S. HRG. 108–745

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Before the Committee on Appropriations

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

Fiscal Year 2005

108*th* CONGRESS, SECOND SESSION

H.R. 5006/S. 2810

DEPARTMENT OF EDUCATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NONDEPARTMENTAL WITNESSES

Labor-HHS-Education Appropriations, 2005 (H.R. 5006/S. 2810)

S. HRG. 108–745

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2005

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

ON

H.R. 5006/S. 2810

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, 2005, AND FOR OTHER PURPOSES

Department of Education
Department of Health and Human Services
Nondepartmental witnesses

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2005

THURSDAY, MARCH 4, 2004

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

The subcommittee met at 9:40 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Hutchison, Stevens, Harkin, Kohl, Murray, and Landrieu.

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

STATEMENT OF HON. RODERICK PAIGE, SECRETARY

ACCOMPANIED BY:
C. TODD JONES, ASSOCIATE DEPUTY SECRETARY FOR BUDGET AND STRATEGIC ACCOUNTABILITY
THOMAS SKELLY, DIRECTOR, BUDGET SERVICES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. The hearing of the Appropriations Subcommittee on Labor, Health, Human Services, and Education will now proceed. I regret being a few minutes late. They have Constitution Avenue blocked off. How did you make it Mr. Secretary?

Secretary PAIGE. I know some shortcuts.

Senator SPECTER. You must have more clout than a chairman, Mr. Secretary.

Secretary PAIGE. I doubt that.

Senator SPECTER. We never know what's going to happen around the Capitol from one day to the next, but Constitution Avenue is blocked off as we came up. They publicized recently that the Capitol is an armed camp but at least the streets were clear, but this morning even the streets are not clear.

Well, on to the business of the subcommittee. We have the distinguished Secretary of Education with us today, came to the administration with an outstanding reputation as the superintendent of the Houston Independent School District. He served as dean of education and athletic director prior to that at Texas Southern University. He takes on a gigantic job, has taken on a gigantic job in the Department of Education, and with the President on a bipar-

tisan basis has led to the enactment of legislation on Leave No Child Behind, which was widely heralded in 2001 when enacted.

The President made a special trip to Massachusetts with Senator Kennedy to show the bipartisan support. Since that time, there have been some growing pains, which we will be exploring in today's hearing, a call for greater flexibility where the Department has responded so far, at least in part, concerns about adequacy of funding, where we are trying to move ahead with more funding.

FISCAL YEAR 2005 EDUCATION BUDGET REQUEST

The budget for the Department as asked for by the administration is in excess of $57 billion, an increase of $1.68 billion over last year for a 3 percent increase, and the administration has recommended additions in very important lines, a billion in title I, a billion in special education. But that is possible by eliminating quite a few programs, which, Mr. Secretary, are very popular with members, and the Constitution gives the Congress the appropriation power, subject, of course, to the President's signature.

So we have always worked it out in the past. We're facing a very difficult year on discretionary spending with one half of 1 percent overall on discretionary spending. We're facing a budget deficit in the range of $500 billion, but in Winston Churchill's famous words, we'll muddle through, and by working together and the relationship the Secretary has had with this subcommittee and with the Congress in general has been excellent and on a cooperative basis.

A group of school leaders had a meeting in southeastern Pennsylvania earlier this week where there were many concerns expressed about the No Child Left Behind Act, and on a last minute basis we've invited some of the people party to that meeting and some other Pennsylvanians to come to the hearing. The chairman is exercising his prerogative as chairman to look to the home State. That's not unusual in Washington, D.C., but it's representative of a national picture.

I talked to Secretary Paige last yesterday afternoon. He has other commitments, but we struck a time agreement, out no later than 11:00, and we appreciate his flexibility. Mr. Secretary, the floor is yours. We have a 5-minute rule, but it is waived for people who can get by the Constitution Avenue blockade.

SUMMARY STATEMENT OF HON. RODERICK PAIGE

Secretary PAIGE. Thank you, Mr. Chairman. I would like to submit material for the record. I'll just provide a summary and try to get it in in 5 minutes.

Senator SPECTER. Well, that's wonderful, Mr. Secretary.

NO CHILD LEFT BEHIND ACT

Secretary PAIGE. Thank you. Let me summarize the statement for you. With this request, President Bush has reaffirmed his longstanding commitment to our Nation's children. Mr. Chairman, in the time since the No Child Left Behind Act became law, we have made tremendous progress in building a solid foundation for educational achievement.

From day one we've been working to provide guidance on implementation of this comprehensive and complicated law. The States will tell you that we've done so at a record pace. We've entered into a historic partnership with the States. In the first year, we hosted meetings with nearly every State to support the development of our accountability plan. Our Teacher Assistance Corps has visited 49 States to date, working to help States meet the law's provisions regarding highly qualified teachers.

We continue to provide regulatory flexibility on the law's implementation, including the recent announcement that benefits students learning the English language for the first time, and also greater flexibility in testing students with disabilities. As we continue to assess the law's impact, we must always keep in mind what is right for the child, but also be fair to the school.

FISCAL YEAR 2005 EDUCATION BUDGET REQUEST

Despite this important progress, we still have much work to do. My message to you this year, Mr. Chairman, is no less urgent than it was in years past. Federal Reserve Chairman Alan Greenspan noted recently, and I quote: "We need to be forward-looking in order to adapt our educational system to the evolving needs of the economy and the realities of a changing society. . . . It is an effort that should not be postponed."

The President's budget proposes $57.3 billion in discretionary appropriation for the Department of Education for fiscal year 2005. This represents an increase of $1.7 billion, or 3 percent, over the 2004 levels, and an increase of $15.1 billion, or 36 percent, since President Bush took office in 2001. This budget request reflects the historic bipartisan commitment of President Bush and the Congress to increase flexibility and accountability in the use of these funds.

KEY BUDGET YEAR FOR NCLB

The 2005 appropriation will fund the 2005–2006 school year, a critical year that will witness two significant milestones under the No Child Left Behind law. The first, States and school districts will begin testing all students in grades 3 through 8 in reading and mathematics in 2005–2006. With the information provided by these annual assessments, teachers will have the data they need to teach each student effectively and parents will be empowered to make informed choices for their children's education—for their educational future. The President is proposing $410 million in 2005 to support the assessment system developed by each State.

The second milestone is that all teachers must become highly qualified by the end of the school year of 2005–2006. There is no better way to improve education than putting a highly qualified teacher in every classroom. The No Child Left Behind Act recognizes this fact and we will continue to work hard with States to make this a reality. The President's Budget proposes $5.1 billion to support teachers through training, recruitment incentives, loan forgiveness, tax relief. This is up from $4.4 billion in 2004 and this is a historic number.

TITLE I GRANTS TO LOCAL EDUCATIONAL AGENCIES

For students who most need our help, the President has again proposed a billion dollar increase in title I, which brings it up to $13.3 billion. Many of these children are on the wrong side of a staggering achievement gap with their more advantaged peers, often struggling in school and also in life. We know that this problem can't be solved in Washington. Local communities know best what to do in order to remedy these conditions.

HISTORIC LEVELS OF RESOURCES AND FLEXIBILITY

So to help schools and districts better meet the needs of these students, we're providing resources that are historic in their scope and also in their flexibility, and we're asking for annual progress assessments in return for this historic investment.

In conclusion, when the President said in his State of the Union address: "We've not come all this way . . . only to falter and leave our work unfinished." I took that message to heart. In the last 3 years, we've witnessed some of the most important milestones yet in education reform, and I believe that one day we're going to look back at this year and see it as a turning point in the educational culture in our country.

PREPARED STATEMENT

Fifty years ago, the historic *Brown* v. *Board of Education* decision began to break down the barriers that prevented some of us from attending classrooms—certain classrooms. But we know now access was not enough. We still have a long way to go to ensure achievement. We believe that today, at the start of the third year of the No Child Left Behind Act, we are closer to making that goal a reality than ever before.

Mr. Chairman, thank you, and I'd be pleased to respond to any questions that you might have.

[The statement follows:]

PREPARED STATEMENT OF HON. RODERICK PAIGE

Mr. Chairman and Members of the Subcommittee: Thank you for this opportunity to testify on behalf of President Bush's 2005 discretionary request for the Department of Education. As all of you know, the effort to control spending while fighting a war on terrorism and ensuring homeland security forced the President to make some tough decisions in his 2005 budget. The significant overall increase requested for the Department of Education shows that the President remains committed to the vision of No Child Left Behind—that all children can learn, and all children deserve the opportunity for a quality education.

A KEY YEAR FOR NO CHILD LEFT BEHIND

Fiscal year 2005 is a critical year for No Child Left Behind. The 2005 appropriation will fund the 2005–2006 school year, a year that will witness two significant milestones under the new law. First, States and school districts will begin testing all students in grades 3–8 in reading and mathematics. This is a necessary step toward giving teachers the data they need to teach effectively and parents the information they need to assess the progress of their children's education.

Second, all teachers must be highly qualified—as defined by States in accordance with the law—by the end of the 2005–2006 school year. Research tells us there is no better single way of improving education than by putting a highly qualified teacher in every classroom. The No Child Left Behind Act recognized this fact, and we'll be working hard with States to make it a reality.

We also continue to explore ways to provide the additional flexibility that States and school districts need to effectively implement No Child Left Behind. In December, the Department published a new regulation giving States greater flexibility in testing students with disabilities. Two weeks ago, I announced two new policies governing the treatment of limited English proficient students in the State accountability systems required by No Child Left Behind. And we are working on some clarifications regarding the law's requirement that all teachers be highly qualified.

In these and other instances, we believe the law is sufficiently flexible to accommodate the legitimate concerns of State and local educators, without undermining the core goal that all students and all student groups must reach proficiency in reading and mathematics.

MAJOR PROGRAM INCREASES

The President's budget proposes $57.3 billion in discretionary appropriations for the Department of Education in fiscal year 2005. This represents an increase of $1.7 billion, or 3 percent, over the 2004 level, and an increase of $15.1 billion, or 36 percent, since President Bush took office in 2001.

As was the case in the President's previous education budgets, most new resources are dedicated to three major programs that form the cornerstone of the Federal role in education. For the Title I Grants to Local Educational Agencies program—the key driver of No Child Left Behind reforms in the areas of accountability and parental options—the President is seeking $13.3 billion, an increase of $1 billion over the 2004 level.

