care on patients who would typically end up back in the hospital without disease management.

Recognizing that early assessment is important to reducing the number of expensive treatments required later in life, St. Joseph's instituted a Wellness Place at a local mall so that people could stop in at their convenience. The Wellness Place provides free, general health screenings such as blood pressure readings, cardiac and diabetes risk assessment, counseling and patient education and seminars. Last year, approximately 15,000 people used the Wellness Place. Nearly 1000 of these people were determined to be at risk for heart disease, diabetes, or vascular problems. These individuals were offered follow-up services intended to change lifestyle, such as nutritional counseling, smoking cessation, exercise programs and other similar regimens. They were also offered a choice of primary care physician if none was identified. This is all done at considerable unreimbursed expense to St. Joseph's but

with the knowledge that a great deal of money will be saved in the long run—for the patient, the Medicare system and the hospital. The most dramatic economic implications I mentioned are encompassed within this concept—but not all. At risk patients are working people who may lose jobs if their disease progresses. It is important to realize, however, that patients with diagnosed diseases or who have congestive heart failure, may still work and lead productive lives if an effective disease management program is initiated at the earliest stage possible. The other economic benefits come in the form of the support required for this program. I will detail those later in this statement.

Assessment is the first line of defense in chronic disease management; but, there are many other factors involved after this step is taken. A program for management of disease must adequately educate patients and then foster a sense of individual responsibility for the importance of following prescribed regimens. This takes a great deal of initial monitoring and time spent with patients by telephone, at community health centers, and in the home. This also requires coordinated community participation by physicians, nurses, pharmacists, physical therapists, educators, behavioral specialists and even employers.

Diabetes, leading to kidney disease and kidney failure, is the most expensive disease in the country. The second most expensive, and #1 admitting diagnosis for Medicare, is congestive heart failure. The U.S. spends more than $7 billion annually in Medicare dollars for these diseases. The clinical relationship between chronic kidney failure and heart disease (e.g., high blood pressure) requires similar early intervention techniques as well as later management, treatment, and rehabilitation. Utilizing resources already developed and in place for our cardiac rehabilitation program, St. Joseph's is proposing to further develop a chronic disease management program focused on hemodialysis. Combining resources in this way will be cost effective and has the potential to radically change the management of kidney disease.

The specific objectives of the program will begin with early identification. Timely referrals to a nephrologist can be improved so that more aggressive treatment can be initiated to prolong kidney function and allow better preparation of the patient for dialysis. Second, we will identify, investigate, evaluate, and implement technology that will promote in-center self care and home hemodialysis modalities. The Aksys Corporation has developed a product that has the potential of achieving this objective. Third, we will utilize the St. Joseph's Cardiac Rehabilitation Model for the renal patient. This model will emphasize education and exercise with the goal of improving the percentage of patients that stay employed, reduce frequency and length of hospitalizations, and improve patient acceptance of and control over disease processes. Finally, we will apply our disease management techniques to our overall goal of reducing the percentage of candidates for kidney transplantation. The ultimate goal of the renal patient and the health care industry is to have renal patients lead a "normal" life. Currently, kidney transplantation is the modality that is most associated with that goal.

Our history of service and specialization in the areas of cardiac and kidney disease has proven that there is a demonstrable need for a chronic disease demonstration in these areas for the Central New York region. The demonstration will involve relationships and initiatives in Dialysis, Cardiac Care, Home Care, and Wellness. What we lack at this point, is a facility that can be shared by both cardiac and dialysis patients. Our current dialysis facility, the largest outside the New York Metropolitan area, is woefully inadequate in every way. The facility was originally built as a modular, temporary, unit over 20 years ago. We now treat our overload of patients in the hallways and have legitimate safety concerns that come with overcrowding and questions as to the future structural integrity of the plant itself. We have not replaced this facility for financial reasons but, fortunately, have been able to treat patients satisfactorily. We have three satellite clinics in the region that are also operating at capacity. Our goal is to implement our demonstration program in an on-campus facility that will provide the space needed for dialysis, exercise facilities, classrooms, meeting rooms, examination rooms, an acute kidney unit, and nurse and allied professional training space. Training of personnel is an important aspect of implementing an innovative chronic disease model.

In terms of economic development for the region, we believe that keeping our patients healthy and productive will have the most dramatic impact on the economy albeit in the long term. For the shorter term, we believe the training programs that we currently provide and will expand in areas such as home care, nursing, rehabilitation specialists, and counseling, to name a few, will bring employment opportunities to people in and around Syracuse. As we expand our efforts, we will likely train people outside the immediate area to be able to serve the outlying areas where our satellite clinics are and in homes in more remote locations. The facility we envision will also provide many construction jobs over the next couple of years. The two-story

facility, equipment and program operation will cost approximately $13.2 million. St. Joseph's has requested Federal partnership grant funding of $5.8 million that will also cover start-up operating costs. Our partnership funding request has increased over the past two year's by $300,000 due to our current need to upgrade our Acute Kidney Unit as part of our overall initiative. We estimate, based on our current services, that our operating budget will exceed $5.5 million per year.

As you know, St. Joseph's received $2 million in fiscal year 2000 from this Subcommittee to begin the planning and site preparation necessary for the new Center. We are very grateful for this support and urge you to complete this investment with an additional $2 million in fiscal year 2001 toward our total requested federal share for the initiative. Having made this request, which we realize is considerable, we would like to assure the Subcommittee that St. Joseph's will provide, through private sources, the remainder of the estimated total for this effort or $7.4 million.

We recognize the magnitude of this request but believe wholeheartedly that this facility, and the implementation of our chronic disease management model will repay this initial investment many times over in terms of Medicare savings and in terms of providing a national model for replication across the country.

Thank you.

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 45 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 2001 appropriations for the Low Income Home Energy Assistance Program (LIHEAP).

APPA urges the Committee to support funding of $1.4 billion in fiscal year 2001 for LIHEAP. APPA also supports the request for $300 million in emergency funds in fiscal year 2001 and supports a funding level of $1.5 billion in advanced funding for fiscal year 2002. Because the majority of LIHEAP monies are 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. Moreover, a severe winter and escalating home heating oil prices in the Midwest and Northeast have depleted fiscal year 2000 emergency funds and highlight the important role LIHEAP plays for the elderly and working poor during winter months.

Funding cuts since LIHEAP's reauthorization in fiscal year 1995 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 being 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 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 as retail markets are opened to competition. 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 their 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 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 house-

holds 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 leaving the public assistance rolls are entering lower paying jobs and continue to 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 fiscal year 2001 funding for LIHEAP. Again, thank you for this opportunity to present our views.

PREPARED STATEMENT OF DENISE ROBERTS, BOARD MEMBER, PULSE OF COLORADO

Mr. Chairman and Members of the Committee: Thank you for the opportunity to submit written testimony regarding this very important issue, Medical Errors.

My testimony concerns a series of errors that occurred as my son was under the care of a pediatrician in Pueblo, Colorado. This doctor already had a long history of providing substandard care to other children. Unfortunately, this information was not public knowledge nor was it reported by this doctor's peers. In early 1999, the Board of Medical Examiners suspended this doctors license in hopes of protecting the children of Pueblo. The decision was an unusual one since it was based solely on consumer complaints. The board felt that it had substantial evidence to act upon regarding this physician who was seeing far too many patients per day. In the grandest of public relations campaign the wealthy physician gained momentum within the community, and eventually the Board had a major conflict with local political leaders, hospitals and the peer review committees who did not initially go forward to protect the public. Several local doctors publicly sided with the physician, placing blame on the parents of the dead and injured children. The others remained silent. Parents and nurses came to the advocacy group that I belong to and informed us of this problem. The parents assumed that the new doctors would report the problems, they were wrong. Many symptoms were ignored and not charted by the doctor in question, the other physicians treated them without reporting the incidents.

In a historic decision, this doctor was given back his license several months after suspension as the board continued to pursue the case. The local medical community closed ranks on the board, making it very difficult for the suspension to remain effective until the hearing. In exchange of that costly process, the doctor and the board agreed to an early retirement in exchange for a clean record with the medial board. This doctor can go and practice in any other state after he retires here and the same problems could happen there.

My son Taylor Michael Roberts passed away on Feb. 25, 1998 at 14 months. He was a healthy baby until he was prescribed medicine on 9/22/97. I would like to give you a brief history of the medical care my son received during his illness.

It all started around the end of October 1997 when my son got sick. I took him to Dr. Kuna's office numerous times. (10–27–97, 10–30–97, 11–12–97, 11–14–97, 11–18–97, 12–13–97, 12–22–97). It was the Friday after Christmas, on Dec. 26, 1997, when I took him to Dr. Kuna's office again. Dr. Rao, Dr. Kuna's partner saw us and sent us to get some test taken to find out what was wrong with Taylor. I brought the test back to Dr. Rao and he told me that Taylor had pneumonia and bronchitis, and to take him home and bring him back Monday. When I took Taylor home he was very sick all day. The next morning I took him to my personnel physician, and was told to get him over to the emergency room immediately. I am not a medical doctor, but a few things occurred at the hospital that I found disturbing: (1) They only took a blood test of my child after I demanded one be taken. (2) It was Dr. Derrington, another pediatrician on call, not Dr. Kuna or Dr. Rao, that ordered blood cultures. The results confirmed that my son was septic and this was the reason he was not getting better. (3) Dr. Kuna wanted to discharge my son days earlier from the hospital reasoning that he would be better off at home and more comfortable there. He stated other children had the same symptoms and were at home. (4) Dr. Kuna lied to us saying that all the tests; blood, and other wise, were all normal upon his release. (5) Dr. Kuna said on the discharge summary (1/5/98) that "I will monitor the CBC carefully", yet, no further blood test were taken until Feb. 22, 1998 when my son was diagnosed with meningitis. (6) I was never aware of the fact that Taylor had staph infection only that he was septic.

I find it most unsettling that a Doctor would lie to us about the care of our child. This only leads me to believe that he must not comprehend or understand how

much a parent could love a child and the lengths they would take to keep a child safe. Does he think that the results of the blood test are irrelevant to the life of my child?

I brought my son back to Dr. Kuna for his follow up appointment on 1/16/98. Dr. Kuna stated, that he was fine, but, to continue the neb treatments. Again, No tests were taken, or results mentioned. I took Taylor back to Kuna's office on 2/3/98 because he and my daughter had a runny nose and a cough. There again in his records he shows that Taylor had bronchitis. This was never mentioned to me during my visit. Then I took him back and on 2/7/98 Dr. Rao said he has a viral infection. I called Dr. Kuna on Sunday morning (2/22/98), and told him that Taylor was very sick and that he needed to be seen immediately. Dr. Kuna agreed to meet me at his office between 9:00 and 9:30. I told him Taylor had the following symptoms: (1) Fever on Friday night of 99 degrees (2) Fever on Saturday night of 103.8 and not very controllable with the baths and switching Advil and Tylenol (3) Vomited once after the Advil (4) Heavy breathing. (5) Bumps on the back of his neck. (6) Was given Tylenol right before our visit.

He informed me that Taylor had a virus infection and was prone to high fevers. I was not satisfied with this diagnosis, and asked him to do a throat culture. He said he had seen one lesion in Taylors throat. Then Kuna checked to see what his oxygen level would register. The machine showed a level under 90; Kuna then squeezed the monitor around his finger. I asked him if this would make the monitor reading high. He said it would have a misleading reading of three to four degrees which would make Taylors oxygen level okay. I still insisted that he should give me some medicine for Taylor. My son did not look very good at all. Later on in the afternoon I called Dr. Kuna and explained to him that my child was still very sick. Once again, I was told not to worry it was just a virus. I noticed on the records of my visit (2/22/98) that Kuna noted Taylor had a questionable dull left eardrum. This was not reported to me during this visit. Kuna then stated in the discharge summary " I requested medicine because I was afraid of him getting an ear infection as in the past". I have no idea how Kuna come up with this conclusion, as I was never informed of the ear infection. This is a great example of the deceptive practice that Dr. Kuna used in his diagnosis of Taylor.

I took my son to the hospital on Monday morning around 6:00 a.m., and told them to call Dr. Kuna immediately. I called the hospital before I left, and was informed that Kuna was scheduled to be on the pediatric floor that morning. My child was not very well at all on arrival at the hospital. I explained to them that I thought that he was breathing heavier than usual, and that his eyes seemed strange to me. The doctor writes in her report that he appears well hydrated and is taking fluids well. She only spent at the most 15 minutes with us. She also writes in her report that she checked Taylors neck. During the 15 minutes she never checked his neck. They poked my son numerous times trying to take the 2nd blood test. After the first blood test they told us the results were fine. They further stated that they could not believe that results turned out to be OK. Because he looked ill they were going to recheck the initial blood test. Taylor barely responded to the numerous times that he poked in the arms while they were trying to obtain blood. They actually had to send in another lab person to take blood, because the second one could not draw any. They continued to ignore my requests to have Dr. Kuna come look at him. But only in the reports does it show that indeed he knew we were there at 8:50. My husband carried my son upstairs to be admitted to the pediatric floor. The nurses once again kept poking him numerous times in the arms to put the IV in. I went over to Dr. Kuna's office to talk to him about Taylor since he never showed up. His nurse told me that he was too busy to talk to me at this time, and I should come back at 12:00. When I went back to his room, my husband and I noticed that he was rocking and acting like he was not looking at us. We kept asking the nurse to call Dr. Kuna. One of the nurses stated that she noticed his eyes looked funny upon his arrival to the pediatric floor, but, she did not say anything. Dr. Kuna finally came over on the request of the nurse. He checked his neck and Taylor cried. Then he took Taylor into get a spinal tap. Immediately after the spinal tap, they had my husband carry him back to his room. Dr. Kuna told us that our son had meningitis. He left us standing there with just the nurse to take care of him. This is the part I now find so disturbing. How could he just leave us there? He stated he was in a hurry to get back to the office to take care of his patients. Moments after Dr. Kuna departed, Taylor went into a seizure that lasted 35 minutes. Dr. Kuna did not reappear until the last minutes of the seizure. I questioned why we were being transferred to St. Lukes hospital instead of Children's hospital. Dr. Kuna than informed me that the same doctors were available at St. Lukes. Upon arrival at St. Lukes, the staff fought for Taylors life until we decided to take him off the machines and medicine on Feb. 25, 1998.

Dr. Kuna lied on the discharge summaries and he lied to the medical board. There is great concern on his ability to provide quality care for his patients. I am in great concern for the safety of other children under this sort of care. After reviewing some of the records and noting some of the mistakes, I am feeling tremendous guilt, because I listened to Dr. Kuna against my better judgment. How could I be so ignorant to trust this doctor with the life of my child? I thought that he would watch out for my child knowing how they misdiagnosed him the first time.

After Taylor's death I learned that there had been a letter of admonition from the medical board regarding Dr. Kuna and the death of another child. This letter really hit home for me. I wish that these letters could be posted in the doctors office for patients to see. In this instance, I feel that the letter could have made a big difference. I also learned that he had been named in several lawsuits and many other consumers had filed complaints with the medical board against him. Had I known that he had gotten in trouble before, I would have gone someplace else. Since joining PULSE, I know now that this problem is nationwide, and many other children have died and been injured like Taylor was due to medical errors, misdiagnosis, etc. I hope someday that full disclosure will exist helped by mandatory reporting of medical errors as I feel that there are children's lives at at stake. Had I been informed, I know in my heart that there would have been a much different outcome.

Thank you for allowing me to give you this written testimony.

PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW CENTER

INTRODUCTION

Mr. Chairman and Members of the Committee, the National Consumer Law Center appreciates the opportunity to submit written testimony regarding appropriation of funds for the Low Income Home Energy Assistance Program for fiscal year 2001. This testimony is submitted on behalf of our low income and elderly clients who face going without food or medicine to avoid disconnection due to an inability to afford utility service.

The National Consumer Law Center (NCLC) is a nonprofit corporation dedicated to the interests of low-income consumers. Founded in 1969, NCLC provides specialized legal support and consulting services to low-income consumers, their advocates, government agencies and private attorneys in all aspects of consumer and utility law. NCLC has helped utilities, regulatory commissions and advocates design low-income affordability programs and has published leading manuals and reports on related law.[1]

NCLC is a strong supporter of the Low Income Home Energy Assistance Program (LIHEAP), as it is the primary safety net between low-income consumers and disconnection of utility service. LIHEAP is designed to target energy assistance to households most in danger of losing that vital service. However, without adequate regular appropriations, LIHEAP cannot get the job done. On behalf of our low-income clients, we urge the restoration of LIHEAP funding to at least $1.5 billion in regular appropriations for fiscal year 2001. This level of funding is slightly less than the level appropriated for this program in fiscal year 1988 and far from the $2 billion level authorized to be appropriated for this program in prior and upcoming years.[2]

We also support additional emergency contingency funding of $300 million and advance LIHEAP appropriations for fiscal year 2002 of at least $1.6 billion. This amount is still below the pre-1987 regular appropriations levels, but would enable states to cover a larger portion of the energy burden for eligible customers and increase energy efficiency efforts to move households closer to energy self-sufficiency.

While emergency funds are critical for responding to life-threatening, brutal winters and summer heat waves, increasing the regular appropriations for LIHEAP will allow the states to design more solid programs for the upcoming year. This includes proactive, timely and appropriately designed responses to crisis situations, as opposed to reactive and potentially ill-timed responses due to the lag time that comes with the dependence on the release of emergency contingency funds. Delays in responding to heating and cooling crisis needlessly jeopardize the health and safety of those Americans eligible for assistance.

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[1] Manuals and reports relating to utility service include Access to Utility Service, Cap the Gap: Assuring Residential Customers Share Benefits of Electric Industry Restructuring, The Regulation of Rural Electric Cooperatives, A Guide to Low-Income Energy Efficiency and Energy and the Poor: The Crisis Continues.

[2] 42 U.S.C. 8621(b).

Those that cannot afford to pay their winter heating bill often face desperate choices. A 1999 survey of LIHEAP recipients in Iowa revealed that when the heating bills were unaffordable, almost 21 percent went without medical care, 12.3 percent went without food and 19 percent went to bed early with lots of blankets.[3] Analysis of recent data from the U.S. Department of Energy, Energy Information Administration show that in 1997, about 2.1 million households suffered from loss of heat. All but 154,000 of the households were LIHEAP eligible.[4] The average period without heat was 3.3 days.[5] The consequences of disconnections include, health and safety risks associated with alternative heat and lighting sources, such as kerosene and candles; hunger and malnutrition; hyperthermia and hypothermia and eviction and increased homelessness.

Census statistics also show a widespread need for the LIHEAP program.

HOUSEHOLDS ELIGIBLE FOR LIHEAP OUT OF 91,993,582 TOTAL HOUSEHOLDS IN THE UNITED STATES

Proverty level	Number of households	Percent total households
Greater of 60 percent SMI [1] or 150 percent of poverty	24,136,925	26.0
150 percent poverty or below	18,718,748	20.0
125 percent poverty or below	14,796,445	16.0
110 percent poverty or below	12,335,430	13.4

[1] State Median Income.

Source: Compiled from U.S. Dept. of Health and Human Service, LIHEAP Division of Energy Assistance/OCS/ACF table on number of all low-income households, by census region and state based on 1990 Census data.

At its peak, regular, non-emergency, funding for LIHEAP was $2.1 billion in 1985. Since then, regular block grant funding has been cut back to $1.1 billion in fiscal year 1999 and 2000. Consistent with the cutback in funding is the reduction of the number of households served. According to the Administration for Children and Families, U.S. Department of Health and Human Services, the number of federally eligible households using LIHEAP assistance dropped from 7.5 million households in 1981 to 4.4 million households in 1996.[6]

At the same time, the percent of LIHEAP recipients' home heating bills covered by LIHEAP has been diminishing as the amount of recipients' total heating bills has been increasing. In 1981, LIHEAP covered around 23 percent of the total bills and since 1987, this percentage has steadily dropped from 19 percent in 1987 to 8 percent in 1996.[7] At the same time total home heating bills have increased in current dollars from $7.0 billion in 1981 to $7.9 billion in 1987 to $10.6 billion in 1996.[8]

Who is hit hardest by the reduction in LIHEAP funding? It is estimated that 43 percent of LIHEAP eligible households have children.[9] A recent survey by the National Energy Assistance Directors Association released in September 1997, showed that of the 1.2 million households that lost LIHEAP assistance between fiscal year 1995 and fiscal year 1997, 313,000 had at least one elderly member and 156,000 had at least on disabled member.

LIHEAP recipients also tend to be on the low-end of the poverty scale. For example, in fiscal year 1995, around 40 percent of households that received assistance were under 75 percent of the poverty level.[10] The proportion of energy costs to household income is called the energy burden. In 1995, NCLC completed a study that illustrated the disparity in energy burden between average residential and low-

[3] Preliminary results of a survey by the Department of Human Rights, Community Action Agencies, Des Moines Iowa. The final results are expected in May 2000.

[4] Derived from 1997 Residential Energy Consumption Survey (RECS), database files, Energy Information Administration, U.S. Department of Energy, Washington, DC. 1999.

[5] Id.

[6] U.S. Department of Health and Human Services, Administration for Children and Families, September 1999, "LIHEAP Home Energy Notebook for fiscal year 1997", p. 27.

[7] Id at 29.

[8] Id at 29.

[9] Oak Ridge National Laboratories, "The Scope of the Weatherization Assistance Program: Profile of Population in Need" March 1994. p. xii.

[10] U.S. Dept of Health and Human Services, Report to Congress for fiscal year 1995: Low-Income Home Energy Assistance Program, p.30, Table 12.

income households. We found the burden for the average residential household is 3.8 percent, while low-income households pay far more. Households receiving welfare assistance paid an average of 26 percent of their income on energy, Social Security recipients paid around 14 percent and minimum wage households paid around 12 percent.[11]

LIHEAP CAN MOVE HOUSEHOLDS TOWARD SELF-SUFFICIENCY

LIHEAP is a block grant that targets assistance to low-income households who pay a high proportion of household income on home energy, assists eligible families in crisis situations, and among other things, provides low-cost weatherization to reduce household energy costs.[12] Increased funding for LIHEAP could work towards reducing dependence on energy assistance in the first place. As noted by Vicky Mroczek, Chief of the Office of Community Services, Ohio Department of Development and the Director of Ohio's LIHEAP program: Reduction in energy assistance dependence over time is self-evident with respect to weatherization, but I think it's also true on the bill assistance side. When someone goes into debt to maintain utility service, there are costs or other needs that go unmet. When someone owes the utility money over a long period, ratepayers bear that expense, too. An unpaid final utility bill on a credit report impinges on a person's ability to buy or rent housing; sometimes it can show up when a potential employer does a background check. Loss of utility services also affects education performance due to excessive moving or unhealthy conditions in the home.

EMERGENCY CONTINGENCY LIHEAP FUNDS

Emergency contingency funds are a critical resource in times of crisis, but should not be counted as part of the overall amount of funding a state has to plan a program. Emergency contingency funds are released only after the emergence of a full-blown crisis, which may arise after the program has shut down for the season. Maintaining current funding levels for LIHEAP regular and emergency contingency funding in lieu of restored regular funding will continue to place vulnerable low-income and elderly households in potentially life-threatening situations time and time again. A more rational approach would be to increase the current level of the regular funding so that programs can effectively plan ahead for crisis situations to mitigate the danger to safety and health.

THE PRIVATE SECTOR

Fuel funds, a form of non-federal energy assistance, play an important role in helping those Americans in dire need of energy assistance; however, these funds are only a small fraction of the LIHEAP. The National Fuel Funds Network estimates that in 1998, around $88 million in non-federal energy assistance was raised nationally. These private sector funds are critical, but simply not large enough to provide the amount of energy assistance to eligible Americans as the LIHEAP and cannot fill the gap left by reduced levels of regular LIHEAP funding.

CONCLUSION

We urge the restoration of LIHEAP assistance to, at a minimum, $1.5 billion in regular appropriations for fiscal year 2001 and $1.6 billion in advance appropriation for 2002. Restored levels of regular funding will enable state agencies design a stronger program for the upcoming fiscal year. Finally, the need for LIHEAP assistance continues, especially as states implement welfare reform and, as demonstrated this past winter with the home heating oil price crisis, inadequate funding levels place the health of financially vulnerable families in jeopardy.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR THE MENTALLY ILL

Chairman Specter, Senator Harkin and members of the Subcommittee, I am Jim McNulty, of Bristol, Rhode Island, a member of the Board of Directors of the National Alliance for the Mentally Ill (NAMI). I am pleased today to offer NAMI's views on the Subcommittee's fiscal year 2001 bill that are of tremendous concern to people with serious brain disorders and their families.

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[11] National consumer Law Center, "Energy and the Poor: The Crisis Continues," January 1995, chpt. II.

[12] 42 U.S.C. section 8624(b).

WHO IS NAMI?

NAMI is the nation's largest national organization, 210,000 members representing persons with serious brain disorders and their families. Through our 1,200 chapters and affiliates in all 50 states, we support education, outreach, advocacy and research on behalf of persons with serious brain disorders such as schizophrenia, manic depressive illness, major depression, severe anxiety disorders and major mental illnesses affecting children.

Like so many NAMI members, mental illness has directly affected my life. In 1986, I was first diagnosed with bipolar disorder, also known as manic-depressive illness.

Mr. Chairman, 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 decade have we seen the first real hope for people with these brain disorders through pioneering research that has uncovered both a biological basis for these brain disorders and treatments that work. From NAMI's perspective, this progress was confirmed for all Americans through two watershed events in 1999—the White House Conference on Mental Health on June 7 and the release of the Surgeon General's Report on Mental health on December 13. Taken together, these two events brought together national leaders and the most comprehensive scientific report ever to substantiate what we have been saying for years—that severe mental illnesses are brain disorders that are treatable. As the Surgeon General noted, current success rates for treating schizophrenia are near 60 percent. Likewise, the success rate for bipolar disorder has risen in recent years and now approaches 80 percent. For major depression, the rate has climbed to nearly 65 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.

SEVERE MENTAL ILLNESS RESEARCH AT THE NIH

The year 2000 marks the end of the Decade of the Brain—an initiative that grew out of the leadership of your colleagues former Senator Mark Hatfield of Oregon and the late Senator and Governor Lauton Chiles of Florida—it is important for us to put into perspective the gains we have witnessed in brain science that have benefited people with serious brain diseases such as schizophrenia and other severe mental illnesses. We also need to plan for the future gains that are so necessary.

I noted earlier that severe mental illnesses are often quite effectively treated. In fact, tremendous advances in treatment of severe mental illnesses occurred during the last ten years, the Decade of the Brain, from the introduction of Prozac and Clozapine and other new drug discoveries that have virtually revolutionized mental illness treatment. Today, many more consumers, patients with serious mental illnesses, stand able to take charge of their lives, to be productive, to enjoy recovery, because of these treatment advances.

But we should not underestimate how much more must be learned about the brain regions involved in these serious mental disorders, the molecules at the roots of the terrible symptoms, and the genes that lead to vulnerability to these illnesses. The Decade of the Brain has really only brought us to the threshold of discovery when it comes to brain diseases such as schizophrenia, manic-depressive illness, obsessive-compulsive disorder, childhood mental illnesses and others. We are only now poised to fully probe and finally understand the biological underpinnings of the most serious mental illnesses.

Treatment for mental illnesses, while impressive and comparable to some of the best treatments in all of medicine, are still unacceptable for patients, families, and our society. Many people with severe mental illnesses find only incomplete relief from their symptoms; disability is still all too commonly associated with these illnesses. In my case, treatment for bipolar disorder has proven effective, but never for all of the symptoms. Individuals with obsessive-compulsive disorder, a brain disorder which has been pinpointed to specific higher regions of the brain, still often fail to achieve much gain in treatment. For children matters are worse because we know so little about the illnesses as they emerge during development, and we know even less about how to effectively and safely treat them.

The national need for severe mental illness research is most starkly demonstrated by particularly terrible statistics. Our nation stands in the midst of a virtual catastrophe: a suicide epidemic. Suicide is the eighth most common cause of death in this country and the fourth most frequent cause of life lost under age 65. Rates are increasing among young men and the elderly. As it stands, 30,000 Americans will die by suicide this year, most of whom have a serious mental illness. The most severe mental illnesses—schizophrenia and bipolar disorder-disproportionately lead to sui-

cide. Ten percent of the 2,000,000 U.S. citizens with schizophrenia are take their lives; about half will make a suicide attempt at some point. Fifteen percent to 20 percent of the approximately 2,000,000 Americans with bipolar illness will die by suicide.

That severe mental illness research ought to be a priority for our nation is also demonstrated by data from the World Bank and World Health Organization. Severe mental illnesses—major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder—account for four of the top 10 most disabling illnesses in the world. These brain disorders account for an estimated 20 percent of total disability resulting from all diseases and injuries.

Mr. Chairman, the public health burden to our nation from severe mental illnesses requires that research on these diseases be a high priority, especially given the scientific opportunities that exist in the brain sciences. Let me concentrate now on what we think are sound goals for NIH and NIMH, respectively, so that we can bring the full force of our research to bear on this most important health emergency.

NIH INVESTMENT: A CALL FOR INCREASED FUNDING AND ACCOUNTABILITY

NAMI applauds your leadership in supporting increases for the NIH. We urge the Subcommittee to follow the recommendations of the scientific community and the Ad Hoc Group for Medical Research Funding and increase overall funding for NIH by $2.7 billion (a 15 percent boost) for fiscal year 2001, up to $20.5 billion. Such an increase would keep Congress on pace to reach the bipartisan goal of doubling NIH funding by 2003.

But increased resources are not the only important objective for NIH: better accountability is also essential. NAMI applauds your efforts to fairly boost NIH funding and limit disease-of-the week approaches to appropriations. Nonetheless, we urge you to press NIH to invest their resources according to public health need as well as scientific opportunity, as the 1998 Institute of Medicine (IOM) report on NIH priority setting called for. NIH must balance its investment among diseases so that increases in the budget go preferentially to address illnesses that are disabling and costly and have been underfunded in the past.

It is obvious to NAMI that severe mental illnesses would, and should be, a top research priority if public health burden is the principal criteria by which public research dollars are allocated. Yet, based on NIH's own recent estimates, $1.00 is invested in research for every $6.86 in costs of AIDS, $9.96 in costs of cancer, $65.65 in costs of heart disease, and $161.26 costs in schizophrenia. In other words, 15 cents is spent on AIDS research per dollar of costs, compared with 10 cents for cancer, two cents for heart disease, and less than one cent for schizophrenia. This is obviously not a wise research investment strategy for the United States.

NIMH: THE KEY TO THE CURE FOR SEVERE MENTAL ILLNESSES

For NIMH, we also applaud this Subcommittee's leadership, demonstrated by your boosting its appropriations significantly in the past few years and by nearly 15 percent in fiscal year 2000, up to its current level of $978.4 million. For fiscal year 2001, NAMI urges the Subcommittee to fund the NIMH up to the "professional judgment" recommendation of $1.169 billion. While NAMI applauds the President's request to increase NIMH's budget by 5.9 percent, up to $1.031 billion, we believe that the "professional judgment" recommendation needed in order to increase the agency's success rate for reviewed grants to at least 750 new and competing grants. NIMH is currently attracting more research grant applications than any other institute due to the leadership of the institute and the tremendous research opportunities that exist in the neuroscience's and in severe mental illness research. NAMI believes that we must ensure that this time of interest, strong leadership, and research opportunity is taken—so that people with serious brain diseases have the best hope for the future, for themselves and for their families and future generations.

We urge you, Mr. Chairman, to help ensure that NIMH continues its move to spend its taxpayer dollars wisely, with investments in basic neuroscience and molecular biology that will undergird the new treatment frontier for severe mental illnesses and also with strong commitments to serious brain disorders directed towards pre-clinical, clinical, and services research. NIMH should continue its efforts to identify genes linked to severe mental illnesses; to fund and expand clinical research into psychotic illnesses, serious disorders in children, and in mood disorders; to continue the probe of the biology of serious mental disorders including schizophrenia, mood, and anxiety disorders.

NIMH should also use the tools of behavioral science to better understand the expression and best treatment of severe mental illnesses. However, NAMI strongly

recommends that research in prevention and psychosocial research should be redirected in order to address problems associated with serious mental illnesses, consistent with the recommendations of NIMH's own National Advisory Mental Health Council. We agree with the recommendations of the Council that the prevention research portfolio has all but excluded serious mental illness research and instead focused on basic behavioral science issues and or social problems such as adolescent relationships, divorce or poor self-esteem. NAMI believes that we cannot let another five years go by studying children who misbehave while we know so little about serious mental illnesses in children and how to effectively treat these disorders.

What research issues are most compelling for our members, the more than 210,000 Americans facing a serious brain disorder? (1) More basic research on the brain and higher brain functioning. (2) More pre-clinical research on the genes, molecules, and brain regions involved in severe mental illnesses. (3) More clinical research aimed at understanding the best treatment for these serious disorders and translating that research into practice. (4) More research aimed at better understanding and treating these brain disorders in children. (5) Research aimed at diminishing relapse and disability in severe mental illnesses. (6) More research on how people with severe mental illnesses best receive treatment and services. (7) An accountable and responsible research investment strategy that will help the nation's individuals with severe mental illnesses and their families, as well as the country at large, which must shoulder the burden and costs of these illnesses.

Finally, Mr. Chairman, NAMI would like to urge that NIMH's colleague institutes, the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol and Alcoholism (NIAAA) be directed to work cooperatively with NIMH and the pressing public health crisis posed by persons diagnosed with a severe mental illness who have a co-occurring substance abuse problem. NAMI believes that a large and growing body of scientific evidence is making clear that integrated treatment, as opposed to parallel and sequential treatment, is the most effective means of treating these co-morbid disorders. NAMI urges that NIMH, NIDA and NIAAA should work in partnership to ensure that progress continues in our efforts to better understand co-occurring mental illness and chemical dependency.

SAMHSA AND CMHS

Mr. Chairman, in addition to urging the Subcommittee to support increased funding for brain research, I would also like to note the importance of federally funded mental illness services through the Center for Mental Health Services at SAMHSA. Federal support for community-based care is a critical resource for people with the most severe mental illnesses. With many states reducing their psychiatric 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 Block Grant (MHBG) now constitutes as much as 40 percent of all non-institutional services spending in some states.

In the President's fiscal year 2001 budget proposal, a $60 million increase is proposed for the MHBG (up from its fiscal year 2000 appropriation of $356 million, to $416 million). While NAMI is extremely grateful for the $68 million increase that the Subcommittee enacted for fiscal year 2000, the reality is that this boost in resources is not enough to keep pace with the continued widening of gaps in the public mental illness treatment system in many states. The consequences of these emerging cracks in the service system are readily apparent, not just to NAMI's consumer and family membership, but also to the public: the growing number of homeless adults on our nation's streets who receive no treatment services, well publicized tragic incidents involving individuals with severe mental illness who are not accessing adequate treatment services and the growing trend of "criminalization" of mental illness and the stress it is placing on state and local jails and prisons.

The causes of these growing gaps in the services are varied and complicated: the trend toward privatizing state Medicaid programs through contracting with private managed care firms, cuts in Medicaid Disproportionate Share Hospital (DSH) funding and expansion of the mission of public mental health programs beyond serving the most severely disabled consumers. Moreover, in recent years state mental health agency budgets have been under increasing pressure as a result of forces beyond their control. Among these forces are restrictions on eligibility for SSI and SSDI for people whose disability is based in part on drug abuse or alcoholism and a 1997 U.S. Supreme Court decision allowing states to commit sexually violent predators to state hospitals.

In addition to supporting the Administration's proposed increase, NAMI further recommends that the Subcommittee target all additional funds for the MHBG in fiscal year 2001 to state and local evidence-based, outreach-oriented service-delivery

models for persons with severe mental illness in the community. In particular, NAMI urges that any increase in MHBG funding be directed to assertive community treatment, including the Program of Assertive Community Treatment, or PACT. PACT programs use a 24-hour, seven day-a-week, team approach that delivers comprehensive treatment, rehabilitation and support services in community settings. High-quality PACT programs are typically implemented at a cost that is significantly less than placing an individual in a jail, a residential treatment program or a hospital. PACT is especially effective in serving persons who are the most treatment resistant, persons with a co-occuring mental illness and substance abuse disorder and persons who are high users of inpatient hospitalization services.

In addition, NAMI recommends that the Subcommittee consider requiring states to report an unduplicated count of persons served by diagnosis, age and services consumed using the targeted initiative MHBG funds. NAMI is also concerned that the Substance Abuse Treatment and Prevention Block Grant is not currently supporting programs serving persons dually diagnosed with mental illness and addictive disorders. As I noted above, evidence-based research, as confirmed by the NIH, verifies that integrated treatment, as opposed to parallel collaborative or sequential approaches, is the most effective model for serving persons with a dual diagnosis. NAMI therefore recommends that the Subcommittee direct SAMHSA to allow states to use funding from both programs to promote integrated treatment services for persons with co-occuring mental illness and addictive disorders.

NAMI is pleased that the President's fiscal year 2001 budget proposes another $5 million increase for the PATH program (up from its current $30 million, to $35 million). PATH is a formula grant program to the states to support local programs serving homeless persons with severe mental illness. This increase in PATH funding will help communities all across the country increase access to treatment and supports for the growing number of homeless with severe mental illnesses.

Mr. Chairman, as you know, the President's fiscal year 2001 budget proposes a new unauthorized line-item as part of the CMHS's programs—Targeted Capacity Expansion (TCE). According to CMHS's own justification for this request, this new $30 million is for undefined prevention and early intervention services for persons who are not diagnosed with a severe mental illness who receive services in "non-mental health settings." While NAMI recognizes that such a new program could offer benefit to many communities, we believe a more pressing public health concern is the alarming trend of "criminalization" of severe mental illness.

NAMI therefore urges that instead of establishing a new TCE line item within the CMHS budget, the Subcommittee instead direct these funds to a new initiative within the agency's Knowledge, Development and Application (KDA) program on criminalization. Such a program should be directed toward innovative state and local programs that (1) divert mentally ill, non-violent criminal defendants and convicts into treatment programs, (2) replicate successful models such as mental health courts, and (3) train police officers in how to appropriately interact with suspects with severe mental illnesses. NAMI is making a similar request to your colleagues at the Commerce-Justice-State Appropriations Subcommittee for a program of similar scope and purpose at the Bureau of Justice Assistance.

In January, The Charlotte Observer ran a five-part investigative series that reported since 1994, at least 35 people with mental or developmental disabilities have died under questionable circumstances while under the care of public and private mental health facilities in North Carolina. Deaths were attributed to suicide, murder, neglect, scalding, and falls, and most went unnoticed by the agencies authorized with investigating such deaths. NAMI recommends that resources be targeted to fund Protection and Advocacy agencies to investigate questionable deaths and serious injuries, like those deaths in North Carolina that have resulted from restraint abuse.

Unfortunately, the Charlotte Observer series is just one of several investigative media reports over the last year that have exposed systemic failures to provide adequate treatments and services to individuals with severe and persistent mental illnesses. The Los Angeles Times, The New York Times, The Hartford Courant, and The Orlando Sentinel have revealed a pervasive pattern of neglect by state mental health systems. The need for further investigation, a system of accountability and mandatory reporting of deaths and serious injuries will help ensure that individuals with mental illnesses don't lose their lives in the very places designed to help them.

DOL AND SSA

Finally, beyond the NAMI's traditional concerns with NIMH and CMHS, I would like to note two other departments under the Subcommittee's jurisdiction that are of concern to NAMI—the Department of Labor (DoL) and the Social Security Admin-

istration (SSA). With regard to DoL, NAMI would like to go on record in support of the Administration request to establish a new Assistant Secretary position for disability policy. At SSA, NAMI would like to express our strong support for full implementation of the Ticket to Work and Work Incentives Improvement Act (TWWIIA) and fiscal year 2001 funding for the new work incentives planning and outreach program. NAMI would like to thank you for your strong support for TWWIIA last year. Enactment of both these proposals will help ensure that progress is made in addressing the barriers to work that still leave more than 80 percent of adults with severe mental illnesses unemployed and out of the economic mainstream.

CONCLUSION

Mr. Chairman, thank you for the opportunity to offer NAMI's views on fiscal year 2001 funding for programs of critical importance to people with serious brain disorders. NAMI looks forward to working with you in the coming months to educate both the general public and your colleagues in Congress about the critical importance of investment in biomedical research and improved services for people living with severe mental illness.

PREPARED STATEMENT OF THE AMERICAN PUBLIC TRANSPORTATION ASSOCIATION

The American Public Transportation Association (APTA) appreciates this opportunity to testify on the fiscal year 2001 Labor, Health and Human Services, Education and Related Agencies Appropriations bill.

About APTA

APTA's 1,270 member organizations serve the public interest by providing safe, efficient and economical public transportation service, and by working to ensure that those services and products support national transportation, energy, environmental, community, and economic goals. APTA member organizations include transit systems; design, construction and finance firms; product and service providers; academic institutions, and state associations and departments of transportation. More than ninety percent of the people who use transit in the U.S. are served by APTA member systems.

We submit testimony to this Subcommittee to make the point that public transportation can make a difference in how people get to jobs, health care, training, and other social services. According to the Federal Transit Administration (FTA), 32 million senior citizens rely on transit as their driving ability decreases with age; 27 million people with disabilities depend on transit to maintain their independence; 37 million people living below the poverty level often cannot afford a car and use transit to reach jobs. There are 56 million children under driving age, many of whom use transit to travel to and from school and for after-school activities. Transit ridership has grown by more than 15 percent over the past four years and annual ridership exceeds the 9 billion mark.

Overview

Mr. Chairman, we bring a message about the role public transportation can and does play in providing services to millions of Americans. We ask that the Subcommittee consider three issues of particular importance to public transit. First, APTA requests that the Subcommittee direct the Department of Transportation (DOT) and the Department of Health and Human Services (HHS) to complete joint coordination guidelines on human services transportation as soon as possible. Second, we urge the Subcommittee to highlight the role that public transportation can play in providing cost-effective access to health care and to work—made better by improved coordination. Finally, we urge the Subcommittee to continue to provide and encourage flexibility with regard to HHS funding being used to pay for the transportation costs of HHS clients—especially those individuals with special transportation needs. Transit agencies have the expertise and infrastructure to provide transportation, and we think that social service agencies could save money on transportation service by working with transit agencies. The Federal Government has already invested in public transportation. Let's not pay twice by allowing separate special purpose systems to be built and subsidized.

Mr. Chairman, transit is delivering. U.S. transit ridership was up more than 4.5 percent in 1999.[1] Ridership is on the rise in every mode, including a 5 percent increase in demand response service. Moreover, these vital services, which provide the

[1] APTA Transit Ridership Report, Fourth Quarter 1999.

only source of mobility for individuals with disabilities and our elderly population, are seeing a dramatic increase in areas all across America—both rural and urban. Demand response services are on the rise in places like Springfield, Illinois; Milwaukee, Wisconsin; Pensacola, Florida; Waco, Texas; Fort Myers, Florida; Dallas, Texas; Miami, Florida; and Baltimore, Maryland.

Background

According to the U.S. General Accounting Office (GAO), federal efforts to streamline the delivery of human services transportation by DOT and HHS began as early as 1986 with the establishment of a Coordinating Council.[2] Over a course of years, the Council successfully identified numerous barriers standing in the way of transportation coordination. However, due to jurisdictional problems, the Council was unable to fully respond to these barriers. Moreover, even when the Council reached out to the States in the mid 1990's, the majority of barriers that were identified were too general to be acted upon with any significant federal response.[3]

In fiscal year 1997, report language first appeared in both the Transportation and Related Agencies and Labor, Health and Human Services Appropriations bills, calling for the development of joint planning guidelines to specifically address the use of public transportation in the delivery of human services transportation. APTA, having worked with Congress to encourage this collaboration, was pleased that the bills directed DOT and HHS to develop joint guidelines for coordination of transportation services, including joint identification of human services client transportation needs and the appropriate mix of transportation services to meet those needs; the expanded use of public transit services to deliver human services program transportation; and cost-sharing arrangements based on a uniform accounting system for HHS program recipients transported by paratransit systems.

Although the joint guidelines have not yet been released, we are hopeful that DOT and HHS will be in a position to release a working draft in the near future. Nevertheless, we again urge this Subcommittee to direct HHS and DOT to complete their joint coordination guidelines as soon as possible, and to consider the feasibility of involving other federal agencies, such as the Department of Labor, in the process.

GAO Report Cites the Value of Transportation Coordination

The report issued by the GAO notes that transportation coordination can have numerous benefits. It also recommends a number of ways that DOT and HHS can better coordinate their activities. They include:

—requiring the Coordinating Council to issue a prioritized strategic plan by a specific date.

—charging the Council with developing an action plan with specific responsibilities.

—requiring an annual report from the Council on its major initiatives and accomplishments.[4]

APTA fully agrees with the recommendations made in the GAO report. During this period of tight budget caps, every dollar dedicated to human services transportation by transit agencies can be stretched further if coordination is implemented at the federal level and encouraged at the State and local level. These joint guidelines will be invaluable in providing policy guidance for coordination activities by transportation agencies and human service providers at the local level. If we can't get the necessary guidance at the federal level, how can we expect coordination at the local level?

TEA 21 Planning Provisions

We are pleased to note that the principal federal surface transportation infrastructure investment law, the Transportation Equity Act for the 21st Century (TEA 21), includes numerous provisions that deal specifically with the importance of coordination of transportation activities. First, the bill requires DOT to encourage metropolitan planning organizations in developing local transportation plans to coordinate the design and delivery of transportation services by all entities receiving federal funds for transportation purposes. Another TEA 21 section requires government agencies and nonprofit organizations receiving assistance from government sources other than DOT for non-emergency transportation services to coordinate the design and delivery of transportation services. The law also requires transportation plans to be consistent with air quality goals under the Clean Air Act. Clearly, trans-

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[2] TRANSPORTATION COORDINATION: Benefits and Barriers Exist, and Planning Efforts Progress Slowly. October, 1999. (Hereinafter, GAO Report).

[3] GAO Report, Page 3.

[4] GAO Report, Page 20.

portation services are coordinated with many federal programs to improve overall efficiency.

PUBLIC TRANSPORTATION PROVIDES AFFORDABLE ACCESS TO NON-EMERGENCY HEALTH CARE

Mr. Chairman, we continue to stress the importance of coordinating transit service with other government functions because of the great potential for saving tax dollars at all levels of government. To lower costs, non-driving outpatients may travel to health care by transit. The alternative may be expensive taxi or ambulance service. Rather than using paratransit services (which can cost 10 times the amount of traditional transit fares),[5] physically able clients can save themselves and human services agencies significant money by taking other types of public transportation. For example, across the nation, transit vans carry thousands of people to and from dialysis treatment, saving as much as $200 to $400 per trip as compared to specialized medical transportation services.

During the past decade, transit systems have made it increasingly possible for transit services to be available to all Americans. Wheelchair accessible buses increased from 40 percent of the fleet in 1990 to 77 percent of the fleet in 1999. Similarly, commuter rail operators reduced the number of non-accessible rail cars by more than half over the same period. Moreover, virtually all fixed route bus service is now accessible to individuals with disabilities.

In 1997, the Health Care Financing Administration estimated that it was spending approximately $1.2 billion annually in non-emergency medical transportation. Since then, many state Medicaid offices have found waste, fraud and abuse within their transportation systems and have improved the delivery of transportation services at a reduced cost by coordinating with local public transit operators. In fact, 20 percent of the nation's Medicaid rides are now on public transit. According to the FTA, in four major programs—Medicare, Medicaid, Food Stamps, and Unemployment Compensation—each dollar invested in low-cost mobility services reduces the transportation cost of these programs by approximately 60 percent.

PUBLIC TRANSPORTATION DELIVERS PEOPLE FROM WELFARE TO WORK

Transit Provides American's Access to Jobs; Employers Gain Access to New Talent

During the late 1990's, Congress and the 50 States took positive steps to get people off welfare and into the workforce. At the same time, a healthy economy has created thousands of new jobs. However, due to America's changing landscape and the growth of suburban sprawl, many of these new jobs are located in the suburbs. How can we bring people who live in central cities, many of whom have no automobile, out to where the jobs are? Public transportation agencies, in coordination with State and local social service agencies and the private sector, have responded to the challenge.

One of the best examples of a successful access to work program (and the value of coordination) is New Jersey Transit's "WorkPass" Program—a comprehensive transportation service and educational program developed to assist public and non-profit agencies in their efforts to move people from welfare to work. The program has provided assistance to more than 50 public and non-profit organizations, including county welfare agencies, Medicare agencies, and other social service organizations who offer public assistance for transportation to jobs, medical assistance and childcare. Partnering with the New Jersey Department of Transportation as well as the State's human services agency, New Jersey Transit was able to have a working program within one month, and more than 5,000 monthly passes and one-way tickets are purchased by WorkPass members each month. The transit agency notes that the success of the program is due to the partnerships it has formed and its ability to adapt to the different agencies seeking its services.

WorkPass is more than just a pass sales program—it has a comprehensive training program which has trained more than 500 welfare and other social service agency representatives. These representatives are taught to read schedules, determine fares and accessibility and provide special transportation services to their clients. New Jersey Transit provides each member with a resource center stocked with schedules, maps, fare charts and other transit information. WorkPass provides participants with access to job training and education, employment opportunities, medical visits, and childcare—all while learning the valuable commuting skills they need to succeed when employed.

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[5] GAO Report, Page 7.

The cost savings as a result of this program have been tremendous. Under the WorkPass Program, instead of providing their clients with a $6 per diem, welfare agencies reduce transportation costs by using bus and rail monthly passes. County welfare agencies are saving between 50 percent—60 percent on each WorkPass participant—an estimated $2 million saved in transportation costs for its members.

More Coordination Needed To Deliver People from Welfare to Work

Mr. Chairman, the successful New Jersey program is representative of the commitment the entire U.S. transit industry has put forth in the effort to assist individuals making the difficult transition from welfare to work. In October 1998, an APTA Access to Jobs Task Force was created to help coordinate and assess APTA member welfare to work activities. New services include new routes to employment locations outside the existing service area; more direct service to reduce very long trip times; late night and early morning service; so-called reverse commute service; and shuttles from rail stations and the ends of bus routes to dispersed job locations. The negative impact that these extra efforts may have on transit budgets is easily outweighed by the changes the programs have made in people's lives.

APTA believes that an awareness of problems encountered by organizations in their welfare to work activities may help other agencies avoid the pitfalls that could reduce the effectiveness of their welfare to work programs. Therefore, we asked our member organizations to describe some of the most common problems that they have encountered in implementing welfare to work activities. Not surprisingly, APTA's 1999 Access-To-Work Best Practices Survey Summary Report reveals that throughout America, the lack of coordination is the number one reason that some well intentioned welfare to work projects have fallen short of their goals.

For example, lack of coordination has hampered programs in Missouri. In St. Louis, there has been a lack of meaningful cooperation with the training staffs of human services agencies. Also, City Utilities of Springfield has experienced difficulty in coordinating information from all the various social service agencies involved with their welfare to work program. In fact, in order for them to put together a comprehensive regional plan, the assistance of an outside consulting company was required to gather all information. Moreover, in Texas, transportation coordination with human services agencies is sorely needed in the Fort Worth Transportation Authority's (The T) attempt to identify employers willing to hire welfare recipients, and to find strong candidates for certain jobs. Moreover, the transit agency says that coordinating various funding sources has been quite difficult—local social services partners are burdened with the task of tracking separate data from separate Federal agencies, including DOL and HUD. This requirement has been a major barrier in streamlining funding for Tarrant County's welfare to work initiatives.

Some 94 percent of welfare recipients attempting to move into the workforce do not own cars and must rely on public transportation to get to work. And while 60 percent of welfare recipients live in central cities, the majority of new jobs are in the suburbs. If we as a nation wish to continue the positive trends in getting more people into decent, productive employment, we must provide the necessary coordination and guidance at the federal level to get them there. In the TEA 21 section authorizing the Job Access and Reverse Commute Program, DOT is required to "coordinate activities with related activities under programs of other federal departments and agencies." Eligible Access to Jobs projects financed under that section must be "part of a coordinated public transit-human services transportation planning process." [6] Mr. Chairman, we need the help of the Coordinating Council's joint guidelines in order to fully implement this provision.

Mr. Chairman, we've come so far in the last ten years with respect to providing people on public assistance with access to decent jobs. But without a concerted effort to improve coordination at the federal level, there's a limit on the amount of services our transit agencies and state DOT's can provide. Coordination is absolutely crucial to the future success of the welfare to work initiative.

INCREASED FUNDS ARE REQUIRED TO MAINTAIN ADA COMPLIANCE STANDARDS

Since the enactment of the Americans with Disabilities Act, transit agencies have made huge progress in their effort to ensure that all forms of public transportation are accessible to individuals with disabilities. But public investment for further on-vehicle lift, ramp and station improvements must keep pace in order for transit agencies to maintain Federal standards. More than 100 million trips were provided on demand responsive public transit in 1999, at an estimated total capital and operating cost of $1.4 billion. Accordingly, APTA urges this Subcommittee to continue

[6] TEA 21, Section 3037.

to provide and encourage flexibility with regard to HHS funding being used to pay for the transportation costs of HHS clients. This is also an area where the joint guidelines would go far in ensuring HHS programs retain their commitment to making adequate transportation resources available.

CONCLUSION

In closing, Mr. Chairman, we again thank you for this opportunity to convey our message about the critical role public transportation can and does play in providing services to millions of Americans. We ask that in developing the fiscal year 2001 Labor, Health and Human Services and Education bill, the Subcommittee direct the Department of Transportation and the Department of Health and Human Services to complete the joint coordination guidelines on human services transportation that have been requested by Congress. Second, we urge the Subcommittee to highlight the role that public transportation can play in providing cost-effective access to health care and to work—made better by improved coordination. Finally, we urge the Subcommittee to continue to provide and encourage flexibility with regard to HHS funding being used to pay for the transportation costs of HHS clients—especially those individuals with special transportation needs.

Once again, we appreciate your consideration of our views. APTA would be pleased to provide you additional information to assist you in your deliberations.

PREPARED STATEMENT OF THE NATIONAL COUNCIL ON INDEPENDENT LIVING

Chairman Specter and members of the Senate Appropriations Subcommittee on Labor, HHS and Education, the National Council on Independent Living (NCIL) thanks you for allowing us to provide written testimony regarding the great need to increase the funding in title VII, Part C of the Rehabilitation Act of 1973, as amended, by $75 million over the next three years. This funding will allow states to strengthen and expand the network of centers for independent living throughout the country.

The National Council on Independent Living (NCIL) is the national membership association of centers for independent living (CILs), statewide councils on independent living (SILCs), people with disabilities and organizations advocating for the rights of people with disabilities.

CILs are community-based, non-profit corporations which are governed, managed and staffed by a majority of people with disabilities. CILs are non-residential organizations, advocating and providing services that support the efforts of people with significant disabilities to live more independently in their own homes, within our communities.

Currently, there are 340 CILs, with more than 224 satellite locations. Of these, 229 CILs and 44 satellites are funded with the $45 million dollars authorized through Title VII–Part C of the Rehabilitation Act of 1973. The balance are supported with state funds.

A center's service area may be one county or a dozen. According to the Rural Institute on Disabilities, CILs cover an average of 5.7 counties. Today, 60 percent (1,911) of our nation's counties receive service from a CIL. This figure is deceiving, however, because a single center may have the task of providing services to an area the size of Pennsylvania.

NCIL is asking that the Senate Appropriations Committee make a strong commitment to independent living. You can do this by increasing funding for CILs by $75 million over the next three years.

As described above, statewide independent living councils are joining in the effort to secure additional funds for CILs. SILCs are governor-appointed bodies which are directed by the Rehabilitation Act to design a network of CILs. Working in conjunction with the state vocational rehabilitation agencies, SILCs must develop plans which address the needs of our unserved and underserved communities. This plan is submitted to the Department of Education and summarized each year for your review. The following are some of the findings from 1998, when CILs were funded at about $40 million nationally. These figures do not include Massachusetts, Connecticut, and Minnesota because of their unique funding formulas.

First, who did we serve?

In 1998, CILs assisted 118,000 people with significant disabilities. Of these, 35 percent were from minority groups, which significantly exceeded the percentage of minorities in the nation as a whole (29.7 percent according to the Census Bureau). One might ask what would contribute to a success rate that makes CILs the envy

of many service providers. Perhaps it is because over 28 percent of center employees are also members of minority groups.

In the introduction, you were informed that CILs must be run by people with disabilities. In 1998, almost 66 percent of the staff were people with disabilities, including 72 percent of the decision-making positions. When we say 19consumer directed', we mean it.

What about services?

If we were VISTA, we might brag about our 2 million hours of community service. Or if we were a single services program, CILs would claim to provide services over 760,000 times. But that isn't who we are. CILs are about assisting people with disabilities so they can live more independently in their communities.

In addition to responding to almost 340,000 requests for information and referral, CILs provided over 54,000 individuals with peer counseling services; 50,000 received assistance finding housing; 34,000 acquired personal assistance services; 33,500 attained transportation services; over 54,000 individuals received independent living skills training, and over 6,000 became employed. In addition, literally tens of thousands of individuals received dozens of other services from CILs, including assistance in moving out of costly institutional settings such as nursing homes.

In 1998, CILs helped over 1,400 people get out of nursing homes AND prevented over 14,500 from going into nursing homes. According to the 1998 State Data Book on Long Term Care Program and Market Characteristics, the average cost of nursing home services across the U.S. is $34,938/person/year. As you can imagine, there is a wide variation in nursing home costs from state to state. In Washington, for instance, the annual cost was $42,340.

Those who leave or avoid entering a nursing home are able to remain in their communities because they receive personal assistance and other community-based services. According to a 1999 report from the National Conference of State Legislatures, the average cost for community based services is $14,902 per person. In other words, when a center is able to help a person move from a nursing home to community-based services, they save taxpayers an average of $20,036. In 1998, CILs saved taxpayers over $318 million. Think of it: A savings of $318 million AND people remain in their own homes with their own families, as contributing members of their communities.

Imagine the financial rewards in Alaska alone, where nursing homes cost $92,520 per year for each resident while home health costs $33, 616. This amounts to a savings of $58,904 per person, per year.

Investing in CILs for independent living makes sense.—If the federal CIL program were a seed or magnet project, it would claim that with the $39,955,310 CILs received in 1998, they were able to attract an additional $144 million outside of the funding from Title VII of the Rehabilitation Act. This includes a variety of government, private foundation, fundraising, and fee-for-service arrangements. In other words, CILs make the taxpayers' money work for us—and for their consumers.

Here's another interesting fact.—The average cost for serving an individual at a CIL was $1,655. This amount is particularly startling when it is remembered that this number does not include the thousands of people who are served through information and referral, community education and systems change activities not counted in the case service records kept by CILs. These are individuals and groups who benefit from the information and referral services provided as a core service at every center and satellite, they are also individuals and groups served through community training and awareness activities, and through the systems change activities that result in sweeping improvements in the way the needs of people with disabilities are met in general.

Thus far, this request has concentrated on statistics and data. NCIL doesn't want to lose track of the fact that this appeal for funding helps real people make real changes in their lives. Sometimes, in the course of advocating for change, both the fiscal and personal costs are lost.

However, these things we know:

—Additional stress will be put on our health care and housing systems as baby-boomers age.

—Our nation is relying on institutions to address the needs of people who are elderly and/or with disabilities.

—Institutions are expensive and much more restrictive than most people need.

—Individuals, given a choice, will remain with their families and in their own homes, participating in community activities.

—Oregon saved $278.3 million dollars between 1981 and 1996, by serving 73 percent of eligible elderly people and those with disabilities in the community.

—The personal attendant services that Kansas offers under Medicaid waivers have saved the state $2,000 per person per year.
—Wisconsin's Community Options program, which offers personal assistance and other services to keep people with disabilities in the community, has saved the state as much as 25 percent of the cost of nursing home placement for people at risk of institutionalization.

In each of the above states, it is due to a strong independent living movement that community-based services have been as successful as the figures would indicate. This movement is initiated and fueled by strong CILs. In Oregon and Wisconsin, it was through the efforts of CILs that those states moved from the typical fragmentation of services, to a single point of entry, thus streamlining service delivery and significantly reducing costs.

That's what CILs do. Here are some examples of the personal impact of their work:

A man in Fulton, Mississippi was injured in an automobile accident and sustained a spinal cord injury. Like most who have this experience, this gentleman was told that he would need 24-hour care in a nursing home at a cost to the state of $30,000/year. A staff member from the satellite center in Tupelo helped him find a wheelchair, counseled him, and helped him get financial assistance from the state's Spinal and Head Injury Fund. Today, this man is living with his elderly mother and receiving four hours a day of personal assistance services at an annual cost of less than $8,000/year.

A woman in New York was facing a life in a psychiatric center at an annual cost of $137,000 due to pressure from her family and her own lack of assertiveness. The center spent $212 to provide peer counseling, advocacy, and other services to help her work with her family and find her own apartment, where she now lives. She receives a HUD rent subsidy of $2,712 per year.

The Hawaii Center for Independent Living has been helping a man who experiences quadriplegia return successfully to his community. In addition to providing independent living skills training and helping him access assistive technology, the center has been working with local vocational rehabilitation services and a small business called Custom Computer Consulting to tie his lights, fans, phones, and other appliances to his computer. Because of their efforts, he is going to make it!

At the center for independent living in Hot Springs there was a consumer who used a power wheelchair due to paralysis, was deaf and visually impaired. This young woman was not very educated, had been labeled as having behavioral problems, and her vocational rehabilitation counselor had virtually given up on her. The center began working with her using very limited signing skills, and taught her typing and computer skills to improve her ability to communicate. Everything about her changed. Suddenly she could express herself and people understood her. She found a job that paid a competitive wage and offers benefits such as medical insurance. This woman, who had been on SSI all her life, is now a taxpayer. The center worked with her approximately two months for a total cost of less than $5,000—less than one year's worth of SSI payments.

CILs keep families together. In Milwaukee, Independence First helped a single parent with quadriplegia. She contacted their assistive technology program for ideas on baby care adaptations while she was still pregnant. After her child was born she used the program to help her get an adapted baby carrier for trips into the community, and ideas for a lifting harness to help her get the baby onto and off of the floor. The technology coordinator worked with Sharon and several county agencies to assure that the child's care needs could be adequately met.

In 1994, a rural nursing home contacted the center in Tulsa, Oklahoma. One of their residents was a young mother in her early thirties who had incurred a traumatic brain injury as the result of a car wreck. The injury had left the mother a paraplegic, with left-sided paralysis. The young mother wanted desperately to leave the nursing home and reestablish a relationship with her three small children. The woman's physician and her own family members refused to help relocate her to Tulsa. The woman didn't even have the $307 needed to pay for her monthly medications. Nor did she have money for food, rental or security deposits. After seven months, the center was successful in locating resources within the community and moved this mother out of the nursing home. Six years later, she is still living independently in her own apartment and enjoying being a mother.

A young Maryland college student injured in an automobile accident at 24 had been discharged from a rehabilitation center into a nursing home in Hyattsville, Prince George's County, MD. A center for independent living contacted the young man who was, "convinced I was going to be there forever." The center for independent living provided peer support and information about resources he could utilize to maximize his re-integration into the community. Today he is living in his

own apartment, attending the University of MD, and majoring in computer science and graphic arts.

Why do we need $75 million?

Today, the CIL network reaches less than one percent of all people with significant disabilities in the United States. While not every person with disability needs a center's help, there remain vast areas of the U.S. where no center exists at all. Forty percent (40 percent) or 1,230 of our nation's counties receive no service whatsoever from a CIL. Hundreds more receive only superficial coverage.

At the current rate of coverage (5.7 counties per center), The Rural Institute on Disabilities estimates that we need at least an additional 216 CILs. Some states have estimated that there should be at least one "fully-funded" center for every 500,000 persons, or an additional 185 CILs nationwide.

What is a "fully-funded" CIL?

Today, CILs are woefully underfunded. The average federally-funded CIL receives approximately $163,285 to support the operations of the center. Most statewide independent living councils believe that CILs need a strong base—anywhere from $200,000 to $500,000 per center per year—to do their job. The National Council on Independent Living (NCIL) believes a center needs at least $250,000 to support day-to-day operations, meet standards and assurances required by the Rehabilitation Act, and address the goals of the community. The Independent Living Research Utilization Program (ILRU) has found limited funding to be the most common reason for the fiscal collapse of CILs.

A $25 million increase in each of the next three years will fill the gap. When we first raised this issue to you last year, several of you expressed concern that the current funding formula, based solely on population, would send most of the money to larger communities at the expense of rural areas. This year, we are suggesting that each $25 million increment be divided roughly in half so that each state receives an flat allocation of $250,000, plus an allocation based on population.

What will be the impact of a $75 million increase over the next three years? In Illinois, funding would increase from $1.5 million to $3.7 million. The Illinois SILC will recommend that the funds be used to address underserved inner-city people, as well as the unserved areas in the four southern counties bordering Indiana.

Pennsylvania's funding would grow by $2.3 million over three years, making it possible for CILs which have been operating at less than half the recommended budget to finally reach their potential, and open long-needed CILs in Du Bois and Johnstown.

In Florida, funding will increase from $1.8 to almost $4.4 million. The Florida SILC will use the additional funds to not only shore up the existing CILs, but also address the needs of the people in 27 of the state's 67 counties who are receiving virtually no service at all.

In a rural state like Idaho, funding will grow from less than $700,000 to almost $1.6 million. This will allow us to strengthen the existing CILs, expand services to Coeur D'Alene and Caldwell, and set up a center on an Indian Reservation.

Kentucky will increase it's budget from $490,000 to $1.7 million. There are four fledgling CILs in Bowling Green, Lexington, Harlan, and Covington which are operating on budgets of less than $70,000 each. This increase would make it possible for those CILs to add the staff they need to begin seriously addressing the independent living needs of people in these communities.

In a large state like California, both urban and rural needs would be addressed. CILs in San Diego and San Francisco are responsible for such large populations (The San Diego center provides services to 11 percent of the state's population) that they have consumers within their local communities who they cannot assist. This will greatly increase their capacity to serve those folks plus allow for the funding of satellites in the adjoining counties.

Arizona is among the most underserved states in the country. With an additional $1.3 million, Arizona will be able to fully fund existing CILs in Phoenix, Tucson, Prescott, and Yuma, plus add new CILs in Flagstaff, Sierra Vista, and the Navajo Nation.

The Texas SILC has identified 18 unserved and underserved areas throughout the state which they would cover with an additional $3.2 million, and Mississippi would turn their satellites in Tupelo, Meridian, McComb and Greenville into CILs plus create a whole new set of satellites.

In other words, an increase of $25 million over each of the next three years will make it possible to fill gaps in a service system which, in spite of proven success over the last twenty years, remains pitifully inadequate.

Centers for independent living are a great bargain for America. They keep people active and involved in their communities. They save the taxpayer money. Given their track record, we know that CILs will use that $75 million to double or triple those dollars. However, even if they didn't, think of the changes and savings. At an average cost of $1,655 per consumer for comprehensive IL services, they will serve an additional 45,317 people. They will help another 1,630 individuals relocate from nursing homes—and prevent another 16,000 from entering.

Funding centers for independent living makes sense: Common sense and dollars and cents.

NATIONAL COUNCIL ON INDEPENDENT LIVING PROPOSED INCREMENTAL REQUEST SUMMARY

The National Council on Independent Living proposes that there be three annual increases in Part C of $25 million rather than one of $75 million. Each $25 million appropriation would be divided into two allocations.

Approximately one-half of each year's appropriation would be granted to states in $250,000 increments. (Note that $250,000×50 states = $12½ million. For appropriation purposes, the District of Columbia and Puerto Rico have traditionally been considered states and the territories have received somewhat less. For the purposes of discussion, we are using a figure of $125,000 for each of the four territories.) This means that each state, regardless of its size or population will receive a base increase of $750,000 over three years. Approximately one half of the $75 million will be appropriated to states in this manner.

The remainder of each year's appropriation, an amount somewhat less than $12½ million because of the allocations to DC and the territories, will be granted to states based upon their percentage of the nation's population. For discussion and projection purposes, we are using the conservative figure of $11½ million.

As part of the appropriation process, NCIL requests that Congress attaches spending authority language regarding the disbursal of these funds, as follows:

—Each center for independent living (CIL) must have a base funding level of at least $250,000. Therefore, before any new centers are created, existing centers must receive at least $250,000 in operating funds from the state and/or Federal Government. Satellite centers may receive somewhat less based upon the recommendation of the statewide independent living council (SILC).

—Receipt of the additional Part C funds is contingent upon maintenance of each state's funding effort. These additional funds are intended to supplement, not supplant existing funds generated in the state legislature for the operation of centers.

—After each center is receiving an annual minimum base funding of at least $250,000, all Title VII funds shall be distributed following the directions set forth in the State Plan for Independent Living.

Attached are two identical worksheets produced in Microsoft Excel and in Word Perfect which show how the $75 million will be distributed state-by-state over three years. The worksheet has seven columns:

—A list of the states and territories;

—Each state's annual distribution based upon its percentage of the nation's population. As explained above, we are using a conservative figure of $11½ million;

—Each state's distribution of $250,000, which we call equity;

—The 1 year total increase that each state is likely to be allotted if we receive an incremental increase of $25 million;

—The 3 year total increase that each state is likely to be allotted if we receive three incremental increases totaling $75 million;

—The funds currently allocated through Title VII Part C are in the 1999 total column;

—The 2003 total is each state's likely allotment if we are successful in our efforts. The 2003 total represents a combination of current (1999 total) and new (3 year total) funds.

CENTER FOR INDEPENDENT LIVING PROGRAM—NCIL INCREMENTAL REQUEST SUMMARY

State	Population	Equity	1 year total	3 year total	1999 total	2003 total
ALABAMA	$183,507	$250,000	$433,507	$1,300,520	$505,225	$1,805,745
ALASKA	26,061	250,000	276,061	828,183	602,952	1,431,135
ARIZONA	181,997	250,000	431,997	1,295,990	536,293	1,832,283
ARKANSAS	107,179	250,000	357,179	1,071,536	486,008	1,557,544
CALIFORNIA	1,362,989	250,000	1,612,989	4,838,968	4,016,347	8,855,315

CENTER FOR INDEPENDENT LIVING PROGRAM—NCIL INCREMENTAL REQUEST SUMMARY—Continued

State	Population	Equity	1 year total	3 year total	1999 total	2003 total
COLORADO	161,674	250,000	411,674	1,235,022	697,758	1,932,780
CONNECTICUT	141,308	250,000	391,308	1,173,925	486,008	1,659,933
DELAWARE	30,937	250,000	280,937	842,810	486,008	1,328,818
FLORIDA	611,229	250,000	861,229	2,583,687	1,801,120	4,384,807
GEORGIA	310,706	250,000	560,706	1,682,118	915,563	2,597,681
HAWAII	51,216	250,000	301,216	903,649	486,008	1,389,657
IDAHO	50,181	250,000	300,181	900,542	695,762	1,596,304
IOWA	122,625	250,000	372,625	1,117,876	486,008	1,603,884
KANSAS	110,674	250,000	360,674	1,082,021	566,935	1,648,956
KENTUCKY	166,550	250,000	416,550	1,249,649	490,775	1,740,424
LOUISIANA	187,347	250,000	437,347	1,312,041	552,059	1,864,100
MASSACHUSETTS	262,079	250,000	512,079	1,536,236	954,181	2,490,417
MICHIGAN	412,016	250,000	662,016	1,986,049	1,269,426	3,255,475
MINNESOTA	198,910	250,000	448,910	1,346,731	523,090	1,869,821
MISSISSIPPI	116,369	250,000	366,369	1,099,107	486,008	1,585,115
MISSOURI	230,494	250,000	480,494	1,441,483	1,060,757	2,502,240
MONTANA	37,538	250,000	287,538	862,615	486,008	1,348,623
NEBRASKA	70,633	250,000	320,633	961,898	789,481	1,751,379
NEVADA	66,016	250,000	316,016	948,047	486,008	1,434,055
NEW HAMPSHIRE	49,533	250,000	299,533	898,600	486,008	1,384,608
NEW JERSEY	342,808	250,000	592,808	1,778,423	1,010,158	2,788,581
NEW MEXICO	72,704	250,000	322,704	968,111	551,100	1,519,211
NEW YORK	782,525	250,000	1,032,525	3,097,575	2,305,881	5,403,456
OHIO	481,139	250,000	731,139	2,193,417	1,417,781	3,611,198
OKLAHOMA	141,438	250,000	391,438	1,174,313	672,259	1,846,572
OREGON	135,527	250,000	385,527	1,156,580	554,713	1,711,293
PENNSYLVANIA	520,878	250,000	770,878	2,312,633	1,534,881	3,847,514
RHODE ISLAND	42,716	250,000	292,716	878,148	709,848	1,587,996
SOUTH CAROLINA	158,481	250,000	408,481	1,225,443	486,008	1,711,451
SOUTH DAKOTA	31,455	250,000	281,455	844,364	486,008	1,330,372
TENNESSEE	226,784	250,000	476,784	1,430,351	668,268	2,098,619
UTAH	84,181	250,000	334,181	1,002,543	547,704	1,550,247
WEST VIRGINIA	78,874	250,000	328,874	986,621	904,979	1,891,600
WISCONSIN	221,045	250,000	471,045	1,413,135	651,358	2,064,493
WYOMING	20,711	250,000	270,711	812,133	486,008	1,298,141
D.C.	23,904	250,000	273,904	821,711	486,008	1,307,719
PUERTO RICO	162,019	250,000	412,019	1,236,058	486,008	1,722,066
NATIONAL TOTALS	11,500,000	13,500,000	25,000,000	75,000,000	44,222,040	119,222,040

FACT SHEET—INCREASED FUNDING FOR CENTERS FOR INDEPENDENT LIVING

What is a Center for Independent Living (CIL)?

A CIL is a non-profit corporation, which assists people with significant disabilities who want to live more independently. CILs are managed and staffed by people with disabilities, are always located in the communities they serve, and assist people with all types of disabilities.

How do CILs assist people?

The foundation of CIL services is the peer relationship—people with disabilities assisting other people with disabilities as role models, mentors, and counselors. Each center is unique because it offers services based upon the particular needs of its community. At the same time, centers are alike in that they all offer core services: information and referral, peer counseling, individual and systems advocacy, and independent living skills training.

How many centers are there in the U.S.?

Currently, there are 340 centers for independent living, with more than 224 satellite locations. Of these, 229 centers and 44 satellites are funded through Title VII–Part C of the Rehabilitation Act of 1973 (as amended). A center's service area may be one county or a dozen. According to the Rural Institute on Disabilities, CILs cover an average of 5.76 counties. Today, 60 percent (1,911) of our nation's counties receive service from a CIL.

What role do satellites play in the CIL network?

Satellites, sometimes called branch offices, are administered by an existing center and fill a critical need in the independent living network. Satellites make it possible for services and programs to be provided in outlying areas while avoiding the overhead of a freestanding, non-profit corporation. Some satellites have only one or two staff while others have more to address the needs of their communities. Costs for satellites vary, therefore, from state to state and community to community.

What must CILs do to receive Title VII–Part C funds?

In addition to submitting a viable application in a statewide competition, CILs must meet standards and assurances set by Congress, as well as goals and objectives, which address the needs of their communities. The assurances are fiscal and programmatic reporting requirement, while each standard has indicators of compliance which address the day-to-day operations of the center. Centers report annually on their progress and are visited periodically as part of a state and federal oversight process.

What is the current funding level for federally funded centers?

Current funding for Title VII–Part C of the Rehabilitation Act is $43,692,496. This is an average of $163,285 per center and $97,821 per satellite.

Are CILs a good investment?

You bet! Last year the Department of Education gathered information from 295 of the centers. In addition to responding to almost 340,000 requests for information and referral, these centers provided over 54,000 individuals with peer counseling services; 50,000 received assistance finding housing; 34,000 acquired personal assistance services; 33,500 attained transportation services; and over 54,000 individuals received independent living skills training. In addition, literally tens of thousand of individuals received dozens of other services from centers, including assistance in moving out of costly institutional settings such as nursing homes.

Why do we need more centers for independent living and satellites?

Today, the CIL network reaches less than one percent of all people with significant disabilities in the United States. While not every person with a disability needs a center's help, there remain vast areas of the U.S. where no center exists at all. Forty percent (40 percent) or 1,230 of our nation's counties receive no service whatsoever from a CIL. Hundreds more receive only superficial coverage.

How many more CILs do we need?

At the current rate of coverage (5.7 counties per center), The Rural Institute on Disabilities estimates that we need at least an additional 216 centers. Some states have estimated that there should be at least one "fully-funded" center for every 500,000 persons, or an additional 185 centers nationwide.

What is a "fully-funded" CIL?

Today, CILs are woefully underfunded. As stated above, the average federally funded CIL receives approximately $162,285 to support the operations of the center. States have set funding targets ranging from $200,000 to $500,000 per center per year. The National Council on Independent Living (NCIL) believes a center needs at least $250,000 to support day-to-day operations, meet the standards and assurances, and address the goals of the community. The Independent Living Research Utilization Program (ILRU) has found limited funding to be the most common reason for the fiscal collapse of centers.

What level of support is needed for CILs?

Centers for independent living need an additional $75 million to build a strong nationwide network of centers. This increase will bring the total budget for Title VII–Part C to $120 million, a fraction of what is expended for other programs assisting significantly fewer persons. CILs have a proven record of accomplishment, distinguishing themselves among consumers, advocates, and providers alike. Support for CILs makes good sense!

PREPARED STATEMENT OF THE CITY OF NEWARK, NJ

Mr. Chairman: Thank you for giving me the opportunity to submit testimony on behalf of the City of Newark, New Jersey regarding two innovative projects that are of importance to us: (1) the Children's Health Care Services Center and (2) the Newark Museum Science Education Project.

CHILDREN'S HEALTH CARE SERVICES CENTER

The Children's Health Care Services Center will provide a coordinated approach to offering health and social services to uninsured/underinsured pregnant women and children between the ages of 0 through 5. The City's Department of Health and Human Services will partner with other community organizations and hospitals to provide a full spectrum of health, social services and mental health services.

There is a tremendous need in Newark for such comprehensive services. The City of Newark has been designated by the Centers for Disease Control and Prevention as a pocket of need for children. An analysis of trends in the City of Newark reveals that 1/5 of Newark resident births in 1996 were to teenage mothers (under age 20). Teenage mothers have accounted for 1 in 5 Newark resident births from 1989 through 1996. Over one-half of Newark resident women who delivered in 1996 began pre-natal care in the first trimester of pregnancy. In contrast three fourths of all New Jersey mothers giving birth in 1996 began pre-natal care in the first trimester. Since 1989 the percentage of Newark mothers receiving pre-natal care in the first trimester has generally declined for all age groups. In fact, the rate of mothers giving birth in 1996 who received no pre-natal care was six times as high for Newark (8.3 percent) as for the State as a whole (1.3 percent). By race, nearly 12 percent of black mothers in Newark and 3 percent of white mothers received no pre-natal care.

In 1996 the number of Newark resident infant deaths 80, a 14.3 percent increase over the 70 infant deaths in 1995. Notwithstanding this one year increase, the number of resident infant deaths in Newark decreased from a high of 189 deaths in 1989 to the current level. Neo-natal deaths have been increasing over the past 8 years, from 52 percent of the total infant deaths in 1989 to 58 percent in 1996. The leading cause of death for infants in Newark in 1996 is low birth-weight. The second leading causes of death were congenital anomalies and sudden infant death syndrome.

Other ailments that affect the health of Newark children include pulmonary dysfunctions such as asthma and lead poisoning. As of December 31, 1998, Newark had a caseload of 1,613 children under age six with blood lead levels over 20 ug/dL. In 1998 an average of 25 percent of nearly 2,000 children tested had blood lead levels over 20 ug/dL.

The objective of the Newark Children's Health Care Services Center is to positively impact on the health of Newark's children through the development of a coordinated health care system that will allow the City to bring health care services to the community.

Through the use of focus groups, the DHHS will assess and re-evaluate Newark residents use of existing services. Focus groups will be conducted to analyze barriers to services and residents utilization rates. Based upon the analysis, the DHHS will design the Children's Health Care Services Center as a consumer friendly service center.

At minimum, the Center will provide services that include, pre-conception counseling, early pregnancy testing, pre-natal care, substance abuse counseling and referral services, family counseling, pediatric practice with related services including WIC, immunization, nutritional counseling and case management services. Health education will be offered to develop parenting skills and managing households.

Through the centralization of services, we believe that we can increase access to the array of health and social services needed by Newark residents to raise healthy children. The City seeks $2.5 million in Federal support for this initiative.

NEWARK MUSEUM

Newark is truly at a crossroad—we are a City with all of the problems of many major urban centers, but we are also a City with vast potential. We have begun to turn the corner—there is a renewed vitality and sense of optimism in Newark.

The Newark Museum seeks $2.0 million to support its new Science Initiative Education. The City of Newark has committed $1.7 million dollars to date toward the preparatory collections care necessary to make this initiative possible. Additionally, The Museum plans a $5 million dollar operating endowment fund based upon a public/private partnership to assure adequate on-going support, of which $1.2 million has been raised to date. Research has shown that the ongoing maintenance cost of science galleries is several multiples of that of art galleries.

The plan calls for the creation of a major permanent exhibition based upon its natural science collection. The exhibition, called Making Sense of the Natural World, will explore scientific phenomena through natural history specimens and live animals. Museum audiences will participate in mindful science learning through stimulating and engaging experiences that integrate the collections, Dreyfuss Planetarium and Mini Zoo. This gallery, along with the Museum's plan to institutionalize

cohesive science education programs parallel to its distinguished art and culture programs, is the core of The Newark Museum Science Education Initiative.

The cohesive science education at The Newark Museum will entail greater use and dissemination of their science gallery, planetarium and live animal resources, thus providing new learning opportunities for individuals, families, schools, and community organizations. This initiative also allows the Museum to safeguard the thousands of scientific specimens, so critical to its success, in proper housing both in the exhibition and in technologically advanced, environmentally appropriate behind-the-scenes storage.

The Newark Museum is recognized as one of the nation's leading cultural institutions. It is located in Newark, New Jersey's largest city, and within Essex County, the State's most densely populated. The Museum's constituency is economically and ethnically diverse, reflecting the distinctive character of the city, northern New Jersey and the metropolitan region. In 1998, The Newark Museum served an audience of 462,000 children and adults.

The Newark Museum's natural science collections of 74,000 specimens in the areas of geology, botany and biology are being utilized today in programs that allow for participatory and inquiry-driven experiences, to engage visitors in meaningful science learning. Science-related programs draw more visitors to The Newark Museum than any other offering, despite the fact that the science galleries have been closed for more than a decade. Realizing the opportunity to attract larger audiences and better serve Newark and New Jersey residents, the Museum has embarked on a new science initiative. It will enable the Museum to reopen the science galleries and builds upon the Museum's proven track record of excellence in interdisciplinary arts and humanities programs.

The Newark Museum New Science Education Initiative: Reshaping Science Education

In planning the new Science Initiative, Museum staff and Trustees have been guided by the principles contained in Goals 2000 and by New Jersey's recently adopted Core Curriculum Content Standards for K–12 education. Critical thinking, mathematical, and scientific understanding will be fostered as visitors question, experiment, compare, and analyze real specimens from the Museum's science collections, and participate in planetarium and Mini Zoo programs designed to effectively communicate complicated and abstract science concepts.

The science plan will also include a Science Resource Laboratory for teachers, which will provide them with a space to research and test curriculum ideas for hands-on activities in the natural and planetary sciences. Based on the results of research conducted with Newark educators, these monthly multi-session and one-time in-service teacher professional development workshops will provide teachers opportunities to become more comfortable teaching science and meet the state-mandated re-certification requirements. The same Science Labs will be used by school classes and in after school and weekend programs to reinforce science concepts that are introduced in Making Sense of the Natural World, the projected new exhibition.

For high school students from Newark and other state urban districts, the Science Initiative calls for a Science Career Ladder. These innovative programs are designed to provide "at-risk" teens with critical exposure to careers in science and to teach workplace ethics and behavior. This builds upon an already successful YouthAlive program at the Museum. In addition, the plan will provide a Science Internship Program, which will offer students a year-long experience in scientific research, collections management, and the planetary sciences at The Newark Museum.

The New Natural Science Exhibition, Making Sense of the Natural World

This gallery, intended primarily for a family and elementary school audience, will be one of the few in the country to combine the best of natural history museums and science centers by marrying actual biological, geological and botanical specimens with hands-on, inquiry-driven activities.

In this exhibit, visitors will experience the wonder of nature's diversity and then look at collections the way scientists look at them. They will begin to learn that natural history specimens individually and collectively provide volumes of information about science. They will understand how ordering the natural world led to the realization that the Earth is constantly changing and that life adapts to those changes. Moreover, they will appreciate that evidence of those changes is as close as their own backyard.

Recurring throughout the exhibit will be the concepts of bio-complexities and dynamic geological forces as fundamentals of the natural world. The museum's striking collections will be the vehicle for explaining—making sense of- these concepts as they relate to living and non-living systems, globally and locally.

The exhibition will be divided into five sections. The first is an Introductory Gallery, called the Diversity Arc, in which visitors will realize that by uncovering relationships within groups of specimens, scientists have been able to order and make sense of the diversity around them. Visitors will meet their video host at the first of several stations that are located throughout the exhibit. The host is a museum scientist who will guide visitors' observations and enhance their understanding of the exhibit's concepts. The host is one of the ways the exhibit will depict people as part of nature and interpreters of it. It will serve to put the exhibit components into context for the visitor.

In the second gallery, The Dynamic Earth: Forces of Change, sound and light will give visitors the feeling of being present at the beginning of the Earth. A short video will elaborate on the formation of the planet, plate tectonics and climate. Video animation will be used to communicate abstract geological concepts. Specimens will be displayed that illustrate the products of geological activity, climate change and glacial activity. Mineral and rock specimens will be chosen for the stories they can tell. Fossils, such as Glossopteris, found on today's widely separated continents, will show how tectonic forces split the continent on which the fern once grew.

Next, the visitor will encounter Life Adapts to Change, which will show the tremendous variety of environments on the Earth—the consequences of where continents and oceans are located today, and climate. Specimens from the African Savannah will show how different species have adapted to a unique biome, the grassland, through color, behavior and structure. The exhibit also contains an interactive natural selection component explaining the process. The remainder of the exhibit will illustrate two different kinds of adaptations to the environment: structural and behavioral.

At this junction, visitors will have the choice of either continuing to Collections: Tools of Knowledge or Diversity in Your Backyard: New Jersey Highlands. In Collections: Tools of Knowledge, visitors will discover that science is a dynamic, ongoing activity that uses specimens and collections as tools to make sense of the natural world. In this section, visitors explore how science is actually conducted. Scientists will tell their own story of how they collect data and analyze it, and there will be equipment which visitors can manipulate in activities designed to mimic the work the scientists perform. For most of the population, science is an abstract art, almost like magic. This area of the exhibit will assign the tasks of the scientist to the visitor, making the process of science much more concrete.

The final, and largest, section is called Diversity in Your Backyard: New Jersey Highlands, which will feature a re-creation, in the form of a walk-in diorama, of an oak-hickory forest biome of the New Jersey Highlands. It is a demonstration of how and why the interdynamics of geology and biology creates an ecosystem. Using New Jersey as a backdrop, this gallery will provide specific examples of Dynamic Earth and Adapting to Change in a recreated environment of the New Jersey Highlands. This will allow visitors to apply the complex ideas introduced earlier to examples familiar to them and to make sense themselves of the natural world. A tented "field station" will offer opportunities for hands-on activities.

In closing, federal support is critical for each of these initiatives. It is my hope that the subcommittee will find them worthy of your support.

Prepared Statement of the University of Medicine and Dentistry of New Jersey

The University of Medicine and Dentistry of New Jersey (UMDNJ) is the largest public health sciences university in the nation. Our statewide system is located on five academic campuses and consists of 3 medical schools and schools of dentistry, nursing, health related professions, public health and graduate biomedical sciences. UMDNJ also comprises a University-owned acute care hospital, three core teaching hospitals, an integrated behavioral health care delivery system, a statewide system for managed care and affiliations with more than 200 health care and educational institutions statewide. No other institution in the nation possesses the resources which match our scope in higher education, health care delivery, research and community service initiatives with federal, state and local entities.

We appreciate the opportunity to bring to your attention our priority projects that are consistent with the mission of this committee. These projects are statewide in scope and include collaborations both within the University system and with our affiliates. Our research projects also underscore UMDNJ's commitment to eliminating racial disparities in health care delivery. New Jersey, with its small geographic size and its large diverse population, is an idea site in which to conduct research and

develop activities that will address this important issue. The first of our priority initiatives is the Child Health Institute of New Jersey:

UMDNJ-Robert Wood Johnson Medical School (RWJMS) has developed the Child Health Institute of New Jersey as a comprehensive biomedical research center focused on the health and wellness of children. At this institute, biomedical researchers address the prevention and cure of environmental and genetic diseases of infants and children. The Child Health Institute is integral to the long-term plan for the enhancement of research at RWJMS in developmental genetics, particularly as it relates to disorders that affect a child's development and growth, physically and functionally. The program will enable the medical school to expand and strengthen basic research efforts with clinical departments at Robert Wood Johnson University Hospital, in particular those involved with the new Bristol-Myers Squibb Children's Hospital.

The CHI will build on a current NIH funding base at RWJMS and its academic partners of more than $50 million with significant strengths in genetic, environmental and neurosciences research at the medical school and the associated joint research and advanced degree programs with academic institutions and the pharmaceutical industry.

The Child Health Institute will focus research on the molecular and genetic mechanisms that direct the development of human form, subsequent growth, and acquisition of function. Broadly, the faculty and students will investigate disorders that occur during the process of development; to discover and study the genes contributing to developmental disabilities and childhood diseases; to determine how genes and the environment interact to cause childhood diseases; and to identify the causes and possible avenues of treatment of cognitive disorders found among conditions such as mental retardation, autism and related neurological disorders.

Approximately half of the admissions to children's hospitals are for genetic disorders, and the majority of these are the result of genes interacting among themselves and with the environment.

Examples include autism, heart defects, diabetes and cleft lip. Babies are five times more likely to have a cleft lip if their mother carries a particular gene and smokes during pregnancy. Mothers with this gene who don't smoke don't increase the risk for their child. Preventing this class of clift lips is now possible through testing mothers coupled with behavior modification.

Despite new therapies, asthma-related problems have risen by 50 percent over the past decade with hospitalization rates 4–5 times higher for African Americans. Effective prevention and treatment will require greater understanding of the molecular mechanisms that elicit asthmatic attacks, and more understanding of the molecular reactions mounted by cells once stimulated by environmental factors. Continued exploration of the basic molecular underpinnings of injury reactions will lead to more rational methods to prevent, minimize and treat asthmatic reactions and deaths. Urban academic medical centers such as RWJMS are at the epicenter of the current escalation in asthma and the Child Health Institute is well positioned to address this critical issue.