Title I helps the children who are most in need of extra educational assistance, who are most in danger of falling further behind, on the wrong side of the staggering achievement gap between poor and minority students and their more advantaged peers. Our determination to help these students—which I know is shared by the Members of this Committee—is reflected in a request that would result in a total increase of $4.6 billion, or 52 percent, in Title I funding since the passage of the No Child Left Behind Act.

The President also is asking for his fourth consecutive $1 billion increase for the Special Education Part B Grants to States program. Under the request, funding for Part B Grants to States would rise by $4.7 billion, or 75 percent, since 2001. The 2005 request would increase the Federal contribution to about 20 percent of the national average per-pupil expenditures for all children—the highest level of Federal support ever provided for children with disabilities.

And for the need-based Pell Grants program, the budget includes an increase of $856 million, for a total of $12.9 billion. This level would fully fund the cost of maintaining a $4,050 maximum award and providing grants to an estimated 5.3 million postsecondary students. More than 1 million additional students are now receiving Pell Grants than when the President took office.

JOBS FOR THE 21ST CENTURY

In addition to these major programs, another priority in the Department's request is a package of proposals, totaling $333 million in new resources, which play a key role in President Bush's Jobs for the 21st Century initiative. These proposals would help ensure that middle- and high-school students are better prepared to succeed in postsecondary education and the workforce. They focus on improving instruction to ensure students are performing on grade level in reading and mathematics and on increasing the rigor of secondary school curricula.

A key proposal, for example, is $33 million for new Enhanced Pell Grants for State Scholars, which is included in the overall request for Pell Grants. We know students who complete a rigorous curriculum are more likely to pursue and succeed in postsecondary education, so this proposal would provide an additional $1,000 for postsecondary freshmen who took challenging courses in high school.

The Jobs for the 21st Century initiative also includes $100 million in new funds to help struggling readers at risk of dropping out of secondary school and $120 million to improve the math skills of secondary school students who are performing below grade level. Another $28 million in new funds is provided to help expand Advanced Placement courses for low-income students, and $40 million is set aside for Adjunct Teacher Corps to bring professionals with sought after knowledge into the classroom.

The request for Vocational Education complements Jobs for the 21st Century by proposing a $1 billion Secondary and Technical Education State Grants program that would promote local partnerships between community colleges and high schools to improve academic achievement and transitions to the workforce. This request in-

cludes $12 million to help those States that do not currently have State Scholars programs to establish such programs.

Jobs for the 21st Century also emphasizes research-based approaches, the importance of which is reflected in our $185 million request for Research, Development, and Dissemination. This is an increase of $19 million, or nearly 12 percent, to fund research on reading comprehension, mathematics and science education, and teacher quality.

OTHER PRIORITIES

The 2005 request provides new funding in other ongoing priority areas, such as reading, expanding choice options, and support for postsecondary institutions serving large percentages of minority students.

Funding for Reading First would grow by $139 million, or more than 12 percent. Reading first offers children in grades K–3 the benefits of research-based, comprehensive reading instruction designed to help meet the President's goal that all children read on grade level by the end of third grade. The request includes $1.1 billion for Reading First State Grants, an increase of $101 million or 10 percent over last year, as well as $132 million for Early Reading First, an increase of $38 million or 40 percent.

Our budget also reflects President Bush's determination to extend educational options to all parents and students—not just those who can afford this freedom. No Child Left Behind has greatly expanded the choices available to students in low-performing schools, including both the option to transfer to a better school and to obtain supplemental educational services from a private-sector provider. And this fall we will for the first time provide federally funded opportunity scholarships to low-income students in the District of Columbia.

The President's 2005 budget would build on these achievements by investing an additional $113 million in expanding choices for students and parents. This total includes $50 million for a Choice Incentive Fund that would support new transfer options, including private school options, and a $63 million increase for the Credit Enhancement for Charter School Facilities program, which encourages greater private sector lending to finance academic facilities for charter schools.

Finally, our request reflects the President's ongoing commitment to postsecondary institutions that serve large numbers and percentages of minority students. We are asking for a total of $515 million for these institutions, an increase of almost $21 million, or 4 percent, over the 2004 level. The total includes $241 million for Strengthening Historically Black Colleges and Universities, $59 million for Historically Black Graduate Institutions, and $96 million for Hispanic-Serving Institutions.

MANAGEMENT IMPROVEMENTS

Another thing that I am proud of is the very real improvement we have made in managing the Department and its programs. I knew when I came to the Department that if we were going to demand stronger accountability from States, school districts, and schools as part of No Child Left Behind, we would have to demand that same kind of accountability from ourselves. This has been a major priority for me and my senior officers for the past three years, and I am pleased to report that thanks to a lot of hard work and discipline, taxpayers can rest assured that their hard-earned tax dollars are managed responsibly at the Department of Education.

Fiscal year 2003 marked the second consecutive year that the Department received an unqualified "clean" opinion from its financial auditors. That may not seem like something worth celebrating, unless you know that the 2003 opinion was only the third "clean" audit in the Department's 24-year history.

We also are continuing to make progress in all areas of the President's Management Agenda. Earlier this year, the Office of Management and Budget announced that the Department received a major upgrade on financial performance—moving from a RED to GREEN status score. Our performance is ranked in the top one-third of all government agencies, and reflects our continued determination to inject accountability into everything we do here at the Department of Education.

CONCLUSION

The President's 2005 budget request for the Department of Education demonstrates his ongoing commitment to investing in educational excellence and achievement. But it also reaffirms that the Federal role in education is not just about money, but more importantly about leadership based on high standards, accountability, and the use of proven educational methods. Only in combination with this leadership—exemplified by the No Child Left Behind Act—will the resources

provided by the Congress have the impact we have all hoped for over the past four decades.

We still have a long way to go before we ensure equal educational opportunity for disadvantaged children, but I believe we are witnessing the turning point. With your help, we'll keep turning in the right direction.

Thank you, and I will be happy to take any questions you may have.

NEW FLEXIBILITY UNDER NCLB REQUIREMENTS

Senator SPECTER. Well, thank you very much, Mr. Secretary. There have already been some significant changes made in the Leave No Child Behind program according to media reports. Secretary Paige, could you tell us a little bit about those changes which have already been made to add flexibility and the reasons for those changes?

Secretary PAIGE. Yes. Let's kind of put this in perspective. It's been about 8 months since school systems began to really exercise the tenets of the No Child Left Behind law, so we can see the impact of it. The first began in September and October just after the accountability plans were approved in June. Accountability programs were approved in June; in September, October, and November, we began to see the impact of these plans.

In October, late October, we assessed what had happened in September and October. We were particularly interested in where the hot spots were or the areas of difficulties that could be found. We began then to assess those difficulties and say, for which of these difficulties do we have regulatory ability to provide more flexibility?

The first was special education because we found it was having—giving us the most heartburn at that point. And so in December we announced some new flexibility, new flexibility with special education. The next one was LEP—limited English proficient students. Our policy people and our legal people studied the LEP issues, they conferred with Congress, they conferred with the White House, and we found ways that we could agree that we could provide more flexibility for LEP students, and so in February we announced new flexibility in accountability requirements for LEP students.

The third challenge was the highly qualified teacher requirement, and the progress is ongoing now in developing some new latitude in the highly qualified teacher requirement; all of this within the confines of the law. And we hope in the next 10 days or so to be able to announce some new flexibility with the highly qualified teacher requirements.

Following that, we hope that we'll be able to take a good—we are in the process now of taking a good look at the 95 percent participation requirement to see if there's any way there that we can find new flexibility in the law.

So there's been a constant march towards providing flexibility to the people who really are going to have to get this done, and those are the people who are at the schools and in the superintendent's office and in the classrooms.

REGULATORY FLEXIBILITY FOR SPECIAL EDUCATION AND LEP ASSESSMENTS

Senator SPECTER. Mr. Secretary, let me shift focus just a little bit on the issue of No Child Left Behind. Earlier this week, last Monday, more than 100 school superintendents from 14 Pennsyl-

vania counties met to discuss the No Child Left Behind law and they signed a petition supporting changes, including flexibility in testing requirements for special education and limited English proficient students, and also full funding for the No Child Left Behind Act. Would you direct your attention to the issues of increased flexibility for special education and limited English proficient students?

Secretary PAIGE. Yes, thank you, Mr. Chairman. Let's start with the point of view that the philosophy of the No Child Left Behind Act is that every student is a concern to us and the law should provide the same kind of protection for every single student. There are some students who bring different challenges to us. Students with disabilities are one of those groups of students. We want to make sure that students with disabilities are assessed just like the other students. The law, in fact, requires it.

What we did in December was to announce an initiative that provided a little flexibility there, but yet kept the spirit of the law that Congress had in mind, Congress' intent, which was that every student is assessed. And so we announced some flexibility such that students with the most significant cognitive disabilities could be assessed against alternate achievement standards. That would be limited to 1 percent of the students tested, which could be 8, 9, 10, 11 percent of the students with disabilities overall.

We also indicated that if a particular school district finds that that 1 percent cap is too tight for them, and they've got a way that they can justify a need for it to be expanded, a process is put in place so that it can be expanded. So the special ed regulations we think are going to provide the kind of flexibility that school districts need in order to get the job done.

Senator SPECTER. Do you think that would be enough to account for students who are not proficient in English and also those who need special education, Mr. Secretary?

Secretary PAIGE. Especially in special education. Now about those students that have limited proficiency in English, we indicated that the test that they're measured with would be a test to measure where they are in that progress to English proficiency, not a content test. Now, that's the law, but many States have different laws that require different kinds of approaches to that.

SINGLE SEX EDUCATION

Senator SPECTER. Mr. Secretary, I notice in this morning's media reports a shift in policy by your Department on single sex education and it is in the formative stage. And there was a comment by Superintendent Vallas of the Philadelphia School District, which we will be inquiring into when he testifies later, that there's going to be a very careful examination of community response on that issue.

But I'd be interested in your professional judgment as to the advantages and disadvantages, and before you start to answer the question, let me say that that's my last question, because I want to stay within the 5-minute rule because we have so many witnesses later. But I'd be interested in your professional judgment on that issue.

Secretary PAIGE. We would like to provide broad flexibility in the kind of systems that we have in schools for the education of children. There's no coercion here. What we're trying to do is to provide options for parents and for those who administer schools. If they decide that a single-sex school or a single-sex classroom brings the kind of advantages that they need in order to accomplish their educational goals, we don't want to restrict that. And so what we are attempting to do now is to provide that kind of flexibility.

We were in New York at the Young Women's Leadership School. I had a chance to talk to girls who felt and expressed that the school that they were attending now gave them a really real new lease on life. This kind of environment they thought was very special and met their needs. They weren't required to attend that kind of classroom, but if this is the kind of classroom that they feel is needed there, then the ability to adapt the structure of the delivery system should be available to the person on the scene, and that's what we're trying to get accomplished.

Senator SPECTER. Thank you very much, Mr. Secretary. I'll turn now to, in order of arrival, Senator Landrieu.

STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman. I have a longer statement I'll submit to the record and, welcome, Secretary Paige. Just for the—briefly though this morning, just say after looking and studying very closely at this budget, Mr. Secretary, I must say, and to the administration, that this budget is wholly inadequate to support the education reform efforts that are underway in this country at our own urging.

Together we set out on a path to help our States and help our cities and help our communities identify the schools and the systems that weren't working, and then when they looked to us to help to provide the resources to hire better qualified teachers, to make smaller classroom sizes, to provide early childhood education, to provide for after-school care, the resources are not there.

Mr. Chairman, I have to say just my general comment about this budget is that it is wholly inadequate to meet the challenges of reform and to strengthen what we understand is a weak economy in the United States at this time, and the only way this economy is going to be strengthened is if we can increase the human capacity and invest in human talent and skill.

Senator SPECTER. Senator Landrieu——

Senator LANDRIEU. So with that——

Senator SPECTER. Senator Landrieu, may I interrupt you for just a moment? While this hearing is going on, there is an executive session of the Judiciary Committee and they need me there for a quorum. I'm going to excuse myself for a few minutes. When you finish your round, Senator Murray will proceed, and if somebody else comes, they may proceed, and I will return momentarily.

Senator LANDRIEU [presiding]. Thank you, Mr. Chairman, and I'm going to be brief because I'll—Senator Murray will have an opening statement and then I'll get back to questions, but you know, Mr. Secretary, I have to go on record as saying I don't know where to begin. And let me just end with one very specific. We called our schools and some around the country just on one specific,

so I can just express and give some real meat to the general statement I just made.

As you know, in New Orleans and Louisiana, we're 5 years into a very strong accountability program in which we used in some measure as a model for the Nation. But unlike the Nation, Louisiana stepped up and tried to fund those reforms. Last year, 35,000 children were identified in failing schools, 1,100 applied for transfers, yet only 400 were transferred because the rest were denied because of lack of space in higher performing schools.

So the plan that we've put in place can't work unless we provide the resources to give them opportunities to move to schools that are performing but they either don't have the teachers or don't have the classrooms, yet every time we've asked this administration for help, for classrooms, for school construction, we've been told no, no, and no.

In Chicago, 125,000 students were eligible for transfer, yet there was only space for 3,000 to transfer to higher public schools. In Baltimore—I mean, in Los Angeles, 230,000 children were eligible, yet only 100 could transfer because there's no space. And yet in the same budget, you all provide space to transfer to private schools, but won't help children transfer to higher performing public schools, and the bias is clear and it is, in my opinion, not right.

PREPARED STATEMENT

I could go on for 3 hours, but I will not. That's just one example, and Senator Murray will have an opportunity for an opening statement now, or questions.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Mr. Chairman, again let me take the opportunity to thank you for your leadership in this area. I am pleased to have the opportunity today to hear from the Secretary of Education, Secretary Paige, about the President's Budget request for Education. As I know you agree, there are few greater investments that can be made in the future of this great country than the investment we make in our children's education. For this reason, I remain committed in my support of a budget that not only reflects national priorities in education, but also invests in them. I am sad to find that the budget that has been put forward by the President does neither. I hope that this committee can work together, as we have in the past, to address the many shortfalls left by this budget and fully invest in our promise to leave no child behind.

As all of us know, our nation is faced with one of the largest federal deficits in our history. While we may disagree as to how we have come to be in this position, there is not a member of the United States Senate who is not aware of the need to enact fiscally responsible policies aimed at restoring balance in the federal budget. Most experts agree that a sound fiscal policy in times of deficit requires limited spending in key priority areas that both increase revenue and spur economic growth. Strategic investments in education not only allow us to develop a strong and competitive workforce but also help citizens to move from a life of dependence on government support to one of individual productivity.

This is not just my opinion, these are the facts. Let me read you a few of the most recent statistics on this point.

According to the Employment & Training Administration, a person with a bachelor's degree earns a million dollars more over a lifetime than a person with a high school diploma and a person with an associate's degree will earn an average of a half million dollars more than a person with high school diploma.

According to the Current Population Survey, those with a bachelor's degree had less than half the unemployment rate of people with only a high school diploma during 2000.

According to the U.S. Department of Labor, occupations requiring at least a bachelor's degree are expected to grow 21.6 percent and those requiring an associate's degree are projected to grow 32 percent.

Recognizing the national importance of investing in the education of our young people, I, along with other members of this committee, have continued to push for a federal education budget that reflects the needs our schools have in educating our future workforce. Year in and year out, these efforts have been met with great resistance by the Administration. Despite this fact, this President continues to claim education as a priority and takes credit for record increases in education spending. Again, let the facts speak for themselves.

In the three years that Bush has been in office, discretionary education spending has increased by a total of 14 percent. In just the last two years of the Clinton Administration, discretionary education spending rose by 40 percent. At the same time, since the passage of the No Child Left Behind Act, increases in spending have been going down while federal expectations for performance have been going up. What this indicates to me is that this President is only committed to investing in education reform when it is politically expedient for him to do so. Unfortunately, Mr. Secretary, that type of leadership is not what we need. We need a President whose promises last beyond the press conferences and photo opportunities.

This administration also claims that any cuts that are made in education programs are part of a overall, "better, more efficient government" economic strategy. In fact, on page two of your budget summary, Mr. Secretary, you state, that the Department of Education supports "the elimination of categorical programs and low-priority activities in favor of funding through flexible State grant programs created by the NCLB Act." As you may know, I was one of the 13 members who voted in favor of an education reform bill called "The Three R's," from which President Bush derived much of his education platform. One of the main principles of this bill was that federal resources in education needed to be consolidated into flexible state grant programs that reflected key national priorities. Consolidation is something I support.

But, once again, your actions do not match your rhetoric, Secretary Paige. Your budget does in fact call for the elimination of 38 categorical programs, such as Art in Education, Even Start, Education Research Labs, and Drop Out prevention, but you do not, as you indicate is your policy, shift these resources toward increases in the state grant programs created by No Child Left Behind. Instead, for the second year in a row, you flat fund two out of the largest, most important NCLB state grant programs, Teacher Quality and Innovation in Education, and recommend a level of funding for the 21st Century After School State Grant Program that is below the level it was in fiscal year 2002. It seems to me that the funds recouped from the elimination of these programs went instead to create 7 new programs that are more in line with the President's personal preferences and political agenda, such as the Choice Incentive Fund and Striving Readers program.

Finally, Mr. Secretary, I am sad to see that despite my stated concerns on the utility of education savings accounts for private elementary and secondary school tuition that they are again included in your budget. As I said last year, a $150 tax savings does not help a single mother of two who makes $30,000 a year to afford $15,000 in school tuition. In your testimony last year, you conceded this point. If we are sincere about helping low-income children trapped in failing schools, then we would be better to invest the $2.0 billion reserved for ESAs in serving disadvantaged students, teacher quality and smaller classes.

In summary, I am very disappointed by this budget. It is wholly inadequate to support the reforms that are underway in every state in the Nation at our request. We made a promise to our schools that if they went the distance and identified failure, we would be there to help them reform. This budget does not fulfill that promise.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you, Mr. Secretary and Senator Landrieu. I share the concerns of Senator Landrieu certainly as I look at this budget, and I just have a few minutes because Budget is meeting right now. I'm on that committee. But the overall funding levels in the 2005 budget request just don't meet the needs in our States as our States are struggling to try and meet the mandates of No Child Left Behind that I put on them.

I will submit my statement for the record, but I just want to echo what Senator Landrieu said. We are really shortchanging our students at a time when we need to invest in their education because we know that, as all of us worry about where the jobs are of the future, if our kids aren't educated, we're just not going to make it.

SINGLE SEX EDUCATION AND TITLE IX

So I'll submit my statement, but I do have a number of questions that I want to ask the Secretary while I have a few minutes here. And the first one, during the passage of No Child Left Behind, you will remember that we reached a bipartisan agreement on single-sex education, and in that we said that schools may provide single-sex programs as long as they are consistent with applicable law, title IX and the U.S. Constitution, and requires the Department of Education to provide guidance on that applicable law.

That law does not direct the Department of Education to change the title IX regulations, but yesterday you released the new proposal to amend 30-year-old title IX regulations on single-sex education. Current law single-sex programs allow such programs when appropriate, but contain protections against sex discrimination. The proposed regulations would dispense with meaningful, anti-discrimination protections and authorize schools to provide alternatives for girls that fall far short of equality. In fact, I believe that the No Child Left Behind would prohibit the adoption of the Department's new proposals.

In the press release announcing the change, you even admit that research on students' performance in single-sex education programs is inconclusive. It seems to me this is déjà vu all over again. In 2002 and 2003, the Department of Education spent hundreds of thousands of dollars to form a commission to look at title IX athletics regulations, and when it was all said and done, thankfully no changes were made to the law due to a strong, bipartisan, and grassroots effort to support title IX.

It seems to me that spending money and efforts on the Department—by the Department of Education helping States implement No Child Left Behind to close the achievement gap would be a much higher priority than throwing out longstanding anti-discrimination laws potentially broadening the achievement gap for our Nation's girls and boys.

Mr. Secretary, wouldn't you agree with me that the Department's efforts should be somewhere where we really need them to focus on right now?

Secretary PAIGE. Senator, with all due respect, I completely disagree with you. May I say first that the administration's position on title IX was brought together based on what the administration thought is best for the country, not because of pressure from any group. We studied the issue, we listened to the Nation speak, we considered all the information that they brought up, we considered their point of view and what we were trying to accomplish. We have great respect for title IX and what it has brought to our Nation, and we want to only build on that and make matters better.