Development of the Child Health Institute will fill a critical gap through the expansion, by new recruitment, of an intellectual base upon which basic molecular programs in child development and health will build. It is expected to cost almost $30 million for our building with an additional $10 million endowment for programs. We are requesting an appropriation of $5 million from the Federal Government to complement $3 million already received from the Federal Government, $18 million raised in the private sector and $10 million we expect to raise from the State.

A second priority is the Gallo Prostate Cancer Center:

The Dean and Betty Gallo Prostate Cancer Center (GPCC) was established at the Cancer Institute of New Jersey (CINJ) with the goal of eradicating prostate cancer and improving the lives of men at risk for the disease through research, treatment, education and prevention. GPCC was founded in memory of Rep. Dean Gallo, a New Jersey Congressman who died of prostate cancer diagnosed at an advanced stage. The purpose of the GPCC is to establish a multi-disciplinary center to study all aspects of prostate cancer and its prevention. The Cancer Institute of New Jersey is a partnership of UMDNJ-Robert Wood Johnson Medical School and hospital affiliates.

Prostate cancer is particularly devastating in New Jersey. With the highest population density in the country, our state has one of the highest prostate cancer rates in the nation. African-Americans diagnosed with the disease are twice as likely to die from it. To help eliminate this health disparity, GPCC is collaborating with organizations such as "100 Black Men" in a prostate cancer initiative that will make educational programs and cancer screenings available in all 21 counties throughout the State.

GPCC unites a team of outstanding researchers and clinicians who are committed to high quality basic research, translation of innovative research to the clinic, exceptional patient care, and GPCC efforts will be focused in four major areas: Basic, Clinical and Translational Research; Comprehensive Patient Care; Epidemiology and Cancer Control; and Education and Outreach.

GPCC scientists will investigate the molecular, genetic and environmental factors that are responsible for prostate cancer initiation and progression. Our researchers will develop appropriate model systems that will facilitate the design and implementation of novel strategies for prevention and treatment. GPCC will foster multi-disciplinary efforts that will lead to the effective translation of basic research, improved patient care and novel clinical trials. Another goal of the GPCC is to understand the etiology of prostate cancer susceptibility and to find effective modalities for prevention of the disease.

The Cancer Institute of New Jersey has received $5 million in federal funding over the last two years for the Gallo Prostate Cancer Center. This important funding has enabled us to establish a world-class program in prostate cancer research that includes publications in prestigious national journals. CINJ has used its findings to leverage additional research dollars for individual investigators from such agencies as CapCure, the Department of Defense and several private foundations. Top investigators have been recruited to initiate programs in prostate cancer research through our education and pilot grant programs.

Additional federal funding is being sought this year to build on our basic research in prostate cancer and to support the development of technological approaches to test new methods of prevention and treatment. This additional funding will also allow us to enhance our treatment of patients with prostate cancer through several new clinical trials for patients at all stages of the disease. We seek $2 million in federal funding to enhance the research, education and cancer care programs of the Gallo Prostate Cancer Center at our New Brunswick facility and to expand these programs statewide.

Another priority this year is to establish a statewide General Clinical Research Center:

New Jersey is the most densely populated state in the nation and hosts some 175 healthcare companies within its borders. Yet, New Jersey has failed to attract large amounts of clinical research dollars because there is no General Clinical Research Center within the state.

As a consequence, patients in the state lack adequate access to the latest in clinical research studies. UMDNJ is well positioned to reverse this trend and requests federal funding to provide the infrastructure to compete more effectively for both NIH and pharmaceutical research dollars.

The UMDNJ-Robert Wood Johnson Medical School Clinical Research Center (CRC) is a 16-bed dedicated clinical research facility located in New Brunswick, New Jersey. New Brunswick is known as the "health care city" and is home to many of the state's major pharmaceutical firms. Robert Wood Johnson Medical School is consistently ranked among the most diverse in the nation.

As such, the University can make significant contributions in the clinical research training of under-represented minorities enrolled in medical, nursing, dental, pharmacy, public health, dietary and other advanced degree programs across the state. The medical school is home to the Cancer Institute of New Jersey, the Child Health Institute of New Jersey and other nationally recognized centers of excellence. We are well positioned to uphold NIH policies regarding the inclusion of women, minorities and children in clinical research studies.

Robert Wood Johnson Medical School has a well-established research environment that provides insight into the basic mechanisms of disease, innovative approaches to patient care that leads to the etiology and pathogenesis of disease, and patient care outcomes. Scientists in the basic and clinical departments continue to make nationally recognized contributions in their areas of expertise. Researchers within the medical school have been in the forefront of medical discoveries, including advances in Parkinson's disease, Lyme disease, disorders of sexual dysfunction, epilepsy, prostate cancer, psoriasis, cardiology, and obesity. In addition to broad-based programs at RWJMS' three campuses in Piscataway, New Brunswick and Camden, the CRC is committed to expanding its research programs by collaborating with other schools within the UMDNJ system as well as with affiliated institutions. This includes:

The UMDNJ-New Jersey Medical School (NJMS) located in Newark is developing a Clinical Research Center on its campus. Once established, both Centers will work together to provide the infrastructure to optimize clinical research across the state. The UMDNJ-New Jersey Dental School (NJDS) has outstanding research in biomaterials and a nationally recognized dental training program. The UMDNJ-School of Health Related Professions (SHRP) has a research team in its nutrition program

that currently collaborates with the CRC at RWJMS. The UMDNJ-School of Osteopathic Medicine located in Stratford in southern New Jersey, the UMDNJ-School of Nursing, with statewide nursing programs and the UMDNJ-School of Public Health provide additional opportunities for collaboration.

Additionally, UMDNJ is affiliated with the Veterans Administration Health Care system in New Jersey and already collaborates with the VA on many initiatives. We would look forward to a partnership with the VA to provide clinical research studies to this large and diverse patient population.

UMDNJ is requesting $1.7 million through an NIH grant to develop a General Clinical Research Center (GCRC) that will link all clinical research activities across our statewide campuses and allow us to expand these activities to affiliated partners such as the VA HealthCare System in New Jersey. The opportunity exists to build a clinical research organization that would be at the cutting edge of new medical practices. Collaborations will result in a powerful unit that can organize medical experts and patients in response to federally and industrially sponsored trials of new therapies. Federal participation is needed to support a single network of clinical research and training programs throughout the state that will provide the impetus for the designation of our statewide program as a General Clinical Research Center.

Our final priority is the establishment of a Center for BioDefense:

In considering the threat of biological weapons use, the New York/New Jersey area is a prime target. UMDNJ is well poised to expand several current areas of expertise in the national response to this threat.

UMDNJ's Center for Education and Training (CET) is the nation's foremost program in education and training concerning chemical threats. The Center has provided hazardous materials training to more than 175,000 individuals, including police, firefighters and health care personnel. Preparing emergency response personnel for chemical and biological incidents is an extension of the Center's existing expertise.

UMNDJ has several Level I and Level II Trauma Centers within its statewide system. A crucial component of the trauma network is the state's helicopter trauma service linking the northern and southern regions of the State. Members of the UMDNJ Emergency Response Team participated in a federally-sponsored "Weapons of Mass Destruction" education program last year.

A number of laboratories in our system are engaged in rapid methods of detection of virulent agents with particular emphasis on the most dangerous multi-drug resistant species. The molecular basis of drug resistance is the focus of our laboratories, as well as the establishment of large libraries of clinical strains available for epidemiological and other studies.

Many of our faculty are advisors to the U.S. Government and serve on various committees and advisory panels. Our researchers are studying the effects of exposure to a variety of chemical and organic agents. UMDNJ has considerable expertise in analysis of genotoxic effects of radiation, toxic chemicals and other agents.

The University's Newark campus is an internationally renowned center for the identification, treatment, and basic research of TB and other emerging and reemerging pathogens. UMDNJ is a founding partner in the International Center for Public Health in Science Park, Newark. The establishment of the Center for Emerging Pathogens at the UMDNJ-New Jersey Medical School will add another layer of expertise in the analysis of a number of pathogens.

Gene chip technology is a recent, cutting-edge technology enabling the simultaneous analysis of thousands of DNA sequences. Recent state funding has led to the formation of the Center for Applied Genetics at UMDNJ. In the context of a biological weapons threat, new chips will be designed displaying sequences representing a panel of potential agents for rapid screening and identification.

Additional funding of $2.5 milllion will enable UMDNJ to provide a comprehensive statewide program ranging from our nationally acclaimed training ability in the public health arena to internationally recognized expertise in infectious disease basic research.

PREPARED STATEMENT OF NEW YORK UNIVERSITY

Mr.Chairman: Thank you for allowing me to submit this testimony for the Promoting healthy lifestyles, eliminating disparities in oral health on the basis of race and ethnicity, and removing barriers to health care access are important priorities for the New York University College of Dentistry. It is therefore a matter of urgency for the College to undertake major renovations to modernize its patient-care facilities.

The NYU College of Dentistry has been in existence for 135 years. NYU educates more than eight percent of the nation's dental graduates, making it the largest dental school in the United States. It is also the nation's largest provider of comprehensive preventive, primary, and specialty oral health care at one site, as well as a major Medicaid provider and safety net for free or low-cost care to the uninsured and working poor.

NYU also provides the nation's most extensive private dental health outreach, preventive education, and screening programs that serve public schools, day care centers, Head Start programs, handicapped facilities, hospitals, and homeless shelters. Indeed, last summer over 1,000 New Yorkers took part in a College-sponsored free oral-cancer screening as part of a national effort to alert Americans about the dangers of oral cancer.

With the heavy, 24 hour-a-day, 365 days-a-year usage of the NYU dental clinics and the need to keep pace with changing technologies and equipment, the NYU College of Dentistry has launched a major capital project to refurbish and upgrade its clinical facilities to ensure that patients will be treated in an environment that promotes their optimal health, safety, and comfort. With 565 clinical operatories (treatment facilities) serving the public on a daily basis, the College seeks to upgrade 256 of its most heavily used and antiquated operatories which are located on four floors of its eleven-story structure.

Recognizing that the clinics are the heart of the institution, NYU is requesting $5 million over three years to renovate and modernize the clinics and labs on these four floors currently serving the oral health needs of a vast number of needy New Yorkers.

WHO ARE OUR PATIENTS?

The NYU College of Dentistry has a long tradition of providing comprehensive, low-cost dental services to people who are unable to afford private dentistry, including many new immigrants. Each year NYU's dental clinics treat tens of thousands of poor and low-income New Yorkers who have no other place to turn for dental care. The NYU College of Dentistry draws the largest portion of its patient population from New York City's largely Hispanic Lower East Side, which is a federally-designated dental health professional shortage area (HPSA), and has many patients from other medical/dental HPSAs in Manhattan, including Chinatown, East Harlem, Central/West Harlem, and Washington Heights/Inwood, as well as shortage areas in Brooklyn.

In all, the NYU dental clinics attract the most multiethnic, multicultural population in the nation, as evidenced by the fact that:

—65 percent of patients are minority Americans, primarily African Americans, members of Hispanic subgroups, Asians, Pacific Islanders, and Native Americans;
—30 percent of patients are senior citizens;
—10 percent of patients are children;
—70,000 of our 250,000 visits annually are made by Medicaid recipients;
—15,000 people receive emergency care every year;
—5,000 emergency patients are treated free of charge each year, and since the average cost of a routine visit to the NYU dental clinics is presently $43.00, compared to $360 to $1,100 for a typical hospital emergency room visit, this is extremely cost-efficient care;
—10,000 school children annually visit the NYU pediatric dentistry clinic; and
—2,500 children receive dental services annually through the Head Start program, both through a three day-a-week busing program which brings youngsters to the College and through on-site care in their neighborhoods, making the NYU College of Dentistry the largest Head Start provider of dental services in the nation.

In addition to the Head Start busing program, the College buses children daily from local public schools to the College for care, and conducts a busing program for elderly adults in cooperation with local social service agencies. The College has also added, at its own expense, a state-of-the-art mobile dental van with four dental stations to expand its outreach effort on behalf of poor children who have been severely impacted by the dramatic decrease in the availability of publicly-funded, pediatric oral health resources.

It is anticipated that the mobile dental clinic program will provide more than 1,500 patient visits each year, consisting of primary dental care and/or preventive services to preschool and school-age children ages 4–13 from poor, minority, and immigrant families. Additionally, staff members inform low-income families of their eligibility for the dental, prescription, and other health benefits available to their

children through the Children's Health Insurance Program and Medicaid. Moreover, since the dental van is staffed in part by minority Americans, including an African-American pediatric dentist, children who visit the van are exposed to role models for health profession careers.

INSTITUTIONAL RECOGNITION

The NYU College of Dentistry's leadership in the health care arena has been recognized through grants for innovative pediatric dentistry programs, a Medicaid Managed Care Provider Grant from the New York State Department of Health to develop a model for school-based dental services, and significant funding from the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH).

The latter includes major support, obtained in collaboration with the Forsyth Dental Center of Boston, to establish a Minority Oral Health Research Center at NYU to improve the oral health status of minorities and increase the number of minorities working in the health professions. In addition, the College has received widespread acclaim for initiating the Consortium for the Prevention and Early Detection of Oral Cancer.

THE COST OF DENTAL EDUCATION AT NEW YORK UNIVERSITY

The high cost of dental equipment and materials, combined with the lack of a hospital infrastructure, has long made the cost of dental education the highest of any profession. As a private dental school, the NYU College of Dentistry is often able to pursue newer, more effective therapeutic approaches and to transfer these advances to practice with more freedom and speed than is possible among some of our public counterparts. However, tuition for dental education is necessarily greater for an independent academic dental institution. For those of us who make our lives among students, it is therefore never easy to increase tuition. But although we have redoubled our efforts at cost containment, we recognize that there is a limit beyond which we cannot go without sacrificing the quality of our academic and patient care programs. As a result, NYU's tuition for the 1999–2000 academic year is $36,886 for each year in the four-year D.D.S. program, making tuition at the NYU College of Dentistry the highest in the nation.

The irony is that although tuition at NYUCD is very expensive, it is nevertheless the most cost effective dental education in the nation. In fact, according to the American Association of Dental Schools, the amount of money it takes to educate a dental student for one year at NYU—approximately $40,000—is substantially below the national mean of $60,000, and less than half of that at some state-supported institutions.

A chief reason for our high tuition is the prevailing poverty of the population we treat, which effectively results in NYU dental students subsidizing the charity care. We provide approximately $4 million in free dental care annually—through tuition.

THE INFRASTRUCTURE TO CARE FOR OUR COMMUNITY

The NYU College of Dentistry does not currently possess the infrastructure to support the treatment needs of its patient community, including the introduction of new technologies. To put it another way, current clinical facilities impede our ability to provide an optimal patient care environment for the thousands of patients who seek treatment daily.

Physically, our clinics are bursting at the seams. Much of the existing clinical care space is over 35 years old and is cramped and out-of-date. To meet appropriate standards of care, this infrastructure must be redesigned immediately. The average size of an operatory is approximately 65 square feet. In order to provide optimal patient care involving a dentist and a dental assistant, each operatory should be 100 square feet. Addressing these concerns will require extensive renovation and modernization of 256 of the existing 565 dental operatories and development of new space for additional clinical facilities to keep pace with the growth of our patient pool.

New York University College of Dentistry's health promotion initiatives, its programs to expand access to mainstream oral health benefits for our neediest citizens, and its reputation as a force for social action in medically-underserved areas all place the College in an excellent position to advance the national agenda for health care. Accordingly, we believe that support for renovated and modernized patient care facilities at the College is an appropriate focus for Congress. The community care goals of the NYU College of Dentistry are entirely consistent with the commitment to make health care an equal opportunity, available to all, regardless of financial means, age, or racial or ethnic group. Our dental clinics also greatly relieve the

pressure on an already over-burdened public health system, and in emphasizing early, preventive and comprehensive treatment, save health care costs down the road.

With help in creating clinical facilities that foster the well being of our community, the NYU College of Dentistry can continue to meet the needs of new Americans and of native racial and ethnic minorities, and to alleviate the disproportionate oral health burden of poor and minority Americans.

Thank you for your consideration.

PREPARED STATEMENT OF THE UNIVERSITY OF MIAMI SCHOOL AND THE LOVELACE RESPIRATORY RESEARCH INSTITUTE

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity to present testimony on behalf of the University of Miami School of Medicine, the Lovelace Respiratory Research Institute in Albuquerque, NM and our jointly proposed Tobacco Addiction Risk Assessment Research Center (TARARC) which will be devoted to the reduction of health risks associated with addiction to tobacco and other harmful substances. We deeply appreciate your leadership, Mr. Chairman. I fully understand and appreciate that you and your congressional colleagues face many constraints and challenges and we appreciate your willingness to devote special attention to the important public health issues related to tobacco addiction and its many harmful consequences. As the former campaign manager for Tom Luken, who served on the Hill for over 18 years, I was personally impressed by the dedication, commitment and hard work that all of you put into serving this great country of ours. We feel strongly that the unique challenges you face have never been greater than at this point in history, but there has also never been a greater opportunity to apply science-based solutions to solving the riddle of addiction and greatly improving public health by eliminating or reducing its negative health consequences.

As you may know, approximately 20 percent of all deaths are associated with tobacco smoking. Tobacco kills more people than murder, AIDS, suicide, illicit drug use and automobile accidents combined. The medical consequences of tobacco addiction include the three leading causes of death: cardiovascular disease, cancer and cerebrovascular disease and its related medical costs are astronomical. For example, in Florida in 1996, tobacco-related Medicaid pay-outs were estimated to be between $264,000,000 and $365,000,000. However, tobacco use is also the most preventable cause of disease and death.

We now know that nicotine is at least as addictive as cocaine or heroin. Recent studies even suggest that nicotine interacts with other drugs of abuse, that it reinforces craving and increases intake of cocaine and other drugs. However, nicotine is a special case of addiction because tobacco is legally sold and its use is not prohibited among adults. In spite of the evidence that nicotine is an addictive drug which affects the brain in the same way that illicit substances such as opiates and cocaine do, nicotine dependence has not been considered substance abuse.

The University of Miami School of Medicine and the Lovelace Respiratory research Institute are uniquely qualified to address the issue of addiction to tobacco and other harmful substances. University of Miami faculty members have significant expertise and experience in many relevant areas including substance abuse, evaluation research, community research, behavioral medicine, disease prevention, treatment of tobacco-related diseases, basic science research, epidemiology and public health. The University of Miami's Tobacco Research Evaluation and Coordinating Center (RECC) has been responsible for the evaluation of Florida's Tobacco Pilot Program. Other strengths in the area of biomedical research and treatment include Pediatric Oncology and the Batchelor Children's Research Center, the Pediatric Environmental Respiratory Center, as well as the proposed Tobacco Addiction Risk Assessment Research Center (TARARC). The Batchelor Children's Research Center is currently under construction and will provide a state-of-the-art clinical and research facility that will be one of the nation's largest devoted to children's health. It is designed to foster collaboration among researchers and clinicians and will include a focus on cancer as well as many other diseases. It, along with the Pediatric Environmental Respiratory Center, will provide an appropriate and ideal setting for the study of tobacco-related, maternal-child health issues as well as a study of the impact of second-hand (environmental) smoke on the respiratory health of children. The Lovelace Respiratory Research Institute has undertaken some of the leading studies of animal models of smoking and the role of nicotine in immune function.

The proposed Tobacco Addiction Risk Assessment Research Center will be devoted to the study of unrecognized health risks associated with addiction to tobacco products, predominantly in minority populations who may be uniquely susceptible to im-

mune suppression, increased fetal HIV transmission, increased respiratory inflammation and infection, synergistic negative health effects with other abused substances and impaired immunological function of non-smoking family members exposed at home or in utero. The Center will use animal models to study disease processes prior to assessing the equivalent condition in human subjects. Finally, the Center will address the culturally relevant behaviors that underlie tobacco use in human populations. The importance of the Center lies in its bridging the use of animal models to the study of disease in people and the subsequent formulation and testing of medical and behavioral interventions to improve or eliminate the negative health consequences associated with tobacco use. Of further interest is the opportunity to compare two different Hispanic populations that differ in genetics and cultural characteristics (Mexican in new Mexican and Cuban in Florida) as well as characterizing African-American and Caucasian populations. Creating the Tobacco Addiction Risk Assessment Research Center represents a unique opportunity to build upon the rich diversity of Florida's population, the commitment of the University of Miami School of Medicine to the community and our experience with behavioral interventions, particularly related to tobacco use and substance abuse. Florida is an ideal location for the proposed Center, being a bellwether state for social, demographic and epidemiological changes that the rest of the nation is currently facing or will face in the near future. Our extensive experience working with traditionally hard-to-reach populations such as minority substance abusers will ensure that the interventions we develop will be culturally and linguistically appropriate and acceptable. We also have a means for rapid dissemination of effective prevention and intervention within minority communities through an already developed community health care coalition.

The goals of the Tobacco Addiction Risk Assessment Research Center are to:

—Identify risk behaviors which lead to tobacco use and substance abuse.

—Reduce the incidence and prevalence of tobacco use and that of other addictive substances.

—Reduce the development of and suffering from disease associated with tobacco and other addictive substances through research and interventions in the basic sciences, clinical medicine and epidemiological research.

—Reduce exposure to environmental tobacco smoke.

—Develop, test and apply science-based community interventions to achieve these goals.

We know that intervention with effective prenatal programs saves a tremendous amount of money that otherwise would be spent on healthcare after birth. The same can be said for early intervention at other points in the life cycle. My own personal research experience with the early detection of breast cancer through the screening of over 30,000 medically underserved women has demonstrated that early detection and intervention saves dollars as well as lives. As is true for cancer, we already possess a great deal of knowledge that could be used to develop interventions and prevention strategies for addiction to tobacco and other harmful substances. Applying this knowledge could effect savings of billions of dollars for state, local and national governments. Equally important, the quality of life will be improved for individuals, families and their communities as well as society at large. It is becoming ever more apparent that we, as a society, cannot afford to ignore prevention and early intervention strategies since crisis management is far too costly in terms of quality of life and unnecessary expenditures of dollars.

By achieving our stated goals, the Tobacco Addiction Risk Assessment Research Center will be in a perfect position to (1) improve quality of life, (2) decrease morbidity and mortality, (3) increase survival and (4) significantly decrease health care expenditures by applying effective prevention and intervention. I thank you very much for your valuable time and stand ready to serve you in any way possible.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION FOR STATE COMMUNITY SERVICES PROGRAMS

The National Association for State Community Services Programs (NASCSP) thanks this committee for its continued support of the Community Services Block Grant (CSBG) and seeks an appropriation of $630 million for the state grant portion of the CSBG. The amount appropriated for the state grant portion in fiscal year 2000 was $530 million. We are requesting an increase of $100 million in order to expand the efforts of the Community Services Network in assisting those families remaining on welfare with the intensive services they need to transition to work and to assist low-income workers in remaining at work through supportive services such as transportation and child care. These additional funds will also assist states in

developing services in the four percent of counties that are not currently served by the CSBG.

NASCSP is the national association that represents state administrators of the Community Services Block Grant (CSBG), and state directors of the Department of Energy's Low-Income Weatherization Assistance Program.

BACKGROUND

The states believe the Community Services Block Grant (CSBG) is a unique block grant that has successfully devolved decision making to the local level. Federally funded with oversight at the state level, the CSBG has maintained a local network of over 1,000 agencies which coordinate over $5 billion in federal, state, local and private resources each year. Operating in more than 96 percent of counties in the nation and serving over 9 million low-income persons, local agencies, known as Community Action Agencies (CAAs), provide services based on the characteristics of poverty in their communities. For one town this might mean providing job placement and retention services, for another developing affordable housing. In rural areas it might mean providing access to health services or developing a rural transportation system.

Since its inception, the CSBG has shown how partnerships between states and local agencies benefit citizens in each state. We believe it should be looked to as a model of how the Federal Government can best promote self-sufficiency for low-income persons in a flexible, decentralized, non-bureaucratic and accountable way.

Long before the creation of the Temporary Assistance for Needy Families (TANF) block grant, the CSBG was setting the standard for private-public partnerships that could work to the betterment of local communities and low-income residents. Family oriented, while promoting economic development and individual self-sufficiency, the CSBG relies on an existing and experienced community-based service delivery system of CAAs and other non-profit organizations to produce results for its clients.

MAJOR CHARACTERISTICS OF THE COMMUNITY SERVICES NETWORK

Locally Directed.—Tri-partite boards of directors guide CAAs. These boards consist of one-third elected officials, one-third low-income persons and one-third representatives from the private sector. The boards are responsible for establishing policy and approving business plans of the local agencies. Since these boards represent a cross-section of the local community, they guarantee that CAAs will be responsive to the needs of their community.

Adaptability.—CAAs have demonstrated success in moving persons from welfare to work and in assisting low-income families in achieving self-sufficiency. CAAs provide a flexible local presence that governors have mobilized to deal with emerging poverty issues.

Leveraging Capacity.—For every CSBG dollar they receive, CAAs leverage nearly $3.50 in non-federal resources (state, local, and private) to coordinate efforts that improve the self-sufficiency of low-income persons and lead to the development of thriving communities.

Volunteer Mobilization.—CAAs mobilize volunteers in large numbers. In fiscal year 1997, the most recent year for which data are available, the CAAs elicited nearly 27 million hours of volunteer efforts, the equivalent of almost 13,000 full-time employees. Using the minimum wage, these volunteer hours are valued at more than $139 million.

Emergency Response.—CAAs are utilized by federal and state emergency personnel as a front line resource to deal with emergency situations such as floods, hurricanes and economic downturns. They are also relied on by citizens in their community to deal with individual family hardships, such as house fires or other emergencies.

Accountable.—The federal Office of Community Services, state CSBG offices and CAAs have worked closely to develop a results-oriented management and accountability (ROMA) system. Through this system, individual agencies determine local priorities within six goals for CSBG and report on the outcomes that they achieved in their communities.

The statutory goal of the CSBG is to ameliorate the effects of poverty while at the same time working within the community to eliminate the causes of poverty. The primary goal of every CAA is self-sufficiency for its clients. Helping families become self-sufficient is a long-term process that requires multiple resources. This is why the partnership of federal, state, local and private enterprise has been so vital to the successes of the CAAs.

WHO DOES THE CSBG SERVE?

National data compiled by NASCSP show that the CSBG serves a broad segment of low-income persons, particularly those who are not being reached by other programs and are not being served by welfare programs. Based on the most recently reported data,

—67 percent have incomes at or below the poverty level; 44 percent have incomes below 75 percent of the poverty guidelines. In 1997, the poverty level for a family of three was $13,330.
—Only 38 percent of adults have a high school diploma.
—37 percent of all client families are "working poor" and have wages or unemployment benefits as income.
—25 percent depend on pensions and Social Security and are therefore poor, former workers.
—23 percent receive cash assistance from TANF.
—60 percent of families assisted have children under 18 years of age.

WHAT DO LOCAL CSBG AGENCIES DO?

Since Community Action Agencies operate in rural areas as well as in urban areas, it is difficult to describe a typical Community Action Agency. However, one thing that is common to all is the goal of self-sufficiency for all of their clients. Reaching this goal may mean providing daycare for a struggling single mother as she completes her General Educational Development (GED) certificate, moves through a community college course and finally is on her own supporting her family without federal assistance. It may mean assisting a recovering substance abuser as he seeks employment. Many of the Community Action Agencies' clients are persons who are experiencing a one-time emergency. Others have lives of chaos brought about by many overlapping forces—a divorce, sudden death of a wage earner, illness, lack of a high school education, closing of a local factory or the loss of family farms.

CAAs provide access to a variety of opportunities for their clients. Although they are not identical, most will provide some if not all of the services listed below:

—employment and training programs
—transportation and child care for low-income workers
—individual development accounts
—micro business development help for low-income entrepreneurs
—a variety of crisis and emergency safety net services
—local community and economic development projects
—housing and weatherization services
—Head Start
—nutrition programs
—family development programs

CSBG funds many of these services directly. Even more importantly, CSBG is the core funding which holds together a local delivery system able to respond effectively and efficiently, without a lot of red tape, to the needs of individual low-income households as well as to broader community needs. Without the CSBG, local agencies would not have the capacity to work in their communities developing local funding, private donations and volunteer services and running programs of far greater size and value than the actual CSBG dollars they receive.

CAAs manage a host of other federal, state and local programs which makes it possible to provide a one-stop location for persons whose problems are usually multifaceted. CAAs manage the Head Start program in many communities. Using their unique position in the community, CAAs recruit additional volunteers, bring in local school department personnel, tap into religious groups for additional help, coordinate child care and bring needed health care services to Head Start centers. In many states they also manage the Low Income Home Energy Assistance Program (LIHEAP), raising additional funds from utilities for this vital program. CAAs often administer the Weatherization Assistance Program and are able to mobilize funds for additional work on residences not directly related to energy savings that may keep a low-income elderly couple in their home. CAAs also coordinate the Weatherization Assistance Program with the Community Development Block Grant program to stretch federal dollars and provide a greater return for tax dollars invested. They also administer the Women, Infants and Children (WIC) nutrition program as well as job training programs, substance abuse programs, transportation programs, domestic violence and homeless shelters, food pantries, as well as gardening and canning programs.

EXAMPLES OF CSBG AT WORK

CAAs in many states have been working diligently to support families receiving cash assistance through the Temporary Assistance for Needy Families (TANF) block grant. The CAAs and the state CSBG offices have been developing methods of creating an effective transition from welfare to work for families.

In Illinois, all 36 Community Action Agencies are providing their outreach workers with training and certification in Family and Community Development. This is a joint effort of Iowa State University and Southern Illinois University (SIU) to develop certification standards. SIU provides three hours of course credits for persons who successfully complete this program. Illinois now has over 500 people certified within its 36 CAAs. These individuals will spend more staff time providing comprehensive assistance to each low-income person to help them become self-sufficient. At first this expanded effort will cost more, but will produce lasting results in the long-term.

Additionally all 36 CAAs have entered into performance contracts with the Illinois Department of Public Aid to assist welfare recipients who are now "on the clock" as far as finding jobs before their welfare benefits lapse. When an agency places a welfare recipient in a job whose salary is above 125 percent of the official poverty guidelines and has benefits, the agency is paid $1,200. They are paid $1,000 for each successful placement in a job whether or not it has benefits or has a salary that is equal to 125 percent of the poverty guideline. The Community and Economic Development Association of Cook County (CEDA) is using these funds for job creation.

In Pennsylvania, community development has been a major focus. For example, Montgomery County Development Commission opened the CADCOM Micro Enterprise Resource Center (CMERC). The purpose of the center is to nurture start-up and emerging small business. The center provides a six-week training course, hands-on management assistance, access to shared office equipment, flexible leases and expandable space. In its first year, the program successfully started three businesses.

In New Hampshire, CSBG funds are being used for alcohol and drug rehabilitation programs for welfare recipients to assist them in staying drug free and in securing and keeping jobs.

To recapitulate: The CSBG provides a community-based service delivery system. Each local organization, through its local board of directors, establishes priorities and serves its community and low-income residents through programs designed and delivered locally in partnership with state and local governments, businesses, civic and religious groups and others. The CSBG leverages resources that are far in excess of the appropriations it receives. Additionally, nearly 27 million hours of volunteer services are contributed to CAAs annually. CSBG agencies have used the increased funds they received for the last two years to continue their activities that lead to self-sufficiency and have become integrally involved in the implementation of TANF in most states across the nation. Those families who remain on welfare have substantially greater impediments to successfully becoming self sufficient, an increase in the CSBG will make it possible to meet these special needs, while still helping working poor families remain in the workforce.

NASCSP therefore urges this committee to provide an increase that factors in inflation and to fund the CSBG grant to the states at $630 million.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the nearly 38,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to submit comments on fiscal year 2001 appropriations for Physician Assistant (PA) education programs that are authorized through Title VII of the Public Health Service Act.

A member of the Coalition for Health Funding (CHF), the American Academy of Physician Assistants supports the CHF recommendation to appropriate $37.7 billion for the Public Health Service in fiscal year 2001. The Academy is also a member of the Health Professions and Nursing Coalition (HPNEC) and supports the HPNEC recommendation to provide at least $335 million to support the Title VII and VIII programs in fiscal year 2001. The Academy believes that a 10 percent increase in funding for the Title VII health professions programs is well justified. The programs are essential to the development and training of primary health care professionals and contribute to the nation's overall efforts to increase access to care by promoting health care delivery in medically underserved communities.

The Academy is very concerned that the Administration's fiscal year 2001 budget request once again proposes to eliminate funding for the primary care medicine and

dentistry programs, through which physician assistant educational programs receive support. We wish to thank the Members of this Subcommittee for your historical role in supporting funding for the health professions programs, and we hope that we can count on your support for these important programs in fiscal year 2001.

OVERVIEW OF PHYSICIAN ASSISTANT (PA) EDUCATION

As many Subcommittee Members are aware, 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 120 accredited PA educational programs.

Physician assistant programs are located at schools of medicine or health sciences, universities, teaching hospitals, and the Armed Services. All PA educational programs are accredited by the Commission on Accreditation of Allied Health Education Programs upon recommendation by the Accreditation Review Committee for PA Education.

Prior to admission, the typical PA student has a bachelor's degree and 45 months of health care experience. The most common prior health experience of PA students involves pre-hospital care, such as emergency medical technicians or paramedics. Other students come from backgrounds in nursing, allied health technologies, mental health fields, and social work.

The typical PA program consists of 111 weeks of instruction. The first phase of the program consists of intensive classroom and laboratory study, providing students with an in-depth understanding of the medical sciences. More than 400 hours in classroom and laboratory instruction are devoted to the basic sciences, with over 70 hours in pharmacology, more than 149 hours in behavioral sciences, and more than 535 hours of clinical medicine.

The second year of PA education consists of clinical rotations. On average, students devote more than 2,000 hours or 50–55 weeks to clinical education, divided between primary care medicine and various specialties, including family medicine, internal medicine, pediatrics, obstetrics and gynecology, surgery and surgical specialties, internal medicine subspecialties, emergency medicine, and psychiatry. During clinical rotations, PA students work directly under the supervision of physician preceptors, participating in the full range of patient care activities, including patient assessment and diagnosis, development of treatment plans, patient education, and counseling.

Physician assistant education is competency based. After graduation from an accredited PA program, the physician assistant must pass a national certifying examination jointly developed by the National Board of Medical Examiners and the independent National Commission on Certification of Physician Assistants. To maintain certification, PAs must log 100 continuing medical education credits over a two-year cycle and reregister every two years. Also to maintain certification, PAs must take a recertification exam every six years.

PHYSICIAN ASSISTANT PRACTICE

Physician assistants are licensed health care professionals educated to practice medicine as delegated by and with the supervision of a physician. In all states except Mississippi, physicians may delegate to PAs those medical duties that are within the physician's scope of practice and the PA's training and experience, and are allowed by law.

A physician assistant provides health care services that were traditionally only performed by a physician. Duties include, but are not limited to, performing physical examinations, diagnosing and treating illnesses, ordering and interpreting laboratory tests, suturing wounds, assisting in surgery, providing patient education and counseling, and making rounds in nursing homes and hospitals. Forty-six states, the District of Columbia, and Guam authorize physicians to delegate prescriptive privileges to the PAs they supervise.

PAs are located in almost all health care settings and in every medical and surgical specialty. Fourteen percent of all PAs practice in rural areas where they may be the only full-time providers of care (state laws stipulate the conditions for remote supervision by a physician). Approximately twenty percent of PAs work in urban and inner city areas. The majority of PAs are in primary care. Nearly one-quarter practice in surgical specialties. Seventy percent of PAs practice in outpatient settings.

In 1999 an estimated 154 million patient visits were made to PAs and approximately 196 million medications were prescribed or recommended.

CRITICAL ROLE OF THE TITLE VII, PUBLIC HEALTH SERVICE ACT, PROGRAMS

A growing number of Americans lack access to primary care, either because they are uninsured, underinsured, or they live in a community with an inadequate supply or distribution of providers. The growth in the uninsured U.S. population increased from approximately 32 million in the early 1990s to nearly 45 million today. Simultaneously, the number of medically underserved communities continues to rise, from 1,949 in 1986 to 2,900 today.

The role of the Title VII programs is to alleviate these problems by supporting access to quality, affordable, and cost-effective care in areas of our country that are most in need of health care services, specifically rural and urban underserved communities. This is accomplished through the support of educational programs that train more health professionals in fields experiencing shortages, improve the geographic distribution of health professionals, and increase access to care in underserved communities.

The Title VII programs are the only federal education programs that are designed to address the supply and distribution imbalances in the health professions. Since the establishment of Medicare, the costs of physician residencies, nurses and some allied health professions training has been paid through Graduate Medical Education (GME) funding. However, GME has never been available to support PA education. More importantly, GME was not intended to generate a supply of providers who are willing to work in the nation's medically underserved communities. That is the purpose of the Title VII Public Health Service Act Programs, which support such initiatives as loans and scholarships for disadvantaged students, scholarships for students with exceptional financial need, centers of excellence to recruit and train minority and disadvantaged students, and interdisciplinary initiatives in geriatric care and rural health care.

TITLE VII SUPPORT OF PA EDUCATION PROGRAMS

Targeted federal support for PA education programs is currently authorized through section 747 of the Public Health Service Act. The program was reauthorized in the 105th Congress through the Health Professions Education Partnerships Act of 1998, Public Law 105–392, which streamlined and consolidated the federal health professions education programs. Support for PA education is now considered within the broader context of training in primary care medicine and dentistry.

Public Law 105–392 reauthorized awards and grants to schools of medicine and osteopathic medicine, as well as colleges and universities, to plan, develop, and operate accredited programs for the education of physician assistants and faculty, with priority given to training individuals from disadvantaged communities. The funds ensure that PA students from all backgrounds have continued access to an affordable education and encourage PAs, upon graduation, to practice in underserved communities. These goals are accomplished by funding PA education programs that have a demonstrated track record of: (1) placing PA students in health professional shortage areas; (2) exposing PA students to medically underserved communities during the clinical rotation portion of their training; and (3) recruiting and retaining students who are indigenous to communities with unmet health care needs.

The program works. A review of PA graduates from 1991–1999 reveals that 16.5 percent of students graduating from PA programs supported by Title VII are from underrepresented minorities, compared to 7.7 percent of graduates from programs that did not receive Title VII support. Similarly, 13.5 percent of the graduates who attended PA programs receiving Title VII support during the eight-year period practice in underserved communities, compared to 10.1 percent of graduates of programs not receiving such support during the same period.

The PA programs' success in recruiting and retaining underrepresented minority and disadvantaged students is linked to their ability to creatively use Title VII funds to enhance existing educational programs. For example, a PA educational program in Iowa uses Title VII funds to target recruitment efforts to disadvantaged students, providing shadowing and mentoring opportunities for prospective students, increasing training in cultural competency, and identifying new family medicine preceptors in underserved areas. PA programs in Texas use Title VII funds to create new clinical rotation sites in rural and undersered areas, including new sites in border communities, and to establish non-clinical rural rotations to help students understand the challenges faced by rural communities. Several other PA programs have been able to use Title VII grants to leverage additional resources to assist students with the added costs of housing and travel that occur during relocation to rural areas for clinical training.

Without Title VII funding, many of these special PA training initiatives would not be possible. Institutional budgets and student tuition fees simply do not provide suf-

ficient funding to meet the special, unmet needs of medically underserved areas or disadvantaged students. Nevertheless, the need is very real, and Title VII is critical in meeting it.

NEED FOR INCREASED TITLE VII SUPPORT FOR PA EDUCATION PROGRAMS

Increased Title VII support for educating PAs to practice in underserved communities is particularly important given the market demand for physician assistants. Without the Title VII funding to expose students to underserved sites during their training, PA students are far more likely to practice in the communities where they were raised or the communities in which they attended school. Title VII funding is a critical link in addressing the natural geographic maldistribution of health care providers by exposing students to underserved sites during their training, where they frequently choose to practice following graduation.

The supply of physician assistants is inadequate to meet the needs of society, and the demand for PAs is expected to increase. A 1994 report of a workgroup of the Council on Graduate Medical Education (COGME), "Physician Assistants in the Health Workforce," estimated that the anticipated medical market demand and the estimated workforce requirements for PAs would exceed demand. Additionally, the Bureau of Labor Statistics projects that the number of available PA jobs will increase 47 percent between 1996 and 2002.

Despite the increased demand for PAs, funding has not proportionately increased for the Title VII programs that are designed to educate and place physician assistants in underserved communities. 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 $6.376 million. PA program funding was slightly increased again for fiscal year 1998 at $6.398 million. The fiscal year 1998 appropriation provided 42 awards to support the training of approximately 1600 PA graduates. The fiscal year 1999 allocation was $6.8 million; the fiscal year 2000 appropriation for the cluster assumes funding for the PA programs at the fiscal year 1999 level.

RECOMMENDATIONS ON FISCAL YEAR 2001 FUNDING

The American Academy of Physician Assistants urges members of the Appropriations Committee to consider the inter-dependency of all the public health agencies and programs when determining funding for fiscal year 2001. For instance, while it is important to fund clinical research at the National Institutes of Health (NIH) and to have an infrastructure at the Centers for Disease Control (CDC) that ensures a prompt response to an infectious disease outbreak, the good work of both of these agencies will go unrealized if the Health Resources and Services Administration (HRSA) 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 educated in Title VII-funded programs. Likewise, CDC is heavily dependent upon an adequate supply of health care providers to be sure that disease outbreaks are reported, tracked, and contained.

The critically important programs administered by NIH, HRSA, and CDC are integral components within the nation's public health continuum. One component is not more important than another, and no one component can succeed without adequate support from each of the other elements. The Academy is particularly concerned that any increase for the NIH not be made at the expense of the health professions education program or other public health programs, as recommended this year by the Senate Budget Committee.

The American Academy of Physician Assistants is particularly appreciative of the modest increase in funding for PA education programs that was appropriated during the 105th Congress. However, the increase has not been sufficient to meet the increasing demand for PA graduates in the growing number of medically underserved communities. Accordingly, the Academy respectfully requests that the Title VII health professions programs, including PA programs, receive a 10 percent funding increase in fiscal year 2001.

Thank you for the opportunity to present the American Academy of Physician Assistants' views on fiscal year 2001 appropriations.

PREPARED STATEMENT OF THE NATIONAL JEWISH MEDICAL AND RESEARCH CENTER

Mr. Chairman and Members of the Subcommittee, thank you for your support last year and the opportunity to present this testimony regarding the National Jewish Medical and Research Center's proposal to build an integrated Center for Environmental Health Research and Service (CEHRS). This Center will, under one roof,

support research and provide clinical services for patients with respiratory and immune diseases with the mission of controlling or eradicating environmental and occupational illness in the Rocky Mountain Region. It will serve as a regional resource and national model for the delivery of environmental clinical health services, conduct both basic and field research on environmental illness, and "translate" new knowledge, to better inform the public and help guide rational environmental policy by government, at both regional and national levels.

National Jewish Medical and Research Center is known worldwide for the diagnosis and treatment of patients with environmental, respiratory, immune and allergic disorders, and for groundbreaking medical research. For the past 20 years, this century-old nonsectarian, nonprofit medical center has earned an international reputation for its treatment of environmental illness and for research leading to the detection and prevention of environmental disorders including asthma, berylliosis, tuberculosis, and building-related illnesses.

With funding from Federal agencies including the NIEHS, NHLBI, NIAID, EPA, DOE, and CDC/NIOSH, as well as foundations and private industry, National Jewish has become one of the leaders in the field of environmental health. National Jewish is deeply committed to providing accessible, affordable and high quality care for environmentally and occupationally exposed individuals, to consulting for government and industries in the region and nationally, and to educating medical professionals and the public on matters of environmental risk and health.

Our nation faces a significant challenge for the 21st century—how to safeguard the health of the American public from environmental hazards. We are faced with the reality that many Americans, particularly the working poor, blue collar middle class, minorities, children and the elderly, are exposed daily to environmental toxins that may cause major lung, heart, immune and allergic diseases, disability and untimely death. We must find ways to better diagnose, treat and, most importantly, prevent environmental disease. In addition, federal agencies and corporations face the daunting task of cleaning up environmental "sins of the past"—without unduly endangering the health of today's hazardous waste workers and the members of communities that surround them.

The State of Colorado has historically been medically underserved, in environmental health services, with fewer than 40 medical practitioners in Colorado who are board certified to practice environmental and occupational health. While the Division of Environmental and Occupational Health Sciences at National Jewish provides consultation to industry, agriculture, community groups, and labor, its services are outstripped by the regional need for expertise. National Jewish is forced to turn away many patients and groups who have environmental concerns because of physical and staffing limitations at the Center. These needs range from community groups seeking advice on the hazards of radioactivity and of metal-contaminated soil, to industries needing help in the control of lead poisoning and biological hazard exposures, to regional agencies seeking aid in the investigation of disease outbreaks caused by airborne molds or tuberculosis-like organisms.

National Jewish is uniquely positioned in the Rocky Mountain region to serve as a model health care institution for implementing innovative environmental health programs that reduce the risk of respiratory and immune system disease. Regionally and nationally, the diseases that are treated at National Jewish Medical and Research Center are on the rise, including asthma, diseases due to environmental tobacco smoke, building-related respiratory and allergic illnesses. National Jewish Medical and Research Center specializes in helping both small and large regional employers address practical issues of toxic exposure assessment, exposure control, medical management of occupational illness, and remediation. Employees and their employers, while aiming to make the workplace safer and more productive, often lack enough information about the toxic effects of airborne chemicals, metals, and organic matter that produce disability. Recent studies show that 1 in 10-hospital admissions is related to a workplace injury or exposure. More than half of all patients seen in general medicine clinics in the central U.S. report past or ongoing exposure to one or more known toxin.

The solutions to these environmental health dilemmas are to prevent exposures from causing disease and, if environmental exposures have already occurred, to detect disease earlier and to develop more effective treatments for disease.

National Jewish can best increase our effectiveness by housing these major activities in a single, dedicated location. The CEHRS will be a showcase for the application of the most advanced environmental science and directly to the prevention of disease in groups of Americans at environmental risk. By showing how a multidisciplinary approach can help eradicate environmental respiratory and allergic diseases, our Center will be a model for other centers around the country who may address other forms of environmental illness, such as those linked to skin disease, neurologic

disorders, liver disease, and cancer. National Jewish Medical and Research Center believes that by maintaining a tight focus of both clinical care and research in an area of great need—the respiratory and immune systems—its Center will be able to deliver long term solutions to the most important forms of environmental disease.

The CEHRS will meet this need by integrating the following existing and new program components in the new Center:

The Clinic for Environmental and Occupational Health Care.—A combined adult and pediatric outpatient clinical practice staffed by experienced environmental and occupational health physicians and nurses who diagnose and treat environmental disorders. Annually, this clinical group screens and evaluates more than 2,000 patients with suspected environmental or occupational lung and allergic disorders.

The Environmental Disease Prevention and Research Service.—A multidisciplinary team of physicians, researchers, epidemiologists, industrial hygienists, and health educators, who conduct practical research aimed at "real life" problems solving by measuring airborne exposures to toxins and implementing innovative programs that detect the effects of chemicals in individuals and in the air. The goal is to devise practical, cost-effective solutions to reducing risks of cancer, lung fibrosis, and allergic lung disease.

The Environmental Away-Team Consultation Service.—A mobile consultation service staffed by a team of environmental and occupational health experts who go anywhere in the country to measure environmental exposures, monitor for disease, and advise industrial and agricultural employers, labor, and private citizens on the management and control of environmental hazards. This service has gone on-site to more than 20 states.

The Respiratory Protection Program.—A mobile service that helps individuals and corporations to educate and provide appropriate types of masks for people being potentially exposed to airborne hazards. Firefighters, hazardous waste workers, municipal employees, and others who encounter potentially lethal exposures to highly toxic materials call on this service.

The Environmental Education/Community Outreach Service.—A risk communication service that utilizes the internet as well as more traditional educational approaches to deliver up-to-date, balanced, practical environmental information to civic groups, labor, industry, and local and Federal Government agencies.

The Occupational and Environmental Medicine Training Program.—Based at National Jewish and the Department of Preventive Medicine and Biometrics at the University of Colorado School of Medicine, this is the only training program for environmental medicine in the State of Colorado.

The Environmental Toxicology Section.—A research unit dedicated to understanding oxidative stress which is a natural process that produces disease when undesirable oxidant gases or dusts are inhaled, causing inflammation.

The Environmental Immunology Laboratory.—A research unit dedicated to understanding how environmental toxins cause allergic diseases.

National Jewish is the only academic research facility in Colorado that provides clinical care for patients with suspected environmental or occupational illnesses. Patients from the region as well as from all 50 states come to National Jewish Medical and Research Center for medical diagnosis and care. Patients receive superior care without regard to their ability to pay. Each year $7 to $10 million of free or heavily subsidized care is provided.

National Jewish was recently ranked as the best hospital in the nation for excellence in treating respiratory diseases in U.S. New and World Report's "America's Best Hospitals." American Health magazine termed National Jewish one of the finest U.S. hospitals in allergy, immunology and pulmonology for both adult and pediatric patients. The Institute for Science and medicine rated National Jewish among the top 10 independent biomedical research institutions—of any kind—in the world, and the only one that also provides patient care. It was ranked as one of the three most influential research institutions for immunology and as the number one private immunology research institution in the world.

Partnerships with governmental agencies.—In addition to conducting research directly funded by several agencies, National Jewish faculty provide advice and consultation to local, regional and Federal Government offices, including: the Colorado Department of Health and the Environment, the Governor's Air Toxics Science Advisory Committee, the U.S. DOE Beryllium Standards Advisory Committee, oversight Boards for Hanford Reservation in Washington State, the Nevada Test Site, and Los Alamos National Laboratories, the EPA air pollution research advisory panel, and the OSHA Metalworking Fluids Standards Advisory Committee, and both CDC/NIOSH and NIH research advisory committees.

Partnership with community health organizations.—Faculty members conduct community outreach, speaking at local hospitals on environmental health. Three of

our faculty have served as presidents of the Rocky Mountain Academy for Environmental and Occupational Medicine, the regional society for all physicians practicing in this field.

Partnership with regional industry and labor.—National Jewish has helped organize and conduct medical education and medical surveillance programs for many regional industries, helping them to protect employees from hazards in the workplace.

National Jewish proposes to establish a public/private partnership with the Federal Government in support of the establishment of the "Center for Environmental Health Research and Service." This partnership will cover the cost of the construction of a new, 50,000 square foot, state-of-the-art facility which will house all basic and clinical environmental research, clinical care, outpatient services, training and consulting services affiliated with the Environmental Health Research and Sciences program.

The total cost of the proposed facility is $14 million. National Jewish received a $1 million HRSA grant from this Subcommittee in fiscal year 1999 and $250,00 last year to carry out the initial phases for the construction of the CEHRS. National Jewish seeks $5 million in HRSA follow-on funding in fiscal year 2001 to help construct the new Center.

Thank you.

PREPARED STATEMENT OF IDAHO STATE UNIVERSITY

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony to the hearing record regarding an important initiative in rural health being undertaken by Idaho State University's (ISU) Institute for Rural Health Studies. Specifically, ISU has requested federal partnership assistance to establish the Idaho Telehealth Integrated Care Center to address the many health challenges faced by Idaho as a rural and frontier state where 90 percent of the geography and about one half of the population is outside of an urban area. The three main objectives of the Idaho Telehealth Integrated Care Center (ITICC) are to:

—improve the quality and quantity of access to healthcare for people living in Idaho's rural and frontier areas,

—promote professional development in telehealth for faculty and practicing professionals, and

—provide professionals-in-training educational experiences in integrated care and telehealth.

This integrative model meets many of the objectives for whole-person primary care outlined in Healthy People 2010. In addition to improving care and provider professional support, this integrated care program can serve as a national model for the integration of general medical, oral health, and mental health.

The goal of this project is to build a comprehensive telehealth clinic providing consultation and technical assistance in a variety of fields to support care in rural and frontier areas. The concept is simple. By contacting the ITICC, facilities in rural and frontier areas can schedule assistance across the health care spectrum. For example, if a rural clinic determines they need support in audiology, they can call the ITICC and schedule an audiology consultation. Rural partners will be recruited from Tribal Nations, Indian Health Service, critical access hospitals, private and public clinics. Particular attention will be taken to provide care in culturally sensitive ways. In addition to supporting patients and caregivers in rural and frontier areas, the ITICC will serve as practice and training outlet for the university community.

Idaho consists of 44 counties covering 83,574 square miles—geographically, the 14th largest state in the U.S. The 1998 population of the state was 1,228,684—only 9 states have a smaller population. Of the 208 towns in the state, 2 have populations over 50,000 and 16 towns have populations less than 100; 186 have less than 10,000 people. About 40 percent of the population lives outside of an urban area, distributed over 9/10ths of the states geographical area. Idaho's per capita income was $18,170, ranking 43rd in the U.S. in 1997. The median household income was $32,000 in 1997. Idaho ranks in the upper 1/3 (16th) of the states in number of persons employed, but 42nd in average annual pay. Just over 400,000 people in the state are employed, largely in the service industry. Forty-one thousand of those people are employed in health related fields.

In Idaho, an estimated 150,000 people—60,000 of whom are children—live below the poverty level. Idaho ranks 3rd in the nation for number of persons under 18 years of age and 40th in persons over 65 leaving the state with an abundance of children and a dearth of older, potentially wiser, elders. Twenty three percent (23 percent) of children under 5 live in poverty. In 1995, five counties had no full-time physician. In 1996, the physician to population ratio was 145 per 100,000 placing

Idaho in the unenviable position of having the worst patient to physician ratio in the United States. Access to mental and oral health is even more limited.

The Office for the Advancement of Telehealth defines telehealth as the use of "telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration." The distribution of telehealth is irregular and largely explainable by an area's resources. According to a 1999 NTIA report on defining the digital divide, the more available resources, the more likely an area is to have access to telehealth. While telehealth has been seen as a panacea for improving health care in rural areas, the very rurality of these areas is preventing appropriate penetration of the proposed solution.

Integrated telehealth combines two promising trends in healthcare to lower social and financial healthcare costs. Integrated telehealth uses telecommunication technology to combine physical and behavioral healthcare to deliver community-based whole-person care. It overcomes social, economic, geographical, and climatological barriers that hinder access. Training students in integrated telehealth care places Idaho as a leader in healthcare training innovation. Integrated telehealth should reduce medical error; improve recruitment and retention of healthcare students and providers; combat burnout and employee turnover; and improve healthcare in rural and underserved areas.

The key to success for ITICC is building a collaborative network. While universities and communities have not traditionally enjoyed strong collaborative relationships, this trend has been reversed in telehealth. The majority of telehealth programs serving communities around the U.S. are based in academic centers. Initially, a working group will be founded composed of consumer, practice, student, and faculty representatives. Using implementation strategies based on other successful projects such as the Alaska Federal Health Care Access Network, East Carolina University, and the Telemedicine Research Center, the working group will development implementation strategies for the ITICC. Four telemedicine practice suites and up to eight rural clinics will be connected with up to an additional 27 rural clinics to follow bringing the total to 35. The ITICC system will interface with the Idaho Critical Access Hospital program that will wire up to 50 hospitals. Between the two projects, up to 85 communities will have access to the ITICC.

The areas of consultation available through Idaho State University include:

—Geriatric Care
—Family Medicine
—Health Education
—Healthcare Administration
—Mental Health, Child & Adult
—Nutrition Sciences
—Nursing
—Occupational & Physical Therapy
—Oral Health
—Pharmacy
—Radiology
—Rural Health Research
—Speech Pathology & Audiology

This project is designed to avoid the mistakes of other telehealth programs, which tend to focus on the technology and overlook the importance of maximizing human capital and the powerful effect of training on system change. The director of this project has been involved in designing, implementing, and evaluating telehealth programs for nearly a decade serving as a technology advisor to national and international groups and is the author of theory and evaluation papers. The clinical staff are mature in their fields. The ITICC team has intentionally chosen a smaller, scaleable project over a larger, riskier enterprise. Ongoing evaluation, using standardized measures, is built into the system design. During Year 3 there will be a special focus on refinement, sustainability, and dissemination of the program so other programs can benefit from the lessons learned by ITICC.

Sustainability is always a concern for any program, especially one that is as heavily invested in equipment as telehealth must be. The core elements of this program are based on proven technology that can be sustained at minimum cost and frustration to users. Because the ITICC is connected with a training institution, ITICC money can be leveraged for other training and research grants. Moreover, because the ITICC target is health professions shortage area, most consultations will be reimbursable under HCFA rural telehealth reimbursement regulations.

Mr. Chairman, ISU is seeking to establish a telehealth model for rural outreach. The 4 million dollars in federal partnership assistance requested will provide training benefits as well as improve the quality of care for Idaho's rural and frontier resi-

dents. We believe this will be an excellent investment of taxpayer funds that will be repaid many times over through local cost-savings and the provision of an integrative health model that can be replicated nationally. For example, it is well documented that local treatment usually results in cost savings. Receiving appropriate care when it is needed reduces the risk of hospitalization. It has been calculated that if each clinic prevents just one hospitalization through appropriate integrative care, there is the potential for 100 percent cost offset across the life of this project. Clearly the dollar cost offset is impressive but when added to the benefits of reduced medical error, better training, and recruitment and retention of providers in rural and frontier areas the benefits mount. Perhaps the most compelling case can be made by looking at the improvement to the quality of life for an individual person and his or her family and community when appropriate community based, whole-person care is finally possible.

Thank you.

PREPARED STATEMENT OF BABYLAND FAMILY SERVICES, INC.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony to the Public Witness Hearing Record regarding a model educational program that will close the "digital divide" among minority inner city children and families. Babyland Family Services (BFS) is a major non-profit child and family service organization, founded in 1968 in Newark, New Jersey, that provides comprehensive child and family development services at 14 sites to 1,500 at risk children and their families each year. The Annie E. Casey Foundation, a national leader in children's issues, highlighted Babyland in its annual 1998 Kids Count report as a model in community-based child and family development. BFS was also one of a select number of agencies that received a 1999 Century of Caring award, from the NJ Division of Youth and Family Services (DYFS), for its service to children and families. Babyland has also taken the lead on several community-wide initiatives: Success By 6, Family and Children Early Education Services (FACES), Abbott Preschool Family Worker Program, and the Pediatric Asthma Reduction Effort (PARE). These initiatives include collaborations with over 30 other child care centers, several public and parochial elementary schools, and several service providers. Together these initiatives serve over 5,000 children and families.

BFS integrates its wide network of services in order to enable each child and individual to reach their potential—intellectually, emotionally, spiritually, socially, and physically. Babyland's holistic philosophy—integrating child, family, staff and community development—serves as a model and has been studied by other communities throughout the nation and as far away as South Africa. Babyland serves at-risk children (from infancy to 18 years old), parents striving to be self-sufficient, teenage parents (including young fathers), struggling families and distressed neighborhoods.

BFS programs provide a continuum of educational services to individual children as well as multiple support services for family members. By virtue of this continuum, the agency is able to build extensive relationships with families and to provide follow-up care. As a result, BFS is in a unique position to launch and oversee a major computer and technology initiative that will provide extensive training and technology support for individual families having no other tangible means of becoming computer literate or of acquiring the requisite skills necessary to be informed and self-sufficient. This initiative would empower not only present clients but also those who will receive BFS services in the future.

BFS services include:

—Quality child care for children under three years old, through the Early Head Start Program;
—Early childhood education for preschoolers;
—After school and summer enrichment programs for school-age children;
—Pediatric health services, including a pediatric AIDS and asthma program;
—Parent education for teenage mothers and pregnant women, young fathers, severely distressed parents, foster parents, and grandparents;
—Emergency shelter and counseling for battered women and children;
—Foster care homes for boarder babies and sibling children;
—Self-sufficiency services that include: life skills, family literacy, substance abuse and mental health counseling, and employment training/placement in conjunction with networking partners;
—Training in the areas of child development, domestic violence, foster care, family support, health and parent leadership; and
—Community organizing and neighborhood leadership training for parents and residents.

Computer technology is transforming the economic and social landscape of this country by offering information and educational opportunities for individual growth and community development. Inner-city children and residents are inadequately prepared to take advantage of these growth opportunities. If the gap in information technology—the digital divide—is not bridged, a large segment of society will be further polarized and left without the tools needed for full participation in society. Specifically, BFS is seeking to establish the telecommunications linkages necessary for the educational development of 670 children and to provide computer and technology training for 2,000 parents, teachers, and employees. As a result, this initiative will strengthen children's educational skills; promote the self-sufficiency of and enhance the educational skills of parents; enable the agency to better track child and family needs in order to enhance client services; and link the community to local and national resource centers. The proposed technological network will link center and home-based child care facilities; community resources and service providers; educational, economic and resource information sources; training centers and administrative offices. The establishment of this network will be a model for educating urban children and serve as a conduit for comprehensive family support services.

The Specific Provisions of the BFS proposal include:

—Computer hardware and software (technical assistance, installation and wiring, modems, printers etc.) for children, parents and residents, and teaching/social service staff in classrooms, homes and social service offices.

—Technology Center, as part of a new multi-purpose community resource center, that will provide distance learning, professional development and training in basic and advanced computer and technology skills for low-income parents, neighborhood residents and entry-level employees.

—Computer Training, Curriculum Development and Professional Development for children, parents and residents, educational and social services staff, as well as national and international community-based family service providers.

The initiative will benefit:

—Preschoolers (550) at eight centers and 120 school-age children (after school/summer enrichment programs) at five centers.

—Parents and family members (1,750) at 13 Babyland sites with links to community resources;

—Agency Staff (250) for client tracking purposes; training and professional development; and access to community resources to be provided through workstations and/or palm pilots for caregivers/teachers and social service staff.

—Parents and children in the home for educational instruction and support, economic and resource information, links to other parents and teachers, parenting education (child and family health, child behavior and development, cultural sensitivity, etc) and professional education (ex. Certifications, GED, etc.).

—Family day care homes with links to community resources, professional education, BFS child care centers and other child and family resource centers.

—Child and family service providers throughout New Jersey, the nation and South Africa.

The BFS digital divide initiative will seek specifically to greatly enhance:

—Early childhood development and education for young children (three to 13 years old).

—The ability of inner city residents, especially low-income parents and teenagers, to learn computer and technology skills.

—Tracking of 1,500 children in center- and home-based child care facilities; teenage parents and victims of domestic violence; homeless families; foster children and families.

—Provision and delivery of professional development for BFS staff and parent education programs and curriculum development efforts.

—Delivery of clinical and therapeutic services to parents and children.

—The ability to fulfill State and Federal reporting requirements.

—The ability to provide consultation to international family service providers.

Current BFS parent and staff training programs that will be continued and expanded through the implementation of this initiative include:

—Foster parent training for over 300 candidates;

—Domestic Violence training for nearly 40 community staff;

—Family Worker training for over 50 Abbott Preschool family workers;

—Child care training and accreditation for nearly 100 child care staff from 30 centers;

—Parent leadership training for 30 parents from three public schools, through a grant from the Victoria Foundation;

—Family literacy training for 40 parents; and

—Family day care training for 20 family day care providers.

Of particular note, Babyland established an international training program with the Goldfield Metropolitan Corporation, a community-based organization in South Africa, in order to exchange information on child care, community development and family services. In 2000, we are looking forward to providing distance learning for over 100 parents and staff at the Early Head Start Program.

Mr. Chairman, as your Subcommittee deliberates funding requests from many qualified candidates coming to you for assistance this year, I urge you to review and consider our request for a $1 million 21st Century Learning Centers Grant to bridge the digital divide among inner-city families in Newark. We make this request in order to help us fulfill our mandate as a provider for thousands in our city but also, in return, to act as a model for other agencies in cities around the country who may also be able to help the technologically disadvantaged gain access to the resources and skills necessary to survive in the 21st Century.

Thank you.

CENTERS FOR DISEASE CONTROL AND PREVENTION

PREPARED STATEMENT OF THE INTERNATIONAL BRAIN INJURY ASSOCIATION

The International Brain Injury Association (IBIA) respectfully requests $15 million in fiscal year 2001 for the Traumatic Brain Injury Act (TBI Act).[1] IBIA is a non-profit organization dedicated to the support and development of medical and clinical professionals and others who work to improve opportunities and successes for persons with brain injury. Headquartered in Charlottesville, Virginia, IBIA is the only international association representing and convening brain injury professionals and specialists throughout the world.

The TBI Act, Public Law 104–166, is the first nationwide attempt to discern the extent of brain injury in this country, to assist states in providing services to persons with brain injury, and to further research on brain injury rehabilitation. Like other medical research and treatment in the United States, the TBI Act serves as a model for the rest of the world. IBIA and its members, therefore, strongly urge your support for $15 million to continue the critical work being done under the relatively nascent law.

The Act defines TBI 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. TBI can also result in the disturbance of behavioral or emotional functioning.

TBI is the leading cause of death and disability in young Americans. Motor vehicle crashes, sports injuries, falls, and violence (including shaken baby syndrome and other child abuse) are the major causes of traumatic brain injury. TBI can strike anyone—infant, youth, adult or elderly person—without warning, and often with devastating consequences. TBI affects the whole family and often results in huge medical and rehabilitation expenses over a lifetime.

Approximately 2 million Americans experience TBI each year. About half of these cases result in at least short-term disability, and 50,000 people die as a result of their injuries. Each year, approximately 230,000 persons require hospitalization for TBI (30 percent of which show disabilities a year post injury), and over 1 million people receive emergency medical care for TBI. The national cost is estimated at more than $48 billion annually. Every year about 80,000 people sustain severe brain injuries leading to long term disability. Through the TBI Act, the Center for Disease Control and Prevention (CDC) has estimated that there are 5.3 million persons living with long term, severe disability as a result of brain injury and as many as 6.5 million persons living with some form of injury including mild and moderate brain injuries.

The TBI Act was enacted "to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury." Under the law, the Centers for Disease Control and Prevention (CDC) is responsible for activities related to assessing the incidence of traumatic brain injury, conducting prevention research and increasing awareness of TBI; the Maternal and Child Health Bureau (MCHB) under the Health Resources and Services Administration (HRSA), is responsible for implementing a TBI State Demonstration Program; and

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[1] Reauthorization of the TBI Act is currently under consideration by the Congress. Funding must continue uninterrupted through fiscal year 2001.

the National Institutes for Health (NIH) has been delegated the responsibility of conducting basic and applied research and holding a consensus conference.

CDC SURVEILLANCE, EDUCATION AND PREVENTION

The TBI Act authorized CDC to support studies in collaboration with State and local health-related agencies to: (1) determine the incidence and prevalence of traumatic brain injury; and (2) develop a uniform reporting system under which States report incidents of traumatic brain injury. CDC has published TBI surveillance methods and guidelines for public health purposes and created and oversees a multi-state, uniform reporting system to provide nationally representative data to define groups at higher risk, causes and circumstances of injury, and outcomes of injury. This information is critical in the planning, implementation, and evaluation of programs for preventing TBI and any accompanying disabilities.

CDC's population based surveillance activities have provided the data for the epidemiologists and statisticians to estimate the incidence and prevalence of brain injury in this country. As CDC's estimates become more refined, the numbers of persons sustaining long term disabilities as a result of brain injury are increasing tremendously. Improving the accuracy of these estimates by conducting surveillance in additional states is crucial to understanding the impact brain injury has on the nation's medical and rehabilitative systems and accompanying costs, educational institutions, lost income and productivity, and the immeasurable toll on persons sustaining brain injury and their families.

The TBI Act also directed CDC to conduct research into identifying effective strategies for the prevention of brain injury, implementing public information and education programs for the prevention of brain injury, and broadening public awareness of the health consequences of such injury. CDC has drafted a brochure for persons with mild TBI who are treated in emergency departments, which discusses potential problems they may encounter and how to identify services. With additional funding the brochure can be widely distributed and other public awareness efforts can be initiated.

For fiscal year 2000, approximately $3 million was appropriated for CDC's work under the TBI Act. CDC has used most of this funding on its incidence and prevalence studies. More money is needed for education and prevention initiatives. We, therefore, respectfully request an increase of $2 million for education and prevention programs. Funding of $5 million for fiscal year 2001 is necessary to continue CDC's surveillance work, as well as to implement effective education and prevention activities.

HRSA/MCHB TBI DEMONSTRATION GRANTS PROGRAM

Under the TBI Act, HRSA directs the Maternal and Child Health Bureaus to provide and administer grants to States for demonstration projects to improve services for persons with TBI. The TBI Demonstration Grants are intended to help States implement statewide systems that ensure access to comprehensive and coordinated TBI services for the 5.3 million persons with long-term disabilities and their families. The projects are to involve all relevant disciplines, organizations and consumers.

State Planning Grants

Planning grantees are developing statewide TBI advisory boards; designating state agency and staff positions responsible for TBI activities; assessing statewide needs to address the full spectrum of care and services from initial acute treatment through community reintegration for individuals with TBI; and drafting statewide action plans to develop comprehensive, community-based systems of care that include physical, psychological, educational, vocational, and social aspects of TBI services.

State Implementation Grants

The implementation grants require states to establish interagency linkages; education and training for persons with TBI and their families; data collection to track programs, resources and enhance program evaluation; develop materials for low literacy and culturally or ethnically distinct populations; develop a pre-discharge model to be used in acute care sites in the development of long term resource plans for individuals with TBI; and develop a model to coordinate financial resources to provide services that most effectively meet the needs of persons with TBI.

In fiscal year 2000, $5 million was appropriated for this program. To maintain the continuity of these projects, we request $5 million for fiscal year 2001.

NIH RESEARCH ON TRAUMATIC BRAIN INJURY REHABILITATION

The TBI Act directed the National Institutes of Health (NIH) to conduct a consensus conference on TBI. In October 1998, the NIH held such a conference regarding managing traumatic brain injury and related rehabilitation concerns. The event was sponsored by the National Center for Medical Rehabilitation Research (NCMRR) within the National Institute of Child Health and Human Development (NICHD). Conference participants evaluated the scientific data concerning rehabilitation practices for persons with TBI. Particular emphasis was placed on rehabilitation of cognitive, behavioral, and psychosocial difficulties associated with mild, moderate and severe TBI. The conference brought together national and international biomedical researchers and clinicians, as well as person with TBI and their families.

Participants undertook a detailed review of the evidence-based scientific evaluations of cognitive and behavioral rehabilitative interventions. In response to "what research is needed to guide the rehabilitation of people with TBI," the conference statement listed the following priorities: [2]

—Epidemiological studies on the risk factors and incidence of TBI are needed for different age groups, gender and race.
—The relationship between substance abuse and TBI should be studied.
—Existing CDC surveillance systems based on hospital discharge summaries or death records should be expanded to include emergency department encounters in order to augment the current database for research.
—Studies of the placement of persons with TBI in nursing homes and psychiatric facilities are needed to clarify what constitutes appropriate placement.
—The epidemiology of mild TBI should be studied.
—The duration, natural history, and life-course manifestations (neurological, cognitive, social, psychological, economic, etc.) of mild, moderate, and sever TBI should be studied.
—Gender differences in survival rates, patterns of severity, and long-term manifestations of TBI should be studied.
—The consequences and effects of rehabilitation after TBI in the elderly should be studied.
—The experience of minority group members with TBI should be studied.
—Research training is needed in the areas of injury epidemiology and clinical research in order to enhance the quality of all research related to TBI.
—The time course of TBI should be studied in animals with respect to injury severity, influence of age and gender and effects of interventions.
—Research is needed on the appropriate timing of therapeutic interventions after TBI.
—Research is needed on the effectiveness of pharmacological interventions for the cognitive, behavioral, and emotional consequences of TBI.
—The neurobiology of TBI in humans should be studied with modern imaging techniques (e.g. positron emission tomography [PET] and functional magnetic resonance imaging [fMRI]) and correlated with neuropsychological findings.
—Promising treatments of TBI derived from animal studies should be tested in humans.
—The epidemiology and management of TBI in sports should be studied.
—Well-designed and controlled studies of the effectiveness of rehabilitation interventions are needed.
—Economic analysis of TBI including major determinants of costs, is needed.
—Innovative rehabilitation interventions for TBI should be developed and studied.
—The predictors of quality of life for persons with TBI, their families, and significant others should be studied.
—Studies are needed to evaluate the relationship between specific cognitive deficits and global outcomes.
—Validation of generic health-related quality of life assessment instruments for use in TBI is needed as well as the development and validation of TBI-specific instruments.
—Uniform standards and minimal data sets to describe injury type, severity, and significant interacting variables, which could provide a total injury profile across a continuum of recovery, should be developed.
—The relationship between the pathophysiology of TBI and the effectiveness of different interventions should be studied.
—The long-term consequences of TBI of varying severity, including the consequences of aging for a person with TBI, should be studied.

[2] The National Institutes of Health Consensus Development Conference Statement on Rehabilitation of Persons with Traumatic Brain Injury, October 26–28, 1998.

—The developmental impact of TBI in childhood with respect to the need for special education, mental health, and rehabilitation services should be studied.
—The effectiveness of community-based rehabilitation of persons with TBI should be studied.
—Severity risk-adjustment models for studies of persons with TBI should be established.
—The effectiveness of peer support for persons with TBI, their families, and significant others should be studied.
—Innovative study methodologies to assess the effectiveness of complex interventions for persons with TBI should be developed and evaluated.

The NIH Consensus statement concludes that "funding for research on TBI needs to be increased." IBIA therefore requests $5 million for brain injury research to be conducted by the National Institutes of Health through the National Center on Medical Rehabilitation Research and/or the National Institute on Neurological Disorder and Stroke.[3]

CONCLUSION

There are few conditions that can strike anyone at any age at any time. Traumatic brain injury is one of them, and as a result is often known as the "silent epidemic." As the United States medical community perfects trauma care and rehabilitation, more individuals (who might have otherwise died) are living with brain injuries than ever before. CDC must keep track of the growth of this epidemic, devise public awareness campaigns and establish effective prevention programs. The states need to assess the needs of their communities and include persons with brain injury in their services. And as the National Institutes of Health conducts basic and applied research on the myriad of disorders that affect the brain, trauma to the brain and the resulting affects on the person and his/her life must not be excluded.

IBIA respectfully requests $15 million in fiscal year 2001 for the Traumatic Brain Injury Act ($5 million for CDC, $5 million for HRSA, and $5 million for NIH).

PREPARED STATEMENT OF THE EPILEPSY FOUNDATION

The Epilepsy Foundation is the national voluntary organization that works for people affected by seizures through research, education, advocacy and service. The national office together with its network of more than 60 affiliates across the country advocate for increased funding for medical research to find better treatment and an eventual cure for epilepsy, and works with Federal Government agencies and Congress to advance the interests of people with epilepsy.

Epilepsy is a neurological condition characterized by recurrent, unprovoked seizures. It is an economic burden on individuals, families, communities, and society as a whole because of resultant increased health care costs. Epilepsy is a formidable barrier to normal life, affecting educational attainment, employment, and personal fulfillment. The stigma that comes from seizures and societal misconceptions about them remain as facts of life for many individuals with epilepsy.

Epilepsy and seizures affect 2.3 million Americans of all ages. Approximately 181,000 new cases of seizure and epilepsy occur each year; 10 percent of all Americans will experience seizures in their lifetimes. According to the most recent data available, in 1995, 300,000 children aged 14 and under had epilepsy; 1.4 million adults under age 64 and 550,000 aged 65 and over had epilepsy. Epilepsy is a chronic condition that usually requires a lifetime of continual medical treatment and education. As many as 44 percent of people with epilepsy continue to have seizures despite treatment; 56 percent have early or delayed seizure control with treatment. Currently, there is no cure for epilepsy.

THE COST OF EPILEPSY IN THE UNITED STATES

Epilepsy is a major, unsolved health problem affecting the lives of millions of Americans and their families. The economic impact in the United States is also tremendous. A three-year study sponsored by the Epilepsy Foundation to determine the financial costs of epilepsy to individuals and the nation was completed in 1999. Using data from actual cases as a basis for the estimate, the annual financial cost of epilepsy in the United States is approximately $12.5 billion. Of this, $1.7 billion (14 percent) are direct medical costs while $10.8 billion (86 percent) are indirect

[3] The National Institute on Neurological Disorders and Stroke engages in numerous research studies, some of which could benefit traumatic brain injury research; NINDS has expressed an interest in undertaking TBI specific research.

medical costs. The study also found marked divisions in costs among those people with epilepsy whose seizures are easy to control and those who continue to experience seizures, despite treatment.

Indirect costs are primarily employment related. Individual men and women who continue to experience seizures despite treatment were estimated to lose hundreds of thousands of dollars in wages while also experiencing loss of productivity at home. Each man lost a total of $317,000 or 35 percent of his lifetime wages. Each woman lost a total of $140,000 or 25 percent of her lifetime wages.

The high concentration of costs among those people with epilepsy who continue to experience seizures emphasizes the importance of seizure control in reducing the economic burden of epilepsy on society and the individual and also demonstrates the cost-saving potential of effective interventions that increase seizure control. Recent advances in medical, surgical, and vagal nerve stimulation therapies hold promise for reducing the frequency and severity of seizures in people with intractable epilepsy.

Epilepsy research is an area largely under-funded compared to other diseases. The results of this cost study provide compelling evidence of the need for increased support in this area. The cure of intractable seizures and all forms of epilepsy must be a research priority for the nation.

CURING EPILEPSY: FOCUS ON THE FUTURE

A White House-initiated conference sponsored by the National Institute of Neurological Disorders and Stroke was held March 30–31, 2000 at the National Institutes of Health. The conference featured clinicians and scientists who discussed innovative discoveries likely to lead to the prevention and cure of epilepsy. Presentations on diverse topics included the prevention of epileptogenesis (how epilepsy begins), ameliorating the effects of epilepsy genes, monitoring epileptogenesis, developing new therapies and using surgery and other forms of technology.

The primary message from the conference is that epilepsy treatment is due to undergo a fundamental change in direction from treating the seizures which are the symptoms of epilepsy to treatment of the underlying condition in the brain. The goals of treatment will be the prevention and cure of epilepsy, no seizures and no side effects for those who have already developed the condition and dramatic new ways of preventing epilepsy that is acquired from injury, infection or errors of development.

Opportunities for further breakthroughs in epilepsy research identified at the conference are dependent upon increased funding to the National Institutes of Health and the National Institute of Neurological Disorders and Stroke and the development of a coordinated plan for pursuing these opportunities.

ADVANCES IN EPILEPSY RESEARCH

In his testimony before the House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Gerald D. Fischbach, M.D., Director, NINDS, described several major initiatives for fiscal 2001. These priorities include efforts to address developmental and degenerative disorders of children, such as epilepsy, that can result in a lifetime of disability. The severe epilepsy syndromes of childhood produce developmental delay and brain damage that can result in a life of dependence on others and continually accruing costs to the health care system and society. Research has led to the discovery of good predictors for remission or relapse of epilepsy in children. For the sake of these children and those others who will develop epilepsy, research focused on the prevention and treatment of epilepsy in our youngest citizens must be a national priority.

One area of research that holds great promise is the identification of the genes responsible for predisposition to certain types of epilepsy. Research has identified several genes for childhood epilepsies in the last few years. During his recent testimony, Dr. Fischbach explained that the NINDS has emphasized gene discovery in epilepsy since even the most common forms, such as febrile convulsions, have a heritable component. Advances in genetic therapy, coupled with genetics research, will not only suppress seizures, but cure certain types of epilepsy.

Another area of great clinical importance to people with epilepsy has been the development of new anti-epileptic drugs. The Foundation recommends research support from the NINDS for comparative trials of anti-epileptic drugs to assure that people with epilepsy receive the greatest possible benefit from these newly available medications. These medications have shown great promise but more research is needed to eradicate this disorder.

CENTERS FOR DISEASE CONTROL EPILEPSY PROGRAM

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, the epilepsy program targets its outreach and education efforts on consumers, health professionals, and health systems. The CDC was appropriated an additional $1 million for fiscal year 2000 to expand epilepsy surveillance, public awareness activities, and public and provider education. The fiscal year 2000 funding is the first significant increase since 1993, illustrating Congress' and CDC's renewed commitment to epilepsy and the issues which surround it.

Current CDC activities in the area of epilepsy include programs geared toward teens and adolescents, a population which struggles with the stigma associated with this disorder. The Foundation hopes to help teens, through a web based teen chat room, forums, and special events, to make more informed decisions about their behaviors and life plans, while at the same time educating the general public.

Experts agree 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 recurring seizures. With additional funding in fiscal year 2001, epilepsy activities can be expanded to include a broader public awareness and communication strategy including laying the groundwork for programs targeted at seniors and children and continued efforts for teens. Increased funding would allow for the implementation of local community activities; improved surveillance and prevention research; and more extensive provider education.

FISCAL 2001 FUNDING RECOMMENDATIONS

Epilepsy research funded by the National Institute of Neurological Disorders and Stroke is vital to continuing the fight against epilepsy. The promise of future breakthroughs in epilepsy research can only be achieved by increased funding for epilepsy research and prevention programs. The Foundation urges Congress to increase the federal commitment to epilepsy research by allocating sufficient funding for the NINDS and Centers for Disease Control.

National Institutes of Health.—The Foundation supports Congressional efforts to double the NIH budget over 5 years and is seeking a 15 percent increase for fiscal 2001, resulting in a total NIH budget of $20.6 billion.

National Institute of Neurological Disorders and Stroke.—The Foundation supports a 15 percent increase for NINDS in fiscal 2001, creating a total NINDS budget of $1.19 billion. This increase is consistent with efforts to double NIH research funding over 5 years.

Epilepsy Research.—The Foundation urges Congress to support a major expansion of epilepsy research within NINDS. In 1999, NINDS spent approximately $74 million dollars on epilepsy research. We are seeking a commitment to triple that amount over the next few years.

Centers for Disease Control Epilepsy Program.—The Foundation is seeking a $5 million increase in fiscal year 2001 support for the CDC's epilepsy program within its chronic and environmental account. With additional resources, the CDC and the Foundation can make great strides in combating the negative consequences associated with epilepsy and seizures.

PREPARED STATEMENT OF ROTARY INTERNATIONAL

Chairman Specter, Senator Harkin, members of the Subcommittee, thank you for this opportunity to present written testimony on behalf of Rotary International in support of the polio eradication activities of the U.S. Centers for Disease Control and Prevention. As you know, 2000 is a water shed year in the battle to eradicate polio. The penultimate goal of the international polio eradication initiative, the interruption of polio transmission, is within our grasp. We remain on track for our primary target: certification of eradication by 2005. This monumental effort, toward which countless millions have endeavored, has required the commitment and fortitude of a climb to Everest's peak. As we near our goal—a world free of polio—we cannot become complacent. We cannot allow the daunting challenges that lie before us to diminish our resolve. As with an expedition to scale Everest, the most difficult stage of our journey, the stage most fraught with the risk of failure, is the final push to the summit.

I would like to take this opportunity to thank you Chairman Specter, Senator Harkin and members of the Subcommittee for your tremendous commitment to this

effort. Without your support of the CDC's polio eradication activities, the battle against polio would be impossible.

The global eradication strategy is working. In 1985, when Rotary began its PolioPlus Program, 100 nations around the world suffered under the burden of polio. The Western Hemisphere has now been polio-free for nearly 9 years, and today polio is confined only to Sub-Saharan Africa, parts of the Middle East, and South Asia.

Thanks to the polio eradication efforts over the last decade, approximately three million children who might have been polio victims are walking and playing normally. Tens of thousands of public health workers have been trained to investigate cases of acute flaccid paralysis and manage immunization programs. Cold chain, transport and communications systems for immunization have been strengthened. A network of more than 140 polio laboratories has been established.

Significant challenges lie before us. Continued political commitment is essential both in polio endemic countries, to support the acceleration of eradication activities, and in donor countries, so that the necessary human and financial resources are made available. Access to children everywhere is needed, particularly in countries affected by conflict. Truces must be negotiated if National Immunization Days are to proceed in these countries. The continued leadership of the United States is critical if we are to overcome these challenges.

Rotary International is a global association of more than 29,000 Rotary clubs, with a membership of over 1.2 million business and professional leaders in 160 countries. In the United States today there are some 7,500 Rotary clubs with 400,000 members. All of our clubs work to promote humanitarian service, high ethical standards in all vocations, and international understanding.

Less than one year remains to defeat this disease in the nations where the poliovirus still causes death and disability. With your continued support, soon no child will ever be struck down by polio again.

FISCAL YEAR 2001 BUDGET REQUEST

For fiscal year 2001, we respectfully request that you provide $91 million for the targeted polio eradication efforts of the Centers for Disease Control and Prevention, a $5 million increase from the fiscal year 2000 funding level, thereby meeting the President's budget request. This $5 million increase is necessary to meet the meet the need for additional oral polio vaccine resulting from the accelerated immunization schedule in 2000. In addition, we must continue to meet the enormous costs of eradicating polio in its final stronghold—sub-Saharan Africa. The underdeveloped and conflict-torn countries of Africa represent the greatest challenges to the success of the global Polio Eradication Initiative. This additional appropriation will allow the CDC to help African nations accelerate polio eradication activities, improve surveillance for polio and other diseases, and support peace-building cease-fires for NIDs. Without the additional $5 million, we may not be able to eradicate polio in Africa by the Target 2000 date, prolonging the need to continue expensive NIDs and routine immunization worldwide. The time for the final assault against polio is now.

ERADICATING POLIO WILL SAVE THE UNITED STATES AT LEAST $230 MILLION ANNUALLY

In 1998 the Chairman of the House Committee on International Relations commissioned the General Accounting Office to investigate the soundness of WHO cost estimates for the eradication or elimination of seven infectious diseases. The United States was a major force behind the successful eradication of the smallpox virus, and the GAO concluded that the eradication of smallpox has saved the United States some $17 billion to date. Even greater benefits will result from the eradication of polio.

Although polio-free since 1979, the United States currently spends at least $230 million annually to protect its newborns against the threat of importation of the poliovirus, in addition to its investment in international polio eradication. Globally, over $1.5 billion U.S. 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 and immunization against it can be discontinued, tremendous resources will be unfettered to focus on other health priorities.

PROGRESS IN THE GLOBAL PROGRAM TO ERADICATE POLIO

Thanks to your leadership in appropriating funds, the international effort to eradicate polio has made tremendous progress.

—Since the global initiative began in 1988, 3 million children in the developing world, who otherwise would have become paralyzed with polio, are walking because they have been immunized.
—The number of polio cases has fallen from an estimated 350,000 in 1988—of which 35,000 were reported—to approximately 6,000 reported cases in 1999. More than 180 countries are polio-free, including 4 of the 5 most populous countries in the world (China, U.S., Indonesia and Brazil).
—Almost 2 billion children worldwide have been immunized during NIDs in the last 5 years, including 147 million in a single day in India. During 74 National Immunization Days, 16 Sub-National Immunization Days and 7 Mopping-up activities conducted in 1999, over 450 million children received oral polio vaccine. This represents nearly 75 percent of all the world's children under the age of five.
—All polio-endemic countries in the world have conducted NIDs—most recently in Sierra Leone and Democratic Republic of the Congo. The achievement of successful NIDs and implementation of APF surveillance in Somalia and Sudan shows that polio eradication strategies can be implemented in all countries.

THE ROLE OF THE U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Rotary commends the CDC for its leadership in the global polio eradication effort, and greatly appreciates your Subcommittee's support of the CDC's polio eradication activities. For 2000, you appropriated a total of $87.2 million for the CDC's global polio eradication activities. Because of Congress' unprecedented support, in 2000 the CDC is:

—Supporting the international assignment of more than 110 long-term epidemiologists, virologists, and technical officers to assist the World Health Organization and polio-endemic countries to implement polio eradication strategies, and 10 technical staff to assist UNICEF and polio-endemic countries. This includes 30 CDC staff provided directly on assignment to WHO and UNICEF.
—Providing over $60 million to UNICEF for approximately 700 million doses of polio vaccine and operational costs for NIDs in some 60 countries in Asia, Eastern Europe, the Middle East and Africa. Many of these NIDs would not take place without the assurance of the CDC's support.
—Providing over $20 million to WHO for surveillance and NIDs' operational costs, primarily in Africa. As successful NIDs take place, surveillance has emerged 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.
—The leading specialized polio reference lab in the world providing the largest volume of both operational (poliovirus isolation) and technologically sophisticated (genetic sequencing of polio viruses) lab support to the 148 laboratories of the global polio laboratory network.
—Serving as the primary technical support agency to WHO on scientific and programmatic issues regarding: (1) laboratory containment of wild poliovirus stocks following polio eradication, and (2) when and how to stop polio vaccination worldwide following global certification of polio eradication in 2005.

OTHER BENEFITS OF POLIO ERADICATION

Increased political and financial support for childhood immunization has many documented long-term benefits. Polio eradication is helping countries to develop public health and disease surveillance systems useful in the control of other vaccine-preventable 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. As a result of this success, measles has been targeted for eradication in the Americas by the year 2000. The disease surveillance system—the network of laboratories and trained personnel built up during the Polio Eradication Initiative—is now being used to track measles, Chagas, neonatal tetanus, and other deadly infectious diseases. NIDs have been used as an opportunity to give children essential vitamin A, as well as polio vaccine. The campaign to eliminate polio from communities has led to increased public awareness of the benefits of immunization, creating a "culture of immunization" and resulting in increased usage of primary health care and higher immunization rates for other vaccines. It has improved public health communications and taught nations important lessons about vaccine storage and distribution, and the logistics of organizing nation-wide health programs. Lastly, the unprecedented cooperation between the public and private sectors serves as a model for other public health initiatives.

RESOURCES NEEDED TO FINISH THE JOB OF POLIO ERADICATION

The World Health Organization estimates that $1 billion is needed from donors for the period 2000–2005 to help polio-endemic countries carry out the polio eradication strategy. The estimated shortfall for the years 2000–2001 now stands at approximately $300 million. In the Americas, some 80 percent of the cost of polio eradication efforts were borne by the national governments themselves. However, as the battle against polio is taken to the poorest, least-developed nations on earth, and those in the midst of civil conflict, many of the remaining polio-endemic nations can contribute only a small percentage of the needed funds. In some countries, up to 100 percent of the NID and other polio eradication costs must be met by external donor sources. We are asking that the United States continue to take the leadership role in meeting this shortfall.

The United States' commitment to polio eradication has stimulated other countries to increase their support. Belgium, Canada, Germany, and Italy are among those countries that have followed America's lead and have recently announced special grants for the global Polio Eradication Initiative. Japan has also expanded its support to polio eradication efforts in Africa. Germany has made major grants that will help India eradicate polio by the target year 2000. In December 1999 the United Kingdom announced two grants totaling U.S. $94.6 million for polio eradication efforts in India and Africa. The Government of India will receive U.S. $62.6 toward its Pulse Polio Initiative over the next two years. In addition, the U.K. will grant a total of U.S. $32 million to African nations that are poliovirus reservoirs, affected by conflict or both. These nations include Nigeria, Ethiopia, Somalia, Sudan, DR Congo and Angola.

By the time polio has been eradicated, Rotary International expects to have expended approximately $500 million on the effort—the largest private contribution to a public health initiative ever. Of this, $373 million has already been allocated for polio vaccine, operational costs, laboratory surveillance, cold chain, training and social mobilization in 120 countries. More importantly, we have mobilized tens of thousands of Rotarians to work together with their national ministries of health, UNICEF and WHO, and with health providers at the grassroots level in thousands of communities.

Polio eradication is the most cost-effective public health investment, as its benefits accrue forever. The world will begin to "break even" on its investment in polio eradication only two years after the virus has been vanquished.

When we reach the summit, we will be able look out upon a world in which the scourge of polio is a thing of the past. This will be our gift to the children of the twenty-first century.

Thank you for this opportunity to present written testimony.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to provide a written statement on the fiscal year 2001 appropriation for the Centers for Disease Control and Prevention (CDC). The ASM is the largest single life science society in the world with more than 42,000 members representing a broad spectrum of subspecialties, including microbiologists who work in clinical, public health, biomedical and industrial laboratories. The ASM appreciates the Subcommittee's ongoing support of the CDC, particularly for the CDC's National Center for Infectious Diseases (NCID), which funds programs, addressed in this statement, related to emerging and drug resistant infectious diseases, public health infrastructure, bioterrorism preparedness and food safety.

The ASM endorses the recommendation of the CDC Coalition to increase the overall CDC budget to a level of $4.1 billion, an amount that exceeds the President's budget request by approximately $600 million. The CDC requires additional new resources to respond to an array of continuing and new public health challenges. As the "Nation's Prevention Agency," the CDC is charged with promoting health and quality of life by anticipating, identifying, preventing and controlling diseases and other public health threats. The CDC must have adequate resources to expect and be prepared for unexpected public health emergencies throughout the country and across the globe, including, for example, a bioterrorism event, a global influenza pandemic, a large scale environmental disease threat or an unforeseen public health danger.

In the following statement, the ASM will focus on specific areas within the CDC budget which are of concern to the microbiological community.

EMERGING AND DRUG RESISTANT INFECTIOUS DISEASES: PUBLIC HEALTH THREATS AND NEEDS

The American people benefit from a well-funded and effective federal health system. In the past year, the rapid response by health officials identified an outbreak of West Nile encephalitis in New York, Connecticut and New Jersey; linked E. coli O157:H7 infection at an upstate New York county fair to contaminated water; and tied a multi-state outbreak of Listeria infections to contaminated hotdogs and cold-cut meats manufactured at a single plant. These successes are due to state-of-the-art molecular laboratory diagnostic tools, as well as to coordinated communications and disease reporting systems among health agencies. Initiated in 1995 by the CDC, the Epidemiology and Laboratory Capacity for Infectious Diseases cooperative agreements are helping to rebuild the nation's public health infrastructure at state and local levels, and making possible success against infectious disease outbreaks. In fiscal year 1999 CDC awarded more than $40 million to all states and four cities to boost preparedness against possible chemical and biological terrorism, and developed laboratory protocols for several of the possible bioterrorism agents to share with state and local laboratories. In 1999 the CDC also distributed nearly 300,000 copies of recommendations for prevention and control of hepatitis C infection (HCV) infection and HCV-related liver disease to physicians and health care providers nationwide.

The ASM recognizes and applauds the breadth of the CDC's contributions to these and other successful public health campaigns. Despite positive past experiences, however, the vigilance needed against disease will only intensify as we move through the 21st century. The blood-borne hepatitis C virus, for example, has infected more than 4 million persons in the United States, 3 million of whom remain chronically infected and therefore at risk for developing cirrhosis or liver cancer. In this country each year, 8000 to 10000 die from cirrhosis or primary liver cancer. The CDC is coordinating the Hepatitis C Public Information Campaign, aimed toward notifying all prior transfusion recipients at risk for HIV infection. It will continue ongoing investigations into various risk factors and modes of transmission, as well as collaborate with other groups like the American Liver Foundation to educate the public about HCV. Sufficient funding would strengthen and expand this multipronged effort against HCV infection. Like the hepatitis viruses, both "old" and newly emerging or reemerging infectious diseases will continue to challenge our society's well-being and productivity, and thus make even more imperative an adequately funded federal public health agency.

The CDC is recognized the world over for its efforts to combat the threats of new, emerging and drug resistant infectious diseases. Infectious diseases are a crisis of global proportions which threaten gains in health and life expectancy and which are now the world's biggest killer of children and young adults. Substantial new funding is needed to enable CDC to fully implement its comprehensive plan, "Preventing Infectious Diseases: A Strategy for the 21st Century." The additional $25 million requested for this initiative in the Administration's fiscal year 2001 budget would not provide adequate resources needed to fully implement the next phase of the plan. The ASM concurs with other supporters of the CDC that an additional $162 million would achieve in the appropriate time frame the CDC goals set forth in 1998 for emerging infections. These goals include a broad range of improvements to such critical functions as detection and prevention of emerging pathogens, communication among all levels of government health agencies, and integration of laboratory science with on-site epidemiology.

Also targeted in the 1998 plan was the alarming trend toward antimicrobial resistance among pathogenic microorganisms. Approximately 28 percent of bacteria that cause hospital-acquired infections in the United States, for example, are resistant to the specific antibiotic once considered most effective against that particular infection. Especially problematic is the reduced susceptibility of Staphylococcus aureus to vancomycin. The CDC has specific plans to address this problem which will require sufficient funding: improved clinical guidelines for antibiotic usage; better public education on the issue of overuse of antibiotics; research on antibiotic resistance genetic markers as monitoring devices; and a national surveillance system to assess the overall impact of antibiotic resistance.

PUBLIC HEALTH INFRASTRUCTURE

The ASM recommends that Congress increase the budget requested to modernize the CDC's outmoded, severely inadequate and deteriorating physical plant. CDC needs funding and authority to modernize existing laboratory and support facilities and construct new facilities according to its long range facilities master plan which addresses building and facilities needs through the year 2009. Almost all of CDC's

laboratory capacity is currently dangerously antiquated, unsafe and unsuitable for modern scientific research activities related to CDC's public health role. CDC has experienced substantial program growth in recent years, and facilities have not kept pace with new programs created in response to an increasing number of dangerous threats from deadly pathogens. The ASM recommends that Congress provide at least the $127 million requested (an additional $70 million over fiscal year 2000) for CDC infrastructure needs and consider providing an even higher level of $175 million to fully meet the facilities needs and repairs at CDC and accelerate planned construction and upgrades.

BIOTERRORISM PREPAREDNESS AND RESPONSE

The CDC has established a national effort to protect the public's health in the event of a biological or chemical terrorist attack. The initiative builds on the efforts begun at CDC in fiscal year 1999 that focused on building core capacity within CDC and in states to establish clinical laboratory surveillance, information technology and epidemiologic expertise for the highest probability agents. The ASM notes that funding for CDC bioterrorism preparedness activities decreases by $6.5 million to a level of $148.5 million in the Administration's budget request. Current funding levels permit only partial implementation of this program, leaving many states and cities with limited or no coverage in some key preparedness areas. Additional funding would allow more state and local health departments to build capacity in essential areas of biological and chemical preparedness including: planing, surveillance and epidemiology, biological and chemical laboratory services and electronic communication.

A recent Institute of Medicine report on "Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response," stresses the need for long-term public health infrastructure improvements. Bioterrorism preparedness is also a part of CDC's larger effort to reinvest in the public health system to establish capability to respond to naturally occurring infectious disease threats. The ASM supports the requested $2 million for CDC deterrence efforts to monitor laboratory compliance with the Antiterrorism and Effective Death Penalty Act of 1996 and to ensure the safe handling of potential threat agents in diagnostic and research laboratories.

FOODBORNE AND WATERBORNE DISEASES

While often not as dramatic as a newly identified infection, foodborne and waterborne disease outbreaks in recent years have been sudden and deadly. The CDC rightly has not neglected this ever-present threat to the American public. In collaboration with the FDA and USDA, the CDC has revitalized measures against further outbreaks caused by contaminated food and water supplies. For example, the CDC PulseNet program, now in more than 30 states, enables local health departments to rapidly identify the microbial agents responsible for an outbreak, by utilizing modern molecular fingerprinting technologies. Rapid response is essential in such outbreaks, as spread of infection can occur if the food or water source is not quickly identified and removed. Foodborne diseases alone are estimated to cause 5,000 deaths and 76 million illnesses in the United States yearly. Therefore, the ASM recommends approval of the Administration's proposed increase of $10 million for foodborne diseases as part of the CDC budget for infectious diseases in fiscal year 2001.

COST EFFECTIVE STRATEGY

An investment today in the CDC is an investment in tomorrow's public health. Finding our way safely through the maze of public health problems often seems costly, but the collective price tag of infectious disease in death, illness, and dollars is alarming. For instance, hospital-acquired infections kill 88,000 people annually in United States and cost more than $4.5 billion each year. Public health officials estimate that foodborne illness costs this nation's economy several billion dollars annually. Just in this country, the influenza pandemics of 1957–1958 and 1968–1969 created combined economic losses of about $32 billion (1995 dollars).

Monetary savings, of course, are not the only reward from a strong, innovative, and forward-looking public health system in the United States. More importantly, the American public rightly receives physical and emotional benefits from its long-standing support of medical and scientific research. Those benefits may be direct and obvious, such as identification of contaminated water supplies, or less obvious but equally important, as in the case of a strengthened infrastructure for public health to develop and share health-related technologies and information among health agencies. A reinvigorated public health system with effective programs will

help protect the public against existing and emerging threats, such as antimicrobial resistance, chronic diseases with infectious origins and pandemic influenza.

Thank you for the opportunity to provide a written statement for the hearing record on the CDC's fiscal year 2001 appropriations.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Chances are heart attack or stroke will be the death or disabler of you or a loved one. Heart attack, stroke and other cardiovascular diseases remain America's leading cause of death and a main cause of disability. Cardiovascular diseases account for nearly 1 of every 2 deaths in the U.S.

The American Heart Association is dedicated to reducing death and disability from heart attack, stroke and other cardiovascular diseases. We commend this Committee for making fiscal year 2000 funding for the National Institutes of Health and the Centers for Disease Control and Prevention a top priority. But, we are concerned that our government is still not devoting sufficient resources for research and prevention of America's No. 1 killer—heart disease—and to our country's No. 3 killer and a leading disabler—stroke.

Heart attack, stroke and other cardiovascular diseases have been America's No. 1 killer since 1919. Nearly 60 million Americans—1 in 5—of all ages suffer from one or more of these diseases. Hundreds of millions of Americans have major risk factors for these diseases—about 50 million have high blood pressure, 40 million have elevated blood cholesterol (240 mg/dL), 49 million smoke, 106 million adults are obese or overweight and 10 million have physician-diagnosed diabetes. As the baby boomers age, the number of Americans afflicted by these often disabling diseases will increase substantially. Cardiovascular diseases cost Americans more than any other disease. Americans will pay an estimated $327 billion for cardiovascular-related medical costs and lost productivity in 2000. These diseases constitute 4 of the top 5 hospital costs for all payers, excluding childbirth and its complications, and 4 of the top 5 Medicare hospital costs. Heart disease is also the leading cause of premature, permanent disability of American workers, accounting for nearly 20 percent of Social Security disability payments.

HOW YOU CAN MAKE A DIFFERENCE

Now is the time to capitalize on a century of progress in understanding heart attack, stroke and other cardiovascular diseases. Promising, cost effective breakthroughs in treatment and prevention are on the horizon. We challenge our government to stay the course to double funding by year 2003 for NIH, for heart and stroke research and to translate research into effective clinical and community initiatives. This will cut health care costs and improve quality of life. For fiscal year 2001 we urge you to do the following.

—*Appropriate a 15 percent increase over fiscal year 2000 funding for the overall NIH—the third step toward the goal of doubling the budget by year 2003. This goal is echoed by groups such as Research!America and the Ad Hoc Group for Medical Research Funding.*

NIH research provides cutting-edge treatment and prevention strategies, cuts health care costs, creates jobs and maintains America's status as the world leader in biotechnology and pharmaceuticals industries.

—*Provide a 15 percent increase over fiscal year 2000 funding for NIH heart research and stroke research.*

Researchers are on the brink of advances that could pave the way to prevention and even a cure so you or a loved one will be spared pain and suffering from heart disease and stroke.

—*Allot a $25.2 million increase over fiscal year 2000 funding to expand CDC's Cardiovascular Health Program to 11 more states for a total of 29 states.*

We must make our science real and applicable through community interventions that encourage Americans to make healthful lifestyle choices to prevent heart disease and stroke.

HEART AND STROKE RESEARCH BENEFITS ALL AMERICANS

Thanks to advances in addressing risk factors and in treating cardiovascular diseases, more Americans are surviving heart attack and stroke. Heart and stroke research and prevention breakthroughs are saving and improving lives. Several cutting-edge examples follow.

—*Emergency Cardiac Care.*—Daily more than 700 Americans suffer sudden cardiac arrest—the unexpected, abrupt loss of heart function. A particular se-

quence of actions known as the "chain of survival" offers hope. Early use of both breathing and chest compression techniques of cardiopulmonary resuscitation and delivery of a powerful electrical shock to re-start the heart are critical to restore life. Each minute of delay in returning the heart to its normal rhythm decreases chance of survival by 10 percent. Our Operation Heartbeat Program, alone, estimates that 100,000 lives could be saved if automatic external defibrillators were more widely available.

—*Advanced Imaging Technology*.—Research has revolutionized imaging technology to diagnose heart disease. You probably know someone who has had an angiogram. In this procedure, a catheter is inserted in an artery and navigated up to the heart. Then a dye is injected so x-rays can show artery narrowing that can trigger a heart attack or a stroke. About 1.2 million patients in 1997 were hospitalized for this procedure which causes discomfort and risk of infection and bleeding, and in rare cases, heart attack or stroke. Now angiograms are being replaced by two new imaging procedures that are easier, safer and cheaper. The high speed CT scan takes fast pictures, producing a measure of blockages in arteries to the heart, and help doctors better tailor treatments. Three-dimensional coronary magnetic resonance angiography (MRA), uses strong magnets to provide detailed images of the arteries to the heart. Taking less than an hour, MRA evaluates heart anatomy and other heart functions, providing a comprehensive, noninvasive, heart examination.

—*Surgery to Reduce Risk for Stroke*.—In many cases surgeons can prevent stroke by removing the buildup of plaque from the main artery to the brain that is severely narrowed. Also, it helps stroke survivors reduce their risk of another stroke. About 140,000 procedures are performed each year.

—*State-of-the-Art Life-extending drugs*.—Research has produced new drugs to help prevent and treat heart attack and stroke. Cutting-edge drugs to control blood pressure and cholesterol are more effective than ever in saving lives and enhancing quality of life. When prevention fails, revolutionary "clotbuster" drugs can reduce disability from heart attack and stroke by dissolving blood clots causing the attack. Use of t–PA, within 3 hours of the onset of symptoms, can restore blood flow through the clot-obstructed artery and reduce chances of permanent disability by 33 percent, saving health care costs. T–PA offers hope for the estimated 1.1 million Americans who will suffer a heart attack and 450,000 at risk of a clot-caused stroke this year.

So Americans can continue to benefit from these types of breakthroughs, we support a doubling of the overall NIH budget by year 2003. We recommend an fiscal year 2001 appropriation of $20.5 billion for the NIH, the third step toward that goal. We have a special interest in individual NIH entities that relate directly to our mission. Our funding recommendations for these institutes and programs follow.

HEART RESEARCH CHALLENGES AND OPPORTUNITIES FOR NHLBI

The above and other advances have been made possible by more than 50 years of American Heart Association-sponsored research and more than a half-century of investment by Congress in the National Heart, Lung, and Blood Institute. Thanks to research, no longer does a heart attack or stroke necessarily mean immediate death. Now that more Americans are surviving, heart attack and stroke can mean permanent disability, requiring costly medical care and loss of productivity and quality of life.

We urge this Committee to double the NHLBI budget, including heart research, by year 2003. As the next step toward reaching this goal, we advocate an fiscal year 2001 appropriation of $2.330 billion for the NHLBI, with $1.355 billion for heart and stroke-related research. A funding level of this amount will allow NHLBI to expand existing programs and invest in promising new initiatives. Several challenges and opportunities to advance the battle against heart disease are highlighted below.

—*Promoting Adherence to Medical and Behavioral Therapies*.—Failure to follow medical recommendations causes tens of thousands of deaths a year, increased hospitalizations and delayed recovery, costing Americans $100 billion annually. An estimated 50 percent of patients do not comply with prescribed treatments. Many life-extending drugs for heart attack survivors and heart failure patients are underused. Medical advances are continually improving chances of survival for Americans who suffer from or are at high risk of heart attack, stroke and other cardiovascular diseases. Not all patients or doctors take advantage of information we now know will reduce or treat Americans at risk of heart disease or stroke. Innovative theories about behavioral, cultural, social, psychological, and environmental methods to increase adherence to lifestyle and medical regimens must be tested. Research is needed on effective indicators to measure

standard of delivery of care of health systems and to change physician behavior and practices. Increased funding in this area will lead to development of better methods for getting patients and healthcare providers to adhere to cost-effective, lifesaving therapies.

—*Immune System Research Programs for Heart Disease*.—Basic knowledge about the body's disease fighting system is increasing rapidly, particularly in its involvement in the causes and development of heart disease and stroke. Innovative approaches are needed to use this knowledge to accelerate progress from basic knowledge to clinical applications. Promising areas that merit further research include, inflammatory response to blood vessel injury that occurs in atherosclerosis (the cause of most heart attacks and strokes); healing of damaged heart tissues after a heart attack; and chronic rejection following heart transplantation. Increased funding in this area would better identify those at risk and may lead to revolutionary treatments to prevent heart disease and stroke.

—*Maintaining Weight Loss*.—An estimated 106 million Americans age 20 and older are overweight or obese, a condition that increases risk of diseases such as heart attack, stroke, high blood pressure and diabetes. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, supported by NHLBI and National Institute of Diabetes and Digestive and Kidney Diseases, reviews evidence that it is possible for overweight and obese Americans to lose a large amount of weight over six months, but only a few maintain it. Increased funding is needed to start studies to improve understanding of weight loss maintenance. Researchers must examine behaviors that influence obesity, weight loss and weight loss maintenance.

—*Heart attack, stroke and other cardiovascular diseases in women*.—Cardiovascular diseases remain a main cause of disability and the No. 1 killer of American females, killing more than 500,000 a year. Cardiovascular diseases kill more females than the next 14 causes of death combined. They kill more females than males. About 1 in 5 females live with consequences of cardiovascular diseases. The clinical course of cardiovascular disease is different in women than in men and current diagnostic capabilities are less accurate in women than in men. Once a woman develops a cardiovascular disease, she is more likely than a man to have continuing health problems and is more likely to die from it. Despite the seriousness of these diseases, they are largely unrecognized by both women and their doctors. Additional funding is needed to allow NHLBI to expand research on cardiovascular diseases in women and to create more informational and educational programs for female patients and health care providers on cardiovascular diseases risk factors as authorized under Public Law 105–340, the Women's Health Research and Prevention Amendments of 1998.

STROKE RESEARCH CHALLENGES AND OPPORTUNITIES FOR NINDS

Stroke is a major cause of disability and America's No. 3 killer. America's 4.4 million stroke survivors often face debilitating physical and mental impairment, emotional distress and overwhelming medical costs. An estimated 600,000 Americans will suffer a stroke this year. Considered a disease that strikes our grandparents, stroke also afflicts newborns, children and young adults. More Americans are dying from stroke than ever before.

We urge a doubling of the stroke research budget through the NINDS by year 2003. An fiscal year 2001 appropriation of $1.184 billion for NINDS, with $125 million for stroke research, the next step toward the goal, will allow the NINDS to expand studies and start new research to prevent stroke, protect the brain during stroke and enhance rehabilitation. Some challenges and opportunities follow.

—*Emerging Stroke Risk Factors*.—Many Americans are controlling major stroke risk factors, such as high blood pressure and smoking, yet the number of people falling victim to stroke continues to rise. With the growing number of strokes, scientists are defining new stroke risk factors, re-examining existing ones and reconsidering a long-held belief that no difference exists in risk between young and older patients with similar risk factors. Researchers are studying heart valve disease coupled with an irregular heartbeat; elevated white blood cell count that signals an infection leading to inflammation and clogging of arteries; long-term effects of previous high blood pressure; and high levels of C-reactive protein in blood that signals inflammation of blood vessels. Increased funding to study these areas may lead to new ways to prevent stroke.

—*Therapeutic Strategies for Stroke*.—Several major clinical trials investigating drugs and techniques have identified progressive methods for preventing and treating stroke in high risk populations. But, more drugs and procedures to pre-

vent strokes need to be developed and evaluated. Funding for new clinical studies are crucial for advancing additional cutting-edge stroke treatment and prevention.

—*Public and Professional Education for Stroke*.—T–PA is the first effective FDA-approved emergency treatment for clot-caused stroke. Yet, only 5 percent of those eligible for t–PA receive it. As a member of the Brain Attack Coalition, a group of national organizations committed to fighting stroke, we are working with NINDS to increase public awareness of stroke symptoms and appropriate emergency action. Together, we are sponsoring and distributing a televised PSA on this issue and striving to develop systems to make t–PA readily available to appropriate patients. When these systems are fully implemented, stroke treatment will change from supportive care to early brain-saving intervention. More funding is needed to educate the public about stroke symptoms and the need for prompt treatment and to assure appropriate community response systems are in place. More health professionals must be educated about t–PA and the need for rapid response.

—*Acute Stroke Treatment Centers*.—Rapid, early treatment must be available to stroke victims who arrive in the emergency department within the three-hour window of opportunity for t–PA. Funding to develop acute stroke treatment centers is key to rapid early treatment. These centers would provide 24-hour emergency transportation, emergency department physician and nurse, a neurologist or stroke specialist, access to a diagnostic neuroradiologist or stroke professional with experiencing in reading and interpreting brain images and a neurosurgeron for treatment of bleeding stroke and serious complications. The centers would provide an opportunity for new stroke treatments to be evaluated early when they could have the most beneficial effect.

RESEARCH IN OTHER NIH INSTITUTES BENEFIT HEART & STROKE

National Institute on Aging defines how the aging process contributes to cardiovascular diseases, a main disabler and No. 1 killer of older Americans. An fiscal year 2001 appropriation of $62 million for cardiovascular research will allow continuation of studies and expansion into promising areas.

National Institute of Diabetes and Digestive and Kidney Diseases studies help in reducing cardiovascular disease death and disability. We advocate an fiscal year 2001 appropriation of $1.313 billion for the NIDDK to advance research to help diabetics, 2/3 of whom die from heart disease or stroke.

National Institute of Nursing Research studies play a key role in promoting self-care and patient education. NINR research is critical to primary and secondary prevention of heart attack, stroke and other cardiovascular diseases. We advocate an fiscal year 2001 appropriation of $103 million for the NINR.

Animal research is critical for heart and stroke research. We support an fiscal year 2001 appropriation of $776.3 million for the National Center for Research Resources to help institutions and researchers get animals and provide humane care. Increased resources will fortify animal research, help correct deficiencies in research animal resources and strengthen Clinical Research Area Centers and Biomedical Technology and Infrastructure Areas.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ, the lead health care quality agency, acts as a "science partner" with public and private health care sectors in improving health care quality, reducing its costs and broadening access to essential services. AHRQ is an active participant in developing evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. We concur with the Friends of AHRQ's recommendation of an appropriation of $300 million for the AHRQ to improve health care quality, reduce medical errors and expand availability of health outcomes information.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The best way to protect the health of Americans and lessen the enormous financial burden of disease is through prevention. Your commitment cannot stop at the laboratory door. You must fund the work that brings research into the places where heart disease and stroke live—the towns and neighborhoods that populate America.

The CDC builds the bridge between what we learn in the lab and how we live in communities. CDC sets the pace on prevention. We recommend an fiscal year 2001 appropriation of $4.1 billion for CDC, with a doubling of the chronic disease prevention line for at total of $570 million.

As a result of the efforts of this Committee, since fiscal year 1998, CDC's Cardiovascular Health Program will cover 18 states. This initiative allows states to design/and or implement programs to meet local needs to prevent and control heart attack, stroke and other cardiovascular diseases. In 1997, CDC released a report outlining what the nation's priorities should be in chronic disease prevention. The report, Unrealized Prevention Opportunities: Reducing the Health and Economic Burden of Chronic Disease, said "strong chronic disease prevention programs should be in place in every state to target the leading causes of death and disability in our society —and their principal risk factors." Until the Appropriations Committee started a comprehensive Cardiovascular Health Program in fiscal year 1998, the CDC-administered Preventive Health and Health Services Block Grant was the only source of federal funding to states for targeting cardiovascular diseases, the No. 1 killer in every state.

We laud this Committee's creation and expansion of a state-based cardiovascular health program that will be in 18 states in fiscal year 2000. An fiscal year 2001 appropriation of $50 million for the Cardiovascular Health Program will allow CDC to expand it to 11 more states for a total of 29 states.

The WISEWOMAN Program uses CDC's National Breast and Cervical Cancer Early Detection Program to also screen uninsured and low-income women age 50 and older for heart disease and stroke risk factors. We commend this Committee for providing funding to expand the program to seven states. An appropriation of $20 million will allow CDC to support 20 states in WISEWOMAN.

The Preventive Health and Health Services Block Grant is a vital resource for states in addressing heart disease and stroke. It is critical in helping states with their role in preventing chronic diseases. We recommend an fiscal year 2001 appropriation of $210 million for the PHHSBG. We urge the Committee to address, as the Unrealized Prevention Opportunities document points out, the need to target risk factors. We support CDC's efforts to build:

—a comprehensive nutrition and physical activity program with an appropriation of $30 million;

—a national program to prevent tobacco use, including a public education campaign to reduce youth access to tobacco, through CDC's Office of Smoking and Health with an appropriation of $130 million; and

—a comprehensive school health education program with an appropriation of $25 million.

Coupled with a nationwide Cardiovascular Health Program, these initiatives will advance the fight against heart disease and stroke. We urge you to make cardiovascular health a national priority.

ACTION NEEDED

Significantly increasing resources for research and community intervention programs will allow this nation to continue making strides in the battle against heart attack, stroke and other cardiovascular diseases.

NATIONAL INSTITUTES OF HEALTH

MEDICAL RESEARCH

PREPARED STATEMENT OF THE ASSOCIATION OF WOMEN'S HEALTH, OBSTETRIC AND NEONATAL NURSES

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to comment on the fiscal year 2001 appropriations for nursing education, research, and workforce programs, as well as programs designed to improve maternal and child health. AWHONN is a membership organization of 22,000 nurses whose mission is to promote the health of women and newborns. AWHONN members are registered nurses, nurse practitioners, certified nurse midwives, and clinical nurse specialists who work in hospitals, physicians' offices, universities and community clinics across North America as well as in the Armed Forces around the world.

AWHONN appreciates the support that this Subcommittee has provided for nursing education, research and workforce programs, as well as maternal and child health programs in the past. We realize that there are many competing priorities for the Subcommittee members, and we appreciate your consistent support.

NATIONAL INSTITUTES OF HEALTH (NIH)

AWHONN joins many others in supporting a 15 percent increase for the National Institutes of Health in fiscal year 2001. With the leadership provided by this Subcommittee, Congress is well on its way to doubling NIH funding by 2003. In addition to the overall support, there are two specific funding recommendations that AWHONN recommends within NIH.

National Institute of Nursing Research

AWHONN encourages this Subcommittee to support the professional judgement budget request of $110 million for the National Institute of Nursing Research (NINR).

One of AWHONN's top priorities is a $20 million dollar increase in funding for the National Institute of Nursing Research (NINR). NINR engages in significant research affecting areas such as: research on health disparities in ethnic groups, training opportunities in genetic research and in health disparities, and studying telehealth interventions in rural/underserved populations. These research programs directly affect patients and families and contribute to decreased medical costs and increased quality of patient care.

In addition, NINR research improves outcomes for women and children. A report by the U.S. Agency for Health Care states that the most common reason for hospital admission in the United States is childbirth. This accounts for 3.8 million annual hospital admissions. This is a joyous event in most women's lives, but complications of pregnancy such as pre-term birth and low birthweight infants are some of the more expensive reasons for hospitalization. Nurse research has helped redesign care delivery models that optimize pregnancy outcomes and shorten hospital stays for vulnerable low birthweight babies.

For example, NINR-funded projects have contributed to breakthroughs in nursing that have improved infant health after hospital discharge for at-risk mothers and babies. One model utilized home follow-up assessment and care by an advanced practice nurse and showed decreased health system costs by shortening the length of stay of the infant and avoiding subsequent re-hospitalization.

Because of the emphasis on biomedical research in this country, there are few sources of funds for high-quality behavioral research for nursing other than NINR. It is critical that we increase funding in this area in an effort to improve the consumer's experience with the health care system, optimize patient outcomes and decrease the need for extended hospitalization.

National Institute of Child and Human Development (NICHD)

AWHONN supports the professional judgment budget, which includes an increase of $294 million, bringing the appropriation for NICHD to just over $1 billion.

NICHD seeks to ensure that every baby is born healthy, that women suffer no adverse consequences from pregnancy, and that all children have the opportunity to fulfill their potential for a healthy and productive life unhampered by disease or disability. With increased funding NICHD could expand its use of the NICHD Maternal-Fetal Medicine Network to study ways to reduce the incidence of low birth weight. Prematurity/low birthweight is the second leading cause of infant mortality in the United States and the leading cause of death among African American infants. AWHONN, like many organizations directly involved in initiates to improve the health of women and newborns, looks to NICHD to provide national initiatives, such as the Maternal-Fetal Medicine Network to assist with the care of pregnant women and babies.

On specific example of the important research that evolves from NICHD is research that led to the remarkable reduction in the rate of HIV transmission from mother to infant during pregnancy and birth. In fact, this past year, grantees focused on treatment that reduces the viral load during pregnancy finding that the risk of HIV transmission from mother to infant can be further reduced. Additionally, NICHD, in collaboration with NIAID, is now conducting studies to evaluate whether nevirapine, administered during the time a mother is breastfeeding can reduce the rate of HIV transmission through breast milk. The results of these studies and many others will lead to significant advances in ensuring that babies are born healthy, while decreasing maternal morbidity.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nurse Education Act (NEA)

AWHONN is requesting an increase of 15 percent over fiscal year 2000 to fund the NEA at approximately $78 million. Fiscal year 2000 funding for the NEA was $67.8 million.

The Nurse Education Act (Public Health Service Act Title VIII) helps schools of nursing and nursing students prepare to meet patient needs in a changing health care delivery system, favoring programs in institutions that train nurses for practice in medically underserved communities and Health Professional Shortage Areas. Reauthorized as the Nursing Workforce Development section in 1998, the new NEA gives the Department of Health and Human Services more discretion over the focus of federal spending, while keeping with previous goals. In addition, funds from the Nurse Education Act support projects that would increase educational opportunities for minority nurses who would then be able to provide culturally competent, linguistically appropriate health care services to underserved communities.

AWHONN supports the continued designation of funds for education and training of critically needed primary care providers—advanced practice nurses. These nurses—clinical nurse specialists, nurse practitioners and certified nurse-midwives—have historically provided a pool of qualified providers for underserved communities. Advanced practice nurses are providing services in communities where physician services are sometimes not even available. Due to the current demand for these services, and expected increases in demand, it is critical that the Division of Nursing, through the Health Resources Services Administration, is provided the funding to address the education and training needs of this essential pool of providers.

While many advance practice nurses are providing greatly needed services in critical areas, the nursing community is facing shortages in nurses with the competence, skills and experience to meet the demands for complex patient care. With greater frequency we are receiving calls from our members reporting gaps in staffing resulting from fewer and fewer available professional registered nurses. We understand that at this time the nursing shortage is regional in nature, but the entire nursing community is anticipating a significant professional nurse shortage to peak around 2010. With the increasing technical complexity of the health care system, it is critical that a pool of highly skilled and experienced professional nurses be available to safeguard the health of our nation. We anticipate that the aging baby boomer generation will require more health care resources in 2010 at the time when there will be a historic low in nurse supply. While we wait for the results of the most recent nurse sample survey to confirm these concerns, AWHONN believes it is critical that Congress act to ensure the continued supply of professional nurses in our nation.

Maternal and Child Health Block Grant

Because of the increasing demands for the services provided through this block grant, AWHONN recommends a substantial increase for the Maternal Child Health Block Grant to $800 million for fiscal year 2001.

This program provides comprehensive, preventive care for mothers and young children, as well as an array of coordinated services for children with special needs. MCH programs are facing increased demands for services due to continued growth in the Children's Health Insurance Program, which in turn identifies more children who are eligible for other MCH Services. Title V complements Medicaid and the State Children's Health Insurance Program by providing "wrap-around" services and enhanced access to care in underserved areas.

Additional funding would give states the resources they need to expand prenatal and infancy home visitation programs, an approach that has been shown to improve the prenatal health-related behavior of women and reduce rates of child abuse and neglect as well as maternal welfare dependence. Postpartum home visits can also increase the percentage of mothers who choose to breastfeed. Many new mothers can get frustrated and stop breastfeeding in the first few days; a visit from a qualified health care provider can greatly encourage women to continue breastfeeding. This can also positively impact the goals of the Healthy People 2010 initiative to raise the rate of initiation of breastfeeding to 75 percent and the six-month rate of breastfeeding to 50 percent.

CENTERS FOR DISEASE CONTROL AND PREVENTION—FOLIC ACID AWARENESS

AWHONN recommends an increase to $20 million in the fiscal year 2001 appropriation to enable CDC to effectively promote folic acid awareness.

For over 30 years, the Centers for Disease Control and Prevention (CDC) has been deeply involved in the prevention of birth defects. The public health impact of birth defects is tremendous. Of the four million babies born each year in the United States, approximately 150,000 are born with a serious birth defect. According to CDC, the lifetime costs of caring for infants born in 1992, with at least one birth

defect [1] or cerebral palsy was about $8 billion. The emotional and financial burden for the families with affected children is devastating.

The first steps in preventing birth defects includes surveillance, to find out what types of birth defects are occurring, how often and where, and research into the causes of birth defects. The ultimate goal of surveillance and research is to develop and implement strategies to prevent birth defects. An example of such a prevention activity is the current folic acid education campaign to prevent neural tube defects (NTDs). Each year in the United States, an estimated 2,500 babies are born with NTDs, birth defects of the brain and spinal cord, such as anencephaly and spina bifida. These NTDs are among the most serious, costly and preventable birth defects. The lifetime cost of each case of spina bifida in 1992 was estimated to be nearly $300,000. Yet, up to 70 percent of NTDs can be prevented if all women of childbearing age consume 400 micrograms of folic acid daily, beginning before pregnancy.

In an effort to spread this information, AWHONN is working closely with the CDC, March of Dimes, and more than 40 public and private organizations, to coordinate a national educational campaign through the National Council on Folic Acid. Last year Congress increased funding for CDC's efforts in support of the folic acid campaign from $1.5 to $2 million. However, current funding is woefully inadequate. We respectfully request that you provide the CDC $20 million in funding to prevent these serious birth defects.

Thank you for the opportunity to submit testimony on these critical areas of funding.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM), representing over 42,000 researchers and clinicians, recognizes with appreciation Congress' historically strong support of medical research funded by the National Institutes of Health (NIH), which is critical to improving the health and well-being of all Americans. The ASM particularly commends the leadership of Senators Specter and Harkin and the members of the Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies for providing a $17.8 billion appropriation for NIH in fiscal year 2000. This investment in basic and clinical research will lead to further advances in disease diagnosis, treatment and prevention.

As an organization knowledgeable about public health threats, the ASM recommends that Congress increase the proposed fiscal year 2001 budget request for NIH to provide additional resources for basic and clinical research to address an increasingly complex set of scientific and medical challenges. The ASM endorses a $2.7 billion increase (15 percent) which would bring the NIH budget to $20.5 billion in fiscal year 2001. During the past two years, Congress has increased the NIH budget by 15 percent each year, steps toward the goal of doubling the NIH budget by 2003 [1].

One of the NIH's highest priorities is the funding of medical research through research project grants, which generate new scientific knowledge and opportunities. Under the proposed fiscal year 2001 budget, the NIH estimates that it would support 7,641 new and competing grants, a disturbing 1300 fewer grants than awarded in the current fiscal year. In addition, noncompeting and competing grants would be allowed only a 2 and 2.1 percent inflation increase, respectively, well below the 3 percent normally allowed and certainly well below general inflation rates.

PUBLIC HEALTH NEEDS

There is no doubt that public health has benefited, not only in the United States but around the world, from bipartisan support for scientific research. The U.S. public expects and deserves, real advances in medicine and science. Through research funding, the NIH consistently contributes to our national health and to a real return on the public's financial investment. Advances from NIH supported research in the past year alone include the identification of a gene in salmonella bacteria linked to pathogenicity and present in many other disease-causing bacteria, suggesting innovative approaches to antibiotics and vaccines. NIH supported scientists also dem-

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[1] These birth defects include: Spina bifida, truncus arteriosus, single ventricle, transposition/double outlet right ventricle, Tetralogy of Fallot, tracheo-esophageal fistula, colorectal atresia, cleft lip or palate, atresia/stenosis of small intestine, renal agenesis, urinary obstruction, lower-limb reduction, upper-limb reduction, omphalocele, gastroschisis, Down syndrome, and diaphragmatic hernia.

[1] The ASM is a member of the Ad Hoc Group for Medical Research Funding and endorses the Ad Hoc Group's recommendation for NIH funding for fiscal year 2001.

onstrated that an inexpensive and simple treatment regimen with the antiretroviral drug nevirapine can reduce transmission of the HIV virus from mother to infant. These and other impressive successes must continue in the fight against infectious and chronic diseases and other threats to public health.

Infectious diseases remain the third largest cause of death in the United States, and a number one killer worldwide. Globally, acute respiratory infection is the leading infectious killer, responsible for 3.5 million deaths in 1998. Pneumonia and influenza are the leading infectious killers in the United States, ranked 5th in preliminary data for 1998. In an age of medical miracles, stubborn infectious diseases such as malaria persist, new infectious diseases such as hantavirus are emerging and old infectious diseases such as tuberculosis (TB) are reemerging. One-third of the world's population has latent TB and multi-drug resistant TB cases have been reported from 45 states over a 5 year period. The disease is the 8th leading cause of death worldwide, and on the rise in this country. Another "old" disease, malaria, is undergoing a global resurgence, with 275 million cases annually resulting in an estimated 1.1 million deaths. In the United States, an estimated 271,000 people are living with HIV infection, while the hepatitis C virus (a cause of cirrhosis and liver cancer) has infected almost 4 million and kills about 9,000 annually. In the United States, the rate of new HIV/AIDS infections is 40,000 per year, and over 420,000 people with AIDS have died as of June 20, 1999. The HIV/AIDS epidemic will soon become the worst epidemic of infectious diseases in recorded history, with over 16 million people estimated to have already died from AIDS at the end of 1999 and 33.6 million living with HIV/AIDS worldwide. Vaccines against both viruses are desperately needed.

As a nation, global health should be a high priority, for humanitarian reasons and because of our own vulnerability. For example, over 60 cases of West Nile virus encephalitis were detected in New York last year, the first documented cases in the Western Hemisphere of a virus restricted to Africa, West Asia and the Middle East.

Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID), has responded aggressively and effectively to microbial threats. The NIAID is the third largest component of the NIH due to the emergence of HIV/AIDS in the early 1980s and the realization that infectious diseases will continue to emerge unpredictably and at times explosively. It is clear that despite the defeat of diseases like smallpox, the dangers of infectious diseases are far from eliminated. One of the most significant threats to public health continues unabated, namely our inability to treat some infectious diseases because of antibiotic resistance. Antibiotic resistance is emerging for almost one-third of hospital acquired pathogens, as well as for many community acquired pathogens. Newly discovered pathogens, reemerging more virulent pathogens, with their sobering potential as bioterrorist weapons, mean that our struggle against infectious diseases is far from over and must be intensified.

The ASM recommends that NIH funding be increased to expand support for research to unlock the basic mechanisms of disease, for antimicrobial resistance, vaccine research, the infectious etiology of chronic diseases, emerging infectious diseases, hepatitis C, Lyme disease, opportunistic infections including tuberculosis, AIDS-related research, and microbial gene sequencing research. This intimidating list of microbial targets represents some of the most serious threats to public health, but also offers exciting possibilities for scientific advancement.

SCIENTIFIC PROGRESS AND OPPORTUNITIES

As we enter the 21st century, scientific opportunities are greater than ever, thanks to historic advances in basic and clinical research over recent years. These opportunities promise future benefits through new knowledge, new treatments, and new prevention strategies. We have witnessed the power of basic research to enhance public health manifested, for example, as effective hepatitis B vaccines or the development of rapid diagnostic tests for specific pathogenic microorganisms. We enter the century with new research capabilities, with more sophisticated laboratory tools and with a scientific workforce that is increasingly interdisciplinary in its attitudes and abilities.

Remarkable opportunities await researchers as a result of DNA and computer technologies developed in the latter part of the 20th century. ASM concurs with the NIAID's strategic plan statement that "DNA technologies are profoundly altering the health research landscape . . . [and] revolutionizing approaches to understanding pathogenesis, microbial physiology, and epidemiology of infectious diseases; radically advancing the understanding of immune activation and regulation; uncovering the genetic bases of disease susceptibility; and accelerating the development of new diagnostic, treatment and intervention strategies." This suggests stunning

returns on public investment in basic research through the NIH. Add to these possibilities those provided by computer modeling, robotics and x-ray crystallography, and our future defenses against infectious diseases will likely look quite different than those of the past century.

NATURE OF AND REQUIREMENTS OF TODAY'S RESEARCH

New technologies will be a trademark of research in the 21st century, but they will not be the only agent of change reshaping our scientific approach to fighting both old and new diseases. The NIH will support the skilled personnel and the knowledge base necessary to adapt to these changes.

Much of the research landscape has changed over the past century, and will continue to change. Undoubtedly, scientific research will become even more expensive. Our increasing dependence on highly sophisticated technologies, such as advanced computers, functional imaging, and gene chips, increases the cost of doing research. The growing use of genetically modified animals and more elaborate animal facilities adds significant cost, as does the obvious need for more clinical research and clinicians participating in multi-institution studies. Scientific advances are cumulative and research is a multi-year process that may not produce a satisfactory product for a long period of time. Long-term funding for research and its underpinning infrastructure remains a necessary part of assuring scientific and medical advances.

Among the factors reshaping how we will do research is the absolute necessity for burgeoning data bases, innovative computer usage, and information sharing within highly complex research projects. The NIH is responding to this new world of information with informatics projects, input from the National Library of Medicine, and interdisciplinary efforts in the fields of biology, computer science, and mathematics. In fiscal year 2001, the NIH plans to provide the infrastructure to train the next generation of interdisciplinary scientists, to develop new means for storing, managing, and accessing vast data collections, and to enhance basic research in biomedical computing. To accomplish these new approaches to research, resources must be sufficient to train scientists in interdisciplinary fields and to encourage cooperative efforts among specialists.

Research in the 21st century must also adapt to significant changes in patient populations. Since the beginning of 20th century, life expectancy at birth in the United States has increased from fewer than 50 years to more than 76 years. As a result, future research will focus more than ever on enhancing the quality of human life. By the middle of this new century, the number of Americans over 65 will more than double and the number over age 85 will increase five-fold, making diseases of the aged a higher priority for researchers. An example is our growing awareness that microorganisms play more of a role in chronic disease than previously thought, an area now being investigated by the NIH. A virus has been found in spinal cords of victims of the neuromuscular disease known as Lou Gehrig's disease. Other chronic diseases with a possible microbial etiology include peptic ulcers, arthritis, cardiovascular disease, conditions affecting the lungs, and some types of cancer.

Women and minorities in the United States and around the world also bear a disproportionate burden of many infectious diseases, including AIDS, sexually transmitted disease, auto immune diseases and end stage renal disease. The NIH supports research to improve the health status of patients affiliated with these diseases.

ECONOMIC BENEFITS

Triumph over diseases that assault human health is not the only reward from research. The financial benefits of research are significant, through both economic stimulus and cost-savings. Approximately 82 percent of the funds appropriated to the NIH flows into research labs across the nation, supporting the work of more than 50,000 researchers affiliated with some 2,000 hospitals, universities, and other research institutions. Federally supported research offers obvious benefits to the biotechnology and pharmaceutical industries, which utilize discoveries from basic research and in return receive increased revenues and a steady input of opportunities for new-product development. In 1999, more than 153,000 highly skilled workers were employed by U.S. biotech companies, generating an impressive $19 billion in annual revenues.

The American public, however, is the greatest recipient of scientific and medical advances. Surveys consistently show that citizens support increased funding for medical research, in recognition of the importance of public health and of research as the foundation underlying success against disease. Through efforts by the NIAID there are clear examples of direct benefits from basic research: the identification of

infectious agents for several human diseases, including Lyme disease, bronchopneumonia, hemorrhagic fevers, and diarrheal illness; and the genomic sequencing of the cause of syphilis, Treponema palllidum, and of E. coli strain K 12 and Chlamydia trachomatis, of a chromosome of the malaria parasite Plasmodium falciparum, and of Mycobacterium tuberculosis. As a result of these laboratory discoveries, we will develop more specific and more effective diagnostic, treatment and prevention strategies. The dividends from public investment in a vigorous and well-funded research enterprise are not merely hypothetical, but very real improvements in public health and the national economy.

The ASM appreciates the opportunity to submit written testimony to support increased funding for the NIH in fiscal year 2001 appropriation.

PREPARED STATEMENT OF TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Mr. Chairman, thank you for the opportunity to submit this testimony for the record on a subject of utmost importance to diabetic patients in Texas and the nation. Texas Tech University Health Sciences Center (TTUHSC), in response to the prevalence of diabetes among the Hispanic and elderly populations that it serves, is proposing to establish a Center for Diabetes Prevention and Control for which TTUHSC is seeking $6.3 million over three years. This center will engage in a wide array of diabetes prevention and control activities including:

—Development and operation of easily accessible diabetes eye care outreach, assessment, and treatment centers;

—Perform clinical investigations of the predisposition to infection among diabetics, especially diabetic Hispanics; and,

—Conduct in-depth surveys that focus on Hispanics and the elderly residents of rural areas to identify persons with undiagnosed and untreated diabetes and to track the incidence, prevalence, and treatment of diabetes among the general populations;

—Examine the use of telemedicine and other technologies as a means of delivering diabetes education, consultation, and care to patients in remote communities and rural areas.

Mr. Chairman, diabetes is one of the most physically and financially debilitating preventable diseases facing our nation. The number of people diagnosed with diabetes continues to increase, especially among Hispanics and the elderly in regions like West Texas. It is for these reasons that the Texas Tech University Health Sciences Center (TTUHSC) seeks funding to support its diabetes efforts and to assist the Health Sciences Center in enhancing its diabetes expertise and facilities.

Today, an estimated 865,347 adults in Texas have diagnosed diabetes and for every recognized diabetic there is at least one case where the disease has not been diagnosed. The situation may be starker still for West Texas because diabetes occurs more often in the elderly and among Hispanics—two groups prominent in the region's population. As in the nation, Hispanics in Texas are two to four times more likely to have diabetes than are members of the non-Hispanic Caucasian population. It is estimated that approximately 22 percent of elderly Hispanics suffer from the disease. Hispanics are already the second largest and are also the fastest growing minority group in the United States. In 1993 there were 27 million Hispanics in the United States, representing 10 percent of the population. By 2050 Hispanics will constitute 21 percent of the U.S. population. In light of this demographic trend, the following statistics on diabetes among Hispanics are indeed ominous. About 5 percent of Hispanic Americans between the ages of 20 and 44 years, and 20 percent of those between the ages of 45 and 74 years have diabetes. These data translate to 1.8 million Hispanic adults with diabetes. About half of those have been diagnosed, but the other half remains undiagnosed and untreated.

The Texas Diabetes Council estimates that 35 percent of the diagnosed diabetics in Texas are Hispanic. Studies conducted in Texas, New Mexico and in Mexico show that the risk of having diabetes in adult Hispanic men and women is 13 to 25 percent, compared to 3 to 8 percent in Anglo adults.

The problem of diabetes in the Hispanic population is aggravated by a variety of financial and non-financial barriers that limit access to modern health care and health information. When limited access delays diagnosis and treatment of diabetes, irreversible complications involving the visual, renal, cardiovascular, and nervous systems are more likely to develop. When education on ways to manage diabetes is unavailable, the disease is much more likely to progress and to result in needless, preventable exacerbation.

The total economic impact of diabetes in 1997 was estimated to be $98 billion. That includes $44.1 billion in direct medical and treatment costs and $54 billion in indirect costs attributed to disability and mortality.

The overall annual cost of diabetes in Texas is approximately $4 billion, $1.6 billion in direct costs and $2.4 billion in indirect costs, largely from long-term disability. The shortage of health professionals in West Texas compounds the problem by limiting the number of people who can screen for the disease and provide proper care, appropriate nutrition education, and other self-management instruction.

Additionally, diabetes is the leading cause of blindness, kidney failure, and amputations as well as a leading cause of heart disease, stroke, birth defects, premature death, and disability. The diabetics' risk of renal disease, ocular disorders, and gangrene is 17 to 50 times greater than that of the general population. Cardiovascular complications among diabetics occur twice as often as they do among non-diabetics. A higher incidence of complications from diabetes, including: nephropathy, retinopathy, and peripheral vascular disease, has been documented among Hispanics.

Kidney failure is one of the most devastating consequence of diabetes—half of the nation's cases of End Stage Renal Disease (ESRD) are caused by diabetes. Annual Medicare costs from ESRD total $15 billion. In West Texas, it is estimated that nearly 70 percent of all ESRD is caused by diabetes. The extraordinarily high prevalence of diabetes-related ESRD in TTUHSC's catchment area is due in part to its large Hispanic and Native American populations, groups having the highest rates of diabetes in the United States. Preventing diabetes-related ESRD has the potential for saving billions of dollars in Medicare costs annually.

The risk of renal disease, ocular disorders, and gangrene in diabetics are, respectively, 17, 25, and 50 times that of the general population. The risk of cardiovascular complications is twice that seen in non-diabetic subjects. The overall annual cost of diabetes in Texas is approximately $4 billion, $1.6 billion in direct costs and $2.4 billion in indirect costs, largely from long-term disability.

The proposed TTUHSC Center for Diabetes Prevention and Control will include the following components:

Diabetic Eye Care Assessment and Treatment Center

Because diabetes is the leading cause of blindness, an Eye Care Assessment and Treatment Center can provide greatly needed evaluation and treatment for all types of diabetic retinopathy, particularly those that respond to laser surgery. Comprehensive eye examinations utilizing digital retina photography detect diabetic retinopathy, photography coupled with angiography quantifies disease severity, and state-of-the-art eye lasers provide sight-preserving treatment. Using public outreach to emphasize the need for regular screenings—even when visual loss is not apparent—centers in both El Paso and Lubbock will help fill the need for quality eye care among the West Texans most prone to diabetes—Hispanics and the elderly.

Population-Based Diabetes Survey

Although estimates can be derived from national surveys, hard data are not available on either the disease's prevalence or the quality of care provided to rural and Hispanic diabetics. Research by TTUHSC faculty suggests that Hispanics and rural elderly are much less likely to receive appropriate medical care than non-Hispanics. The proposed survey would provide precise estimates of the prevalence of diabetes in a region with substantial numbers of rural and Hispanic residents as well as information on ethnic differences in the continuity and quality of medical care afforded diabetics. To derive estimates of the prevalence, along with the additional needed information, a base sample of approximately 6,600 completed surveys will be obtained.

Diabetes Clinical Research Center

Cardiovascular disease (CVD) is the nation's leading cause of death and diabetics have a higher incidence of CVD than do non-diabetics. Because TTUHSC serves a region with particularly high rates of diabetes, CVD is very prevalent among its patients. By establishing a Diabetes Clinical Research Center, TTUHSC can better identify diabetics at increased risk for CVD. Center investigations can also help predict the specific form of CVD to which these patients are most prone—heart attack, heart failure, stroke, disease of blood vessels in the legs and arms, or kidney failure. Armed with this knowledge, physicians can customize their patients' disease management.

Research Project: Diabetes Mellitus and Infections

Diabetics are particularly prone to infection, perhaps because of the effects of high glucose levels and other diabetes-related changes on the white blood cells that de-

fend the body against infection-causing organisms. However, definitive evidence on possible diabetes-linked changes in the function of these blood cells is lacking.

This project will evaluate white blood cell activity in Hispanic diabetics. Cells will be examined for possible causes of any changes in their protective function. If compromised cellular function can be documented, then clinical trials of medications that inhibit white cell damage would follow. Prevention of infection and related complications of diabetes would represent a clinical "cure" of the disease.

Diabetes Education Telemedicine Project

A two-year demonstration project will evaluate the medical efficacy and economic feasibility of telemedicine as a means to deliver diabetes education to underserved diabetics, particularly Hispanic and elderly residents of remote, rural West Texas counties. Over a network linking rural health facilities with TTUHSC-El Paso, a bilingual Certified Diabetes Educator (CDE) will serve diabetics and their family members who cannot access effective education on diabetes management.

The CDE will implement and manage the project in four rural communities. The project will be evaluated to determine the medical efficacy and economic feasibility of providing diabetes education and related services to rural communities via telemedicine technology.

The funds requested for the proposed Center will allow TTUHSC to significantly enhance it faculty expertise and expand its diabetes prevention and control activities and facilities. TTUHSC has as its major objectives the provision of quality education and the development of academic, research, patient care, and community service programs to meet the health care needs West Texas. The 108 county region served by TTUHSC which comprise 50 percent of the state's land mass and 13.9 percent of the population of the total state. This 131,000 square mile service area that is home to 2.55 million people has been and remains highly underserved by health professionals and accessible health care facilities.

This initiative brings the clinical and scientific expertise of TTUHSC to bear on the provision of comprehensive, accessible and affordable diabetes outreach, education, prevention and care for the underserved and Hispanic and elderly populations of West Texas. The proposed Center will provide a national model of diabetes outreach, education, prevention and care. Because the region's Hispanic population tends not to be transient, the Center can track significant disease indicators and outcomes over a substantial period of time in a large Hispanic sample, data available nowhere else in the United States. Such data will be crucial for federal and state efforts to create prevention and care programs that reduce long-term health care costs and improve state and national health indicators. The Center's national relevance justifies TTUHSC's request for federal support.

Mr. Chairman, we here at Texas Tech Health Sciences Center look forward to working with you to successfully implement this initiative over the coming three years. We are seeking $6.3 million over three years for the complete implementation of this initiative.

Thank you for the opportunity to submit this testimony for the record.

PREPARED STATEMENT OF SANTA MARTA HOSPITAL

Thank you Mr. Chairman for the opportunity to submit this testimony for the written record on a very important initiative underway at Santa Marta Hospital in Los Angeles California, The Diabetes Education and Management Program. This initiative has been implemented in response to one of the most critical and expensive medical crises threatening our patients. This program will provide a national model for diabetes education, outreach and disease for underserved and highly at-risk populations, specifically, Hispanic Americans.

Santa Marta Hospital's three-year multi-site, Diabetes Education & Management Program will focus on the provision of diabetes education, outreach and health care services to an extremely at-risk, underserved and economically disadvantaged Hispanic population. Approximately 40 percent of the target population for the Diabetes Education and Management Program are uninsured, and live at or below the federally defined poverty line.

This initiative will address the urgent diabetic epidemic that is affecting the Hispanic population in Santa Marta's service area, the State of California and the nation. This innovative community-based program will use specially trained residents of the community to provide educational presentations, information and outreach to the residents of the hospital's service area. These "Health Promoters" who will themselves be graduates of the Diabetes Education program, will be trained to provide screening, educational presentations, preventative services and outreach for

primary medical care to residents of the neighborhood. The specific Objectives, Methods and Evaluation strategies that will be implemented as part of this initiative include:

Objectives

1. To train initially 20 (and ultimately 100 over the three year life of the demonstration) Community Health Promoters who will then provide diabetes education and medical services to at least 150 people in the East Los Angeles community annually, moving to 200 people in year three.
2. To develop 70 courses annually that will include educational presentations addressing stages of diabetes, symptoms, nutrition and treatment options, both in Spanish and English.
3. To provide low cost or no cost lab tests, medical care, and diabetes treatment to members of the East Los Angeles community.
4. To expand the scope of community outreach to include a much broader range of diabetes medical, educational and psychosocial services provided to poor people in East Los Angeles.

Methods/Strategies to be used to meet the program objectives

1. The program will be composed of both diabetes education classes and preventative and primary care medical services. The education component will focus on diabetes presentations addressing symptoms, nutrition, and treatment. Approximately 10 or 12, 12-week courses will be offered serving approximately 30 people per class (at least 200 people per year, by year three).
2. Primary care programs will include: regular medical check-ups and lab work, screenings for diabetes, referrals to specialized physicians, and referrals to psychosocial services. Lab work and medical family history will be obtained at the beginning and end of the 12-week program. Results will be compared and used as a performance evaluation tool for the Diabetes Education & Management Program.
3. Diabetes education and management courses will be taught first by trained hospital staff. Eventually, 20 community Diabetes Education & Management Program participants, diagnosed diabetics themselves, will receive 50 hours of training to become diabetes educators in order to increase the number of people providing screenings in the community. This will improve program effectiveness because this community responds positively to community based programs.
4. The community outreach program will continue to be supplemented by regular visits from Santa Marta's Mobile Health Care Delivery Van. This mobile clinic, staffed by doctors and nurses, will provide basic medical evaluations, testing, health education materials, and referrals to the Diabetes Education & Management Program.

Evaluation Strategies

1. Monthly, the project Clinical Director will review progress and present status reports to Santa Marta Hospital. The project Clinical Director's report will list the number of people benefiting from the education program, accomplishments, problems, corrective actions, and campaign status.
2. At the end of each 12-week course, participants will fill out evaluation forms assessing course effectiveness. The results will be compiled by the project Clinical Director quarterly and presented to the Hospital.
3. At the end of year one, the program will be thoroughly reviewed by the hospital President & CEO to determine program effectiveness, formulate recommendations, and make required changes to ensure its continued success. Their report will be shared with all interested parties, including donors and local health and social service agencies.

The Diabetes Education & Management Program will provide education, medical and psychosocial services to people living in East Los Angeles. The program includes: free educational classes, two free lab work visits per participant (one at the beginning of the 12-week course and one at the end to test compliance and program effectiveness), and low or no cost medical services for related health effects of diabetes.

Diabetes is known to be one of the most under identified causes of and contributions to death and that it disproportionately affects the Hispanic population. Additionally, it is widely recognized that the Hispanic population is three times more likely to have diabetes than other non-Hispanic populations. Today, there are approximately 15.7 million people or 5.9 percent of the population who have diabetes. While an estimated 10.3 million have been diagnosed, 5.4 million go undiagnosed. Hispanics represent 12 percent to 14 percent of all diabetes cases nation-wide. Additionally, it is estimated that approximately 22 percent of elderly Hispanics suffer from the diabetes. Hispanics are the second largest and fastest growing minority

group in the United States. In 1993, there were 27 million Hispanics in the United States, representing 10 percent of the population. By 2050 Hispanics will constitute 21 percent of the U.S. population.

Ninety-seven percent of the population surrounding Santa Marta Hospital is Hispanic.—The Hospital's census indicates that 66 percent of its patient population suffers from undiagnosed and diagnosed diabetes, and there are alarmingly high statistics for those who suffer from complications such as gangrene, kidney failure, heart disease and blindness. Of that number the Hospital estimates that it can target at least 2,440—2,840 with its Diabetes Education and Management Program.

Located within an inner-city neighborhood plagued by poverty, gang violence and drugs, Santa Marta Hospital is a sanctuary of hope for the 19,000 people who walk through its doors each year as well as the 955,000 who reside in its service area. Ninety percent of Santa Marta's patients rely on Medicare and MediCal programs to access health care services. The remainder can pay only a small portion of their hospital expenses or rely on Santa Marta's charity care. Given the poverty of its patients, the hospital depends on the partnership of corporations, foundations and individual donors to fund the cost of new medical programs and necessary major capital expenditures.

The per capita cost per diabetic admission to hospitals in California is $8,600. This does not include non-hospital-based dialysis and other medical supply costs; lost work time; or other societal effects. The cost of doing nothing is $4,472,000 (520 people × $8,600), and these costs are generally supported by Medicare and MediCal (Medicaid) reimbursement. Santa Marta's proposed program will save Medicare/MediCal programs in California alone $2,400,000.

Given the financial ability of the affected population and the high expense of diabetes, Santa Marta Hospital is seeking $2 million in fiscal year 2001 for the full implementation of this needed community based prevention, education and management initiative.

Poverty, gang violence, drug dealing, alcohol abuse, rampant teen-age pregnancy and an exceptionally high school dropout rate are just some of the harsh realities impacting the seven-mile area surrounding Santa Marta Hospital. There are over 9,000 hardcore gang members and 58 established gangs who shadow the community with a constant threat of violence. As the only Catholic Hospital in an overwhelmingly Catholic population, Santa Marta provides a sense of sanctuary where patients experience safety and care with dignity.

Founded in 1924, Santa Marta Hospital was originally a ten-bed maternity hospital. Today the hospital's maternity department delivers over 1,500 newborns each year, and coordinates Comprehensive Perinatal Service Programs for the almost 1,000 poor pregnant women who walk through its doors annually. The hospital expanded in 1971, and grew into a 110-bed acute care facility offering medical services including: Radiology, Surgery, Labor and Delivery, Nuclear Medicine, Laboratory, Pharmacy, Cardiopulmonary, and Physical Therapy. In 1989, a 20,000 square foot, 24-hour Emergency Room Intensive/Coronary Care Unit (ICU/CCU) transformed the hospital into a complete comprehensive medical facility.

The hospital prides itself on offering several critical programs that impact the health of the larger community. Santa Marta is a place of hope and service in their community. They know that the hospital doors are open, and that no one is ever turned away or refused care on the basis of race, religion, gender, sexual orientation, age, national origin, disability, or ability to pay.

Enhancing its broad range of hospital services, Santa Marta coordinates the structure for Pediatric, Family Care, and Obstetrical Clinics to assist overall outpatient health care. "Health Fairs" and "Health Seminars for Seniors," reinforce the hospital's outreach to the medically indigent with an emphasis on preventative care. Additionally, the hospital coordinates a highly successful program for "at-risk" youth that has the collaboration of local area schools, social service agencies, juvenile authorities, and youth/adult employment programs. The program introduces teens to a professional environment where they can explore positive, future-oriented alternatives to the world of drugs and gang violence. Each year over 250 at-risk residents of the community work more than 9,600 hours and are exposed to positive role models, while gaining the self-esteem resulting from helping others in need.

In the fiscal year ending June 1999, Santa Marta Hospital treated over 19,000 patients and wrote off more than $11 million in fee reductions, and more than $2.1 million in charity care. The hospital also spent nearly $900,000 in community service programs. Nearly 90 percent of Santa Marta's patients are government reimbursed cases (45 percent Medicare and 45 percent Medi-Cal). And due to extreme hardship, the remainder are treated for a very low fee or at no charge.

Santa Marta understands well that patient education is critical. People with diabetes can reduce their risk for complications if they are educated about their dis-

ease, learn and practice the skills necessary to better control their blood glucose levels, and receive regular checkups from their health care team. Santa Marta Hospital encourages its patients to work with them to set goals for better control of blood glucose levels, as close to the normal range as is possible for them. Health care education is vital.

Because people with diabetes have a multi-system chronic disease, they are best monitored and managed by highly skilled health care professionals trained with the latest information on diabetes to help ensure early detection and appropriate treatment of the serious complications of the disease. Santa Marta Hospital is proposing its Diabetes Prevention and Management as a team approach to treating and monitoring this disease in an extremely at-risk population.

Hospital statistics indicate that members of the East Los Angeles community are more likely than the national average to suffer, or be at risk of suffering from diabetes. In addition to genetic predisposition, many community members are obese, have poor nutrition, and do not practice strong preventative medicine. Consequences of untreated or unmanaged diabetes include blindness, amputations, kidney failure, high blood pressure and strained work, financial and family relations. Remember, there is no cure for diabetes.

This initiative, at its core a twelve week program of diabetes screening, education, and management program, will be culturally and linguistically sensitive order to address diabetes from a prevention perspective, preserving the health and financial resources of our patients, our hospital, and governmental health care programs.

Santa Marta estimates that the program cost to test, educate, and provide initial medical treatment to program participants will be between $1,000 and $1,500, depending upon the seriousness of pre-existing diabetes-related conditions. In 1997, the average cost of health care for people with diabetes nationally was $10,071, as opposed to $2,699 for individuals without the disease.

By learning to manage their diabetes, participants of Santa Marta's Diabetes Education & Management Program can potentially eliminate days missed from work due to diabetes, costly hospitalizations, and permanent disability from blindness, amputation, or kidney-failure. Given program compliance, the cost of the educational program would be recouped in health care savings within three months. Using 1997 health care cost data, the initiative could demonstrate $200 million savings over a twenty-five year span.

Thank you Mr. Chairman for the opportunity to submit this testimony. We look forward to working with you this year to secure $2 million in fiscal year 2001 to implement this very needed community based diabetes education and management program.

PREPARED STATEMENT OF THE UNIVERSITY OF MICHIGAN

Good afternoon. I am Gilbert Omenn, Executive Vice President for Medical Affairs of the University of Michigan and CEO of the University of Michigan Health System. I am an internist and a geneticist, as well as a former Associate Director of OSTP and of OMB.

I am submitting this testimony on behalf of a coalition of over 20 academic health centers across the nation to highlight several specific needs in the NIH budget. The recommendations which I will present have been endorsed in various parts by the Association of American Medical Colleges (AAMC) and the Federation of American Societies for Experimental Biology (FASEB).

I want to thank all the Members of this Subcommittee for your outstanding support of the National Institutes of Health. The funding increases you have provided over the past several years have had—and will continue to have—a significant impact on our nation's biomedical and behavioral research enterprise. We are hopeful, even confident, that the NIH budget will continue on the trajectory to double by fiscal year 2003. The remarkable scientific advances from recent decades have positioned our nation to exploit very responsibly what is certain to be a "golden era of biology" for benefits in medicine, public health, and the broader economy and society.

I seek your support for three specific items in the NIH budget that will enhance the extraordinary partnership between academic institutions and the federal government, representing the research community and the investing public:

—Increase extramural construction funding so that academic investigators supported on a project basis by NIH can have a greater probability of access to state-of-the-art facilities to carry out their highly valued biomedical and behavioral research.

—Adjust the salary cap to treat extramural researchers similarly to their colleagues in the intramural programs of NIH itself.
—Establish a peer-reviewed, flexible grant program for shared resources to meet evolving and transitional research needs at the institutional level, aligning the efforts of the institutions and not just the faculty in the research agenda of the NIH.

INCREASE FUNDING FOR FACILITIES: CONSTRUCTION, RENOVATION, AND EQUIPMENT

It is vitally important that we have the facilities and equipment to fully exploit research opportunities and utilize the increased project grant funding. Exciting developments in genomics, chemical biology, neurosciences, cancer, and many other fields require new kinds of equipment and facilities. Even the best minds cannot compensate for outdated equipment and facilities.

We thank you and your Senate colleagues for including $75 million in competitive funds for extramural construction in the fiscal year 2000 budget through the NIH National Center for Research Resources (NCRR).

The National Science Foundation (NSF) completed a study in 1998 on the status of scientific research facilities at U.S. colleges and universities. This analysis generated an estimate of $3.6 billion in deferred biomedical research construction and repair or renovation projects. In a March 1998 report, the Association of American Medical College (AAMC) stated that "The government should reestablish and fund an NIH construction authority, consistent with the general recommendations of the Wyngaarden Committee report of 1988, which projected at that time the need for a 10-year spending plan of $5 billion for new facilities and renovation." In June 1998, the Federation of American Societies of Experimental Biology (FASEB) reported that "Laboratories must be built and equipped for the science of the 21st Century. Infrastructure investments should include renovation of existing space as well as new construction, where appropriate."

Thus, there is a well-documented need for several billion dollars to rectify this situation as we ramp up the research project investments. Such funding must come from all possible sources, of which federal participation is a key element.

We urge the Subcommittee to provide a funding level of $250 million for extramural construction in fiscal year 2001. The funds would be awarded on a peer-reviewed, competitive basis and would require institutional matching funds to leverage these NIH resources.

RAISE THE SALARY CAP ON EXTRAMURAL SCIENTISTS

NIH and the academic community share a major concern about recruiting and retaining excellent clinician-investigators in biomedical and behavioral research. These physicians typically have considerable accumulated debt from their medical and post-graduate training, and they have an opportunity cost in choosing research careers. Medical schools increasingly expect them to earn their way through clinical service and by earning support for their research time by competing for federal grants. Both clinical practice and industrial research opportunities offer substantial higher incomes.

As these faculty move up the ranks and develop successful careers, they or their academic departments are penalized by a salary rate cap imposed back in 1991. Unfortunately and, I believe, unintentionally, Congress omitted a salary adjustment to account for inflation. Thus, the maximum salary rate (on a 100 percent basis, prorated for the proportion of time spent in funded research) was locked at $125,000 from 1991 through 1998. Of course, NIH pays only a portion of each faculty member's salary, so the rate is set at competitive levels at the institution and the vast majority are below the maximum.

Meanwhile, the NIH intramural program—through the Senior Biomedical Research Service (SBRS)—can pay senior investigators salaries up to $157,000 a year. This amount is roughly equal to what the salary cap on academic researchers would be if it had been indexed for inflationary increases over the past decade.

Congress has wisely moved, step-by-step, toward achieving equivalent maximal salary rates for the extramural program. Starting with fiscal year 1999, as you know, Congress established the principle of increasing the cap by linking the salaries to the Senior Executive Pay Scale of the Senior Biomedical Research Service, at Level III in fiscal year 1999 and level II ($141,300 per year) in fiscal year 2000. This process can be completed this year by setting the maximum for senior investigators at Level I.

In sum, in order to retain the most talented academic researchers in biomedical and behavioral research, especially clinician-investigators, and in order to assure equity between intramural and extramural scientists, we seek your support in raising

the current salary maximum for extramural academic researchers to Executive Level I, or $157,000 per year.

ESTABLISH A FLEXIBLE INSTITUTIONAL RESEARCH FUND TO ENHANCE THE EFFICIENCY OF RESEARCH

Government, universities, and industry observers all have called for attention to various inefficiencies in the federal-academic partnership. The White House Office of Science and Technology Policy has held four hearings around the country, including the final hearing in New York City, at which I was a speaker, to draw attention to ways to strengthen the relationship between the federal government and universities for research.

As you know, during the past decade, financial pressures on the clinical enterprise of academic medical centers have intensified, particularly so since the implementation of the Balanced Budget Act of 1997, which was on a path to generate far deeper spending cuts than Congress intended in 1997 (partly redressed in 1999). It is increasingly difficult to generate institutional margins to underwrite research needs that are not covered well in the individual project grant mechanism.

We want to enhance the impact of NIH funding by being flexible enough to change with the science, accommodate and align ourselves with new national priorities, and make the most of the NIH and institutional investments in individuals throughout their careers. Glitches in funding cycles, changes in NIH policies and priorities, needs for research resources, and opportunities to mobilize research in new directions could be addressed better with a modest fund in the hands of the institutional leaders, based on competitive funding. Collaborative, interdisciplinary research initiatives can be stimulated much more effectively and accountably through a modest amount of flexible resources at a level above the individual investigators.

Thus, we propose that you provide funding for NIH to establish a "Flexible Institutional Support for Health Research" or "FISHR" program. Program resources would provide institutional support for the following priorities: to fund interdisciplinary, shared research resources; to assist postdoctoral fellows and beginning investigators to establish independent research projects; and to rapidly infuse short-term resources into investigations which offer tremendous promise for research progress.

We recommend that the NIH establish such a peer-reviewed, three-year grant program through the National Center for Research Resources. Grants could be in the range of $25,000 to $300,000 per year for Deans of medical, public health, nursing, dental, and pharmacy schools which qualify through having NIH project awards. Applications would provide general plans for needs anticipated to evolve. Awards would permit flexibility within the institution to determine spending priorities, within the categories approved (as proposed above). To assure accountability, we suggest two mechanisms: (1) a local internal review committee, comprised of NIH-supported investigators at the institution, to review specific proposed allocations, on a prospective basis; and (2) a retrospective review by NIH research program staff prior to approving eligibility to submit a competitive renewal application at the end of the grant award period.

We urge you to include $60 million in the fiscal year 2001 appropriation for NIH to initiate this Flexible Institutional Support for Health Research (FISHR) Program. Such annual funding would favorably modify the impact of the recent stresses experienced by research and academic institutions which threaten the efficiency of our national research enterprise.

CONCLUDING REMARKS

Mr. Chairman, the extramural research community applauds the bipartisan actions and commitments to increase funding for biomedical and behavioral research through the NIH. Based on polls conducted by Research!America, including polls in my state of Michigan, we know that the American public strongly supports these investments and has high expectations for payoff in new knowledge and medical and public health innovations. We also applaud the investments in related federal agencies, such as the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the National Science Foundation.

We are confident that the Congress and the NIH can enhance the impact of the project-based investments by taking the three additional steps we recommend: provide $250 million in fiscal year 2001 to upgrade extramural laboratory space and instrumentation; increase the maximal salary rate on NIH grants to Executive Level I so that extramural salaries can match the maximum for intramural scientists; and initiate a Program for Flexible Institutional Support for Health Research (FISHR). Each of these steps will increase the productivity and efficiency of

the academic/government partnership in biomedical and behavioral research and research training.

On behalf of academic health centers across the nation, I thank you for your attention to these needs and recommendations. Best wishes to each of you and to your families and staff members.

PREPARED STATEMENT OF THE AMERICAN PHYSIOLOGICAL SOCIETY

The American Physiological Society is pleased to have this opportunity to submit its views on fiscal year 2001 funding for the National Institutes of Health. The APS appreciates this Subcommittee's strong support for biomedical research, its dedicated efforts for many years, and in particular, the extraordinary efforts that yielded 15 percent funding increases over the past two years, placing the NIH on the path to a five-year doubling of its budget.

The American Physiological Society (APS) is a nonprofit scientific society that seeks to integrate life sciences research and education from the molecule to the whole organism. The APS was founded in 1887 and currently has more than 9,000 members. Our members conduct research and educate the next generation of physicians and scientists at colleges, universities, and medical schools throughout the U.S. Many of our members are also engaged in research activities in industry and government.

The APS is grateful for the $17.8 billion that Congress has provided for the NIH for fiscal year 2000. This is a time of abundant scientific opportunity. One emerging area of particular interest to the APS is the new field of physiological genomics. Thanks to the revolution in information technology, scientists have been able to accomplish large-scale genome sequencing, and some are already working on the analysis of these huge collections of data. With our growing ability to analyze this data and zero in on key genes, we find ourselves poised before a promising and challenging new era. As the editors of the new on-line and print journal Physiological Genomics observed in an editorial published on-line July 15, 1999, "[T]he enormous task of linking genes to function has now begun." The editors go on to explain that our current state of knowledge now permits us to trace biological processes from the first actions of genes within the nucleus of cells through cellular processes, the influence of specific genes upon the functions of tissues and organs and, ultimately, their impact on the workings of the whole organism. Conducting such studies on individual genes and gene combinations responsible for particular diseases will permit us to identify how the internal environment defined by our genetic makeup interacts with external influences to keep us healthy or make us sick. The promise of physiological genomics is that this knowledge will point the way to new therapies, diagnostic tools, and better overall health management.

The APS offers this as an example of how NIH-funded research is leading us toward a treasure trove of medically useful knowledge. The APS joins with the Federation of American Societies for Experimental Biology and the Ad Hoc Group for Medical Research Funding in urging Congress to provide a $2.7 billion or 15 percent increase in fiscal year 2001 as the third step toward doubling the NIH budget by fiscal year 2003.

PREPARED STATEMENT OF THE AMERICAN CHEMICAL SOCIETY

The American Chemical Society (ACS) would like to thank Chairman Arlen Specter and Senator Tom Harkin for the opportunity to submit testimony for the record on the Departments of Labor, Health and Human Services, and Education Appropriations bill for fiscal year 2001.

As you may know, ACS is a non-profit scientific and educational organization, chartered by Congress, representing 161,000 individual chemical scientists and engineers. The world's largest scientific society, ACS advances the chemical enterprise, increases public understanding of chemistry, and brings its expertise to bear on state and national matters. ACS firmly believes that no investment the government makes generates a higher rate of return for the economy than research and development (R&D). In fact, economic experts maintain that today's unprecedented economic growth would not have been realized but for the substantial research investments by the public and private sectors over the past few decades. Looking ahead, the American Chemical Society (ACS) is concerned that constant dollar declines in federal support for basic research over the past decade, particularly in the physical sciences, have weakened the roots of innovation in all fields and put future economic growth at risk. In order to sustain our technological leadership and living standards, increased funding for basic research should be a top priority for use of the non-So-

cial Security budget surpluses. As a framework for increasing R&D funding, ACS supports doubling federal spending on research within a decade, as well as balanced funding among different areas of science.

NATIONAL INSTITUTE OF HEALTH BUDGET RECOMMENDATIONS

ACS commends Congress and the administration for the 15-percent increase last year for the National Institutes of Health (NIH) and we support a comparable increase for fiscal year 2001. As the major supporter of biomedical research in the United States, NIH is the primary source of new biomedical discoveries that are leading to longer, healthier lives as well as reduced health-care costs due to prevention, early detection, and more cost-effective treatment of disease. An example of the enormous return on this investment is the recent decline in both the incidence of cancer and the mortality rate from it. In addition, NIH-supported research provides training for new scientists, stimulates technological advances in the pharmaceutical and biotechnology industries—both of which contribute positively to the balance of trade—and makes the United States a world leader in biomedical research.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

As the largest source of federal funding for basic research, NIH should leverage its investments in biomedical research by maintaining strong support for all areas of basic research critical for sustained advances in public health and quality of life. Strong support for chemistry and the other physical sciences that underlie or complement biomedical research must be maintained if cutting-edge biomedical discoveries are to continue. For this reason, ACS believes it is essential that the National Institute of General Medical Sciences (NIGMS) receive increases proportional to the other NIH institutes. NIGMS supports quality, non-disease specific basic research and training that underpins advances in other institutes. NIGMS plays a central role in generating basic knowledge across science disciplines, strengthening the roots of innovation in the biomedical community, and fostering tomorrow's breakthrough discoveries.

NATIONAL CENTER FOR RESEARCH RESOURCES

The National Center for Research Resources (NCRR) supports the state-of-the-art research infrastructure necessary to provide high-quality biomedical and behavioral research, including the expansion, remodeling, and construction of extramural research facilities. The Center facilitates the development of new technologies and techniques by which scientific inquiry can be undertaken. In addition, NCRR provides grants such as the Shared Instrumentation Grants program, which provides a cost-effective mechanism for groups of NIH-supported investigators to obtain commercially available, technologically sophisticated equipment costing more than $100,000. Through these contributions, NCRR offers the potential for revolutionary approaches to health-related research.

Strong and steady support for cutting-edge researchers that advances human health is absolutely essential to ensuring the large return investment made on NIH research over the past decade. Sustained growth in funding for NIH is needed to build upon past scientific achievements, address present medical needs, and anticipate future health challenges. Volatility and significant fluctuations in funding can be as harmful to the research enterprise as inadequate growth.

PREPARED STATEMENT OF THE NATIONAL MULTIPLE SCLEROSIS SOCIETY

Mr. Chairman and distinguished members of the subcommittee, we appreciate the opportunity to submit written testimony on behalf of the National Multiple Sclerosis Society. The Society is the world's largest private voluntary health agency devoted to the concerns of all those affected by MS. Throughout the Society's 53-year history, our number one priority has been research to understand MS and apply this knowledge to the development of new treatments and a cure. Cumulatively, the Society has expended over $260 million in research funds in the United States and abroad. Our current annual budget for research exceeds $20 million. This represents the largest privately funded program of basic, clinical, and applied research and training related to multiple sclerosis in the world.

MULTIPLE SCLEROSIS

MS is an often progressive, degenerative disease of the central nervous system, unpredictable in its course, and devastating in its effects. It can cause spasticity, tremor, abnormal fatigue, bladder and bowel dysfunction, visual problems and mo-

bility impairment. The disease usually is diagnosed between the ages of 20 and 40—but is life long. Many people with MS live thirty years or more with constant unpredictability and increasing disability. MS affects more than twice as many women as men, can result in loss of employment and loss of a place in society and the community. Recent studies sponsored by the MS Society show that the annual cost to each affected individual as a result of MS averages $34,000, and the total cost can exceed $2 million over an individual's lifetime. For all people with MS in the United States—some third of a million individuals—the annual cost is nearly $9 billion. Ending the devastating medical, personal and financial effects of this unpredictable disease is completely dependent upon the discovery of safe and effective treatments that halt progression of the disease and reverse its symptoms.

RECOMMENDATIONS FOR FUNDING

NIH plays the major role in maintaining our country's preeminence in biotechnology and provides worldwide leadership in health research and discovery. The National MS Society recognizes that new discoveries and breakthroughs could come from any area of biomedical research and could apply to the primary concern of our members: finding new treatments and eventually a cure for MS. Therefore we encourage Congress to focus on NIH as a whole and on agencies of particular relevance to our concern, knowing that a well-funded federal research enterprise will benefit all of us.

The National Multiple Sclerosis Society believes that in order to take advantage of current opportunities in biomedical and rehabilitation research, Congress must continue the trend of the last two budget cycles. A further 15 percent increase in NIH funding for fiscal year 2001 would bring us closer to doubling the NIH budget over the five-year period 1999–2003. In order to pursue cutting edge research, the Society recommends that this translate into a parallel 15 percent increase for the National Institute of Neurological Disorders and Stroke, the National Institute of Allergy and Infectious Diseases and the National Center for Medical and Rehabilitative Research, the primary institutes that conduct nearly all of the MS-related research undertaken by the Federal Government.

NEUROSCIENCE CENTER

The NIH budget proposal for fiscal year 2001 includes $73 million over two years for construction of a new National Neuroscience Center at NIH. The Center will bring together in one facility, with necessary new lab space, both basic and clinical intramural scientists from the many institutes involved in neuroscience in order to encourage their interaction and the translation of basic research findings. The Center will emphasize important cross cutting themes such as neurodegeneration, regeneration and repair of neurons, neurogenetics and pain research. Federal funding for the Center would increase the pace of discovery in all areas of neuroscience and help translate laboratory discoveries into new and effective treatments for patients. The proposed funding is included in NIH's Building and Facilities budget, and it is our understanding that it will not affect funding for research. The National MS Society recommends fully funding the proposed National Neuroscience Center at NIH.

STRATEGIC ANALYSIS OF MS RESEARCH

The National MS Society has commissioned the National Academy of Sciences/Institute of Medicine (NAS/IOM) to undertake a strategic analysis of basic and clinical research for multiple sclerosis. The NAS/IOM will review current knowledge about the cause and treatment of MS and recommend a strategic plan to guide future investment. The study will be broadly based, assessing current and future contributions from private and governmental organizations, both in the U.S. and aboard. An important goal of the study will be to identify areas of research that may not have been exploited in the past and to identify new fields of research. At the completion of the study, we anticipate a set of recommendations for future strategies that can be considered not only by the NMSS, but also other MS societies around the globe, governmental funding agencies, and by pharmaceutical and biotech companies involved in MS programs. The analysis was initiated in May 1999, and should be completed early in 2001. We look forward to the opportunity to report the results to the Subcommittee in our testimony next year.

SUMMARY

The National MS Society recognizes that new discoveries and breakthrough findings could come from almost any area of biomedical research and could apply to the primary concern of our members: finding a cure for MS. We thus encourage Con-

gress to focus on NIH as a whole, and on agencies of particular relevance to our concern, knowing that a well-funded federal research enterprise will benefit all of us. Continuing the 15 percent annual increase in funding through 2003 is an extraordinarily good use of federal resources, and we encourage you to do whatever you can to make this a reality. In addition, in order to take advantage of potential discoveries in all areas of neuroscience and help translate these discoveries into new and effective treatments for patients, we recommend fully funding the proposed National Neuroscience Center at NIH.

PREPARED STATEMENT OF NEW YORK-PRESBYTERIAN HOSPITAL

I am Dr. Herb Pardes, President and CEO of New York-Presbyterian Hospital. For the last several years, I was Dean of the College of Physicians and Surgeons of Columbia University in New York. I submit this testimony on behalf of academic health centers across the nation that play a vital role in advancing the frontiers of medicine by conducting extramural NIH biomedical and behavioral research.

We in the academic health community urge you to improve this academic/federal partnership by recognizing the following three concerns which limit the extramural biomedical and behavioral research community from operating at optimal capacity and efficiency:

—the need for state-of-the-art facilities to carry out the increasing volume of federally-supported biomedical and behavioral research;
—the need for competitive salaries for extramural researchers; and
—the need for a peer-reviewed, flexible grant program for shared resources to meet evolving and transitional research needs at the institutional level.

INCREASE FUNDING FOR FACILITIES-CONSTRUCTION, RENOVATION, EQUIPMENT

Exciting developments in genomics, chemical biology, neurosciences, cancer, and many other fields require new kinds of equipment and facilities. Even the best minds cannot compensate for outdated equipment and facilities. It is vitally important that we have the facilities and equipment to fully exploit research opportunities and utilize the increased project grant funding.

The National Science Foundation (NSF) completed a study in 1998 on the status of scientific research facilities at U.S. colleges and universities. This analysis generated an estimate of $3.6 billion in deferred biomedical research construction and repair or renovation projects. In a March 1998 report, the Association of American Medical College (AAMC) stated that "The government should reestablish and fund an NIH construction authority, consistent with the general recommendations of the Wyngaarden Committee report of 1988, which projected at that time the need for a 10-year spending plan of $5 billion for new facilities and renovation." In June 1998, the Federation of American Societies of Experimental Biology (FASEB) reported that "Laboratories must be built and equipped for the science of the 21st Century. Infrastructure investments should include renovation of existing space as well as new construction, where appropriate."

My colleagues and I urge you to provide the NIH with $250 million for extramural facilities construction in the fiscal year 2001 Labor/HHS/Education funding bill. The funds would be awarded on a competitive basis, requiring institutional matching to leverage the NIH resources.

RAISE THE SALARY CAP ON EXTRAMURAL SCIENTISTS

Another case of cost-shifting by the Federal Government is the cap on salaries for academic researchers. Since the cap was first imposed in the early 1990s, at roughly $125,000 a year, the Consumer Price Index has risen more than 20 percent. The result is two-fold. Academic medical centers and universities have been increasingly forced to bear more of the costs of investigators' salaries; and many promising researchers have been driven out of academic research altogether, drawn by more lucrative posts in the private sector.

Physician investigators are critical to translating the substantial fundamental scientific advances to patients. Additional years of postgraduate training, after physicians receive their MD degree, are required for board eligibility, independent of research training and career development. Newly trained MDs are incurring insurmountable debts as a result. In 1997, nearly half of all medical school graduates held debts greater than $75,000. Mounting debts combined with the salary cap serve as disincentives for the youngest and brightest physicians from pursuing careers in academic research. The results are dramatic and disturbing: Between 1994 and

1997, the number of MDs submitting new grant applications to the National Institutes of Health dropped by more than 32 percent.

At the same time, the National Institutes of Health has created new mechanisms such as the Senior Biomedical Research Service (SBRS) to keep its most talented intramural scientists on the NIH campus. Under the SBRS, the NIH can pay its senior investigators up to $157,000, (Executive Level I) roughly equal to what the salary cap on academic researchers would be if it were indexed for inflationary increases over the past decade.

In fiscal year 1999, Congress tied the extramural salary cap to Level III of the Executive Pay Scale, which—at that time—was $125,900. Thus, the increase was not significantly above the previous cap of $125,000. In fiscal year 2000, Congress raised the salary cap from Executive Level III to Executive Level II (now $141,300). While this takes into account increases in the cost-of-living over the past decade, the extramural salary cap is still not on par with intramural NIH scientists who can receive a maximum salary of Executive Level I.

I urge you to raise the current cap on academic researchers should to Executive Level I ($157,000/year) to match the cap currently imposed by the NIH on its own senior scientists under the Senior Biomedical Research Service.

ESTABLISH A FLEXIBLE INSTITUTIONAL RESEARCH FUND TO ENHANCE THE EFFICIENCY OF RESEARCH

A third concern to our nation's academic medical institutions is inefficiency in the federal-academic partnership. As you know, during the past decade, financial pressures on the clinical enterprise of academic medical centers have intensified, particularly so since the implementation of the Balanced Budget Act of 1997 during the past year. It is increasingly difficult to generate institutional margins to underwrite research needs that are not covered well in the project grant mechanism.

These funds would be used to enhance the impact of NIH funding by being flexible enough to change with the science, accommodate changing national priorities and make the most of the NIH and institutional investments in individuals throughout their careers. Glitches in funding cycles, changes in NIH policies and priorities, needs for research resources, and opportunities to mobilize research in new directions could be addressed better with a modest fund in the hands of the institutional leaders, based on competitive funding. Collaborative, interdisciplinary research initiatives can be stimulated through resources at a level above the individual investigators.

Thus, I urge you to provide funding for NIH to establish a "Flexible Institutional Support for Health Research" or "FISHR" program. Program resources would provide institutional support for the following priorities: to fund interdisciplinary, shared research resources; to assist postdoctoral fellows and beginning investigators to establish independent research projects; and to rapidly infuse short-term resources into investigations which offer tremendous promise for research progress.

Academic health centers recommend that the NIH establish such a peer-reviewed, three-year grant program through the National Center for Research Resources. Grants could be in the range of $25,000 to $300,000 per year for Deans of medical, public health, nursing, dental, and pharmacy schools which qualify through having NIH project awards. Applications would provide general plans for needs anticipated to evolve. Awards would permit flexibility within the institution to determine spending priorities, within the categories approved (as proposed above). To assure accountability, I would suggest two mechanisms: a local internal review committee, comprised of NIH-supported investigators at the institution, to review specific proposed allocations, on a prospective basis; then a retrospective review by NIH research program staff prior to approving eligibility to submit a competitive renewal application at the end of the grant award period.

I urge you to include $60 million in the fiscal year 2001 NIH funding bill to initiate this Flexible Institutional Support for Health Research (FISHR) Program. Such annual funding would favorably modify the impact of the recent stresses experienced by research and academic institutions which threaten the efficiency of our national research enterprise.

CONCLUDING REMARKS

The Congress and the NIH can enhance the impact of the project-based investments by taking three additional steps: increase to $250 million the funding to upgrade extramural laboratory space and instrumentation; increase the maximal salary rate on NIH grants to match the maximum for intramural scientists; and initiate a Program for Flexible Institutional Support for Health Research (FISHR).