So I don't want it to be viewed that the administration's output on the title IX issue resulted from pressure groups bringing pressure for one point of view or another.

Senator MURRAY. Oh, I don't think—I didn't imply that at all. But there was strong bipartisan support to—at that time, grassroots support that the commission listened to and ended up supporting title IX.

Secretary PAIGE. Well, that's——

Senator MURRAY. I don't call that outside pressure groups. I call it this country.

Secretary PAIGE. That was our goal, to listen to the country, and that's why we had an outstanding panel go around the United States and conduct hearings and listen to the country and take that into consideration. So our listening and taking into consideration is what brought us to the conclusion that we came to.

NO CHILD LEFT BEHIND AND SINGLE SEX EDUCATION

With respect to single-sex schools and single-sex classrooms, our view is that it expands opportunities for the development and achievement of No Child Left Behind as a goal. Many young girls—I met many of them in New York when I attended the Young Women's Leadership School, who felt that they were being left behind, and only were able to catch up because of the existence of that school.

So we are, without coercion, simply trying to expand opportunities for communities and systems who choose——

"SUBSTANTIALLY EQUAL" CLAUSE

Senator MURRAY. Mr. Secretary——

Secretary PAIGE [continuing]. To have an environment like that.

Senator MURRAY [continuing]. Let me just say that my concern is that under your proposal you use substantially equal rather than the protections that we have under title IX under No Child Left Behind. The term, substantially equal, concerns me a great deal.

Mr. JONES. Senator, the provisions in No Child Left Behind were obviously to reaffirm the protections of the Constitution, and the protections of the title IX statute itself, but also to recognize that the regulations under title IX are something at the discretion of the implementation or the implementers of the law within the public notice and comment process.

When those regulations were originally put in place, the limit of what was known about single-sex education was somewhat more narrow than it is today, but it——

Senator MURRAY. Well, but you even in your report say that the research is inconclusive. Mr. Secretary, I have a few other questions. Let me just say I am deeply opposed to your proposal.

Secretary PAIGE. Thank you. We would——

Senator MURRAY. The words, substantially equal, to any one of us who have been through this process for a lifetime——

Secretary PAIGE. Senator——

Senator MURRAY [continuing]. Leaves us with great concern——

Secretary PAIGE. We would——

Senator MURRAY [continuing]. For what the future's going to bring.

Secretary PAIGE. We would invite continued discussions with you around your concern.

Senator MURRAY. Okay. And I would, I'd love to have you come in and talk with me about this, but we will have further discussions. I think the term, substantially equal, leaves many of us very concerned.

Secretary PAIGE. We would welcome continued discussions.

EDUCATIONAL VOUCHER PROGRAMS

Senator MURRAY. All right. Let me ask you too, because the President's budget includes funding for vouchers, which were rejected when we had our long debates and battles throughout No Child Left Behind. At the end of the day, No Child Left Behind rejected vouchers, but the Bush budget again includes $50 million for the Choice Incentive Fund and $14 million for the D.C. voucher program, when even the Senate never voted on these programs.

I just don't understand how you can repeatedly abandon public education by giving just 1,700 students $7,500 to attend schools that are unaccountable to students and their families and the Department of Education, and meanwhile we can't even increase Pell grants for low-income students to help them, especially at a time when we know that getting education at a higher level is important.

It seems to me that we keep focusing on a narrow program, just as a matter of principle rather than trying to look at where we can put our dollars in a substantial way to help a number of students who are struggling today. And I know you and I disagree philosophically, but I remind you that when we debated the No Child Left Behind Act and passed that, the voucher discussion was an essential part of that, it was rejected at the end of the day, Congress said no, yet we keep seeing the Bush administration put money forward for it.

Secretary PAIGE. Senator, it's because we believe that it adds to the possibility of authentic school reform. We think that the proposals we put forth are to benefit public schools, not to detract from public schools. We think public schools, when bound in the kind of monopolistic organizational structures that they operate in now, that this penalizes them and constrains innovation and constrains creativity. And that is why we keep pushing for broader choice. We think in an environment with broad choice, public schools will prosper.

Senator MURRAY. Mr. Secretary——

Senator SPECTER [presiding]. Senator Murray, you're about 3½ minutes over now.

Senator MURRAY. Okay.

Senator SPECTER. How much longer would you like?

PREPARED STATEMENT

Senator MURRAY. Well, I have questions, a number of questions. I'll submit my questions for the record. I would just say that it seems to me when we have our debates within the No Child Left Behind Act, at the end of the day we agree on it, and then we keep seeing the budgets come back outside of what we all agreed on, for No Child Left Behind. It leaves all of us disconcerted.

Thank you, Mr. Chairman. I apologize for going over my time. I will submit my questions for the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Mr. Secretary, thank you for coming to talk with us today about the President's fiscal year 2005 education budget request. I am concerned about overall funding levels for education. Instead of providing real funding for critical education programs, the President robs Peter to pay Paul by cutting funding from some programs and adding it others, expecting it to count as an increase. Further, the President continues to fund unproven private school voucher schemes, but cannot seem to fund after school programs or provide increases for Impact Aid.

In fact, the President's budget only increases NCLB programs by $1.8 percent over the fiscal year 2004 Omnibus Appropriations bill—shortchanging the reforms included in the bill by over $9.4 billion. The level of Title I funding in the President's budget leaves more than 4.5 million low-income children behind. In Washington State alone, the difference between the President's request and the promise of NCLB means that over 27,000 low-income students will be left behind. Currently, secondary schools only receive 15 percent of Title I funds so we are shortchanging education at all levels when we shortchange Title I. I was pleased that the President wants to provide funding for math gains in secondary education, but we need to be putting real funding into our high schools. Our high schools need increase funding for literacy and counseling to ensure that our students have the skills and knowledge for true access to higher education and training.

The President's budget eliminates 38 programs including dropout prevention, elementary and secondary school counseling, smaller learning communities, and important literacy programs like Even Start. The President's budget request also freezes critical education programs, which is actually a cut in funding with increasing enrollments and other costs to run schools and programs. The President froze funding for Impact Aid, after-school, Teacher Quality, migrant education, and rural education. At a time when thousands of soldiers and reservists from Washington State—more than a 130,000 from around the country—are serving in Iraq and Afghanistan, I am shocked that this President would level fund Impact Aid instead of increasing funding to make sure their families are well cared for in our communities and schools. Further, funding after school at the President's request will mean 1.4 million students will be without a safe, adult-supervised environment after school.

The President's budget does not fully fund our share of special education costs, failing yet again to fulfill that commitment to our communities, our schools and our disabled students.

Under the President's budget funding for higher education programs continue to stagnate. The President should not punish students for increasing college costs by not increasing Pell grants.

We know what the needs are out there. We know what works to help our children succeed. That's why I'm so disappointed that the President's budget shortchanges America's students, and shortchanges our country in the long run.

Senator SPECTER. Thank you very much, Senator Murray. Senator Landrieu, I understand you have 2 minutes left.

PUBLIC SCHOOL CHOICE FUNDING

Senator LANDRIEU. Thank you. I'm going to try to get in two questions if I can. Mr. Secretary, to follow-up on my original comments, in your budget you make mention of the fact that there are 2.5 million children eligible for transfer to higher performing schools, yet the budget only reflects a $27 million figure for public school choice.

There is an additional $50 million for public school choice and private school choice, but only $27 million for public school choice. Just putting the pencil to it, at $10,000 a student, which in some areas may be too high, some areas may be too low, my math would say that we'd need to come up with $25 billion. So how did you all come up with the $27 million figure to help 2.5 million children who to date have been identified as eligible? How did we arrive at that figure?

Secretary PAIGE. Well, the $27 million you refer to is over and above the dollars available under the title I allocations, which each district has. So that is not limited to $27 million.

Senator LANDRIEU. But our title I, based on just the basic, is short $160 million, just the title I under Leave No Child Behind, and now in addition we have just in our State 35,000——

Secretary PAIGE. Is short? What do you mean by short?

Senator LANDRIEU. Shorted based on the commitment that this administration made to fund No Child Left Behind.

Secretary PAIGE. Please explain. I'm not sure I understand.

Senator LANDRIEU. Well, the Leave No Child Behind Act is about $9 billion short based on the agreement that was made, if reforms were put in, the resources would be there.

TEACHER CERTIFICATION

But let me ask my second question. Again on teachers, one of the points of No Child Left Behind that the White House insisted on, and I actually agreed to with some hesitation, was that all teachers would be certified by 2005. Now, I had 40 percent of my teachers uncertified, but I was willing to say, okay, in 3 years we'll get them certified, and the White House said, we'll help you do it.

I look at this budget and title II, teacher quality, is flat-funded. So what should I tell the 40 percent of my teachers that need to get certified?

Secretary PAIGE. You may say to them that this budget——

Senator SPECTER. Mr. Secretary——

Senator LANDRIEU. Could he answer the question?

Senator SPECTER. The time is expired, but you may answer the question.

Secretary PAIGE. You may say to them that, this budget has $5.1 billion in it to support teachers, and if the States decide to use those dollars for certification purposes, the flexibility is there to provide opportunities for them to do that, and the $5.1 billion to support teachers is historic in its level.

Senator SPECTER. Thank you, Senator Landrieu. Senator Hutchison.

STATEMENT OF SENATOR KAY BAILEY HUTCHISON

Senator HUTCHISON. Thank you, Mr. Chairman. Mr. Secretary, I applaud that you are coming forward with the regulations on single-sex schools as an option for public schools to be able to meet the needs of individual children in school districts. This is not a mandate. This is another option. If a school district, because of input from parents or principals or teachers, believes that they have behavioral problems or specific problems that single-sex classes or schools would address, they would have the option to do it.

SINGLE SEX EDUCATION

In the Washington Post this morning, there is the picture of Moton Elementary School that on its own decided to go to single-sex classes in 2001—2000 or 2001—and they are now—they were at the bottom of the achievement measures in the District of Columbia and now they're at the top, and they credit the opportunity

to have single-sex classes for doing that. It was 2001 that they started this program.

So yesterday you did come out with the regulations and you will have public comment, and I know, maybe there's a disagreement on the specific language, substantially equal, but the purpose was to assure that you could offer classes that are tailored to boys or girls and not have a requirement of equality when that would defeat the purpose of offering specialized courses.