Each of these steps will increase the productivity and efficiency of the academic/government partnership in biomedical and behavioral research and research training.

On behalf of academic health centers across the nation, I thank you for your attention to these needs and recommendations. Best wishes to each of you.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS

The Bioengineering Division of the Basic Engineering Group of the Council on Engineering, American Society of Mechanical Engineers (ASME International), is pleased to provide comments on the bioengineering-related programs in the NIH fiscal year 2001 budget request. The ASME Bioengineering Division is focused on the application of mechanical engineering knowledge, skills and principles from conception to the design, development, analysis and operation of biomechanical systems.

THE IMPORTANCE OF BIOENGINEERING

Bioengineering is an interdisciplinary field that applies physical, chemical and mathematical sciences and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ systems level, and develops new and novel biologics, materials processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health. From the perspective of mechanical engineering, bioengineering provided for the development of the artificial heart, prosthetic joints and numerous rehabilitation technologies, as just several examples.

THE NEED FOR INCREASED INVESTMENT IN BIOENGINEERING

The Bioengineering Division recommends that support for Bioengineering Research as a percentage of the total NIH research project grants (RPGs) budget be increased to meet the future explosion in Biomedical Engineering Research. In addition, it recommends that a separate, independently funded institute be established to provide adequate support for basic Bioengineering Research.

BACKGROUND

NIH is the world's largest and most eminent organization dedicated to improving health through medical science. During last 50 years, the NIH has played a preeminent role in the major breakthroughs that have increased average life expectancy by 15 to 20 years.

The NIH is comprised of different Institutes and Centers that support a wide spectrum of research activities including basic research, disease and treatments related studies, and epidemiological analyses. The missions of individual Institutes and Centers may focus on a particular organ (e.g. heart, kidney, eye), on a given disease (e.g. cancer, infectious diseases, mental illness), or on a stage of development (e.g. childhood, old age), or, may encompass crosscutting needs (e.g. sequencing of the human genome).

Investigator-initiated RPGs continue to be one of the NIH's highest funding priorities. In fiscal year 2001, RPGs represent 56.9 percent of the total NIH budget, and provides $10.3 B, a 6.1 percent increase over fiscal year 2000, to fund an estimated 31,524 research project grants. This represents an addition of 237 grants over the fiscal year 2000 total. Total grants include non-competing grants and competing new grants. NIH estimates it will support 7,641 competing new RPGs in fiscal year 2001. This number is 1,309 below estimated fiscal year 2000 levels.

CURRENT INVESTMENT IN BIOENGINEERING IS INADEQUATE

In fiscal year 1999, Bioengineering Research Support was at $0.645 B or 7.6 percent of the total NIH RPGs budget. In fiscal year 2000, Bioengineering Research Support is estimated at $0.661 B or 6.8 percent of the total NIH RPGs budget. While the Bioengineering Division acknowledges that there is a small increase in the budgeted support for Biomedical Research, it also notes there is an actual decrease in the percentage of funding, a trend which could indicate a decrease in emphasis on Bioengineering within NIH.

The focus of bioengineering issues at the NIH is the Bioengineering Consortium (BECON), which consists of intramural and extramural senior-level representatives from each of the NIH institutes, centers, and divisions plus representatives of other federal agencies with funding authority for bioengineering research. BECON itself does not have funding authority.

Because BECON is not independently funded, the individual Institutes and Centers under the NIH umbrella must use their annual appropriations to support bioengineering research, a practice that may contribute to the under-funding of bioengineering research. For example, the National Institute of Dental and Craniofacial Research's (NIDCR) share of the total RPG NIH budget, excluding AIDS, is approximately 1.38 percent for fiscal year 2000. Yet, it is anticipated that NIDCR will allocate 41.28 percent of that budget, or $55.4 million, to bioengineering research, an amount representing 8.38 percent of the total RPG NIH budget for fiscal year 2000. ASME's Bioengineering Division believes that this is indicative of the under-investment being made in Bioengineering Research.

CONCERNS

While ASME's Bioengineering Division supports NIH and the priorities identified in the fiscal year 2001 Budget Request, it is concerned about two issues: the reduction in the number of new projects; and, the lack of a direct support mechanism for bioengineering research.

Reduction in the Number of New Projects.—NIH estimates it will support a total of 7,641 new and competing RPGs in fiscal year 2001. This number is 1,309 below estimated fiscal year 2000 levels, a reduction of 14.6 percent. This reduction appears to be inconsistent with the theme of recruiting and training new clinical investigators, especially in Bioengineering where the number of researchers is increasing rapidly in Bioengineering academic departments at universities across the nation. As an example, the number of applicants for CAREER Awards in Biomedical Engineering at the National Science Foundation increased from 38 in fiscal year 1999 to 55 in fiscal year 2000, an increase of 45 percent. ASME's Bioengineering Division believes this is an early indication of the coming explosion in Biomedical Engineering Research.

Lack of a Direct Support Mechanism for Bioengineering Research.—Funding for Bioengineering research remains a small portion of the total NIH research budget. BECON does not include resources for the collaborative support of extramural research. At this time, an intramural bioengineering research program does not exist for broad-based, multidisciplinary research. This situation places a burden on individual NIH Institutes, and appears to be inconsistent with the vision of the role of Biomedical Engineering in increasing biological knowledge, facilitating the development of novel devices and drugs, and providing the technological means to improve health care.

RECOMMENDATIONS

To address the concerns listed above, the ASME Bioengineering Division recommends that:

—support for Bioengineering Research as a percentage of the total NIH RPGs budget be increased to meet the future explosion in Biomedical Engineering Research; and,

—a separate bioengineering research institute be established to:

provide an administrative structure to assist in the coordination, communication, and promotion of bioengineering research supported by the many institutes within NIH to increase the opportunities for new collaborations, dissemination of new technologies or research findings and the availability of funding opportunities, special seminars, conferences, and related activities;

have the authority and funding to provide extramural grants specifically targeted to support activities that do not fall within the disease-related institutes of NIH (e.g., proposals for the development or evaluation of generic technologies that cross many health disciplines; training grants for pre-doctoral and post-doctoral trainees in bioengineering; and, funding for specialized extramural centers which would enable universities to develop core support structures for enhancing the training, research endeavors and development of technology in all fields of bioengineering); and,

support the development of a modest intramural program in Biomedical Engineering to focus primarily on new technologies that could evolve to become core resources for both intramural and extramural investigators.

—as an interim measure prior to the establishment of a separate Bioengineering Institute, the NIH create an Office of Bioengineering Research modeled after the Office for Research on Minority Health (ORMH) to:

serve as the coordination center within the Office of the Director for Bioengineering Research issues; and,

have the legislative authority to award grants for priority bioengineering research that other Institutes or Centers are unable to fund.

CONCLUSION

The ASME Bioengineering Division endorses the National Institutes of Health's fiscal year 2001 budget request for bioengineering. Triumph over disease and disability, and speeding the rate at which fundamental discoveries are translated into effective therapies, are essential for the vitality of this nation.

The Division is concerned about details of the budget request. To address these concerns, the ASME Bioengineering Division recommends that:

—support for Bioengineering Research Support as a percentage of the total NIH RPGs budget be increased to meet the future explosion in Biomedical Engineering Research;

—a direct support mechanism for bioengineering research be established to provide adequate support for basic bioengineering research, a centralized focus for extramural bioengineering research at NIH, a strong intramural bioengineering program at NIH, and increased coordination of bioengineering research within the highest levels of NIH and among other federal agencies; and,

—as an interim measure, the NIH establish an Office of Bioengineering Research based on the ORMH model.

ASME International's Bioengineering Division appreciates the opportunity to present its views to the Subcommittee on Labor, Health and Human Services and Education.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR CANCER RESEARCH

On behalf of the 26 organizations which comprise the NCCR and consist of 80,000 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; 90 cancer hospitals and cancer centers across the country; and more than 2 million volunteers. It is on their behalf that I submit this testimony in support of the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention.

Indeed, the harvest of the past investment of the American people and Congress in supporting biomedical research is now being realized as we are bringing on line powerful new tools that are delivering more precise and rapid information that is already enhancing our understanding and control of cancer. As just one example, I will focus here on diet and the prevention of cancer to illustrate one facet of this exciting advancement.

We have all known that eating more fresh vegetables and fruits are good for us. For example, eating broccoli appears to be beneficial in lowering the risk of cancer. A few years ago, a group at Johns Hopkins isolated and identified the active sulfur compound from broccoli called sulforaphane that when administered to animals prevented cancer from developing when they were subjected to carcinogens. Most recently, Dr. James Brooks and Dr. Pat Brown at Stanford University have illuminated the mechanisms through which this compound might prevent cancer. When cells were administered this sulforaphane, they turn on a battery of genes that increase the cell's defense system that protects DNA from damage. Conversely, sulforaphane turns off a set of enzymes that tend to activate the carcinogens to a more DNA damaging form. This double barrel effect of sulforaphane of both enhancing the "good guys," while eliminating the "bad guys" in the carcinogenic mechanisms, is at the heart of how sulforaphane might protect us from cancer.

This new DNA chip assay allows us to test many other similar compounds and select the ones that would be most beneficial. This study was made possible by another application of this new DNA chip technology of which Dr. Klausner spoke to you in his testimony on February 15. He reported how this technology was used to accurately identify two different forms of what appeared to be similar cancers that had responded differently to the same therapy. Therefore, the DNA chips are not only being used to identify specific types of cancers and how they might respond to different drugs, but are also being used to study how factors in our diet might lower the risk of cancer.

For a long time, we have known that people living in China and Japan have one-tenth the rate of breast and prostate cancer in comparison to the United States. However, when the people from Asia migrate to this country, their breast and prostate cancer rates increase dramatically toward that which we experience here within the United States population. What is it in the diets and environments that brings this dramatic change about? Is the increased rate due to a loss of a protective factor or the addition of a detrimental factor such as a carcinogen? We have always suspected that there are many things in our diet that might alter our cancer risks, and through the use of these new molecular techniques, it will be possible to hunt these

agents out in a more systematic and rapid form. This means that much of the initial testing can take place in cell systems using these DNA chips and then extending the information to a more definitive study in animals and then in clinical trials in humans. More is coming from the new DNA technology, and this is only the first steps in a major revolution in how we study cancer that resulted from your previous investments, and it is now applicable to many diseases.

Another exciting area of research is on human pluripotent stem cells. A new, emerging theory is that cancer is a stem cell disease. The potential applications for stem cell research could have an incredible impact on improving cancer treatment and prevention. The research in this area is just emerging, and it would be a tragedy to restrict. The NCCR urges Congress to permit the National Institutes of Health (NIH) to fund and provide oversight for research on human pluripotent stem cells and strongly opposes any attempts to ban this very promising area of research. The NIH guidelines, which the NCCR supports, create a federal regulatory framework for appropriate applications and derivations of stem cells, require that stem cell research is accountable to federal oversight and federal reporting mechanisms, and ensure that stem cell research is pursued in an ethical and responsible manner under public scrutiny.

There are dozens of other discoveries and exciting possibilities as delineated in the NCI Bypass Budget Report and elsewhere that need to be funded. We know that the control of cancer will only come through research. The bad news is that we are not taking advantage of these opportunities in an appropriate manner. The question that always comes up is, "Are we paying for bad research." It is important to realize that when President Richard Nixon declared "war on cancer" we were funding at 40 percent of the approved grants, and today we have dropped down to 32 percent of the approved grants. There is little doubt that if we now extended this up to 50 percent of the approved grants that we would have a much better chance of finding discoveries at a more rapid rate. No one knows where the next major discovery will come from, and history has shown that many of the experts have often guessed wrong on this matter. It would seem apparent that funding more approved projects would increase the chances.

This increase in funding is not a waste in comparison to the cost to the nation—over $107 million and half a million lives annually—and the need to stop the devastation and carnage of cancer as quickly as possible. I think we need to bet on more horses in the research race. We all might be surprised at which research will win, but one will win as it did for Lance Armstrong in his fight against cancer so he could finally reenter and win the grueling Tour De France bicycle race. I am confident that increasing our bets to funding the top 50 percent of the approved grants will prove to be a good bet for the American people. To do this, we would have to extend the budget to $4.1 billion for the National Cancer Institute, the level recommended in the fiscal year 2001 Bypass Budget.

More funding for young physician scientists is also of critical importance, because the goose that lays the golden eggs is now dying of malnutrition. The work to which I just referred, on diet studies, of Dr. James Brooks at Stanford as well as other important discoveries in this area by Dr. William G. Nelson at Johns Hopkins are the results of a young surgeon and a young medical oncologist having the opportunity to carry out laboratory based research on cancer while still practicing as leading physicians. They are some of the most valuable warriors in our fight against cancer. Unfortunately, there has been a dramatic drop in the number of these young physicians entering research, and this is witnessed by the M.D. postdoctoral training funded by the National Institutes of Health (51 percent decrease in six years) and in those trainees funded by the Howard Hughes Medical Institute (57 percent decrease in two years). These numbers are documented in a study appearing in Science (Vol. 283, Page 131, 1999) by Dr. Leon Rosenberg.

These young physician scientist are under intense pressure as funds have moved away from our non-profit medical institutions and over to become the profits of the insurance companies. The insurance companies do not invest in the training of these young scientists and neither do they fund their research. At prior times, the non-profit medical schools used funds that they received for medical care to support these young physician scientist. All that has happened is that the funds have now shifted from one pocket to the other, and the support for the development of physician research has evaporated. The insurance companies may be the only major industry that does not return any appreciable percent of their profits to support research and development and to protect their customer, the patient, in the future.

This shift in research funding is a tragedy that is choking the goose that lays the golden egg of research discovery for our people. It is urgent for Congress to act to support the National Cancer Institute and the NIH in these dire times and to help stop this hemorrhaging of our major medical training centers that is choking our

young physician scientist who are forced away from the laboratories and research to desperately try to fill beds to compete for the decreasing care dollar distributed from the insurance companies.

Insurance companies are also slowing the pace of research by denying payment for and, therefore, patient access to clinical trials. Investigational therapy administered under the aegis of a fully approved clinical trial is often 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 absolutely essential to achieve progress in cancer care. Both patients and research suffer when health insurers will not reimburse for routine patient care costs in clinical trials. This is compromising our capacity to translate research from the laboratory bench to the bedside. The NCCR supports legislative efforts to ensure third-party payer's coverage of patient-care costs in clinical trials.

In my 40 years in research at Johns Hopkins, I have never seen such a dramatic change as that which has occurred in the past few years, and it certainly is not for the good of the patient nor for the future generations. America deserves better. I know these are difficult and sensitive issues, but I hope you can help lead us into an exciting future. Increasing NIH and NCI support would certainly make a tremendous difference, and it is most needed.

I am also here to assure you that cancer researchers are committed to upholding the integrity of the clinical trial process, so that patient safety and confidentiality are of the utmost importance. There are inherent risks to being a cancer patient, as there are to receiving anesthesia or any drugs. The critical points are to ensure patient safety through close patient evaluation and informed decision-making, which are hallmarks of clinical research. Informed decision-making is enabled by explaining all potential risks and benefits to patients. This process is an essential component to clinical trials, so that patients are fully aware of complications that could occur and can weigh the risks and benefits in order to determine whether or not to participate.

An oversight structure, comprised of federal guidelines and oversight as well as local oversight through institutional review boards (IRBs) and data safety monitoring boards (DSMBs), closely tracks research protocol activities to safeguard patient care in research. Further, investigators and protocol nurses carefully monitor the progress and safety of patients participating in clinical trials. In conclusion, clinical trials provide excellent care for patients, are a necessary and important step in research, are very closely monitored, and serve as the lynchpin between research and accepted medical practice for making advancements in the war against cancer.

The NCCR thanks you for providing this year's 15 percent increase to NIH as the second installment to double the budget of the NIH over five years. In terms of funding for fiscal year 2001, we are requesting the third 15 percent increase for NIH, $4.1 billion for the NCI, and $622 million for cancer control efforts and the CDC. This third increase to NIH will bring us within 2 years of doubling the NIH budget.

While amazing progress has been achieved in cancer treatment, cancer remains the second leading cause of death in America. Let me share with you a few facts which indicate the wide-reaching scope and magnitude of cancer. One in two males and one in three females will develop cancer of the course of a lifetime. Look to your left and look to your right. The odds are that one of these individuals will be diagnosed with cancer. One in four Americans will die form cancer. Now, look to your left, look to your right, and look at me. The odds are that one of us will die from cancer. Today alone, more than 3,000 people will be diagnosed with cancer, and over 1,500 will die from cancer. Over the course of this year, over 1.2 million Americans will be diagnosed with cancer and over half a million will die from cancer. Too many people live with cancer, Mr. Chairman, and too many people die from cancer. We have a moral obligation to aggressively pursue cancer research and turn cancer from a too-often terminal disease into a treatable, preventable disease.

It is important that we understand the magnitude of cancer statistics both now and in the future. While cancer rates—the number of people per thousand in the population who develop cancer in a given year—have dipped slightly by 2.6 percent between 1991 and 1995, cancer incidence, the new cases of cancer reported each year, is expected to increase hugely over the next decades. As the Baby Boom Generation ages, the number of Americans over age 65 will double to 69.4 million in 30 years, and the number of Americans over age 85 will quadruple. Currently, 64 percent of cancer occurs in patients over 65, the Medicare population. By 2010 cancer incidence is expected to increase 29 percent and mortality 25 percent with annual costs exceeding $200 billion. The Medicare program is already facing serious problems, but it will be utterly overwhelmed and crippled if cancer prevention and

treatment options do not improve significantly over the next thirty years. It is imperative, thus, to mount an aggressive cancer research front immediately.

Let me summarize for you what is needed to mount an aggressive and successful, federal campaign against cancer that can fully exploit the promising research opportunities that abound and then apply that knowledge to improve cancer prevention, detection, and treatment at a time when the incidence of cancer is projected to increase dramatically. We need a 15 percent increase in the NIH budget and $4.1 billion for the National Cancer Institute. These increases will enable high-quality and innovative research, much needed support and training for young investigators, new equipment for researchers and institutions, and the necessary infrastructure to support cancer research in our increasingly technologically sophisticated age. We also need to fully support the important cancer related programs at the CDC, such as the cancer registries, breast and cervical cancer detection programs, and the Environmental Health lab among others. We recommend that the Committee provide $622 million for cancer control efforts at the CDC. The combined efforts of and adequate funding for NIH, NCI, and CDC are integral to understand, prevent, diagnose, treat, and ultimately eradicate cancer. I wish to thank you for allowing me to present this to you for your consideration.

PREPARED STATEMENT OF THE CHILDREN'S HEART FOUNDATION

Mr. Chairman and Distinguished Subcommittee Members: On behalf of The Children's Heart Foundation and all who are suffering from congenital heart defects we enter this testimony for consideration at the fiscal year 2001 budget hearings.

According to the NIH Guide (Gene Nutrient Interactions in the pathogeneses of congenital heart defects), September 1994, 42 percent of all birth defects are caused by congenital heart defects. Eight percent of all deaths during the first year of life are caused by this condition, and of the 30,000 babies born each year with this anomaly, 2,900 of them will die before their first birthday. Thirty six hundred children under the age of fifteen die annually from congenital cardiovascular malformations (CCVM) or congenital heart defects.

In addition to the incredible impact on families, the social costs are great as well. Many children who survive infancy are forced into a life of dependency on medications, medical procedures, and repeated open-heart surgeries. In 1992 nearly $500 million was spent to pay for 44,000 hospitalized children who were under fifteen years old.

Because so few of these children live long enough to have children of their own, it has been difficult to carry out genetic studies of CCVM. However researchers have now come to the conclusion that most CCVM occurrences are caused by genetic defects. According to information provided by the NHL&BI, the direct cause for at least eight different structural heart defects may be genetic.

While we at The Children's Heart Foundation appreciate the genetic studies that have been ongoing at the NIH, we also realize that clinical studies on procedures and methods of treatment are vital to the future of patients suffering with congenital heart defects. We wish to encourage the committee to support more clinical projects in congenital heart research. It is our understanding that at present the budget for congenital heart research at the NHL&BI is fifty million dollars.

We ask that the members of this committee grant fifty million additional dollars to the NHL&BI with directives to increase clinical and molecular research concerning congenital heart defects. The increase will bring the budget to 100 million dollars, but in a budget of, what we understand to be 15 billion dollars this is a small increase to support research in America's number one birth defect.

In the next few pages we will present the stories of some of the families who have lived with these life-threatening conditions. One of these families has lost the battle while others still live with the daily difficulties that accompany their illness. Please accept these testimonies and the requests to testify before this committee under the auspices of The Children's Heart Foundation.

Individuals and grassroots efforts can only do so much. Congress must take on this effort and increase appropriations. So again, we implore this committee to grant an increase of fifty million dollars to the fiscal year 2001 budget earmarked to the NHL&BI for congenital heart defects research. We thank you for your attention to our requests.

PREPARED STATEMENT OF JESSICA COWIN

Mr. Chairman, members of the committee and all who hear this testimony. My name is Jessica Cowin and I am 16 years old. I am requesting to be slotted to testify before the appropriations subcommittee.

I have had five heart surgeries since I was 4 days old because I was born with a hypo plastic left heart. A hypo plastic left heart is a heart that has no left side, in other words I had no pump. At 4 days and 18 months the doctors performed closed heart surgeries on me. At 5 years and 13 years, I had open-heart surgeries. All of these surgeries worked, for a while, but my heart began to fail in the last two years. The doctors and my parents agreed that I needed a heart transplant. It was very scary to think that the doctors were going to put someone else's heart inside of me, but if I wanted to live longer that's what I had to do.

On September 25, 1999, my mother got a phone call from the Children's Memorial Hospital in Chicago (where I have had all of my surgeries), saying that they had a heart for me. It has been two months since my transplant and even though I am on a lot of medication I already feel better. Before the transplant I had no energy and got sick more often than other children. It also took me longer to get better. I have also missed a lot of school in the past three years and I missed my friends, too.

This has been very stressful for my family because everyone worries a lot about me. I still have to go to a lot of doctors, physical therapy, counseling and cardiac rehabilitation. I know my mom worries a lot about the medical bills even though she tries not to show it.

Without the research for congenital heart defects, I would not be here today. I was born in 1983 at Children's Memorial Hospital. At that time they were not even doing heart transplants there. They started doing transplants in 1988, when I was 5 years old. I have personally benefited from the research of all of my five surgeries.

My mom tells me that there are still babies born with heart problems that do not live and that I am really lucky that I have such good doctors and that they knew what to do for me. I agree with her. Please provide more federal funding for congenital heart research to the National Institute of Health.

PREPARED STATEMENT OF ANDREA PIWOWAR

My name is Andrea Piwowar. Twenty-three years ago, I was born with several congenital heart defects. I was diagnosed with tricuspid atresia with transposition of the great arteries and a large ventricular septal defect associated with pulmonary hypertension and an absent pulmonary valve.

When I was three months old, I had a banding of the pulmonary artery. In January of 1982, I had a modified Fontan, a surgical procedure which makes it possible for blood to enter the lungs without being pumped in by the right ventricle. This is achieved by connecting the pulmonary artery directly to the right atrium. In my situation, since I had transposition of the great arteries and a ventricular septal defect along with tricuspid atresia, the underlying need for the Fontan procedure, the surgeon corrected the transposition and closed the hole between the two atria.

Seven months following the modified Fontan, I had a stroke. In December of the same year, I had yet another stroke. It is my understanding that it was thought that clots were forming in the pulmonary stump; therefore, after the second stroke, I was operated on again and the pulmonary stump was removed. The doctors could not find where the clots came from. Even to this day, there is no explanation of the strokes. After that operation, I was put on Coumadin and Lanoxin.

As a result of the strokes, which occurred after my corrective heart operations, I have both orthopedic and speech impairments and require the use of an electric wheelchair for mobility purposes. Throughout my childhood, my parents fought for the appropriate accommodations to be made in the school systems and for my right to be in classes with able-bodied children. I felt like it was necessary for me to work harder on class assignments just so I could keep up with the class. I also felt that I had to prove myself to my teachers.

I am now an Indiana University graduate and am currently looking for a job. I have had a couple of interviews and have spoken with employers and recruiters over the telephone. At times, I feel as if my impairments make it difficult for me to make a good first impression with potential employers. I have been hung up on while speaking with recruiters and employers have postponed and cancelled interviews with me.

Like other patients who have had the Fontan operation, I am beginning to see some of its side effects. Within two years, I have had atrial fibrillation three times,

each time requiring a cardio version to get back into normal rhythm. I also have an enlarged atrium which is causing my blood return to become sluggish.

My first bout with atrial fibrillation occurred during the week of college midterms. I thought it might have been something that I had brought on myself, because I had been working on several projects at one time and staying up late to study, but I hadn't done anything differently than I did during the previous semester. It wasn't until I was in the hospital that I found out that atrial fibrillation was a side effect from the Fontan procedure.

No one had informed me of any possible side effects of the Fontan. Only by speaking with my cardiologist and reading personal experiences of other Fontan patients I am beginning to understand more about the side effects; however, I have yet to understand why some people with congenital heart defects have strokes while others do not. As I mentioned earlier, no one can explain why I had two strokes after the Modified Fontan operation.

Several years ago, I wrote a letter to Dr. Thilenius, the cardiologist who saw me before and after the modified Fontan procedure was performed, inquiring about Hypo plastic Left Heart Syndrome. I received a response that explained what Hypo plastic Left Heart Syndrome was and the surgical procedures that could be performed, depending on the severity of this disease. I was also given an explanation of my congenital heart defects and the surgical procedure that were performed to correct them. I was informed that strokes rarely occur after a Fontan procedure, so rarely in fact, that it is not even mentioned as a complication, but yet they still occur and no one seems to know why.

So, I ask you, the distinguished members of the subcommittee, to increase appropriations to the National Heart Lung and Blood Institute to support clinical studies in the area of congenital heart research. As more congenital heart research is performed, researchers may discover why some people with congenital heart disease are more prone to having a stroke than others and find a way to prevent them from occurring.

I would like to submit my request to be given the opportunity to testify before you, the distinguished members of the subcommittee, on the issue of allocating increased funds to the National Institute of Health for congenital heart research.

Thank you for your time.

PREPARED STATEMENT OF MEGAN VAN PELT

My name is Megan Van Pelt and I am the mother of a child born with a congenital heart defect. Congenital heart defects have been a part of my life since I was a child. My Cousin was born with a very severe congenital heart defect and underwent many open-heart surgeries. Being a child I could have never understood the magnitude or impact on the family during this time. Doctors told my aunt that he would not live past the age of nine. By the grace of god and congenital heart research twenty-nine years later my cousin is still alive and functioning as a normal healthy adult. Who could know that twenty-seven years later, I myself would deal with the issue of congenital heart defects. In the summer of 1997 my husband and I were anxiously awaiting the arrival of our first child. During my routine twenty-four week check up I was excited to finally see our baby in an ultrasound. As the ultrasound progressed the technician informed me that she needed to get the obstetrician to come in and look at the baby's heart. After the doctor reviewed the tape, he informed me that our unborn child had a complex congenital heart defect. For my husband and me the next three months were a blur of cardiology visits and Internet research. On October 10, 1997 my amazing son, John "Jack" Ryan Van Pelt, came into our lives, changing us forever. Nothing could have prepared me for the next four months. Jack was born a navy blue color which according to the doctors was normal because of the lack of oxygen his body was getting. Jack weighed 4.5 pounds at birth. He was immediately transported to Children's Hospital in Chicago. I have never felt so helpless.

A heart catheterization which was done shortly after Jack arrived at Children's Hospital, confirmed the initial diagnosis of transposition of the great vessels as well as three holes in his heart. This meant that Jack's heart had developed backwards and all his blood was flowing in the wrong direction. Because of Jack's size the Cardio-Thorasic team did not feel that he was strong enough or big enough to survive the complicated surgery that he needed. We spent the next two months in the Neonatal Intensive Care unit, waiting. Because of his heart Jack experienced liver and kidney failure. Everyday was a hurdle for Jack and many days were touch and go. I thanked God for everyday I had with him.

Finally on December 4th the surgeons felt Jack's condition was deteriorating and the surgery could no longer wait. The surgeons explained at length the surgery that Jack would undergo. The procedure was relatively new and if successful Jack would not need to undergo future surgeries. I will never be able to verbalize how it felt to sign my son's life over to this team of doctors. The actual surgery took ten hours. When Jack came out of surgery everyone warned us he would look horrible, I am happy to say, they were all wrong. My husband and I could not believe how pink he now looked. His body was finally receiving oxygen. The doctors warned us that the next 48 hours would be the most critical. Jack came through with flying colors. He had fought for his life and won. My son was a survivor.

Through those three months I could not believe the amount of people I became close to who had children surviving with congenital hearts defects and dying from congenital heart defects. This is the number one birth defect that children are born with, why don't most parents know this? Why isn't there better education? But most importantly why isn't there more research? There are children that I met who will undergo open-heart surgery every three years as their hearts grow. Unfortunately the funding for projects is not there to help researchers find ways to fix defects the first time so it will be the only time these children are forced to undergo additional lifesaving procedures.

I am happy to say that Jack is doing very well at the age of two. We visit the cardiologist once a year. With every visit I hold my breath afraid that he will need another surgery. Should that day come we will take it in stride. The most terrifying part of having one child with a congenital heart defect becomes the fact that every child you have following has an even higher chance of being born with a congenital heart defect. One out of every 115 babies is born with a congenital heart defect in the U.S. each year. There are many worthy causes and issues today, but there needs to be a greater awareness of this, our number one birth defect. Because of our experience it has been extremely important to my husband and I to give back. We have become involved with the Children's Heart Foundation, which raises money for research in congenital heart defects. Many of our recipients have gone on to receive funding from the NIH for pediatric congenital heart research. When it comes right down to it, the funding that is needed isn't there. The American Heart Association gives less than 1 percent of their funding to research of congenital heart defects.

I ask you to take the time to visit a cardiac wing in a pediatric hospital. There is a great chance that your family, friends, or associates have been or will be affected by a congenital heart defect. My family is reminded of it daily my cousin whom I spoke of earlier and his wife are seven months pregnant. Sadly they have just found out through ultrasound that their child will need to have open-heart surgery. I ask you to sincerely consider dedicating more money for the research of pediatric congenital heart research. Help us to educate the public and find the answers to the number one birth defect. Thank you for your time and consideration. We have an opportunity as the leading healthcare nation in the world to find cures and new surgical procedures to help these brave young fighters and I encourage you to support us in the fight.

Thank you for your attention.

PREPARED STATEMENT OF TERESA TAYLOR

Mr. Chairman; and Members of the Committee. I am requesting to be slotted to testify before the appropriation sub-committee and I am honored to give my personal testimony.

My name is Teresa Taylor from Skokie, Illinois in the county of Cook, the 21st Congressional District of Illinois in the United States of America. I would like to address this committee on behalf of all the children born with congenital heart disease, those surviving, and in honor of those that have lost their lives including my son, Sam. It is with a personal story and a family history that I testify.

I want to go down on record that my son Sam and countless others that have died prematurely not forgotten but remembered. And to be a constant reminder for the need for additional federal funding for research on congenital heart defects.

My son Sam, was born in Chicago, Illinois April 1993. He was born with hypo plastic left heart syndrome. In other words, his left side of his heart was underdeveloped. The left side of the heart is the main pumping chamber of the heart and pumps blood to the rest of the body.

The devastation over our son's condition has caused us great sorrow and pain. We knew very little in 1993 of his disease. There was little that we could do except listen to the Doctors' prognosis and go along with the treatment they suggested. In 1993, the options for Sam were immediate open-heart surgery, or wait for a heart

transplant. We opted to place Sam on a heart transplant list originally called the UNOS (united network of organ sharing). We were told that Sam would probably get a heart within the next 6–9 weeks. We did not receive a heart when we had thought. The heart for Sam came when he was 5 months old. He lived in the hospital his whole life on a ventilator. I would not call this life support but assistance so that his heart and lungs would not flood up with blood while he waited for a heart. Sam died 2 weeks after transplantation. He died due to lung and hospital related infections. Because Sam waited only two days short of the longest wait for an infant heart doctors did not know what to expect of his out come. Today doctors know that an infant and most likely any patient waiting for a heart transplant cannot survive as long as Sam did on a ventilator. Because of Sam, doctors know that it is critical to find better ways to manage a patient waiting for a heart transplant and open-heart surgery. Today at Children's Memorial Hospital in Chicago, doctors have perfected open-heart surgery that would have been used on Sam instead of transplantation (the procedure is called Norwood). Research helped in this matter and patients like Sam helped them in their research. Sam and other children paid with their lives to help doctors understand congenital heart defects and find ways to better manage and treat their condition.

I make a plea to this committee, let this show that research is direly needed to prevent cases where the doctors only learned after the child's death of appropriate treatment for a child with a congenital heart defect.

My story does not end here. I had a brother who died from a congenital heart defect called tetralogy of Fallot. Today, many are living many more years thanks to research. These dedicated Doctors to find ways to manage and treat children with congenital heart defect such as tetralogy of Fallot. My family history of congenital heart defects goes back at least three generations. All of those in my family who died were boys. I would like my daughters to one day have children of their own. I would hope that they will feel safe that if they have a boy and he is born with congenital heart disease that they will not have to grieve for the loss of their son but embrace his survival. It is my personal dream to see my son in the face of my daughter's children, happy and healthy.

I want this story to someday have a happy ending to parents across the country because federal dollars were spent in providing research in this area, we need as parents to take a stand and ask questions. Why did this happen to my child, is there research being done in this area, what is the treatment for these children, what is their long term prognosis, will we learn something from this and can our children have the future that they deserve so much?

I have heard countless stories subsequent to our son Sam's death. Stories of survivors with the same condition Sam was born with. These children are living today because of research in congenital heart defects. I only wish today that my son had this chance for a life. I can only wish to carry on a legacy in his name, to help other children have a chance to live and enjoy life like other children. The more money that can be generated toward research, the more children in the future will live with a heart defect not die of it. I plead to this committee to pleases allocate more federal dollars to the to the Heart, Lung and Blood Institute, and to direct research funds on congenital heart disease.

Thank you for your attention in this matter.

PREPARED STATEMENT OF THE DORIS DAY ANIMAL LEAGUE

The Doris Day Animal League is a non-profit, member supported national animal advocacy organization located in Washington, D.C. On behalf of our 295,000 members and supporters, we respectfully present to the subcommittee our concerns relating to The Coulston Foundation of New Mexico and continued federal funding of that facility.

The Coulston Foundation is a private animal research laboratory based in Alamogordo, New Mexico. It reportedly owns more than 600 chimpanzees, 300 other primates, and an unknown number of other animals who are kept at two facilities, one on civilian ground, the other on Holloman Air Force Base.

The Coulston Foundation has the worst animal care record of any research facility in the history of the Animal Welfare Act, and has long been of concern to the animal protection community and many Members of Congress. The laboratory has been investigated seven times by the U.S. Department of Agriculture (USDA) for serious violations of the Animal Welfare Act. While the seventh investigation is ongoing, the previous six have led to formal charges against the lab.

In August 1999, The Coulston Foundation and USDA signed an unprecedented settlement agreement pertaining to the most recent set of charges. Under the settle-

ment, The Coulston Foundation agreed to divest 300 of its chimpanzees by January 2002, allow external financial and animal welfare monitors to inspect the facilities, and to "cease and desist" from further violating the Animal Welfare Act. Yet at least five chimpanzees have died at The Coulston Foundation since the agreement was signed.

The case of Donna, a 36 year old chimpanzee is perhaps the most shocking of these recent deaths. She died last November from severe infection to the uterus, bowels and peritoneal cavity after carrying a dead fetus in her womb for at least two weeks. Records indicate that veterinary staff at The Coulston Foundation were aware of Donna's condition, but failed to provide adequate care in a timely fashion.

In total, at least 14 chimpanzees and 4 other primates have died negligent deaths at The Coulston Foundation since 1993. Three chimpanzees died at the lab that year when the temperature in their cage soared to 150 degrees. In 1994, four monkeys died at the laboratory from water deprivation and resultant dehydration. In 1997, a healthy 11 year old chimpanzee named Jello died after being improperly anesthetized. In March of that year, another chimpanzee, Echo, died when veterinary staff failed to stabilize her for shock before surgery. In early 1998 a chimpanzee named Holly died during a drug testing protocol. In June 1998, two more chimpanzees died during a protocol involving the same drug tested on Holly. In May 1999, a chimpanzee who was being used in an invasive spinal study died from negligent care. Five others, including Donna, died at The Coulston Foundation in the second half of 1999.

The USDA is not the only federal agency concerned with the deteriorating situation at The Coulston Foundation. In fact, in December 1999, the Food and Drug Administration placed a restriction on The Coulston Foundation for 270 violations of Good Laboratory Practice standards, and warned the lab that no protocols or data would be accepted by the agency until the violations are corrected.

As a major funder of The Coulston Foundation, the National Institutes of Health (NIH) has also shown concern over the laboratory's record, and in February, 1999, it placed a restriction on funding to the lab. According to the restriction, future funding would depend on The Coulston Foundation's hiring of seven "fully qualified" veterinarians. However, it is our understanding that the laboratory has only two full-time veterinarians to date.

The situation at The Coulston Foundation is quickly deteriorating. Documents obtained from NIH under the Freedom of Information Act state that "Based on current cash flow of [The Coulston Foundation], it appears unlikely that it can continue operating for much more than two or three months longer".

That document was dated April 29, 1999. Since that time, NIH has granted at least $1.1 million in "supplemental awards" to the laboratory. This continued funding appears to be in direct contravention of NIH's own restriction and the Health Research Extension Act of 1985, under which the Director of NIH must "suspend or revoke Public Health Service funds" to any facility which has failed to correct violations of the Animal Welfare Act.

It is time for a candid reassessment of the Federal Government's involvement with The Coulston Foundation. The prospect of the laboratory going bankrupt is very real, and the short- and long-term ramifications for the welfare of hundreds of animals there are serious. While my organization understands that NIH is not ultimately responsible for the welfare of the animals at The Coulston Foundation, it does bear some moral responsibility for the animals there, many of which were bred for and used in NIH-funded research.

There is immense public concern for the welfare of the animals at The Coulston Foundation, many of whom were previously owned by the Air Force and are the survivors and descendants of America's space program. There is also frustration over the financial aspect of the situation. While The Coulston Foundation is seemingly incapable of complying with the law, it has been the recipient of millions of federal dollars (at least $27 million since 1993), and continues to receive taxpayers' money through NIH.

The government must address the situation at The Coulston Foundation and work to avert what could be a potentially disastrous scenario. We, therefore, respectfully ask the government to take emergency action and appropriate $5 million via fiscal year 2001 Appropriations for Labor, Health and Human Services, Education and Related Agencies for the care of the 300 chimpanzees which The Coulston Foundation is under federal order to divest. While the ownership and care of the animals certainly ought to be transferred to another party, the chimpanzees could feasibly remain on Holloman Air Force Base for the time being.

As a long-term solution to the problems at The Coulston Foundation, we urge Congress to pass the Chimpanzee Health Improvement, Maintenance and Protection

Act (H.R. 3514), which would create a network of federally supported private sanctuaries to which chimpanzees no longer needed in research could be retired.

The chimpanzees and other animals at The Coulston Foundation are unable to advocate for themselves, and the laws which are supposed to protect them are failing to do so. While it is The Coulston Foundation's ultimate responsibility to provide for the animals in its care, it seems incapable of doing so. The government has enabled the situation to escalate by continuing to fund the breeding and use of animals at the laboratory.

A new direction is desperately needed. We respectfully ask this Congress to ensure that our own government does not perpetuate a situation which is ultimately harmful to the very animals it is charged with protecting, and instead takes action to remedy the deteriorating situation at The Coulston Foundation. Thank you for your consideration.

PREPARED STATEMENT OF THE FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

Mr. Chairman, Mr. Harkin, Members of the Subcommittee: The Federation of American Societies for Experimental Biology, FASEB, is the largest organization of life scientists in the United States. Founded in 1912, FASEB is comprised of 20 societies with a combined membership of more than 60,000 scientists. Each year, FASEB brings together representatives of our member societies to review the biomedical research programs at NIH and other federal agencies. After considerable deliberation and debate, these scientists produced funding recommendations for each agency examined. This year's proposals are contained in a report released for this budget cycle.[1]

First, we would like to thank both the chairman and ranking member for their ardent support for the research programs at the National Institutes of Health (NIH) and for their efforts over the past two years toward doubling the NIH budget within five years. We also would like to ask that both Mr. Specter and Mr. Harkin continue to work with their colleagues to press forward with this vital national investment. We urge them to provide NIH with a 15 percent increase for fiscal year 2001, making the third installment toward the bipartisan goal to double the NIH budget. This additional funding is needed to sustain and further increase the momentum within NIH programs that has been begun through your hard work.

While FASEB believes there are many issues important to the continued long-term success of the NIH and health research in this nation, our statement will focus on our two highest priorities. First, we need to fund more research projects, especially investigator-initiated research projects, and second, we need to ensure a continued supply of highly-talented science personnel to carry out that research.

Research that is conceived and initiated by individual scientists, investigator-initiated research, has been the key to the nation's extraordinary progress in science. The magic that NIH has produced over its history has occurred by supporting creative scientists to do excellent research in laboratories around the nation. We have required them to compete for support, under scrutiny of their peers and competitors, in the marketplace of ideas. The resulting scientific innovation and progress produced by this mechanism is attested to by the fact that since 1945, 57 of the 76 U.S. winners of the Nobel Prize in Physiology or Medicine were supported by NIH before they won their award, including the 1999 award-recipient, Dr. Gunter Blobel. The competitive, peer-reviewed system has excellence at its core and should remain the principal mechanism used by NIH to distribute research support. NIH should support the work of more scientists in their laboratories; this will be the key to increasing research productivity of the system as a whole. This competitive system is, we truly believe, the most efficient, cost-effective and productive way to carry out biomedical research and to maximize the return we get from it.

Budget increases, therefore, should be used largely to support more research grants and to fund them at the lengths and levels approved by the peer-review process. In some study sections, where grant applications are reviewed, my colleagues report that projects rated among the top twenty to twenty five percent come back for re-review when the NIH is unable to fund them. We need more resources to eliminate the redundant and discouraging cycle of re-submission and re-review. We need scientists doing research, not "in the system" of review. There is no shortage of good ideas. Therefore:

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[1] Federation of American Societies for Experimental Biology. 2000. Federal Funding for Biomedical and Related Life Science Research fiscal year 2001. http://www.faseb.org.

—the central principle guiding dispersal of research funds by NIH is—and should remain—competitive merit review by their peers; and
—the first priority in allocating NIH budget increases should be to support more grants for research initiated by individual scientists and to fund proposals at the durations and levels recommended by peer-review.

With a 5.6 percent increase in funding for fiscal year 2001, NIH predicts that it will be able to fund 31,524 research project grants, an increase of only 237 grants over the fiscal year 2000 estimate. We recognize that several mitigating issues contribute to this situation. One appears to be the prudent concern about making too many long-term commitments without the assurance of continuity of growth in NIH funding. That is, if too many grants are funded one year then many fewer grants might be renewed the next year if growth does not continue. There was also significant need to re-build base programs that were unable to be fully developed by NIH in the past due to financial restraints. Furthermore, an increasing number of scientific questions today require interdisciplinary strategies. These strategies tend to involve powerful new areas of science and involve complex new technologies and, consequently, they are typically very expensive.

However, the inability to fund more grants illustrates the limitations of the proposed 5.6 percent increase. The total number of funded projects will rise only less than one percent, and the number of new grants awarded will actually decrease. With the continued increase in the NIH budget that we advocate here, it is now time to turn our attention toward investigator-initiated projects and substantially increase their numbers.

In summary, the best way to sustain the phenomenal productivity flowing from laboratories across the country is through competitively reviewed, investigator-initiated research projects. Further increasing the number of investigator-initiated projects will accelerate our efforts to prevent, treat and cure diseases affecting millions of Americans and their families.

Hand in hand with the need for more research projects is the need to invest in the training of more scientists. We need to inspire young people to pursue careers in science. To attract a new generation of highly talented individuals, we must present them with a vision of opportunity to make a career in academic biomedical research with a realistic chance for success. Funding new investigators brings new and creative ideas into science and sets the stage for future progress. A decrease in new grants sends a devastatingly negative message to the young people of this nation.

The absolute number of proposals from first-time applicants has declined as a percentage of total grant applications during the 1980s and 1990s. This is an unfortunate loss to the science community, as young investigators have frequently been the source of the novel insights that have led to major scientific breakthroughs. We are successful at ensuring that our young scientists have the appropriate skills to succeed, but we must also make sure that they do not lose the desire or lack the means to establish their own laboratories and initiatives. Therefore we encourage NIH to continue developing and implementing competitive funding mechanisms that provide salary support and start-up funding to facilitate the transition of outstanding young investigators from their post-doctoral training to independent positions.

One indispensable group of researchers, physician-scientists, is already facing a critical shortfall. Physician-scientists bring a unique perspective to medical research and education. This group plays an essential role in the cross-fertilization between medical research and medical practice. Their contributions in laboratory and clinical settings are central to the progress in the battle against disease. In addition, they play an essential role in training tomorrow's physicians in the practice of scientific medicine. To ensure the rapid and effective translation of research knowledge into health care practice, and to ensure that insights from medical practice reach the laboratories, we need to have a strong cadre of physician-scientists working in medical schools and teaching hospitals across the nation.

Concern over the relative decline in the numbers of physician-scientists led FASEB to initiate a major review of issues related to the education and career development of this important research resource. Our study concluded that there is a real threat to the future supply of physician-scientists. There has been a decline in the number of new physicians choosing to pursue research careers. Concomitantly, the current pool of physician-scientists is aging. We found that the proportion under the age of 45 was at an all-time low. These findings suggest that we may have lost our ability to recruit young, talented physicians to careers involving research.

One plausible cause for this trend is that increasing medical school debt compels newly trained physicians to enter clinical practice in order to pay off their sizable loans. Other possible factors include a dearth of physician-scientist role models in

medical schools and residency training programs, a decrease of emphasis on research and the science underlying medicine in medical school curricula, as well as perceptions that the research career is too daunting or prone to failure. Furthermore, declining revenues in academic medical centers (brought on by managed care and other external forces) have tended to increase the clinical burdens placed on physician-scientists and have adversely affected the attractiveness or feasibility of this career path.

Combined M.D./Ph.D. programs such as the Medical Scientist Training Program (MSTP) have been quite successful in producing physician-scientists; however, these programs do not support many or most M.D./Ph.D. candidates because funding for positions in these programs is so limited. FASEB therefore recommends that you enhance the contribution of this successful program by doubling its budget, thereby increasing its capacity to recruit and train bright, young physician-scientists.

MSTP and other M.D./Ph.D. programs are designed for first-year medical students who know they seek a career in medical research; however, there are also insufficient training opportunities for medical students and medical graduates who become interested in pursuing this career path after their medical training begins. FASEB has proposed a series of recommendations to correct this situation:

—a national program for debt forgiveness for physicians who receive rigorous research training and pursue research careers;

—support for the training and mentoring of early career physician-scientists through expansion of research training programs for medical students, residents and physicians who have already completed specialty training; and,

—elimination of the statutory salary caps on NIH awards to extramural investigators so as to remove disincentives to research careers in medical centers.

Our principal reason for submitting our perspective to the subcommittee is to ask their continued support for doubling NIH funding by fiscal year 2003. We need to fund more research projects and support more researchers. Quantifiable results will take time to see from this new investment. But as evidenced by the spectacular achievements resulting from our past investment that are being realized in doctor's offices and biotechnology companies today, the funds that we invest now will yield amazing future results that will further revolutionize medicine.

For instance, a recent NIH-sponsored breast cancer prevention trial offers to make an enormous impact on public health, and the lives of countless American women, by providing the first proven measure to reduce the risk of breast cancer. In this trial, the drug tamoxifen, was shown to reduce the incidence of breast cancer in women at high risk for the disease. The underlying evidence that led the NIH investigators to pose this particular question was grounded in studies initiated decades ago. Specifically, tamoxifen was first developed more than 20 years ago as a treatment for breast cancer, and the genetic mapping efforts that culminated in the identification of two breast cancer related genes, BRCA 1 and 2, were also initiated in the 1980s. Today, scientists are continuing to look for other drugs that might similarly reduce the risk of cancer and also reduce the side effects associated with use of this drug in some women. Thus, the cycle continues and the gains to be had are amplified. But such benefits take time to accomplish.

Another example is the discovery that mutations of the RET proto-oncogene cause medullary thyroid carcinoma; a cancer that is often hereditary and is difficult to treat once it develops. This discovery made it possible to identify the carriers of this mutated gene within high-risk families with 100 percent certainty. The thyroid gland of carriers of the mutated gene could then be removed in early childhood before any tumors developed and metastasized. NIH-funded research supported investigators at each stage of this work from the discovery of this gene to the mapping of the genetic locus and the identification of mutations. Nearly 15 years elapsed from the initiation of the mapping to the identification of the causative gene. Today, the discovery process stemming from this research continues with the identification of other components in the RET system and the unexpected recent recognition that mutations in some of these other components cause Hirschsprung disease, which is the most common cause of intestinal obstruction in childhood.

In conclusion, Mr. Chairman (and members of the subcommittee), the public has expressed its support for increased funding for medical research and leaders both in Congress and in the Administration have supported the goal of doubling the NIH budget within five years. Funding increases in the last two years have enabled NIH to sow the seeds of discoveries that we will reap three to five years from now. With increased support for young investigators and physician-scientists, we will inspire and encourage researchers who will continue to make these discoveries a decade from now.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

I am Susan Pingleton, M.D., FCCP, President of the American College of Chest Physicians, Professor of Medicine at the University of Kansas Medical Center, Director of the Pulmonary and Critical Care Division at the University of Kansas Medical Center, Medical Director of the Medical ICU, Chair of the ICU Committee, and a member of the KU Internal Medicine Foundation Board Trustees and the Graduate Medical Education Committee.

Thank you for affording me the opportunity to submit this testimony for the record on behalf of the American College of Chest Physicians ("ACCP"). The ACCP is a professional medical specialty society of more than 14,500 physicians, scientists, allied health professionals and educators who specialize in diseases of the heart, lungs, and circulatory system. Since it was established in 1935, the College has been a leader in cardiopulmonary medicine. Its members are specialists in pulmonology, cardiology, cardiovascular and cardiothoracic surgery and critical care medicine. The College provides a unique opportunity for these specialists to further their professional education and to combine expertise from several disciplines in the study of heart and lung disease.

The ACCP appreciates the opportunity to offer its views to this important Committee on fiscal year 2001 appropriations for the National Institutes of Health ("NIH") and the Centers for Disease Control and Prevention ("CDC"). The ACCP is proud of its historic role in working with and supporting various institutes at NIH who in turn support and encourage biomedical research of great importance to our patients and the entire country.

The President's budget request for NIH of approximately $18.8 billion, while laudable, does not go far enough to prevent and combat all of the health problems over which the NIH has responsibility. We applaud this Committee's efforts to make fiscal year 2000 funding for the National Institutes of Health a top priority, but we still need to commit substantial resources to research and prevention of pulmonary and cardiovascular disease. Therefore, the College urges you to appropriate a 15 percent increase over fiscal year 2000 funding for the overall NIH. We agree with such groups as the Ad Hoc Group for Medical Research Funding and the American Heart Association that an increase of this level is necessary to sustain the high standard of scientific achievement embodied by the institutes. Thus, we recommend a fiscal year 2001 appropriation of $20.6 billion for the NIH. We also support a 15 percent increase over fiscal year 2000 funding for NIH heart and lung research specifically.

The College supports significant increases to the budgets of the National Heart, Lung and Blood Institute ("NHLBI") and the National Institute of Allergy and Infectious Disease ("NIAID") to levels that will enable these fine institutes to continue their wide spectrum of research, both basic and applied, for the prevention and treatment of cardiovascular and lung disease. With respect to the NHLBI, the ACCP recommends a fiscal year 2001 appropriation of $2.330 billion. This level of funding will allow the NHLBI to expand many of its existing programs and fund exciting new initiatives. The NHLBI is committed to maximizing the use of new technologies that are quickly becoming available and ensuring that standard health practices throughout the country reflect a thorough utilization of the knowledge that researchers and health professionals have acquired. This increase in funding will allow the NHLBI to expand its programs for genomic analysis in cardiovascular, lung, and blood diseases, in an effort to more precisely identify the causes and appropriate treatments of disease. NHLBI will be able to continue and advance a pilot program that is testing new uses of MRI technology to diagnose heart attack patients who may be candidates for thrombolytic therapy, a clot-dissolving treatment that may be able to significantly limit damage from heart attacks. This increase in funding will also enable NHLBI to establish innovative new clinical research networks, and study the underlying reasons for health disparities among various segments of the population in order to reduce these disparities.

Combating asthma is a high priority for the College. We know it is a priority for both the NHLBI and NIAID. The ACCP supports a fiscal year 2001 appropriation of $935 million for NIAID, not including the estimated allocation for AIDS. More than 50 million Americans suffer from allergies and/or asthma, and these diseases are major causes of illness and disability. The economic costs associated with asthma are enormous. Asthma costs the U.S. about $7.5 billion annually. Between the years 1980 and 1994, the prevalence of asthma in the U.S. rose 75 percent. The prevalence of pediatric asthma rose 160 percent during these years. In addition, asthma morbidity and mortality rates have been increasing in the United States over the last decade, with over 5,500 people dying in 1996 as a result of an asthma attack. These increases have been concentrated disproportionately in children and

minorities. These increases are alarming to the ACCP. We therefore strongly support the efforts of the NHLBI and NIAID in working to establish control over this disease.

The need for continued funding of tuberculosis ("TB") prevention and treatment is painfully clear. TB is the eighth leading cause of death worldwide. Two million people will die from TB this year. One out of every three people in the world has latent TB, thus creating a huge potential for transmission of the disease and development of active TB. Multi-drug resistant TB, which is caused by incorrect or incomplete treatment, is an increasing problem in this country and throughout the world, with as many as 50 million individuals infected. Multi-drug resistant TB kills more than half of those infected in the United States and is usually fatal in the developing world. These statistics underscore the necessity of continued funding for TB prevention and treatment activities.

Given the ease with which TB is transmitted, however, the statistics of reported cases do not reveal the whole story. Consider these statistics: an infected person with a normal immune system has approximately a 10 percent lifetime risk of developing active TB. If a person is HIV co-infected, he or she has an 8 percent annual risk of developing active TB. Therefore, if a person is infected with HIV and TB, and lives five years from the time of the TB infection, there is a 40 percent chance that person will develop active TB with the risk it will be spread to others. If that same person lives 12 years, it is a virtual certainty that he or she will develop active TB. With the lives of our children at stake, our Nation's future, now is not the time to reduce funding for TB. A decrease in federal funding is likely to lead to a surge in active TB cases, including deadly multi-drug resistant TB cases. Tuberculosis is an immense economic drain on families and on nations and is a significant cause of poverty. The ACCP, therefore, urges this Committee to increase funding for TB prevention and treatment activities. Through its federally-funded research, NIAID has already determined the complete genomic sequence of two strains of the TB bacterium. These exciting breakthroughs are crucial to NIAID's plans to develop a TB vaccine, but these efforts cannot advance without Congress's substantial financial support.

We urge the Congress to support basic and applied research to the fullest capabilities. Without it, many of the crucial health benefits produced by the NIH would not be possible. With respect to the NHLBI, we continue to be impressed with the quality of leadership of its Director, Dr. Claude Lenfant. Research sponsored by the NHLBI has led to tremendous strides in combating cardiovascular and pulmonary diseases as well as hematological disorders. We recognize the strains that have been placed upon the federal budget in recent years. Nonetheless, diseases of the heart and lungs continue to pose the most serious threat to our Nation's health. The desirability of exercising fiscal austerity should not cause us to lose sight of the significant health and financial benefits of funding medical research. The recent scientific achievements of the NIH, and in particular NHLBI, have created promising opportunities for understanding disease and improving medical care. In order to benefit from these efforts and create new opportunities for advancement, Congress must increase its funding of both existing and proposed research projects.

These scientific achievements hold a personal interest for me. I was born with a serious heart defect that had to be corrected through primitive cardiac surgery when I was a child. I had to be packed in ice to slow down my heart rate. Today, bypass machines do this work, leaving surgeons to concentrate on the heart itself. My heart stopped during the operation, and the resulting nerve and muscle damage to my legs required me to learn how to walk again. I was given a low probability of surviving past my teenage years, yet here I am today, partially due to scientific achievements.

These experiences led me to enter into the medical profession. They also lead me now to support substantially increased funding for clinical research. Indeed, we believe that NIH in general and NHLBI in particular ought to devote greater resources to clinical research, the primary focus of many of our members.

I am compelled to share with the Committee some very telling NIH statistics about the prevalence of heart and lung disease. Cardiovascular diseases afflict more than 60 million people. Cardiovascular diseases account for nearly 1 out of every 2 deaths in the U.S., and lung disease accounts for 1 out of every 7 deaths in the U.S. In addition to the untold costs of human suffering, the economic costs associated with diseases of the heart, blood vessels, lungs and blood represent 25 percent of the total economic costs due to illness, injury, and death in 1999. More than 30 million Americans suffer from a chronic lung disease. Lung diseases alone cost the U.S. economy an estimated $85 billion annually in direct medical expenditures. The most telling statistic, however, is that heart disease continues to be the number one cause of death in this country. Cerebrovascular disease ranks third, and chronic ob-

structive pulmonary disease (COPD), including asthma, ranks fourth. Thus, three of the top four leading causes of death are diseases that NHLBI is charged with combating.

These numbers point to NIH's need for continued federal support for its vital programs. The ACCP continues to do its part to support research. Through our CHEST Foundation, many ACCP members voluntarily donate their own funds every year to support young investigators. This year, the CHEST Foundation will award more than 20 clinical research grants to young investigators. We believe this is unique compared to other medical societies. We are committed to improving the quality of the lives of the most important people we represent—our patients. But we cannot do it alone. NIH appropriation levels must be increased to ensure that our progress toward that goal is not thwarted. The Federal Government must not waiver in its strong commitment to biomedical advances of the future that would yield tens of billions of dollars in health care savings. Therefore, funding levels consistent with the important goals and essential mandate of NIH must be achieved.

As first hand observers of hundreds of thousands of deaths each year caused by tobacco usage, the members of the ACCP urge this Committee to fully fund the tobacco control efforts of the NIH and Centers for Disease Control and Prevention ("CDC"). Smoking is the primary cause of preventable death and disability in America, causing more than 400,000 deaths, and costing approximately $89 billion annually in medical expenses alone. An estimated 48 million Americans smoke cigarettes, and over time, about half will suffer death or disability as a result of their addiction. Smoking diseases, such as lung cancer, emphysema, and coronary artery disease, and other cardiopulmonary diseases have become a major socioeconomic problem of transcending importance. Treatment of these diseases will continue to drain over $800 billion from the Medicare Trust Fund. There are over 40 diseases/conditions that are caused by or aggravated by the use of tobacco. Lung cancer is the leading cause of cancer-related death in our population. Yet, the numbers of cancer diagnoses could be drastically reduced if we could make serious inroads by curtailing the use of tobacco—the number one cause of lung cancer. The NHLBI has made important strides in identifying the deleterious health effects of smoking, especially with respect to women. The ACCP, which has its own Task Force on Women, Smoking, and Lung Cancer, supports the Institute's continued efforts in this important area.

Increasing social, political, and legal pressure nationwide against smoking has, overall, made a modest dent in reducing the prevalence in smoking. As physicians, we confront on a daily basis debilitating disease and death that result from inhalation of tobacco smoke. While the ACCP has been active for more than 30 years in educating the public about the harms of smoking, even our best efforts cannot match the power of Congress to direct funds to combat lung cancer and other deadly diseases that result from tobacco use.

As part of our commitment to improving the health of our patients, the ACCP supports the work of the CDC in reducing death and chronic morbidity caused by tobacco use. Adequate funding of the tobacco-related research and state initiatives of the CDC are critical. We urge Congress to increase funding for this tobacco prevention work at the CDC to $130 million. CDC plays a leadership role in implementing and coordinating state-based efforts and is focused on preventing initiation among youth and promoting cessation. States that are planning to commit tobacco settlement funds to tobacco prevention have requested considerable technical assistance from CDC as they seek to develop comprehensive and effective state programs. States such as Florida, Massachusetts and Mississippi that already have comprehensive programs in place relied considerably on CDC's expertise. Funds for tobacco prevention at CDC are also used to maintain a comprehensive database of smoking and health information and conduct laboratory work regarding the dangers of nicotine and other toxic compounds in tobacco. An appropriation of $130 million will significantly expand the capacity of health and education departments to build and evaluate comprehensive tobacco control programs, develop and promote health communication campaigns for target audiences, and expand school health programs that equip young people with the skills and knowledge to avoid tobacco addiction.

Medical science has made giant strides in eliminating some diseases that have afflicted populations in the United States and throughout the world. The ACCP continues to seek new and improved treatments and procedures to ameliorate the effects of diseases resulting from the direct and indirect inhalation of tobacco smoke. We urge this Committee to take action to curtail the national epidemic of tobacco-related death and disease and to protect our Nation's children from tobacco addiction and disease.

On behalf of the American College of Chest Physicians and our millions of patients, I would like to thank you for affording us this opportunity to submit our

views for your consideration. The ACCP would be happy to answer any questions you may have in the future.

PREPARED STATEMENT OF THE AMERICAN GASTROENTEROLOGICAL ASSOCIATION

SUMMARY OF RECOMMENDATIONS

The American Gastroenterological Association ("AGA") urges Congress to increase funding for medical research on digestive diseases and disorders over fiscal year 2000 by 15 percent for the National Institutes of Health ("NIH"), by 41 percent for the Centers for Disease Control and Prevention ("CDC"), and by 47 percent for the Agency for Healthcare Research and Quality ("AHRQ"). Within NIH, AGA recommends at least a 15 percent increase for the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), the National Cancer Institute ("NCI"), and the National Institute of Allergy and Infectious Diseases ("NIAID").

MEDICAL RESEARCH RECOMMENDATIONS

AGA appreciates the opportunity to present its views regarding fiscal year 2001 appropriations for NIH, CDC, and AHRQ. AGA is the nation's oldest, not-for-profit specialty medical society, consisting of over 10,000 gastroenterologic physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. As the nation's largest and leading voice of the gastrointestinal research community, AGA is uniquely qualified to advise Congress on the current status of federally-supported digestive disease research programs and the areas in need of further research.

Each year more than 62 million Americans are diagnosed with digestive disorders.—Among the more common gastrointestinal disorders are inflammatory bowel disease, irritable bowel disorders, gastrointestinal cancers, and foodborne illness. In some of these areas, medical research has brought us close to developing lifesaving treatments and cures. Yet, in others, we still lack even a basic understanding of the cause and transmission of the disease. This testimony focuses on these serious health problems and makes recommendations on how Congress should allocate this country's precious medical research dollars. Specifically, AGA recommends that Congress urge NIH to issue research grants in the following areas:

—Intestinal diseases caused by combinations of luminal (including nutritional and bacterial), environmental, and genetic factors with an emphasis on inflammatory bowel diseases and GI cancers;

—Modulation and understanding of epithelial injury and repair to include: understanding of epithelial cell cycle regulation in the GI tract; the effect of aging; and studies of epithelial stem cells and their use for developing new approaches to organogenesis;

—Cellular and molecular regulation of intestinal nutrient and electrolyte transporters—to include effects of nutritional factors, genetic abnormalities, aging, and disruption of transport function to understand physiology and pathobiology; and

—Development of physiologic tests to characterize the phenotypic subgroups of functional gastrointestinal disorders, including non-ulcer (functional) dyspepsia, functional constipation and irritable bowel syndrome (motility).

The following discussion supports the need for research in the aforementioned areas.

Inflammatory Bowel Disease (Ulcerative Colitis and Crohn's Disease)

It is estimated that one million Americans have inflammatory bowel disease ("IBD").—The two forms of IBD are Crohn's Disease and Ulcerative Colitis. Crohn's Disease usually causes intermittent inflammation deep within the intestinal wall of the small intestine whereas Ulcerative Colitis causes continuous inflammation and sores in the top layers of the lining of the large intestine. Although older and younger people may also develop this disease, IBD usually begins between the ages of 15 and 40 and persists throughout life with remissions. IBD affects people in the prime and most productive years of their lives and results in substantial morbidity and economic loss to them and society. It is especially brutal in children who may suffer developmental delays or stunted growth. People with IBD experience abdominal pain, fever, bowel sores, intestinal bleeding, anorexia, weight loss, fullness, diarrhea, constipation, and vomiting. In severe cases, IBD can cause death. In addition to potentially disabling gastrointestinal problems, people with this disease may also suffer from arthritis, skin problems, inflammation of the eyes or mouth, kidney stones, gallstones, or other diseases of the liver and biliary system. Further, ap-

proximately five percent of people with ulcerative colitis will develop colon cancer with the risk increasing based on the duration and extent of involvement of the colon.

Studies on the cause of IBD are desperately needed in order to have a better understanding of the disease and work towards more effective management and treatment. Specifically, AGA recommends that NIDDK support genomic research aimed at identifying abnormal genes in persons with IBD and finding the causes of IBD.

Motility Disorders

It is estimated that up to thirty percent of all Americans may be affected at some time during their lives by motility disorders.—Irritable bowel syndrome ("IBS"), the most common motility disorder, is especially troubling because a patient does not present with any pathognomonic symptoms or laboratory findings of the disease, making diagnosis and treatment extremely difficult. Instead, patients present with abdominal pain, bloating, gas, diarrhea, and constipation. It is believed to be caused by overly sensitive intestines that have muscle spasms.

Further research is needed in this area due to the high prevalence and the lack of a basic understanding of IBS, a factor which has made drug manufacturers reluctant to fund research. If more federally funded research was focused on IBS, it would stimulate more private-public partnerships, and lead to advances in medical knowledge. As such, AGA urges Congress to direct the NIDDK to focus additional resources on IBS and to encourage the Office of Research on Women's Health to devote more of its attention to these areas of research in light of the high incidence of IBS among women. Specifically, AGA recommends that NIDDK support research into the development of physiologic tests to characterize the phenotypic subgroups of functional gastrointestinal disorders, including non-ulcer (functional) dyspepsia, functional constipation, and irritable bowel syndrome (motility).

Gastrointestinal Cancers

Approximately 226,600 new cases of gastrointestinal cancers will be diagnosed this year.—Sadly, 129,800 Americans will die from these cancers. The most common cancers involve the colon/rectum, stomach/esophagus, and pancreas.

—*Colorectal cancer is the second leading cause of cancer-related deaths in the United States and ranks fourth as the most common cancer.*—Although risk factors, such as race (increased prevalence and mortality for African Americans), influence the development of this cancer, 70 percent to 80 percent of colorectal cancer cases involve average-risk individuals. If diagnosed early, this cancer is highly curable. However, many people with colorectal cancer are asymptomatic until the later stages of the disease and wait to seek professional advise until this time. As such, research and early detection through screening remains the key to preventing, treating, and curing this disease. We applaud Congress for its major step forward in preventing and curing this disease by providing Medicare coverage for screening and declaring March "National Colorectal Cancer Awareness Month". We encourage Congress to continue this work and require coverage for screening for all Americans. Further, we urge Congress to support additional research on colorectal cancer. Finally, we commend NCI for its work on the Progress Review Group ("PRG") for colorectal cancer.

—*Pancreatic cancer will be diagnosed in 28,300 Americans in 2000 with 28,200 people projected to die from this disease.*—It is a highly lethal form of cancer with the lowest survival rate among all major malignancies. Like other digestive cancers, this cancer is frequently asymptomatic. African Americans have a 50 percent higher incidence and mortality rate than Caucasians. Further, age may increase the risk for this disease because the average age at diagnosis is 70 and it rarely occurs before 40. Diabetes mellitus has also been linked to the development of this cancer. We appreciate NCI's recognition of this growing problem and the need for research in this area through its establishment of pancreatic cancer PRG.

—*Of increased concern to AGA are esophageal and stomach cancers. Lower esophageal and upper stomach cancers are the second most common gastrointestinal cancers.*—It is projected that 33,800 Americans will be diagnosed and 25,100 will die in 2000 from these cancers. These cancers also often remain undetected because they are asymptomatic or present with vague symptoms. In fact, only 10 percent to 20 percent of patients with stomach cancer are diagnosed at an early stage. Both are more common in African Americans with stomach cancer also occurring more frequently in Hispanics and Asian Americans. Of heightened concern to AGA is Barrett's esophagus, a precursor to esophageal cancer, and the relationship between Barrett's and chronic gastroesophageal reflux disease ("GERD"). Five to ten percent of people with Barrett's esophagus develop

cancer of the esophagus. We urge Congress to direct the NCI to fund a Progress Review Group ("PRG") on esophageal and stomach cancers to further study these deadly diseases. AGA encourages the NIDDK to support research into the modulation and understanding of epithelial injury and repair to include the understanding of epithelial cell cycle regulation in the gastrointestinal tract and studies of epithelial stem cells and their use for developing new approaches to organogenesis and transplantation.

Foodborne Illness

Foodborne illness is estimated to cost annually $5 to $6 billion dollars in direct medical costs and productivity losses.—Most foodborne illnesses attack the gut causing gastrointestinal problems which may lead to dehydration and shock, and if not treated, death from vascular collapse and renal failure. Those populations at-risk for severe repercussions from foodborne illness include those with decreased immune systems, pregnant women and fetuses, young children, elderly, and those with inadequate access to health care. We appreciate NIDDK's efforts to further our understanding of this illness through its RFA on foodborne illness research which was cosponsored by AGA through the American Digestive Health Foundation ("ADHF") and the National Cattlemen's Beef Association. AGA recommends that Congress encourage the NIH, including NIDDK and NIAID, and others conducting foodborne illness research like the United States Department of Agriculture and the CDC to concentrate more intensively on research into treatments for foodborne illness. AGA urges NIDDK and NIAID to support research on (1) intestinal diseases caused by combination of luminal (including bacterial), environmental, and genetic factors with an emphasis on inflammatory bowel diseases, and (2) the reaction of the gut to foodborne pathogens, including research on the pathogenesis of the disease, the reasons for antibiotic resistance, the reaction of the gut to infections, the development of animal models to test therapies, and the invention of vaccines or substances that bind with the toxins to prevent the illness.

Training of Physician-Scientists

While research has expanded our medical knowledge and enabled providers to better prevent diseases, diagnose disorders, and treat people, there is growing concern that the number of physician-scientists (e.g., investigators who have medical degrees) is declining and that this decline will negatively impact many key future research endeavors. A recent study documenting this decline points to the tremendous debt incurred by medical school graduates who have more lucrative options outside of research as a primary cause. See Tamara R. Zemlo et al., The Physician-Scientist: Career Issues and Challenges at the Year 2000, 14 The FASEB Journal 221–230 (2000). Also influencing this trend is a decline in mentorship due to a decrease in the number of physician-scientist faculty in basic science departments and the increased clinical responsibility currently assumed by such faculty members. AGA views this problem as an immediate and serious threat to the future of biomedical research generally, and gastrointestinal research in particular. As such, AGA urges Congress to take the following steps:

—Increase pre- and post-doctoral research training stipends;
—Raise the salary cap for individual grant recipients to the maximum amount allowable under the Senior Biomedical Research Service; and
—Enact the "Clinical Research Enhancement Act of 1999" (H.R. 1798, S. 1813).

PREPARED STATEMENT OF THE NATIONAL DEPRESSIVE AND MANIC-DEPRESSIVE ASSOCIATION

The National Depressive and Manic-Depressive Association is pleased to have this opportunity to submit written testimony in support of fiscal year 2001 funding for mental health research supported by the National Institutes of Health and the National Institute of Mental Health.

With nearly 300 affiliated groups in nearly every major metropolitan area, National DMDA is the nation's largest patient-directed, illness-specific organization committed to advocating for research toward the elimination of mood disorders; educating patients, professionals and the public about the nature of depression and manic-depression as treatable medical diseases; fostering self-help; eliminating discrimination and stigma; and improving access to care. National DMDA was founded in 1986 and is headquartered in Chicago, Illinois. A distinguished Scientific Advisory Board of nearly 65 members reviews all materials published by National DMDA for medical and scientific accuracy and provides critical and timely advice on important research opportunities and treatment breakthroughs. This Board includes the leading researchers and clinicians in the field of mood disorders.

THE IMPACT OF MOOD DISORDERS

More than 20 million American adults suffer from unipolar or major depression every year. An additional 2.3 million people suffer from manic-depression or bipolar disorder. Women are more than 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, their symptoms are blamed on personal weakness. Depression is the leading cause of suicide in the United States. In fact, the suicide rate is 50 percent higher than the homicide rate in the United States.

According to a recent study by the World Health Organization (WHO), the World Bank, and the Harvard School of Public Health, unipolar major depression is the leading cause of disability in the world today and bipolar disorder is the seventh-ranked cause of disability. The economic cost of mood disorders in the United States was estimated in 1996 to be almost $44 billion per year in direct and indirect costs including absenteesim, mortality and lost productivity. The fact that mood disorders carry a higher burden of disease in our society than cancer illustrates the need for more adequate funding in this area for research. We can no longer continue to ignore the burden of mood disorders for our society and must focus our research resources on better understanding these illnesses, significantly improving treatments, and seeking a cure.

PROGRESS IN DIAGNOSIS, PREVENTION AND TREATMENT

Depression and manic-depression are highly treatable medical illnesses, if diagnosed and treated correctly. In fact, their treatment success rates are higher than for other chronic illnesses. However, one of the biggest obstacles to expanding access to services is the historical stigma surrounding mental health treatment, exemplified by arbitrary and unfair limits placed on access to mental health services by private health insurance plans. Access to treatment due to financial limitations is, for many patients, a huge barrier.

Increased public awareness and understanding of mood disorders would contribute significantly to improved diagnoses and treatment rates for these potentially fatal illnesses. Tragically, individuals untreated or undertreated for major depression have a suicide rate in excess of 15 percent. The rate for those with untreated or undertreated bipolar disorder is over 20 percent.

National DMDA is encouraged by the heightened attention being paid to mental illness as evidenced by last year's White House Conference on Mental Illness and the recent Surgeon General's Report on Mental Health. Getting people to talk openly and publicly about mental illness is an important first step toward reducing the stigma. But there is much left to be done.

As the Surgeon General's report notes, there is a link between research yielding explanations of and effective treatments for mental illnesses and reduction of this stigma. We know that science destigmatizes. As more and more people come to understand that mood disorders are medical illnesses, not character flaws, and that they are treatable, we can make significant reductions in both the human and economic costs of these illnesses.

Research supported by NIMH has already led to many discoveries resulting in improved diagnostics, prevention, and treatments, which has saved lives and billions of tax dollars. For example, more than $145 billion has been saved since 1970 as a result of the development of lithium treatment for bipolar illness—almost $6 billion per year. A study supported by NIMH showed that intervention to prevent depression in the workplace resulted in $1,314 per person in increased federal and state taxes generated over a two and a half year period, with a cost of only $286 per person. Finally, it has been shown that every $1 spent on treatment of mood disorders yields between $3 and $9 in net economic return on employment earnings.

NIMH-supported research has led to new and more effective medications for both depression and manic-depression. We also have a better understanding of mood disorders and are learning more about their impact on cardiovascular disease, stroke and diabetes. The co-morbidity of depression and alcohol and tobacco use is also becoming clearer. Research indicates that treating addiction but not depression leads to failure and relapse and vice versa.

GENETICS

Current research indicates that there is a genetic predisposition to manic-depressive illness and major depression, involving multiple genes. Understanding the genetic basis of mood disorders will lead to vastly superior methods of prediction, diagnosis, treatment and prevention. We support a continued investment in NIH to

achieve the completion of the human genome sequencing project and applaud the accelerated timetable for completion. Mapping of the human genome will be critical to uncovering the genetic factors involved in mental illness and clarifying the phenotypes of major mental disorders. We are pleased that NIMH has compiled a database of families with mental illness for genetic analysis as the science and technology becomes available in the near future. A high priority should also be the epidemiology and clinical evaluation of individuals with manic-depression and their family members. Of utmost importance as these projects move forward is respect of the privacy of those individuals involved, especially given the continued struggle to fight the stigma of mental illness. Confidentiality is of critical importance in the management of all medical records.

CLINICAL RESEARCH

National DMDA believes that the translation of research from the laboratory to the bench in a rapid and efficient manner is of paramount importance and is pleased to see the Surgeon General's report and NIH leadership acknowledge the need for increased clinical research. The expansion of NIMH's Translational Centers program, dedicated to rapidly moving basic science from the lab into the clinical setting, is another strong step toward getting new and improved treatments to patients more quickly. Requiring third-party payors to support important patient care costs associated with promising experimental therapeutics would further facilitate completion of clinical evaluation at the earliest possible moment.

National DMDA plays an important role in several large NIMH-sponsored clinical trials. Our representatives are members of oversight committees for trials studying the effectiveness of treatments for bipolar disorder (STEP–BP), the study of treatments for adolescents with depression (TADS), and the study treatment of individuals with depression who do not benefit from standard initial treatments (STAR*D). We are also on the advisory board of the trial studying the efficacy of Hypericum perforatum (St. John's wort), a compound millions of Americans take with very little scientific data available to show efficacy or safety. National DMDA participates in the oversight of these trials because of its belief that the priority of all clinical trials must always be the safety of the patient.

We fully support NIMH plans to further expand clinical trials of treatments for mental illnesses, including exploration of depression in young children. We urge a significant increase in research of mood disorders in child and adolescents with special emphasis on the efficacy and safety of current treatments, the epidimology of these illnesses and improved diagnostic tools.

MOOD DISORDERS IN CHILDREN AND ADOLESCENTS

The issue of mood disorders in children and adolescents is of particular concern to National DMDA. Up to 2.5 percent of children and up to 8.3 percent of adolescents suffer from clinical depression, which if left untreated is the predominant cause of suicide, the third leading cause of death in males ages 15 to 24.

While mood disorders in children and adolescents is a critical area of concern, virtually no research about this population exists. As the Surgeon General's report points out, to be effective, diagnosis and treatment of mental illness must take into consideration a variety of characteristics including age. Further, identifying depression in children as well as understanding its causes and how best to intervene during childhood offers the best hope for preventing many cases of adult mental illness.

National DMDA supports the aggressive research agenda NIMH is pursuing in this area, including a study to examine the course and outcome of bipolar disorder with onset in childhood and early adolescence, and research examining underlying bioregulatory processes, neurobehavioral system, adolescent pubertal development and their links to major depressive disorder. We are particularly encouraged by NIMH efforts to strengthen the field of children's mental health research by creating new incentives for experienced investigators to move into studies of mental illness in children.

We are pleased that NIMH will play a lead role in the Surgeon General's upcoming report on youth violence and support the continued coordination between NIMH and Centers for Disease Control (CDC) and other agencies to research the relationship between mental illnesses—including mood disorders—and suicide and other forms of violence.

BIPOLAR DISORDER (MANIC DEPRESSION)

The World Health Organization has identified bipolar disorder as the seventh-ranked cause of disability in the world today. Nearly one in 100 Americans suffers from manic depression yet research in this area has been seriously underfunded. In

fact, In 1998, NIMH spent only $39 million on bipolar research and it is expected to spend just $46 million in fiscal year 1999. Congress must continue to increase its investment in this important area of mental health research.

RESEARCH OPPORTUNITIES

National DMDA urges NIMH to pursue genetic research aggressively in collaboration with other NIH Institutes, academia, the private sector and by continuing studies of individuals with manic depression and their family members. Other factors to examine in relation to genetics include building and refining knowledge of risk factors for mood disorders, developing better predictors of risk, designing and piloting new screening measures, advancing early-intervention strategies for these risk factors, and studying the role stress and the environment play.

Neuroscience advances bring us to the brink of tremendous opportunities to understand underlying deficits in major mental disorders. We know more about neurobiology today than ever before and we must support, as a national priority, continued efforts to enable us to more fully exploit our recent advances. Flexibility of connections in the nervous system underlies many of the adaptive responses of the individual to the environment—including response to psychological and physical trauma and the more general processes underlying learning and memory—and such changes in the neural function are central to most mental disorders. The field is now poised to make deep inroads into the understanding of these critical processes.

Other important opportunities include research to better characterize subtypes of depression; to find treatments with fewer side effects and understand the psychopharmacology of current antidepressants; and studies to close the gap between what is known about treating mood disorders and what is practiced, particularly in managed care settings. These are just a few of the research areas where great opportunities exist.

FUNDING REQUEST

An aggressive research agenda requires sustained funding. While we recognize the Subcommittee's budgetary constraints, National DMDA supports the effort initiated in fiscal year 1999 to double the budget for NIH and NIMH by fiscal year 2003. This will allow us to take full advantage of the many exciting mental health research opportunities that exist today. To continue the successes toward achieving this important goal, we strongly support the fiscal year 2001 funding recommendation of the Ad Hoc Group for Medical Research Funding of $20.5 billion for NIH. National DMDA supports a corresponding increase for NIMH.

Sustained, stable growth in funding for NIH is needed to build upon past scientific achievements, address present medical needs, and anticipate future health challenges. Dramatic fluctuations can be as harmful to the research enterprise as inadequate growth.

We appreciate your past support and look forward to working with you in the future to ensure a sustained commitment to mental health research. Together we can provide the gateway to new discoveries that will improve access to care and eliminate discrimination and the stigma associated with depression and manic-depression.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

The American Association of Colleges of Nursing (AACN) appreciates the opportunity to present this statement on funding recommendations for nursing research and education programs within the jurisdiction of the Subcommittee. AACN represents over 540 baccalaureate and graduate nursing education programs in senior colleges and universities across the United States.

We thank the Subcommittee members for providing fiscal year 2000 funding to the National Institute of Nursing Research (NINR) at its full Professional Judgment Budget level. AACN also appreciates the leadership of Chairman Specter and the Subcommittee over the years in funding nursing and health professions education programs to benefit the health and well being of the Nation. Our appreciation extends to the Subcommittee's leadership regarding the Health Resources and Services Administration's (HRSA) Health Profession Programs, particularly the Nurse Education Act (NEA) (Public Health Service Act Title VIII) and Scholarships for Disadvantaged Students (SDS) programs (in PHSA Title VII).

NATIONAL INSTITUTE OF NURSING RESEARCH

Mr. Chairman, we thank you and the Subcommittee for NINR's significant funding increase for fiscal year 2000 at an adjusted level of $89.522 million, an increase of $19.734 million or 28 percent more than the fiscal year 1999 level. The entire nursing community is grateful for this funding level, which brought the estimated success rate for NINR research project grants for fiscal year 2000 to 24 percent, compared to the projected average of 31 percent for NIH overall. This is an enormous improvement over fiscal year 1999 when NINR's success rate was only 14 percent.

Unfortunately the excellent progress made by the Subcommittee last year is threatened by the Administration's fiscal year 2001 request of $92.524 million, an increase of only $3 million or 3.3 percent for NINR. This is the lowest proposed increase of all NIH Institutes and Centers. The fiscal year 2001 request would continue NINR's disproportionately slow growth rate compared to NIH in general. Since 1986, NINR has received only $75.5 million, or 0.6 percent of the total NIH growth of $12.3 billion. In fact, the entire fiscal year 2000 total for NINR is less than the increase provided by the Subcommittee in fiscal year 2000 for 10 NIH Institutes and Centers. Finally, the Administration's proposed NINR funding level would plunge NINR's projected research project grant success rate for fiscal year 2001 to 14 percent compared to the 26 percent success rate projected for NIH overall. Clearly this would result in missing a significant amount of important scientific opportunities.

AACN, supported by the Tri Council for Nursing and the 33 members of the Coalition for Nursing Research Funding, urges funding the NINR at $110 million, $17.476 million above the Administration's request. At this funding level, NINR could conduct significant new research recommended by its Professional Judgment Budget such as: research on health disparities in ethnic groups, self management of chronic illness, expanding end of life research to address pain, nausea, weight loss and caregiver issues, and studying telehealth interventions in rural/underserved populations.

NINR is the lead institute at NIH to coordinate research on end-of-life care that is critically important to our aging population. End-of-life care utilizes many of the skills of nursing such as management of pain, handling of chronic conditions, and family counseling. As the American population continues to age, the importance of this research both to reduce morbidity and health system costs continues to grow. While 13 percent of the current U.S. population is 65 years of age or older, by the year 2030 this proportion is projected to be 20 percent.

The Subcommittee investment in NINR is well justified as nursing research contributes extensively to wellness and health outcomes. The NINR performs a wide span of clinical research, developing and testing interventions to improve patient care, treat disease, manage chronic conditions and address other concerns. There is growing evidence of advances made possible through NINR research, but we will highlight just five recent success stories. AACN believes that based on these and numerous other examples, there is broad agreement that nursing research is making a difference in health outcomes. For example, NINR research has made a difference by identifying interventions to:

—Facilitate early hospital discharges of high risk elderly patients, reducing the length of stays, the hospital re-admission rate and Medicare costs;
—Reduce the rate of low birth weight babies among high risk women, as well a reducing the rate of subsequent emergency room admissions of the mothers and their babies;
—Estimate the (often fatal) improper insertion of feeding tubes with the use of a low cost bedside chemical test;
—Reduce high blood pressure in young urban African-American men at high risk for cardiovascular disease and reduce cholesterol levels in minority children; and
—Avoid the need for nursing home care of elderly women by controlling urinary incontinence.

THE NURSE EDUCATION ACT

The Nurse Education Act (Public Health Service Act Title VIII) helps schools of nursing and nursing students prepare for a changing health care delivery system. Reauthorized in 1998, the NEA offers flexibility through expanding specific program initiatives, including Advanced Education Nurse Grants, Work Force Diversity Grants, Basic Nurse Education and Practice Grants, and an education loan repayment program to attract nurses to practice in shortage areas.

Advanced Education Nurse Grants to schools help educate advanced practice primary care nurse practitioners and nurse midwives. The program also provides grants to educate master's and doctoral students as clinical nurse specialists, public health nurses, nurse administrators, faculty (a major shortage exists), nurse anesthetists, and non-primary care nurse practitioners and includes traineeships for master's and doctoral students with a limit of 10 percent of appropriations for doctoral traineeships. The growing number of elderly, increasing number of individuals with chronic diseases, high infant mortality rates, and rising number of uninsured and underserved individuals all drive the demand for affordable, cost-effective health care. This need is successfully met by nurses with advanced nursing education.

The Work Diversity Grants program provides funds to increase opportunities for nursing education for disadvantaged students including underrepresented minorities by providing scholarships, stipends, pre-entry preparation, and retention activities. In addition to contributing to the preparation of a racially and ethnically diverse nursing workforce, this program contributes to the basic preparation of disadvantaged and minority nurses for leadership positions within nursing and the health care community. The minority enrollment in schools of nursing supported by this program is 46 percent compared to the national average of 19 percent.

The Basic Nurse Education and Practice Grants can support nursing centers as training and care delivery sites, increase undergraduate enrollments (a nursing shortage looms), provide entry level training for practice within underserved populations, managed care facilities, to develop cultural competence and for other purposes. AACN recommends $78 million for Title VIII Nurse Education Act programs in fiscal year 2001, $10.2 million or 15 percent more than requested by the Administration.

SCHOLARSHIPS FOR DISADVANTAGED STUDENTS (SDS)

Scholarships for Disadvantaged Students (SDS) is a PHSA Title VII program that provides funds to disadvantaged and minority health professions students. Federal law directs 16 percent of the funds appropriated to nursing students in the program-making this the major federal scholarship source for undergraduate nursing students.

The goals of the SDS Program are to increase diversity in the health professions and nursing workforce and improve access to health care. The program provides scholarships to financially needy students from disadvantaged backgrounds who are enrolled in schools of nursing, and in programs of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, chiropractic, behavioral and mental health, public health, allied health, and physician assistants. The SDS program allows eligible students the opportunity to pursue health professions or nursing education by eliminating or reducing financial barriers that might otherwise prevent these students from enrolling.

AACN recommends funding the SDS program at $43.7 million for fiscal year 2001, a $5.61 million or 14.7 percent above the fiscal year 2000 level. AACN is a member of and supports the Health Professions and Nursing Education Coalition's recommendation of $335 million for Public Health Service Act Titles VII and VIII, which support health professions and nursing education programs.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to support, conduct, and disseminate research that improves the outcomes, quality, access to, and cost and use of health care services. This mission, which focuses on the effectiveness and value of health care in daily practice, is unique and complements the biomedical and behavioral research responsibilities of the NIH. The products of the Agency include knowledge that supports decision making to improve health care, and tools that help improve quality and reduce costs. In view of the AHRQ's significant contributions to health outcomes, the AACN recommends appropriate increases for the AHRQ budget in fiscal year 2001.

NATIONAL INSTITUTES OF HEALTH

AACN applauds the leadership of Chairman Specter and the Subcommittee in the continuing campaign to double the NIH budget in 5 years. The investment in biomedical and behavioral research has propelled a remarkable transformation in our understanding of the life sciences and has given us a bounty of new ways to prevent, treat, and cure disease. Major threats to public health have been reduced, quality of life has improved, and life expectancy has continued to rise. A child born in the United States today can be expected to live 76.5 years, 3.9 years longer than

a child born in 1975. AACN joins the Ad Hoc Group for Medical Research Funding in recommending a fiscal year 2001 funding level of $20.47 billion for the NIH, a 15 percent increase over the fiscal year 2000 level.

INDIAN HEALTH SERVICE

Mr. Chairman, the Indian Health Services (IHS) provides vital health services to our Native American populations and nursing professionals have been a central component of the IHS health delivery system since the agency's inception. The IHS provides direct health care services in 37 hospitals, 61 health centers, 4 school health centers, and 48 health stations. Tribes and tribal groups, through contracts with the IHS, operate 12 hospitals, 134 health centers, 4 school health centers, and 241 health stations (including 168 Alaska village clinics.) The IHS, tribes and tribal groups also operate 7 regional youth substance abuse treatment centers. AACN recommends increases for the Indian Health Service for fiscal year 2001.

HIGHER EDUCATION ACT PROGRAMS—STUDENT FINANCIAL AND GENERAL ASSISTANCE

There are several student financial and general assistance programs that are particularly important to the nursing community. The Pell Grant Program helps ensure access to post secondary education for low and middle income undergraduate students by providing grants that, in combination with other sources of student aid, help meet post secondary education costs. The Federal Work Study Program ensures access by assisting needy undergraduates and graduate students in financing post secondary education costs through part time employment. The TRIO Programs fund post secondary education outreach and student support services designed to encourage individuals from disadvantaged backgrounds to enter and complete college. AACN recommends increases for each of these programs over the levels provided in fiscal year 2000.

SUMMARY OF AACN HIGHEST PRIORITY FISCAL YEAR 2001 FUNDING RECOMMENDATIONS

[In millions of dollars]

Highest AACN priority recommendation	Fiscal year		Fiscal year 2001 AACN recommendation
	2000	2001	
National Institute of Nursing Research	89.5	92.524	110
Nurse Education Act	67.8	65.576	78
Scholarships for Disadvantaged Students	38.09	38.09	43.7

PREPARED STATEMENT OF THE HUMANE SOCIETY

We appreciate the opportunity to provide testimony to the Labor, Health and Human Services, and Education Subcommittee on two funding items of great importance to The Humane Society of the United States (HSUS) and its 7.3 million supporters nationwide. As the largest animal protection organization in the country, The HSUS urges the Committee to address these priority issues in the fiscal year 2001 budget.

CLASS B RANDOM SOURCE ANIMAL DEALERS

The HSUS is grateful for the leadership of Chairman Specter, Ranking Democrat Harkin, and this Committee in raising concerns last year about the problem of Class B dealers, who acquire the animals they sell to biomedical research facilities from a variety of sources, including "free to good home" ads, animal shelters, and outright theft of family pets. Squalid conditions, abusive handling, sickly and under-cared for animals, and sloppy record-keeping are the hallmarks of Class B dealers. As Robert A. Whitney, D.V.M. and former Director of both the National Center for Research Resources and the Office of Animal Care and Use at NIH, testified in July 1997, "The continued existence of these virtually unregulatable Class B dealers erodes the public confidence in our commitment to appropriate procurement, care, and use of animals in the important research to better the health of both humans and animals."

Committee Report language accompanying the fiscal year 2000 appropriations encouraged NIH to consider extending its intramural research practice of using only purpose-bred animals (not those obtained from Class B dealers) to the extramural

research funded by NIH as well. Unfortunately, NIH has taken no clear steps since last year's legislation to ensure that taxpayer dollars will not be used in the future to support research on animals obtained through Class B dealers. Consequently, we urge the Committee this year to direct NIH, in bill language, not to award grants for research projects that utilize random source dogs or cats supplied by Class B dealers. We commend NIH for its internal research practice, but feel strongly that NIH should exercise the same caution and concern with respect to its grant recipients. The public deserves to know that animals used in government-funded research have not been stolen from their families or obtained through other disreputable means commonly employed by Class B dealers.

CHIMPANZEE SANCTUARIES

We also consider it a high priority for the 106th Congress to enact H.R. 3514, legislation to establish a federal chimpanzee sanctuary system for the permanent retirement of chimpanzees no longer needed in medical research. This cost-effective and humane approach to dealing with the problem of "surplus chimpanzees," who were overbred and languish in laboratories across the country, deserves to be enacted by this Congress. It will save taxpayers considerable money in the long run, and significantly improve the quality of life for these animals who have served humanity but are now simply being warehoused in costly research facilities.

Along with the united support of the animal protection community, H.R. 3514 has been endorsed by more than 100 members of the scientific and academic community who have particular expertise involving chimpanzees, as follows:

Jonathan S. Allan, D.V.M., Scientist—Department of Virology and Immunology, Southwest Foundation for Biomedical Research (San Antonio, TX)

American Zoo and Aquarium Association (Silver Spring, MD)

James Anderson, Ph.D., Senior Lecturer in Psychology—University of Stirling (Stirling, Scotland)

Kate Baker, Ph.D., Research Associate—Yerkes Regional Primate Research Center, Emory University (Atlanta, GA)

Marc Bekoff, Ph.D., Professor of Environmental, Population and Organismic Biology—University of Colorado (Boulder, CO)

Carol Berman, Ph.D., Professor of Anthropology—University of Buffalo (Buffalo, NY)

Tammie Bettinger, Ph.D., Curator of Conservation and Science—Cleveland Metroparks Zoo (Cleveland, OH)

Joseph T. Bielitzki, MS, DVM, Chief Veterinary Officer—NASA (Mountain View, CA)

Mollie Bloomsmith, Ph.D., Director of Research and Director of TECHlab Zoo Atlanta; Affiliate Scientist—Yerkes Regional Primate Research Center, Emory University (Atlanta, GA)

Carolyn Bocian, Ph.D.

Sarah Boysen, Ph.D., Director of Primate Cognition Project and Associate Professor of Comparative Psychology—Ohio State University (Columbus, OH)

Hilary O. Box, Ph.D., Senior Lecturer in Psychology—University of Reading; Vice President for Captive Care, Primate Society of Great Britain and the International Primatological Society (Reading, UK)

Linda Brent, Ph.D., President Chimp Haven, Inc. (San Antonio, TX)

Betsy Brotman, Director—Vilab II (Robertsfield, Liberia) and the New York Blood Center (New York, NY)

Hannah Buchanan-Smith, Ph.D., Lecturer in Psychology—University of Stirling, (Stirling, Scotland)

Thomas Butler, D.V.M.

Richard W. Byrne, Ph.D., Professor of Evolutionary Psychology—The University of St Andrews; Vice President for Membership, International Primatological Society (St Andrews, Scotland)

Nancy Caine, Ph.D., Professor of Psychology—California State University San Marcos (San Marcos, CA)

John Capitanio, Ph.D., Associate Professor of Psychology—University of California at Davis; Staff Scientist—California Regional Primate Research Center

Gary Comstock, Ph.D., Associate Professor of Philosophy and Religious Studies & Coordinator Bioethics Program—Iowa State University (Ames, IA)

Robert Cooper, D.V.M.

Colleen Crangle, Ph.D., Computer Science (Palo Alto, CA)

Steve Davis, D.V.M., Professor of Animal Sciences—Oregon State University (Corvallis, OR)

David DeGrazia, Ph.D., Associate Professor of Philosophy—George Washington University; Senior Research Fellow—Kennedy Institute of Ethics, Georgetown University (Washington, DC)

Frans de Waal, Ph.D., Chandler Professor of Primate Behavior Psychology Department, and Director of LIVING LINKS CENTER—Yerkes Regional Primate Research Center, Emory University (Atlanta, GA)

Wendy Dirks, Ph.D., Assistant Professor of Anthropology—New York University (New York, NY)

Merelyn T. Dolins, Ph.D., Director of Physical Therapy—Department of Child Development and Rehabilitation, Valley Hospital (Paramus, NJ)

Francine L. Dolins, Ph.D., Program Scientist for Research, Behavioral Primatologist Animal Research Issues—The Humane Society of the United States (Washington, DC)

Alessandro Duranti, Editor, Journal of Linguistic Anthropology, Department of Anthropology—University of California at Los Angeles (Los Angeles, CA)

Stephen Easley, Ph.D., Director—Easley and Associates, Professional Consultants (Alamorgordo, NM)

Sian Evans, Ph.D., The DuMond Conservancy (Miami, FL)

Brian Fay, Ph.D., Professor of Philosophy—Wesleyan University (Middletown, CT)

Jo Fritz, Director—Primate Foundation of Arizona (Mesa, AZ); Member, National Research Council Committee that produced 1997 Report, Chimpanzees in Research: Strategies for Their Ethical Care, Management, and Use

Randy Fulk, Ph.D., Curator of Research—North Carolina Zoological Park (Asheboro, NC)

Paul A. Garber, Ph.D., Professor of Anthropology—University of Illinois (Urbana, IL)

Michele L. Goldsmith, M.S., Ph.D., Assistant Professor of Environmental and Population Health Center for Animals and Public Policy—Tufts University School of Veterinary Medicine (North Grafton, MA)

Jane Goodall, Ph.D.—The Jane Goodall Institute (Silver Spring, MD)

Thomas Gordon, Ph.D., Director—Yerkes Regional Primate Research Center, Emory University (Atlanta, GA)

Lisa Gould, Ph.D., Assistant Professor of Anthropology—University of Victoria (Victoria, Canada)

Victoria Hampshire, D.V.M., Director—Advanced Veterinary Applications (Bethesda, MD)

Beatrice H. Hahn, M.D., Professor of Medicine and Microbiology—University of Alabama (Birmingham, AL)

Lynette Hart, Ph.D.

Ned Hettinger, Ph.D., Professor of Philosophy—College of Charleston (Charleston, SC)

Robert A Hinde, Ph.D., Professor Emeritus—Cambridge University; Fellow of the Royal Society; Honorary Foreign Associate of the National Academy of Sciences (Cambridge, UK)

William D. Hopkins, Ph.D., Professor of Psychology—Berry College (Rome, GA); Research Associate—Yerkes Regional Primate Research Center, Emory University (Atlanta, GA)

Sue Howell, Ph.D., Research Director—Primate Foundation of Arizona (Mesa, AZ)

Robert Hubrecht, Ph.D.—University Federation for Animal Welfare, United Kingdom

Ellen Ingmanson, Ph.D. Assistant Professor of Anthropology—Dickinson College (Carlisle, PA)

Thomas Insel, M.D. , Director—The Center for Behavioral Neuroscience, Emory University (Atlanta, GA)

Joseph Jacquot, Ph.D., Professor of Biology—Grand Valley State University (Allendale, MI)

Alicia Karas, D.V.M., Dipl. ACVA, Assistant Professor of Anesthesiology—Tufts University School of Veterinary Medicine, Foster Hospital for Small Animals (North Grafton, MA)

Michael Kastello, D.V.M, Executive Director, Research Resources—Merck & Co., Inc. (Rahway, NJ)

James King, Ph.D., Professor of Psychology—University of Arizona (Tucson, AZ)

Bette Korber, Ph.D., Research Scientist—Santa Fe Institute (Santa Fe, NM)

A. Lanny Kraus, D.V.M., Dipl. ACLAM, Professor Emeritus—Division of Laboratory Animal Medicine, University of Rochester School of Medicine & Dentistry, (Rochester, NY)

Susan P. Lambeth, Environmental Enrichment Director—M.D. Anderson Cancer Center (Bastrop, TX)

Louise Lamphere, Ph.D,, Professor of Anthropology—University New Mexico (NM)

Virginia Landau, Ph.D., Staff Primatologist—The Jane Goodall Institute (Silver Spring, MD); Director—ChimpanZoo (Tucson, AZ)

Clark Larsen, Ph.D., Amos Hawley Professor of Anthropology—University of North Carolina (Chapel Hill, NC)

Alecia Lilly, Ph.D., Research Fellow—Department of Anthropology, State University of New York (Stony Brook, NY)

Orla Mahoney, D.V.M.—Tufts University, School of Veterinary Medicine (North Grafton, MA)

Terry Maple, Ph.D., President and CEO—Zoo Atlanta (Atlanta, GA)

Linda Marchant, Ph.D., Professor of Anthropology—Miami University (Oxford, OH)

Preston A. Marx, Ph.D., Senior Scientist and Professor of Tropical Medicine—Tulane University Medical Center (Covington, LA) and Aaron Diamond AIDS Research Center (New York, NY)

William C. McGrew, Ph.D., Professor of Zoology—Miami University (Oxford, OH)

Patrick Mehlman, Ph.D., Director of Mondika Primate Research Center—Department of Anthropology, State University of New York (Stony Brook, NY)

Robert Mitchell, Ph.D., Associate Professor of Psychology—Eastern Kentucky University (Richmond, KY)

John Moore, Ph.D., Scientist—Aaron Diamond AIDS Research Center, The Rockefeller University (New York, NY)

Toshisada Nishida, Ph.D., Professor of Anthropology, President of the International Primatological Society—Kyoto University (Kyoto, Japan)

April Nowell, Ph.D., Professor of Anthropology—University of Victoria (Victoria, Canada)

John Oates, Ph.D., Professor of Anthropology—Hunter College, City University of New York (New York, NY)

Barbara Orlans, Ph.D., Senior Research Fellow—Kennedy Institute of Ethics, Georgetown University (Washington, D.C.)

Sue Taylor Parker, Ph.D., Professor of Anthropology—Sonoma State University (Rohnert Park, CA)

Gary J. Patronek, VMD, PhD, Director—Tufts Center for Animals and Public Policy (North Grafton, MA)

Andrew Petto, Ph.D., Editor and Assistant Professor—National Center for Science Education, University of the Arts (Philadelphia, PA)

Evelyn Pluhar, Ph.D., Professor of Philosophy—Penn State University (University Park, PA)

Trevor Poole, Ph.D.—University Federation for Animal Welfare (England)

Alfred M. Prince, M.D.—The New York Blood Center (New York, NY)

Jill Pruetz, Ph.D. Postdoctoral Fellow—Department of Anthropology, Miami University (Oxford, OH)

Anne E. Pusey, Ph.D., Distinguished McKnight Professor of Ecology, Evolution & Behavior—University of Minnesota (St Paul, MN)

Ed Ramsey, D.V.M., University of Tennessee

Viktor Reinhardt, Ph.D., Laboratory Animal Specialist—Animal Welfare Institute (Washington, DC)

Vernon Reynolds, Ph.D. Professor of Biological Anthropology—Institute of Biological Anthropology, Oxford University (Oxford, UK)

Anthony Rose, Ph.D., Director—The Biosynergy Institute (Hermosa Beach, CA)

William E. Roudebush, Ph.D., Associate Professor of Obstetrics & Gynecology and Molecular Cell Biology & Pathobiology; Treasurer, International Primatological Society—Medical University of South Carolina (Charleston, SC)

Andrew N. Rowan, D. Phil., Senior Vice President of Research, Education & International Affairs—The Humane Society of the United States (Washington, DC)

Thomas Jefferson Rowell, D.V.M., Director—University of Southwestern Louisiana, Lafayette-NIRC (New Iberia, LA)

Duane Rumbaugh, Ph.D., Director—Language Research Center, Georgia State University (Atlanta, GA)

Lilly-Marlene Russow, Ph.D., Professor of Philosophy—Purdue University (West Lafayette, IN); Member, National Research Council Committee that produced 1997 Report, Chimpanzees in Research: Strategies for Their Ethical Care, Management, and Use

Anthony Rylands, Ph.D.—Conservation International and IUCN/SSC, Primate Specialist Group

Dale Schwindaman, D.V.M.

Jack F. Sharp, President—Biomedical Research Foundation of Northwest Louisiana (Shreveport, LA)

James Serpell, Ph.D., Associate Professor of Humane Ethics & Animal Welfare, and Director—Center for the Interaction of Animals & Society, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania (Philadelphia, PA)

Yukimaru Sugiyama, Ph.D., Professor Emeritus of Kyoto University and Dean of Faculty of Humanities—Tokai-gakuen University; President of Primate Society of Japan

Erna Toback, Ph.D., Assistant Professor of Psychology—Santa Monica College (Santa Monica, CA) and University of Stirling (Stirling, Scotland)

Joel Trupin, Ph.D. Professor of Biochemistry—Meharry Medical School (Nashville, TN)

Caroline Tutin, Ph.D., Senior Research Fellow—Centre International de Recherches Medicales, (Franceville, Gabon); Department of Biological and Molecular Sciences—University of Stirling (Stirling, Scotland)

Augusto Vitale, Ph.D., Research Fellow in Animal Behaviour Section of Comparative Psychology—Laboratorio di Fisiopatologia di Organo e di Sistema, Istituto Superiore di Sanita' (Rome, Italy)

Janette Wallis, Ph.D., Associate Professor of Research—Department of Psychiatry & Behavioral Sciences, University of Oklahoma Health Sciences Center (OK)

Lyna Watson, Ph.D. Affiliated Scientist—Zoo New England (Boston, MA)

Francoise Wemelsfelder, Ph.D., Research Fellow in Animal Welfare, Animal Biology Division—Scottish Agricultural College (Edinburgh, Scotland)

Brent C. White, Ph.D., Matton Professor of Psychology—Centre College (Danville, KY)

Roger D. White, M.D., Anesthesiology (Rochester, MN)

Thomas Wolfle, D.V.M., Retired Director—Institute of Laboratory Animal Research, National Research Council; Program Director, National Research Council Committee that produced 1997 Report, Chimpanzees in Research: Strategies for Their Ethical Care, Management, and Use

Richard Wrangham, Ph.D., Professor of Anthropology—Department of Anthropology, Harvard University (Cambridge, MA)

Stephen L. Zawistowski, Ph.D., Certified Applied Animal Behaviorist, Senior Vice President and Science Advisor—The American Society for the Prevention of Cruelty to Animals; Co-Editor, Journal of Applied Animal Welfare Science (New York, NY)

The HSUS was very pleased to learn of the possibility, raised by House Subcommittee Chairman John Porter at a recent hearing, that H.R. 3514 may be incorporated into the fiscal year 2001 Labor-HHS Appropriations bill. We would strongly support that as a way to ensure enactment of this vital legislation in the 106th Congress. We also strongly support efforts in this appropriations bill to address the crisis facing hundreds of chimpanzees at The Coulston Foundation in Alamogordo, New Mexico, where recurrent mismanagement and inappropriate veterinary care have caused several painful and needless chimpanzee deaths.

Again, we appreciate the opportunity to share our views and priorities for the Labor, Health and Human Services, and Education Appropriation Act of fiscal year 2001. We hope the Committee will be able to accommodate these requests to alleviate some very pressing problems affecting animals across the United States. Thank you for your consideration.

PREPARED STATEMENT OF THE NATIONAL SLEEP FOUNDATION

Mr. Chairman, distinguished Members of this Subcommittee, thank you for allowing us to present testimony on fiscal year 2001 Appropriations for the Centers for Disease Control and Prevention.

The National Sleep Foundation (NSF) is a science-based, non-profit voluntary health organization dedicated to promoting awareness about the importance of good sleep, sleep disorders, and the consequences of sleep deprivation.

The National Institutes of Health estimates that 40 million Americans suffer from chronic sleep disorders the vast majority of which remain undiagnosed and untreated and another 20 to 30 million suffer intermittent sleep-related problems. An NSF survey found that fifty-eight million Americans report suffering excessive daytime sleepiness at levels that interfere with their day-to-day activities. Evidence tells us that Americans sleep debt is on the rise, yet numerous studies have concluded that the general public and primary care physicians lack the basic sleep knowledge to address these problems. As a result, the toll on human health, safety and productivity is enormous. NSF and sleep experts like myself take this chronic sleep deprivation very seriously. Lack of adequate amounts of sleep has been associated with significant physical and mental problems. For example, cardiovascular

disease, gastrointestinal disorders, mood disorders and drug abuse are more prevalent among shift workers. This problem is more than simply getting a good nights rest. It encompasses medical problems, lack of education, and the tools required to address this public health crisis.

Sleepiness, whether the result of untreated sleep disorders or volitional sleep deprivation has been identified as a causal factor in a growing number of on-the-job injuries. This corresponds directly in lost productivity, personal injuries, medical expenses, property and environmental damage due to fatigue, sleep disorders and sleep deprivation and is estimated to exceed $100 billion each year. It is, however, the personal injuries that are the most tragic part of this equation. In my daily practice, I routinely hear stories of drivers who fall asleep at the wheel and kill themselves, a family member, or an innocent bystander.

In the first-ever case-controlled epidemiological study of drowsy driving crashes recently completed by one of our partners, the AAA Foundation for Traffic Safety, work and sleep schedules were strongly associated with involvement in a sleep-related crash. Compared to drivers in non-sleep crashes, drivers in sleep crashes were nearly twice as likely to work at more than one job and their primary job was more likely to involve an atypical schedule. This characterizes many Americans and yet, represents a crisis in our country that remains to be largely unaddressed except by organizations like the National Sleep Foundation and AAA.

The National Sleep Foundation has taken some small steps to work on lowering the number of injuries associated with sleepiness. NSF, in cooperation with many partners, has successfully mounted state programs in New York, Arkansas, California, Washington, Oregon and Idaho that target fatigue-related injuries. In New York, NSF worked with state and federal agencies and other partners to launch the nations first statewide public information and injury prevention program related to the dangers of sleep deprivation. Unfortunately, NSF alone does not have the resources to continue to mount these state-by-state campaigns. Information gathered by our sleep polls and work in the states also suggests that the percentage of population adversely affected by sleepiness is higher than current statistical information provides.

Let us provide one example that illustrates the problem. The AAA study points out that countermeasures or strategies that drivers typically employ, rolling down the car windows, turning up the radio, or stopping to stretch are largely unsupported by the scientific literature. Yet these strategies were often cited by our drivers and are believed by them to be anywhere from somewhat, to very effective in countering drowsy driving. Let us be clear almost all experts agree that the only truly effective strategy drowsy drivers can take to prevent a crash is to immediately stop driving and get some sleep. If this is not possible, drivers should be encouraged to stop, drink some caffeine (the equivalent of two cups of coffee), and take a brief nap before getting back behind the wheel.

Traffic safety data is incomplete due to the difficulty in measuring the role sleepiness played in an accident investigation. This is in part due to the fact that sleepiness is often overlooked when investigating work or traffic related injuries. This problem exists in every area that sleepiness is a problem. Yet we believe, through work at the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC), we can begin to adequately address this crisis, particularly in the area of physician education.

In our discussions with CDC it is clear that sleepiness crosscuts many centers. This is not only an issue for the National Center for Injury Prevention and Control but also the National Institute for Occupational Safety and Health and the National Center for Chronic Disease Prevention and Health Promotion at the very least. The common question of all these Centers revolves around data collection. It is this first step we would propose that the Subcommittee consider providing funding for.

The NSF has the network of experts in the sleep field. The CDC has links to other health divisions who address at risk patient populations including shift workers and adolescents. We seek support for the development of evaluative research, including data collection, through the National Center for Injury Prevention and Control at CDC. This would likely include an attempt to validate or improve existing surveys and survey methodologies. It would also evaluate new ways to capture data and validate program effectiveness. The data from this research will allow us to develop accurate and informative material and model programs to provide to states as they address these important issues.

NSF experts are willing to work with CDC to reach out to corporations and other partners to develop accurate data collection methods to identify the scope of the problem. One area where more data would be helpful is with the accurate medical diagnosis of sleep disorders. A recent study in Walla Walla, Washington concluded that sleep apnea is significantly under recognized by primary care physicians. The

study was done through the utilization of primary care physicians who were trained to recognize the warning symptoms of certain sleep disorders. With this training, physicians were able to diagnose and ultimately recommend treatment to hundreds of people for sleep apnea and restless legs syndrome. These disorders are not unique to Walla Walla, but are believed to affect millions of Americans. Patients are receiving no diagnosis or treatment due to a general lack of training within the physician community. In this instance, a significant public health problem is identified and a solution established. Accurate data from the health care community along with additional training would show the extent of the problem and allow us to target physicians who are on the front lines of our health care system.

Current CDC resources within the National Center for Injury Prevention and Control are allocated for other projects that are of equal importance to the country. It is with this recognition that we ask the subcommittee to increase the overall budget for this center by $1.2 million to allow the Center to act as the coordinating body for the gathering and evaluation of the types of data discussed above.

This data will allow the NSF, CDC, and other federal agencies to develop and distribute accurate medically sound information. This information coupled with training for those involved with public health and safety at the state level will begin to turn the tide of injuries and costs associated with sleepiness and sleep disorders.

Thank you for consideration of this request.

PREPARED STATEMENT OF THE NATIONAL CENTER FOR LEARNING DISABILITIES

Mr. Chairman, my name is Anne Ford and I am the volunteer Chairman of the Board of Directors for the National Center for Learning Disabilities (NCLD). NCLD is a not-for-profit organization founded in 1977, which seeks to ensure that all individuals with learning disabilities (LD) gain access to research-based knowledge and opportunities to fully achieve their potential. NCLD protects the rights of individuals with LD and promotes the widespread implementation of effective research-based instructional methods. As Chairman of NCLD for the past ten years, and as a parent of a child with learning disabilities, I am keenly aware of the need for greater access to services and increased awareness among parents, early child care providers, teachers and other professionals about how early recognition and intervention can lead to greater success for children in school and beyond.

I am pleased to submit this testimony to encourage the committee's endorsement of a Literacy Early Screening Initiative supported by the National Institute of Child Health and Human Development (NICHD), in partnership with NCLD. The focus of the initiative is to assure that parents, early child care providers, teachers and other professionals have a research-based, easy-to-use tool to screen preschool-age children for behaviors that place them at risk for reading failure, and the information, training and support to implement screening on a nationwide basis.

BACKGROUND

The impetus for this early reading screening initiative comes from the convergence of data from a number of sources. Studies of early learning (Ramey, et al, 1985), patterns of early care in families (Hofferth, 1996), the efficacy of early instruction and intervention (Snow, et al, 1998), the benefits of quality child care (Phillips, et al, 1987), early brain development (Huttenlocher, 1995), and the benefits of early identification of risk factors in young children (Fletcher et al, 1994) all support the initiative's premise that learning difficulties identified early in a child's life can circumvent the longer-term consequences of school failure.

Due in great part to longitudinal studies conducted by NICHD, there is already a considerable body of evidence regarding the specific aspects of young children's physical, cognitive, and social behaviors that are most predictive of later learning difficulty, particularly in the area of early reading and related literacy skills (National Reading Panel, 2000). Studies have shown that learning to read is a process that begins very early in development, well before children enter formal schooling. There is a strong and critical relationship between the amount and quality of early language, literacy interactions and experiences, and the acquisition of linguistic skills necessary for reading (Lyon, 1999).

NEED FOR RESEARCH-BASED SCREENING

A number of complementary efforts are underway to ensure that the United States becomes a nation of readers. The America Reads Challenge, the Reading Excellence Program and the creation of the National Institute for Literacy are a few examples of major efforts through which commitments have been made by the fed-

eral government. These programs are working to enable all citizens, both young and old, with and without special educational needs, to develop strong reading and other literacy skills. These and other successful programs show how government and private organizations are working to assure universal school readiness to all our nation's youth.

There is a shared vision among parents, early care providers, educators, and policy officials to develop strong reading and other literacy skills in our nation's children. However, there has been no coordinated effort to date that addresses the need of parents and early care providers to identify children who show signs of early literacy difficulties and, in particular, to provide research-based information and support. This initiative will provide parents and early care providers with an understanding of these findings, an ability to screen children for behaviors that place them at risk for reading failure, and the information needed to take effective steps toward assuring all children early success in learning to read.

THE INITIATIVE

Through the Literacy Early Screening Initiative, NCLD, under the direction of NICHD, will direct the development of a research-based screening tool. This tool will reflect the most current knowledge on reliable early predictors of reading success and early identification of literacy problems in the preschool and early elementary grades. The initiative will create and support a development team of national experts to design the screening tool. An advisory committee will also inform the ongoing collaborative relationships upon which the implementation of the initiative will be based.

As a leading not-for-profit organization committed to the well being of all children, including those with learning disabilities, NCLD is ideally suited to work with NICHD and launch a collaborative initiative of this nature. In May 1999, NCLD hosted a national summit on research in learning disabilities in partnership with the U.S. Department of Education, Office of Special Education Programs (OSEP) and the National Institutes of Health, NICHD. With our partners, NCLD released syntheses of 20 years of study and convened over 400 national leaders to propose ways to shorten the distance between research and classroom practice.

In the first phase of the project, NCLD will take the following steps to launch the initiative in Kentucky and Mississippi:

—Establish a nationally recognized Development Team to assess the research evidence and select key predictors for the core of the tool.
—Establish an Advisory Committee of nationally recognized experts to provide ongoing expertise and guidance.
—Engage a Project Director to manage the work.
—Identify successful strategies to reach target audiences.
—Design and pilot test the screening tool.
—Confirm partnerships in key states for roll out.
—Develop content and infrastructure on NCLD's Web site and other information sources.
—Conduct outcome evaluation activities.
—Develop a plan for national roll out.

IMPLEMENTATION

Once the screening tool is developed, training, dissemination, and marketing activities will be carried out in Kentucky and Mississippi in partnership with early childhood education, child care, and family support organizations as well as with professional organizations whose activities focus on the well-being of young children and their families. Local and national partners may include:

—American Library Association
—National Association for the Education of Young Children
—National Association for Family Childcare
—National Center for Family Literacy
—National Head Start Association
—National Institute for Literacy
—National Parent Teachers Association
—Reach Out and Read
—WGBH/Between the Lions
—Yale University Bush Center/21st Century Schools
—University of Louisville
—University of Southern Mississippi/Center for Literacy and Assessment

Working in partnership, we will use select media conduits and other methods known to be effective in reaching specific groups of individuals such as parents of

preschool-age children, early childhood educators, health care professionals, and other information and service providers.

Based on its own research and marketing strategies, the project will ensure extensive use of the tool by promoting its 'user friendliness' and utility for non-expert users through its own and other organizations' Web sites. Opportunities for volunteer marketing through food, toy and clothing manufacturers will also be explored, as will ways to incorporate information about the screening tool in corporate employee assistance programs and human resource services. Of special interest will be opportunities to promote the use of this early screening tool through relationships with major PBS outlets.

Mr. Chairman, by supporting this project, you have the chance to bring our collective investment in research to the next level. It's an exciting challenge and opportunity. Together, we can help parents and others vested in our children's success have direct access to an easy-to-use tool that can determine whether to seek early intervention and professional assessment to prevent reading failure. By spending a limited amount of time and money early in a child's life, we can help prevent spending hundreds of thousands later. Perhaps we can stop the heartache and frustration that comes from wondering what could have been done if we had only known. Let's take action with the reliable science available to us and give young children an early chance at success in school and in their lives. Thank you for your consideration and support.

PREPARED STATEMENT OF THE COUNCIL FOR CHEMICAL RESEARCH

Issue.—The National Institutes of Health (NIH), through the National Institute of General Medical Sciences (NIGMS), is one of the largest funders of synthetic chemistry—the heart of advances in medicinal chemistry. While the Administration's requested fiscal year 2001 budget for NIH contains a 5.6 percent increase, it fails to meet the 7 percent needed to reach the congressional goal of doubling federal spending on research in ten years.

POSITION

The Council for Chemical Research (CCR) endorses the congressional goal of doubling the total federal spending on research within a decade. To achieve this end requires an average increase for NIGMS of 7 percent each year for ten years. For this reason, the CCR applauds the commitment Congress made to NIH with the approval of a 14.2 percent increase for fiscal year 2000. The Council believes that in the present, strong economy it would not be prudent for the NIH–NIGMS budget to increase at a rate less than the 7 percent average needed to reach our mutual goal. Therefore, the CCR strongly supports increasing the federal investment in NIH beyond the Administration request to further strengthen the national investment in basic research, since discoveries in biomedical research are very highly dependent progress in chemistry and chemistry related sciences. Moreover, increasing our investment in research will lay the basis for the future continuation of our strong economy.

RATIONALE

NIGMS provides the enabling research and training for the biomedical community that underpins the advances and discoveries of other NIH institutes. This Institute is responsible for generating basic knowledge and new technologies which is the spring from which discovery in the biomedical field pours. NIGMS supports three crucial aspects of chemical research:

—Basic research in chemistry provides the foundation of many biomedical advances. It has led to combinatorial chemistry methods and rational drug design, which allow for the more efficient development of pharmaceuticals having greater potency, higher selectively, and fewer side effects.

—The single most important element of any research program is the presence of well-trained, talented, and dedicated investigators. Training programs at NIGMS develop the multi-disciplinary skills demanded by modern biomedical and pharmaceutical research. Well-trained researchers not only increase productivity for the rapidly expanding biotechnology, pharmaceutical, and diagnostic industries, but also help maintain the world leadership of these industries in extremely competitive markets. Moreover, to maintain this strong pool of researchers the first priority in allocating NIH budget increases should be to support more investigator-initiated research grants and to fund this increased

number of proposals at the appropriate levels needed for their successful execution.

—Basic research requires access to modern instrumentation ranging from computers to high-field nuclear magnetic resonance (NMR) spectrometers, laser systems, x-ray light sources, and mass spectrometers. Emphasis on high performance computing applications in basic biomedical studies is a particularly timely use of resources. These instruments enable researchers to directly observe the fundamental chemical and biomedical processes involved in life and to gain much-needed insight into the workings of the chemistry of living organisms. Through continued modification and refinement, research instruments often develop into clinically important tools. Thus, instrumentation supported by the National Center for Research Resources (NCRR) plays a crucial role in providing the underpinning for biomedical research.

Research in chemistry supported by NIGMS and NCRR provides the strong foundation necessary to ensure progress in the quest for improvements in health and the quality of life. The CCR supports strengthening NIH since it provides training for new scientists, stimulates the pharmaceutical and biotechnology industries—both of which contribute positively to the balance of trade—leads to reduced healthcare costs, healthier lives, and, ultimately, makes the United States a world leader in biomedical research.

PREPARED STATEMENT OF THE JOSLIN DIABETES CENTER

INTRODUCTION

Mr. Chairman, I am Dr. Gordon Weir, Chief of Section on Islet Transplantation and Cell Biology and former Medical Director of the Joslin Diabetes Center in Boston, Massachusetts. I am here today to request for full funding of the first year recommendations of the report issued by the Congressionally mandated Diabetes Research Working Group.

BACKGROUND

Diabetes Research Working Group.—The Diabetes Research Working Group was established by this Subcommittee and its Senate counterpart through the fiscal year 1999 Conference Agreement, House Report 105–635.

The charge to the Diabetes Research Working Group called for the development of a comprehensive plan for all NIH-funded diabetes research efforts, including the recommendations of future diabetes research initiatives and directives. The Conference Agreement language specifically instructed the DRWG to include overall cost estimates to accomplish its recommendations in the final research plan. The final report was provided to the Appropriations Committees in mid 1999. Fiscal year 2001 will be the first year the Congress can act on the funding recommendations contained within the DRWG Report.

The Chairman of the Diabetes Research Working Group, C. Ronald Kahn, M.D., a distinguished researcher, is the former Executive Vice President and Research Director and now President of Joslin Diabetes Center in Boston.

Fiscal year 1999 base funding for the categories addressed in the DRWG report totaled $442.8 million. The DRWG recommended increment for the first of five years over the fiscal year 1999 base was $384.5 million, for a total recommended funding level of $827.3 million.

H. Res. 325.—On November 16, 1999, in the closing days of the First Session of the 106th Congress, H. Res. 325 was considered and approved by the House 414–0. Every Member of this Subcommittee, and every Member of the Full Appropriations Committee, voted YEA on the passage of H. Res. 325. A similar resolution passed the Senate 93–0.

In voting for H. Res. 325, you individually and collectively approved the principles underlying the recommendations for funding that were contained in the report submitted by the Diabetes Research Working Group.

The first component of H. Res. 325 expresses "the sense of the House of Representatives that:

—the Federal Government has a responsibility

—to continue to increase research funding, as recommended by the Diabetes Research Working Group, so that the causes of, and improved treatment and cure for, diabetes may be discovered . . ."

Fiscal year 2000 funding resulted in an increase for diabetes research of approximately 15 percent above the fiscal year 1999 funding level.

FISCAL YEAR 2001 FUNDING

The fiscal year 2001 Budget for NIH, and specifically NIDDK, requests increased funds for NIH research, though not at the level recommended by the Diabetes Research Working Group. We realize that funding constraints represent a significant obstacle to reaching the diabetes research levels the DRWG recommends for fiscal year 2001. If the Committee is unable to increase the diabetes research recommendations with the DRWG of an increase of approximately $350 million, there are immediate priorities that we would urge you include within funding for fiscal year 2001 appropriations.

Dr. Kahn, Chairman of the DRWG, has indicated that, absent full funding at $827.3 million for diabetes research in fiscal year 2001, the following categories represent the highest priority among the DRWG recommendations. While we still request the full increase recommended by the DRWG, the following four categories represent the most urgently requested activities, which total $79 million, in increases above the fiscal year 2001 President's Budget:

—Create new Comprehensive Diabetes Research Centers to provide enhanced infrastructure support, and enhance the effectiveness of existing Diabetes Centers (DERCs and DRTCs) by significantly increasing their funding levels and expanding their mission ($6 million);

—Create new regional centers with advanced technologies required for metabolic and functional imaging studies, such as nuclear magnetic resonance (NMC), positron emission tomography (PET), and related technologies, which are required for contemporary diabetes research, and provide ongoing support ($5 million);

—With regard to Autoimmunity and the Beta Cell ($30 million):

Define the immunological basis of type 1 diabetes and develop methods for prevention of the disease;

Advance research on islet cell transplantation for treatment of diabetes; and

Develop methods to stimulate beta cell growth and regeneration; and

—With regard to Cell Signaling and Cell Regulation ($38 million):

Complete the dissection of hormone signaling pathways, particularly the pathways of insulin action, and define their alterations in diabetes, including insulin resistance;

Define mechanisms regulating beta cell function and their alterations in type 2 diabetes; and

Allow metabolic staging of diabetes and identify the mechanisms of complications.

Thank you, Mr. Chairman, for this opportunity to present the views and recommendations of Joslin Diabetes Center for diabetes research funding through NIH in fiscal year 2001.

PREPARED STATEMENT OF THE LOVELACE RESPIRATORY RESEARCH INSTITUTE

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity on behalf of the Lovelace Respiratory Research Institute (LRRI) to endorse and elaborate upon the written testimony of Dr. Clyde B. McCoy from the University of Miami School of Medicine (UMSM), with whom we are collaborating for our proposed Minority Health Tobacco Research Center (MHTRC).

IMPACT OF SMOKING

Nicotine is a drug. It is a highly addictive drug that is unregulated. It is also a drug that appears to have profound inhibitory effects on the mammalian immune system. The delivery system of choice for this drug is the cigarette. There is no doubt that the use of tobacco products causes untold human injury and suffering.

What is less well studied is the effect of secondary smoke (and by inference the delivery of nicotine to non-smokers) on the health of family members and co-workers of addicted users of these products. We propose the creation of a Center designed to study the physiology and behavioral medicine of secondary smoke combining the unique capabilities of two leading complementary research institutions: the University of Miami School of Medicine and its Drug Abuse Research Center and the Lovelace Respiratory Research Institute in New Mexico.

Extensive experience in health research at UMSM in minority substance abuse and minority health will be linked to the world class physiology, cell and molecular biology and toxicology expertise present at LRRI to model the role of secondary smoke on the biology of the individual using cellular and rodent models followed by

studies of family members of smokers. Medical and behavioral interventions will then be developed based on the resulting data.

THE NEED TO FOCUS ON THE MINORITY POPULATION

Surgeon General David Satcher reported in a March 23, 2000 news release that there is an increase in tobacco use, especially among teens from African American, American Indian and Alaska Natives, Asian Americans, Pacific Islanders, and Hispanic communities. This increase in use will lead to an increase in cancer, heart disease, emphysema, stroke and other diseases among minorities. In addressing this increase, the Surgeon General noted, "Unless they are reversed, these increases in tobacco use are a time-bomb for the health of our minority populations . . . If tobacco use continues to increase among minority adolescents, we can expect severe health consequences to begin to be felt in the early part of the next century."

"This new report clearly shows tobacco's increasing grip on racial and ethnic minorities—the fastest growing segments of the American population," said HHS Secretary Donna E. Shalala. "This new report underscores the need for Congress to pass comprehensive tobacco legislation this year based on the President's five key principles that include a significant price increase and plans to dramatically reduce youth tobacco use."

Of particular relevance to this proposal to fund the MHTRC, were the following major conclusions:

—"Cigarette smoking is a major cause of disease and death in each of the four population groups studied in this report . . . Differences in the magnitude of disease risk are directly related to difference in patterns of smoking . . .

—No single factor determines patterns of tobacco use among racial/ethnic minority groups . . . These patterns are the result of complex interactions of multiple factors, such as socio-economic status, culture characteristics, acculturation, stress, biologic elements, targeted advertising, price of tobacco products, and varying capacities of communities to mount effective tobacco control initiatives.

—Rigorous surveillance and prevention research are needed on the changing cultural, psychosocial, and environmental factors that influence tobacco use to improve our understanding of racial/ethnic smoking patters and identify strategic tobacco control opportunities. *The capacity of tobacco control efforts to keep pace with patterns of tobacco use and cessation depends on timely development of appropriate community-based programs to address the factors involved."* (emphasis added)

Please note that the report went on to call for more research into the effects of tobacco use among the groups, and called for studies to determine the health effects of exposure to secondhand smoke.

Given the concentration of the Native American population in New Mexico, the focus of the MHTRC will also include American Indians. The Surgeon General found that "Nearly 40 percent of American Indian and Alaska Native adults smoke cigarettes, compared with 25 percent of adults in the overall U.S. population. They are more likely than any other racial/ethnic minority group to smoke tobacco or use smokeless tobacco . . . American Indians . . . were only one of the four major U.S. racial/ethnic groups to experience an increase in respiratory cancer death rates in 1990–1995." (www.cdc.gov/tobacco)

The bad news continues. The need to focus on the minority population is even more significant given the underutilization of the health system by the population. This disturbing fact is documented in a recent study produced by the Commonwealth Fund and published on February 18, 2000. The report discovered that Hispanics account for an alarming one-quarter of the nation's 44 million uninsured people. According to the report, "Nearly 40 percent of Hispanics under the age of 65 do not have insurance. Despite their increasingly vital contribution to the nation's economy." Hispanics are twice as likely as the general population to go without coverage. "Overall, 18 percent of the population under age 65 has no health insurance . . . Among whites, one of seven lacks insurance; among blacks, one of four lacks insurance; and among Hispanics, nearly two of five is uninsured. . . ." (bkb@cmwf.org)

LRRI AND UMSM ARE UNIQUELY QUALIFIED TO ADDRESS TOBACCO AND HARMFUL SUBSTANCE ADDITION IN THE MINORITY POPULATION

As Dr. McCoy points out, the University of Miami School of Medicine researchers have significant expertise and experience in the treatment of tobacco-related disease including the evaluation of Florida's Tobacco Pilot Program. LRRI has also gained a national reputation for its research work in the areas of prevention and cure of respiratory disease.

Because of LRRI's unique capabilities to perform basic science research, LRRI and UMSM bring their strengths to the formation of the MHTRC. LRRI has undertaken some of the leading studies of animal models of smoking and the role of nicotine in immune function. It is one of the few research organizations capable of undertaking complex inhalation exposure protocols with appropriate animal models that predict human physiological responses.

BOTTOM LINE

LRRI will undertake experimental protocols investigating the role of second hand smoke on neonates, children and adults. These models determine the precise immunological defects that result from these exposures. This data will then be compared to the cellular immune function of newborns, older children, and family members of minority subjects.

UMSM will use its experience with understanding the unique cultural and social systems found in these minority populations, and as preserved in their unique database, to tailor medical and behavioral interventions to treat and prevent this terrible disease, not only on those who choose to smoke, but more importantly, on those who are exposed, yet have no choice.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

The American Society of Clinical Oncology (ASCO) represents more than 14,000 physicians involved in cancer research and treatment. ASCO is the leading voice among medical professional societies concerning issues of cancer clinical research. The Society is pleased to have the opportunity to comment on fiscal year 2001 appropriations for the National Institutes of Health (NIH) and other issues related to the mission of NIH. These matters are of great importance to clinical researchers and their patients.

FISCAL YEAR 2001 APPROPRIATIONS FOR NIH AND NCI

ASCO applauds the commitment of this Subcommittee to doubling the budget for NIH between 1999 and 2003. This panel's leadership has been essential to ensure predictability and stability in the NIH appropriation and allow scientists to pursue exciting new research endeavors. We believe the biomedical research effort of this country is as strong as it has ever been, in no small part because of the unwavering support of Congress.

In order to sustain progress toward the goal of doubling the NIH budget by 2003, a funding boost of 15 percent is necessary in 2001. We strongly support a 15 percent increase for NIH. In addition, we recommend that funding for the National Cancer Institute (NCI) be enhanced in accordance with the Bypass Budget. Funding NCI at a level of $4.1 billion will allow the Institute to fund promising and innovative investigator-initiated research proposals and facilitate research that capitalizes on important advances in molecular biology. ASCO believes the Bypass Budget includes a persuasive rationale for boosting the NCI budget to $4.1 billion, and we urge the Subcommittee to begin the new millennium by implementing the Bypass Budget recommendation.

CLINICAL RESEARCH STUDY SECTION

If promising basic research advances are to have meaning for Americans, they must be translated into medical practice. This translation process can only be accomplished through clinical research. Unfortunately, investigator-initiated clinical research proposals have historically not fared well at NIH because they have been reviewed by basic researchers who are not well versed in clinical research. ASCO has maintained that allowing basic researchers to dominate the review of cancer clinical research proposals is inequitable, a position endorsed by several blue ribbon panels charged with oversight of the NIH peer review process. Furthermore, according to recent reports, physician scientists' success in obtaining NIH funding for investigator-initiated research has a significant impact on their willingness to remain in the field. Therefore, the research review process has a significant impact on today's research and on the future of clinical research.

ASCO has previously brought the issue of peer review of cancer clinical research to the attention of this Subcommittee, and the panel has supported efforts to improve the grants evaluation process. As a result of Subcommittee directives to the NIH, the Center for Scientific Review (CSR) appointed a special emphasis panel to review clinical oncology research proposals. The special emphasis panel is composed of clinical researchers who have the expertise and experience to evaluate cancer

clinical research proposals. The early reports from the special emphasis panel have been positive. ASCO believes this model for review has been successful and should be made a permanent study section. We believe this would result in a system of fair and informed review of clinical oncology research.

We are concerned, however, that CSR has announced plans to reinstate a system in which clinical oncology research proposals will be evaluated by panels in which as few as one-third of the members will have clinical research expertise. This situation—where basic researchers dominate the review of clinical research proposals—is one that external NIH advisors recommended be avoided. ASCO urges the Subcommittee to renew its directive to NIH officials to maintain a peer review system that has clinical researchers reviewing cancer clinical research proposals. ASCO believes that a rigorous and fair peer review system is fundamental to a strong clinical research effort and urges the Subcommittee to ensure that clinical researchers will review clinical research proposals.

CLINICAL TRIALS COVERAGE

ASCO has worked for several years for enactment of the Medicare Cancer Clinical Trials Coverage Act, which would require Medicare to reimburse the routine patient care costs for those enrolled in cancer clinical trials. More recently, we have been actively involved in efforts to ensure clinical trials coverage provisions in the Patients' Bill of Rights. Although coverage for routine patient care costs is not technically a matter for this Subcommittee, assurance of such coverage is critical to the efficiency of the research enterprise and is therefore surely a concern for this panel. Only if treatments can be tested in clinical trials can clinical researchers determine their effectiveness. If reimbursement denials or the fear of such denials slow accrual to clinical trials, this will adversely affect the ability of researchers to answer questions about new treatments. ASCO believes it is absolutely necessary that barriers to enrollment in clinical trials, including possible reimbursement uncertainties or denials, be eliminated.

ASCO appreciates the opportunity to submit its views on NIH funding and clinical research. On behalf of oncologists and their patients, we urge Congress to continue its strong support of NIH. We also recommend that special attention be paid to the clinical research enterprise to ensure that basic research findings are promptly brought to the patient bedside.

PREPARED STATEMENT OF THE NATIONAL PROSTATE CANCER COALITION

Mr. Chairman and members of the Subcommittee on Labor, Health & Human Services and Education Appropriations, the National Prostate Cancer Coalition (NPCC) is a vital organization that includes, on its board of directors, representatives from the American Foundation for Urologic Disease, the Cancer Research Institute, CaP CURE, the Huntsman Cancer Center and Us TOO! International. Other coalition partners include the American Urological Association, B'nai B'rith International and Men's Health Network. NPCC supporters are also thousands of survivors and their families, researchers and health professionals.

Mr. Chairman, the NPCC strongly urges you and your colleagues to make appropriations to the National Institutes of Health (NIH) and the National Cancer Institute (NCI) such that $324.4 million will be available to carry out the fiscal year 2001 commitment to the NIH five-year investment strategy for prostate cancer research. This funding will give hope to the nearly 200,000 men who learned they have prostate cancer in 1999. And it will bring closer the day when the coalition no longer has to cite the chilling fact that nearly 40,000 American men lost their lives to prostate cancer last year.

The amount required for NIH is an increase of 15 percent over the fiscal year 2000 appropriation. We also request full funding of the NCI director's professional judgment, or "bypass," budget at $4.1 billion.

As you know, the bypass budget goes directly to support badly needed investigations that will hasten new treatments and cures for cancer. The 15 percent increase to NIH is necessary to fulfill Congress's 1998 bipartisan commitment to double the NIH budget within five years. Reaching that funding target will allow NIH to pursue research opportunities that will make a difference in the lives of every family fighting a dread disease, including those facing cancer.

Mr. Chairman, in addition to asking for your support of prostate cancer research, the men and their families of the NPCC also congratulate you and the members of this committee. You took a dramatic step to improve the nation's biomedical research capabilities when you committed to double the NIH budget between fiscal

year 1999 and fiscal year 2003. Last year, you showed how serious you were when you provided NIH with about $2.0 billion more than it received in fiscal year 1999.

And you also took specific action on behalf of prostate cancer research. Your hearing, in June 1999, brought together oncologist Christopher Logothetis, M.D., Senator Bob Dole, Michael Milken and Yankees' great Joe Torre to discuss the near-term promises for prostate cancer research. As a product of that hearing, NIH presented its five year investment strategy for prostate cancer research, recognizing that funding in this important area has fallen far short of meeting the disease's challenges.

Prostate cancer has been the number one diagnosed non-skin cancer in the country. It has accounted, on average, for 15 percent of all cancer cases and 15 percent of cancer deaths among men. Yet, until you and your colleagues acted, an average of only 5 cents of every federal cancer research dollar had been allocated to find a cure for this disease.

While recent increases in prostate cancer research funding are vital, Mr. Chairman, the unfortunate truth is that they still fall far short of the need—and they alone are not sufficient to fund all of the most promising paths to treatment and cure. The NPCC's Medical and Scientific Advisory Committee—which includes some of the nation's leading prostate cancer researchers and clinicians—has already identified more than $500 million in promising research that has not received funding. Missed opportunities cost lives. The NPCC believes we must accelerate treatment opportunities by providing the resources to fund all promising research on the horizon.

We have a strong working relationship with NIH and NCI and applaud the agencies' leadership and their intramural and extramural researchers for the tremendous work they have done to help prostate cancer patients and their families. We've worked hard for NIH's five-year prostate cancer research strategy. But, because we must remain attuned to opportunities, we must revisit that strategy next year. The program's budget was based on conservative projections. We believe that new treatments could be available soon, but they call for rapid acceleration of commitments to translational and clinical research. We must end the bottlenecks in drug development to allow agents to move quickly from the laboratory bench to the patient's bedside and medical clinics, where they can end the toll that prostate cancer takes on America's families.

We support NCI's existing innovative programs in translational and clinical prostate cancer research, particularly its RAID and QuickTrials projects. We would like to see these expanded—and married to innovative collaborations among public and private funders and providers of prostate cancer research. We also appreciate NCI's commitment to increase the number of prostate cancer Special Programs of Research Excellence (SPOREs) and other opportunities that mobilize interdisciplinary research talent and accelerate institutional collaborations.

Mr. Chairman, I want to conclude by stressing to the committee that an investment in cancer research really is an investment, one that will yield dividends both in lives saved and in dollars and cents.

It may seem shocking to think that, in the past five years, more than one million men in the United States learned they had prostate cancer. But the real shock is that we've seen just the tip of the iceberg.

The American population is aging. Between 1996 and 2014, the 76 million members of the baby boom generation—31 percent of our American population—turn fifty years old. Those born before 1957 are turning fifty at the rate of one every seven seconds. Because the risk of cancer increases after this milestone, more and more Americans will battle cancer—including prostate cancer—in the coming years.

Cancer care already costs this country more than $100 billion annually. With the graying of the baby boomers, THE MARCH Research Task Force had estimated, in 1998, that, if unchecked, the cost of cancer will jump to more than $200 billion within a decade. Even if Congress's commitment to cancer research continues to grow at its current rate, we will still be spending 20 times more on care than cure.

In 2000, one American man in every six is at risk of prostate cancer; one cancer diagnosis in every seven will be prostate cancer; and one male cancer death in every eight will be prostate cancer. Some clinicians note that the number of men in their forties and fifties who are battling prostate cancer is increasing, and they report seeing more aggressive forms of the disease in younger men.

Mr. Chairman, in the face of these daunting facts and as you consider the future investments in NIH and NCI research, NPCC asks you and your colleagues to be mindful of the impact of prostate cancer on the country as a whole.

While advancing research in these important programs costs federal dollars, we ask you to remember the greater costs involved in any further delay to the cure of prostate cancer.

General Norman Schwarzkopf, a very wise military leader and himself a prostate cancer survivor, recently discussed cancer research in the context of military strategy. He put the issue this way: "There always comes a time when you must get on with the battle. You cannot sit back and do nothing, because you'll never have perfect intelligence on the enemy. Base your battle plan on the best information you have and be ready to modify your strategy and line of attack. The important thing is just to get on with it."

Thank you for your consideration.

PREPARED STATEMENT OF THE CANCER LEADERSHIP COUNCIL

The Cancer Leadership Council (CLC) is a forum of national advocacy organizations addressing public policy issues in cancer. CLC participants include organizations representing patients and their caregivers. We are pleased to have this opportunity to submit comments to the Subcommittee regarding funding for the National Institutes of Health (NIH), including the National Cancer Institute (NCI). We are particularly concerned about clinical cancer research and have recommended special actions that must be taken to protect clinical research and ensure that basic research findings are rapidly translated into improved therapies.

FISCAL YEAR 2001 NIH FUNDING

The CLC commends the Subcommittee for its leadership in securing substantial increases in funding for NIH in fiscal year 1999 and fiscal year 2000 and ensuring steady progress toward a goal of doubling the NIH budget between 1999 and 2003. Because of the commitment of the Subcommittee to biomedical research, NIH has experienced a period of predictability and stability in its funding, and the research enterprise has benefitted greatly.

The CLC wholeheartedly supports increasing NIH funding by 15 percent in fiscal year 2001, a boost that is necessary to ensure movement toward the year 2003 funding goal. We also urge that Congress fund the NCI according to the Bypass Budget, or at a level of $4.1 billion. The Bypass Budget outlines promising research opportunities that could be funded if NCI receives that level of funding. CLC believes that important cancer research projects are being abandoned because of funding constraints, and Congress could ensure that good science is funded if it meets the Bypass Budget funding recommendation.

COVERAGE FOR CLINICAL TRIALS

In order to move basic research findings to the patient bedside, they must be tested in clinical trials. The optimal clinical trials system is one that enrolls patients promptly and tests therapies rapidly to answer questions about the best possible treatments. Unfortunately, there are a number of barriers that prevent individuals from enrolling in trials and therefore slow the clinical trials process.

CLC and others in the cancer community have worked diligently to remove barriers to patient enrollment in clinical trials, and our efforts have focused on guaranteeing that third-party payers reimburse the routine patient care costs of those enrolled in cancer clinical trials. In this Congress, we are seeking passage of the Medicare Cancer Clinical Trials Coverage Act and inclusion of a clinical trials coverage provision in the Patients' Bill of Rights.

Although Medicare and other third-party payer policies are not in the jurisdiction of the Subcommittee, they are vitally important to the health of the clinical research effort. If researchers face obstacles to enrolling patients in clinical trials due to real or perceived difficulties in reimbursement, the speed and efficiency of clinical trials will be adversely affected and the translation of basic research findings into new therapies will be slowed.

The CLC urges your support for efforts to guarantee third-party reimbursement for those enrolling in cancer clinical trials. This coverage is a necessary component of the biomedical research enterprise and is of utmost concern to cancer patients and their caregivers.

CLINICAL RESEARCH STUDY SECTION

In the past, CLC has asked the Subcommittee to direct NIH to revise the peer review process to ensure that cancer clinical research proposals receive a fair evaluation. Cancer clinical research proposals have historically been reviewed by basic researchers, and several advisory groups to the NIH have concluded that this results in inequitable review of clinical research because basic researchers are not well versed in clinical research and the challenges associated with it.

This Subcommittee previously directed NIH to alter its peer review process, and the NIH finally responded by establishing a Clinical Oncology Research Special Emphasis Panel. This panel represented a significant advance because it provided for the review of clinical cancer research proposals by clinical researchers. Regrettably, the Center for Scientific Review (CSR) has indicated that it will reinstitute a system in which basic researchers will review clinical research. We urge you to direct the NIH to retain the Special Emphasis Panel and abandon plans for a system in which cancer clinical research will again be reviewed by basic researchers.

The CLC is pleased to have the opportunity to submit comments to the Subcommittee. This panel's steadfast advocacy for biomedical research is very important to the CLC, and we lend our enthusiastic support to your efforts to enhance NIH funding. We request your special consideration of our proposals to protect and foster clinical cancer research.

Cancer Leadership Council

Alliance for Lung Cancer Advocacy, Support, and Education, American Cancer Society, American Society of Clinical Oncology, Cancer Care, Inc., Cancer Research Foundation of America, The Children's Cause, Inc., Cure For Lymphoma Foundation, Coalition of National Cancer Cooperative Groups, Inc., Colorectal Cancer Network Kidney Cancer Association, The Leukemia & Lymphoma Society, Multiple Myeloma Research Foundation, National Coalition for Cancer Survivorship, National Patient Advocate Foundation, National Prostate Cancer Coalition, North American Brain Tumor Coalition, Oncology Nursing Society, Ovarian Cancer National Alliance, The Susan G. Komen Breast Cancer Foundation, US–TOO International, Inc., and Y–ME National Breast Cancer Organization.

PREPARED STATEMENT OF THE LYMPHOMA RESEARCH FOUNDATION

Chairman Specter and Members of the Subcommittee: My name is Neil Ruzic and I have lymphoma, cancer of the lymph system. So do 600,000 other Americans. This country is suffering a lymphoma epidemic. The incidence of lymphoma is increasing the second fastest of all cancers, the fastest of cancers that cannot be prevented. That is, unlike melanoma (the fastest growing) and unlike lung cancer, you can't prevent lymphoma by staying out of the sun or stopping smoking. The cause is unknown.

Another 87,000 or more Americans will contract lymphoma this year. Our children are getting it—60 percent of childhood cancers are lymphoma or the related disease of leukemia. Our men are dying from it—lymphoma is the fourth leading cause of death by cancer. Our women are dying from it at almost the same rate.

The Lymphoma Research Foundation of America does what it can to help these people. It funds research projects mostly of young PhD or MD scientists. It is the nation's primary organization dedicated to providing information and support to lymphoma patients and their families. On behalf of the Lymphoma Research Foundation, I want to thank Chairman Specter, Ranking Member Harkin and the Subcommittee for being instrumental in the NCI's convening a Progress Review Group on lymphoma later this year. Panels of prominent scientists will review NCI's lymphoma research portfolio and recommend a plan of action that will speed progress, helping ensure that limited resources are used optimally. These are important steps . . . but there could be more.

A year and a half ago, following surgery to remove my spleen that had grown four times too large, I was diagnosed with mantle cell lymphoma. This is the deadliest of the lymphomas, whose victims have an average time from diagnosis to death of three years. Despite the lack of a cure, oncologists at five leading institutions advised me to take aggressive chemotherapy. Nothing else, they said at the end of 1998, was proved and "probably would not work." They admitted that chemo would only "buy time," and in the long-run—if there was one—would work for shorter and shorter times until it destroyed my immune system.

Instead of taking chemotherapy, I immediately stopped the book I was working on and devoted my time to learning about lymphoma by reading scientific papers and visiting the nation's medical research centers. After 18 months of looking, I can tell you that the cures are there, in the brains and experiments of the medical researchers. These discoveries are in their infancies and require much more research and testing, but they are there—right now—in the laboratories of the United States.

I am one of the lucky ones, at least so far. Without treatment of any kind, my lymphoma for unknown reasons not only remains indolent but seems to be subsiding. That is, the lymph nodes or glands in my abdomen, once the size of golf

balls, now are the size of grapes, and some have shrunk to normal size (the size of a pea.) I am not sick. I have no symptoms. Why?

I approached a team of creative gene researchers at UCLA, and together with the Lymphoma Research Foundation and the Mantle Cell Group (an e-mail information assembly of patients), sponsored a project to try to answer that question. The idea was that if we could render lymphoma quiescent, or indolent, it would be almost as good as finding a cure. The project, now underway, is a small part of the sudden revolution in genetics and molecular biology. New therapies are being tested every day, even faster than the completion of the human genome project, which already is of enormous benefit to cancer research.

There are good scientific reasons why funding should be increased immensely for lymphoma research. Lymphoma is to the lymph system what leukemia is to the blood system. The liquid lymph contains white blood cells that produce antibodies which, in turn, fight infection and filter out pathogens. Because lymph cells move freely between the lymph and blood systems, an actual and comprehensive cure for lymphoma must begin with a basic understanding not only of the interplay between these systems but also of how the immune system works, how the chromosomes and genes function, how the very molecules of the cells work together. Because of this systemic nature of lymphoma, any actual cure would be applicable to lung, colon, breast, prostate, and other kinds of cancer.

As important as is the study of lymphoma to curing all cancers, lymphoma research constitutes a mere 2.2 percent of the budget of the National Cancer Institute! And the NCI's budget for all cancer research, even now that it has been increased, is only $3.3 billion.

That satisfaction with the status quo is wrong when human lives are at stake. For the first time in history, lymphoma and other hopeless diseases are suddenly and uniquely vulnerable to a massive, coordinated attack by government and university laboratories. There has never been a better time than right now.

Significant breakthroughs in previously unrelated fields of engineering, chemistry, biology, and physics have been quietly maturing—remarkably at the same time—and everything at last is finally coming together. Computer technology, for instance, finally has merged with gene engineering so that we actually can put DNA on a microchip and isolate genes that are broken, or determine the pathways of genes responsible for specific diseases.

Common wisdom says that cancer is not just one, but hundreds of diseases—lymphoma, leukemia, lung, breast, prostate and other organ cancers, and so on—leading you to believe that curing cancer requires an equal number of hundreds of different approaches. That assumption is no longer true. All cancers have in common uncontrolled cell growth, and for that to occur a series of mutations in the genes which control cell growth and behavior must take place. Tremendous progress in the understanding and manipulation of genes has been made in just the past year or so.

Yet genetics researchers such as Dr. Jonathan Braun, Dr. Phillip Koeffler, and their teams at UCLA, who are at the front lines in this battle, lack funds for a truly large expansion of their programs and can test only a small number of their ideas. Typically these labs employ 10 to 20 scientists and technicians. They could expand to 100 or 200 workers, effectively, without wasted effort, and thereby hasten the research payoff .

A novel approach pioneered by Dr. Judah Folkman at Children's Hospital in Boston that stops angiogenesis or "blood growth" that feeds tumors has caused scores of new compounds to be tried. Dr. Parkash Gill and his group at the University of Southern California, for instance, have found ways to alter the genes to cut off tumor blood supply. These researchers and others at Northwestern University have wiped out cancer in near-death patients who have had metastasized cancers all over their bodies. But Dr. Gill, chronically underfunded, lacks the means to pursue all but a few animal studies. Like others in small labs, he must take valuable research time to seek the funding he needs. (The average project leader in this field spends a third of his research time writing proposals or otherwise seeking grants.)

As new therapies begin to replace outmoded, often-harmful chemotherapies, we must speed up testing and clinical trials of other techniques, even as the more fundamental, ultimate, solutions such as gene therapy are being refined. For instance, antibodies made from human cells and cloned to produce large numbers of them now are targeted to kill cancer cells specifically, instead of killing all cells that grow, normal or diseased (as does chemotherapy.) These monoclonal antibodies also are being combined with radioisotopes to be even more effective.

Another new technique applicable to all cancers is the stimulation of the body's own "T cells," our immune system's most effective killers of viruses, bacteria, and parasites. The problem is that cancer cells have evolved mechanisms to hide them-

selves from T cells. It's like having an Air Force armed with one-ton bombs ready to destroy an army of invaders but not bombing the enemy troops because you can't find them. Dr. Carl June and co-workers at the University of Pennsylvania have discovered that by stimulating two different receptors they can get the T cells to launch an immune response. In fact, the T cells are so sensitive to co-stimulation they also secrete chemical messengers that work to make even more T cells. Now not only can we use those one-ton bombs, but they are multiplied! This project has received private funding from many sources, including the author's. But with the massive governmental spending increase envisioned here, other labs could replicate the results and help push it to the hilt.

Vaccines—not to prevent but to cure—are being grown from patients' tumors and customized to kill lymphomas in those lucky enough to get into the right protocol. Human trials run by such pioneers as Dr. Ronald Levy at Stanford and Drs. Larry Kwak and Wyndham Wilson at the NCI include only hundreds instead of hundreds of thousands of cancer patients.

Most of these and other potential new cures began with research into lymphoma, but they are applicable to all cancers!

In addition there are the important basic research projects of hundreds of bright, mostly young medical scientists which have had to shut down before hardly getting started for lack of funding. Individuals and foundations contribute at least as much as the government, but most of those funds go for education and prevention. Pharmaceutical companies add another $4.8 billion annually for research—almost double that of the government—but little of this sum is spent on untargeted basic research

The 10,000 universities in this country are among America's greatest assets. Let's use them to the hilt. These institutions not only educate the brightest of our young men and women but also attract the best foreign students who earn advanced degrees and often stay to work in the U.S. All graduate students in science do basic research. It is this constant probing into fundamental knowledge in molecular and even atomic biology, immunology, genetics, and into even seemingly unrelated research in bioengineering, chemistry, and computer technology that will cure cancer. The research freedom at the universities and peer reviews to decide on worthy ideas are good practices that should not be changed. Instead, the government should seek opportunities to expand the existing system and infrastructure massively.

The key question is whether the new money could be spent profitably so that real cancer cures will be in use in ten years. Here are five spending steps that occur to me, which I am sure can be improved upon by university and NCI scientists:

Massively increase funding for non-targeted basic research, using the majority of the funds.—Here are two examples of how basic research, which when undertaken was not directed toward curing any specific disease, but now is leading to specific cancer-fighting studies: The 1953 discovery that earned the Nobel Prize for Watson and Crick, showing that the double helix shape of DNA contained subunits of nucleotides, led directly to the current sequencing of more than 100,000 genes on our 23 pairs of chromosomes. Dr. Gunter Blobel of New York's Rockefeller University recently was awarded a Nobel Prize for his discoveries into how proteins locate themselves in cells and how environmental mutations in the process lead to disease.

Ask every university cancer project leader which of them could gear up to handle-effectively and efficiently—10 or 20 times their present funding.—If their answers make sense, fund them. That may not be the most cost-effective method of funding in the short run, but any money wasted on the way to the greater goal will pale in comparison to the overwhelming financial benefit of a cancer-free economy. We can not afford to let research funding remain a zero-sum game where spending additional money on, for instance, breast cancer, detracts from, say, lymphoma research.

Proselytize young people into following scientific careers in medicine, medical engineering, immunology, genetics, and related fields, both at the professional and technical-support level.—Yes, education takes time. But these new people will be needed in the massive fight against cancer, and the sooner they start the sooner they will contribute. We should offer full economic assistance for students to enter such careers, and for graduate students to earn combined MD and PhD degrees. Such funding will relieve professors from having to pay their graduate students out of their research grants, thereby also making them more productive. Such a program should be publicized widely to attract the most creative people from throughout the world.

Create a dozen more big cancer centers of excellence throughout the country, letting the universities compete for the new sites.—Encourage competition by funding post-doctoral researchers and by endowing chairs in medical research laboratories. It is through competition, the engine of progress, that enormous goals are realized. Biotechnology is the "dot com" of the new decade. The U.S. has benefited profoundly from the internet change relative to other countries because of the technological infrastructure already in place. Intensifying the infrastructure and career develop-

ment in bioscience for cancer breakthroughs is a role that government plays well, and industry does not.

Coordinate the research results of the NCI, universities, and others by instituting a worldwide central data base and ultrafast communications system.—The recent inauguration of PubMed Central and the database of the National Library of Medicine are welcome steps, but the effort is still terribly underfunded. Researchers need to be informed instantly of discoveries elsewhere that may bear upon their work. One can picture a thousand information experts at their computers alerting university researchers to meaningful experiments. It is important that the government avoid playing the role of director of this War on Cancer; the government should be the coordinator.

If, in providing for such an expansion, the Congress voted for a dramatic and immediate increase for the NCI of some $30 billion—with the majority of the money going for basic research—the returns would begin to pour in almost right away. They would build to a flood in a few years. They would race to a crescendo by the end of the decade.

Is it worth the money?

Yes, in terms of misery and death avoided. Yes again, in economic terms. The annual cost of cancer to the U.S. alone currently is $107 billion, including direct and indirect costs. According to economists Kevin Murphy and Robert Topel at the University of Chicago, if all forms of cancer were eliminated the economic value to the United States would be $46.5 trillion, which is more than all U.S. assets! The economic and humanitarian benefit to other nations also would be overwhelming. What a fantastic tool of foreign policy, the exportation to other countries of the cure for cancer!

Elimination of death by cancer would usher in a new era of worldwide health and prosperity, removing misery, and rendering human life more productive and happier. Progress in the various sciences is rushing steadily toward the cure of cancer. From the viewpoint of government appropriations, whether that cure arrives in ten years or in fifty years, or somewhere in-between, is only a matter of money.

PREPARED STATEMENT OF THE NATIONAL NUTRITIONAL FOODS ASSOCIATION

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to present public witness testimony on behalf of the National Nutritional Foods Association (NNFA). My name is Patrick Toomey. I am President of NNFA, a trade association representing 3,000 independent health food stores and 1,000 manufacturers, distributors and suppliers of natural health products, including organic and natural foods, natural ingredient cosmetics and dietary supplements.

In addition to being the President of NNFA, I also own a small natural foods store, Toomey's Natural Foods in Milford, Ohio. I have been an industry retailer for 25 years and for the past ten years I have served on both national and regional boards of the NNFA.

CONGRESSIONAL MANDATE MIRRORS CITIZEN DEMAND

National interest in access to reliable information on safe and effective vitamins, minerals, herbs, amino acids and other dietary supplements has grown steadily since the Dietary Supplement Health and Education Act (DSHEA) unanimously passed the House and Senate to become the law of the land in 1994.

Approximately 158,000,000 Americans are taking dietary supplements, spending, by some estimates, as much as $14.5 billion a year in health food stores alone. Americans are looking to safe, natural alternatives to prescription drugs to treat and prevent disease, and to maintain good health by supplementing inadequate diets with vitamins and minerals.

NUTRIENTS CAN PREVENT CHRONIC DISEASE

We are entering a new era of recognition of the value of natural pathways to good health. For example, the Food and Nutrition Board of the National Academy of Sciences, which devises Recommended Daily Allowances (RDAs) for nutrients for the Food and Drug Administration, has issued the first of a series of reports presenting revised nutrient intake guidelines. Originally introduced in 1941, RDAs were intended to prevent classical nutrient deficiency diseases nearly extinct in the U.S. today, such as scurvy, beriberi and rickets. Now, these reports are revising and expanding RDAs to reflect compelling evidence, which supports the use of nutrients to help prevent chronic disease, such as osteoporosis. We agree with the Chairman

of the Food and Nutrition Board, who characterized this approach as ". . . a major leap forward in nutrition science."

Similarly, the report of the President's Commission on Dietary Supplement Labels endorsed continued research on the benefits of dietary supplements in health promotion and disease prevention. The Commission hailed the increasing research-based documentation of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions, and called for continuation of this welcome trend. NNFA continues to endorse the Commission's recommendation that, ". . . the public interest would be served by more research that assesses the relationships between dietary supplements and maintenance of health and/or prevention of disease."

HERBS AND BOTANICALS ARE BENEFICIAL AND COST-EFFECTIVE

In addition to supporting these kinds of exciting new findings on the health benefits of nutrients, NNFA urges the Committee to continue to support research on medicinal herbs and botanicals, also classified as dietary supplements under the DSHEA. The results of a study on ginkgo biloba, published recently in the October 22, 1997 Journal of the American Medical Association, indicates that administration of this herbal extract, recognized for centuries in Chinese medicine for its ability to stimulate and improve blood circulation in the brain, could delay the onset of Alzheimer's Disease for up to six months. This could represent tremendous savings of lives and dollars from a disease, which costs society approximately $90 billion a year. Other studies show saw palmetto more effective than prescription medicine at reducing benign prostate enlargement, with far less expense and no reportable side effects. In 1998, Harvard University completed a 14-year study of 80,000 nurses, concluding that large amounts of vitamin B6 and folic acid could prevent heart attacks by an astounding 51 percent.

Millions of Americans are turning daily to herbal remedies and seeking primary health care from the alternative, holistic providers who prescribe them. There is an urgent need for a dramatic increase in support for research on herbs and botanicals, justified by consumer demand and the Congressional intent expressed in DSHEA. The Dietary Supplement Commission report recommends that, ". . . Federal agencies continue to support off research on the health benefits and safety of dietary supplements. Research should be expanded beyond the traditionally supported areas associated with vitamin and mineral supplements and include research on some of the more promising botanical products used as dietary supplements." NNFA wholeheartedly agrees.

Ours is one of the few cultures in the world for whom the prevention and treatment of disease with non-prescription herbal medicines is the exception rather than the rule. This is largely due to the fact that foreign research oftentimes is deemed unacceptable by the Food and Drug Administration for use in justifying health claims for herbs and botanicals. We urge the Committee to provide the adequate funding for research on the safety and benefits of medicinal herbs.

NIH'S OFFICE OF DIETARY SUPPLEMENTS

The Office of Dietary Supplements (ODS) was established at the National Institutes of Health by DSHEA, to stimulate, coordinate and disseminate the results of research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease. It is my understanding that ODS will receive its authorized level of $5 million for fiscal 2000. NNFA requests a further increase for this office in fiscal 2001.

NNFA agrees with the President's Commission on Dietary Supplement Labels that if fully-funded, " . . . ODS could play a valuable role in providing consumers with information about dietary supplements . . . including [the] promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet [the] mandates of the Act." ODS now has the capacity to provide useful information to consumers whereby meeting the Congressional mandate of the Office.

We also urge continued funding for the botanical research initiative which began in fiscal 1999 at the ODS. ODS has recently funded two botanical research centers located at the University of California at Los Angeles (UCLA) and the University of Illinois at Chicago (UIC). ODS expanded the botanical research center initiative by releasing an additional request for application for a botanical research center at the end of 1999. ODS' long-term goal is to expand the initiative and obtain botanical research centers throughout the country. NNFA supports this goal.

NATIONAL CENTER FOR COMPLIMENTARY AND ALTERNATIVE MEDICINE

In 1992 Congress directed the National Institutes of Health to establish the Office of Alternative Medicine with the expressed task of assuring objective, rigorous review of alternative therapies to provide consumers reliable information. In fiscal 1999 the Office of Alternative Medicine was elevated to a Center with its own grant making capabilities. Funding for the Center has grown along with its increased authority from $2 million in fiscal 1992 to $50 million in fiscal 1999 to $68.8 million in fiscal 2000. I thank the Committee for its support of NCCAM. NNFA supports increased funding for this important Center in fiscal 2001. This has given alternative research a well-deserved boost and is more in line with the health choices of most Americans.

A 1998 Newsweek study states that some 83 millions Americans, about 40 percent of the adult population, are seeking alternative medical treatment. Also, findings from the "National Survey of Alternative Medicine Use," published in the January, 1993 New England Journal of Medicine, reveal that Americans made an estimated 425 million visits to alternative medical therapy providers in 1990, exceeding the 338 million visits made to all U.S. primary care providers that year. The survey also showed that out-of-pocket expenditures associated with alternative therapies totaled $10.3 billion in 1990, approaching the $12.8 billion in out-of-pocket expenses incurred for all U.S. hospitalizations during the same period. It is crucial for the health and security of all Americans that objective, scientific research is done to determine the effectiveness of complementary and alternative therapies.

DEMONSTRATION PROJECTS AT AHRQ AND HFCA

The Agency for Healthcare Research and Quality (AHRQ) is often directed by the Committee to pursue projects designed to research the cost-effectiveness attendant to novel approaches to the treatment and/or prevention of illness. The time is right for investigation of the worthiness of certain dietary supplements, based on well-designed, cost-effectiveness research.

Every year, treatment of chronic conditions and illnesses—from flus and colds to hypertension to dementia and Alzheimer's disease—generates enormous publicly and privately funded health care expenditures. There exists an opportunity to trim such burgeoning costs through prevention and/or treatment of these chronic ailments—or delay of their onset—with safe, effective, low cost dietary supplements. NNFA is confident that basic research at NIH can lead to appropriately structured, cost/outcome research at AHRQ which would demonstrate the value of dietary supplements in comparison to contemporary medical intervention. This evidence can, in turn, lead to Health Care Financing Administration (HCFA) projects to determine if a policy of reimbursement could be established.

Despite the growing popularity and demand for herbs and nutritional supplements, and their widespread use for prevention and intervention of chronic illness, precious few large-scale outcome studies on American populations are available to give health professionals the information they need to make decisions on alternatives to contemporary medical approaches. Echinacea has been shown to be effective in preventing and treating colds and flus; folic acid has been shown effective for neural tube defects and also homocysteine levels in cardiovascular disease; herbal/nutritional combinations have been shown to provide control for hypertension without the side effects which cause many patients to stop using their prescription medicine; and the use of glucosamine sulfate for joint function. NNFA believes that a sufficient body of botanical and nutrient research may exist in certain instances, to whet AHRQ's appetite and to warrant Congressional consideration of cost-effectiveness studies in this area.

NNFA urges the Committee to consider directing AHRQ to work with the Office of Dietary Supplements and the National Center of Complimentary and Alternative Medicine to review the existing outcome research on dietary supplements. The AHRQ could then investigate the feasibility, under appropriate protocols, of developing cost-effectiveness projects designed to compare the value of herbs and other dietary supplements in the treatment and prevention of chronic illness to typical medical approaches. The areas I have mentioned are but a few of the many possibilities which urgently present themselves for research and evaluation. Once the necessary biomedical and cost-effectiveness research have been completed, NNFA urges the Committee to direct HCFA to investigate the potential reimbursement for promising alternative therapies and treatments involving nutritional supplements and herbs.

A SOUND INVESTMENT IN THE HEALTH AND WELL-BEING OF ALL AMERICANS

Science and experience ably demonstrate a wealth of benefits attendant to the regular use of vitamins, minerals, amino acids, enzymes, herbs and botanicals—all classified by DSHEA as dietary supplements. Dietary supplements are allowing millions of American consumers to take charge of their own good health by safely and effectively preventing and treating a host of illnesses and conditions. The body of research supporting use of these products is impressive, but sorely requires immediate and dramatic expansion. NNFA urges the Committee to endure the Congressional mandate expressed in DSHEA by investing in the scientific research which holds the key to our knowledge of the remarkable importance and value of dietary supplements.

Thank you.

PREPARED STATEMENT OF THE NYU SCHOOL OF MEDICINE

I want to begin by thanking you, Mr. Chairman, and members of this Subcommittee for your continued support of the National Institutes of Health (NIH). You clearly recognize the importance of a strong Federal investment in medical research and that today's investments may represent tomorrow's treatment and cures for many disorders and diseases. This Subcommittee has been a leader in ensuring that our nation remains a leader in the field of medical research, and on behalf of the NYU School of Medicine, I thank you.

The NYU School of Medicine takes pride in a history that goes back to 1837 and includes the initiation of and the participation in many of the major events in American medicine through two centuries. The School annually graduates 150 physicians, and it employs 3,000 individuals including more than 800 faculty members. For 150 years the School has provided high quality patient medical services and medical supervision to Bellevue Hospital Center, New York City's premiere municipal hospital. The mission of the School is threefold: the training of physicians, the search for new knowledge, and the care of the sick. These three missions must be carried out simultaneously for they are wholly dependent upon each other, not only for inspiration, but for their very means of success. At the School of Medicine, we recognize that in order to excel in these three missions, we must be responsive to the major events and trends that are shaping medicine in our time. These include: the revolution in molecular biology and medical technology; the societal imperatives imposed by rising health care expectations and the finite limits on resources; the explosive growth in biomedical information; and the increasing role of the patient in the decision-making process.

In my opinion, there has never been a more exciting time to enter medicine. Enormous breakthroughs have allowed great advances in our understanding of disease and our ability to devise new therapies. We know with certainty that this explosion of knowledge will continue. With continued federal support for basic, cutting edge research supported through the NIH, we will continue to move closer to our goal of translating the promise of scientific discovery into an improved quality of life for all Americans. As we enter this century, we must continue to provide the resources and investments necessary to seize upon these tremendous opportunities. The NYU School of Medicine supports the recommendation of the Ad Hoc Group for Medical Research Funding, a coalition of nearly 200 patient and voluntary health groups, medical and scientific societies, academic and research organizations, and industry, of $20.5 billion for NIH in fiscal year 2001. This $2.7 billion (15 percent) increase represents the third step toward fulfilling the bipartisan goal of doubling the NIH budget by fiscal year 2003.

As the volume of NIH research increases, we must address the need for upgraded, state-of-the-art facilities to carry out this federally-supported biomedical and behavioral research. A 1998 National Science Foundation (NSF) study on the status of scientific research facilities at U.S. colleges and universities identified an estimated $11.4 billion in deferred research construction and repair/renovation projects, as well as a decrease in new construction of health research facilities across an array of institutions. Adequate laboratory space and research instrumentation are necessary to obtain the best data from NIH research dollars. For this reason, I urge you to provide $250 million for extramural facilities construction at the National Institutes of Health (NIH) in your fiscal year 2001 bill.

In addition to providing significant funding increases for NIH—including increased funds for extramural research infrastructure—I thank you for raising the salary cap imposed on extramural researchers from Executive Level III to Executive Level II ($141,000) in last year's bill. The higher salary level will allow many institutions, such as the NYU School of Medicine, to attract and retain the best inves-

tigators in their respective academic research programs. However, under the Senior Biomedical Research Service (SBRS) program on the NIH campus, the NIH can pay its senior investigators up to $151,000—roughly equal to what the salary cap on academic researchers would be if it were indexed for inflationary increases over the past decade. To seek a level playing field with intramural NIH researchers, we seek your support in raising the current salary cap to Executive Level I in the fiscal year 2001 bill.

Over the past decade, several trends in the health care marketplace and fiscal stewardship of the public-private partnership have destabilized research institutions and the pool of specially trained personnel necessary to continue to push the frontiers of medical research. For this reason, the medical center supports the proposal that the NIH establish a Flexible Institutional Support for Health Research (FISHR) program. This peer-reviewed, three-year grant program will provide institutional resources to meet evolving needs in research in the range of $25,000 to $300,000 a year for deans of medical, public health, nursing and dental schools. We suggest a funding level of $60 million in fiscal year 2001 for this competitive, renewable pool of accountable resources which will help modify the impact of the recent stresses experienced by research and academic institutions and will serve to maintain the integrity of our national research enterprise.

I would like to highlight an exciting initiative at the School of Medicine. The School of Medicine is developing a comprehensive Program in Women's Cancer (PWC). This program will be an integral component of the Comprehensive Cancer Center (CCC). The PWC will encompass the full spectrum of clinical services, advanced training, fundamental and translational research into those cancers that exclusively or primarily affect the female reproductive tract. The components of this program include: etiology and biology; risk identification and prevention; screening; diagnosis and treatment; palliation and rehabilitation; and psycho-social support.

The PWC will function as a multi-departmental entity with on-site clinical services provided by the Departments of Medicine, Obstetrics and Gynecology (Ob/Gyn), Pathology, Radiation Oncology, Radiology, and Surgery. The physicians from these departments will be supported by a team of social workers, physical and occupational therapists to ensure continuity between in-patient and out-patient care.

The School is seeking the Subcommittee's support to expand its PWC. The School is requesting $5 million in support through the Health Resources and Services Administration's Health Facilities Construction account in your fiscal year 2001 bill.

Thank you again, Chairman Specter, for your attention to these important issues.

PREPARED STATEMENT OF THE TEXAS NEUROFIBROMATOSIS FOUNDATION

The Texas Neurofibromatosis Foundation is pleased to submit testimony in support of funding for the National Institutes of Health and for neurofibromatosis in your fiscal year 2001 bill.

The Texas Neurofibromatosis Foundation was established in 1981 and is committed to meeting the needs of people challenged with NF by providing care, comfort, support, information, education, funding, and other resources for the treatment, prevention, and eventual cure of this disease. With offices in Dallas and Houston, the Foundation coordinates support groups, organizes fundraising events and educational symposiums, and assists with NF clinics across the state that serve the more than 5,000 individuals with NF in Texas. Dedicated volunteers form the heart of the organization, giving their time and talents to increase public awareness and raise the money necessary to support patient programs and research projects. Advocates from around the country look to the Texas NF Foundation as a model when establishing new a NF organization in a state. Texas is also home to some of the most exciting NF research described below.

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/or death. It is the most common neurological disorder caused by a single gene. While not all NF patients, like myself, suffer from the most severe symptoms, all of us live our lives with the uncertainty of not knowing whether we too will be severely affected because NF is a highly variable and progressive disease. Approximately 100,000 Americans have NF, and it appears in approximately one in every 3,500 births. It strikes worldwide, without regard to gender, race or ethnicity. There are two types of NF; type 1, which is the more common of the two and NF2 which primarily involves acoustic neuromas causing deafness and balance problems as well as other types of tumors such as schwannomas and meningiomas.

With your continued support and a relatively small Federal investment, NF has become one of the great success stories in the current revolution in molecular genetics. Because of the enormous advances that have been made, one leading NF researcher has stated that more is known about NF genetically than any other disease. Accordingly, many NF researchers believe that NF should serve as a model to study all diseases. The future promise of NF research is based upon these successes. Let me highlight for you some of the advances in NF research that have occurred since 1990:

—The discovery of the NF1 and NF2 genes and gene products;
—Determination of the close connection between NF and cancer, brain tumors, learning disabilities, heart disease, and other neurological disorders;
—Determination and understanding of the functions of the NF1 and NF2 genes and gene products including the discovery of new pathways impacted by the NF genes and gene products;
—Development of advanced animal models;
—Development of drug and gene therapies;
—Commencement of clinical trials at NCI;
—Establishment of an international consortium of NF researchers and patients;
—Rescuing learning deficits in animal models with NF1;
—Substantial increase in the number of NF researchers

The enormous promise of NF research—and its potential to benefit tens of millions of Americans in this generation alone—has gained increased recognition from Congress and the NIH. This is evidenced by the fact that five Institutes at NIH are currently supporting NF research (NCI, NINDS, NIDCD, NICHD, and NHLBI) and NIH's total NF research portfolio has increased from $11 million in 1995 to approximately $18 million in 2000. The National Institute on Disability Research and Rehabilitation (NIDRR) within the Department of Education has also expressed an interest in pursuing NF research in the learning disability area since 35–60 percent of children with NF suffer from learning disabilities. For fiscal year 2001, the Subcommittee's continued support will be critical to build upon the basic and clinical research described below which is essential to moving us closer to a treatment and cure for this disease.

Since the discovery of the NF gene, researchers have established the connection between NF and the following diseases and disorders:

Cancer.—Dr. Samuel Broder, former Director of the National Cancer Institute, stated that NF was at the "cutting edge" of cancer research. Studies have investigated the connection between the ras oncogene, which is critical to control growth and development in healthy cells (and when mutated contributes to the formation of tumors), and the NF1 gene which is a tumor suppressor. The studies showed that ras activity can be inhibited by the NF1 protein neurofibromin. Since elevated ras activity is involved in 30 percent of all cancers, the inhibition of ras by neurofibromin may result in a cure, not only for NF, but also for many of the most common forms of cancer.

Learning disabilities.—In addition to NF's connection to cancer, NF also provides a unique opportunity to begin to uncover a molecular basis for cognitive impairment, and it holds the prospect of possessing a radiologic marker for brain dysfunction. Specific learning disabilities are the most common neurological complication in children with NF1. The reported frequency of learning disabilities in children with NF ranges between 30–65 percent. Uncovering the molecular and cellular causes for the learning deficits caused by NF should also reveal important clues on what causes and how to cure tumors in NF1 patients, because the same molecular mechanisms underlie both tumor formation and learning disabilities. For example, recent research on mice with the same mutation that causes NF1 in humans (NF1 mice) has shown that treating the mice with a drug (farnesyl transferase inhibitor) that decreases ras function (the same ras that causes cancer and tumors) CURES their learning disabilities. Studies on fruit flies have also demonstrated that the protein made by the NF1 gene is part of the c-AMP pathway, the pathway which is known to control learning and memory.

Deafness.—Leading NF researchers believe that the science has progressed to the point when a gene therapy for NF2 can be developed and tested. Unlike other genetic forms of deafness, in which mutation leads to a development or structural abnormality in the ear for which it would be difficult to envisage a treatment in the adult, NF2-associated deafness is potentially preventable or curable if tumor growth is halted before damage has been done to the adjacent nerve. NF2 accounts for approximately 5 percent of genetic forms of deafness. It is also related to other types of tumors including schwannomas and meningiomas, as well as being a major cause of balance problems.

Heart disease.—Recently published research has also demonstrated the relationship between NF and heart disease. Researchers have demonstrated that mice completely lacking in NF1 have congenital heart disease that involves the endocardial cushions which form in the valves of the heart. This is because the same ras which causes cancer and learning disabilities also causes heart valves to close and neurofibromin suppresses ras, thus opening up the heart valve. Errors in valve formation account for a large percentage of congenital heart disease in humans, and congenital heart disease is the most common type of congenital defect. Researchers believe that further understanding how an NF1 deficiency leads to heart disease may help to unravel molecular pathways affected in genetic and environmental causes of heart disease. This finding opens up a new area for future research in congenital heart disease. In addition, the role of NF1 in neural tube closure suggests that NF1 research may bear on the understanding of causes of Spina Bifida, a common birth defect.

NF research is on the precipice of many major discoveries that will have broad and significant implications for Americans suffering from many disorders and diseases. For example, NCI is currently conducting clinical trials on NF patients involving the use of farnesyl transferase inhibitors in pediatric patients with refractory solid tumors. Other areas of research opportunity include:

—Further clinical trials;
—Expansion of drug and genetic therapies for NF and related disorders;
—Further development of NF animal models;
—Maintenance and expansion of consortium of NF clinical researchers and patients;
—Further determination of the connection between NF and cancer, tumors, heart disease, learning disabilities, deafness, bone and other disorders;
—Further determine function of the NF genes and gene products;
—Expansion of pool of NF researchers

This Subcommittee recognizes that our goal should be to translate the promise of scientific discovery into an improved quality of life for all Americans. To accomplish this goal, we must, as a nation, continue to invest in medical research at the NIH. Sustained, stable growth in funding for the NIH is needed to build upon past scientific achievements, address present medical needs, and anticipate future health challenges. Volatility and dramatic fluctuations in funding can be as harmful to the research enterprise as inadequate growth. Towards this end, I encourage the Subcommittee to support the recommendation of the Ad Hoc Group for Medical Research Funding, a coalition of over 200 patient and voluntary health groups, medical and scientific societies, academic and research organizations, and industry, which calls for a fiscal year 2001 appropriation of $20.5 billion for the National Institutes of Health (NIH). In addition to providing increased funding for the NIH as a whole, this Subcommittee has recognized the promise of NF research and has included language in your fiscal year 2000 Report encouraging NCI, NINDS, NICHD, NIDCD, NHLBI, and NIDRR at the Department of Education to increase their NF research portfolios through the use of: Requests for Applications, Program Announcements, the National Cooperative Drug Discovery Group Program, and Small Business Innovation Research Grants, as appropriate. I urge the Subcommittee to continue to encourage these Institutes to continue this trend.