So I applaud the effort that you are making, and this is the language in your regulations that are proposed: Single-sex classes will be permitted as long as they are part of an even-handed effort to provide a range of diverse educational options for male and female students, or if they are designed to meet particular identified educational needs.

So, Mr. Secretary, I hope you are going to pursue this. You have a 45-day comment period, which is expedited because if a school district wants to offer this option, they will be able to plan for the next school year. My question to you is this. Are you going to have funding under the title that allows for funding creative programs to help some of these schools implement these single-sex schools and classes?

Let me go further and just say that Houston is already offering in their public schools a boys school. Dallas is on the brink of offering a girls school and the headmistress of the finest girls school in North Texas, Hockaday School, has said that when she retires in July of this year, she is going to volunteer her time to create a girls school in the public school district, Dallas Independent School District.

So I am so happy that they are going to have this chance, and I would like to know if there will be grants available for people who are trying to be creative and offer these options to the people that attend public schools throughout America?

Secretary PAIGE. Thank you, Senator, and we are going to move forward with this. We are now awaiting the 45-day comment period. As soon as we receive those comments we're going to move faster, for the issues involve other agencies. The Justice Department was involved as well. But now it's in our court, so you can expect that we're going to move with dispatch with this.

Senator HUTCHISON. Will there also be grants available?

Secretary PAIGE. The answer is yes.

Mr. SKELLY. Senator, money is available under the State grants for innovative programs budget, a continuing grant program of approximately $297 million.

Senator HUTCHISON. Well, thank you, because, you know, so many schools—Secretary Paige, you visited the Young Women's Leadership School in Harlem with me, and that school is in a part of New York that has a very low rate of graduation and college attendance, and in fact, since that school was created, every graduate, every graduate has gone to college, every one. And 60 Minutes has interviewed those girls and they have applauded the opportunity that they have, so I just am very pleased that you are moving forward and it can't be fast enough.

I would say to my colleagues who are concerned about the language, why not try it? We have had failing schools for 25 years in

this country and we have had people throwing up road blocks to innovation and creativity, so let's try and see if we can work with this language. Nobody wants schools or classes to be inferior for boys or girls. This is America, so let's be creative, and I applaud your efforts in what you're doing.

It appears that my time is up, but I hope that we will finalize those regulations so school districts will have the option, not the mandate, to go forward with hopefully creative grants that will give us more knowledge about the benefits that can be given—gotten from creativity in our public schools.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Hutchison. Senator Kohl.

STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Thank you, Mr. Chairman. Secretary Paige, like many of my colleagues, I am also troubled by the funding levels in the President's budget for No Child Left Behind. We voted for that legislation because we believed it would provide a real chance for real reform. As you know, for the first time schools in States would be held accountable for results and the Federal Government promised that they would provide the dollars necessary to help them meet the new requirements.

NO CHILD LEFT BEHIND FUNDING LEVELS

Both the President and the Congress agreed to this and parents, teachers, principals, and administrators all expected that we would live up to our word. But now for the third year in a row, the President's budget falls short of the promise. His fiscal year 2005 budget request, as you know, is $9.4 billion short of what was discussed and we believe promised when the No Child Left Behind law was enacted.

You and the administration have stated that schools have plenty of money to implement the laws. Let me tell you just a little about what's happening in my own State of Wisconsin. In 2003, Mr. Secretary, Milwaukee public schools received an $8 million increase in title I funds, but the new requirements for supplemental services and transportation for students to better performing schools cost over $10 million. In other words, the new mandates cost $2 million more than the total increase the Milwaukee Public Schools received, and they had to make up the difference. To cover the costs, they were forced to eliminate their popular summer school program, which had served 17,000 students.

This is only one example. Across Wisconsin, school districts are being forced to cut staff and increase class sizes, cut music, art, foreign language education, and cut textbook purchases. Some have even had to keep their schools colder, believe it or not, to cut down on their heating bills, or restrict how many pages students can print from their computers. These are clearly not the results that we all want.

Problems exist also at the State level in Wisconsin. Our State Department of Public Instruction is working hard to implement the new law, but they believe they'll need more funding to create new data systems to meet new data collection and reporting require-

ments. They'll also need more funding for technical assistance teams to help schools and districts in need of improvement.

In a recent Washington Post op-ed, you argued that studies show that No Child Left Behind funding is sufficient. Many researchers, however, argue that you are underestimating the huge new cost that schools are facing. The President himself agreed to higher funding levels when he signed No Child Left Behind. He agreed that those authorized funding levels were needed to help schools succeed.

So I have a problem with people in my State who wonder what you would say in response to the statement that I just made.

AUTHORIZATION VS. APPROPRIATION LEVELS FOR NCLB

Secretary PAIGE. Senator, I'm confused by the word "promise," and I've asked clarification on that on many occasions, and some have pointed out that they view the authorizing level as a promise. And when I look up what that really means, I found that it means that you can spend no more, but it does not say that you must spend that much as a promise. In fact, I've been able to identify without much effort lots of examples where there's a difference between the appropriated level and the authorized level, and I have found that it has been consistent throughout various administrations, both Democrats and Republicans, where this delta appears. And this is the first time that I've been able to understand it being characterized as a promise.

The second point would be that my experience as a superintendent tells me that all these schools are under extreme pressure as far as funding is concerned. I know what the superintendent is doing now in Houston without even talking to her. She is preparing their budget, and she is wrestling with how they're going to take care of their health care costs or how they're going to take care of the transportation cost that is increasing.

We empathize with all of that. But that has nothing to do with the requirements of the No Child Left Behind Act. There was one State that even indicated that in order to meet the requirements of the No Child Left Behind Act that they would have to have a laptop computer for every student. I would be pleased to have a laptop computer for every student, but it has nothing to do with the requirements of the No Child Left Behind Act.

The budget that the President has proposed has ample dollars in it to meet the needs and the requirements of the No Child Left Behind Act, and as you know, the Act has language in it that says, if it isn't funded, it isn't required. That would be my response to it, but I don't want to be perceived as not being empathetic to the fact that all of these schools are under real tight budget constraints now, and we empathize with that. But compliance with the No Child Left Behind Act is not responsible for many of those cost elements.

Senator KOHL. Well, the President's budget in 2005 is $24.91 billion. The authorized—and we can debate what that meant—the authorized level was $34.32 billion. The difference there is almost $9½ billion. Now, I would agree with you the authorized level was not something that was legally put in that had to be met, but the implication was very clear to those of us who engaged in putting

together the law and signing it. You don't put a number in there unless you have some intention or some hope of seeing that number fulfilled.

As you know, yes, there's no legal requirement and we understand that and you're pointing that out. But clearly there is a perception out there, which I'm sure you can understand——

Secretary PAIGE. Absolutely.

Senator KOHL [continuing]. That we're being shortchanged, because that was the number that we put into that law.

RELATIONSHIP BETWEEN FUNDING AND ACHIEVEMENT

Secretary PAIGE. Could I just briefly say——

Senator SPECTER. Mr. Secretary, Senator Kohl's time has expired, but you may finish your answer.

Secretary PAIGE. I would just like to say very briefly that the assumption that there is a tight link between spending and student achievement has not been established. In fact, I can point out very easily many places where there is a very high average per-pupil expenditure and very low performance. Washington, D.C. public schools would be one example. I have examples here that I could provide for anyone who wants to have this information. There simply does not exist this tight correlation between those two variables.

In fact, I would go further and even say in some cases the argument about money may even be a destructive element in that it masks some of the real challenges that need to be discussed and looked at, and I have evidence of that in many places. But I don't want to be perceived as not wanting more money. I know the school systems want more money, and that's not my argument at all. I would like for them to have more money. My argument is that the requirements of the No Child Left Behind Act are sufficiently and amply funded in order to get those things carried out.

Senator KOHL. Thank you, Mr. Chairman.

Senator SPECTER. We've been joined by the distinguished ranking member, Senator Harkin.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you, Mr. Chairman. I apologize for being late.

WASHINGTON POST OP-ED BY SECRETARY PAIGE

I would just say, Mr. Secretary, that this budget, if enacted, will enact in the smallest increase for education in 9 years, shortchanges title I by over $7 billion, underfunds No Child Left Behind by $9.4 billion and eliminates programs like school counselors, arts and education, and drop-out prevention.

There's a lot more I want to say, but just a couple of statements I want to make here before I ask a question. You wrote an op-ed in the Washington Post that talked about Members of Congress: ". . . who voted for the law and support its ideals but now see opposition as being to their political advantage." That was your statement in an op-ed piece in the Washington Post.

Well, I hope you weren't referring to me, Mr. Secretary. I voted for the law, I was involved in the negotiations that led up to it as a member of the authorizing committee, but I do have concerns about how the Department is implementing it and how it's funding it, and these concerns come from dozens of conversations I've had with parents and teachers from Iowa. You visited Iowa recently. You heard the same concerns I did. Just because I'm trying to address them doesn't mean I'm, quote, seeking political advantage. I'm trying to represent my constituents. That, Mr. Secretary, is what they elected me to do.

Now, you and I have always gotten along well, Mr. Secretary, and I respect you personally. Believe it or not, you and the White House don't always have all the answers to all these questions. You might learn something from people in Congress on both sides of the aisle and sometimes from our constituents, even those who disagree with you.

UNSPENT FEDERAL EDUCATION FUNDS

Here's one bit of advice I'll give you, Mr. Secretary. Stop making claims that States have billions of dollars for No Child Left Behind at their disposal that they aren't bothering to spend. You and I both know from your own Department statistics the States are spending the money that they get from the Federal Government as fast as they can, and yet you wrote that States are not fully utilizing the Federal education funds available to them in a timely manner, allowing billions of dollars to remain in the Federal Treasury instead of improving the education of our children.

You know full well, Mr. Secretary, the States don't spend Federal money as soon as it's appropriated. It takes time. It's like the situation where you put an addition on your house. It costs $10,000, you don't pay for it all up front. You pay $1,000 and you may pay a little bit later on, then you pay something at the end of the time when it's over with. Schools work the same way. They agree to contracts but they don't write the checks until the services are provided. You know that, and yet you're accusing States of sitting on their money.

Our chief school officer in Iowa, Ted Stilwill, responded in a letter to you in January and said: "the implication that we have let huge sums of Federal money languish, that the funds are at our disposal to use at our discretion, or that we have not been good stewards of the public's money is not only unfair, but patently insulting."