In closing, I will end with a statement that appeared in an edition of Cold Spring Harbor Laboratory's newsletter which focused on major breakthroughs in NF research: "the hope is that the day may come when doctors can flip critical switches to repair the broken circuits in each of these disorders and diseases. Such life-changing therapies will be the reward for years of enthusiastic basic research." I believe, Mr. Chairman and members of the Subcommittee, that with your continued support, that day will soon be here.

PREPARED STATEMENT OF THE WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER

I would like to begin by thanking the members of this Subcommittee for their continuous support of and tireless efforts to increase funding at the National Institutes of Health. You have all been leaders in helping to advance science to ensure that today's discoveries translate into tomorrow's treatments and cures for millions of Americans. Your leadership has also helped to ensure that America remains a leader in the field of medical research. The Wake Forest University Baptist Medical Center stands behind your goal of doubling the budget of the National Institutes of Health (NIH) by the year 2003. As you have stated so eloquently many times, Chairman Porter, there are more opportunities in basic and clinical research than ever before. And as we enter this century, we must provide the resources and in-

vestments necessary to seize upon these opportunities. The medical center supports the Ad Hoc Group for Medical Research Funding's fiscal year 2001 request of $20.5 billion for NIH. This $2.7 (15 percent) increase represents the third step toward fulfilling the bipartisan goal of doubling the NIH budget by fiscal year 2003.

As the volume of NIH research increases, we must also recognize the need for upgraded, state-of-the-art facilities to carry out this federally-supported biomedical and behavioral research. A 1998 National Science Foundation (NSF) study on the status of scientific research facilities at U.S. colleges and universities identified an estimated $11.4 billion in deferred research construction and repair/renovation projects, as well as a decrease in new construction of health research facilities across an array of institutions. Adequate laboratory space and research instrumentation are necessary to obtain the best data from NIH research dollars. For this reason, I urge you to provide $250 million for extramural facilities construction at the National Institutes of Health (NIH) in your fiscal year 2001 bill.

In addition to providing significant funding increases for NIH—including increased funds for extramural research infrastructure—I thank you for raising the salary cap imposed on extramural researchers from Executive Level III to Executive Level II ($141,000) in last year's bill. The higher salary level will allow many institutions to attract and retain the best investigators in their respective academic research programs. However, under the Senior Biomedical Research Service (SBRS) program on the NIH campus, the NIH can pay its senior investigators up to $151,000—roughly equal to what the salary cap on academic researchers would be if it were indexed for inflationary increases over the past decade. To seek a level playing field with intramural NIH researchers, I am seeking your support in raising the current salary cap to Executive Level I in the fiscal year 2001 bill.

Over the past decade, several trends in the health care marketplace and fiscal stewardship of the public-private partnership have destabilized research institutions and the pool of specially trained personnel necessary to continue to push the frontiers of medical research. For this reason, the medical center supports the proposal that the NIH establish a Flexible Institutional Support for Health Research (FISHR) program. This peer-reviewed, three-year grant program will provide institutional resources to meet evolving needs in research in the range of $25,000 to $300,000 a year for deans of medical, public health, nursing and dental schools. We suggest a funding level of $60 million in fiscal year 2001 for this competitive, renewable pool of accountable resources which will help modify the impact of the recent stresses experienced by research and academic institutions and will serve to maintain the integrity of our national research enterprise.

There are many exciting initiatives under development and underway at the medical center. This year, we are seeking support from this Subcommittee to complete two floors in the Center for Research on Human Nutrition and Chronic Disease Prevention facility to expand research in the area of prostate cancer and women's health. Specifically, we are seeking $5 million in the Subcommittee's fiscal year 2001 bill through the Health Resources and Services Administration's Health Facilities Construction Program for this important project.

Prostate cancer is the most common cancer in men and the second most common cause of cancer deaths among men. Nationally, one in nine men will, during their lifetime, be affected with prostate cancer. Given the high incidence (28 percent), high prevalence (41 percent), and low mortality (7 percent) of prostate cancer, the need for better diagnosis, prevention, treatment and supportive care is compelling. North Carolina and the Southeast have pockets of the highest incidence and mortality of prostate cancer in the country. Areas of South Carolina and eastern North Carolina have an exceedingly high incidence of the disease. One North Carolinian will die from prostate cancer every 7.3 hours. Explanations of this high incidence have included the typically Southern high fat diet as well as exposure to agricultural pesticides. These epidemiologic associations, however, are still inconclusive and more research is needed. Further, strategies to prevent prostate cancer by altering dietary habits or environmental exposures have been incompletely developed. African American men are particularly prone to prostate cancer for a number of reasons. Incidence of prostate cancer is higher in African Americans than in Caucasians and African Americans are diagnosed at later stages of the disease. The Comprehensive Cancer Center at Wake Forest University Baptist Medical Center has a long history of achievement in the area of minority population research as it relates to cancer, and this program will build on this strength. This program initiative will integrate basic, clinical and population science research.

In this decade, most women can expect to live 30 years or more beyond menopause. Several critical health issues and chronic conditions begin to emerge during this stage in a woman's life, yet we are just beginning to examine and understand these conditions. This program will build upon the nationally-recognized work of in-

vestigators at the Medical Center in the area of postmenopausal women. The Medical Center is already recognized as a world leader in research concerning the role of hormone therapy in the prevention of cardiovascular and other chronic diseases. The goal of this program is to establish a well-integrated primary clinical care program for women in their post-menopause years as well as expand the research in this area. Developing and testing multiple models to understand the complex relationship between estrogen and other estrogen-related products and various systems in women will be a major focus of this program.

Thank you, Chairman Specter for considering these important issues.

PREPARED STATEMENT OF THE FDA-NIH COUNCIL

INTRODUCTION

The FDA-NIH Council appreciates the opportunity to submit testimony concerning the National Institutes of Health (NIH) as the world's largest and most distinguished organization dedicated to maintaining and improving health through medical science, and we consider investment in medical research to be our greatest hope for a healthy future. To that end, the FDA-NIH Council joins the medical research advocacy community, the Ad Hoc Group for Medical Research, in supporting an appropriation of $20.47 billion for the NIH in fiscal year 2001, with the goal of doubling the Agency's budget within five years. We believe that it is an important priority for the Congress to continue its commitment to double the budget of the NIH, and the Council is indebted to the Committee for keeping the NIH a priority within the Congress.

The FDA-NIH Council is a broad based coalition 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 and enhancing the noble missions of the Food and Drug Administration (FDA) and the NIH.

Medical research and innovation aim to improve health and the quality of life by finding better ways of diagnosing and treating, and preventing and curing disease. Breakthroughs come from a process of innovation, each advance building upon the one that preceded it. From research in academic, government and industry laboratories, and from the accumulation of clinical experience in managing disease, our information about the mechanisms of disease and innovation in medicine are continually developed. We 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 for our ability to bring research discoveries from the laboratory to the patient.

Together with its partners in medical discovery and innovation—academia, biomedical research industries, voluntary health foundations, health professionals and consumers—the work funded by the NIH and subsequent product development with its partners has jettisoned the United States into international preeminence in this area. All of the partners in the process of medical discovery are interdependent, each contributes a critical piece to the puzzle. The success of our national enterprise is not possible without each piece remaining 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. Breakthroughs such as the development of antibiotics and organ transplantation, life-extending and life-saving cancer therapies, the identification of the AIDS virus and the drugs to treat AIDS, have given the American public a glimpse into the potential offered through the rapid advances in medical science. But, we must take these "half-way" technologies all the way to the finish line by continuing our strong funding commitments to research breakthroughs.

The FDA-NIH Council supports the research themes advanced by the NIH, including:

To Exploit Genomics by accelerating the human genome project; expanding work on model animal systems; learning to gather and use complex biological information; and building bioinformatics.

To Reinvigorate Clinical Research by recruiting, training, and retaining clinical investigators; strengthening clinical research centers; supporting clinical trials, networks, and databases; and developing partnerships with managed care organizations, foundations, industries, and other Federal agencies.

To Harness the Expertise of Allied Disciplines, such as chemistry, engineering, computer science, mathematics, optics, and physics in order to work with medical scientists in, for example, designing new drugs; imaging molecules, chromosomes, cells, and organs; developing biomaterials; and analyzing bioinformatics and clinical data.

To Reduce Health Disparities at Home and Abroad through research and training, testing interventions, and building international research capacity.

We are now on the threshold of the next great revolution in modern medicine, gene therapy. With the identification of the genes responsible for a large number of our normal functions and the genetic abnormalities that cause many diseases, we gain greater understanding into disease and keys to unlock the future of medicinal research. Each time researchers discover a gene, they open the door to a new therapy or cure. Today, when we talk about our medical research enterprise, we speak from the standpoint of great success and even greater opportunities.

The health of our nation is dependent upon a strong national commitment to medical research. As we enter the new millennium, 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.

The FDA-NIH Council would like to draw your attention to the growing capacity of our national research enterprise and the need to sustain its long term health as it undergoes the transformation required to meet the challenges of this century.

—*Investigator-initiated Research.*—The support of basic medical research through competitive, peer-reviewed, and investigator-initiated research project grants continues to be among the highest of funding priorities. As new knowledge is discovered, it is vitally important for the NIH to support early patient-oriented research to determine the application of laboratory advances to persons with disease. Further, training and educational programs require adequate resources to ensure that the next generation of clinical scientists is in place to continue the rapid translation of research from the bench to the bedside.

—*Eliminating Health Disparities.*—A key component to eliminate health disparities among populations in the United States is medical research and research training. We need to ensure that multidisciplinary collaborations take place to understand the causes of health disparities; develop new and improved prevention strategies, diagnostics, and treatments to reduce health disparities; and enhance communication of research results to scientists, health professional, affected communities, and the public.

—*Clinical Research.*—To take full advantage of rapid research advances, the NIH is planning to initiate new pilot and early-phase clinical trials, thereby speeding the testing of new therapies. Further, the NIH has expanded the national clinical trials database, and made it more accessible to the public through the Internet (ClinicalTrials.gov). The early research conducted through the NIH is imperative prior to the maturation and full exploitation of advances in the marketplace.

—*Research Facilities.*—The sophistication of the research initiatives requires an ever-increasing sophistication in the physical plants and research laboratories. Research facilities, equipment and instrumentation, and animal facilities must be state-of-the-art in order to fully exploit our research potential.

The FDA-NIH Council recognizes the inherent difficulties in terms of weighing the available resources and supporting numerous worthy federal programs. We recognize and are extremely grateful for the support that this Committee has provided to the NIH in the past. However, we also believe that the functions of the NIH are vital to our economy as well as the health and welfare of our citizens and urge your support for continued strong funding.

The FDA-NIH Council thanks the Committee for the opportunity to submit testimony. We appreciate the support of this Committee.

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; Albert B. Sabin Vaccine Foundation; Merck & Co., Inc; Pfizer, Inc.; American Veterinary Medical Association; Joint Council of Allergy, Asthma and Immunology; American Society of Tropical Medicine and Hygiene; American Academy of Pediatrics; National Multiple Sclerosis Society; Glaxo Wellcome, Inc.; Cystic Fibrosis Foundation; Bristol-Myers Squibb Company; Society of Toxicology; Research Society on Alcoholism; Theracom; Parkinson's Action Network; Academic Contract Research Orga-

nization; American Academy of Allergy, Asthma and Immunology; Bermuda Biological Station for Research; and the Cancer Research Foundation of America.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH

My name is Mike Veeck. I am the owner and operator of five professional baseball franchises. My daughter, Rebecca, has a blinding retinal degenerative disease called cone-rod dystrophy. I appreciate the opportunity to present this written testimony on behalf of the National Alliance for Eye and Vision Research (NAEVR), an umbrella organization of thirty professional, lay advocacy and industry organizations dedicated to expanding our national capacity to address eye and vision research opportunities. I am an active member of the Foundation Fighting Blindness, which is an active participant in the National Alliance for Eye and Vision Research.

I would like to begin by thanking you, Chairman Specter, and members of this Subcommittee for your continuing commitment to medical research supported by the National Institutes of Health (NIH) and the National Eye Institute (NEI). Mr. Chairman, you and your colleagues have been tremendously supportive of pushing the frontiers through unprecedented support of the NIH. We know that you have many difficult decisions with regard to funding priorities in your Appropriations Bill and we appreciate the strong support that you have provided NIH. Without this support we would not be on the verge of many new treatment breakthroughs for blinding eye diseases. Due to the amazing advances in basic and clinical science, we are beginning to reap the benefits of our research investment. However, more and more we are forced to prioritize what areas of research to support because we do not have the funding available to support all of the opportunities that exist. This is true in all areas of vision research, and in the public and private sectors.

The written testimony that follows focuses on three specific issues:

—Fiscal year 2001 funding request for the NIH and NEI

—Scientific opportunities in eye and vision research

—Why eye and vision research is so important to me personally

FISCAL YEAR 2001 FUNDING REQUEST

The National Alliance for Eye and Vision Research urges your continued commitment to the campaign to double the budget for NIH by fiscal year 2003, referred to as the NIHx2 campaign. We strongly support the recommendation of the Ad Hoc Group for Biomedical Research Funding calling for a $2.7 billion, or 15 percent, increase for NIH in fiscal year 2001, which is the level necessary to pursue a doubling of the NIH budget.

Within the context of the NIH budget, the National Alliance for Eye and Vision Research seeks your strong support for the NEI professional judgement budget calling for a 20 percent increase in fiscal year 2001. The priorities identified in this budget were a part of long range strategic plan, Vision Research—A National Plan: 1999–2003, in which the entire extramural research community participated. This funding level would provide $90.5 million above current year levels resulting in an NEI budget of $543 million in fiscal year 2001. This level of increase for eye and vision research is called for as a result of previous disparities which have disadvantaged NEI in the NIH priority setting and funding allocation process. Historically, the NEI ranks among the lowest Institutes relative to the percentage increase in funding provided by the Congress.

As you know Mr. Chairman, the professional judgement budget reflects the funding necessary to continue ongoing research initiatives and pursue new scientific opportunities that have resulted from the nation's investment in eye and vision research. I would like to discuss some of the exciting research opportunities that will be pursued with this level of investment to assure you that an investment in eye and vision research will be a wise and cost-effective investment.

SCIENTIFIC OPPORTUNITIES IN EYE AND VISION RESEARCH

Neurodegeneration Research.—Research on neurodegeneration and the rescue and regeneration of neural cells is an area of tremendous opportunity with application to many neurological diseases and conditions, and to cases of traumatic injury, including:

—*Rescue of Photoreceptor Cells in Retinal Degenerative Diseases*.—Retinal degenerative diseases such as macular degeneration, retinitis pigmentosa and Usher syndrome affect more than six million Americans of every age and race. NEI funded scientists have already developed several promising experimental treatments for preventing or dramatically slowing vision loss from these blinding dis-

eases. Pharmaceutical and neurotrophic agents, retinal cell transplantation, and molecular and genetic technologies have shown therapeutic value in laboratory animals. Further laboratory research is needed to advance these promising therapies to clinical trials.

—*Survival of Retinal Ganglion Cells in Glaucoma*.—Retinal ganglion cells (RGCs) can be studied in culture conditions, providing a special opportunity for investigating signaling mechanisms that normally promote survival and how these mechanisms are altered by injury.

Protection of Nerve Cells in Glaucoma.—Researchers have found elevated levels of nitric oxide synthase in the optic nerve heads from human eyes with glaucoma and animal models of glaucoma. By pharmacologically inhibiting the production of nitric oxide in these animals, scientists found that axons of the optic nerve were protected from neurodegeneration.

Resources for Research on the Visual System.—In order to better understand the molecular and genetic basis for inherited diseases of the eye, it is essential that research be conducted to identify and sequence genes that are expressed in the visual system and to identify disease-causing genetic mutations. There are a number of research projects, which could be pursued more aggressively with additional NEI funding. This genetic information will be collected from ocular tissues that are qualitatively and quantitatively representative of the genes expressed in the visual system and optimized to detect rare or unique sequences. It is anticipated that this catalogue of genes expressed in the visual system will be publicly available in an easily accessible and retrievable format to facilitate research on eye diseases with the goal of improving treatment or preventing their occurrence.

Control of Angiogenesis.—Diseases that affect retinal blood vessels are among the major causes of visual disability and blindness in this country. These include diabetic retinopathy, retinopathy of prematurity, neovascular glaucoma, and age-related macular degeneration in which the proliferation of abnormal new blood vessels can result in the rapid and irreversible loss of vision. Scientists have discovered that inhibitors of certain growth factors and enzymes are ideal candidates for the treatment of these diseases.

Bioengineering and Advanced Instrumentation.—NEI is pursuing the development of advanced assistive devices for the visually impaired, adaptive optics and other imaging techniques to improve non-invasive examination of ocular tissues for both research and disease diagnosis, instruments to analyze the biomechanics of the eye, and instruments to analyze visual performance. NEI is continuing research on the further development of laser-targeted dye delivery systems which could revolutionize the visualization of blood vessels in the retina and the treatment of eye disorders; and optical coherence tomography and confocal scanning laser polarimetry for quantitative measurements of the retinal nerve fiber layer.

Clinical Research and Health Disparities.—Research in this area will enhance our understanding of glaucoma, diabetic retinopathy, and myopia incorporating studies of comorbidity, natural history, and genetics with special emphasis on populations at increased risk. For example, rates of blindness from glaucoma are six times higher in African-Americans than in Caucasians, however age-related macular degeneration is rare for African-Americans as compared to Caucasians.

Low Vision.—A related area of concern is low vision, or vision impairment which is not correctable by glasses or contact lenses. As many as 12 million Americans suffer from visual impairments which affect their ability to read, drive, work, and perform many everyday activities we all take for granted. The most common eye diseases that cause visual impairment in adults are AMD, cataract, glaucoma, diabetic retinopathy, and optic nerve atrophy. Even more serious are eye diseases that cause visual impairment in children. These include certain forms of retinitis pigmentosa, Stargardt and Best disease, retinopathy of prematurity, cortical visual impairment, and coloboma. Low vision in children often affects their development and results in the need for special education, vocational training, and social services throughout their lives. The cost of these impairments is more than $22 billion each year.

Under the auspices of the National Eye Health Education Program (NEHEP), NEI has developed and is initiating a program directed at low vision in order to increase public awareness about visual impairment and the impact it has on everyday life. The Low Vision Traveling Exhibit will be displayed in shopping malls around the country during the next five years and was recently launched in Birmingham, Alabama. The program provides information about low vision services and the devices, which are currently available to assist those with visual impairments. This effort is directed at those suffering from visual impairments and also to medical professionals, eye care specialists, managed care organizations, and family members. NAEVR supports this public education partnership and urges the Committee to support it as well.

MY PERSONAL INTEREST IN EYE AND VISION RESEARCH

Mr. Chairman, I am in a race against time. Each day, my eight-year old daughter, Rebecca, loses more of her vision to a blinding retinal degenerative disease called cone-rod dystrophy. Retinal degenerative diseases are slowly robbing the vision of more than six million Americans of every age and race. Vision researchers working in NEI funded laboratories across the country have already developed several promising therapies that dramatically slow vision loss in animal models. Although my wife, Libby, and I are excited about this progress, we also live in fear that sight-saving treatments won't happen fast enough. With increased support for the NIH and NEI, we can speed these experimental treatments to clinical trials while my Rebecca can still see.

Conclusion.—Mr. Chairman, the members of the National Alliance for Eye and Vision Research are supportive of an increased research focus on eye and vision disorders, such as those outlined above, and hope that the Committee will allocate a 20 percent budget increase to the NEI to allow these critically important research efforts to continue and expand. As we enter the 21st Century, we must ensure that we are doing our best to find ways to prevent and treat eye and vision disorders, and are providing quality eye care services and devices for those who are already suffering from visual impairment.

Thank you.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE

Mr. Chairman and members of the Subcommittee, the American Society of Tropical Medicine and Hygiene (ASTMH) is pleased to have the opportunity to present its views on fiscal year 2001 funding priorities to the Subcommittee. The ASTMH, founded in 1903, is a professional society of approximately 3,500 researchers and practitioners who are dedicated to addressing the growing global threat of tropical infectious diseases. The collective expertise of our members is in the areas of basic molecular science, medicine, vector control, epidemiology, and public health. ASTMH is the principal voice for tropical medicine research within this country.

The staggering burden of tropical and infectious diseases and the impact on global health confronts us on a daily basis. Poor health and the spread of infectious disease across borders has profound impacts on the social and economic development and stability of nations around the globe. With the enormous volume of travel and trade today, and with the expanded deployment of American troops, infectious diseases can impact populations around the globe within 24 hours. The globalization of infectious disease has brought an increased realization that infectious diseases represent not only a humanitarian concern but also a bona fide threat to the health and national security of the United States.

In June 1996, President Clinton issued a Presidential Decision Directive calling for a more focused U.S. policy on infectious disease. The State Department's Strategic Plan for International Affairs lists protecting human health and reducing the spread of infectious diseases as U.S. strategic goals, and Secretary Albright in December 1999 announced the second of two major U.S. initiatives to combat HIV/AIDS. The unprecedented UN Security Council session devoted exclusively to the threat to Africa from HIV/AIDS in January 2000 is a measure of the international community's concern about the infectious disease threat.

Furthermore, the CIA's National Intelligence Council issued a hard-hitting report this past January entitled "The Global Infectious Disease Threat and Its Implications for the United States." The report concludes that infectious diseases are likely to account for more military hospital admissions than battlefield injuries. The report assesses the global threat of infectious disease, stating "New and reemerging infectious diseases will pose a rising global health threat and will complicate U.S. and global security over the next 20 years. These diseases will endanger U.S. citizens at home and abroad, threaten U.S. armed forces deployed overseas, and exacerbate social and political instability in key countries and regions in which the United States has significant interests."

Now more than ever, we must continue to be vigilant in our efforts to control and eradicate infectious diseases through prevention, treatment, and continued surveillance. As we enter the 21st century, we must marshal the efforts of government, industry, international organizations and private foundations if we are to protect our national security against biological and chemical attacks and protect Americans against infectious disease and antimicrobial resistance.

NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, the Society thanks you and members of the Subcommittee for your strong leadership in the area of biomedical research and for pursuing budget increases that will effectively double the NIH budget by fiscal year 2003. As a result of the 15 percent increase provided to the NIH in fiscal year 2000, new scientific and research opportunities are being pursued that hold the potential to prevent and control tropical and infectious diseases around the world. Your actions reflect the extraordinary importance of biomedical research to our national interest and are also helping to attract growing numbers of young scientists to the fields of academia and basic and clinical research.

The American Society of Tropical Medicine and Hygiene requests your continued support for the NIHx2 campaign by providing a $2.7 billion, or 15 percent, increase for NIH in fiscal year 2001 as advocated by the Ad Hoc Group for Biomedical Research Funding. An appropriation of $20.5 billion for NIH in fiscal year 2001 will allow promising research avenues to be pursued, including the development of new vaccines and treatments for diseases such as malaria, dengue fever, cholera, diarrheal diseases, HIV/AIDS, and a myriad of other viral bacterial, fungal and parasitic disease agents.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The NIH's tropical disease research program is funded primarily by the National Institute of Allergy and Infectious Diseases (NIAID) and there are several important on-going issues relating to NIAID's research efforts that we would like to highlight.

Malaria.—Globally, infectious diseases are the leading cause of morbidity and mortality, accounting for 1–3 times the mortality and morbidity resulting from heart disease, cancer and stroke combined. Of these infectious diseases, malaria continues to be the most devastating with a World Health Organization estimate of nearly 500 million clinical cases and up to 2.7 million deaths annually. Every 30 seconds a child somewhere dies of malaria. Even in the U.S., over 1,000 cases of malaria are reported every year, with local transmission being documented by the Center for Disease Control and Prevention (CDC).

The Society commends the NIH and NIAID for their continued leadership and focus on malaria. We strongly support the NIAID research agenda which has made malaria vaccine development a high priority and has involved collaborative research efforts with private sector partners, including the Malaria Vaccine Initiative. We urge the Subcommittee to strongly support these efforts. Malaria is a complex disease and its control will require a significant research effort in therapeutics as well as in vaccine development for improved disease treatment. We encourage an equally vigorous effort in development of new antimalarial drugs.

Tropical Medicine Research Centers.—The three centers overseas are most important in facilitating the NIAID's international tropical infectious disease research collaborations in areas endemic for these diseases. The research in the center is carried out in the endemic area by U.S. and local scientists. These centers are critical for the advancement of our scientific understanding and preparedness for emerging, reemerging and other tropical infectious disease threats. The awarding of these centers is highly competitive. The Society strongly urges that the Subcommittee express its continued support for these unique research opportunities.

Challenge Grants.—The Society of Tropical Medicine and Hygiene would like to thank the Subcommittee for its support of the new NIH Challenge Grants that were funded through the Public Health and Social Services Emergency Fund in fiscal year 2000. This initiative was created to promote collaborative research and development efforts between NIH, biotechnology, pharmaceutical and medical device industries to reduce the impact of infectious disease both nationally and worldwide. This unique investment in research and development will facilitate greater industry participation in the global effort to combat tropical and infectious diseases while at the same time leveraging private sector resources through the program's dollar for dollar matching requirement. The Society is pleased to note that NIAID has identified priority areas where the agency believes successful product research and development efforts could make a significant impact. The areas identified are malaria, tuberculosis, influenza, and emerging and resistant infections. The Society strongly urges the Subcommittee to provide continued support for the NIH Challenge Grant program in fiscal year 2001.

The Society commends Congress for its leadership in combating infectious disease and encourages this Subcommittee to work with your colleagues and the Administration to create additional incentives that encourage public-private partnerships in the battle against tropical infectious diseases. We strongly endorse efforts such as the President's Millennium Vaccine Initiative and legislation pending in the House

and Senate that provide a catalyst for research, development and production of vaccines and drugs, and make these products accessible in developing countries hardest-hit by infectious disease. If we hope to win the war against new and re-emerging tropical and infectious disease we must engage the collective resources of the private and public sector—both at home and abroad—in order get infectious disease under control until we can effectively conquer and prevent it.

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center (FIC) is a unique component of NIH with a mandate to support training in biomedical research on behalf of the developing nations of the world. The ASTMH wishes to acknowledge the significant contributions of the FIC in overall support of tropical disease research of direct vital importance to American travelers, servicemen, missionaries, Peace Corps volunteers, and foreign service officers, among others. Less obvious are the indirect benefits of training in tropical disease research for our foreign biomedical counterparts.

The Society supports the continued focus by the FIC to establish appropriate ethical standards relevant to internationally-based research. A delicate balance must be achieved between the need to facilitate vaccine and drug development and the testing of new products on human subjects in developing countries. The Society is pleased that the FIC has identified ethical principles and practice in patient-oriented research as one of four priorities it pursues in establishing research capabilities in developing nations. The Society encourages the Subcommittee to be supportive of FIC collaborations with its counterparts abroad and with international organizations in the pursuit of a broad ethic to be applied to internationally-based research initiatives.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The ASTMH appreciates the Subcommittee's past support for the CDC's infectious diseases program and requests your support for at least the President's fiscal year 2001 request of $202 million for these critically important public health initiatives Increased funding will help support the development of a national electronic disease surveillance network that will enable State and local health departments to respond to infectious disease outbreaks and share information about infectious disease emergencies and trends. The President's funding request will also increase the investment in the CDC's Food Safety Initiative, expanding the ability to more rapidly identify and track disease-causing bacteria including E. coli and Salmonella, and Shigella Sonnei, and provide for the implementation of a national prevention and control plan for hepatitis C.

CONCLUSION

As we enter the 21st Century, we must aggressively pursue the battle against tropical and infectious diseases, that undoubtedly will intensify in the years ahead. We must have adequate surveillance systems and modern infrastructure, coupled with scientific expertise in both basic and clinical research, if we are to develop the tools necessary to rapidly respond to, and control, the threats posed by tropical infectious diseases.

The Society greatly appreciates your support for our nation's investment in infectious disease research, control, and prevention activities. We urge you to continue your efforts to double the NIH budget over the next five years and towards this end we request a 15 percent increase for the NIH budget in fiscal year 2001. We also request that the Subcommittee support the Administration's proposed increase of $26 million for the CDC's infectious disease activities.

The Society of Tropical Medicine and Hygiene appreciates the opportunity to express our views and for your consideration of these requests.

PREPARED STATEMENT OF THE SOCIETY OF TOXICOLOGY

The Society of Toxicology is pleased to have this opportunity to present its views concerning research in toxicological sciences and its strong support for the National Institutes of Health (NIH), and specifically for the National Institute of Environmental Health Sciences (NIEHS).

The Society of Toxicology is a professional organization that brings together over 5,000 toxicologists in academia, industry, and government. The Society of Toxicology is dedicated to supporting research in toxicological sciences that leads to sound scientific information that can be employed to reduce uncertainties in assessing risks to human health and the environment. Enhancing science-based risk assessment

benefits everyone through improved decision-making that protects the health of people and their environment while at the same time providing for a more rational use of our limited financial resources, i.e., a win-win situation.

FUNDING REQUEST

First, the Society of Toxicology would like to thank you, Chairman Specter, and thank your colleagues on this Subcommittee for demonstrating tremendous leadership in the area of biomedical research by providing a 15 percent increase to the National Institutes of Health (NIH) in both fiscal years 1999 and 2000. Your commitment to the campaign to double the budget for NIH by fiscal year 2003 provides great hope to Americans afflicted with disease and disabling conditions and ensures that we will continue to unlock the mystery of disease, including diseases that may be attributable to causal agents in the environment.

Mr. Chairman, the Society of Toxicology strongly supports you in this goal and urges that you continue the NIHx2 campaign in fiscal year 2001. We urge the Subcommittee to support the recommendation of the Ad Hoc Group for Biomedical Research Funding calling for a $2.7 billion, or 15 percent, increase for NIH in fiscal year 2001. We also urge the Subcommittee to support the professional judgement budget recommended by the NIEHS calling for a 19 percent increase in fiscal year 2001, given its important role in increasing our understanding of how the environment potentially affects our health. Whether it is exploring asthma incidence in children, testing for the toxic potential of chemicals, or better understanding the genetics underlying environmental risk factors, NIEHS supported research is leading the way in bridging the gap between public policy and environmental health science.

RESEARCH OPPORTUNITIES

Basic research focused on discerning the mechanism or mode of action of a particular agent of interest is of fundamental importance to society. It provides the basis on which we make reasonable estimates as to whether or not harm might occur to people or the environment under realistic conditions of exposure. Furthermore, as we explore mechanisms by which chemical and physical agents may produce toxicity we learn more about basic biology; thus, toxicology is one of the basic biomedical sciences.

The quality of life in our Country has improved markedly over the past century. For example, life span was approximately 45 in 1900 and today it is 75+ years. Indeed, much of the good life that many of us enjoy is attributable directly to the proper use of chemicals, including medicines, to benefit people. Research in toxicology, including the use of animals, has and continues to play a key role by defining the conditions of use under which we may employ chemicals for good causes that benefit society. Yes, there have been some problems/mistakes made; however, importantly, we are striving to improve and research focused upon the key aspects of risk assessment (outlined below) will permit us to continue to make progress.

The scientific basis of risk assessment can be enhanced by the development of improved test systems and improved means for interpretation of results. Key aspects of any risk assessment include an emphasis on: (1) selection of doses used for testing and extrapolation, e.g., there should not be an emphasis on the use of excessive doses; (2) dose-response relationships, including extrapolation from high to low doses, e.g., effects that occur at high doses do not necessarily occur at low doses; (3) species-to-species extrapolation; and (4) exposure assessment, e.g., we need to take into consideration the relationship between doses used in testing as compared to the amounts that people might actually encounter. It is important to define conditions under which chemicals may be used, beneficially with a high degree of safety, and to identify those situations when a chemical's use should either be restricted severely or it should be banned. This entails hypothesis-driven research and it is consistent with the notion that it is the dose which makes the poison. Members of the Society of Toxicology believe strongly that our investment in biomedical research must be increased and sustained over the long-term if we are going to take advantage of the many exciting research opportunities that exist in environmental health sciences. We support the research agenda and priorities identified by NIEHS Director Dr. Kenneth Olden. These can further the development of the science that is necessary to provide a basis for sound decisions leading to both improved protection of human health and the environment.

NIEHS research on the Environmental Genome Project will help us to better understand why some people might be more susceptible to environmental exposures leading to disease development than others. This area of risk assessment is one which we know the least about. In this context, it is important to understand that exposure assessment, as noted above, is a key aspect of risk assessment. In order

to be credible, a risk assessment must be based upon realistic data concerning exposure. The Society of Toxicology commends NIEHS for its planned interagency collaboration with the Centers For Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) to improve the technological sophistication of exposure assessment and the use of exposure assessment in developing disease prevention strategies.

The Society of Toxicology supports the partnership between the NIEHS and the Environmental Protection Agency to establish a national network of Children's Environmental Health and Disease Prevention Research Programs to study children's health issues that might be linked to the environment, such as pediatric asthma and other respiratory diseases. These illnesses have lifelong adverse health implications for children and consume substantial health care dollars. Furthermore, basic research is required in order to learn whether or not there is a difference in the susceptibility of children as compared to adults with regard to the toxic potential of particular chemicals.

A strong investment in NIEHS will continue the study of the potential adverse effects of chemicals that might be able to disregulate endocrine activity. It is important to ascertain whether or not these compounds, often referred to as endocrine disrupters, actually contribute to human disease at the levels they are found in the environment. The Society is especially pleased that NIEHS is moving forward with a number of studies to examine the possible linkage between exposure to alleged endocrine disregulating chemicals and disorders affecting both male and female reproductive health.

We applaud the NIEHS for spearheading the NIH research effort in collaboration with the FDA and industry and academia, to develop biomarkers for the efficacy and safety of new drugs. It is imperative that promising therapeutics move from the laboratory to the patient in a more timely manner with a high level of assurance concerning their efficacy and safety. You can be sure that the Society of Toxicology will continue to promote this important research collaboration. Under Dr. Olden's direction, NIEHS has taken a leadership role with regard to encouraging partnerships involving government, academia and industry to work on environmental health-related issues.

NIEHS continues to play an important role in the multi-agency effort to identify the research needs on the safety and efficacy of herbal medicines. Of the approximate 2,000 herbal products in use, only a few have been adequately tested for efficacy and toxic potential. As the use of these alternative therapies becomes more widespread, there is the need for scientifically valid information about both the benefits and risks of their use.

SUPERFUND HAZARDOUS SUBSTANCES BASIC RESEARCH PROGRAM

The Society of Toxicology also wants to express its strong support for the Superfund Hazardous Substances Basic Research Program. This program is administered by NIEHS although it is funded through a pass through from the EPA to NIEHS. The Superfund Hazardous Substances Basic Research Program is the only scientific research program focused on health and cleanup issues for Superfund hazardous waste sites. It represents an important collaboration between EPA and NIEHS, and it should ensure that environmental cleanup decisions are based on sound environmental health science.

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. 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 and technology base needed for making accurate assessments of human health risks and developing cost-effective cleanup technologies.

The primary purpose of Superfund Hazardous Substances Basic Research Program 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. The Society of Toxicology is disappointed that the President's budget request reduces funding for this important program by $11.5 million. We hope Congress will consider restoring funding for this program to its fiscal year 2000 level of $60 million. We understand that this funding matter is not under the jurisdiction of this Subcommittee. With that said, we urge the Members of the Subcommittee to engage in the necessary discussions with the VA–HUD and Independent Agencies Appropriations Subcommittee to ensure that these resources are continued.

CONCLUSION

Once again, thank you for continued leadership in the area of biomedical research and for considering the funding priorities outlined above. The Society of Toxicology looks forward to working with you to continue the campaign Congress initiated two years ago to double the NIH budget by 2003, and to continue the pursuit of the many promising research opportunities at hand as a result of the nation's investment in biomedical research. Under Dr. Olden's leadership, the NIEHS is taking a leadership role with regard to enhancing the scientific basis that is necessary in order to make better decisions concerning our environment.

Thank you.

PREPARED STATEMENT OF FORMER CONGRESSMAN LOUIS STOKES

Mr. Chairman and Members of the Subcommittee, I respectfully submit the following testimony on my own behalf. As a former member of the House Subcommittee for Labor-HHS, I am so very proud of the work this Subcommittee and its House counterpart has accomplished in providing the vision and the leadership that has led to tremendous strides in the prevention, diagnosis, and treatment of disease and disabling conditions and has greatly enhanced the quality of education and training opportunities for all Americans. As you know, while serving in the House I shared your interest in developing programs and strategies to protect those most vulnerable in our society. I am continuing to pursue this interest by serving as a member of The Pew Environmental Health Commission. This Commission is an independent panel of representatives from the health field, industry, government, academia and the nonprofit community. Launched in May 1999, and chaired by my colleague, former three-term senator and governor of Connecticut, Lowell Weicker, Jr., the Commission's charge is to provide leadership, vision, and visibility for strengthening the country's defenses against environmental threats.

My interest and passion for these issues brings me here today to discuss opportunities for this Subcommittee to once again exercise leadership by strengthening the federal investment in our public health infrastructure. I submit to you that if our nation's best and brightest researchers and public health officials had the tools necessary to develop meaningful disease prevention strategies, we would witness extraordinary achievements in health outcomes and in reducing the nation's health care costs.

For more than a quarter century, we have made enormous strides in protecting our air and water quality and preserving areas of natural beauty and biological diversity essential to a healthy environment. Last month, Governor Ryan from the state of Illinois awarded over $950,000 to plug 148 abandoned oil and gas wells in Clinton and Lawrence counties and to clean up and restore a waste crude oil site in Saline County. The state of New York is successfully restoring the Hudson River, and California is doing a tremendous job of revitalizing its brownfields. Despite the progress made in cleaning up and preserving the environment around the country, we have lost our focus on protecting our children from health hazards arising from exposure to environmental contaminants.

The Pew Environmental Health Commission is issuing a series of reports on children's health, including a report on birth defects which was released this past November and a report on childhood asthma which will be released later this Spring. As part of the birth defects report, entitled Healthy from the Start: Why America Needs a Better System to Track and Understand Birth Defects and the Environment, the Commission has called for a national approach for monitoring exposures linked to the environment and building the capacities and strategies for monitoring and evaluating chronic disease.

Birth defects are the nation's leading cause of infant death in the United States, resulting in approximately 6,500 deaths annually. However, a major analysis of national data on birth defects and the environment has found unexplained increases in certain birth defects and related conditions that point to the need for strengthening the public health system. Even though birth defects are the nation's leading cause of infant death, one-third of the states, the District of Columbia and Puerto Rico—with a total population of nearly 59 million—fail to track birth defects, and 25 more states have systems that need improvement. Without this data, public health officials are literally working in the dark. This makes it much more difficult to identify emerging disease clusters and tackle environmental threats that may cause sickness and death in our children.

As many of you know, I took an active role in mitigating the effects of lead and protecting the health of Americans from lead exposure during my service in Congress. Congressional intervention, coupled with the efforts of CDC, EPA, and other

private and public partners, has resulted in the reduction of the percentage of children in the U.S. with elevated blood lead levels from 88.2 percent in the late 1970's to 4.4 percent in the early 1990's. This is a prime example of how having good public health data can significantly improve our environmental decision-making process.

When the EPA decided to phase out lead in gasoline in 1973, Congress received considerable pressure to reverse the regulation. While lead was a well-known neurotoxin, with children being most vulnerable to permanent neurological damage, it had been widely used in gasoline to prevent engine "knocking." EPA's theoretical models suggested that a ban on lead would result in only minimal changes in human lead levels, but health data from the CDC saved the day by showing dramatic decreases in human lead levels, persuading Congress that EPA's restrictions on leaded gas were appropriate. Unfortunately, CDC does not routinely monitor the level of dangerous pollutants in the American population despite important past lessons during the great debate over leaded gasoline. If there is no significant change in our data collection system, we will be apt to make many costly mistakes.

We have just been reminded of such a mistake with another fuel additive, Methyl Tertiary Butyl Ether, or commonly referred to as "MTBE." The federal Clean Air Act Amendment requires MTBE to be used for reformulated gasoline in an effort to reduce air pollution.

Shortly after the beginning of its widespread use in the gasoline supply, communities around the country began complaining about health problems—including headaches, eye, nose, and throat irritation, nausea, and disorientation—linked to MTBE. Yet before its widespread use we never investigated nor gave the money to CDC to track Americans' exposure to this chemical—despite having the technology. Since then, CDC has been given limited funding to study levels of MTBE in humans, but at this point—despite the numerous complaints and public outcry—population exposure to this compound cannot be evaluated. We have not paid appropriate attention to the health problems. Instead, we waited until leaks in storage tanks led to contaminated water supplies. If we had focused on health, we could be saving ourselves millions of dollars in clean up. This was a lesson learned from lead.

This is why we need a modern public health system that readily tracks the health of Americans. In order to develop ways of testing whether people have been exposed to hundreds of carcinogens and toxic substances, we need an increase in environmental health funds. The President's budget request for the CDC's National Center for Environmental Health would more than double the $10 million given to the Federal Government in fiscal year 2000, and would enable the CDC to move toward monitoring human exposures to more than 100 potentially toxic substances, up from the current 25. This is a positive first step, but it is just a start.

The Pew Environmental Health Commission recommends a broader national approach to biomonitoring that will encompass tracking all environmental health hazards that science suggests have a linkage to chronic and infectious diseases. It is estimated that the cost, about $275 million, or $1 for every man, woman, and child in America, would develop the monitoring capacity to identify and protect against agents in the environment that pose great risk to the public's health. This is a modest price to pay to prevent the many chronic and infectious disease killers which science suggests are linked to environmental causes and extract billions of dollars in health care costs each year. A $275 million investment in the CDC's National Center for Environmental Health will put real teeth into our nation's effort to protect the public from environmental hazards and preventable disease.

Mr. Chairman and members of the Subcommittee, I know you realize the time has come to renew our investment in a public health system that will prevent the chronic diseases and disabilities that afflict millions of Americans. While medical science has advanced to conquer many infectious and chronic diseases, preventing chronic illness through public health programs has failed to keep pace.

As you know, the President has also proposed to provide a $20 million increase to the CDC's emerging infectious disease program to develop a national electronic disease surveillance network to assist local and state public health officials in responding to disease outbreaks. Again this is a start, however it too represents a piecemeal approach. The President's plan does not seize on the opportunity to provide a comprehensive, integrated strategy to the public health burden of chronic and infectious disease.

While infectious disease remains important, chronic disease is now the no. 1 killer, responsible for three of every four deaths in the U.S. annually—about 1.8 million Americans—and a yearly economic cost of $325 billion. And the numbers are rising! I am, by no means, suggesting that infectious disease is not important. But while it is important to remain vigilant in protecting against infectious disease, we should also focus on causes and prevention of chronic disease and disability. These health

problems might be preventable if only we knew more about the complex interactions among the social, biological and environmental factors that affect us.

In 1995, health studies estimated that of the 30 years added to Americans' life expectancy since 1900, only five years on average are due to improvements in clinical medicine. The majority, 25 years, are attributable to public health programs. The steepest decline in mortality resulted from improvements to environmental conditions that prevented the spread of infectious disease, such as treatment of drinking water and removal of wastes, and better nutrition and food handling practices.

When it comes to resources, our nation rightly spends billions of dollars to monitor the impact of the environment on plants and animals. However, as a nation, we do little to monitor the impact of the environment on our public health.

At the turn of the 20th century, our nation faced the tremendous challenge of infectious disease by marshaling the resolve and the resources to conquer these killers. Now at the turn of the 21st century, it is chronic diseases—such as birth defects, asthma, and cancer—that are taking an immense toll on our public health. Our country needs to have a strong public health system. I am asking you to join me in supporting the following:

—An investment of $275 million for a comprehensive national biomonitoring program that will alert us to hazards in our communities that pose serious, but preventable, health risks.

—A renewed commitment to the public health infrastructure that mirrors the strength of our national commitment to biomedical research.

It is time for CDC to step up as a leader in disease prevention. It is with your help that we can make the investment to get them there. We must rise to this challenge by utilizing the best research, treatment, and tracking tools to win the war against health threats and disease that cause enormous human pain and suffering.

Thank you.

PREPARED STATEMENT OF THE KENNEDY KRIEGER INSTITUTE

Mr. Chairman, Members of the Committee, thank you for the opportunity to submit testimony for your consideration in the fiscal year 2001 budget for programs under your committee jurisdiction.

THE KENNEDY KRIEGER INSTITUTE

The Kennedy Krieger Institute is an independent research institution located adjacent to Johns Hopkins University. The mission of the Institute is to focus solely on disorders related to the brain and central nervous system. Brain related disorders effect one in four adults and one in ten children at a cost to society of $400 billion per year. The overall goal of research at the Kennedy Krieger Institute is to understand the developing central nervous system through the study of relationships between genes, the brain and human behavior. While the Institute has special expertise with regard to children, the research scope includes studies of changes in the brain and the CNS across the lifespan. Our Institute integrates cutting edge neurobiological research efforts into a comprehensive program which includes inpatient and day treatment services; outpatient services; home and community services; and school programs for children with disorders of the brain. The Institute is well-known for its strong interdisciplinary research and care in many fields including medicine, psychology, education, physical and occupational therapy, audiology, speech and language therapy, social work, child development, nutrition and nursing. In our statement to the Committee, we will highlight the efforts of three federal agencies under your jurisdiction and the important work that they do to strengthen the capacity of Institute's, such as ours, to make progress in this important area.

BASIC AND CLINICAL RESEARCH

We are currently experiencing an unprecedented appreciation of the benefits to health and life quality that can result from biomedical and behavioral research. Of particular note is the most welcome present and predicted increase in public sector funding for basic research and the dramatic, if not explosive, private sector investment in biology. With such appreciation and tangible support comes the responsibility to organize the scientific enterprise so as to produce effective interventions. And, our challenges are many.

Many children with developmental disabilities and neurological diseases display severe behavior problems. The mission of our basic and clinical research, clinical care and educational programs is to improve the quality of life for these children and their families through a variety of mechanisms including: providing advanced

and comprehensive treatment services; promoting the widespread dissemination of effective interventions; and improving treatment technologies through basic and clinical research. With that said, we support treatment and research initiatives including but not limited to behavior programs, pediatric feeding disorders, neuroimaging, basic and clinical research efforts and training.

The National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological Diseases and Stroke support a number of important initiatives with regard to brain biology; neurobehavioral assessment and protocol development; translation studies related to cognition pathways of learning disorders from a developmental perspective; molecular sciences to further understand the molecular basis of many developmental disabilities; brain mapping; and other basic and clinical programs which are at the core of the programs conducted at the Kennedy Krieger Institute. Further, the National Center for Research Resources (NCRR) supports important neuroimaging studies for neuroscience, metabolic and other research. We have support from the NCRR for our General Clinical Research Center (GCRC) in which we are conducting studies related to functional imaging. We believe it is important for the Committee to consider an NIH National Imaging Network for Clinical Research which will enable NCRR to provide the resources to create links between the GCRC to the imaging center. This sort of infrastructure would be vitally important to facilitate and integrate research networks.

We are very excited regarding planning underway at the NICHD with regard to pediatric trauma. While injuries and violence are, respectively, the first and third most frequent causes of death in children 5 to 18, many clinical treatments are tailored to the adult population. NICHD is planning a multi-disciplinary, collaborative programs under the egis of its National Center for Medical Rehabilitation Research. This program will enable the development and assessment of therapies specifically targeted to the physical, emotional and social needs of children through a series of basic and clinical research initiatives. Mr. Chairman, this initiative marks the first such federally-funded program of its kind. The NICHD should be applauded for its efforts in this regard.

We urge the Committee to continue its efforts in support of the NIH. The Kennedy Krieger Institute endorses the recommendation of the Ad Hoc Group for Medical Research Funding for fiscal year 2001 which recommends a 15 percent increase to double the budget of the NIH by 2003.

EDUCATION

Our approach to severe behavioral problems in many children with developmental disabilities and severe behavior problems is multi-focused. The Severe Behavior Program provides comprehensive diagnostic evaluations, parent training and school consultative services. The linkage to the child's school and school district is imperative to develop and effectively implement effective strategies to deal with the behavioral problems many of our patients present with. This initiative is complemented by inpatient and outpatient behavioral management services for children who display severe destruction behavior.

The Institute's Lower and Middle Schools, recipients of the U.S. Department of Education's National Blue Ribbon Awards in 1996 and 1997, respectively, are recognized models in special education. Their track record includes: innovative models of education based upon current scientific understanding of brain functioning; creative integration of technology in the classroom; comprehensive curriculum tailored to unique needs of the student; and training in the field of special education. We are in the process of opening a high school which will serve as a national model of a comprehensive approach to school-to-work transition for youth with serious learning, emotional, neurological, and developmental disabilities. Our high school has a school-to-work curriculum. The Career and Technology High School is unique in that it will be the only program in the area to make career training the foundation of, and not merely a supplement to, the school's core curriculum. Drawing on the most current educational, work-readiness, and industry standards, the high school staff develop partnerships with business and community groups to develop a state-of-the-art model that will result in economically and personally rewarding employment for youth with disabilities. The Career and Technology High School will take students challenged by severe learning, emotional, traumatic brain injury, and developmental disabilities and provide a school-to-work instructional model that addresses the needs of students with serious disabilities with the skills to undertake meaningful employment. Students will leave the school with the knowledge and work and social experience they will need for successful post-secondary employment in a specific career clusters including: Information Technologies; Hospitality; Tourism Construction and Manufacturing; Business and Finance; Arts and Graphics;

and Communications. Programs supported by the Department of Educations, including the Star Schools Program and the Technology Innovation Challenge Grant program are critical to enable cutting edge programs such as our to fully develop our capacity to create model systems which can be applied nationwide. The strong support that this Committee has provided to these programs in the past have been a worthwhile investment and we urge your continued support.

NATIONAL CENTER FOR BEHAVIORAL RESEARCH IN CHILDREN AND YOUTH

We, at the Kennedy Krieger Institute, believe that the time is right to build on our leadership in behavioral research and are establishing a National Behavior Center to address such problems as teenage smoking, substance use and abuse, school failure, violence, teen pregnancy and other behavioral problems of children and use which have similar causes and solutions. The National Behavior Center will: (1) study the causes of these behavior problems from multiple perspectives (e.g. family, society, environmental toxins, neuro-developmental, etc.); (2) design, evaluate and implement prevention and intervention programs for these problems; (3) train other professionals to significantly impact these important child and adolescent behaviors; and (4) serve as a national resource for other institutions of higher learning and government agencies.

The National Behavior Center will expand the Institute's efforts from a primary focus on brain related disorders to the broad spectrum of child and youth behavior. We expect that it will have a national impact in terms of understanding children's behavior and how to identify and prevent the dramatic problems we see on the news every evening that every parent fears.

As adults in society we have become all too painfully aware of behavior and health problems that our children are facing. Data demonstrates that serious attention must be paid to behavior problems of children and youth to address many societal challenges. School students are being directly exposed to unprecedented levels of violence: 80 percent of the children surveyed report witnessing threats and actual assaults, and 50 percent of students believe that violence like we saw in Litteton, Colorado could happen in their school. Tragically 50 percent of students in large city and rural schools know someone their age who has committed suicide.

But our concerns for our children should not stop with issues related to violence. Only 58 percent of high school dropouts are employed, and one-third of major U.S. corporations spend $250 billion annually to provide basic academic skills training for employees, such as reading and math. Drug use has a strong link to the use of tobacco as a "gateway" drug. One million youth start smoking each year, 3,000 every day. One million also begin to use smokeless tobacco. As few as 3–5 cigarettes a day can increase the risk of mental retardation of an unborn child by 25–30 percent.

The use of alcohol by children and youth causes automobile, pedestrian, and cyclist accidents, interpersonal violence, drowning and burns, suicides, fetal alcohol syndrome, alcohol poisoning, and alcohol dependence and abuse. In terms of interpersonal violence alone, alcohol contributes to 16 percent of all child abuse as well as to over a third of all robberies, assaults, rapes and murders. The estimated cost to society is $60 billion annually.

One out of every ten women become pregnant at least once before they reach the age of 20. One million teenagers each year have an unwanted pregnancy with a yearly cost to society for medical care, foster care, decreased work productivity, welfare, and the like of some $7 billion. Further, an unwanted pregnancy often initiates a cascade of problems. Children of teenage mothers have lower birth weights, are more likely to perform poorly in school, and are at greater risk for abuse and neglect. Sons of teenage mothers are more likely to end up in prison and daughters are more likely to become teenage mothers themselves. Most unmarried teenage mothers end up on welfare.

Mr. Chairman, a research and public education collaboration between the federal agencies you have identified is necessary if we are to get handle on the best approaches to the rapidly escalating problem of destructive behavior in youth in our society. It is of paramount importance to establish a comprehensive and multidisciplinary initiative that will enhance our understanding of why children become aggressive, why they commit violent acts, why they are unable to control their behavior, or why children choose to engage in risky behaviors. Efforts need to focus on identifying the varied roots of child and adolescent behavior and violence by addressing an array of potential influences, including social and cultural variable, family relationships and family violence, peer influences, child temperament and health, genetic influences, neurological processes and biological risk factors. We need to begin to apply what we have learned in the field of neurobiology, brain mapping,

and behavior analysis in the developmentally impaired individual to the broader population of children and youth demonstrating behavioral problems.

A coordinated national science agenda addressing the problems of behavior in children must include these components: enhance research, ranging from basic and to clinical, from genes to behavior, related to the behavior of children and youth; employ 21st Century technology for reliable behavior change; and establish a network to coordinate disciplines and delivery systems. Mr. Chairman, Members of the Committee, we applaud your efforts in this regard and look forwarding to working with the agencies involved in this important initiative.

Thank you for the opportunity to present our views.

PREPARED STATEMENT OF THE SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION

THE COULSTON FOUNDATION AND THE CHIMP ACT (H.R. 3514)

The Society for Animal Protective Legislation (SAPL) urges the Subcommittee to support the efforts of the House Appropriations Labor, Health and Human Services and Education Subcommittee, led by Chairman John Porter, to find short and long-term solutions to ensuring the humane treatment of chimpanzees at The Coulston Foundation.

The Coulston Foundation, a private biomedical research facility located in Alamogordo, NM, currently houses the largest chimpanzee colony in the world with over 650 chimpanzees and hundreds of other animals at the facility. The Coulston Foundation is the only research facility to be officially cited three times by the U.S. Department of Agriculture for violations of the Animal Welfare Act (AWA). The AWA violations are based on numerous negligent deaths of chimpanzees and monkeys over the past seven years. In fact, the USDA has completed six formal investigations of the Coulston Foundation and is currently in the middle of its seventh investigation in as many years. The sixth investigation ended with an unprecedented agreement between The Coulston Foundation and the USDA where The Coulston Foundation agreed to divest itself of 300 chimpanzees by 2002. Sadly, another six chimpanzees have died since the August 1999 USDA settlement. We have included six of the deaths reported at The Coulston Foundation: (1) Terrance, Muffin and Holly died from the well-known side effects of a drug that was later tested in children; (2) Donna, a former Air Force chimpanzee, died on November 9, 1999 due to carrying a large, dead fetus inside her womb for up to two months. TCF veterinarians removed one liter of pus from her abdomen during a belated C-section and reported seeing the skull of her decomposed fetus through the ruptured wall of her necrotic uterus; (3) Another chimpanzee died during a drug study after losing 29 per cent of his body weight in just 2–4 weeks (three other chimpanzees lost similar life-threatening amounts of weight). Responding to the FDA's citation of these violations, TCF actually told the agency that the lab had "anticipated" this fatal weight loss.

In August 1999, Food and Drug Administration (FDA) investigators documented more than 270 violations of Good Laboratory Practice (GLP) regulations at The Coulston Foundation on just three studies reviewed. According to the FDA, GLP regulations exist to ensure data integrity and human safety. The FDA confirmed many of the USDA's findings, and identified new violations of animal welfare laws. On 12/22/99, the FDA issued a rare Warning Letter, finding the conditions at TCF to be "serious violations" with "wide spread consequences" for data integrity and human safety, and stating "that there will be no further studies conducted that are subject to the FDA GLP regulations until corrections are made and verified."

We understand that the National Institutes of Health may be working on its own solution to the problem at The Coulston Foundation, yet no such plan has been presented, and the situation at The Coulston Foundation has continued to worsen. The problems at The Coulston Foundation are not new. In fact, circumstances at the laboratory have been deteriorating for several years. Meanwhile, NIH has done little to alleviate the situation but provide continued financial support to this non-compliant laboratory while the USDA and the FDA have filed several charges against the laboratory for hundreds of violations of federal law relating to human safety and animal welfare. Now is time for Congress to step in and put an end to the abuse and financial waste at this laboratory. NIH has spent over $30 million on The Coulston Foundation over the past 7 years while nothing has been done to ensure animal care or data integrity on the research.

The only long-term solution to ensure the well being of the Coulston chimpanzees and all chimpanzees used in federal research is the passage of legislation creating a national chimpanzee retirement sanctuary. Legislation has already been intro-

duced in the House that would create such a system (Chimpanzee Health Improvement, Maintenance and Protection Act—H.R. 3514). The Act will create a network of federal/private-supported sanctuaries to which chimpanzees formerly used in research will be retired. This approach is not only morally and ethically responsible, but will save the taxpayers several million dollars a year.

A critical component of a chimpanzee retirement sanctuary, which we would like to address, is that of permanent retirement, the cornerstone of a chimpanzee sanctuary. Unfortunately, NIH has expressed concerns with this component, reportedly fearing that there might not be a sufficient number of chimpanzees to use in research, should an emergency arise which might warrant wide use of the species for research purposes. To address this concern, we wish to present the following details designed following the recommendations presented in the 1997 NIH requested and funded National Research Council (NRC) Report, Chimpanzees in Research: Strategies for Their Ethical Care, Management and Use. The NRC report specifically recommends that NIH maintain a core population of chimpanzees in case of just such emergencies. However, the report further states that the current chimpanzee population is above and beyond the number necessary both for current research needs and anticipated emergency use. It therefore concludes that several hundred "excess" chimpanzees should be retired to sanctuary facilities. The report suggests that to do so makes financial and moral sense. The sanctuary system would only apply to chimpanzees clearly no longer needed for research. It would not prevent the use of chimpanzees in research, nor would it prevent NIH from maintaining a "reserve" of chimpanzees in case of an unforeseen public health emergency. In addition, once a chimpanzee is no longer needed for research, the respective research facility has the sole authority to retire the chimpanzees, not the animal welfare community. This is especially important because there are currently several research facilities ready and willing to retire chimpanzees. The creation of a permanent retirement sanctuary system has the broad support of primate specialists including Dr. Jane Goodall, Dr. Frans de Waal, Thomas Insel, M.D., Thomas Gordon, Ph.D. and Michael Kastello, D.V.M., Executive Director, Research Resources, Merck & Co., Inc. to mention a few. We hope this information will satisfy any concerns NIH may have regarding permanent retirement of chimpanzees.

Former National Academy of Science official and supporter of national sanctuary system Thomas Wolfle, was correct when he said that the NIH is "morally responsible" for caring for the chimpanzees it paid to breed and infect. It is time to live up to our moral obligations, first by providing alternative care for the chimpanzees at The Coulston Foundation, and then by creating a sanctuary system to provide permanent retirement to the Coulston chimpanzees and the hundreds of other chimpanzees who remain warehoused in laboratories.

STOLEN AND FRAUDULENTLY OBTAINED FAMILY PETS ARE BEING USED IN TAXPAYER FUNDED EXPERIMENTS

Approximately 100,000 dogs and cats are used for research purposes in the United States each year. The majority of these animals are obtained from breeders who raise the animals under controlled conditions and have extensive information on the health status and genetic background of the animals. Other dogs and cats are obtained directly from municipal pounds or the animals may come from breeding stock within the research facility.

Unfortunately, despite extensive documentation strongly discouraging the practice, some research facilities are still purchasing dogs and cats from random source dealers. These dealers, with a Class B license designation by USDA, are notorious for selling animals to laboratories that have been acquired through theft or fraud and for their widespread failure to comply with the minimum requirements under the Animal Welfare Act.

Recognizing the severity of the problem, the U.S. Department of Agriculture increased its enforcement efforts at the premises of Class B dealers approximately three years ago. Stronger enforcement drove some of the random source dealers out of business, but it has not solved the problem. These dealers continue to fail to maintain the legally mandated records identifying where they are getting the dogs and cats they sell to laboratories for hundreds of dollars each.

The records are not completed (and traceable to a legitimate source) because these animals are being purchased from illegal sources (people who have not bred and raised the animals and/or did not willingly give them up for research purposes). For example, the inspection report from a USDA-licensed dealer in Iowa cited the following apparent violation, "Records indicate that 290 dogs were sold to research, but only 83 animals exhibit required acquisition paperwork by this licensee. Fully 207 adult dogs are not accounted for via the release forms paperwork. Also, the dealer

is listing himself as the source of animal acquisition, when this dealer is actually acquiring animals from a variety of individuals. . . .''

This dealer has allegedly supplied more than one thousand dogs for experimentation that he acquired through fraud. Further, it is alleged that the individuals who bred and raised the animals were deceived by the dealer into believing that their dogs, former racing greyhounds, were being adopted to good homes. This situation became public this month, since then the dealer has disconnected his home and business telephone service. Now he is under investigation by USDA and the Wisconsin State Division of Gaming. As is usually the case, it is too late to rescue any dogs since all of the animals the dealer sold to laboratories have been euthanized following their use in experimentation.

Meantime, the National Institutes of Health continues assuring Congress and the public that they are ''committed to ensuring the appropriate care and use of animals in research.'' NIH has left the decision of whether or not to use dogs and cats from Class B dealers ''to the local level on the basis of scientific need.'' NIH acknowledges ''Class B dealers provide biomedical researchers with animals that may not be available from other sources, such as genetically diverse, older, or larger animals.'' In fact, the animals needed are available from other sources; genetically diverse, older or larger animals could be acquired directly from those pounds that choose to supply animals for experimentation.

The distinction between non-purpose-bred animals from pounds versus Class B dealers needs to be made and emphasized. By using Class B dealers instead of pounds, researchers are contributing to the problem. In their search to fill researchers demands for ''genetically diverse, older, or larger animals,'' random source dealers are stealing pets from backyards and farms or they are acquiring animals through fraud by collecting animals offered ''free to a good home.''

Following is a statement recently circulated on the web from a gentleman in Jonesboro, Arkansas: ''I am no animal rights activist—I am a neurosurgeon, an avid hunter, conservationist, dog lover, horseman and all-'round country boy. I was brought up to believe in caring for the animals that we own and I love my 4 year old black Lab, Rebel, second only to my kids. He was stolen from my home on Dec. 18, 1999. I have solid information that he was taken by (or for) a nearby 'buncher' who sells dogs to research facilities. . . . As a neurosurgeon, I support animal research for worthwhile purposes when the data cannot be acquired any other way and when the animals are properly procured and properly cared for—but not when they are our pets that have been stolen.''

Each year as NIH and the researchers it funds fail to take action, more companion animals are stolen and the numbers of distraught and outraged pet owners continues to grow. This taxpayer financed supply, which has continued for decades, desperately needs to stop.

Last year the Subcommittees in both Houses of Congress provided report language reflecting their regarding Class B dealers. We greatly appreciate the interest of this Subcommittee in this issue. Unfortunately, we must report that the problems continue and no action has been taken. We therefore respectfully request the Subcommittee include the following language in the appropriations bill: ''None of these funds shall be used for research which utilizes dogs and/or cats obtained from random source Class B dealers.''

Implementation of this policy will allow research utilizing dogs and cats to continue—unhindered by the dark shadow currently cast by Class B dealers and their illegal practices.

NIH NEEDS TO REDO THE ANIMAL CARE AND USE SECTION OF ITS REGULATORY BURDEN REPORT

In the fiscal year 1998 budget, the House Committee on Appropriations requested an effort by NIH to streamline and rationalize duplicative and unnecessary federal regulations that govern extramural scientific research. The report drafted by NIH failed to focus on the internal regulatory burden that NIH has the power to address. Instead, the report is being used as a vehicle to assault the federal Animal Welfare Act by those who wish to dismantle it.

The use of animals in research includes a weighty responsibility to ensure the best possible care and treatment for these animals whose lives will be sacrificed following experimentation. Animals who are treated well will produce more sound research results with a lower variance. The Animal Welfare Act is the chief federal law ensuring proper treatment of laboratory animals and due consideration of alternatives.

The Improved Standards for Laboratory Animals amendments to the Animal Welfare Act were adopted in 1985 following widespread public concern and extensive

documentation of the need for legislation and of the failure of institutions to self-regulate, hearings in both the House of Representatives and the Senate, and careful consideration and negotiation. Many researchers and the lobbyists who represented them fought against this law, as those before them fought against the Laboratory Animal Welfare Act of 1966 (later renamed the Animal Welfare Act). Having lost that battle, opponents fought against regulations for enforcement of the law until weakened regulations were finally adopted nearly six years later. Now, we are faced with an effort to dismantle the remains.

NIH should take an introspective look at ways in which it can reduce the regulatory burden to researchers and better streamline the process. For example, following is a review of site visits:

There is great usefulness in the current system that mandates, at minimum, biannual inspections by the IACUC (self-regulation), but augmenting this with the unannounced inspections by USDA veterinary inspectors. Law mandates annual inspections by USDA. Review of USDA inspection report forms provides powerful evidence of the utility and great need for these compliance inspections. USDA has reported that it finds noncompliance with the minimum requirements under the Animal Welfare Act at 45 percent of the facilities it inspects.

Perhaps NIH can do away with their site visits since this is not an activity that they undertake with regularity. In those instances where a registered research facility receiving NIH funds is not in compliance with the law, perhaps it is a USDA inspector, already familiar with inspection of the facility, who should be sent in to conduct an unannounced inspection, rather than a team of individuals organized by NIH who make a scheduled visit.

This is but one example of the usefulness and practicality of the Animal Welfare Act. And an example of the need for NIH to pay particular attention to ways it may be able to improve the process internally.

Thank you very much for your consideration.

PREPARED STATEMENT OF THE FACIOSCAPULOHUMERAL SOCIETY, INC.

Mr. Chairman, it is a great pleasure to submit this testimony to you today.

My name is Daniel Paul Perez, of Lexington, Massachusetts, and I am testifying today as President & Chief Executive Officer of the Facioscapulohumeral Society (FSH Society, Inc.) and as an individual who has this devastating disorder.

As a chief patient activist for the tens of thousands of individuals living with Facioscapulohumeral Disease (FSHD) in the United States, I will continue to argue the case of wanting to live life free from disease.

My testimony is about the profound and devastating effects of a disease known as Facioscapulohumeral Disease which is also known as FSH Muscular Dystrophy or FSHD and the urgent and immediate need for NIH funding for research on this disorder. In past years (1994, 1995, 1997, 1998, 1999) and again this year we will submit testimony before both House and Senate Committees which states that the National Institutes of Health (NIH) and Congress could help bring about a significant research and scientific discovery program which, with modest investments, would benefit hundreds of thousands of people worldwide.

The FSH Society has previously informed the members of this Committee of the United States Congress on the need and rationale for research on FSHD. We have updated you on the most recent developments in clinical medicine with respect to FSHD, kept you abreast of the latest breakthroughs in the molecular genetics of the disease and given you insight into the difficulty of living a lifetime with this disease.

Thanks largely to your efforts, Mr. Specter, NIH research funding continues to grow to its current level of $17.793 billion annually up two billion from 1999. Our gratitude fuels our hope for promising research solutions for FSHD. Ironically, I must in all candor express our frustration that promising FSHD research support and programs have yet to appear from the NIH, even in light of Congressional mandates and report language for such. While NIH has seen a tremendous increase in funding in the past decade, FSHD research through the NIH has not benefited at all. In fact, research funding has gone significantly down, not up. Since the FSH Society first testified before Congress in 1994, FSHD research has decreased from between $300–500,000 to between $100–250,000. During this time, Congressional directives to NIH regarding the state of FSHD research have been either ignored or responded to in an untimely manner. We have met with NIH officials, testified before the Institute of Medicine (IOM) Committee and taken the path indicated to put forth our goals and the situation has only gotten worse.

THE FSH SOCIETY, INC.

The FacioScapuloHumeral (FSH) Society, incorporated in 1991, solely addresses specific issues and needs regarding facioscapulohumeral muscular dystrophy (FSHD). The Board of Directors and Scientific Advisory Board (SAB) of the Society are comprised of the top medical and research experts in neuromuscular and muscle disease several of whom are past and current NIH grant recipients, employees of the Howard Hughes Medical Institute and serve on the prestigious Institute of Medicine (IOM) at the National Academy of Sciences (NAS). We provide public awareness of FSHD by providing information, referral, education, and advocacy on FSHD. Additionally, the FSH Society offers assistance and support to patients, families, physicians, and other professionals. The Society publishes a newsletter with information about advances in research, political action effecting FSHD research and profiles of people with FSHD. We have awarded $500,000 in grants toward the prevention, cause and treatment of FSHD for research projects, post-doctoral and research fellowships and provided training support to institutions and fellowships to individuals in the field of FSHD research worldwide. The FSH Society promotes collaborative research and collects and disseminates research information. The Society organizes and sponsors annual international and national Scientific meetings on FSHD as well as annual international and national patient network day meetings.

THE CLINICAL PICTURE OF FACIOSCAPULOHUMERAL MUSCULAR DYSTROPHY (FSHD)

FSHD is a neuromuscular disorder that is inherited genetically and has an estimated frequency of one in twenty thousand (1/20,000). FSHD affects 12,500–37,500 persons in the United States. The major consequence of inheriting this disease is that of a clinically unpredictable and progressive and severe loss of skeletal muscle, with the usual pattern of initial noticeable weakness of facial, scapular and upper arm muscles and subsequent developing weaknesses of other skeletal muscles. Retinal and cochlear disease can often be associated with FSHD although the pathogenesis and causative relationship to FSHD remains completely unknown. FSHD wastes the skeletal muscles and gradually but surely brings weakness and reduced mobility. Many with FSHD are severely physically disabled and spend the last 30 years of their lives in a wheelchair. The toll and cost of FSHD physically, emotionally and financially is enormous. FSHD is a life long disease that has an enormous cost-of-disease burden and is a life sentence for the innocent patient and involved persons. Clinically FSHD is quite variable. It can be very extreme causing devastating incapacity at an early age or it can be barely detectable in very old age. Often, the patient lives with the certainty and anxiety that the course of their disease will be reliably unpredictable and totally uncontrollable. FSHD can happen to anyone of us.

NEW FRONTIERS DISCOVERED IN HUMAN GENETICS THROUGH FSHD RESEARCH.

The FSHD gene was linked to the distal end of chromosome 4, a location known as 4q35, in 1990 by scientists in the Netherlands. At that time it was assumed that genetic testing would be imminently achievable and that the identification of the abnormal gene product(s) would soon follow. Genetic testing is now available though with reservation for certain patients with complicated novel genetic presentations. A decade of progress has led to the discovery of a novel genetic phenomena of crossover of subtelomeric DNA between chromosomes (4 and 10) in both normal individuals and diseased individuals and to the discovery that facioscapulohumeral muscular dystrophy may be the only human disease caused by a deletion-mutation causing a position effect variegation (PEV). PEV causes DNA in one part of the genome to affect DNA in other parts of the genome. In FSHD, DNA at the very end of the chromosome (telomere) interferes with DNA upstream towards the center (proximal) of the chromosome. Despite remarkable genetic insight and immense progress by a small team of scientists worldwide, the nature of the gene product(s) remain enigmatic and the biochemical mechanism and cause of this common muscle disease remains absolutely unknown and elusive.

In the meantime, during the past decade, the genes and gene products for a significant number of other myopathies, most of which are rarer than FSHD, have been identified and classified. Although great progress has been made in these other myopathies and muscle diseases, our ability to intervene, treat and cure these diseases is rare. Ironically, FSHD research has not led to the identification of the gene(s) and the corresponding protein(s) encoded by the FSHD deletion-mutation causing FSHD. Instead, it has led the scientific community to discover a novel human genetic phenomenon that challenges the entire view and understanding of Mendelian genetics. In essence, FSHD has produced the anomaly that forces the sci-

entific community to question the paradigm of Mendelian genetics. This finding will begin a whole scientific revolution in human genetics that will have far greater implications for medical genetics that will extend far beyond the study of FSHD.

RESEARCH DOLLARS ALLOCATED DIRECTLY TO FSHD AS WELL AS MUSCULAR DYSTROPHY ARE MINIMAL.

The Subcommittee members need consider and rationalize the following numbers. Neuromuscular and muscle disease has one of the highest cost-of-disease burdens in the U.S. economy. Yet, of $17.793 billion annually given to NIH, $16.5 million is spent on Muscular Dystrophy and, of that amount, conservatively $250,000 is spent on the third most prevalent and third largest dystrophy FSHD. That makes nine hundred twenty one-thousandths (920/1000) of one percent (1/100) of the total NIH budget for Muscular Dystrophy and fourteen one-thousandths (14/1000) of one percent (1/100) of the total NIH budget for FSHD. Clearly, the Muscular Dystrophies as a class of disease are more than significantly under-funded by NIH. Secondly, FSHD research funding by NIH is woefully disproportionate given its ranking and severity. Thirdly, at best, $16.00 and at worst, $5.33 is spent on each person living with FSHD. The numbers on FSHD and Muscular Dystrophy research are appallingly and inexplicably low.

Furthermore, muscular dystrophy is frequently overlooked and of no interest to the pharmaceutical industry, biotechnology industry and Wall Street. No privately or publicly owned company is currently pursuing FSHD research. FSHD is not Alzheimer's, Parkinson's disease or breast cancer with hundreds of millions of research dollars from the NIH supplemented by the enormous investments of hundreds of millions of dollars from the pharmaceutical and biotechnology sector. We have nowhere to go in the private sector and cannot even possibly go lower at the NIH. We are ostensibly at zero funding. The NIH has failed and is failing in its public responsibility to the muscular dystrophy and FSHD citizen by not carrying through on its public health responsibility.

CONGRESSIONAL DIRECTIVE HAS BEEN AND IS REPEATEDLY IGNORED BY THE NIH.

It should be noted that the FSH Society has given twelve (12) Congressional testimonies in seven years and has succeeded in three successive years in incorporating report language on Facioscapulohumeral Disease (FSHD) in both U.S. House and U.S. Senate Appropriations Committee Reports accompanying the budget. We have had over one hundred and fifty meetings and interactions with the three NIH Institutes primarily responsible for FSHD: The National Institute of Neurological Disorders and Stroke (NINDS/NIH), The National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS/NIH) and the Office of Rare Disease (ORD/NIH). We have the distinct honor of working with the prestigious and talented Directors and Staffs of all three of these Institutes since 1992.

NIH is seriously out of compliance with previous Congressional Directives. NIH has not responded and is responding very slowly to the past three years of Report Language. Four (4) calendar years have passed and the NIH has still not convened a research planning conference. NIH is just now convening a research planning conference on Tuesday, May 9, 2000 responding to your directive three years too late. We await the results and plan that comes from that meeting. We request that your Committee ask for and receive the results of that planning conference in an immediate and timely manner.

The Report Language for 2000 has been responded to in an untimely manner and mainly ignored. The status of action on Report Language for fiscal year 2000 will be "current year items not done". The 2000 Report Language is as follows: "The Committee is concerned that NIH has not responded to a previous request to develop a plan for enhancing NIH research into Facioscapulohumeral (FSH) disease. The Committee urges NIH to promptly convene a research planning conference and to establish a comprehensive portfolio into the causes, prevention, and treatment of FSH disease through all available mechanisms, as appropriate. The Director is requested to be prepared to testify on the status of this initiative at the fiscal year 2001 appropriations hearing." (House Report 3037, p. 81 for NINDS, p. 97 for NIAMS.)

The status of fiscal year 2000 Report Language is as follows: Not done in the majority. Plan not created and no comprehensive research portfolio exists. NIAMS has no R01 or P01 grants on FSHD. NINDS has one R01 grant on FSHD. Intramural research on FSHD is non-existent at NIH.

The Report Language for 1999 has been ignored and the status of the Report language for fiscal year 1999 is not done. The 1999 Report Language is as follows: "The Committee encourages the Institute to continue and expand research efforts focused

on aiding in the diagnosis and treatment of FSHD." (House Report, NINDS Section, p. 103.), and, "The Committee was pleased with the Institute's response to last year's request which encouraged NIH to stimulate research in the area of facioscapulohumeral disease (FSHD). However, the Committee notes that NIAMS has not responded in developing a plan for enhancing FSHD research, and has not addressed the question of whether an intramural program in this area would be beneficial. Therefore, the Committee urges NIH to conduct a research planning conference in the near future in order to explore scientific opportunities in FSHD research, both intramurally and extramurally." (House Report, NIAMS Section, p.120–121.)

The status of 1999 Report Language is as follows: Not done. Plan not created and research portfolio is not expanding. NIAMS has no R01 or P01 grants on FSHD. NINDS has one R01. Intramural research on FSHD is non-existent at NIH.

The Report Language for 1998 has been ignored and the status of Report language for fiscal year 1998 is not done. The 1998 Report Language is as follows: "The Committee has heard compelling testimony about facioscapulohumeral (FSH) disease, which causes progressive and severe loss of skeletal muscle. FSHD research includes aspects such as molecular genetics, neurological function and muscular dystrophy involving multiple NIH Institutes. The Committee encourages NIH to take steps to stimulate research in this area and requests NIH to develop a plan for enhancing NIH research into FSH disease (FSHD), including an assessment of whether an intramural research program in this area would be beneficial." (House Report, p. 101.)

The status of 1998 Report Language is as follows: Not done. Plan not created and no FSHD specific initiatives are undertaken to stimulate research. NIAMS has no R01 or P01 grants on FSHD. NINDS has one R01 grant for the majority of the year. Intramural research on FSHD is non-existent at NIH.

NIH STILL LACKS PRESENCE IN THE AREA OF FSHD RESEARCH.

NIH has not funded any new grants to "establish a comprehensive portfolio into the causes, prevention, and treatment of FSH disease" even though the previous two years of report language request that this happen. The Committee has asked NIH several times "to establish a comprehensive portfolio into the causes, prevention, and treatment of FSH disease through all available mechanisms, as appropriate." And still, at the time of this testimony not one new P01 or R01 grant will have been issued on FSHD in the entire past year.

NIH has not implemented or announced any new mechanisms to enhance funding on FSHD research in the last year despite the fact that last year's language requests that NIH do this "through all available mechanisms, as appropriate."

NIH continues to inexplicably reject grant applications on FSHD. On March 8, 2000 a second submission within this year of a major grant application from a world renowned researcher was left unscored by the Center for Scientific Review (CSR) study section Brain Development and Child Neurology 3 (BDCN 3). Additionally, other grants in FSHD have not been funded within the last year.

REVIEW OF THE NIH TRACK RECORD ON FSHD AND CONGRESSIONAL DIRECTIVE ON FSHD

NIH has ignored and is responding slowly to three (3) and now four (4) years of Congressional Directives.

NIH has been slow and unorganized in convening the research planning conference and in developing the research plan on FSHD called for in the last three (3) years Report Language.

NIH has not even begun to establish a portfolio in the causes and treatment of FSHD as called for in the past two years of House and Senate Report Language. A comprehensive portfolio has not even been initiated.

NIH has not established "a comprehensive portfolio through all available mechanisms, as appropriate" as called for in last years Language. No new funding mechanisms have been announced.

NIH has not funded any new R01 or P01 projects in FSHD.

There is a complete disconnect between the fact that Institute Directors state that FSHD is a priority in long range planning papers, Congressional testimonies before the Committee, in their responses to questions raised by the Committee and in personal communications and yet NIH continues to inexplicably reject grant applications on FSHD.

NIH has not yet responded to Congressional questions asked of the Director of NIH, Dr. Ruth Kirchstein, on February 15, 2000 and of the Director of the NINDS, Dr. Gerald Fischbach, on February 29, 2000 by the U.S. House Appropriations Com-

mittee, Subcommittee on Labor, HHS, Education (Hon. Randy "Duke" Cunningham).

NIH is far from the $5–10 million needed to accelerate efforts in the area of FSHD.

In 2000 to date, NINDS has only one issued grant in its portfolio that is for FSHD. In 2000, to date, NIAMS has no grants presently issued with FSHD in their title. That is correct, in 2000 NIAMS currently has funded $0 (zero) on FSHD research projects. NIAMS and NINDS state that they are beginning the process of organizing the research planning conference for May 9, 2000 and, less than four weeks before the conference, we still do not have a final roster for planning panel participants. NIH must understand that FSHD requires their attention.

Although FSHD research may have benefited indirectly from NIH funding of the Human Genome Project, direct funding of FSHD research by the NINDS and the NIAMS at NIH has been minimal. The total NIH funding for directly titled FSHD research currently for the fiscal year 2000 (fiscal year 2000) to date is approximately two hundred-fifty thousand dollars.

FSHD researchers express incredulity with the lack of funds and rejection of grants submitted by the top laboratories in the world.

WE IMPLORE THE COMMITTEE TO ACT IMMEDIATELY

Mr. Chairman, we know that the Committee is overwhelmed in hearing from patient groups such as ours. We know that you trusted that the Institute of Medicine (IOM), the Center for Scientific Review (CSR) and the NIH would set their priorities correctly. The truth is that we have come before Congress to testify year after year, given testimony in a wheelchair from the back of the room at the IOM as it was not wheelchair accessible, worked hard to have NIH take a more active, deliberate and responsible role and yet the NIH is not listening to the Congress, the scientific community and the patients on this issue.

Mr. Chairman, this is a clear and disturbing trend regarding NIH's disregard for Congressional Report Language and for the scientific and medical opportunities present in FSHD research.

There presently is very little funding of FSHD from NIH—perhaps two hundred-fifty thousand dollars. I re-iterate, this is clearly inadequate given the recent advances and the high likelihood of making significant progress in the very near future. With a budget of $17.793 billion dollars, NIH is spending a miniscule amount on FSHD research. This tiny amount is utterly unconscionable and defies logic and reason given the prevalence of FSHD and the cost of doing molecular genetics research in 2000.

Mr. Chairman, we ask the Subcommittee to earmark a dollar amount to FSHD research. We request that an amount of not less than five (5) million and not more than ten (10) million dollars be earmarked for FSHD research. We know that this Committee does not approve of earmarking. However, the record of six years indicates that NIH ignores Congressional direction as well as scientific opportunities. Earmarking appears to be the only way to get NIH attention.

The FSHD community demands that the Congress of the United States of America take action on funding research on FSHD. We are asking today for a promise to people living with FSHD which commits to funding FSHD research in the following areas:

—Cloning the gene, characterizing the nature of mutations in the gene,
—Launching a major effort to understand the normal function of the FSHD gene and how its alteration causes the disease,
—Conducting natural history studies to provide a baseline for future therapeutic techniques, and
—Developing therapies based on information in 1, 2, and 3 above.

Additionally, the FSHD community is requesting that Congress ask NIH to research and make recommendations on the following:

—Creating a Center of Research Excellence (CORE) for FSHD research,
—Enacting intramural NIH programs for FSHD research immediately,
—Extramural contract programs for FSHD, and
—Programs to attract and expedite extramural grant applications.

The men, women and children who live with the daily consequences of this devastating disease are your friends, neighbors, fellow taxpayers and contributors to the American way of life. With an historic 88 percent employment rate and an average educational achievement level of 14 years, we personally bear our burden of the health care costs and training expenses to prepare for and maintain financial and personal independence. We appeal to you today to take our hard earned tax dollars commensurate with our numbers and valuable contributions to American Society.

We urge the United States Government to allocate a proportion of our tax burden toward research on FSHD.

This is the United States of America, and in a country as great as ours with all of its technical means and ability it should be absolutely clear that the number one priority for individuals with FSHD and the one absolutely commanding imperative for the Federal Government is to initiate and accelerate in any way possible, research on FSHD. With modest funding and a clear direction from Congress to the NIH to support research on FSHD significant progress can be made in conquering and eliminating this and other devastating diseases.

Mr. Chairman and members of this Committee, let us remember that as the Constitutional Convention at Philadelphia drew to a close in 1787, James Madison noted some concluding remarks by the elder statesman, Benjamin Franklin. Franklin's observations had to do with a sun painted on the back of the chair of the presiding officer. He said, "often and often in the course of the Session, and the vicissitudes of my hopes and fears as to its issue, I looked at that behind the President without being able to tell whether it was rising or setting. But now at length I have the happiness to know that it is a rising and not a setting sun."

Our founding forefathers toiled, fought and worked for Liberty and Freedom from oppression. They fully recognized that if their partial liberty gave way to full fledged oppression, the opportunity for freedom would be lost for a long time and that liberty threatened can be recovered. Living with a lifelong progressive and chronic neuromuscular disease imposes the same thoughtful consideration.

In the same way as our forefathers, before the founding of this great country, I too, lose my physical Liberty every day as naturally and eventually as the sun rises and sets. My liberty is in constant decline and my happiness and courage sometimes is setting as the sun to the West. Everyday I choose to fight on, I am curious to know about what the next day will bring, simply curious. Despite the full fledged constant decline of my liberty, I live for the rising sun and have the faith that this country is great enough and powerful enough to enact change where it is needed. My liberty will surely be lost in my life time if I do not find it within me to fight for the recovery of my liberty and freedom from my natural born oppression. It is my duty and my obligation, as a citizen of this country, to act as my ancestors and their fathers did to ensure that the government acts responsibly carrying out its duty to uphold the public trust.

Mr. Chairman, we trust your judgement on the matter before us. Please remember, we need your help to ensure that the sun is rising on FSHD.

Mr. Chairman, again, thank you for providing this opportunity to testify before your Subcommittee.

PREPARED STATEMENT OF THE SCLERODERMA RESEARCH FOUNDATION

The Scleroderma Research Foundation appreciates the opportunity to submit this written statement urging Congress to become our partner in pursuit of a cure for scleroderma.

As we have in past years, the Scleroderma Research Foundation asks for a partnership that combines the strengths of the private, academic and public sectors in seeking a cure for this debilitating, often fatal disease, which strikes half a million Americans.

Scleroderma is a chronic, degenerative disorder that leads to the overproduction of collagen in the body's connective tissue. The overabundance of collagen hardens the connective tissue (scleroderma means "hard skin") and damages the organs involved. About eighty percent of scleroderma patients are women. In approximately half the cases, the primary organ involved is the skin, which hardens and scars, often causing severe pain and disfigurement. The other half of patients suffer from systemic sclerosis which hardens internal organs, such as the heart, kidneys and lungs. Almost seventy percent of patients with systemic sclerosis die within seven years of initial diagnosis.

The Scleroderma Research Foundation was established to fill a virtual void in research on this awful disease. From scratch, the Foundation has built an effective, respected, progressive research program dedicated to finding a cure for scleroderma. We have made astounding progress, to the point that our team of advisors and scientists agree that scleroderma is now a solvable problem. The researchers at our two centers—t University of California San Francisco and at Johns Hopkins University—ave made great advancements in understanding the key processes in the fibrosis and vascular problems of scleroderma. In other groundbreaking investigations, researchers have found several key antibodies that are unique to scleroderma. This work clearly points the way to identifying the environmental factors which lead to

disease development, as well as helping isolate genes involved in its predisposition. Remarkably, these breakthroughs have been accomplished almost exclusively through funding from private donations. The lion's share of donations are contributed by individuals, many who are scleroderma patients, their family and friends, and many who have lost loved ones to this disease.

At a time when we have renewed hope for a cure, we need help to reach our goal. The breakthroughs we have achieved have advanced our understanding of scleroderma and brought us closer to a cure. There is a surge of interest from scientists in related fields in opportunities to collaborate on this research. The right people and technology now exist to cure this disease. It is only a question of providing the resources necessary to get the job done. What is needed is your timely support in bringing the vast resources in science and technology to our mission. Clearly, there is a life saving opportunity here. Your partnership is vital if we are to continue to progress.

PROPOSAL FOR PARTNERSHIP

Specifically, the partnership we are seeking is a collaboration with our research centers at University of California San Francisco and at Johns Hopkins University. Our request is not for a gift; we are requesting a match. We ask Congress to allocate funds to match what we, private individuals across the country, have given to fund our research centers. Since 1987, the Foundation has invested $4.874 million in research projects. With this match, we can strengthen our highly regarded "cure advocacy" approach to research, maximizing the efficiency and progress of our programs.

Cure advocacy brings together scleroderma experts and top scientists from all basic scientific disciplines to analyze where we stand in the science of scleroderma and to identify the most promising research opportunities. Our team comprises scientists from Johns Hopkins University Medical Center, the National Institutes of Health, Stanford Medical Center, the University of California San Francisco, the University of Maryland, and Ohio State University. They participate in a truly interdisciplinary, multi-institutional environment, working together, sharing resources and ongoing research information with one common goal—to find a cure for scleroderma.

Through cure advocacy the Scleroderma Research Foundation, in partnership with the private and academic sectors, is able to direct and manage the science on behalf of the patients. The Foundation is, in other words, driving the science in the direction of a cure. Now, we ask you to join this partnership in support of well-focused, results-oriented, disease-driven research, and in support of the hundreds of thousands of scleroderma patients awaiting a cure.

We are also requesting your partnership in launching a new and innovative post doctorate program that will bring the efforts of the best and brightest new scientists to bear on finding a cure for scleroderma. Our goal is to create a program that focuses scientists in the field of scleroderma research at the beginning of their career, when they can devote their work early and exclusively to saving lives. Here again, the Scleroderma Research Foundation is working to raise funds for the post doctorate program from private donations. Our request is for a match of our funding at $1 million (five scientists located at five laboratories for a three-year period each).

CONCLUSION

As a private medical research foundation, we have attempted, repeatedly, to create a public/private partnership. Year after year, there has been no response. What more can we, as an organization dedicated to an important and singular mission, do in terms of educating Capitol Hill and raising awareness of the urgency of finding a cure for scleroderma. There is still, after all, no known cause or cure for the disease. There are still no FDA-approved therapies. There are still hundreds of thousands of Americans, mostly women, suffering—nd dying—rom scleroderma. We cannot do this alone.

From its beginnings, the Scleroderma Research Foundation has maintained a sharply focused program to insure no time is wasted in reaching our goal of saving lives. We have accepted this challenge, and extend the challenge to Congress, to the National Institutes of Health, and to the medical research community in this country: To channel today's incredible technologies into helping people and advancing science that is driven by saving lives. We ask Congress to participate in our mission by matching our efforts and speeding our progress to a cure.

Thank you for providing us the opportunity to present this statement. The Scleroderma Foundation welcomes any questions Members of the Committee may have.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN UNIVERSITIES

Mr. Chairman and distinguished Members of the subcommittee, I am Dr. Virginia Hinshaw, Dean of the Graduate School and Senior Research Officer at the University of Wisconsin-Madison. I write today to provide several perspectives on research, because I've been fortunate to serve in different capacities during my own research career.

For 25 years, I worked as a scientist and my research, specifically on influenza viruses, was made possible by the funding I received from the National Institutes of Health. So I certainly recognize the value, as well as the highly competitive nature, of obtaining such funding.

Currently, I serve as a university administrator with the goal of facilitating research efforts of others. I certainly recognize the fact that the University of Wisconsin-Madison, as a major research institution, is highly dependent on NIH funding in that over 50 percent of our federal funding comes from NIH.

Also, I am pleased to represent the Association of American Universities (AAU), an organization of 61 public and private research universities across the U.S. and Canada. I currently serve as president of the Association of Graduate Schools, a group within AAU. Many of you have AAU institutions within your States. We are joined in this statement by the American Council on Education, the Council of Graduate Schools, and the National Association of State Universities and Land-Grant Colleges.

You have heard over the past several weeks from many organizations and individuals advocating increases in NIH funding—patient groups, scientific societies, and research institutions. I speak on behalf of research institutions, whose faculty translate NIH research grants into findings that improve human health and well-being. This is a great time to be in research—there is so much we can do and so much that needs to be done. A number of exciting, new areas being investigated by faculty at UW-Madison include genomics, chemical biology, nanotechnology, biomedical engineering, bioinformatics and many more. These are just a few examples of the kind of cutting-edge science that is going on all over the United States, due to this nation's wise investments in biomedical research at NIH. This investment is improving our lives and the lives of future generations.

I also know that many of these advances depend on efforts in many other fields of science, including physics, chemistry, mathematics, computer science, and engineering. For example, lasers evolved from mathematicians and physicists studying light waves, and, because of those efforts, lasers are now common tools in medicine. A decade ago, cataract removal represented major surgery with substantial recuperation time; today, this is done with lasers as outpatient surgery with rapid recovery—that is progress through research by both physical and biological scientists. We hope that NIH, as well as the other science agencies, will be provided with the resources needed to support these other scientific fields that I can attest are critical to the success of biomedical research.

Past investments in biomedical research have paid off for human health and for the American economy. For example, recombinant DNA research at our universities in the 1970's opened the door for today's multi-billion dollar biotechnology industry. It also allowed us to begin the human genome project, which is now nearly complete, again through a partnership between the Federal Government and research universities. This achievement is the next step in the genetic revolution which could profoundly alter our approaches to preventing, treating, and curing disease. Other examples include the tremendous progress NIH-supported researchers have made in discovering ways to reduce the tragedy of mother-to-infant transmission of HIV. As NIH has reported, a 1994 study indicated that zidovudine (AZT) could reduce the rate of transmission by two-thirds, and once these findings were widely disseminated, the number of AIDS cases from mother-to-infant transmission in the U.S. decreased dramatically—by 43 percent between 1992 and 1996.

Advances in cancer treatments enable many of us to be here today, including myself. I'm a breast cancer survivor and thriver. My father has had prostate cancer and is still active and vital at 83. So I have a strong personal, as well as professional interest, in seeing advances in our understanding of cancer which leads to improved treatments and hopefully prevention. Along with the subcommittee, I want our granddaughters and grandsons to be free of those threats to their health. That will only happen through research.

Even with the great successes in research, I think it is important to remind ourselves that research is not an investment with guaranteed outcomes. We are seeking answers to questions with unknown answers. That means there are wrong turns and dead-ends as we search for those answers. I always tell students to remember the "re" in research which means that we search and then we search again and

again to determine if our direction is the correct one. I surely believe that research is a wonderful adventure into the unknown, but that adventure also involves hard, repetitive, exhaustive work and requires patience in getting to the long term benefits. We need your steadfast support to make that adventure productive in the long term for the whole of society.

This subcommittee has charted us on a bipartisan course to double NIH funding, which will enable us to continue making progress like this into the future. The associations I represent here, as well as my faculty colleagues, are tremendously grateful to Senator Specter and Speaker Harkin, and all the members of the Subcommittee, for having provided 15 percent increases in each of the last two fiscal years. We hope that the subcommittee will be able to repeat that success in the fiscal year 2001 bill as the third step on the path to double NIH funding by 2003. As you know, NIH makes grants for multiple years, and therefore needs stable support. As an investigator myself, I know the challenge and the stress of maintaining support for an active laboratory group—that responsibility keeps most of us awake at night, busy writing more grants to ensure continuity of our research personnel and programs.

The President's Budget for fiscal year 2001 is a good start, but its 5.6 percent increase after two years of 15 percent increases would not even allow NIH to fund the same number of new grants in fiscal year 2001 as the year before, sending a terrible message back through the biomedical research enterprise. The effects of the extraordinary funding increases this subcommittee has been able to provide are already producing positive results in the research community, where researchers are more likely to be able to get their innovative ideas funded and graduate students can again see biomedical research as a promising career choice. I want to underscore the fact that research universities are the educational homes for graduate students who are our nation's future researchers—we must keep that future strong. To accomplish that, we need to keep the momentum going, instead of reverting to the old boom-and-bust cycles that characterized NIH funding in the past.

Some have asked whether there are enough good research ideas to be able to wisely spend a 15 percent increase. The simple answer is yes; there are truly a wealth of great research ideas yet to be pursued. The current state of research in so many fields abounds with promise. Advances in basic research in genetics, cell biology, and biochemistry, as well as in clinical applications for cancer, infectious disease, and aging, put us on the brink of discovery in a wider array of disciplines than ever before. Staying the course by providing another 15 percent increase will enable further research advances in these areas to the benefit of all Americans in the future. We recognize that the Subcommittee is faced with enormous challenges in finding sufficient funds to keep NIH on the path toward doubling, while adequately funding other important programs in the bill, given the constraints on discretionary spending. We hope that an agreement will be reached again this year to continue investing in basic research to support investments that are vital to the long-range health of the nation.

Within biomedical research, several areas are particularly important to note. Support for clinical research remains vital if laboratory advances are to be translated to the bedside. Likewise, support for research infrastructure is critical for continued advances. As research funding increases, additional resources must be invested in renovating outdated facilities, financing state-of-the-art instrumentation, and providing new informational and computer technologies—all are critical and connected priorities. Great research ideas are constantly being generated by our faculty, staff and students but pursuing those ideas requires modern facilities and equipment, along with the analytical and communication tools rapidly emerging through computer technology.

Let me conclude with a few words about federal student aid programs. The associations I represent encourage increased support for student financial aid programs funded by this subcommittee. My efforts are primarily directed at graduate students, but I know that many of them could never pursue graduate degrees without the support of student aid at the undergraduate level. An increase in the maximum Pell grant of $400, and additional support for the Supplemental Educational Opportunity Grants (SEOG), the Perkins loan program, Federal Work Study, the Leveraging Educational Assistance Partnerships (LEAP) and TRIO programs are essential to assist needy students in accessing higher education without the accumulation of excessive debt. It is important to note that high debt loads are a substantial deterrent to our minority and low income student populations in pursuing graduate degrees. To have full participation of all students in the educational process, we must work to reduce that financial barrier.

In addition, I encourage, on behalf of these organizations, continued and increased support of the graduate education programs authorized under Title VII of the High-

er Education Act. The Graduate Assistance in Areas of National Need and Jacob Javits Programs support graduate students with financial need in the sciences, arts, humanities and social sciences. These programs reduce loan dependency, shorten the time to degree and create incentives to enter essential but not particularly lucrative careers, such as teaching and research. And finally, I encourage support for the Title VI International Education Programs which are so important to the participation of students and faculty in today's global community.

Today, as I ask for your support, I also want to assure you that research institutions recognize their responsibilities in receiving such support by being accountable and responsible in the use of these funds. We take that responsibility very seriously and we know that this government-university partnership demands that we meet those responsibilities.

Thank you for this opportunity to express our views about funding for biomedical research and federal student aid programs, and I hope that the subcommittee colleagues will be as successful in supporting these areas as it has been in recent years.

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA AND THE ASSOCIATION OF POPULATION CENTERS

Thank you, Mr. Chairman for this opportunity to present the position of the Population Association of America (PAA) and the Association of Population Centers (APC) to the Subcommittee on Labor, Health and Human Services and Education on fiscal year 2001 funding for the National Institutes of Health (NIH), specifically the National Institute on Aging (NIA), and the National Institute of Child Health and Human Development (NICHD). You are a long-standing friend of both organizations and we want to emphasize how grateful we are for your appreciation and support of demographic research.

As you know, PAA is a scientific and educational society of professionals working in demographic research. APC is a consortium of 27 leading American population research centers. In addition to their academic roles, members of both organizations provide federal, state and local government agencies, as well as private sector institutions, with data and research to guide decision-making.

Demographic research covers many issues important to our nation, such as retirement, minority health, disability and long term care, child care, immigration, labor force participation, worker retraining, family formation and dissolution, and population forecasting. The United States is undergoing far-reaching shifts in its demographic composition and distribution. Such changes often are not recognized or understood until they confront society with new and immediate needs—often requiring federal and state expenditures. Incorporating demographic, social and behavioral research into long term policy discussions allow such changes to be tracked and anticipated in a manner that promotes more coherent and efficient planning and policy implementation.

The National Institute of Child Health and Human Development (NICHD) and the National Institute on Aging (NIA) provide primary support for demographic research. We would like to take this opportunity to share with you information concerning aging, the effects of welfare reform on children and families, profiles of legal immigrants, and changes in fatherhood.

THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

NICHD has a well-established, successful population research program. NICHD is currently funded at $859.3 million with approximately $58.6 million of that budget dedicated to research funded through the Demographic and Behavioral Sciences Branch in fiscal year 1999. Among the many areas of demographic research supported by NICHD are families and household composition; marriage and family change; fertility and family planning; teen pregnancy; mortality; HIV prevention; and population movement, distribution and composition. NICHD also funds a highly regarded population research centers program. Population research centers provide a critical core of professionals who conduct research in a cost-effective manner. Further, the centers' training programs are an essential source of population scientists who bring fresh perspectives, ideas and improved methodologies to demographic research.

NICHD-supported demographic research provides important, ongoing information critical to policymakers. We are pleased to provide information in this testimony that focuses on the Fatherhood Initiative, the effects of welfare reform on children and families, profiles of legal immigrants, and the Family and Child Well-Being Research Network.

Fatherhood

The decline of the incidence of marriage weakens the ties of men to women and children, with a resulting burden to the welfare system and to women and children themselves. Thus, it is important to understand the conditions which help to sustain men's participation in their family's lives. NICHD, in conjunction with the Federal interagency Forum on Child and Family Statistics and the National Center on Fathers and Families, launched a Fatherhood Initiative to review the capacity of the federal statistical system to conceptualize, measure and gather information from men about how they became fathers and how they provide economic and emotional support to their children.

Among the results of this effort are the inclusion of men in the National Survey of Family Growth and the development of a father's component in the Early Childhood Longitudinal Survey and the inclusion of basic research on fathers in the Early Head Start Research and Evaluation Project. NICHD is also supporting research to understand factors leading to stable unions among unmarried fathers and mothers.

The roles fathers play in the lives of their children are strongly affected by the father's relationship to the mother: the access of fathers to their children is highest when parents are living together. In cases of divorce, a NICHD grantee has shown that many fathers have enormous desire to maintain contact with their children, and with intervention can continue to be major influences in the lives of their children even after the divorce.

Welfare Reform Effects on Children and Families

The 1996 welfare reform act and the subsequent changes in the welfare programs of nearly every state constitute the greatest shift in social policy for low-income families with children since the Social Security Act of 1935. Since the passage of welfare reform legislation, welfare caseloads have dropped 40 percent. Yet we know very little about how these changes will affect these children and families. Both positive and negative scenarios can be constructed.

The positive scenario is that leaving welfare for a job will make a mother feel more self-sufficient, raise her self-esteem, bolster her parenting behavior and provide a better role model for her children to emulate. Critics point to the challenges of combining employment and parenting for single parents with few economic resources. Jobs are difficult to find, low paying, and often do not provide health insurance. Good and affordable child-care may be difficult to obtain. The risk for children is increased parental distress, poorer parenting, inadequate childcare and greater economic hardship.

We simply do not know which scenario will prove most accurate over time. NICHD is supporting several projects to study the effects of welfare reform on children and families. The NICHD supported studies in several cities should provide us with a clearer understanding of the ways that children and their families are affected by this momentous change in social policy. These in depth community based studies will examine the impact of support from family, community networks, and public programs in helping families make the transition to self-sufficiency while assessing the impact on child health and development.

Research on Immigration

Understanding the trends in immigration and the characteristics of immigrants is vital for making informed policy decisions. NICHD, the Immigration and Naturalization Service (INS), the National Science Foundation (NSF), and the National Institute on Aging (NIA) have cooperatively funded a New Immigrant Survey Pilot Study (NIP). This study will provide immediate policy relevant information on immigrants in the U.S. and also serve as the foundation for long-term research on immigrants.

Much of the conventional wisdom on immigrants has been repudiated in recent NICHD supported studies. For example, legal immigrants are better schooled, on average, than the native born; the proportion with postgraduate education is almost three times larger than among the native born, at the same time, there is also a substantial group without a high school education. Overall, however, the quality of legal immigrants entering the U.S. is improving. Influenced by changes in immigration laws and changing economic conditions, the skill composition of immigrants to the U.S. has risen.

Family and Child Well-Being Research Network

We would also like to bring you up-to-date on NICHD's Family and Child Well-Being Research Network—an interdisciplinary data system focusing on child- and family-related research that relies on cross-agency cooperation. This year the network has been renewed and expanded. The new network is comprised of scientists

from nine universities collaboratively working with federal officials from NICHD, the Office of the Assistant Secretary for Health, of the Department of Health and Human Services (HHS), the Administration of Children and Families of HHS, the Census Bureau and the Department of Education. This network currently addresses a variety of questions about the interrelations between parent characteristics, family structure and organization, neighborhood attributes and different forms of social support. The network is committed to increasing the visibility of basic research findings to those involved in formulating public policy. Projects such as the Family and Child Well-Being Research Network perform the important task of helping synthesize research into sensible policy solutions.

The Network, in cooperation with federal statistical agencies and the research community developed a comprehensive set of indicators of child well-being. The information from these indices are compiled annually in the report America's Children: Key National Indicators of Well Being. This report provides a much improved information base that summarizes the changes in the overall well-being of American children and families on an annual basis.

PAA and APC enthusiastically support initiatives such as NICHD's Family and Child Well-Being Research Network that provide quick access to data and are efficient and effective resources for time sensitive policy-related research in cross-disciplinary fields.

THE NATIONAL INSTITUTE ON AGING (NIA)

The NIA also has a well established and widely respected demographic research program, which provides crucial information on the implications of an aging of the American population for our country. Currently, the NIA is funded at $687.8 million, with approximately $39.6 million of that budget dedicated to demographic research—training, career development, and demographic, economic and epidemiological research. As the U.S. population ages and Congress contemplates sweeping changes in Medicare and Social Security, the demography of the elderly steadily becomes more important. The NIA has a strong history of supporting the collection of data, which allows demographers to study questions of concern to policymakers. Chief among these is the NIA-supported studies, the Health and Retirement Study (HRS) and its auxiliary survey, the Asset and Health Dynamics of the Oldest-Old (AHEAD) study. You have been a solid supporter of these studies over the years, Mr. Chairman, and we would like to express our gratitude for your support.

Health and Retirement Study

The Health and Retirement Study (HRS) was launched in 1992 with baseline interviews for a representative sample of persons born between 1931 and 1941. These respondents were interviewed again in 1994, 1996 and 1998. The most recent round of data collection, HRS2000, is now in the field. Starting in 1993, the HRS was augmented by the AHEAD (Asset and Health Dynamics of the Oldest-old—those born before 1924). The AHEAD respondents were interviewed in 1995, 1998 and the survivors are being contacted now as part of HRS2000. In 1998, samples of two other cohorts were added, those born between 1924 and 1930, the so-called children of the Depression, and those born between 1942 and 1947, or the "early baby-boomer cohort". With the addition of these cohorts, HRS is nationally representative of the population over age 50. Since 1998, the entire study is now referred to at the HRS.

The original HRS focused on mid-life work and health dynamics. Biennial data are now available for all respondents on health, disability, work, health insurance, pensions and retirement plans, and transfers to and from family. Using the original HRS data, researchers have been able to explore issues related to health, work and retirement; prospects for economic security; cognitive changes, health insurance coverage and use of health care services.

Researchers have long known that persons with higher levels of wealth and income have better health and live longer. The reasons for this relationship are not well understood. Is it that income and wealth cause better health through better access to health care? Or is it that poor health causes lower levels of wealth and income by decreasing work, reducing earnings, and increasing health care expenditures? HRS panel data are shedding some light on these difficult questions. An economist from RAND has recently shown, for example, that out-of-pocket health expenses account for only a small share of the reductions in wealth after an adverse health event. Furthermore, those with health insurance have just as large a decline in wealth as those without health insurance. Subsequent to a major health event, middle-aged persons tend to reduce their work hours or retire completely and use their accumulated savings in place of earnings. These results have important impli-

cations for spend-down to Medicaid eligibility and old-age poverty, especially for older women who tend to outlive their spouses.

Education also is linked to health as well as wealth and income. Analyses of HRS by researchers suggest that education appears to have an enduring effect on health decisions. Among respondents who suffered a heart attack between the first two waves of the HRS, 90 percent of college graduates quit smoking compared with only 10 percent of those with less than high school education. Related HRS research also shows that, among middle-aged diabetics, education raises their health investment in managing their disease through diet.

Asset and Health Dynamics of the Oldest-Old (AHEAD)

The companion survey of HRS, AHEAD, provides unique information on the dynamics of health, economic resources and health care services. The study provides badly needed data on the costs and burdens of chronic disease and the consequences for the extended family. AHEAD provides data on how families redistribute their resources across generations, and how these flows interact with public sector transfers. AHEAD informs policy decisions on initiatives such as Medicare/Medicaid coverage for community long-term care and prescription drug benefits.

In addition to economic factors, sustained activity, such as part time work and volunteering, are thought to affect the well-being and health of the very old. AHEAD data indicate that there is a beneficial effect of volunteer work on cognition, health and survivorship. Volunteer work also is associated with higher education and wealth suggesting that social activities may be yet another pathway by which socio-economic status affects health, even in advanced old age.

AHEAD data also corroborate improvements in old age health, respondents have shown little overall decline in basic cognitive functioning. Higher education is protective of cognitive ability in old age.

Finally, PAA and APC are interested in and support the current efforts to strengthen the Federal Forum on Aging Related Statistics that coordinates data across federal agencies. The forum is an example of NIA's interest in supporting NIH's innovative endeavor of streamlining federal databases and making data accessible to researchers from varied fields.

CONCLUSION

PAA and APC would like to thank you for the opportunity to present this information. Demographic data and research are important tools for policymakers that can both save public funds and promote more informed decision-making. If this vital research is to continue producing relevant and timely information, adequate funding and Congressional support are needed. The Population Association of America and the Association Population Centers support an increase in the range of 15 percent to sustain the momentum of demographic research in the National Institutes of Health as part of the broadly based support to double the funding for the NIH over the next 5 years. However, the increases that NIH has enjoyed have not been evenly applied amongst the various institutes; in particular, budgetary growth at NICHD, while significant, has not kept pace with many of the other institutes. PAA and APC also support a more even distribution of any increase in funding for NIH.

PREPARED STATEMENT OF THE PARKINSON'S ACTION NETWORK

I am one of a million Americans afflicted with Parkinson's disease and related disorders. I also am President of the Parkinson's Action Network, which was created in 1991 to give a voice to our community in the effort to speed research delivering breakthroughs and a cure for this dreadful disorder.

I have the job today of focusing your attention on the particular needs of my community, and to convince you that the 2001 budget of the Labor-HHS Appropriation must—yes, must—include a substantial increase for Parkinson's-focused research funding.

Why am I so emphatic?

—Because the current federal policy on Parkinson's wastes billions in public and private dollars coping with its effects, when millions would produce a therapy that would restore function, and bring us back into the world.

—Because the disparity in funding attributable to variations, invisibility or political clout cannot continue.

Parkinson's—the disorder.—Parkinson's is a movement disorder caused by the degeneration of brain cells that produce dopamine, a neurochemical controlling motor function. By the time 80 percent of those cells stop functioning, symptoms of stiffness, tremor and slowness of movement begin to emerge.

The conventional treatment for Parkinson's is a 30-year-old drug commonly known as "L-dopa" which attempts to replace the missing dopamine with an artificial substitute. It usually restores function to a certain extent and it may seem at first like a miracle drug. But it works inefficiently, it produces side-effects, and eventually it does not work at all. As the dopamine cell degeneration advances, it strips away automatic movements needed to walk, talk, swallow, even move at all.

Despite the common myth that Parkinson's only affects the oldest sector of the country, in fact the average age of symptom onset is 57, with a third of all victims' symptoms starting in their 20's, 30's and 40's. As a result, Parkinson's-caused early retirements and forced disability are the norm. Some lose their jobs simply due to the stigma. The financial impact is enormous.

In my case, as a practicing lawyer and now running am advocacy organization for our community, these are my daily struggles: worrying about getting to a morning meeting and wondering when my first dose of medication will "kick in," enabling me to function; needing to make a phone call, but not being able to hold the telephone still with a shaking hand; seeing others put off by my lurching gait, or my trembling hand.

The impact on daily functioning.—At some point the symptoms become an impossible hurdle, as the tiny number of dopamine neurons left functioning just can't team up with the medication any more, and are complicated by drug side-effects. At that point, the swing between too little and too much movement is just too much to manage in the outside world. We may continue living for a long time, but we drop out of sight.

As a consequence, we have been neglected. For decades, NIH funding of Parkinson's research has languished far behind many other diseases, and far short of the level warranted by the research promise. Estimated 1999 Parkinson's-focused spending totaled less than $45 million, or $45 per patient. Although the NIH reports higher figures, independent analysis of the actual projects NIH classifies as "Parkinson's research" shows that only about one third of funding supports research actually focused on understanding or curing the disease. This is a serious ongoing concern and I hope Congress will take steps to ensure more accurate accounting of NIH research funding.

There is another important reason the Congress must increase Parkinson's funding in 2000. As federal taxpayers, we are owed a rational health spending policy. That requires spending money to cure us rather than just care for us.

The cost to America.—The cost of Parkinson's in America is massive. In testimony before the Senate Special Committee on Aging in 1995, Dr. Ole Isacson of Harvard estimated the cost to be in excess of $25 billion. The Network's surveys of the costs Parkinson's disability incurs on the country—in treatment, physical therapy, hospitalization, disability payments, lost productivity, and assisted living—indicate an equal or greater amount, which translates into a massive burden on public sources such as Medicare, Medicaid, and Social Security disability.

The cost is so high because we typically live in a disabled state for a long time, and the battle against loss of function is ongoing, and expensive. Parkinson's medication alone is very expensive, probably costing Americans well over a billion dollars. The largest costs can be due simply to losing the ability to work or care for oneself, which is absorbed by the government through higher Social Security, Medicare and Medicaid spending. This takes a huge toll on the American families hit by Parkinson's, but it also burdens the society and hits the taxpayer.

This massive financial waste will rise steeply if Parkinson's is not cured before my generation of "Baby Boomers" hits the years when Parkinson's symptoms are most prevalent. Imagine the additional burden of lost tax revenue, medical care and disability from Baby Boomers with Parkinson's.

The scientific promise.—An examination of the scientific promise of this disorder shows that an investment in Parkinson's research would return many-fold. The Dana Alliance for Brain Initiatives describes Parkinson's as "one of the brightest spots in brain research." There is no doubt that huge, revolutionary breakthroughs are coming, and they will drive breakthroughs for many other neurological and non-neurological disorders—Huntington's, ALS, Alzheimer's, spinal cord injury, diabetes and more. Consider:

—Neural growth factors, animal studies have shown growth factors are capable of reviving dormant cells and producing dramatic symptomatic improvement. Further research, including human clinical trials, is needed.

—Neural cell transplantation, from a variety of sources, has shown that symptomatic improvement results from the flourishing of transplanted dopamine neurons. A few patients are now symptom-free without medication.

—Advances in evidence and understanding of the links between Parkinson's and environmental factors and chemical compounds such as heavy metals, herbicides and pesticides.
—Steady increase in insights into the exact disease process, in which the cells appear to self-destruct after assaults from one or more of those causative factors.

But without question, these discoveries are coming in slower than they need to. Many scientists describe immense frustration with the slow pace of working on these breakthroughs because of the tiny research investment. That translates directly into a breakthrough deferred into the future.

According to testimony before the Senate Labor-HHS Appropriations Subcommittee last year by NINDS Director Dr. Gerald Fischbach, a focused and adequately funded research agenda could produce new Parkinson's treatments or even an effective therapy or cure within 5 to 10 years. According to a study by Dr. Roger Kurlan of the University of Rochester, even a 10 percent slowing of progression will save $327 million per year.

In recognition of both the current costs and tremendous scientific potential of Parkinson's disease, Congress requested the NIH develop a Parkinson's-focused research agenda including professional judgment funding projections for the next 5 years. The NIH held a 2-day interdisciplinary workshop that included a cross section of some of our nation's top scientists, clinicians and advocates. This broad, interdisciplinary approach to evaluating the current state of Parkinson's research must be continued to stimulate new ideas and ensure that the limited federal funding is supporting the best, most promising research.

Although this research agenda is a good first step and acknowledges the need for substantially increased federal research investment, it is not a complete and comprehensive plan. For example, while the NIH research agenda calls for a $71.4 million increase in Parkinson's research in fiscal year 2001, the Parkinson's Action Network has worked in concert with the scientific community to identify $244 million in research projects that could and should be funded in 2001. The NIH needs to work in close consultation with the research community, clinicians and patient advocates to expand, revise and update the research agenda in order to remain relevant and identify the most promising areas of research.

Congress should encourage the NIH to expand its use of innovative funding mechanisms such as accelerated review, targeted research, research supplements and young investigator awards to attract a new generation of researchers into the field.

And the resources are available to implement this increase. I applaud the hard work Congress has done the past two years to put the NIH budget on track to double over five years because of the benefits to all categories of medical research, and also because it allows for the needed expansion in Parkinson's-focused research.

Conclusion.—The human suffering that results from Parkinson's is immense and incalculable. That alone is a good reason to invest in a cure. The fiscal drain compels it. At the request of Congress, the NIH has produced an initial plan to pursue a Parkinson's cure. Congress must now follow through by providing the increase called for—at least and additional $71.4 million in fiscal 2001—to capitalize on the unprecedented scientific opportunity. This directed increase for Parkinson's is a small fraction of the projected overall NIH increase, and it would bring us one step closer to relieving the enormous burden Parkinson's places on individuals, families and our nation as a whole.

PREPARED STATEMENT OF THE CURE FOR LYMPHOMA FOUNDATION

Dear Chairman Specter and Senator Harkin: Thank you for this opportunity to participate in the fiscal year 2001 process. I am a survivor of non-Hodgkin's lymphoma—the second fastest rising cancer in the United States. I am also the founder and President of the Cure For Lymphoma Foundation (CFL), a nationwide, not-for-profit organization dedicated to funding research and supporting those whose lives have been touched by Hodgkin's disease and non-Hodgkin's lymphoma. While other cancers are on the decline, non-Hodgkin's lymphoma is one of two cancers where mortality rates continue to increase. The number of persons diagnosed with non-Hodgkin's lymphoma has doubled since the early 1970's. Despite exceptional breakthroughs in understanding the biology of lymphomas, the causes remain unknown. Therefore, as the baby boomer population ages, this disease is expected to dramatically increase. For this reason, CFL asks for your assistance in increasing funding for lymphoma research so that we can find a cure for lymphoma before it becomes a national epidemic.

YOUR CONSTITUENTS WANT MORE LYMPHOMA RESEARCH

Last year, in order to help heighten lymphoma awareness in Congress, CFL launched "CAMPAIGN 64,000"—a national letter writing campaign. In response, hundreds of advocates sent letters to you and your colleagues asking to make lymphoma a national priority. Patients from more than 31 states shared their hopes for new research, as highlighted below:

Susan of Wallingford, Pennsylvania.—"I am writing to urge your support for making Hodgkin's disease and non-Hodgkin's lymphoma cancers of the lymphatic system—a national health priority. I care very deeply about breakthroughs in lymphoma research because I am the sister of a person with low-grade lymphoma."

Patricia of Iowa City, Iowa.—"My brother was recently diagnosed with non-Hodgkin's lymphoma and currently there is only a 51 percent survival rate after 5 years. More money for biomedical research will bring us one step closer toward finding a cure for lymphoma . . . and all other cancers."

Sharyn of Bothell, Washington.—"I . . . urge your support for making Hodgkin's disease and non-Hodgkin's lymphoma . . . a national health priority. I am a spouse of a survivor. My husband received chemotherapy in 1995, which severely damaged his heart. Plus the chemo failed. He got into a clinical trial in 1996 and remained in total remission until his death in January 1999, which was from heart failure caused by the chemotherapy. Had the clinical trial drug (now FDA approved) been available at the time he went through chemotherapy he would still be with me today."

LeVonia of Orange, Texas.—"I have been fighting lymphoma for the past three years. When lymphoma strikes someone, her entire family is affected; it really takes a toll on the family—physically, emotionally, financially. It is my hope that you . . . will work toward funding resources for finding better treatments and, ultimately a cure for lymphoma."

Marvin of Wisconsin Rapids, Wisconsin.—"Personally, I am 75 years old and have been in remission for the past ten months with non-Hodgkin's lymphoma which has no known cure. It is only because of a caring oncologist . . . and the professional staff that I have a new chance and outlook on life. It is most likely that the cancer will return. My second oldest son, 48 years of age, has been diagnosed with non-Hodgkin's lymphoma/lymphomcetic leukemia, which according to authorities is not hereditary. His case is far worse than mine. Your support for the much needed funds will be greatly appreciated not only by researchers but by the thousands of persons searching for a cure."

Patricia of Phoenix, Arizona.—"My father was diagnosed with non-Hodgkin's lymphoma (low-grade, B-cell) in 1992 and has undergone various treatments over the past 7 years. Fortunately, he has been able to take advantage of some of the newly developed and approved treatments and medications, which have prolonged his life. He's been lucky in that respect, but there is no cure yet. Please take the next step by making finding the cause and cure for lymphoma a national priority!"

Earl of Los Altos, California.—"I am a survivor (so far). The follicular type I have is currently incurable, and I have suffered with it for over 12 years. There are very exciting new possible treatments such as antiangiogenisis inhibitors and other approaches that offer hope of real cures. Increased funding would offer new hope for finding a cure before I die."

INCREASED NCI FUNDING HAS IMPROVED THE LIVES OF LYMPHOMA PATIENTS

As Dr. Richard Klausner, Director of the NCI shared in his written testimony submitted to your subcommittee in March, increased funding for the NCI led to the development of a new tool, called the "Lymphomachip." This will assist doctors in identifying which patients will respond to chemotherapy and which patients should consider instead alternative therapies like bone marrow or stem cell transplant. Thanks to this new tool, many patients will not have to undergo unnecessary chemotherapy treatment as they have in the past.

With your encouragement the NCI has taken an important initial step towards "identifying disease specific priorities" by undertaking a Progress Review Group (PRG) on Lymphoma, Leukemia and Myeloma, this fall. The PRGs are important because they are comprised of researchers, health professionals, industry and advocates who together (1) assess the state of knowledge, (2) identify scientific opportunity and need and (3) chart a course for further research. We are hopeful this PRG will help outline and prioritize a national research agenda for these three hematologic malignancies.

YOUR SUBCOMMITTEE HAS TWICE ENDORSED LYMPHOMA REPORT LANGUAGE—IT IS TIME TO TAKE THE NEXT STEP

Your Subcommittee endorsed lymphoma-specific language last year that was adopted as part of Senate Report 106–166 and the previous year as part of Senate Report 105–300. This year we ask that you continue your support in funding the research essential to improving treatments and finding a cure for lymphoma. Specifically, we ask you:

—To encourage the National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), Centers for Disease Control and Prevention (CDC), Department of Defense (DOD), Veterans Administration (VA), as well as other key agencies to develop a national agenda for lymphoma and to expand research into lymphoid malignancies;

—To ensure funds are available to support new research opportunities; and

—To further investigate potential environmental, bacterial and viral factors associated with development of lymphoma.

Finally, we thank you for your consideration in this matter. Should you have any questions, please feel free to contact us.

PREPARED STATEMENT OF 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 25-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 Mended Hearts, Inc., a support group of 24,000 members throughout the United States. I have been appointed lobbying and legislation chairperson of that group—a volunteer position.

I am 57 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 18 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, cardio-

vascular diseases last year killed more than 950,000 Americans, more than 151,000 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 National Institutes of Health, I ask for a doubling of National Heart, Lung, and Blood Institute budget by year 2003. To reach this funding goal, I advocate a fiscal year 2001 appropriation of $2.330 billion for the NHLBI to help reduce further the incidence and degree of heart disease.

PREPARED STATEMENT OF ERIN BOSCH

I am submitting this testimony because I am convinced that together we can make a difference. I submit this testimony on behalf of the almost one million Americans that are living today with consequences of congenital heart disease in our nation. For the last four years I have worked as an advocate for the American Heart Association and during that time I have seen the difference that being a public advocate can make in people's lives.

Since my diagnosis of hypertrophic cardiomyopathy at age eight, I have been through many procedures, both for the purpose of diagnosis and treatment, including open heart surgery at the Mayo Clinic. I have had numerous doctor and hospital visits and I will take medication every day for the rest of my life. I will never compete in athletics again, which I dearly loved. I face the possibility of many more procedures during my lifetime. Clearly, the success of additional research could make my adult years more hopeful. I anticipate that when the day comes for me to bear a child of my own, I will be able to say with certainty he or she will be born free of heart disease.

Most people know that heart disease is the number one killer and a leading cause of disability in adults, but few recognize that congenital heart defects are the most common defect in new born babies. Every year thirty two thousand children are born with a congenital heart defect. I was one of them. Twenty one hundred of these children will die before their first birthday. I am one of the lucky ones.

I am confident these statistics can be changed. I have addressed the Committee for the last three years about the importance of continued research for heart disease and every year you have come through with critical research dollars. It was funding that this Committee provided that has allowed for the successful research and development of surgical procedures, pacemakers and intracardiac defibrillators that myself and other children depend on. Other devices and procedures are in the throws of development as we speak which depend on the continuance of these research dollars. I have great faith in the determination of our scientific researchers who work day and night to find new treatment methods for those who suffer with illness and disease. I also have great faith in you as the doorkeepers of governmental funding to continue to provide the necessary funds for children who have been born with heart defects.

DEPARTMENT OF EDUCATION

PREPARED STATEMENT OF THE CORE FOUNDATION

KEY ISSUES FOR HIV/AIDS

We are at a critical point in the care of patients with HIV/AIDS. We have achieved major goals in our basic science understanding of the course of HIV disease and have applied this understanding to the care of patients. Recent breakthroughs in drug therapies give reason to be hopeful for the successful treatment of HIV/AIDS.

Throughout the country, we have witnessed a steady decline in the number of hospital admissions for AIDS care and outpatient clinics are experiencing a dramatic increase in the demand for out-patient care and services. These successes have led to increased numbers of AIDS patients surviving longer and once again becoming productive members of society. Although science has taken big steps toward making AIDS a long-term manageable disease, by no means do we have a cure for the largest public health crisis of the century.

These favorable trends can be attributed in part to advances in opportunistic infection prevention and to highly active antiretroviral therapy (HAART). There are over 200 potent combinations of antiretroviral treatments that can be used in the

fight against HIV/AIDS. For each of these different regimens and drug combinations, there is a wide variation in a patient's adherence.

With the hectic pace of the development and release of new drug treatments and care regimens for HIV/AIDS patients, it can be difficult even for specialty-care providers, and much more so for community-based care providers, to keep abreast of the most recent advances in care and medication usage. Without the ability to keep up with new drug developments, disease management is difficult, if not impossible, for community-based providers and patients.

While the technology exists to implement sophisticated education networks for HIV/AIDS, there is no successful system in place that provides caregivers and patients the education and scientific tools needed to ensure that they make the most of the advances in care.

Additionally, recent research has shown that the disproportionate incidence of HIV/AIDS among inner-city, minority populations is due in large part to low rates of adherence and lack of effective community-based, comprehensive, health education and training systems for providers and patients.

Lack of access to up-to-date information also hinders the ability of patients to fully understand the importance of adhering to their prescribed therapy. Unfortunately, incomplete adherence with medication regimens greatly increases the risk of the emergence of strains that are resistant to the newest therapies thus increasing the likelihood of the spread of HIV/AIDS.

Low rates of adherence can most often be attributed to the following:

Cost.—The cost for HAART therapy is enormous, as much as $10,000–$15,000 per patient per year. Although the federal program, AIDS Drug Assistance Program (ADAP), is designed to provide financial assistance for uninsured or underinsured HIV/AIDS patients in purchasing required medications, it has been unable to keep up with the increasing demands;

Testing.—Many individuals are still hesitant to be tested for HIV and often go without a diagnosis. As a result, patients go without care until the symptoms become evident and they are in need of immediate services. Delays in testing result in patients who are much sicker when they present for therapy.

Education.—Many HIV infected patients are unable to get timely clinical care or to adhere to complex and difficult drug regimens. Often patients have little or no understanding of newer therapies and their potential benefit, resulting in low levels of adherence and decreased health status.

Disparities among inner city, minority populations are also evident in the effectiveness of HAART therapies. While there have been dramatic new developments in HIV care due to these new and more powerful medications, including a 42 percent decrease in the death rate from AIDS,[1] the outcomes have not been as positive for minority populations.

This disparity in opportunistic infection trends between population groups most reflects differences in access to the full range of new therapies now available. It is also indicative of a lack of targeted outreach, education and adherence enforcement efforts aimed at high risk populations and at those lifestyles which contribute significantly to the transmission of HIV.

The treatment of patients with HIV/AIDS in Chicago and other urban areas is made more difficult by the large number of patients receiving care and the large number of potential patients whose infections have not been diagnosed who will ultimately need care.

Specialists alone are not able to provide primary care for all affected patients, especially those in underserved communities. This means that other providers need to be trained in the complicated care of patients with HIV/AIDS to insure that the new HIV medications are used appropriately and to the greatest benefit for all patients.

To be effective, these community providers must have current medical data and protocols at their fingertips. They must be able to access immediate expertise to ensure the most accurate interventions and care for patients. Today, due to the lack of use of computerized clinical information systems in health care, especially for HIV/AIDS care, they are often unable to access this type of critical information or feedback in a timely fashion.

21ST CENTURY TECHNOLOGY FOR EDUCATION AS THE KEY

While many piecemeal technology based health education systems for HIV/AIDS exist throughout the United States, there are none that are taking full advantage of today's cutting-edge scientific landscape.

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[1] Centers for Disease Control HIV/AIDS Surveillance Report, June 1998.

The adoption of computerized clinical information systems in health care lags behind the use of computers in most other sectors of the economy. There is no HIV educational system that provides care, clinical assistance and interactive education, while integrating the patients and community-based providers into the care giving and decision-making process. Especially given today's technological advances, this is a striking deficiency in health education systems for HIV/AIDS.

At this critical time in the evolution of the long-term treatment of HIV/AIDS, it is important that we focus on the creation and implementation of comprehensive provider and patient education and training systems. This focus will:

—Improve ability to manage disease and related conditions;
—Improve treatment and prevention efforts;
—Increase the rate of the early detection of HIV;
—Increase the rate of treatment adherence; and,
—Decrease the spread of HIV.

The Department of Health and Human Services has recognized that effective education of providers and patients as well as adherence management programs are the only way to prevent those behaviors that lead to the spread of resistant strains of HIV. It is critical that the Federal Government continue to focus its resources on creating comprehensive HIV education and training systems that fully integrate specialists, community-based providers and patients and evaluate the outcomes of those systems.

The CORE Center believes that the most effective educational system is one which uses today's state-of-the-art technology and creates interactive networks of education that provide real-time feedback and enables providers to optimize care for HIV/AIDS patients.

Thus, the Center has proposed the Community and Minority Education and Training Initiative (COMET) for HIV/AIDS which maximizes the Center's extensive technological resources and care expertise to create and implement a unique, regional HIV/AIDS education and training network for HIV/AIDS providers and patients in community based settings, especially minority communities.

THE COMMUNITY AND MINORITY EDUCATION AND TRAINING INITIATIVE

To address this significant health crises in the minority communities specifically, the African American community, The CORE Center in Chicago, Illinois, proposes the implementation of its "Community and Minority Education and Training (COMET) Initiative". This initiative will demonstrate the significant improvements in care, prevention and education services through the use of a regional computer network. COMET will expand upon existing technology at the CORE Center to provide computer assisted patient shared decision making and HIV/AIDS education, training and care feedback to providers and patients in the Chicago metropolitan area.

This demonstration project will create a national model of a technology-based education and training system for specialty and non-specialty, community-based HIV/AIDS care providers as well as the education of HIV/AIDS patients. It will address an existing national need in minority communities for the effective integration of educational programs to enhance provider performance and improve provider and patient ability to manage disease. It will improve patient response and adherence to treatment regimens and place emphasis on the incorporation of patients into a shared decision making process.

The Community and Minority Education and Training Initiative will result in several key outcomes including:

—Improve non-specialist and patient access to the most current information on HIV/AIDS care, treatment, and drug protocols
—Provide critical and, as of yet non-existing, access to immediate feedback for providers to proposed patient care regimens
—Facilitate the supervised integration of community-based providers into the care of HIV/AIDS—thus expanding patient access to care for HIV/AIDS
—Provide a model for computer assisted patient shared decision making
—Improve physician's and patient's ability to manage HIV/AIDS and related infectious diseases.
—Improve patient adherence to complex care regimens
—Improve surveillance and response efforts at the local, state and federal levels
—Increase providers' ability to identify population specific treatment and care issues
—Reduce the emergence of additional resistant strains of HIV/AIDS

—Provide nationally relevant outcomes data that will be useful to cities across the United States as they grapple with issues of access, adherence, and cost and quality of care.

Through the implementation of a community-wide HIV education and training network, this initiative will provide nationally relevant outcomes data which will be useful to cities across the United States as they grapple with issues of access, adherence, and cost and quality of care.

The CORE Center, with its location in the heart of an inner-city, minority neighborhood, its single-site location for comprehensive HIV outpatient services, screening clinic, and its state-of-the-art information system, is uniquely positioned to implement this technology-based provider and patient education initiative. Additionally, because the Center's population is predominately African American and Latino, it will provide a unique model for improving the quality, efficacy and cost of care for minority populations through the use of a technology based education system for providers and patients of HIV/AIDS care.

Project COMET will demonstrate the efficacy of the technology-based education and training system in the following areas:

Education.—Demonstrate the ability of a technology based educational system (or distance learning system) to update and educate specialty and community-based providers and to educate and involve patients in a shared decision-making process.

Early Intervention.—Demonstrate the effect of a technology based educational system on the ability of the community-based and specialty care providers to target HIV screening of inner-city populations with sexually transmitted diseases (STDs), so that advances in HIV care will be made available as early as possible in the course of HIV disease and prevent risky behaviors that result in the spread of the HIV and related infectious diseases;

Adherence.—Demonstrate the ability of the system to enable non-specialty and community-based care providers to implement an aggressive adherence program to ensure the application of sound treatment principles and protocols, medication adherence and clinical follow-up of inner-city, minority patients; and,

Outcomes Research.—Collect and analyze data to measure patient outcomes, the cost of care by different specialty and community-based providers as well as patient and provider adherence. In addition, this initiative will disseminate these findings.

Mr. Chairman, thank you for this opportunity to submit testimony for the record. We very much appreciated your support in fiscal year 2000 in securing the initial $1.25 million for this important initiative. We look forward to working with you to secure the remaining $8.75 million in federal funding to complete this nationally significant initiative that will thoroughly examine the effectiveness of a technology based educational system on the improvement of care and treatment of HIV/AIDS. Lessons learned from this important initiative will be beneficial not only to the Federal Government as it endeavors to develop appropriate HIV/AIDS policy, but to cities across the nation as they grapple with this very complex issue, especially as it pertains to minority communities where the epidemic is expanding most rapidly.

PREPARED STATEMENT OF THE PINON COMMUNITY SCHOOL BOARD, INC.

Thank you for this opportunity to submit testimony regarding the fiscal year 2001 Labor, Health and Human Services, and Education budget. We are pleased with the long-overdue emphasis that has been placed on Indian programs in the proposed fiscal year 2001 budget. The critical needs of Indian Country's educational system in particular rise above partisanship, recognized by leaders on both sides of the aisle as a pressing concern worthy of renewed attention by the U.S. Congress. With this in mind we ask that, at a minimum, your committee fully support the direct and indirect funds for services to Indian students contained in the Administration's request, including the following:

—$115.5 million overall for Indian Education
—$10 million for continuation of the Indian Teacher Corps program
—$5 million to create an American Indian Administrator Corps
—$2.7 million to support comprehensive Federal research on Indian education
—$20 million for Special Programs for Indian Children
—$50 million earmark for Title I grants to 119 LEAs with at least 50 percent of their students residing on Indian lands
—$200 million earmark under the School Modernization Bonds proposal for renovations and repairs to Indian schools
—$175 million for Indian Head Start programs
—$460 for bilingual education including Native language instruction materials.

Our community of 11,000 is comprised of Pinon and seven other Chapters of the Navajo Nation. While we have made much progress in recent years, our community suffers many of the same problems that plague tribal communities nationwide. In 1990, more than one-third of all Indian children ages 5 to 17 were living below the poverty level. The high school completion rate for Indians ages 20 to 24 is 12.5 percent below the national average. The problems we face are deeply entrenched and will not change overnight, but your full support for budget increases in the areas listed above will represent a critical step toward empowering tribal schools in our efforts to confront and reverse these troubling statistics.

DEPARTMENT OF EDUCATION

Indian Education.—The Administration's request for $115.5 million for Indian Education in fiscal year 2001 represents an important step toward addressing long-time shortfalls in this area. We urge you to fully support this request and related funding to benefit educational efforts in Indian Country.

We strongly support the Administration's fiscal year 2001 request for $92.8 million in Grants to LEAs for activities to improve the educational achievement of Indian students. The proposed budget also contains $20 million for Special Programs for Indian Children, a much-needed increase for which we also ask your full support.

American Indian Teachers and Administrators.—We are particularly excited about the Administration's request for funding to recruit, train, and provide in-service professional development for American Indian teachers and administrators. In support of the President's 1998 Executive Order on Indian Education, the proposed budget includes $10 million for continuation of the Indian Teacher Corps program and a new $5 million initiative to create an American Indian Administrator Corps to recruit, train, and provide professional development for American Indians in the field of school administration. We strongly support this request.

HEAD START

A critical element in any effort to raise the academic achievement level of students in Indian Country must be high-quality early childhood education programs. There is overwhelming evidence that programs like Head Start lay the groundwork for developing effective learning skills that can have a lifelong impact on a child's education. Therefore, we urge the Subcommittee to take the following actions with respect to Head Start:

—Fully fund the Administration's fiscal year 2001 budget request of $6.3 billion for the Head Start program, including at least the requested level of $175 million for Indian Head Start programs

—Prioritize the construction of badly-needed tribal Head Start facilities; and,

—Encourage the Department of Health and Human Services (HHS) to allow tribal organizations to administer Head Start programs under Public Law 93–638 self-determination contracts.

Program Access for More Eligible Children.—At the Pinon Community School, we see regular, concrete evidence that children who have attended Head Start are more prepared to learn when they graduate to our school. Unfortunately, the current funding level does not allow us to serve all of our area's Head Start-eligible children. The Pinon Head Start program serves 20 children, plus another 30 children though home-based instruction. That said, at least 391 children are eligible for comprehensive Head Start services, but we lack the funding and facilities to expand our program. They are falling through the cracks, and there is no second-chance at these critical learning years.

We want every child in our community to have the early educational attention they deserve. We strongly support the Administration's long-range goal of increasing Head Start enrollment to one million. If the Subcommittee fully funds the Administration's fiscal year 2001 budget request of $6.3 billion, nearly 950,000 children can be reached by Head Start, and 54,000 toddlers could reap the benefits of Early Head Start. These are not just numbers, they are each individual lives being shaped, someone's child that will have a better chance at fulfilling their dreams in life. We ask your support for these children at the onset of their educational journey.

Replacement Facility Construction.—Without funding to build new—and safe—facilities, the goal of increasing Head Start enrollment to one million will be meaningless to Pinon. Currently, our Head Start program is located in a 20-year-old classroom that only accommodates 20 students. In order to expand services to even a fraction of the 391 children who are eligible for Head Start in our area, we will need an additional building. Other areas suffer similar facilities constraints on their programs. We ask you to allocate a specific portion of the fiscal year 2001 Head Start

appropriation for facility needs to break down this barrier to access for additional eligible children.

Tribal Administration of Local Head Start Programs.—Section 102 of the Indian Self-Determination Act (Public Law 93–638) directs the Secretary of Health and Human Services (HHS) to contract with tribes to operate federally-funded programs for their members. DHHS, however, has interpreted this provision narrowly to require contracting only of programs "operated for the benefit of Indians because of their status as Indians." Thus, only Indian Health Service programs are deemed contractible by DHHS.

We would like to be able to contract to administer Head Start programs as a direct grantee under the American Indian Programs Branch of the Head Start Bureau. The Pinon Community School Board has successfully contracted education programs since 1988 and has continually improved student services during this time period. The Board believes that administering a tribal Head Start program through a self-determination contract would be beneficial to the community and the participating children. It would decrease the amount of federal bureaucracy that we must navigate by allowing us to receive all of our funds directly from Head Start using one funding document and would give us the flexibility to run our local programs to meet local needs. Currently, we receive our funding from the Chinle Agency, which in turn receives the funding through the Navajo Nation, Division of Dine Education, Department of Head Start.

We ask you to consider including report language in the fiscal year 2001 LHHS-Ed Appropriations bill that would encourage the Secretary to work with tribes to fully implement the Indian Self-Determination Act so that tribal organizations may contract Head Start.

BILINGUAL EDUCATION

We urge your Committee to provide the full $460 million requested for Bilingual and Immigrant Education. In addition, we ask that you take steps to ensure funding within this budget for the dissemination of instruction materials in Native languages.

In 1994, Congress authorized the Secretary of Education to provide grants to develop, publish, and disseminate instructional materials in Indian, Native Hawaiian, Pacific Islander, and outlying territories languages. This program has never been funded. We urge the Subcommittee to include report language instructing the Secretary to allocate fiscal year 2001 funding for this purpose.

At Pinon, 86 of our students are considered to have Limited English Proficiency. It is our goal to provide these children with comprehensive bilingual education so that they can learn English and meet challenging academic standards while maintaining a knowledge of and respect for their native language. To meet this goal, it is critical that we have funding to train personnel and develop innovative bilingual education programs at the local level.

CONCLUSION

Thank you for considering our concerns and comments. The Pinon Community School appreciates the funding that the Subcommittee has provided in the past to programs of concern to our school, and we look forward to your continued support.

PREPARED STATEMENT OF ELMIRA COLLEGE, ELMIRA, NY

Mr. Chairman, thank you for this opportunity to submit testimony for the record regarding Elmira College's proposed Technology Enhancement Initiative.

Today, unlike any other time in history, we have a substantial opportunity to apply the information age technologies to schools that are so effective outside the classroom for educational purposes. For schools to make the most of this opportunity, they must rethink education from the ground up.

The power of information technologies to reshape education is already becoming unmistakable. In scattered locations around the country, schools are using state-of-the-art technologies and interactive multi-media to engage students more actively in learning and to teach them skills they will need to thrive in an information based workplace and world. This is particularly true with non-traditional students who have little if any access to traditional classrooms and educational services.

As information age infrastructure is developed, more and more students and teachers will gain access to a global web of information and exchange ideas, services and education globally.

The Internet and other information technologies are bringing interactive instruction to schools in our cities and suburbs. Importantly, the past several years have witnessed a stronger focus on providing those information technologies in rural areas of the country. These technologies are allowing students to build "communities" with their counterparts around the world and create lifelong beneficial links between schools and the communities around them.

Taking advantage of this new capability will require profound changes in the roles of teachers, students and schools. Instead of being the repository of knowledge, teachers will be guides who will help students navigate through electronically accessible information. They will use the new technologies to build networks with each other, with parents and students, with academic and industrial experts and with other professionals.

In order to ensure that students (K–12, undergraduate, graduate, continuing education or professional development students, students in rural areas) receive the full potential of the technology age, the technological access must exist in flexible locations and provide continuous access to their extended communities. Equally as important, teachers must receive extensive training in how to use existing and emerging information technologies and how to design and implement appropriate curricula for a state-of-the-art 21st Century classroom.

To make technology a viable instructional and professional development tool requires schools to have enough computers to provide full easy access for all students including students with disabilities.

Institutions of higher education are central to the national effort to ensure that all students and teachers are equipped to take full advantage of the technology era. By providing education, training, and technical assistance these institutions can work in partnership with local school districts, human service agents and professionals to address problems associated with the rapid onset of the information age, including: educational, economic and social infrastructure of their surrounding communities.

Elmira College is an institution of higher education that accepts that responsibility willingly, recognizing the benefit to its students, students in surrounding school systems and community colleges, and individuals in nearby communities in need of continuing education or professional development. As such, it is implementing its "Technology Enhancement Initiative" to address its own and regional educational and technology training needs.

THE "TECHNOLOGY ENHANCEMENT INITIATIVE" AT ELMIRA COLLEGE

As it approaches the 21st Century, Elmira College, in Elmira New York, stands at an important crossroads in the development and expansion of its educational resources. To ensure its continued strength as a four-year institution of higher education the College is proposing the implementation of its "Technology Enhancement Initiative" to relocate and improve its technology infrastructure.

This initiative will address the ever-growing need in the southern tier of New York and northern tier of Pennsylvania for access to higher education, teacher technology education and training and professional development services. It will provide the College the opportunity to expand its technology resources and to meet its own and regional technological and services demands.

Elmira College proposes to establish a partnership with the Federal Government that will:

—Relocate, consolidate and improve all student and administrative computing services from McGraw Hall, which is handicapped inaccessible, to the Gannett-Tripp Library which is handicapped accessible;

—Upgrade existing "hub" hardware to state-of-the-art technology which will be able to meet and manage the demands of the upgraded system; and,

—Wire every dormitory, classroom and administrative meeting room as well as every faculty, academic, and administrative office building for direct access to the Gannett-Tripp Library, the Steele Memorial Public Library and an interface with the local public library system and with the Internet.

As a result of the improvement to its technological infrastructure, Elmira College will have the opportunity to expand existing and implement several new educational and training programs in partnership with local school systems and human service agencies. Specifically, the initiative will enable the College to:

—Offer access to higher education courses in 12 rural and underserved counties and 21 K–12 school districts (58,308 students), 8 community colleges and a variety of community sites via distance learning;

—Offer access to Elmira College library resources, including the federal depository at the College, at a variety of community sites via distance learning to underserved counties;
—Provide teacher technology education and training both on and off campus;
—Provide expanded professional development and technology education and training services;
—Provide leadership and technical assistance to local K–12 systems in the development of state-of-the-art technologically advanced classrooms and prepare its Education students (future teachers) and regional teachers to teach effectively in this technologically advanced era.

In addition to the obvious educational benefits that the Elmira College "Technology Enhancement Initiative" will have for the College and its students, there are several significant benefits for teachers in the regional community.

As a result of the Technology Enhancement Initiative, Elmira College will have the opportunity to work in partnership with regional school systems to address the education and training needs of their teachers and staff.

Elmira College will work to identify technology education and training expertise in the region and the nation and work with local school districts to develop critical professional linkages needed for the local school system to take full advantage of that expertise for their students.

In addition, as part of its own curricula, Elmira will provide expanded in-depth technology education and training for students in its Masters of Education programs.

The Technology Enhancement Initiative will provide Elmira College the ability to offer these teacher education and training courses through any of its distance learning capabilities to teachers in the classroom, on-site at their own schools, at local libraries, community colleges or even in the home. Graduate students at Elmira will continue their training within the local schools, but will have an increased ability to conduct classroom observations, information exchanges and training as a result of the Technology Enhancement Initiative.

To do so, the College will expand existing and implement new education, training and professional development programs, including courses such as Computers in Education, Interactive Media for Educators, The Internet for Educators, Video Production for Educators, and Microcomputer Applications for Educators. Finally, it will provide the College with the opportunity to play a leading role in improving the social and economic infrastructure of the region.

The Technology Enhancement Initiative will create an expanded opportunity for cooperation in the provision of higher education courses between Elmira College and local community colleges. It will help those institutions to provide timely and relevant programming at the same time it helps to prevent unnecessary duplication of academic programs and/or courses at Elmira or the community colleges.

As it is proposed, the relocation, expansion, and consolidation of all computing functions at Elmira College will provide three methods of distance learning in the future, including:

—Computer Based Research
—Internet Conferencing
—Compressed Video

Students and professionals in the field will have the ability to access education, training or professional development from home (if the connection exists) from libraries, other designated community sites or from any of the eight sites where Elmira currently provides minimal programming including:

—Bath
—Corning
—Ithica
—Owego
—Penn-Yan
—Watkins Glen
—Rome
—Syracuse (adult education)

Elmira College will have the ability to share faculty experiences across institutions and establish partnerships on select courses with regional community colleges, including general education courses, courses to support selected major requirements, and coursework providing a valuable supplement to existing offerings. Elmira College currently holds articulation agreements with three regional community colleges that will be expanded as a result of the Technology Enhancement Initiative. Those institutions include:

—Tompkins Cortland Community College
—Corning Community College

—Broome Community College

To enable the completion of this important initiative, Elmira College is seeking $3,399,000 million in federal support. To date, the College has invested $500,000 in campus infrastructure in preparation for the implementation of this initiative (these dollars are not counted as part of the official project cost, but are calculated into the College's contribution). The College is firmly committed to the completion of the project and the implementation of this important and enabling technology infrastructure and therefore will contribute an additional $1 million towards the total cost of the initiative. Total project cost is $5,923,680 million.

Mr. Chairman, this initiative is critical to the long-term economic viability of Elmira College as well as the regional the K–12, undergraduate, graduate, continuing education and professional development systems in the southern tier of New York and the southern tier of Pennsylvania. We look forward to working with you to secure the final phase of funding for this very important initiative in fiscal year 2001.

Again, thank you for the opportunity to present this testimony for the record.

PREPARED STATEMENT OF THE NORTHWEST REGIONAL EDUCATIONAL LABORATORY

My name is Dr. Ethel Simon-McWilliams, and I am the CEO and Executive Director of the Northwest Regional Educational Laboratory (NWREL), in Portland, Oregon. I take this opportunity to share with you the need for trained Retired and Senior Citizen Reading Tutors; and, a program that the NWREL has proposed for training these citizens so that they can serve more effectively as reading tutors for children, youth and adults.

America now enjoys not only the largest and fastest-growing group of older adults in our history, but the healthiest, most vigorous, and best educated. According to a 1999 survey of older Americans, engaging in community service is an important part of the retirement plans of most seniors. More than half of older Americans polled have volunteered within the past year in their communities, and working with children and youth has been a top priority for their time and talent.

At the same time, school districts are struggling to meet the needs of low performing students to increase their reading achievement. Local school districts across the nation are faced with restricted budgets, larger class sizes and reduced services for students with special needs. Thirty-eight percent of fourth-graders read below basic level and lack even partial mastery of reading skills needed for proficient grade-level work. By 12th grade, 23 percent of students remain below basic level. These struggling readers are disproportionately from families living in poverty.

The experience of the federal America Reads Challenge in 1998 and 1999 clearly showed that adults who are effectively prepared to be reading tutors can have a positive effect on students' achievement. The Northwest Regional Educational Laboratory has provided a range of supports to volunteer service programs since 1995, and in 1998–1999 was selected by the Corporation for National Service as the national provider of training and technical assistance to education-focused senior programs. The Northwest Laboratory examined reading tutor programs across the country and found, among other things, that the success of a tutoring program rides on the abilities, energy, and commitment of its volunteer tutors, as well as a strong school capacity and support for tutors.

One-on-one tutoring is clearly shown to be the most effective use of retired and senior volunteers. Senior tutors provide children with an important caring adult and an intergenerational presence that is often missing in today's mobile society.

Our research shows that volunteers are more likely to continue volunteering if they feel that their efforts are well-utilized. Well-trained senior volunteers, armed with research-based skills and strategies, offer an important boost toward helping children learn to read and gain academic and social success.

There are many successful tutoring programs in schools across the nation. We know with some confidence the elements of these programs that make them successful, or on the other hand, what lacking elements cause them to be less successful.

Therefore, I urge the support of a demonstration program, funded through the U.S. Department of Education's Fund for the Improvement of Education (FIE), that will validate the combination of elements of a model tutoring program that effectively taps the human resource pool of senior citizens. At the same time, such a demonstration project will result in the necessary resources to assist and guide states and schools across the nation implementing the model: a guide for statewide implementation for use by state education agencies, a tutor training package, and a project resource kit for schools. The Northwest Regional Educational Laboratory has the unique combination of experience and capabilities in technical assistance to school-based tutor programs, training of seniors as tutors, and evaluation of effec-

tiveness of tutor programs to conduct this demonstration program in collaboration with school districts and senior volunteer organizations in Alaska, Oregon, and Washington.

Our analysis of 61 effective volunteer reading tutoring programs across the country has shown that, to be successful, they must have:

—A clear definition of the roles, responsibilities, and accountability
—A plan for sustainability and capacity building
—A pro-active, well-qualified program director and an effective advisory committee
—Strong school and teacher commitment
—Effective and sustainable tutor recruitment
—Access to groups of tutors via universities, civic organizations, businesses, etc.

The operation of effective senior reading tutor programs needs to include:

—Consistent onsite supervision of tutors
—Tutoring sessions that support district curriculum and classroom instruction
—Tutor commitment

It is critical that tutor training be provided, based on a clearly defined, research-based training model. Training must accommodate tutors' varying expertise, learning styles, and schedules, and ongoing training and onsite support should include: (1) tutor consultations with a seasoned tutor, reading specialist, or teacher; (2) support and guidance for tutoring session planning; and (3) recognition and appreciation of tutors. Reading tutor programs must utilize high-quality materials, including a program-specific handbook and resource library for tutors, tutor-training manual, materials that support school standards, and record-keeping and assessment tools.

The benefits of effective tutoring programs in schools is well documented. In general, tutoring:

—Increases students' mastery of academic skills
—Improves self-esteem and self-confidence
—Improves students' attitude toward school and reduces dropout rates, truancies, and tardies
—Breaks down social barriers and creates new friendships
—Adds emotional support and provides positive role models

It is also clear that seniors who are tutors receive: (1) a sense of pride and accomplishment for having helped someone else, (2) increased self-esteem, confidence, and sense of adequacy as a result of being a tutor, (3) new or increased sense of responsibility and awareness for what teachers must do to transmit knowledge to students, and (4) empathy for students for whom learning may be much more of a struggle.

The Northwest Regional Educational Laboratory has trained senior program staff in supporting and training reading volunteers, reading tutoring strategies, and partnering effectively with schools. Utilizing these experiences and capabilities in conducting a demonstration program on seniors tutoring students in reading with federal support provided by the U.S. Department of Education's Fund for the Improvement of Education will be an important step to implementing effective senior tutoring programs in schools across the country.

I urge the Members of the Subcommittee to provide $1,000,000 in the fiscal year 2001 Labor/HHS/Education Appropriations bill for the Northwest Regional Educational Laboratory to carry out this program to train Retired Senior volunteers in Oregon, Washington and Alaska to serve as reading tutors in the most needy schools according to reading scores. The resulting model will be shared with other states.

Thank you for your affording me this opportunity to share the details of the NWREL's proposed retired and senior tutor training demonstration project.

Prepared Statement of the Federation of Behavioral, Psychological and Cognitive Sciences

Mr. Chairman, members of the Subcommittee, my name is Patrice O'Toole. I am the Assistant Director of the Federation of Behavioral, Psychological, and Cognitive Sciences. I am testifying today on behalf of the scientific societies that comprise the Federation, the American Psychological Association, the Society for Research in Child Development, and the Consortium for Social Science Associations. Our organizations represent most of the scientists who carry out the nation's educational research and many of the scientists who carry out its health-related research. My testimony will, therefore, be directed at the funding requests for those two areas of research.

I want to begin by thanking Senator Specter for his support and efforts on behalf of the scientific community. During his entire tenure in Congress, Mr. Specter has

been a champion of biomedical and behavioral and social science research. The American people are healthier today because of the basic and applied research Mr. Specter's work has made possible.

OFFICE OF EDUCATIONAL RESEARCH AND IMPROVEMENT

The Office of Educational Research and Improvement has been profiting from the leadership shown by Assistant Secretary Kent McGuire. The quality of peer review, which has been a concern both to Congress and to the scientific community has increased markedly, and further strengthening is taking place. Dr. McGuire has been giving direction and form to the initiatives of OERI. We are particularly pleased that the second round of proposal solicitations for the Interagency Education Research Initiative has just begun. One of the problems in educational research has always been that there has not been enough money to carry out research on large-scale applications. The combined funding of OERI, the National Science Foundation, and the National Institute of Child Health and Human Development is helping to make such research a possibility. The funds available even from three sources hardly approaches the funds that go into clinical trials of new pharmaceuticals, but this program is a big step in the right direction. As you know, NICHD was not able to contribute funds to the first round of grants. NICHD's requested funding for this effort for fiscal year 2001 is still less than that contributed by the other partners. We ask that NICHD's contribution be raised to $20 million to make it an equal partner in this important undertaking both in terms of intellectual effort and in terms of funds.

NICHD and OERI are also cooperating in an initiative to identify the factors that lead to acquisition of English reading and writing skills for children whose first language is Spanish. The statistics that reflect the difficulty Spanish speaking children encounter in school are well known. We think the OERI/NICHD partnership to improve this situation are to be welcomed and fully supported.

We also believe OERI is on track with its implementation of Comprehensive School Reform Demonstrations and its general effort to measure the impact of school reforms. It has so often been the case in education that new approaches are implemented with little concern for the research base supporting them and even less concern about evaluating outcomes. There are some positive signs that OERI is helping to change that, and these efforts need to be encouraged.

Before the last reauthorization of OERI, one of the most glaring omissions from OERI's research programs was a robust program of field-initiated research. We have been delighted to see the gradual change that has occurred over the years of the current authorization. From less than $1 million before the reauthorization, the field-initiated research program has grown to about $15 million. It is a small amount when compared to the amounts NSF, and NIH spend on research whose subject matter has been determined by researchers rather than by federal directives, but again, the steps have been in the right direction.

While we believe that much more emphasis is needed on basic, applied, and development research to improve teaching and learning, we are strongly supporting the requested $30 million funding increase for research and statistics by OERI. Space does not permit a thorough treatment of the value of the statistics gathering work of the National Center for Education Statistics. It is this work, however, that tells us enough about teaching, learning, and their lifelong effects to make it possible to devise evidence-based public policies that address real problems in effective ways. These statistics have been valuable precisely because they are measures of the state of education and learning. We have been concerned for years that NCES has been brought into the effort to design national tests. Our concern has been and remains that NCES's involvement in development of high-stakes testing will undermine the ability of NCES to be perceived across the nation as an objective, impartial evaluator of the state of education in the country. There is room to debate the wisdom of national tests. It is unfortunate, however, that we have been unable so far to keep that divisive issue from endangering the ability of NCES to keep its finger on the nation's educational pulse.

Finally with respect to OERI, we are disturbed that the Department of Education has chosen to present its request for OERI research programs as a single line item, a move that is consistent with the design for OERI being proposed in OERI's reauthorization draft, but that is inconsistent with the current structure. There are items of the proposed reauthorization with which we take issue. We support the overall request, but note that it is out of place to make assumptions in the budget presentation about the future structure of OERI before an authorization has been passed in either house.

NATIONAL INSTITUTES OF HEALTH

The administration is requesting a $1 billion increase this year for the National Institutes of Health (NIH). This would increase NIH's budget to nearly $19 billion. This is an increase that is substantially lower than needed to stay on track to doubling the research budget over five years. We are asking Congress to stay on track toward doubling the budget by increasing the budget by 15 percent which would bring the fiscal year 2001 budget to $20.5 billion. Beyond the expressed commitment of many in Congress to accomplish this doubling, we also base our recommendation on several observations.

(1) Fulfilling NIH's priorities for fiscal year 2001, which include increased attention to health disparities research, requires the increased funding. (2) Solid funding has increased the pace of discovery across the health sciences, and nothing should slow that momentum. (3) Health care costs have become unbearable for millions. The best way to control those costs is 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 life span.

Let me mention just a few of the uses to which the funding increase would be put.

NIH has established a working group, led by NIH Acting Deputy Director Yvonne Maddox and National Institute of Allergy and Infectious Diseases Director Anthony Fauci, to examine health disparities. In addition, NIH's fiscal year 2001 budget contains a request for $20 million to establish within the Office of Research on Minority Health (ORMH) a Coordinating Center for Health Disparities. We support this request.

The Human Genome Project is expected to complete human gene sequencing by this summer. Already NIH has been at the forefront of research in genetics and neuroscience. That research is helping us understand many diseases including Parkinson's, Alzheimer's, drug addiction and diabetes. With sequencing nearing completion, we are poised for an explosive growth in discoveries in the years ahead.

Scientific advances in knowledge about brain disease have been possible because of new methods for the study of the nervous system, such as neuroimaging. Identifying the molecules that guide the formation of the brain and increasing understanding of how the processes occur are allowing neurobiologists to visualize how the developing nervous system organizes itself, to explain complex behaviors, and to describe neurological and psychiatric diseases with a new level of precision. However, equally important is the role that behavioral, psychological, socio-cultural, and environmental factors play in health. Our beliefs, our emotions, our behavior, our thoughts, our family and cultural systems, our socio-economic status, as well as the environmental context in which we live, are all as relevant to our health as our genetic inheritance and our physiology.

The emergence of cross-disciplinary collaboration has been a major component in the fast-paced research developments in these arenas. 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 take the medications properly—a discipline that can be trained by application of techniques developed through behavioral research.

Similarly, recent NIH-supported behavioral research has produced useful new knowledge, including a better understanding of basic behavioral and social processes and how they interact with biological processes. This understanding is coming from many lines of research: studies of lifestyle choices, dietary habits, the desire and ability to maintain exercise or medication regimens, psychological functioning, and influences of one's social and cultural environment on behavior.

All these lines of research converge to give us a picture of the factors that can affect an individual's ability to remain healthy or to recover from disease or to function well despite a chronic condition. And that knowledge leads to treatments and other interventions to maintain health throughout the life span.

NIH's Office of Behavioral and Social Sciences Research (OBSSR), created in 1995 has been pivotal in supporting these studies and translating the findings into effective prevention and treatment strategies. OBSSR, under the purview of the Office of the Director of NIH, coordinates all the institutes and centers in marshaling their individual resources to collaborate on behavioral and social sciences research. OBSSR's congressionally mandated primary mission is to foster the development of cross-disciplinary communication and research collaboration among behavioral and

social sciences and between the behavioral and social sciences and biomedical sciences.

OBSSR, under the auspices of its first Director, Norman Anderson, has achieved great success in its short existence. We believe it can accomplish a great deal more with the continued support of Congress and the necessary resources to do so. A key role for OBSSR has been assuring that development of effective behavioral interventions is keeping pace with technological advances.

OBSSR has been successful, yet continues to operate with a small staff and a small budget. Last year, Congress approved a $7 million increase for OBSSR to continue its efforts to encourage cross-institute collaboration and research in the behavioral and social sciences. This money is being used to fund a trans-NIH initiative on adherence to medical and behavioral interventions across a number of diseases and conditions. OBBSR is also funding a trans-NIH initiative seeking effective interventions to curb youth violence. And as episodes of violence between children mounts, the need for these programs is critical to reducing the overall level of violence. More research is needed on children and youth at risk. We need a richer understanding of the social, environmental, psychological, developmental and biological factors involved in risk as well as a deeper understanding of how the factors interact.

Despite the pressing need for this research, the President's request for fiscal year 2001 provides no increase for OBSSR's budget. OBSSR's current budget is $19.86 million. The Federation supports an increase of ten percent for OBSSR, bringing its budget to $21.84 million for fiscal year 2001. This increase would significantly augment OBSSR's ability to continue coordinating research across institutes. This is an efficient use of resources and a beneficial mode of operation, because it links areas of related knowledge that might otherwise remain separated.

A prime example of benefits of behavioral research has been the identification of factors that aid in protection from disease and that promote recovery from illness. They include certain personal attributes such as optimism, effective strategies for coping with stress, and meaningful sources of social support and affiliation.

NIH funding has permitted us to use research wisely, that is, in the combinations that will be most efficient in reaching solutions to typically multifaceted health problems. To continue successful biomedical and behavioral research at this level requires Congress' ongoing commitment to finding resources for expanding NIH's budget.

With increased support, the current pace of discovery and collaboration can be sustained. The largest per person expenditures for health care occur near the end of life. One goal of research is to understand what interventions through the life span will have the greatest promise of assuring that the period of great illness before the end of life is minimized. As more of the U.S. population reaches advanced age—the number of Americans aged 65 and older is expected to double by the year 2030 to nearly 68 million—it becomes increasingly vital to the health of our entire society that we age well. Many of the problems that accompany aging, especially chromic diseases, stem from behaviors that place individuals at risk of negative outcomes.

The National Institute of Child Health and Human Development (NICHD) conducts research on human growth and development from conception through birth, infancy, childhood, adolescence, reproduction, and through maturity to old age. As such, NICHD addresses some of the most important health and development problems facing our children and families.

Based on this broad spectrum of research, we believe that NICHD's fiscal year 2001 budget should be increased by 23.9 percent, bringing its budget to $1,064,800. Historically and chronically, NICHD has been one of the lowest funded institutes even though it conducts research that has immediate, proven and successful applications through behavioral intervention. We urge the subcommittee to press for higher funding of NICHD.

Behavioral research has a large role to play in contributing to the nation's health, because controllable choices and behaviors in life have a heavy impact on the quality of life. Obviously, such behavioral choices as to smoke or not to smoke, what foods and quantities of food to consume, and how regularly one exercises 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 shrinkage of health care costs 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 down at the same time.

We strongly urge the Subcommittee to recommend a 15 percent increase for NIH because the investment in knowledge will result in healthier citizens and health care cost savings that far exceed the research investment. Slighting research will assure that rising health care costs will remain among our most serious national crises.

We thank the Subcommittee for the opportunity to present our views.

PREPARED STATEMENT OF THE UNITED NEGRO COLLEGE FUND

Mr. Chairman and Members of the Subcommittee. My name is William H. Gray, III and I am President and Chief Executive Officer of the United Negro College Fund (UNCF). I thank you for the opportunity to bring UNCF's fiscal year 2001 recommendations for higher education programs before you.

UNCF is America's oldest and most successful black higher education assistance organization, representing 39 private, four-year historically black colleges and universities with either independent or religious affiliations. UNCF has been committed to increasing and improving access to college for African Americans since 1944. The organization remains steadfast in its commitment to enroll, nurture, and graduate students who often do not have the social and educational advantages of other college bound populations.

Since its inception, the fundamental mission of UNCF has been to raise critical operating funds for member institutions and their students, faculty, and staff. Mr. Chairman, I am proud to say that over the years, this mission has broadened to include over 450 successful scholarship programs, internships, research and study abroad opportunities for all historically black colleges and universities (HBCUs), Hispanic-serving institutions (HSIs), Tribally-controlled colleges, and majority institutions. We also provide technical assistance to our trustee programs such as the fiscal and strategic technical assistance program (FASTAP) and faculty training, for institutions both domestic and abroad.

UNCF is committed to educating tomorrow's workforce. America's markets are growing more diverse, and demographic trends indicate that early in the 21st Century, African Americans and other racial and ethnic minority groups will constitute a major part of the workforce.

The more than 55,000 students enrolled at UNCF institutions are from diverse backgrounds. Our schools mirror the mosaic that is America; we are African American, White, Hispanic, Asian, and Native American. While our student body consists of varied economic backgrounds, approximately 34 percent of all UNCF students come from families with incomes below $25,000 (compared with 17 percent of students attending four years colleges nationwide). Approximately 90 percent of UNCF students require some form of financial assistance. Forty percent are the first in their families to attend college compared with the national average of 35 percent.

In spite of these challenges, UNCF students and members institutions have accomplished much. They are noted for their consistent standards of excellence and outstanding achievements. HBCUs are the major source of African American college graduates and black professionals in America. In fact, 16 Members of Congress are alumni of HBCUs. HBCUs contribute significantly to the production of African American baccalaureate degree holders in the sciences. HBCUs also graduate the most African American doctoral degree recipients. In addition, more than 50 percent of the nation's African American public school teachers and 70 percent of African American dentists and physicians earned degrees at HBCUs. These are but some of the extraordinary roles HBCUs have played in educating minority Americans.

Mr. Chairman and Members of the Subcommittee, the impressive achievements that I noted have an even greater significance at UNCF institutions in that our schools have accomplished all this for a fraction of the cost compared to that of majority institutions. The average cost of attending a UNCF institution in 1997–1998 was $13,368, which is substantially below the average cost of $21,424 at four-year private colleges nationwide. In fact, UNCF's tuition increased only 43.5 percent over the last decade compared to a 51.6 percent increase at all private, four-year colleges during the same period. However, this cost still remains above the financial means of most of our students and their parents. Furthermore, keeping the costs of a college education down while educating "at-risk" students comes at a financial price for UNCF member institutions.

Consistent with our commitment to providing access to higher education to economically disadvantaged, first generation students, we applaud federal efforts to make college affordable for all. As you know, students from low-income back-

grounds, when compared to all other students attending four-year colleges and universities, are more likely to drop out and less likely to earn a degree. In fact, according to a recent survey of beginning postsecondary students released by the U.S. Department of Education, 42 percent of students from the nation's poorest families (with incomes less than $20,000) received a bachelor's degree within five years while 35 percent—a significant portion of similarly situated students—had dropped out entirely.

Additionally, students have increasingly turned to borrowing in order to manage rising education costs. More full time undergraduate students are also working while enrolled. The burden of borrowing and working plays a significant role in how students pay for their education and whether they graduate.

Clearly, students with adequate financial resources have an increased chance of obtaining a degree over those without access to similar means. However, most research on the subject indicates that simply increasing financial aid to low income students does not appear to have any particular significance in determining successful outcomes (i.e., improving the chances of staying in college and graduating). We know that a freshman or sophomore, low-income student may choose to leave college rather than face the prospect of assuming loan debt. Mr. Chairman, Congress should recognize that certain types of aid actually serve as a disincentive for the nation's neediest students! Congress should be mindful that what is important is the type of aid low-income students receive; when it is given; and what other services are afforded to them.

For these reasons, UNCF strongly supports increased student financial assistance. Specifically we support the funding recommendations of the Student Aid Alliance of which UNCF is a member. Most important to our students is increased Pell Grant aid, preferably awarded to a student in their earlier years of college, with a maximum award of $3700 in fiscal year 2001. Moreover, we support the Administration's proposal to enhance college persistence and completion through the College Completion Challenge Grant. This is a new program supporting a comprehensive approach to increasing minority retention and completion rates through such activities as a pre-freshmen summer program, support services, and increased grant aid to students. This program would be funded at $35 million and operated under the successful TRIO program, which UNCF also recommends receive an increased $70 million in overall funding for fiscal year 2001. Other student financial assistance programs we advocate higher funding for are: SEOG ($731 million); LEAP ($100 million); Perkins Loans ($200 million); and the Federal Work Study Program ($1.1 billion).

Mr. Chairman, it is important to note, for the record, that growing debate about making college affordable and providing a means to a college education centers on the premise of providing tax credits for students and their parents. Findings, however, support the position that, while such tax credits benefit middle income and affluent families, low-income families are better served by grant and scholarship aid. UNCF firmly believes that a better of use of tax dollars to achieve access to college would be to provide more grant support in the manner that I recommended earlier.

In terms of institutional support, UNCF strongly recommends increasing Title III, Part B, section 323 to $175 million and Title III, Part B, section 326 to $40 million. These programs have been the mainstay of UNCF schools through the years. For many UNCF institutions in particular, Title III grants are the only form of institutional assistance received from the Federal Government. These grants are used for academic program enhancement, faculty development, student services, and the construction, maintenance, and renovation of buildings. We also support increases to the other institutional aid programs under Title III.

Mr. Chairman, at a time when the education of tomorrow's workforce tops agenda's nationwide, minorities are underrepresented in numerous professions across the board—science, engineering, law, teaching. Thus, UNCF strongly supports the Administration's proposed new Dual Degree Programs at Minority Serving Institutions initiative that addresses this very issue. This program complements existing curricula at HBCUs and other minority-serving institutions and channels students into careers in which minorities are underrepresented. Funding for this new effort is $40 million. Several other programs provide critical institutional support to UNCF member institutions that educate a preponderant number of minority professionals while addressing these shortages. Accordingly, UNCF recommends increases for these initiatives, including the Minority Science and Engineering Improvement Program (MSEIP) to $40 million, Title VI International and Graduate Programs to $82.5 million (and the Institute for International Public Policy/IIPP), the Thurgood Marshall Legal Education Opportunity Program $5 million, and Teacher Quality

Enhancement Grants to $140 million. UNCF also stands firmly behind increased funding for the Department of Education Office of Civil Rights at $78.605 million.

Minorities are also underrepresented in the international arena while our country competes increasingly in a global marketplace. To counteract this trend, UNCF believes Congress should increase its support of IIPP to $2.5 million in fiscal year 2001. Currently, entering its fifth year, IIPP will serve more minority students with more programs than ever before. However, this program is increasing its impact with only a 2 percent increase in its funding since the program's creation in 1992. Surely, there is a need to have a diverse cadre of international professionals in this global community.

Mr. Chairman, it is clear that UNCF member institutions leverage federal dollars to the maximum potential. Even though we have smaller endowments and a greater percentage of students needing financial aid, UNCF institutions capitalize on our federal partnerships in extraordinary ways to address national concerns. Currently, like the rest of the nation, UNCF is facing the digital divide challenge, a problem that is greater in higher education than it is among the nation's households. A great many of the programs I have mentioned today help us address this challenge—particularly the Minority Science and Engineering Improvement Program. This important program provides a critical resource for baccalaureate granting institutions like UNCF member schools that miss out on the majority of federal dollars allocated to science, engineering, and related areas, since funds are traditionally targeted to majority research-performing institutions. Consequently, our schools are hampered early on in their ability to qualify and compete for funds—even though we contribute so much. For this reason, it is imperative that Congress show leadership by funding those proven programs that are designed to not only increase access and opportunity for African American students and the HBCUs they attend, but also those programs that have demonstrated a capacity to have considerable impact on this nation's future.

Mr. Chairman, on behalf of the United Negro College Fund member institutions, I thank you for the opportunity to provide testimony on the fiscal year 2001 appropriations for higher education programs and look forward to working with you to ensure strong alliances between our schools and the Federal Government.

PREPARED STATEMENT OF FLORIDA STATE UNIVERSITY

Mr. Chairman, I would like to thank you and the Members of the Subcommittee for this opportunity to present testimony before this Committee. I would like to take a moment to briefly acquaint you with Florida State University.

Florida State University is a comprehensive Research I university with a liberal arts base. The University's primary role is to serve as a center for advanced graduate and professional studies while emphasizing research and providing excellence in undergraduate programs. Faculty at FSU have been selected for their commitment to excellence in teaching, for their ability to perform research and creative activities, and for their commitment to public service. Among the faculty are numerous recipients of national and international honors, including four Nobel laureates and eight members of the National Academy of Sciences. Our scientists and engineers do excellent research, and often they work closely with industry to commercialize their results. Florida State ranks third this year among all U.S. universities in revenues generated from its patents and licenses, trailing only Columbia University and the entire University of California system. 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 or medical school, few institutions can match our success.

Florida State attracts students from every county in Florida, every state in the nation, and more than 100 foreign countries. The University is committed to high admission standards that ensure quality in its student body, which currently includes some 192 National Merit and National Achievement scholars, as well as students with superior creative talent. We consistently rank in the top 25 among U. S. colleges and universities in attracting National Merit Scholars. At Florida State University, we are very proud of our successes as well as our emerging reputation as one of the nation stop public universities.

Mr. Chairman, let me tell you about a project we are pursuing this year involving the U.S. Department of Education and distance learning. Florida State University is pioneering the use of distance education to provide access to baccalaureate degrees for students with Associate of Arts degrees who, due to family or work situations, may not be able to relocate to a college or university to complete their degree work. FSU is currently offering three programs entirely on line for students to re-

ceive their baccalaureate degree: Computer Science, Information Studies, and Software Engineering. A new program in Social Science will begin in Fall 2000 with other undergraduate programs to be developed. This 2 + 2 program is being offered in cooperation with 18 community colleges in Florida, which provide computer labs and proctored testing facilities where needed. Florida State University's distance learning initiative has focused not only on a quality course development model based on that of the British Open University, but has placed a major emphasis on student support for the distance education teaching and learning environment. This ranges from having all major student administrative services available on line, to partnering with Blackboard, Inc. in the development of Course Info Enterprise Edition for course development and delivery of courses. Students can do everything on line from applying, getting their dial up e-mail account, registering in courses, checking grades, to getting a copy of their transcript.

But most important for student support and student success is our use of mentors in addition to the faculty teaching the course. Mentors take a proactive stance toward the students, contacting them on a regular basis to see if they can provide help with any problems the student is having, and are available electronically at any time to deal with students questions and concerns. Student support is a key factor in insuring student motivation to complete distance courses and do well.

This program can be scaled up to constitute a model of effective distance learning anywhere at the undergraduate level. Our focus has been on Florida, though we have a small number of out-of-state students in our distance degree programs. With additional support, more majors can be added, and the program can be expanded to serve a wider range of students geographically. Front-end development activities are essential for quality courses and require significant expenditure to add majors, train mentors and offer degree programs on a larger scale. Granting such front-end funds will have a major pay off in terms of providing access to a college degree to many place-bound individuals who represent a significant and diverse part of our population.

Florida State as a research university is heavily invested in new technologies and learning ideally positioned to provide further leadership in student supported high quality distance learning. The University was recognized in 1999 as one of the 100 most wired campuses in America and the U.S. Department of Education has selected FSU as one of its 15 demonstration projects on distance learning and financial aid.

We are seeking an appropriation of $2 million within the Department of Education's Higher Education account for this activity in fiscal year 2001.

Mr. Chairman, this is just one of the many exciting activities going on at Florida State University that will make important contributions to solving some key problems and concerns our Nation faces today. Your support would be appreciated, and, again, thank you for an opportunity to present these views for your consideration.

PREPARED STATEMENT OF THE UNIVERSITY OF TULSA

It is proposed that the Department of Education support an information technology center for the University of Tulsa. We are seeking $15 million for building and equipment needs.

THE UNIVERSITY OF TULSA CENTER FOR INFORMATION TECHNOLOGY

It is a reality that economies are increasingly linked to technology. In February 2000, Oklahoma Governor Keating hosted a round table discussion of technology, educational, and commerce leaders in Tulsa. As a result of that meeting, a Center of Excellence in Information Technology and Telecommunications was formed. Participants in the Center include the University of Tulsa, Oklahoma State University-Tulsa, the University of Oklahoma's Tulsa operations, Oral Roberts University, Tulsa Community College and Tulsa Technology Center.

The University of Tulsa is poised to help ensure that the Center of Excellence in Information Technology and Telecommunications meets the needs of industry and fulfills its mission of advancing the industry through research and educational programs. However, we are in need of a state of the art technology center to optimize our educational and research opportunities.

There are a number of significant benefits that will flow to the State of Oklahoma and the Tulsa community from an investment in a TU Center for Information Technology (IT). These include:

—Attracting and retaining quality students
—Enhanced educational opportunities
—Research opportunities for both faculty and students

Attracting and Retaining Quality Students

TU is committed to quality education. The University of Tulsa faculty is nationally recognized. For example, last year the Carnegie Foundation honored two University of Tulsa professors for the Advancement of Teaching and Learning. One was named a Carnegie Professor of the Year and one was named a Pew Scholar. In the past five years, The University of Tulsa, MIT and Stanford produced an equal number of Goldwater Scholars, tying for seventh place in the nation. The TU Center for IT would provide the infrastructure to maximize the potential of integrating these quality students with quality faculty. However, the Center would prove beneficial even before students arrive on campus. The recruiting competition for quality students is fierce. Students judge the technology infrastructure of a college or university when selecting an institution of higher learning. Students often make the decision to stay at a college or university based on opportunities for access to state of the art technology. TU wants to educate the technology knowledge workers to enter the digital economy work force and the Center would allow us to nationally recruit quality students to Oklahoma.

Enhanced Educational Opportunities

The TU Center for Information Technology will enhance educational opportunities in three areas:

—by providing tools/resources to enhance learning in all academic areas and disciplines,

—by providing an infrastructure for technology based program students (such as management information systems, computer information systems, and computer science) students to complement in class learning by applying their classroom learning, and

—by enabling TU to deliver education to a broader range of constituents—students in divers geographic regions. It will also enable TU to reinforce the lifelong learning we encourage our alumni to pursue.

Research Opportunities

The TU Center for Information Technology will provide resource opportunities for both University of Tulsa faculty, and graduate/undergraduate students. Due to the number of industry leaders located in Tulsa, TU researchers have access to a significant volume of relevant subjects and data. TU's research program for undergraduate students (known as TURC—the Tulsa Undergraduate Research Challenge) is nationally recognized and acclaimed. Students have won a variety of national scholarships and grants from prestigious organizations such as the National Science Foundation and the Department of Energy. The enhanced research labs available in the TU Center for IT would further enhance the success of this program.

In summary, the combination of quality professor, students, and technology infrastructure will result in a win-win proposition for students of higher education in Oklahoma and the Oklahoma economy.

PREPARED STATEMENT OF FIGHT CRIME: INVEST IN KIDS

Littleton, Paducah, Springfield, and Mount Morris. In the wake of each of these tragedies, the American public has clamored for solutions.

No one can say with certainty how each particular terrible tragedy could have been prevented. But a great deal is known about how to sharply reduce the incidence of school and youth violence. That is why it is frustrating to those of us who represent law enforcement and victims of violence when public officials wring their hands and pretend they can do nothing to prevent the next tragedy. Law enforcement is virtually unanimous about the steps that can help prevent future incidents, and have issued a 4-point School and Youth Violence Prevention Plan that calls on public officials to:

—Assure all kids access to after-school programs that connect them with caring adults during the peak hours of violent juvenile crime;

—Assure all families access to quality early childhood development programs;

—Prevent child abuse and neglect and help heal those who have been abused and neglected;

—Assure that troubled kids get early, effective help.