RATE OF STATE SPENDING

According to the data from your own Department, States are actually spending their Federal money faster than expected. I have a chart from your Department showing that as of February 20, using normal spending rates, States should still be waiting to spend about 7 percent of their money from fiscal years 2000 and 2002. As a matter of fact, States have spent all but 6 percent.

So, Mr. Secretary, if you know that States are spending the money faster than your own Department expects them to, why are you criticizing them for not spending it fast enough?

Secretary PAIGE. Senator, I hope that I can explain that, that's not characterized as a criticism. It is a statement of fact that I asked our office early in December to give me a report, and early in December they did give me a report, about December 12 or somewhere nearby. The report they gave me indicated that there was better than $6 billion available that had been appropriated for various educational purposes that went all the way back to the year 2000. In fact, there are examples of some States who had money lapse that had been on the table so long that it was no longer available to them. So I was making that as a statement of fact, not as a statement of criticism.

Senator HARKIN. Well, facts are facts. They're stubborn things. This is from your own Department, Mr. Secretary, from your own Department.

Senator SPECTER. Senator Harkin, how much more time do you think you will need?

Senator HARKIN. Well, do we have another round?

Senator SPECTER. The Secretary has to leave at 11 a.m. and we have six people here, some superintendents who I would like to have him hear their testimony, but I don't want to cut you short.

Senator HARKIN. Well, I appreciate that, Mr. Chairman. This is very, very important because the allegation has been made by the Secretary, and I have the figures right here from your own Department, I have these figures. Now, yes, there is $6 billion, but as I said, Mr. Secretary, they don't spend this money as soon as they get it. They have 27 months in which to spend this money, 27 months. Obviously they haven't obligated yet. They're spending it as it goes out.

SPENDING RATE BY STATES OF FEDERAL EDUCATION FUNDS

Your Department expected, as I said, that 7 percent would still be unspent. They now have 6 percent left of the total amount of money, so they're spending it even faster than your own Department anticipated, and yet you say, and I'm only saying what you wrote, that they're not utilizing these Federal education funds available to them. I don't know how you explain this. I don't know how you explain it, Mr. Secretary. Whoever you asked for this gave you some very, very bad advice.

Senator SPECTER. Senator Harkin, would it be sufficient if the Secretary responded for the record?

Senator HARKIN. Yes, I would appreciate that, and as long as you're responding for the record, I would like to have the Secretary respond to the fact that there is $1.5 billion cut in the President's budget from fiscal year 2005 to fiscal year 2006, and I'd like to know where you're going to find that $1.5 billion.

Senator SPECTER. Will you respond for the record, Mr. Secretary?

Secretary PAIGE. Yes. I'll have Todd respond to the first point.

Senator SPECTER. Anything further?

Mr. JONES. Senator Harkin, the issue of draw-down——

Senator SPECTER. I want the response—I'm sorry, Mr. Jones—for the record because we're very short of time so we can honor our commitment to the Secretary to leave at 11.

[The information follows:]

UNSPENT FUNDS

President Bush and the Congress have provided unprecedented levels of funding to implement the No Child Left Behind Act (NCLB Act). In fiscal year 2002—the first year of implementation—funding for the Elementary and Secondary Education Act programs reauthorized by the NCLB Act increased by $4.6 billion, or almost 27 percent. Subsequent increases in fiscal years 2003 and 2004 have raised the total increase to $6.9 billion, or 40 percent, since the NCLB Act was signed into law. Nevertheless, many critics continue to insist that the new law is underfunded, and even cite this alleged underfunding as an excuse for not fully meeting the law's requirements.

In this context, the Administration and the Department believed it was appropriate to point out that States and school districts have not yet spent very significant portions of already appropriated Federal education funds. Our intention in publicizing the facts about these unspent funds was not to imply any wrongdoing or negligence on the part of State or local officials, but simply to show that there is a great deal of money in the pipeline, with about $6 billion remaining from 2000 through 2002 and billions more available from the 2003 and 2004 appropriations. The point is especially important because these balances contrast with the claims from some State and local officials about the inadequacy of these record Federal appropriations increases.

The availability of this very substantial, multi-year funding for the NCLB Act is important, because major provisions of the law are being phased in over time. For example, States were not required to implement the new reading and mathematics assessments in grades 3–8 until the 2005–2006 school year. Similarly, veteran teachers have until the end of the 2005–2006 school year to demonstrate that they are highly qualified. In this context, data showing that States and school districts are still drawing down 2002 funds simply provides another perspective that we believe helps demonstrate that the law is adequately funded.

As for the Senator's concern about 2006 funding levels for Federal education programs, I would note that outyear figures in the President's budget are primarily for planning purposes. The Department will begin developing its 2006 request later this spring, and that process will provide another opportunity to address concerns about the appropriate level of funding for fiscal year 2006.

Senator SPECTER. We've been joined by the distinguished chairman of the full committee, Senator Stevens.

STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Mr. Secretary, I'm very pleased to be able to get here today so I can express my appreciation to you for what you're doing and I think you're doing a marvelous job.

Secretary PAIGE. Thank you, Senator.

ALASKA'S EDUCATION CHALLENGES

Senator STEVENS. Your visits to Alaska have been really a breath of fresh air to deal with the challenges that we face in Alaska. We have one-fifth of all the land mass of the United States and we have over 750,000 people. We are committed to making No Child Left Behind work in Alaska, and thanks to you and what you've done, I think we'll be able to achieve that goal.

Our schools want to meet the high standards set forth in No Child Left Behind legislation and we're looking forward to working with you even more to find ways to bring that about. Unfortunately, as you found out, in too many of our schools English is the second language, and also, we have too many schools where we don't have any teachers right now because of the lack of teachers that are willing to go to the rural areas. Thankfully, you came up and looked and found, along with my colleague, Senator Murkowski, Lisa, who really deserves a lot of credit for what the two of you have done really in finding out one of the reasons they

weren't staying was because they didn't have adequate housing. I think you found one teacher living in a broom closet.

Secretary PAIGE. In a closet, yes, I did.

ALASKA NATIVE EDUCATION EQUITY ACT

Senator STEVENS. Now, we're anxious to work with you and I'm pleased that your budget contains funding for the Alaskan Native Education Equity Act. Those programs will bring opportunities to these native students who are out in rural Alaska, and we will meet the requirements of this bill by tele-education, by utilizing Internet and direct access. All of these schools are hooked up to the Internet now. We can have live presentations from qualified teachers with master's degrees and Ph.D.s in our Alaska universities throughout the State.

CAROL M. WHITE PHYSICAL EDUCATION PROGRAM

But your budget also contains continued funding for the Carol White physical education program, that is named after my former chief of staff who's now the longest living person after a brain tumor operation in the world. So we are delighted. This program really is a great joy to her to read about and I want to thank you for that.

PHYSICAL EDUCATION AND OBESITY

One of the things I would like to ask you about—as I try to move around the country and particularly around my State, we're moving forward in education, we're moving backward in obesity. Have you thought about doing anything more to bring the concepts of physical education and discipline to our schools to try to teach our children when they're younger about the basic essentials of exercise and diet?

I read—we all read every day more and more stories about how we are exceeding the world in obesity. I would hope it would be part of the educational program that you foster as you develop this No Child Left Behind to deal with the obesity factors that do affect the outcome of the education that we're seeking to give our children.

INCREASED NCLB FLEXIBILITY FOR RURAL AND SMALL SCHOOLS

Secretary PAIGE. Senator, thank you for inviting me to Alaska. We learned much there, and especially about the need to have more flexibility under the highly qualified teacher elements of the No Child Left Behind Act. We have provided some flexibility already, but you can expect in the next 10 days an additional announcement that will provide additional flexibility that is aimed primarily at helping rural and small schools meet the No Child Left Behind Act requirements.

EPIDEMIC OF OBESITY

With respect to obesity, we're very concerned about that. There's an epidemic of obesity, even in our young people. My colleague, Tommy Thompson, and I are in the process of discussing ways that we can be helpful. We are collaborating in developing some strate-

gies and some ways that we can try to stem what we think is a very dangerous, very dangerous trend that's going on now.

Senator STEVENS. Well, if you need any additional flexibility under existing law to deal with that, I hope you'll talk to the chairman or to me, because I think that one of the keys to the success of the No Child Left Behind Act is to develop children that are capable of retaining their education, and they can't do it if they're suffering from obesity, in my opinion.

Last, I want to go on record and invite you to come back, as a matter of fact. I was out in some villages and they told me to stay home and send you and Lisa back.

Secretary PAIGE. We'd enjoy it. We enjoyed our stay there and would enjoy going back again sometime.

Senator STEVENS. Well, I'm serious. There's some other things we'd like to work with you on to make sure this law works. I went to the State legislature this year. We have a strange procedure in Alaska. We speak to a joint session of the State legislature. And I told them: "We do not need your request to modify this law, we need your cooperation to work with Secretary Paige to make it work." So we—again, we thank you. I think you're doing a marvelous job, Mr. Secretary.

Secretary PAIGE. Thank you.

Senator STEVENS. Thank you, Mr. Chairman.

INCREASES IN THE FISCAL YEAR 2005 EDUCATION BUDGET

Senator SPECTER. Thank you very much, Senator Stevens. Senator Hutchison asked me to point out for the record that the President's proposal of $13.3 billion for title I grants to local education agencies is an increase of $1 billion, or 8 percent, over last year. The proposal of $11.1 billion for individuals with disabilities is an increase of $1 billion, or 9 percent, over last year. And the President's proposal of $73 billion for postsecondary student aid is an increase of $4.4 billion, or 6 percent over last year. And also that historically black colleges and universities have had an increase of 30 percent by 2005, nine such colleges in her State of Texas, and that for Hispanic-serving institutions, in fiscal year 2005 the request is $96 million, which is a significant increase.

TEEN SUICIDE

Mr. Secretary, I'd like you to answer one more question for the record and that is on the issue of teen suicide. In a small, rural Pennsylvania county, Potter County, there were three teenage boys who committed suicide and they did not appear to be linked in any way except that they were troubled youth who needed counseling.

In our committee report last year, we urged you to make availability screening programs more widely known and to encourage school districts to implement similar teenage programs. We have received a report, one page, which is, I think fairly stated, not adequate in response to that request or that issue and I would appreciate it if you would supplement that for the record.

[The information follows:]

SCREENING PROGRAMS FOR TEENAGERS

The Department is taking several steps to make school districts, juvenile justice facilities, and community-based organizations aware of and encourage them to use screening tests to detect depression, risk of suicide, and other mental health disorders in teenagers.

RAISING AWARENESS OF EXISTING PROGRAMS

The Department's Office of Safe and Drug-Free Schools (OSDFS) has worked with the Columbia University "Teen Screen" program (www.teenscreen.org) to make school districts more aware of tools that are available to screen students for depression, suicide ideation, and other mental disorders. The Columbia Teen Screen program was developed in 1999 by Columbia University and a range of national and community partners to identify youth who are at risk for suicide and/or suffering from undiagnosed mental illness, and to help them obtain appropriate treatment. The ultimate goal of the program is to ensure that all youth are offered a mental health check-up before graduating from high school.

In October 2003, staff from the Columbia University Teen Screen program made a presentation at the OSDFS National Conference. The presentation provided conference participants with an overview of the problem of youth mental illness; information about why it is necessary to screen for youth mental illness; information about the Columbia Teen Screen program, including how it has been implemented in schools and the results; and how participants can bring this program to their own schools. Several school representatives contacted the Columbia program after hearing about it through the OSDFS conference.

The Department will feature the Columbia Teen Screen program on the agenda for the April 2004 Safe Schools/Healthy Students Conference (scheduled for April 26–30, 2004) to promote the screening program. The Safe Schools/Healthy Students initiative is a discretionary grant program that is jointly sponsored and funded by the Departments of Education (ED), Health and Human Services (HHS), and Justice (DOJ), and supports local educational agencies and communities in developing and implementing comprehensive programs that create safe, disciplined, and drug-free learning environments and promote healthy childhood development.

In fiscal year 2003, ED and HHS awarded more than $161 million to 89 Safe Schools/Healthy Students grantees in communities across the Nation. These funds support locally developed comprehensive plans that address the following elements: (1) Safe School Environment, (2) Alcohol and Other Drugs Violence Prevention and Early Intervention, (3) School and Community Mental Health Preventive and Treatment Intervention Services, (4) Early Childhood Psychosocial and Emotional Development Services, (5) Educational Reform, and (6) Safe Schools Policies. The mental health element of the Safe Schools/Healthy Students comprehensive plan has a dual purpose: (1) to provide metal health preventive services early to reduce the risk of onset or delay the onset of emotional and behavioral problems for some children; and (2) to identify those children who already have serious emotional disturbance and ensure that they receive appropriate referral, treatment, and follow-up services.

At the Safe Schools/Healthy Students Conference on April 24, 2004, Columbia Teen Screen will present a session called "Suicide Prevention: Who's At Risk?" This workshop will offer an opportunity for Safe Schools/Healthy Students grantees and for grantees from the HHS Youth Violence Prevention and Mental Health Targeted Capacity Expansion Grants programs to learn more about the Columbia Teen Screen tool. This information may be particularly helpful to any grant site that has not already adopted a suicide risk screening tool, or is interested in learning more about other existing screening tools.

In addition to the specific workshop about the Columbia Teen Screen program, several of the other 232 workshops offered throughout the 3-day Safe Schools/Healthy Students conference will address the prevention of mental health issues in young people. For example, in another workshop that will be offered multiple times throughout the conference, the National Suicide Prevention Resource Center will address current issues in the prevention of youth suicide. The Rhode Island Department of Children Youth and Families will offer a session about youth with mental health issues who are transitioning out of the juvenile justice system. The National Mental Health Association will present a session about training communities around the language of mental health. These are just a few examples of the mental health disorder screening and prevention issues training opportunities that will occur at this spring's Safe Schools/Healthy Students Conference.

IDENTIFYING DISTRICTS FOR SCREENING PROGRAMS

The Department will also work with the Teen Screen program to identify school district sites where this type of program has a likelihood of success. Because resources are limited and as not all communities have to have the ability to provide mental health services to those who need them (which is a requirement of the screening program), advocacy for such screening tests needs to be targeted appropriately if it is to have the greatest possible effect. By way of example, the Columbia University Teen Screen program will provide assistance to applicants for Project SERV (School Emergency Response to Violence) grants. Project SERV provides education-related services to local educational agencies in which the learning environment has been disrupted due to a violent or traumatic crisis.

Since the beginning of the 2003–2004 school year, the Department has received requests for Project SERV funding from four school districts in response to student suicides: Three of the four districts experienced multiple suicides within a calendar year; the fourth district experienced a student suicide on campus during school hours. In each instance, the learning environment was severely impacted. Requested services for responding to each incident consisted primarily of student mental health screening; grief and suicide prevention counseling; and information sessions for parents, students, and teachers regarding suicide prevention. Columbia Teen Screen program staff members are in contact with three of these school districts about how their program services can help with some of the recovery efforts. OSDFS will continue to work with Columbia Teen Screen to identify other school districts that may be able to benefit from the program's resources.

HIGHLIGHTING SCREENING PROGRAMS IN GRANT APPLICATION PACKAGES

The OSDFS is reviewing relevant announcements for upcoming Department of Education grant competitions so that language about screening programs can be included in grant application packages where appropriate. For example, the Safe Schools/Healthy Students Initiative (discussed earlier) published a Notice of Proposed Priority for the fiscal year 2004 grant competition in the Federal Register on March 18, 2004. Under the proposed priority, grantees would be required to provide for school and community mental health preventive and treatment intervention services, which could include screening programs to detect depression and other mental health disorders. In addition, one of the proposed requirements for the competition is that grantees and their local public mental health authority sign a memorandum of agreement in which the local public mental health authority must agree to provide administrative control and/or oversight of the delivery of mental health services. This agreement also must state procedures to be used for referral, treatment, and follow-up for children and adolescents with serious mental health problems. Accordingly, we will include guidance in the application package to urge applicants to consider including screening for depression and other mental health disorders in their overall comprehensive plan.

ADDITIONAL STEPS

Over the next few months, we will pursue additional steps in this area. For example, we have discussed coordinating the Department's efforts on mental health screening with the HHS Center for Mental Health Services (CMHS). We understand that CMHS plans to support mental health screening activities with its own funds, and there is an opportunity to work collaboratively with them on this effort.

We will also make our Safe and Drug-Free Schools and Communities State coordinators more aware of what mental health screenings are, how they can be used, and the positive benefits they can have for youth so that they can disseminate this information to school districts and communities in their States. Toward that end, we intend to allocate a small amount of Safe and Drug-Free Schools and Communities National Programs funds this year to develop a short publication on mental health screening strategies that we would publicize and make available, for example, on the Department's world wide web site over the Internet as well as in print.

Senator SPECTER. We now have a second panel and five of our witnesses are going to be talking about the No Child Left Behind Act, so, Mr. Secretary, if you and your two colleagues would come up and sit on the panel here with us, it would be a good vantage point to listen to the witnesses, and it is my request, as you know, for you to hear what they have to say.

STATEMENT OF JAMES WEAVER, PRESIDENT, PENNSYLVANIA STATE EDUCATION ASSOCIATION

Senator SPECTER. I want to move now to the introduction of the first witness, Mr. Weaver, president of the Pennsylvania State Education Association, coordinator for the Social Studies Department at the State College Area School District, bachelor of science from Lockhaven College and master's from Pennsylvania State University. Mr. Weaver, your 5 minutes begin right now.

Let me ask Dr. Melissa Jamula, Dr. Jim Scanlon, Dr. Marie Slobojan, Dr. Paul Vallas, Mr. Sam Evans, and Dr. C. Delores Tucker also to take seats at the witness table. Thank you for joining us.

Mr. Weaver, I wanted the Secretary to hear what your concerns are about the No Child Left Behind Act.

Mr. WEAVER. Thank you, Senator Specter. I appreciate the invitation to be here this morning to share some thoughts regarding No Child Left Behind. I do especially want to thank you for inviting those of us from Pennsylvania who have been working back home in Pennsylvania to do our best to make every school a good school and provide quality education for everyone.

Senator SPECTER. This hearing responds to a meeting which was held earlier this week in southeastern Pennsylvania, so I called the Secretary and he graciously agreed to stay on to hear your concerns. Nothing like having the Secretary's ear, Mr. Weaver.

Mr. WEAVER. That's correct. Well, what I'd like to share with you really is not so much from the perspective of being president of the Pennsylvania State Education Association but really being a teacher and being a teacher who represents other education support personnel folks and other teachers.

NO CHILD LEFT BEHIND ACT

Really it deals with the frustration that educators have with the law, and quite frankly that frustration often brings my colleagues to tears when they see what is happening not only to their students in terms of the testing requirements but also to the quality curriculum that they feel is being abandoned as a result of the law.

There are a number of things wrong with the law and we believe many of the issues can be corrected, but the problem of a one-size-fits-all kind of approach for not only how students learn and how they can be assessed in terms of their proficiency, that is a fundamental flaw of the law and it's fundamentally wrong in what the impact is on the programs that are being taught back in our school.

Every child can learn, but also every parent and every teacher knows that every child does not learn at the same rate, does not achieve at the same rate, nor in the same way. I've had teachers tell me that the pressure on their schools to meet adequate yearly progress both in math and reading is so strong that they're pressured really to teach little else but what is going to be taught on the test.

We recently gathered a group of our members along with some administrators back in Harrisburg together to discuss the law. During the course of the discussion, several of the comments that were made I think are revealing. One teacher said the PSSA test is dominating my classroom. Each year as the stakes get higher I

spend more time on how to take tests than teaching my curriculum, and for those that may not be familiar, PSSA is the State-prescribed test in Pennsylvania that we use to demonstrate adequate yearly progress.

Another teacher said, and this is—well, it's just shocking—we have a gun at our heads. We must meet the requirements but we don't have the tools or the funding to offer the interventions that are proven to help children. Even our vocational technical school educators point out that they're not teaching all the important skills in many of their programs, their vocational skills, because they're now working to ensure that their students pass the math and reading test, and they believe they're sending out their students with less skills in their technology areas now than before the law was enacted.

Probably most important is a special education student—or teacher—said, important life skills curricula that are being sacrificed to teach to a test that really doesn't measure the identified goals of the IEP. But probably the most resounding and discouraging, disheartening statement that I hear a lot from my members is that they feel they're being set up for failure by No Child Left Behind.