Our members, more than 700 police chiefs, sheriffs, prosecutors, leaders of police organizations, and crime survivors, know that this committee's decisions will have a profound impact on juvenile crime rates in the years to come.

As a first step towards implementing our School and Youth Violence Prevention Plan, we urge that you provide for fiscal year 2001 at least:

—$6.3 billion for Head Start, so that the program can expand to serve more eligible children, and further strengthen its quality.
—$2 billion for an Early Learning Trust Fund so communities can fund parenting-education programs and quality child development services to children under five.
—$7.5 billion for the Child Care and Development Block Grant, maintaining appropriate set-asides for quality, infants and toddlers, school-age care, and resource and referral agencies. The discretionary portion of these funds should be increased by at least $818 million to be made available October 1, 2000.
—$1 billion for the 21st Century Community Learning Centers to expand after-school programs that provide constructive activities and connect kids with caring adults during the peak hours of violent juvenile crime.
—$2.38 billion for the Title XX Social Services Block Grant. Recent drastic cuts in this program have shortchanged child care (15 percent of state spending under the block grant), child abuse prevention, removal and placement of abused children, drug treatment, and other critical crime-prevention investments.
—$10.5 billion for Title I—Education for the Disadvantaged.
—$250 million for Title V of the Juvenile Justice Act for local delinquency prevention programs.

Those on the front lines of the battle against crime know that these investments are among our most powerful weapons against crime. That's why over the last year, virtually every major national law enforcement organization—including the Major Cities [Police] Chiefs Organization, the Police Executive Research Forum, the National Sheriffs' Association, and the National District Attorneys' Association—have all adopted forceful calls for boosting critical crime-prevention investments, such as educational child care and after-school programs, preventing child abuse, and providing intensive services to help troubled kids get back on track.

A recent poll of police chiefs conducted for Fight Crime by George Mason University professors Scott Keeter and Steve Mastrofski showed that nearly nine out of ten of police chiefs agreed that "expanding after-school programs and educational child care programs like Head Start would greatly reduce youth crime and violence." Nine out of ten agreed that if America fails to make greater investments in these programs now, "we will pay far more later in crime, welfare and other costs." Police chiefs picked these investments as "most effective" in reducing youth violence by a margin of four to one over such alternatives as trying more juveniles as adults or hiring more police officers, and by seventy-to-one over installing more metal detectors.

Collectively, the four steps mentioned in our School and Youth Violence Prevention Plan would dramatically reduce violent juvenile crime. There are no substitutes for loving parents, but, government's fundamental responsibility is to protect the public safety, and it can't meet that responsibility by pointing fingers and saying parents should do a better job.

The evidence is clear that well-designed programs for kids can dramatically reduce crime and violence, and keep kids from becoming criminals. But these programs remain so under-funded they reach only a fraction of the youngsters who need them. For example:

—In a five-city study, half of a group of at-risk high-school kids were assigned to participate in the Quantum Opportunities after-school program. The boys left out of that program were six times more likely to be convicted of a crime in their high-school years. Yet roughly seven million youngsters under twelve, and millions more teens, lack after-school programs that put them in touch with caring adults providing supervision and constructive activities.
—A High/Scope Foundation study at the Perry Preschool in Michigan randomly chose half of a group of at-risk toddlers to receive a quality Head Start-style preschool program, supplemented by weekly in-home coaching for parents. Twenty-two years later, the toddlers left out of the program were five times more likely to have grown up to be chronic lawbreakers, with five or more arrests. Yet inadequate funding for Head Start and the Child Care Development Block Grant leaves millions of at-risk children without critical early childhood services.
—A Montreal study showed that providing disruptive first- and second-grade boys with social skills training and counseling cut in half the odds that they would later be in special classes, rated highly disruptive by a teacher or by peers, or have been required to repeat a grade in school—all signs that the risk of future violence has been sharply reduced.
—The Prenatal and Early Infancy Project randomly assigned half of a group of at-risk mothers to receive visits by specially trained nurses who provide coach-

ing in parenting skills and other advice and support. Rigorous studies show the program not only reduced child abuse by 80 percent in the first two years, but that fifteen years after the services ended, these mothers had only one-third as many arrests, and their children were only half as likely to be delinquent.

Many of our members are conservatives who believe we should, in the long run, be able to cut taxes. Our experience and hard scientific evidence prove, however, that boosting investments in children now will save lives and tax dollars, leaving far more money for tax cuts, paying down the debt, and preserving social security down the road. For example:

—Economist Steven Barnett found that the High/Scope Foundation's Perry Preschool study saved $150,000 per participant in crime costs alone. Even after subtracting the interest that could have been earned by investing the program's funding in financial markets, the project produced a net savings of $7.16—including more than six dollars in crime savings—for every dollar invested.

—A study by Professor Mark A. Cohen of Vanderbilt University estimated that for each high-risk youth prevented from adopting a life of crime, the country would save between $1.7 million and $2.3 million.

—A Rand Corporation report showed that, even without counting the savings to crime victims and society, the resulting savings to government alone from effective early childhood programs exceeded by two to four times the cost of the programs.

Yet these dollars savings do not measure the greatest savings of all.

One child was killed in Mount Morris, 12 in Littleton. In an average week, 40 children are killed in America by violence. About 98 percent of these killings take place outside of school. That's over 150 Littletons a year if we do nothing.

The Fight Crime: Invest in Kids School and Youth Violence Prevention Plan will not prevent every incident of violence, but it can save thousands of lives—whether from school shootings or the out-of school tragedies that take an even more massive toll on our children—in the years ahead, all the programs for which we are calling for funding increases are consistent with our School and Youth Violence Prevention Plan.

The programs for which we are calling for increased investments are consistent with the recommendations made by the Bi-Partisan Working Group on Youth Violence. Speaker Hastert and Minority Leader Gephardt created the working group to examine the evidence on measures to curb youth violence and to recommend a plan of action for Congress to take. Not surprisingly, the working group's conclusions to cut you violence echo the recommendations of law enforcement and crime survivor leaders:

—"Effective federal programs must be fully funded to achieve the largest impact on early childhood development and, ultimately youth violence. Studies have estimated that for every dollar invested in quality early education, about seven dollars are saved in later costs."

—"Congress should increase funding for high quality effective early childhood programs, evaluate all federally-subsidized early childhood programs, and identify areas for improvement and where new areas could be implemented."

—"The subgroup recommends that Congress provide increased support for a range of prevention and early intervention strategies targeted toward at-risk youth and their families, including school-based and after-school programs."

—"Congress needs to take steps to ensure that every child has access to high quality after-school activity. . . . We agree with the nation's police chiefs that after-school programs for youngsters are a more effective way to fight crime."

—"We need to make sure that child protective services staff have sufficient resources to identify and treat abused and neglected children. We must also act before children are hurt by expanding programs proven to reduce cases of abuse and neglect."

Speaker Hastert promised that the working group's recommendations "which are legislative in nature would follow the normal committee process but be addressed promptly." Now it is time to act.(A copy of the report can be found on Jennifer Dunn's website http://www.house.gov/dunn/workinggroup/wkg.htm.)

We hope that you choose to put Congress this year on a path to full implementation of our School and Youth Violence Prevention Plan and of the recommendations of the Bi-Partisan Working Group on Youth Violence. Following this path will produce massive cuts in crime and violence.

Thank you for your consideration.

PREPARED STATEMENT OF THE NATIONAL MILITARY FAMILY ASSOCIATION

NMFA and the families we represent are grateful to this Subcommittee and to the United States Senate for its actions on behalf of military children and the Impact Aid Program. We thank all the Congressional supporters of Impact Aid, especially the members of the House and Senate Impact Aid Coalitions, for securing another increased appropriation for the program for fiscal year 2000. Your continued support of this program translates into better education for approximately 550,000 military children and several million of their civilian classmates in school districts across the country.

THE MILITARY CHILD

NMFA presents this statement on behalf of military families, or more specifically on behalf of military children:

—Military children move every 2 to 4 years and attend an average of six different schools. Less than 20 percent of these children attend Department of Defense Schools; the overwhelming majority of military children attend civilian schools dependent on Impact Aid.

—Military children bring a wealth of cultural experiences gained from living in many parts of the world to their new schools. They also frequently come with gaps in their education that their new teachers must quickly fill while moving the rest of the class ahead. Sometimes they are far ahead of their new classmates, adding boredom to the list of reasons why they hate moving to yet another new school.

—Because of varying course standards, school schedules, and state graduation requirements, they sometimes lose credits needed for graduation or they must take state accountability tests on subject matter they never learned. A change of schools at any time is traumatic, but a change in the middle of the school year is especially so. A mid-year transfer can place some children so far behind, they cannot catch up the rest of the school year, especially if a district does not have the resources for a good transition program.

—Because of the high operations tempo of today's military, the military child often has to adjust to the new school, face that week of standardized tests, fight for the spot on the newspaper staff, play the basketball game before a crowd of strangers all without the support of their military parent. Worry about the safety of a parent in a place far from home where people are shooting at each other makes for a powerful distraction from the business of education.

Military families want to be involved in their children's education and list education as one of their top quality of life issues. While a concern about the quality of their children's education is rarely the sole reason military members leave the service, the stress caused to a child by one-too-many moves, the special services not received when needed, or the prospect of an assignment at an installation where the schools have a poor reputation may be enough to convince a service member that it is time to leave the military.

WHY IMPACT AID? THE FEDERAL RESPONSIBILITY

Military families understand that the Impact Aid program supports basic education services provided by their local school districts. They understand the impact the federal presence has on the tax base of these local districts and their states. They understand the impact their children and the transient military lifestyle can have on their local schools.

—Children living on Fort Belvoir, Virginia attend the Fort Belvoir Elementary School, operated by Fairfax County. In school year 1998–1999, the school's highest enrollment was 1,320 students. During the year, the school experienced a turnover rate of over 50 percent. Not counting the summer rotations, 706 students came in and out of the school. Think of the records that must be prepared, the evaluations and testing for special programs that must occur, the children unable to concentrate because another best friend has moved away, the anxiety faced when the newcomers don't know anyone who will eat lunch with them!

—The average soldier at Fort Hood, Texas deployed 120–160 days in fiscal year 1999. The average airman at Offutt Air Force Base, Nebraska deployed over 120 days. Think of the Parent-Teacher conferences missed, the volunteers unavailable to support school activities, the families stretched too thin. Research shows that involved parents promote academic achievement. Deployment makes that involvement more difficult both for the deployed servicemember and the spouse trying to keep things together at home.

Military families hold the government, and the citizens they have sworn to serve and protect, accountable for living up to their promise to provide a quality education for their children. The districts have accepted the responsibility to educate military children; the Federal Government must provide the resources it has promised to support that education.

—The intent of the original Impact Aid legislation (Public Law 81–874) was "to provide financial assistance for those local educational agencies upon which the United States has placed financial burden." It originally provided an "in-lieu-of-tax" payment equal to the local per-pupil costs for students whose military parent both lived and worked on a federal installation (these students were designated A students) and one-half of the local per-pupil cost for students whose military parent worked on a federal installation but lived in the civilian community (B students).

—It costs an average of over $6,000 to educate a child in the United States today. But the current average Impact Aid payment for an A child is approximately $2,000; the average payment for a B child (now set at only .10 of the amount for the military A students) is $200, nowhere near the original intent or actual cost of educating a child.

Once again, NMFA thanks this Subcommittee for its continued funding of Impact Aid for the military children who live off the installation, the "military Bs." Although military families living in the civilian community pay property taxes to help support local schools, they often do not contribute to other sources of education funding. States provide an increasingly larger share of local districts' funding. Many military members pay no state tax on their military income. They also shop in military exchanges and commissaries, thus paying no sales tax. Under the provisions of the Soldiers' and Sailors' Relief Act, they are often exempt from paying personal property taxes or license fees for automobiles if they are on military orders away from their home state.

—The local tax base for the Bellevue, Nebraska school district that educates the children living on or near Offutt Air Force Base generates only $12 million of the district's $54 million annual budget. Each year the county loses $5 million in license plate fees because military members stationed at Offutt may license their vehicles in their home states rather than Nebraska.

—The Copperas Cove Independent School District serves children whose parents are assigned to Fort Hood, Texas. All but about 100 of the district's 2,700 military children live in the civilian community adjacent to Fort Hood and approximately 30 percent of the district's budget comes from Impact Aid. If funding for military B students was discontinued, district officials estimate they would have to raise property taxes 51.3 cents per $100 of valuation.

—As the military services look to the civilian community to provide more housing for military families, the number of B students will increase, thus raising the burden on districts charged with educating them.

FIX THE SCHOOLHOUSE

For a newly-arrived family in a military community, the sight of a well-maintained, safe, child-friendly school building can calm many anxieties about their latest move. Unfortunately, too many military children must deal with those anxieties in a school facility that has seen better days.

—Although Impact Aid provides much of a heavily-impacted district's working capital, it cannot be stretched to fund the facility maintenance and improvements old school buildings need. Military families at many installations voice concerns about the repairs needed for these buildings and the lack of available funds. At Grand Forks Air Force Base, for example, parents with children at the combined elementary/middle school note the work needed. The district only recently allocated funds to meet accessibility laws. The building has no handicapped-accessible bathroom, entrance or exit ramps, or lift or elevator to the second floor. Designed as an elementary school, the building has no adequate gym space for middle school programs and needs a new boiler. It has windows that are boarded up and frosted over or, as described by one military spouse, "windows that have been re-caulked so many times there is more caulk than window sill."

—NMFA remains concerned about the upgrade and maintenance needs of school buildings owned by the Department of Education. The Waynesville R–VI School District, for example, operates seven buildings owned by the Department of Education on Fort Leonard Wood, Missouri. Although one school has been recently renovated, the district estimates that it needs approximately one million dollars per school to bring the rest up to standard. The district used its own

funds to wire the Department of Education buildings for the Internet so that the military children attending these schools would not fall behind their peers in district-owned buildings. In addition to facing pressing maintenance and renovation needs, the district is also coping with the addition of 600 Army children it received from units moved to Fort Leonard Wood following the closure of Fort McClellan, Alabama. To a district with only 5,100 students in old school buildings, an additional 600 children becomes a strain on the system.

ONE CHILD, MANY SCHOOLS

The education of a military child is a continuum. As the military child moves from school district to district—from a school receiving Impact Aid in Texas, to another Impact Aid school in Virginia, to a Department of Defense school in Germany to another Impact Aid school in Illinois—the quality of education she receives in each school will affect the education she and her classmates receive in the next. Children whose schools are unable to provide the necessary educational services could easily fall behind their peers in other districts. Schools serving these children could face difficulties in maintaining accreditation as tough new standards are implemented in many states. A smooth transition into their next school, whether across the state or across the country, benefits military children, their classmates, and their communities.

The Impact Aid program enables districts affected by the presence of a military installation to offer not only a quality basic education program, but also the support services needed by military children as they transition from school to school.

—Over 50 percent of the 3,783 students in the Indian River Central School District in New York are military children whose parents are stationed at Fort Drum. Because of Impact Aid, the district can afford the Reading Recovery program to help first graders master important reading skills to reach grade level. At the high school level, the district is developing a remediation system to help newly-transferred students prepare for the New York Regents exams, which will soon be required for graduation. Impact Aid funds help buy stringed instruments for the district's orchestra program. They provide for the support system—the counselors, psychologists, and social workers—often needed by children when their military parent deploys. The 10th Mountain Division recently returned to Fort Drum after its deployment to Bosnia. While the school administration was initially concerned about a flight from the community during the deployment, it found that most military families chose to remain in the area. The strong assistance system at Fort Drum and the community support as evidenced in the school programs funded through Impact Aid persuaded families to stay.

—School districts serving military children recognize their interdependence and their shared responsibility for the education of those children. They are increasing their communication with each other to ease the transition of military children in and out of different school systems.

—Recognizing that service members view quality education as an important quality of life factor and a retention issue, the military services have stepped up their efforts to establish partnership programs with local schools, to train installation school liaison officers, to provide better information to families about local schools, and to study the problems faced by military children as they move. They are working across the services on common issues and are reaching out to military-related and education organizations, such as NMFA, the National Association of Partners in Education, and the Military Child Education Coalition.

Military parents view the partnerships between their schools and the military services—from the unit adopting the local elementary school to the presence of service and DOD leadership at annual educational conferences on "Serving the Military Child"—as progress toward relieving some of the anxieties about their children's education. The educational focus of these efforts is a legacy of a successful, well-funded Impact Aid program. When the Federal Government fulfills its responsibility to provide funding for basic education to districts serving military children, the schools can concentrate on providing a high-quality education program for all students. We thank you, the Members of this Subcommittee, for your leadership in this partnership for the education of military children. We ask you to continue this role by fully funding Impact Aid.

PREPARED STATEMENT OF THE NATIONAL INDIAN IMPACTED SCHOOLS ASSOCIATION

The National Indian Impacted Schools Association represents public school districts which contain Indian trust land and Alaska Native lands. The Impact Aid program 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, primarily lands held in trust by the federal government for Indian tribes.

Approximately 90 percent of Indian and Alaska Native elementary and secondary students nationwide attend public schools. Most of the remaining 10 percent of students attend Bureau of Indian Affairs-system schools whose operating budgets come through BIA appropriations.

Summary of Request.—We ask the Subcommittee to recommend the following with regard to the fiscal year 2001 Department of Education budget:

—*Impact Aid Basic Support Payments*.—$818 million for Impact Aid Basic Support payments under Section 8003(b) of the Impact Aid statute. This is the same as the request of the National Association of Federally Impacted Schools (NAFIS) and is 10.9 percent over the fiscal year 2000 enacted level.

—*Impact Aid Facility Repair*.—$25 million under the authority of Section 8007 of the Impact Aid statute for payments for facility repair, renovation and construction. This is the same as the request of NAFIS and compares to the fiscal year 2000 enacted level of $10.1 million and the Administration's request of $5 million. While this is termed a "construction" account in the authorizing statute, the funds are distributed by formula to schools, making the amount individual school districts receive so miniscule that it cannot make a significant impact on facility construction needs. In fiscal year 2000, $3 million was earmarked by Congress for three specific schools.

—*Forward Funding of Impact Aid.*—Impact Aid is one of the few major federal education programs which are not forward funded. Even if we were not experiencing delays in distribution of Impact Aid funds as we are now, it would be enormously helpful for planning and budgeting purposes for the program to be forward funded.

The Impact Aid Program in 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. One of the great attributes about the Impact Aid program is that it provides flexible funds to school districts. Because Impact Aid funds are actually in lieu of a property tax base, it is logical that they are not geared toward specific program use.

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 Impact Aid program in 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 consists 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.

—The Impact Aid program provides a formal link between tribal governments and 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 within tribal boundaries. 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 statute.

The Level of Impact Aid Effects Student Performance—the Santee School Experience.—We would like to give you an example of how increased Impact Aid funds resulted in dramatic academic improvement for the students of the Santee School District.

On March 17, 1999 the House Education and the Workforce Subcommittee on Early Childhood, Youth and Families held a hearing on reauthorization of the Impact Aid program at which Chuck Squier, Superintendent of the Santee School, testified. The Santee School District in northeast Nebraska is made up of entirely In-

dian trust lands and its students are Santee Sioux. Superintendent Squier testified about the impressive student gains which have been made since his school district has received an increase in Impact Aid funds.

Prior to 1995 the school district had been receiving only 60 to 70 percent of the amount of Impact Aid for which it was eligible. Reading scores had dropped during the previous three years: 1st grade scores dropped from 1.8 to 1.2 GME; [1] 8th grade scores dropped from 7.4 to 5.9 GME, and 11th grade scores dropped from 10.2 to 9.4 GME. In an effort to reverse this trend, the school district formed a Curriculum Committee composed of school staff, parents and other community members. They reviewed current research on ways to improve student reading and decided on a plan of action which included teacher training, a reading management system, multiple copies of books, a daily focus on reading and ninth hour tutoring. Specific programs included reading recovery, accelerated reader, school at the center, foss science, and project read. However, the recommendations of the Curriculum Committee were not able to be implemented because of lack of money.

But when the Impact Aid program was re-authorized in 1994, Impact Aid funding increased for the Santee Sioux school. The school district was able to use that money to leverage additional grant dollars for teacher training and research-based reading programs and the rest of the plan recommended by the Curriculum Committee. The plan was implemented. Students are tested in the fall and in the spring, and the results have been very impressive. Last year, 28 percent of the students in grades 3–12 increased their reading level two grade levels. Another 25 percent of students raised their reading level 1.5 or more grade levels, and 36 percent of students raised their reading level 1 or more grade levels. Particularly gratifying was the 9th grade results, as this class had declining scores for the previous three years. Expansions of the school-wide reading program are planned for next year, along with rewriting the math/science studies/language arts curriculum—financial resources permitting.

The Santee School District program is shared through the Nebraska Native American consortium, which serves 98 percent of all students in Nebraska living on tribal lands.

The Impact Aid Program Should Be Forward Funded.—We urge Congress to take the long overdue step of providing appropriations to forward fund the Impact Aid program. Other major education programs, e.g., Title I, Individuals with Disabilities Education Act, and Bureau of Indian Affairs school operations, are forward funded. Public school administrators in heavily impacted districts must make very difficult and risky program and personnel decisions for the upcoming school year or the next school year without knowing how much Impact Aid funding they will be receiving. For many Indian lands schools, Impact Aid is the primary source of school operations funding and the schools would close without it.

While school administrators cope with this system, it makes much more sense for a school administrator to know 6–12 months prior to the beginning of the school year what its budget will be. For example, in Minnesota we are required to sign contracts for tenured teachers by April 15th for the upcoming school year. For non-tenured teachers, we must sign contracts by June 1 for the Fall term. Because Impact Aid is not forward funded, we must sign contracts for tenured teachers 4½ months prior to the knowing the amount of money we will receive—and that is under circumstances when we have a Labor-HHS-Education Appropriations bill which is signed by October 1st—a rare occurrence, as you know.

When the government shut down several years ago, Impact Aid schools had to borrow money just to stay open and had to pay large amounts of interest—tens of thousands of dollars for some schools—for which they were not reimbursed. Some Impact Aid schools are in the position now of having to borrow money because of problems at the Department of Education resulting in chronically late Impact Aid payments. We know that Congress understands this problem because it has made most federal education programs forward funded. Impact Aid is a program of basic support for schools—it hires the teachers, pays the utility bills, transports students, etc. and this makes it all the more urgent for it to be forward funded.

We realize that the first year of forward funding will strain the appropriations process as Congress would have to make available two years worth of funding. On the other hand, we have a budget surplus and there is support from the Administration and both parties in Congress for increased federal education funding.

If the Impact Aid program cannot be forward funded in total, we suggest that the Basic Support and the Disabilities portions of the program could be forward funded or Congress could look at the possibility of a phased-in approach to forward funding.

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[1] GME stands for Grade Means Equivalency.

School Facilities.—School facilities construction and renovation, including making facilities ready for education technology, is a high priority for our organization. We urge you to appropriate at least $25 million for school facility repair as authorized under Section 8007 of the Impact Aid law. Ultimately however, we need more than a band aid approach to school construction needs.

NIISA has and will continue to work with Congress on pending school construction proposals to make them responsive to the needs of our schools—Indian lands public schools. School construction bills have been introduced in a steady stream during the last two Congresses and also the current Congress. We have seen in these bills a growing recognition that there needs to be accommodation for public school districts which have little, if any, bonding capacity (including those schools in the Bureau of Indian Affairs system). For instance, there are now bills which would allow a state to issue school construction bonds (not just the LEA) and which would require the state application to explain how they will assist schools that lack the fiscal capacity to issue bonds on their own. This could be helpful to some school districts with Indian lands. To the extent that a school district has limited ability to generate revenues because of a federal presence (e.g., the existence of Indian trust land or federal property in the school district), there is a clear federal responsibility toward the education of the children attending those schools.

The condition of public and Bureau of Indian Affairs school facilities has been documented in General Accounting Office (GAO) surveys. Because the GAO surveys did not report data specific to Indian lands public schools, our organization, in October, 1996, undertook a survey of school districts which receive Indian lands Impact Aid funding. Some of the findings from the survey, which we have previously reported to this Subcommittee, are:

—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 unhoused students;
—59 percent of school buildings have inadequate laboratory science space;
—63 percent of schools are not well served for before/after school care.

Thank you for your interest in the need of 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.

PREPARED STATEMENT OF THE UNITED STRIBES TECHNICAL COLLEGE

Summary of Request.—For thirty years United Tribes Technical College [1] (UTTC) has been providing postsecondary vocational education, job training and family services to Indian students from the Great Plains and throughout the nation. UTTC was assisting Indian people in moving from public assistance to economic self-sufficiency long before the 1996 welfare reform act. We have a sustained placement rate of well over 80 percent. Our request for fiscal year 2001 funding for tribally controlled postsecondary vocational institutions as authorized under Carl Perkins Vocational and Applied Technology Act is:

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[1] The college is owned and operated by five federally-recognized tribes situated wholly or in part in North Dakota—Spirit Lake Sioux Tribe, Sisseton-Wahpeton Sioux Tribe, Standing Rock Sioux Tribe, three Affiliated Tribes of the Fort Berthold Reservation, and 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.

—$5 million, or $400,000 over the fiscal year 2000 enacted level and the Administration's request. This funding is essential to our survival as we receive no state-appropriated vocational education monies.

—Committee Report language asking for the report required of the Department by the Vocational and Applied Technology Education Act regarding training, facilities and housing needs of the tribally controlled postsecondary vocational institutions. (20 USCA § 2327(g) (2) and (3). This report should be undertaken in close collaboration with the affected institutions. Attached is the statutory provision.

Funding Authority.—Section 117 of the Carl Perkins Vocational Education and Applied Technology Education Act Amendments of 1998 authorizes funding for tribally controlled postsecondary vocational technical institutions. Under this authority funding is currently provided to UTTC and one other tribally controlled postsecondary vocational institution, the Crownpoint Institute of Technology. The Administration's fiscal year 2001 request is $4.6 million, the same as the fiscal year 2000 enacted level. There is a glitch in the Perkins Act in that it caps funding for Tribally Controlled Postsecondary Vocational Institutions at $4 million instead of "such sums as may be necessary" in the out years as is the case for other vocational education programs. This was inadvertent and we ask for a technical correction to provide for "such sums as may be necessary" for fiscal year 2000 and the out years.

A Unique Inter-Tribal Educational Organization.—United Tribes Technical College is the only inter-tribally controlled, campus-based, postsecondary vocational institution for Indian people. Our campus is the site of the Fort Lincoln Amy Post, an 110-acre area near Bismarck, North Dakota. We currently enroll 367 students from 32 tribes and 14 states. And we serve 159 children in our pre-school programs and 148 children in our elementary school, for a direct services population of 654.

Educating Students and Placing Them in Jobs.—We are proud of the education, skills and services provided by UTTC for our students and their families. And we are proud that this education is taking place in a setting they where can maintain and strengthen their tribal heritage. We have had a sustained job placement rate exceeding 80 percent over the last 10 years. This success is all the more gratifying in light of the background of our students, most of whom come from tribal areas where poverty and unemployment are the norm. Many of our students are from the 14 tribes in the Dakotas, where unemployment among Indian people is chronic. BIA Labor Force data reports the percentage of potential Indian labor force on and near reservations in the Aberdeen Area who are jobless is 71 percent. Of those persons who are employed 33 percent are still living below the poverty guidelines. (Source: Interior Department 1997 Labor Market Information On the Indian Labor Force.)

UTTC New Course Offerings.—We offer 9 Certificate and 15 Associate of Applied Science degree programs (see attached list). We are very excited about the recent additions to our course offerings, and the particular relevance they hold for Indian communities. The modest increases in our Department of Education funding has helped make these new programs possible. These new programs are:

—Injury Prevention
—Dietetics Technician
—Tribal management, including gaming management
—Computer Science Technology
—Distance Learning programs for the Denver Indian Community

Dietetics/Diabetes.—Through collaborative efforts with the American Diabetes Association, UTTC will develop the only accredited Dietetics Technician's Degree program in the state. We will meet the challenge of fighting diabetes through education. As this Subcommittee knows, the rate of diabetes is very high in Indian county, and with some tribal areas experiencing the highest incidence of diabetes in the word. About half of Indian adults have diabetes ("Diabetes in American Indians and Alaska Natives, NIH Publication 99–4567, October, 1999).

Injury Prevention.—Through our Injury Prevention Program we are addressing the injury death rate among Indians which is 2.8 times that of the U.S. population (Source: IHS fiscal year 1999 Budget Justification). We received assistance through the IHS to establish the only degree-granting Injury Prevention program in the nation.

Distance Learning.—We are bridging the "digital divide" by providing critical computer and Internet skills from our North Dakota campus to American Indians residing in the Denver area. Technology training allows all American Indians an opportunity to overcome barriers such as geographic isolation and access to information. Through technology partnership programs, UTTC is meeting the challenge of providing technology skills and training to Indian country.

UTTC has been, in addition, a member since 1994 of the Interactive Video Network of North Dakota's colleges, universities and tribal colleges. This allows for ar-

ticulation agreements with other college and universities, expanding the educational opportunities for our students.

Job Training and Economic Development.—UTTC is a designated Indian Minority Business Center serving Montana and the Dakotas. We also administer a Workforce Investment Act program and an internship program with private employers. And we are assisting tribes and tribal members in the Aberdeen Area with rebuilding buffalo herds.

Coordination with State Welfare-to-Work Efforts.—UTTC is working in cooperation with the state of North Dakota on welfare reform. We are serving state-referred Temporary Assistance for Need Families (TANF) recipients who are able to participate in our Cooperative Education internship program with private employers. By attending UTTC, these TANF recipients can meet their work, training and volunteer requirements. And we are providing child care for 20 children of state-referred TANF recipients.

In North Dakota, only 30 percent of state TANF recipients are allowed schooling as a work activity. And we also take exception to the 12-month statutory limit on the length of time a TANF recipient can be enrolled in a vocational education course and still be eligible for TANF. This limits TANF recipients to taking one-year certificate courses at UTTC. Our experience shows that the students who graduate from a two-year, rather than a one-year, course have significantly higher earning power. Many of our students come to UTTC planning to take a one-year course, and then, finding themselves in a supportive environment and seeing the economic benefit of the longer course, decide to work for the two-year degree.

Serving Families Contributes to Education and Job Placement.—We believe that a primary reason for UTTC student success is that we serve the students' social, academic and cultural needs. Many of our students are the first generation in their family to attend college, and for many it is their first experience in living away from home. Many students are on public assistance and many have families of their own. Some of our services are:

—Early childhood services for 145 children, ages birth to five years and an additional 15 elementary children for extended care;

—Theodore Jamerson Elementary School serving 148 Indian students;

—A health clinic whose services includes immunization, health education, eye and dental exams, and referrals to other health care providers;

—Family housing and dormitories for solo parents and for students without children;

—A local transportation system for students for school activities and necessary appointment e.g., (doctor appointments) outside the campus. Most UTTC students do not have cars.

UTTC Seeks Non-Perkins Funds.—UTTC is aggressive in seeking non-Perkins funding for special needs, e.g., we combined Department of Agriculture, Economic Development Administration and state Community Development Block Grant funds and replaced our aging water, sewer and gas systems in 1997.

Our elementary school received a Department of Education grant for computer technology, and was one five BIA-system schools to receive this funding. We also received a Kellogg Foundation grant to develop buffalo management skills for the tribes and their members throughout the Aberdeen Area, as they attempt to rebuild herds of buffalo decimated more than 100 years ago. And this year we received a $75,000 grant from U.S. West to assist us in developing a series of distance learning classes at the Indian Center in Denver. Additionally, our Injury Prevention Program has been assisted through a grant from the IHS.

The above mentioned grants are highly competitive, restrictive, one-time grants, and they cannot provide for day-to-day operations. We cannot survive without the basic operating funds which come through the Perkins Act.

Facility Study/Current Needs.—We are dismayed that the Department of Education has paid no attention to the requirement in the 1998 Perkins Act Amendments to undertake a study of our housing, facility, and training needs. Discussions with the Department shows that it is not even on its radar screen. Such a study would certainly be of benefit to us in planning and in seeking funds. Below are some of our financial needs of which we want you to be aware:

—*Housing*.—We need new and rehabilitated campus housing so that we can increase student enrollment. Many of our buildings are of historic importance. The College occupies the old Fort Lincoln Army Post, and many people visit our campus to see these buildings. Other than the more recently constructed skills center and the community center, UTTC's core facilities are 90 years old. Estimates for new facilities total over $12 million, according to a 1993 Dept. of Education report.

—*Salaries.*—We were able to provide a cost-of-living increase for our employees last year. However, our faculty still receive salaries that are lower than in any state college system.
—*Emergency Repair.*—We need funding for emergency repair on student housing and instructional facilities. Funding is also needed for maintenance and repair related to damaged caused by inclement weather, including blizzards, high winds and extremely low temperatures.
—*Course Offerings/Student Services.*—We want to change some of our courses to better meet new market demands, e.g, training to increase the number of students in the allied health professions, updating of technology. We also need to expand our diagnostic capabilities in tribal-specific areas and in the areas of literacy and math-science background. And we want to make improvements in our student follow up, career development, and job market research efforts.

Thank you for your consideration of our request.

RELATED AGENCIES/GENERAL TESTIMONY

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for providing me the opportunity to submit testimony to this Subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the President and CEO of the National Federation of Community Broadcasters I speak on behalf of 150 community radio stations across the country. NFCB is the sole national organization representing this group of stations which provide service in the smallest communities of this country as well as the largest metropolitan areas. Nearly half of our members are rural stations and half are minority controlled stations.

In summary, the points we wish to make to this Subcommittee are that NFCB:
—Supports the CPB request of $365 million for fiscal year 2003;
—Requests the Subcommittee to ensure that CPB utilizes digital funds it receives for radio as well as television needs;
—Supports CPB activities in facilitating programming services to Latino and Native American radio stations;
—Supports CPB's efforts to help public radio stations utilize new distribution technologies and requests that the Subcommittee ensure that these technologies are available to all public radio services and not just the ones with the greatest resources.

Community radio fully supports $365 million for the Corporation for Public Broadcasting in fiscal year 2003.—Federal support distributed through the CPB is an essential resource for rural stations and for those stations serving minority communities. These stations provide critical, life-saving information to their listeners. Yet they are often in communities with very small populations and limited economic bases so that the ability of the community to financially support the station is insufficient without federal funds.

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 is dominated by national program services and concentrated ownership of the media.

In the last year, CPB has increased supported to rural stations and committed resources to helping public radio take advantage of new technologies. We commend these activities but want to be sure that the smaller stations with more limited resources are not left out of this technological transition. We ask that the Subcommittee include language in the appropriation that will ensure that funds are available to help the entire public radio system utilize the new technologies, particularly rural and minority stations.

NFCB would like to commend CPB for the leadership it has shown in supporting and fostering the programming services to Latino stations and to Native American stations. Satélite Radio Bilingüe provides 24 hours of programming to stations across the United States and Puerto Rico addressing issues of particular interest to the Latino population. In the same way, American Indian Radio on Satellite (AIROS) is distributing programming for the Native American stations, arguably the fastest growing groups of stations. There are now over 30 stations controlled by and serving Native Americans, primarily on Indian reservations.

CPB plays a very important role for the public and community radio system. They are the convener of discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving lis-

teners. And they provide funding to programming, new ventures, expansion to new listeners, and projects that improve the efficiency of the system. This is particularly important at a time when there are so many changes in the radio and media environment with new distribution technologies and media consolidation.

Finally, community radio supports funding for conversion to digital broadcasting by public radio and television.—While public television's needs are more immediate, the Federal Communications Commission is now in the process of identifying a standard for digital radio transmission. We expect that there will be funds available for radio conversion as well as television conversion. More immediately, the television conversion process is already having an impact on public radio stations. As television stations increase the space they need on their towers to accommodate both analog and digital signals, radio stations that rent space on TV towers are losing their leases and being forced to move to other towers—sometimes with very short notice. This situation will only get worse over the next three years as we approach the FCC deadline for television conversion. We would like to see emergency funding to help public radio stations who lose their tower space do the necessary engineering studies and move to new tower locations.

We appreciate Congress' direction to CPB that it utilize its digital conversion fund for both radio and television and ask that you ensure that the funds are used for both media. Congress stated, with regard to fiscal year 2001 digital conversion funds:

"The required (digital) conversion will impose enormous costs on both individual stations and the public broadcasting system as a whole. Because television and radio infrastructures are closely linked, the conversion of television to digital will create immediate costs not only for television, *but also for public radio stations* (emphasis added). Therefore, the Committee has included $15,000,000 to assist radio stations and television stations in the conversion to digitalization . . ." (S. Rpt. 105–300)

This is a period of tremendous change. Digital is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the Internet are changing how we define the business we are in; the concentration of ownership in commercial radio makes public radio and particularly community radio, more unique and more important as a local voice than we have ever been. During this time, the role of CPB as a convener of the system becomes even more important. And the funding that it provides will allow the smaller stations to participate along with the larger stations who have more resources, as we move into a new ear of communications.

Thank you for your consideration of our testimony.

Prepared Statement of the National Association of Foster Grandparent Program

We are pleased to submit this testimony in support of fiscal year 2001 funding for the Foster Grandparent Program (FGP), the oldest and most well-known of the three programs known collectively as the National Senior Volunteer Corps, which are authorized by Title II of the Domestic Volunteer Service Act of 1973, as amended (DVSA) and administered by the Corporation for National and Community Service (CNS).

NAFGPD is a membership-supported professional organization whose roster includes the majority of more than 350 directors who administer Foster Grandparent Programs nationwide, as well as local sponsoring agencies who support the work of FGP.

THANK YOU

Senator Specter, before we begin our testimony, we must first thank you for the courage and leadership you showed during the fiscal year 2000 appropriations process in preserving the original mission and purpose of the Foster Grandparent Program: to enable seniors living on incomes less than 125 percent of the national poverty level to serve as Foster Grandparents and contribute to their communities. Your clear direction to the Corporation for National and Community Service—that funds appropriated by Congress may not be used to pay a non-taxable, non-income payment to individuals whose incomes exceed 125 percent of the national poverty level—has preserved our program for those low-income seniors for whom it was originally intended. Again, thank you for your leadership.

FGP: AN OVERVIEW

Established in 1965, the Foster Grandparent Program was the first federally funded, organized program to engage older volunteers in significant service to others. From the 20 original programs based totally in institutions for children with severe mental and physical disabilities, FGP now comprises nearly 350 programs in every state, the District of Columbia, Puerto Rico, and the Virgin Islands. All programs are now primarily based in community volunteer sites—where most special needs children can be found today—and are administered locally through a nonprofit organization or agency and an Advisory Council comprised of community citizens dedicated to FGP and its mission. FGP represents the best in the federal partnership with local communities, with federal dollars flowing directly to local sponsoring agencies, which in turn determine how the funds are used. There are currently 28,500 Foster Grandparent volunteers who give over 24 million hours annually to more than 180,000 children.

The Foster Grandparent Program is unique. We are one of only two volunteer programs in existence that enable seniors living on very limited incomes to serve their communities as volunteers by providing a small non-taxable stipend and other support which allow volunteers to serve at little or no cost to themselves. Our volunteers provide intensive, consistent service—20 hours every week, usually four hours every day. FGP provides extensive pre-service orientation and at least 48 hours of on-going training annually to keep volunteers informed on how to work with children who have special needs. And our volunteers provide one-to-one service to their assigned children, exactly what is required to help prepare our nation's neediest children to become self-sufficient adults.

The rapidly growing number of older people living at poverty-level incomes across the country represent a virtually untapped resource that must be utilized to help address the serious problems of today's children. In order to continue to provide these cost-effective services in even more local communities the Foster Grandparent Program requires more volunteers, and more locally-based programs. We need funding levels that will enable us to keep pace with the ever-increasing number of income eligible seniors—currently 6,000,000, a number which will grow to 13,200,000 by the year 2030—and the countless number of at risk children who will need the one-to-one attention of an older person with the time to help show them the way to independence and productive adulthood.

THE ADMINISTRATION'S FISCAL YEAR 2001 REQUEST FOR FGP

Unfortunately, in a budget which requests increases in excess of 23 percent ($100 million) for AmeriCorps and related programs, the Administration has, for the second year in a row, proposed an increase of $1.79 million (1.87 percent) for the Foster Grandparent Program—again, for the second year in a row, the smallest increase requested for any of the programs administered by CNS. Rather than investing federal funds in increasing the number of FGP volunteers serving nationwide, the Administration's request appears to set as a priority a 67 percent increase for senior demonstration targeted mainly to make grants to national organizations which have nothing to do with FGP or the other two senior volunteer programs. The largest, oldest and most well-known of the three senior volunteer programs—the Foster Grandparent Program—is virtually ignored in this budget, as it was in the Administration's fiscal year 2000 budget.

In addition, by way of a never-before-used interpretation of Section 225 of the Domestic Volunteer Service Act of 1993 (Programs of National Significance, or PNS, grants), which was enacted in 1989, the Administration fails to designate at least one-third of the fiscal year 2001 increase requested for FGP for PNS expansion grants for existing programs. The intent of Sec. 225 when enacted was to ensure that at least one-third of any increases would be made available to current FGP, SCP, and RSVP projects to expand the number of volunteers in their communities. In fact, since 1989 the one-third PNS set-aside has been the ONLY mechanism by which current programs have been able to expand their volunteer numbers and meet their communities' needs. CNS even held fast to the one-third PNS set-aside in fiscal year 1997, when the increases received by the three programs represented only a restoration to fiscal year 1995 levels after the programs experienced appropriations cuts in fiscal year 1996. This new interpretation is whimsical and unacceptable, and will establish a dangerous precedent for the use of future appropriations if allowed to stand.

The Administration's budget also fails to request funds to increase the non-taxable, non-income stipend provided to our low income volunteers. While the stipend has not increased since January, 1998; the increase in the cost-of living since then has caused the costs of volunteering to escalate dramatically, especially the price

of gasoline and other costs associated with daily transportation. We believe that the current stipend of $2.55/hour is no longer adequate to cover the costs associated with volunteering.

THE ADMINISTRATION'S FISCAL YEAR 2001 REQUEST FOR SENIOR DEMONSTRATION

Although fiscal year 2000 appropriations conference and bill language has effectively stopped the payment of a non-taxable, non-income stipend to people whose incomes exceed the income eligibility requirements set in the DVSA for FGP and SCP, the administration is again requesting demonstration funds to continue to pay RSVP Leaders in fiscal year 2001, using the rationale that RSVP has no statutory income requirements for its volunteers. We are very aware that Congress intended to exclude from those receiving a non-taxable, non-income stipend all FGP, SCP and RSVP volunteers whose incomes exceed the income requirements set in the DVSA for FGP and SC (125 percent of the national poverty level). Both NAFGPD and the National Association of RSVP Directors believe the Administration's request is a flagrant violation of the intent of Congress as expressed in fiscal year 2000 appropriations law, and should not be funded.

The Administration also requests demonstration funds for grants to national organizations to develop plans to use more senior volunteers to further their missions. We believe that these challenge grants will be used by the national organizations to implement programs that will, in essence, be the beginning of a 4th senior volunteer program that will use non-federal funds to continue the practice of paying non-taxable, non-income stipends to people meeting no income eligibility requirements.

NAFGPD is not opposed to demonstration efforts which will improve the way FGP, SCP, or RSVP deliver services, or which will help to test innovative program and volunteer activities which will improve the existing programs. We are opposed to demonstration activities that will be used to start a 4th—and totally unnecessary—senior volunteer program, especially one designed to pay volunteers who can afford to volunteer without a financial enabler. We are also opposed to using scarce federal dollars to fund efforts that will in no way improve the three existing senior volunteer programs. In fact, this new 4th program will actually duplicate the services performed by the 25 year old RSVP program, which now engages nearly ½ million volunteers who serve without any payment at all! The federal demonstration dollars requested by the Administration for national organizations are better invested in FGP to enable low-income seniors to serve.

NAFGPD'S FISCAL YEAR 2001 REQUEST FOR FGP AND SENIOR DEMONSTRATION

Given the growing number of eligible low-income seniors and the staggering number of troubled and challenged children in America today, we believe that the Administration's request does not invest adequately for the future in the Foster Grandparent Program, and actually diverts funds which could be invested in FGP into demonstration activities we cannot support. We ask that you (1) adopt a different fiscal year 2001 funding allocation for FGP, one which will more properly address the important role our programs must play in engaging more of our nation's low-income elders in addressing serious community needs in more communities nationwide; and (2) refrain from appropriating any federal dollars to senior demonstration. Our fiscal year 2001 request is as follows:

[In millions of dollars]

Foster Grandparent Program	107.177
Senior Demonstration	

This request represents an $11.189 million increase over FGP's fiscal year 2000 level. We also request that the Committee include report language accompanying the fiscal year 2001 funding measure which supports and specifies the following allocation priorities for use of the fiscal year 2001 increase:

First, for the Foster Grandparent and Senior Companion Programs, increase the stipend which enables low income volunteers to serve from $2.55/hour to $2.65/hour. Funds should be available to pay for the additional $.10 per hour for non-federally funded volunteers for one year;

Second, award an administrative cost increase of 3 percent to each existing FGP in order to maintain quality and sustain the work already being done by programs;

Third, allocate funds for the $1.1 million requested by the Administration to allow programs to increase their technological capabilities to meet standards set by CNS;

Fourth, in accordance with the Domestic Volunteer Service Act (DVSA), use 1/3 of the increase over the fiscal year 2000 level to fund Program of National Significance (PNS) expansion grants to allow existing FGP programs to expand the num-

ber of volunteers serving in areas of critical need as identified by Congress in the DVSA; areas which may not be limited to America Reads activities, and with no minimum or maximum grant size specified by CNS;

Finally, begin 20 new Foster Grandparent Program projects in geographic areas currently unserved.

This funding proposal will generate opportunities for more than 4,000 new low-income senior volunteers contributing in excess of 4.1 million hours of service annually to more than 15,900 additional children. In addition, 20 more communities will receive the multifaceted services of FGP, a small step toward NAFGPD's fiscal year 2000 goal of beginning 100 new Foster Grandparent Programs nationwide by 2004.

A New York Times article (March 21, 1999) on volunteers and retirement stated that ". . . Thousands of older people are on the waiting list for the Foster Grandparent program, in which 25,000 older adults whose income is below the poverty line receive a small stipend for volunteering 20 hours a week to be grandparents for disabled or disadvantaged youngsters. Many young people need mentors and foster grandparents, but lack of money precludes more participation." Our experiences strongly support this statement. In communities that already have a Foster Grandparent Program, unfilled requests from local organizations for more Foster Grandparents are the rule, not the exception. And when Congress provided funds for 25 new Foster Grandparent Programs in fiscal year 1998—the first new programs in 18 years—125 high-quality applications were submitted by local community organizations nationwide.

In addition, a 1998 AARP survey conducted by Roper Starch Worldwide indicated a "sea change" in retirement patterns: the majority of "babyboomers" intend to continue to keep their jobs and never retire from work! The 1998 Independent Sector study showed that seniors who are still working are more likely to volunteer on an informal basis than to volunteer in a program like FGP that requires a commitment of 20 hours of service every week. It will be the "boomers" who have not acquired the skills needed to keep their jobs as they age or who have worked at low-paying jobs who will be available to volunteer every day, who will need FGP to provide them with opportunities to stay active.

Please help us tap one of the nation's only increasing national resources—our low-income seniors—by supporting a total fiscal year 2001 appropriation of $107.177 million for the Foster Grandparent Program, and allocating no funds to senior demonstration for fiscal year 2001.

PREPARED STATEMENT OF THE AMERICAN MUSEUM OF NATURAL HISTORY

Thank you, Mr. Chairman, for allowing me to testify before the Subcommittee today. My name is Craig Morris, and I am speaking on behalf of the American Museum of Natural History and in support of the Institute of Museum and Library Services.

ABOUT THE AMERICAN MUSEUM OF NATURAL HISTORY

Founded in 1869, the American Museum of Natural History [AMNH] is one of the nation's preeminent institutions for scientific research and public education. Throughout its history, the Museum has pursued its joint missions of science and education, of examining critical scientific issues and educating the public about them. It is renowned for its exhibitions and collections, which serve as a field guide to the entire planet and present a panorama of the world's cultures. Museum collections of some 32 million natural specimens and cultural artifacts provide an irreplaceable record of life on earth. Its explorers and scientists have pioneered discoveries and offered us new ways of looking at nature and human civilization. The Museum's power to interpret wide-ranging scientific discoveries and convey them imaginatively has inspired generations of visitors to its grand exhibition halls and educated its three million annual visitors—500,000 of them schoolchildren—about the natural world and the vitality of human culture.

Since 1887 the Museum has sponsored thousands of expeditions, sending scientists and explorers to every continent; currently more than 100 field projects are conducted each year, including ongoing research in such countries as Chile, China, Cuba, Madagascar, Mongolia, and New Guinea. Some of the most influential scientists of the twentieth century, including Margaret Mead, George Gaylord Simpson, Roy Chapman Andrews, and Ernst Mayr were either staff members of or affiliated with the Museum.

Today more than 200 active Museum scientists with internationally recognized expertise, led by 47 curators, conduct laboratory and collections-based research programs as well as field work and training. Scientists in five divisions (Anthropology;

Earth, Planetary, and Space Sciences; Invertebrate Zoology; Paleontology; and Vertebrate Zoology) are sequencing DNA and creating new computational tools to retrace the evolutionary tree, documenting changes in the environment, making new discoveries in the fossil record, and describing human culture in all its variety. The Museum also conducts graduate training programs in conjunction with a host of distinguished universities, support doctoral and postdoctoral scientists with highly competitive fellowships, and offer talented undergraduates an opportunity to work with Museum scientists.

In many ways, the AMNH is similar to a research university, with its scientific faculty from diverse fields such anthropology, earth and planetary sciences, astrophysics, and all branches of zoology. Yet the Museum is distinct in that its mission extends beyond research and training. Museum curators are also deeply engaged as exhibition and education advisors and as caretakers of the Museum's ever growing collections. They help to promote public understanding of science, of where we come from and where we may be headed.

In exhibitions, which are among the Museum's most potent educational tools, AMNH scientific knowledge and discovery are translated into three dimensions. The Museum is proud to continue its tradition of creating some of the world's greatest scientific exhibitions. Last month, in one of the most exciting chapters in the Museum's long and distinguished history of advancing science and education, it opened the spectacular new Rose Center for Earth and Space. The Rose Center includes a newly rebuilt and updated Hayden Planetarium that allows visitors to journey among the stars and planets in our own and in other galaxies; and the Lewis B. and Dorothy Cullman Hall of the Universe, where interactive technology and participatory displays elucidate important astronomy and astrophysics principles. The adjoining Gottesman Hall of Planet Earth, which opened in 1999, explores the processes that determine how the Earth works; it in turn leads to the recently opened Hall of Biodiversity. Together, the new planetarium and halls provide visitors a seamless educational journey from the universe's beginnings to the formation and processes of Earth to the extraordinary diversity of life on our planet.

The Museum's Education Department spearheads the AMNH's commitment to promoting public education, particularly in an informal setting. It builds on the Museum's unique resources to offer rich educational programming dedicated to increasing scientific literacy, to encouraging students to pursue science and museum careers, and to providing a forum for exploring the world's cultures. The Department targets its efforts particularly to New York City's diverse and often underserved communities and school districts, to those populations traditionally poorly served by schools, those underrepresented in science, and those for whom museums typically are not a welcoming destination.

Each year hundreds of thousands of students, teachers, and schools participate in workshops, courses for college credit, and visits to the Museum. Annually, more than 500,000 students and teachers visit on school trips, prepared and supported by curriculum resources and workshops. For schools that cannot get to the Museum, Moveable Museums offer off-site access, free of charge. As well, Education Department lectures, field trips and workshops on subjects ranging from birding to earthquakes, gospel music to Native American culture, and Hudson River geology to gorilla conservation attract large audiences of adults, children, and families.

In 1997 the Museum launched in partnership with NASA the National Center for Science Literacy, Education, and Technology to advance science literacy throughout the United States and to extend the Museum's educational reach and impact to a national audience, including local communities. In creating the National Center, the Museum and NASA recognized an opportunity to combine and leverage their incomparable resources, and through new technologies to bring learning and discovery, materials, and programs into homes, schools, museums, and community organizations around the nation.

SUPPORT FOR THE INSTITUTE OF MUSEUM AND LIBRARY SERVICES

The American Museum of Natural History supports the goals and accomplishments of the Institute of Museum and Library Services [IMLS]. The Museum's own collections of more than 32 million artifacts and specimens are considered to be the largest non-federal Museum collection in America, and one of the largest and most significant biological collections in the world. Its Library houses one of the world's preeminent collections of natural history and anthropology materials. It shares IMLS commitments to increasing technological access to the nation's museum and library resources and to building partnerships to address community needs; and it urges increased investment in IMLS so as to advance public access to these vital educational institutions.

Scientific and Cultural Collections

The cumulative result of 130 years of exploration, collecting, and research, the AMNH collections are a major scientific resource providing the foundation for the Museum's interrelated research, education, and exhibition missions. Those collections are organized around the departments of Entomology, Herpetology, Ichthyology, Invertebrates, Mammalogy, Ornithology, and Vertebrate Paleontology. They often include endangered and extinct species as well as many of the only known "type specimens," or examples of species by which all other finds are compared. Within the collections are many spectacular individual collections, including the world's most comprehensive collections of dinosaurs; fossil mammals; Northwest Coast and Siberian cultural artifacts; North American butterflies; spiders; Australian and Chinese amphibians; reptiles; fishes outside of their home countries; and one of the most important bird collections. Collections such as these are historical libraries of expertly identified examples of species and artifacts, associated with data about when and where they were collected. Such collections provide essential baseline data for Museum scientists as well as more than 250 national and international visiting scientists each year. And the collections are all located on-site to allow scientists' with ease of access.

The Museum's halls of vertebrate evolution provide an excellent example of the relationship among science, collections, education, and exhibition. In these halls, visitors walk directly along a phylogenetic tree indicated by a pathway on the floor. At each branch in the tree, a visitor can stop and view fossils that exemplify sets of anatomical features that inform scientists about natural groups of organisms. The collections are also the source of the extraordinary "Spectrum of Life" exhibit in the new Hall of Biodiversity. This exhibit features more than a 1,000 expertly mounted specimens from 28 scientific classifications; it is perhaps the world's most comprehensive display of the diversity and evolution of life. It includes interactive computer kiosks that visitors use to identify and interrelate organisms on evolutionary trees. The confluence of collections, evolutionary research, and beautiful exhibition makes these halls among the Museum's most compelling educational features.

Natural History Library

The American Museum of Natural History is also home to the largest unified natural history library in the Western Hemisphere. In addition to supporting the work of the Museum's scientific staff, the Library serves the world's scientific and scholarly communities as well as students from the colleges and universities in the tri-state area and interested members of the public. Each year thousands of users visit the Library, and its staff answer more than 26,000 reference questions.

The Library contains over 485,000 volumes, including pamphlets, reprints, books, journals, photos, several hundred films, and rare books dating to the fifteenth century. It also houses the Museum's astronomy collections, including the Perkins Library of more than 35,000 volumes and the Bliss Collection of rare and ancient scientific instruments. The archives contain more than 1,900 linear feet of materials and 250 reels of microfilm. Additionally, the Library maintains approximately 1,000,000 photographic images documenting specimens and scientific work, 3,000 documentary films, and over 2,700 art objects and memorabilia.

Other highlights of the Library collection include over 300 manuscript collections of notable naturalists and scientists; a unique collection of 13,000 rare books that spans over 500 years of scientific and expedition literature; and diaries and logs, including Captain James Cook's account of Australia (1783) and Charles Darwin's zoology of the voyage of "H.M.S. Beagle" (1839–1843).

Preservation and Access

By assuming stewardship of these irreplaceable Library holdings and scientific collections, the Museum serves as custodian of one of the most important records of life on earth. And as steward and custodian, it places the highest possible priority on preservation and access, so that the collections will be protected and available for research, for exhibit, and for education for generations to come.

The Library is engaged in a major pilot effort, with private foundation support, to digitize its holdings and link them to the scientific collections. This model project, illustrative of the digitization initiatives the IMLS supports, will help to pave the way in transforming access to and ways to use the Museum's collections and holdings. An expansion of the digitization project would increase access enormously for researchers, students, teachers, and the general public to the Museum and Library holdings.

The Museum has also undertaken major efforts to improve storage, preservation, and access of its vast collections. This year Museum departments will move into a new nine-story Natural Science Building. This facility will significantly increase ex-

hibition and collections storage space, with 30,000 sq. ft. of climate-controlled compact storage facilities for portions of the scientific collections, along with a digital imaging laboratory.

The Anthropology Division is also nearing completion of a 25-year collection storage upgrade and related digitization project. Scheduled for completion in 2002, and with support from the National Endowment for the Humanities, this upgrade will ensure scholarly access to these vital and magnificent collections. The new digital image database and accompanying electronic catalog will facilitate access for staff, visiting scholars, and off-site researchers.

BIOLOGICAL COLLECTION STORAGE UPGRADE AND DIGITIZATION PROJECT

With the successful Anthropology storage upgrade and digitization project nearly complete, the Museum now turns its focus to critical improvement of other storage facilities and to digitizing the biological collections for upgraded preservation and wider access. The IMLS has a distinguished history of supporting cutting edge collection and technological practices. We do seek partnerships with IMLS that will allow us to provide leadership in collection practices and serve as a national model in improving public access to museum and library resources through technology.

Technological Innovation for Greater Public Access

Biological science at the Museum centers on expert documentation of species and investigation of their evolutionary and ecological relationships. The collections therefore provide essential baseline data for scientific inquiry. Due to the unparalleled interest in the Museum's biological collections and unwieldliness of the specimens, comprehensive digital imaging and electronic cataloging of many of these collections will allow the Museum readily to share our resources through technology with a national and international audience. We would like to develop a database, with a web front end for worldwide general audience access, to allow digitized specimens and field data to be searched across many fields (for instance, by locality or age). Detailed digital renderings would allow ready and safe access to often fragile archival material and allow off-site researchers and users to peruse the collection and strategically plan Museum visits. These last two matters are key. If using the database can help researchers can plan Museum visits, the productivity of their visits will be significantly enhanced.

Collection Storage Facilities

Collections preservation and access are top Museum priorities. The Museum's collections are the heart and soul of our scientific research, permanent and temporary exhibitions, and education programs. Access to the collections allows undergraduate, graduate, post-graduate, and even high school students to conduct real research projects in intensive learning programs. As the collections grow, questions about how to curate them, including how to use limited physical storage space, arise. While many similar institutions house their collections separately from their faculty, the Museum is committed to keeping its scientists, educators and collections together by expanding on site. The new Natural Sciences Building, for example, can accommodate a substantial amount of new compact storage, including a unique super-cold storage facility to allow for the preservation of tissue samples for future of DNA study.

As these endeavors demonstrate, the American Museum of Natural History supports the important goals of IMLS to preserve and expand access to library and museum resources and to reach out to broad audiences and diverse communities.

PREPARED STATEMENT OF THE COLONIAL WILLIAMSBURG FOUNDATION

Chairman Specter and members of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, I want to thank you for the opportunity to submit the following two proposals that we at Colonial Williamsburg are excited about and feel could help to re-calibrate our national compass and engage future generations in a stimulating discussion about the basic principles of democratic government that have made this country a world leader.

You may know Colonial Williamsburg as John D. Rockefeller, Jr.'s famous restored eighteenth century town. But the significance of this town goes far beyond the bricks and cobblestones. We are the nation's largest outdoor living museum. Our conservancy museums have one of the largest collections of eighteenth century Antiquities in the world. There are over 600 original and restored eighteenth century buildings in our 173 acre Historic Area. We also have a large and talented interpretive staff who can bring American history and the democratic principles of our fore-

fathers to life in a fun and stimulating learning environment. Quite simply, Colonial Williamsburg is an educational institution. Its significance is both public and personal, educational and experimental. Its mission is to tell the story of a diverse group of people who fought to create a new community in a new land, based on new ideals.

Our living history approach creates the environment of the past—a colonial town—and populates the streets, homes, and shops with costumed interpreters. Visitors can actually touch history. They can talk with tradesmen, ask them questions, and examine their crafts. They can sit as a local magistrate at the colonial county courthouse. They can eat a meal in an authentic eighteenth century colonial tavern, help make bricks for the foundation of a house, even engage in a political discussion with George Washington, Thomas Jefferson, or the royal governor. They hear the echoes of Patrick Henry's denunciation of the Stamp Act resonate throughout the halls of the Colonial Capitol. Visitors can literally immerse themselves in the past. The result is a dynamic method of history education that generates an excitement for learning about the ideas and principles upon which our democracy is based.

Over three million people visit our site each year from all 50 states and from many other countries. But our goal of fulfilling Jefferson's objective of an educated populace does not stop with just those guests who are able to visit Colonial Williamsburg in person.

Colonial Williamsburg has long been the leader in providing distance learning with a variety of educational programming activities for over fifty years. Today, with the best technological communication resources at our command, we are able to reach millions of students and teachers throughout the country through broadcast, internet, interactive media and digital satellite. One of the results of these advances in technology is our award winning Electronic Filed Trips that allow students and teachers to "visit" Williamsburg via interactive television programs, while our www.history.org web site offers convenient access to our educational and research resources on the Internet.

Our Electronic Field Trips provide a live, interactive format by Colonial Williamsburg to over one million registered students. These programs are also viewed by another three million students on a delayed basis courtesy of local PBS stations. We provide seven Electronic Field Trip programs each year. The programs deal with a variety of topics from methods of travel in the eighteenth century, to slavery, apprenticeships, and indentured servitude, to tradesmen rebuilding the houses and structures of Colonial Williamsburg. Schools that register for the program receive printed lesson plans, resource materials, internet activities, and other materials to prepare students during the month preceding the program. The program comes live into the classroom and registered students can phone in questions to interpretive staff who appear in the program segment. Over 30 other interpretive and research staff take calls, email, and internet messages and respond to the students. Material remains on our web site for 30 days after the program. During one of our most recent programs, over 1,300 calls from across the country were received.

While we currently reach over four million students with these award-winning, state-of-the-art programs, we feel we have an obligation to help more schools and students meet national standards of learning. We have been informed that in schools using the Electronic Field Trips these scores have gone up. The programs address more than just history SOL's—they cover science, math, and other subjects as well.

We would like to be able to offer our Electronic Field Trips, free of charge to an additional 10,000 schools across the country. This would mean reaching an additional five million students a year. We have already developed the facilities and the high tech programmatic infrastructure for these programs. We have proven how successful they can be in exciting and educating students. We believe that if we can reach these additional 10,000 schools, the programs will become self-supporting. We believe we can convince these schools and others that the seven programs are worth $500 a year. As stewards of an important segment of our American heritage, we are asking for a one-time appropriation of $3 million to reach an additional five million students and to help students, teachers, and schools in all 50 states provide the type of state-of-the-art programs that teachers want and that will use twenty-first century technology to develop an understanding in the students of timeless eighteenth century principles.

We want to expand our educational programs to many more areas and students across the country. The Electronic Field Trips offer stimulating, state-of-the-art, fun, yet challenging programs. They have allowed millions of students and teachers to learn and understand the events that have shaped the nation's history. They also

ensure we keep alive John D. Rockefeller Jr.'s goal for Colonial Williamsburg "that the future may learn from the past."

You may accuse me of bias, but I believe Mr. Rockefeller would be proud of our educational programs. He would also encourage us to do more with his vision in mind. The advent of the twenty-first century provides an appropriate time to reflect on America, the democratic values that have influenced representative government, and the legal principles that have always protected a free society. Indeed, the onset of the new century in an opportune time to focus on the History of America.

Responding to the challenge to learn from the past and prepare new generations of American leaders, the College of William and Mary and Colonial Williamsburg, two of the most prestigious educational institutions in America and preeminent stewards of early American history, are collaborating to establish a unique and challenging residential program for scholarly historical research at Virginia's Colonial Capital. We are tentatively calling it the Institute of American History and Democracy.

The goal of the institute will be to assist the nation in re-calibrating its internal compass to enhance the understanding of college and high school students in our nation's historic journey and to encourage the ongoing review of America's founding principles. The Institute would be open to visiting undergraduates from colleges and universities across the United States and from the international community. Academic credit would be provided by the College of William and Mary.

Joint William and Mary and Colonial Williamsburg faculty, as well as nationally-recognized historians would develop the curriculum and present the courses. Course topics would include early American history, constitutional history, governmental institutions, social history, military history, archeology, and museum-related fields.

During the summer, this joint faculty would provide a similar program of courses for outstanding high school students from across the country. Summer high school students would be able to earn advance college credit for these courses. Colonial Williamsburg has been providing a similar program for teachers for the last ten years. Our Teacher Institutes have helped to avoid teacher burnout and have instead rekindled the passion for history and raised the teaching skills of those attending, several of whom have later been named teacher of the year in their states.

Both Colonial Williamsburg and the College of William and Mary have developed some of this country's most advanced and interactive methods of education. College and high school students who attend the proposed Institute would become involved in interactive and hands-on learning experiences, as well as being exposed to extensive original research materials. These teaching methods along with state-of-the-art technology will engage the students and bring history alive. It is our hope that the curriculum developed for the Institute could also be adapted to our outreach capabilities and thereby made available to an even wider audience.

We are seeking a one-time award of $5 million to cover the initial start-up costs for the Institute including curriculum development, staff training, program marketing, and facility modifications. Housing will be provided by Colonial Williamsburg at existing facilities. Classroom space will be provided by Colonial Williamsburg and the College of William and Mary at existing facilities. Once established, the program will be self-supporting through tuition and private donations.

I should note that Colonial Williamsburg has never sought this type of federal funding support before. We are seeking this assistance now because we believe these two programs will add significantly to future generations' understanding of basic democratic principles and will help to keep those principles alive and well for many generations to come. We want to help keep the ship of state pointed in the right direction by ensuring all of our citizens understand and can apply the basic principles and ideals of democracy that were established in this country in the late 1700's by the founders of our nation.

Again, thank you for the opportunity to submit what we believe are two very exciting proposals. We hope you will agree and will help us make them a reality.

PREPARED STATEMENT OF THE NATIONAL MINORITY PUBLIC BROADCASTING CONSORTIA

The National Minority Public Broadcasting Consortia (Minority Consortia) submits this statement on the fiscal year 2003 appropriation for the Corporation for Public Broadcasting (CPB). Our primary missions are to bring a significant amount of programming from our communities into the mainstream of PBS and public broadcasting. In summary, we request that the Committee support:

—The Administration's request of $365 million for CPB for fiscal year 2003, a $15 million increase over fiscal year 2002;

—The Administration's request of $20 million in CPB fiscal year 2001 funds for digital conversion; and we request that some of this funding be available to independent minority producers for conversion to digital production;
—With regard to the Minority Consortia and multicultural programming we request that the Committee support—
An increased allocation of CPB program funds to expand our programming, including a 15 percent increase in the Multicultural Program Fund (currently at $3.2 million) which we administer;
An increased allocation of CPB system support funds to expand our administrative capacity, at an amount at least commensurate with the overall CPB increase;
Increased CPB outreach efforts to promote the multicultural television productions expected to air on PBS this year.

The National Minority Public Broadcasting Consortia consists of the National Asian American Telecommunications Association, the National Black Programming Consortium, Native American Public Telecommunications, Pacific Islanders in Communications and the Latino Public Broadcasting Project.

A federal appropriation of $365 million as requested by the Administration for CPB would be a reasonable, albeit modest, contribution toward our national treasure of public broadcasting. The debate of the past several years regarding public television and public radio has highlighted the great esteem in which they are held. We urge Congress to provide at least as much as has been requested by the Administration for CPB for fiscal year 2003.

Public broadcasting, including PBS and NPR, 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 quality programming for national audiences. Additionally, public television and radio is universally available. In 1994, CPB initiated research among Asian American and Native American communities which documented that respondents felt their communities were negatively stereotyped on commercial television and that that PBS had more realistic portrayals. (REACHING COMMON GROUND: PUBLIC BROADCASTING'S SERVICES TO MINORITIES AND OTHER GROUPS, July 1, 1994, pages 41–41 of the Appendix). 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 and community groups and tribal organizations. Earlier CPB surveys of Latino and African American communities showed similar findings.

This is the Optimum Time to Increase Resources for CPB's Mission of Diversity.—The Minority Consortia works closely with CPB. We value our relationship with President Coonrod and the CPB staff and appreciate the financial and technical assistance provided to us by that organization. We do not doubt CPB's commitment to increasing the diversity of programming on public television and radio, but also believe they can do more with the resources at hand. The stated commitment of CPB and Congress for increased multicultural programming combined with three years of funding increases make this an ideal time for significant progress. It may be now or never.

Since 1988, ten Congressional authorizing and appropriations reports have expressed support for the Minority Consortia and/or for increased multicultural programming on public television.

The CPB fiscal year 2000 funding received by the Minority Consortia organizations—$1.53 million for institutional support ($307,000 per organization—a $28,000 increase per organization over fiscal year 1999) and $3.2 million in programming funds ($636,000 per organization)—is certainly modest compared to the cost of producing an increased amount of quality multicultural programming for public broadcast. Our programming and administrative support funding combined is 1.56 percent of the CPB fiscal year 2000 budget (Fiscal years 2001 and 2002 funds have not yet been distributed). We appreciate that CPB has identified an additional $2.5 million in program funds which we, along with others, can compete, but the commitment for diverse programming should be larger than that.

The Minority Consortia shared in the CPB fiscal year 1997 and 1998 budget reductions. Now, however, we are in a period for which Congress has appropriated increased funding for CPB. The CPB fiscal year 2001 appropriation, which has not yet been distributed, is $340 million, a $40 million increase over fiscal year 2000. And the fiscal year 2002 appropriation is $350 million, an increase of $10 million over fiscal year 2001.

The testimony of CPB President Bob Coonrod before this Subcommittee on March 28, 2000 discussed the need to increase the diversity of public broadcasting offer-

ings, including multicultural programming. He also noted that the younger segment of our society is even more ethnically diverse than the older population. We applaud CPB's public discussion of this need, and intend to work collaboratively with them and the entire public broadcasting community to help make this a reality. But in order to do this, the amount of funding allocated for the development of multicultural programming must substantially increase. And at a minimum, the administrative funding for the Consortia should increase commensurate with the overall CPB budget (a proposed 4.2 percent increase for fiscal year 2003).

Audience Building.—We ask your support in encouraging CPB to increase its efforts to build audiences for PBS programs presented by the Minority Consortia. The good news is that number of programs presented by the Minority Consortia on public television are increasing. On the other hand, the small administrative an program budgets of the Minority Consortia are not sufficient to do the kind of community and national outreach we would like for building audiences for these programs. Obviously, we engage in audience building, but much more can and should be done.

The most recent shows on national public television from the Minority Consortia organizations include regret to inform, homecoming—sometimes I am haunted by memories of red dirt and clay, and warrior in two worlds.

Digital Conversion Assistance.—Much attention was given at the March 28, 2000 House appropriations hearing regarding the opportunities which digital technology will provide in the area of programming. With stations able to broadcast on multiple channels, there will be a need for a tremendous amount of new, quality public broadcasting programming. There are costs involved in the conversion which go beyond the significant equipment and hardware needs of stations. It will also take additional money to produce programming for digital broadcast. All producers will face these new, higher costs. Film producers will need to use equipment that is high definition quality, and that is an expensive proposition. Most producers with whom we work do have not the finances for this new equipment. CPB is currently providing some technical assistance to producers regarding digital conversion. However, independent producers also need financial assistance in acquiring or accessing the means to produce programming for digital broadcast.

We also point out that the Minority Consortia organizations are jointly seeking non-federal sources of funding to support digital production for independent producers, and like their counterparts in public television and radio stations, independent producers also need federal assistance to make this transition.

Work of the Minority Consortia.—The Minority Consortia organizations work both individually and collaboratively. In the past twenty years the Consortia organizations have individually provided to public broadcasting's schedule hundreds of hours of programming addressing the cultural, social and economic issues of the country's racial and ethnic communities. Individually, each Consortia organization has been engaged in cultivating ongoing relationships with the independent producers community by providing technical assistance, program funding, programming support and distribution. We also provide numerous hours of programming to individual public television and radio stations.

On the collaborative front, the five organizations comprising the Minority Consortia are working to jointly write and publish a catalog, newspaper ads, Open Calls for Proposals, and a newsletter.

Perhaps of most potential significance is our planned joint production of a four-part series which will explore the complex demands of our rapidly changing multiracial, multicultural society in America. We will work with many film producers and with CPB and PBS on the production, and CPB will provide some financial assistance. The production is entitled Matters of Race, and we have engaged noted producer/writer Orlando Bagwell (Malcom X: Make it Plain, Eyes on the Prize, A Hymn for Alvin Alley, Fredrick Douglass: When the Lion Wrote History) to produce this series. The project will result in more than television programming. The project will utilize an advisory group of teachers and will be designed so that modules that can be pulled out for classroom use. It will also be formatted for radio broadcast and for the internet, and will include such broadcast applications as extended interviews. There will be great opportunity for extensive and diverse community outreach and collaboration on this project throughout its development, distribution and use.

Currently the five consortia groups are in discussion with other public broadcast entities to pool and share resources to increase awareness of PBS's and public broadcasting diversity initiative. Some of these collaborations include centralizing program distribution with American Public Television, creating minority outreach for stations with the Public Television Outreach Alliance, and working with CPB and PBS to formulate a long range strategy for minority programming for public

broadcasting. The Minority Consortia organizations work collaboratively with a number of television stations, and hope to increase such working relationships.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and we as minority communities in public broadcasting thank you for your long time support of our work on behalf of our communities.

PREPARED STATEMENT OF THE NATIONAL CONGRESS OF AMERICAN INDIANS

INTRODUCTION

Good morning Chairman Specter, Senator Harkin and distinguished members of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. My name is Susan Masten and I am the President of the National Congress of American Indians (NCAI), the oldest and largest Indian advocacy organization in the United States and Chairperson of the Yurok Tribe. On behalf of the 250 member tribes of NCAI, I would like to thank you for this opportunity to submit this statement regarding the President's budget request for fiscal year 2001.

NCAI is extremely optimistic about this year's budget process. For the first time in a generation, the President has requested a total of $9.4 billion for new and existing Indian programs. If preserved through the appropriations process, this request will provide an increase of $1.2 billion over the fiscal year 2000 budget. The last time the Federal Government enacted an increase of a similar scope, was in the mid-1970's, as a part of President Nixon's Tribal Self-Determination policy. The President's fiscal year 2001 budget request represents a commitment to Indian programs and will better serve Indian communities. It also exemplifies a meaningful step toward honoring the Federal Government's treaty and trust obligations to Indian nations. As Congress advances the appropriations process for fiscal year 2001, NCAI seeks support from this Subcommittee to fully fund the Indian programs in the Departments of Education, Health and Human Services, and Labor.

DEPARTMENT OF EDUCATION

For fiscal year 2001, the President's budget request for the Department of Education Office of Indian Education (OIE) is $116 million, a 50 percent increase over the fiscal year 2000 enacted level. NCAI fully supports this request as it will allow the Department's OIE to fund formula grants to Local Education Agencies (LEAs), fund new discretionary programs for OIE, and start a new program for American Indian administrators. Additionally, NCAI fully endorses the Administration's effort to fund the initiatives under the 1998 Executive Order on Indian Education.

For fiscal year 2001, $92.8 million is requested for OIE's formula grant program to public schools, an increase of $30 million over fiscal year 2000. These funds are provided to BIA supported schools for the improvement of educational achievements of Indian students by allowing for the initiation and expansion of Indian specific programs and services. Within the fiscal year 2001 requested budget is a $20 million request for Special Programs, an increase of $6.7 million over fiscal year 2000, for awards for school readiness demonstrations, educator professional development grants, and continuation of the American Indian Teacher Corps. NCAI supports President Clinton's commitment to recruit and train 1,000 new Indian teachers over a five-year period who will then teach in schools with high concentrations of Indian students. Additionally, the President has requested $5 million for the American Indian Administrator Corps. Within the President's fiscal year 2001 proposed budget for Higher Education, $40 million has been requested for a new dual degree program. NCAI strongly supports these funding initiatives to advance Indian education and develop an educational system responsive to the needs of Native students and teachers.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The fiscal year 2001 budget requests $44 million for the Administration for Native Americans (ANA), an increase of $9 million over the fiscal year 2000 enacted level. In awarding grants in fiscal year 2001, ANA will give special attention to energy development and the creation of tribal codes and ordinances. NCAI urges Congress to support this much-needed increase that will support tribal government infrastructure and increase tribal government capacity to administer programs.

The fiscal year 2001 request for the Administration for Children and Families (ACF) Federal Administration line-item is $165 million, an increase of $17 million over fiscal year 2000. From this total, funding is provided to the Division of Tribal

Services (DTS). The DTS provides programmatic support to 22 tribal TANF programs, which directly affects 94 tribes and Alaska Native villages. It is estimated that by fiscal year 2001, approximately 50 percent of all federally-recognized tribes will either administer or be served by a tribal TANF program. While the ACF has tried to provide necessary funding to carry out these duties, without line-item funding authorization for the DTS, the increasing needs of Indian tribes surrounding these social support programs will not be met. NCAI requests a $10 million line-item funding for DTS.

While the fiscal year 2001 budget requests $2 billion for the discretionary Child Care Development Block Grant (CCDBG), an increase of $817 million dollars over the fiscal year 2000 enacted level, tribal governments, who receive a 2 percent set aside of the CCDBG, will still fall far short of meeting child care needs on their reservations. There is a critical need for safe, healthy, nurturing child care environments, particularly on Indian reservations, where parents have a higher median number of children than the national average. NCAI request an increase in tribal child care funding from its current level of 2 percent of the total appropriation.

The fiscal year 2001 budget boosts funding for Head Start by $1 billion in fiscal year 2001, the largest funding increase ever. The budget also provides a total of $175 million, including a $30 million increase over fiscal year 2000, for Indian Head Start. NCAI strongly supports this much-needed increase to Indian Head Start programs, many of which are stretched to capacity.

Three provisions under the purview of the Administration on Aging, authorized in the Older Americans Act (Pub. L. 89–73, as amended), are of special importance to American Indian and Alaska Native elders. The first is Aging Grants for Native Americans authorized in Title VI. The President's fiscal year 2001 budget requests $24 million, an increase of $5 million over the fiscal year 2000 enacted level, for Title VI grants to tribes and tribal organizations. Current grantees report a 20 percent increase in the number of elders eligible for the service between 1996 and 1999. Because of this growing population of Native elders, NCAI requests that the full $30 million authorized for Title VI be appropriated in fiscal year 2001.

The second provision is Aging Research and Training, also authorized in Title VI. For fiscal year 2001, NCAI requests an appropriation of $630,000 with at least $130,000 earmarked for a continuing grant to NICOA to gather information on Indian elders and to quantify their needs. The remainder should be directed to grants for training Title VI service providers to better serve Indian elders.

The third provision is ombudsman/elder abuse prevention authorized in Title VII: Allotments for Vulnerable Elder Rights Protection Activities, Subtitle B: Native American Organization Provisions. Prevention programs for tribes are desperately needed—yet no funds have ever been provided for Subtitle B, despite an authorization level of $5 million. State programs currently receive $4.5 million for ombudsman services and $4.7 million for prevention of elder abuse programs. However, these programs seldom, if ever, reach Indian Country. NCAI seeks full funding of $5 million in fiscal year 2001, specifically for tribal programs as authorized in Subtitle B of Title VII.

In fiscal year 2001, there is a need of $600,000 for special HIV surveillance studies to be undertaken in order to better understand the extent of the HIV epidemic in the Native American population, and to supplement the existing AIDS case and HIV infection data presently available. Additionally, $200,000 is needed to contract out a series of meetings between states, CDC, IHS, tribal representatives, and epidemiologist to make recommendations on improving the disease surveillance system in Native America. NCAI seeks the support of this Subcommittee in this request.

The President's fiscal year 2001 budget request for the Centers for Substance Abuse Prevention is $48.8 million. NCAI seeks the support of this Subcommittee in securing a targeted funding program whose purpose is to involve Native American substance abuse prevention treatment programs more actively in the effort to slow the spread of HIV.

The President's fiscal year 2001 budget request for the National Institute of Health (NIH) is $3 million. Unfortunately, there is a shortage of funding for research related to HIV in Native America within NIH. NCAI requests the support of this Subcommittee in seeking critical funding for behavioral research in particular, to help better understand the underlying components of risk behavior leading to HIV infection in the Native American population.

DEPARTMENT OF LABOR

Under the Workforce Investment Act (WIA) at least $55 million can be appropriated for the Indian Comprehensive Services program. In fiscal year 2001, the Administration has requested $55 million. NCAI regards WIA as an opportunity to

more effectively provide job training services and urges Congress to fully fund this program.

The fiscal year 2001 budget proposal includes $255 million for a new "Fathers Work/Families Win" initiative, $10 million of which is set aside to provide grants to help Native American low-income families. These proposed funds are aimed at addressing the working poor and fathers, in the aftermath of no new WtW funding. NCAI supports the $10 million set aside for applicants from the Native American workforce agencies.

The fiscal year 2001 budget request also provides $15 million for the tribal supplemental youth employment services program that replaces the former JTPA Summer Youth Program, and supports year-round activities. In addition, the President proposes to increase the Youth Opportunity Grant (YOG) program from its current $250 million funding level to $375 million in fiscal year 2001. NCAI requests sufficient funding to provide reliable and consistent opportunities for youth. NCAI also supports adequate funding of other DOL programs that benefit American Indians, including the Administrations's Disabilities Services request for $43 million in the fiscal year 2001 budget. NCAI asks that these work incentive grants and services be extend to tribes.

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 2001 budget request acknowledges the fiduciary duty owed to tribes. We ask that the Congress maintain the federal trust responsibility to Indian Country and continue to aid tribes on our journey toward self-sufficiency. Thank you for allowing me to present for the record the National Congress of American Indians' comments regarding the President's fiscal year 2001 budget request.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE TO END HOMELESSNESS

The National Alliance to End Homelessness is a national membership organization with nearly 2,000 members around the country. Most are local nonprofit community-based and faith-based organizations that are doing the hands-on work to end homelessness for families and individuals. As our name implies, our primary focus is ending homelessness, not simply making it easier to manage. There is nothing inevitable about homelessness in the United States. We know more about homelessness and how to address it than we ever have before. We know what program models are effective for what kinds of people. It remains only to bring these solutions to a scale commensurate with the problem, and to focus them on bringing homelessness to an end.

It is our contention that an end to homelessness is a goal that we can achieve by the end of the decade. To do so we need to pursue four lines of attack simultaneously. We must:

—Plan for outcomes
—Close the front door in to homelessness
—Open the back door out of homelessness and in to housing
—Build the infrastructure.

PLANNING FOR OUTCOMES

We have an extensive system for dealing with homelessness. Too often, however, this system focuses only on managing the problem and not on a permanent solution. To change this focus we need to be sure we have accurate information on who homeless people are, how they become homeless, and what works to allow them to secure and stay in housing. We need to commit ourselves to ending homelessness as the outcome of the system's activities. And we need to use the data to plan strategically to bring about the result we want.

Recommendation.—Encourage all programs to collect information about homelessness among those the programs serve. Much of the recent explosion of information and know-how about homelessness has come as a result of research funded by this subcommittee. This effort needs to be extended to the state and local level.

Recommendation.—Encourage federal agencies and state governments funded by programs such as the substance abuse and mental health block grants to plan for reducing homelessness among the population served. An important mandatory spending item in the Administration's budget request is a $10 million initiative to provide money to a small number of states to coordinate services for homeless people by programs not specifically targeted to homeless people. The request is in the budget for the Health Care Financing Administration, partly because Medicaid is such an important program for homeless people. We urge the subcommittee to encourage agencies under its jurisdiction to cooperate with the initiative and work to make their services better coordinated and more accessible to homeless people.

CLOSING THE FRONT DOOR IN TO HOMELESSNESS

We need to hold government-funded systems accountable for, at the very least, ensuring that the Americans they serve do not become homeless. We must treat homelessness among people with mental illness as sign that the mental health system needs improvement; homelessness among former foster children as a similar sign for the child protection system; homelessness among people with addiction disorders for the substance abuse treatment system.

Recommendation.—Encourage mainstream programs such as the substance abuse and mental health block grants to address homelessness and housing stability among their target populations. Over the past few years this subcommittee has encouraged agencies that oversee large "mainstream" (i.e. not homeless-targeted) programs to pay attention to the amount of homelessness among the populations they serve. This has led to important work by the agencies involved, to examine ways to make these programs more conscious of housing stability as an end to be achieved. More remains to be done, and the subcommittee should continue its diligence in this regard.

OPENING THE BACK DOOR OUT OF HOMELESSNESS AND IN TO HOUSING

Most people who become homeless find housing on their own in relatively short order. We need to speed up that process, and prevent disruptions during the period of homelessness. A minority, however, remains homeless for a long time. Among this group, disabilities are prevalent, including mental illness, substance addiction, and HIV/AIDS.

This subcommittee's work can have a huge impact on efforts to rehouse people who are chronically homeless and chronically ill. Besides housing, they need treatment and services:

—Outreach, particularly to long-term homeless people with mental health and substance abuse problems, to ensure that they make use of the services that are available.

—Short-term treatment in a residential setting aimed at stabilizing these individuals and transitioning them into permanent housing.

—Treatment and long-term aftercare linked with permanent housing, creating permanent supportive housing, a powerful model that improves the lives of long-term homeless people while saving public money that would otherwise be spent on hospital emergency rooms, emergency detoxification, acute mental health care, shelters and jails.

—Help with employment, as soon as homeless people are stabilized in a residential setting.

—Case management to ensure that all services are available.

—Preparing people with few skills for success, once their housing situation has been stabilized.

—Assistance, particularly with children, to avoid disruption of family life during times of homelessness.

Recommendation.—Appropriate $100 million for the Grants for the Benefit of Homeless Individuals program. This program, first authorized in 1992, has the potential to fill the most gaping hole in the system of supports for chronically homeless people—the lack of effective substance abuse treatment services. The program would provide competitive grants from the Substance Abuse and Mental Health Services Administration to local agencies, to provide specific services for homeless people with addictive disorders and/or mental illnesses. GBHI would provide an ideal mechanism for linking HHS-funded services with HUD-funded supportive housing. There is not an existing appropriation for this program, but we request that the subcommittee pass a new appropriation for it because it fills such a crucial need, for substance abuse treatment and for treatment for mental illnesses that are not considered "severe" (i.e. schizophrenia, bipolar disorder, major depression).

The Grants for the Benefit of Homeless Individuals program was authorized by Section 506 of the Public Health Service Act. As is true of all other SAMHSA programs, its authorization has expired, but we urge Congress to respond to this as it has responded for other SAMHSA programs, by making year-to-year appropriations until the reauthorization process can be completed. The Senate-passed bill to reauthorize SAMHSA programs, S. 976, would reauthorize the GBHI program.

Recommendation.—Appropriate $75 million for Projects for Assistance in Transition from Homelessness. PATH provides formula grants to each state for outreach, case management and treatment for homeless people with severe mental illnesses, including those with a dual diagnosis of mental illness and drug or alcohol addiction. PATH is ideal for funding outreach and case management, allowing people with severe mental illness to be brought into the system of care, their treatment stabilized, and services to continue once they are permanently housed.

Recommendation.—Provide $129 million for Health Care for the Homeless (through a $1.5 billion appropriation for Consolidated Health Centers). Health Care for the Homeless is part of the Consolidated Health Centers line item in the budget for the Health Resource Services Administration. The program funds clinics that specialize in the unique treatment challenges presented by people who are homeless, often for long periods of time. Clinics provide primary care, as well as diagnostic, preventive, emergency medical, pharmaceutical, addiction, and mental health services. They also conduct intensive outreach and case management, linking patients to housing, income and transportation. HCH projects are ideal to provide outreach and to stabilize the worst-off homeless people.

Recommendation.—Appropriate $120 million for the Runaway and Homeless Youth Programs. The Administration for Children and Families within HHS operates coordinated competitive grant programs addressing the problems of homeless and runaway youth. Runaway and Homeless Youth programs support cost-effective, community-based services that protect youth from the harms of life on the streets and either reunify them safely with family or find alternative placements. RHYP ends homelessness by engaging in outreach, and quickly rehouses as many homeless youth as possible. For others, it provides services that will prepare them to enter adulthood housed.

Recommendation.—Appropriate $15 million for the Homeless Veterans Reintegration Program. The Homeless Veterans Reintegration Program, within the Department of Labor's Veterans Employment and Training Service, provides job placement and related services to homeless veterans. Homeless veterans have many barriers to employment. According to DoL, HVRP helps overcome those barriers and places veterans in jobs at a rate of about $1430 per placement, making it extremely cost-effective. While successful, HVRP has been able to serve only a small portion of the homeless veteran population, due to insufficient funding. Last year an increase for this program received bipartisan support. This year, the Administration has requested, and we support, the full authorization level of $15 million.

Recommendation.—Appropriate $50 million for Education for Homeless Children and Youth. A struggle for homeless service providers who serve families with children is to maintain the children's stability during a time when their lives are turned upside down. Even if new housing can be found in a short time, the lasting effects of a spell of homelessness can be devastating, if everything in their lives is disrupted. The most important potential source of stability for these children is school—but only if they can continue to attend school. That is the mission of the Education for Homeless Children and Youth program. EHCY removes obstacles to enrollment and retention by establishing liaisons between schools and shelters and providing funding for transportation, tutoring, school supplies, and the coordination of statewide efforts to remove barriers. As a result, the percentage of homeless school age children attending school increased from 50 percent prior to establishment of the program to 88 percent in 1997. This encourages quick rehousing of families by retaining ties to their communities.

BUILD THE INFRASTRUCTURE

In addition to initiatives that focus on homelessness, bringing homelessness to an end will require larger systemic reforms to improve the incomes of the poorest Americans, to make housing more affordable, and to make services widely available to those who need them. This subcommittee's efforts in areas such as child care, education and employment are critical in this regard. Two programs under this subcommittee's jurisdiction are particularly important:

Recommendation.—Fully fund the Labor Department's "Fathers Work/Families Win" initiative. The Department of Labor has made great strides over the last few years in making it's programs work better for the lowest income people, including

homeless people. The proposal in the DoL budget for the "Fathers Work/Families Win" initiative provides great promise to continue the work begun by the mandatory Welfare to Work Grants Program—making sure the poorest Americans have the tools they need to succeed in the workplace. We urge the subcommittee to approve that initiative while encouraging the Department to continue to make those services, and the services of Workforce Investment Act programs, fully available to people who are struggling with homelessness.

Recommendation.—Appropriate $1.4 billion for the Low-Income Home Energy Assistance Program. Inability to pay for utilities is second only to inability to pay rent as an economic cause of homelessness. LIHEAP has for many years proven an effective program with bipartisan support, designed to help low-income people afford these charges and avoid homelessness. We encourage Congress to provide adequate funding for this important program.

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