PREPARED STATEMENT

I'm mindful of my time, so I'll say that educators don't object and do not fear accountability, but they do understand that trying to boil down the complicated process of educating a child to a specific test score is at best problematic, if not downright impossible. We believe that we need to remove the threat of No Child Left Behind and replace it with a helping hand, replace it with things like fully-funded programs that work, replace it with the encouragement of our teachers and our school support professionals and our administrators——

Senator SPECTER. Ten seconds left, Mr. Weaver.

Mr. WEAVER [continuing]. And our parents. Let's replace that, the threat of No Child Behind, with the encouragement of all those stakeholders in the education process.

[The statement follows:]

PREPARED STATEMENT OF JAMES R. WEAVER

Good morning Senator Specter and members of the committee. Thank you for inviting me here this morning. I especially commend Senator Specter for inviting those of us from Pennsylvania who are doing our best to make every public school a great one for our children. We have worked with Senator Specter for many years, and we know that you, Mr. Chairman, want what is best for our children.

I also commend the group of superintendents who showed great professional leadership by holding a news conference back in Pennsylvania this past Monday to draw attention to the failings of the No Child Left Behind Act.

Rather than repeat what I said at the news conference Monday, I'd like to spend my time focusing on what I'm hearing from the teachers and school support professionals about their frustrations with the Act.

And frankly, Senators, that frustration brings many of my members to tears when they see what is happening to their students and to the quality curriculum that is being abandoned as a result of this law.

There are a number of things wrong with this law—some of which can be corrected—but because it is focused on a one-size-fits-all approach for learning and for demonstrating proficiency, it is fundamentally flawed and it is fundamentally wrong in what it is doing to the programs in our schools. Every child can learn, but par-

ents and teachers know that all children do not achieve at the same rate and in the same way.

I have had teachers tell me the pressure on schools to meet Adequate Yearly Progress in math and reading is so strong that they are forced to abandon teaching anything other than what is to be tested.

We recently gathered together several of our members, along with school administrators to discuss this law. During the course of our discussion, one teacher said, "The PSSA test is dominating my classroom. Each year as the stakes get higher, I spend more time teaching how to take tests than teaching my curriculum." The PSSA is the state-prescribed test in Pennsylvania for demonstrating Adequate Yearly Progress.

Another teacher said, "We have a gun at our heads. We must meet the requirements, but we don't have the tools or the funding to offer the interventions that are proven to help children succeed."

Our vocational-technical school educators point out that they are not teaching all the important skills in many of their programs because they are working to ensure that their students pass the math and reading tests. They believe this law is causing them to send their graduates into the work force with fewer skills now than before this law was enacted.

A special education teacher had this to say: "Important life skills curricula are being sacrificed to teach to a test that does not measure the identified goals of the IEP."

The most resounding message that I receive from my members is that they have been set up for failure by NCLB. And that is very disheartening. Educators do not object to accountability. But they do understand that reducing the complicated process of educating a child to a specific test score is at best problematic, if not impossible.

Our National Education Association lobbyists have circulated to this subcommittee our recommendations specific to the education budget. I want to highlight briefly these points:

—Funds for Title I and special education must be funded at their promised levels, and

—The programs that work to improve student learning—many of which are eliminated by the proposed budget, must be continued and fully funded. These include Dropout Prevention, Gifted and Talented programs, School Counseling and Smaller Learning Communities. They all have a track record of success.

Before I end my remarks, I must mention the sanctions portion of the Act. Secretary Paige and his staff continually assert that the NCLB is based upon research.

One of the remedies for schools not making AYP is to convert them to charter schools. The law also allows for privatization of school services.

Where is the evidence that charter schools, that for-profit schools, that cyber schools, that private education services succeed in improving student performance? The evidence of the success of these so-called "remedies" does not exist. Yet these are the "remedies" for schools not making AYP.

We believe that if this Administration were interested in improving public schools for all children, if it were interested in making Great Public Schools for Every Child, it would focus less on punishment and more on what actually works.

It would provide the funds to reduce class size—especially in our schools which serve the most-difficult to reach students. It would provide initiatives for full-day kindergarten, and it would fully fund Head Start.

There is indisputable evidence that these programs make a difference in students' long-term success.

Frankly, Mr. Chairman and members of the subcommittee, I don't believe that the No Child Left Behind Act can be "fixed" as long as it is focused on punishment and abandonment and not on what will make our schools better for every child.

Our educators want a fair opportunity to show progress in their efforts. We need to remove the threat of No Child Left Behind and replace it with a helping hand. Replace it with fully-funded programs that work, and replace it with the encouragement our teachers, our school support professionals, our administrators, our students and their parents need to make our public schools great for every child.

Again, thank you for this opportunity to share my thoughts.

STATEMENT OF DR. MELISSA JAMULA, SUPERINTENDENT, READING SCHOOL DISTRICT

Senator SPECTER. We have to turn now to Dr. Melissa Jamula, superintendent of schools for the Reading School District. We'll put

your impressive curriculum vitae and statement in the record. Dr. Jamula, you have 5 minutes.

Dr. JAMULA. Thank you, Senator Specter, and thank you for the opportunity to speak with you today about No Child Left Behind. I would request that the testimony be submitted for the record.

As superintendent of a large urban school district, I strongly support the tenets that No Child Left Behind was created to support. I absolutely believe that all children can succeed and that public schools should be held accountable for that success. I believe that every child has the right to be taught by highly qualified teachers in a safe environment.

Those beliefs, as stated in No Child Left Behind, without question should be the hallmarks that drive our public education. But I also believe that there are specific mandates within the law that undermine the spirit of No Child Left Behind and truly discriminate against poor minority children and the schools that serve them, and I believe that Congress' willingness to address these mandates will be fundamental to whether or not No Child Left Behind goes down in history as a piece of legislation that significantly helped to improve the quality of education by all of America's children, or as legislation that derailed public schools.

READING SCHOOL DISTRICT

Today I would like to provide you with what I think to be a vivid example of how one school district is struggling without success to comply with the mandates of No Child Left Behind. I'm the superintendent of the Reading School District in Reading, Pennsylvania. Of the 501 school districts in Pennsylvania, we are the fifth largest. We have a diverse student body, 64 percent of our children are Hispanic, 19 percent are white, 15 percent are African-American, 2 percent are Asian or other nationalities. Of our student population, 12 percent are formally identified as students in the English language acquisition program and another 12 percent are formally identified as special education students.

About 3 years ago, the Pennsylvania Department of Education hired Standard & Poor's to compare data on the 501 school districts in Pennsylvania. In order for you to understand my grave concerns as they exist in No Child Left Behind, I need to have you please consider these facts about the Reading School District. Compared to the other 500 school districts in Pennsylvania, the Reading School District ranks in the 98th percentile for the percentage of students who are at or below the poverty line. We rank in the 99th percentile for children who have English as their second language. We are in the 100th percentile for mobility.

Last year, the Reading School District had 16,280 students. From the time we opened our doors in September until May 1, over 8,000 students either enrolled or disenrolled from one of our schools. We rank in the 100th percentile for our dropout rank. We rank only in the 1st percentile for adults in the community with a high school diploma, and conversely, in the 99th percentile for single-parent households.

We have a very needy student and community population, but although we are a poor community, we place high value on our children's education. The citizens of Reading make the highest local

tax effort in Berks County and are in the top 15 percent in the State of Pennsylvania, yet we're able to spend $2,000 less per student than the average. We have a $106 million general fund budget. If we could spend only the average of the State's spending per child, we could increase that budget by over $33 million. In truth, if we could spend what our neighbors directly to the north of us spend, we could increase that budget by $70 million.

To me it is unconscionable that in this country the quality of a child's education is determined by his zip code. For those who argue otherwise, I would ask you to consider these facts. Again, as compared to the other 500 school districts in Pennsylvania, the Reading School District is in the 93rd percentile for the number of students per teacher, the 92nd for classrooms with 30 or more children. We're in the 99th percentile for the number of students who need to share one computer. We're in the 99th percentile for students per administrator and the 88th percentile for our professional turnover rate.

We have many children with many needs, and as our teachers and our children are working so hard every day to close the educational gaps, these children have—when they enter our schools, they're being told by No Child Left Behind that they're failures.

Members of Congress, we know exactly what needs to be done to give these children the same opportunities as other children across the Nation.

Senator SPECTER. Dr. Jamula, you have 30 seconds.

PREPARED STATEMENT

Dr. JAMULA. Yes, thank you. But these initiatives will take tens of millions of dollars, dollars that we don't have. I urge Congress to fully fund the mandates of No Child Left Behind. I urge Congress to reconsider the mandates for the current method of evaluating and testing special education students. I urge Congress to reconsider the timelines established for the evaluation of children who are limited English proficient, and I urge Congress to consider to hold us accountable by instituting value-added evaluations for special education and limited education students.

[The statement follows:]

PREPARED STATEMENT OF DR. MELISSA JAMULA

Members of Congress: Thank you for the opportunity to speak to you today about No Child Left Behind.

As superintendent of a large urban school district, I strongly support the tenets upon which No Child Left Behind was created: I believe that all children can succeed; that public schools should be held accountable for their success; that we should focus special attention on children who have traditionally been underserved; and, that all children deserve to be taught by qualified teachers in a safe environment. Those beliefs, as stated in No Child Left Behind, without question, should be the hallmarks that drive our public education system.

But I also believe that there are specific mandates within No Child Left Behind that undermine the spirit of the law and truly discriminate against poor, minority children and the schools that serve them. I believe that Congress' willingness to address these mandates will be fundamental to whether No Child Left Behind goes down in history as a piece of legislation that helped to significantly improve the quality of education received by all of America's children, or as legislation that derailed the public school system.

Today, I would like to provide you with a vivid example of how one school district is struggling, without success, to comply with No Child Left Behind.

I am the superintendent of the Reading School District in Reading, Pennsylvania. Of the 501 school districts in Pennsylvania, we are the fifth largest, with approximately 16,700 students. We have a diverse student body: 64 percent of our students are Hispanic; 19 percent are white; 15 percent are African American; and 2 percent are Asian or other nationalities. Of our student population, 12 percent of the children are in a formal English Language Acquisition Program and another 17 percent are formally identified as special education students.

About three years ago, the Pennsylvania Department of Education hired Standard and Poors to analyze annually thousands of pieces of data, comparing the 501 school districts in the state. This analysis ranges from academic performance to finances to demographic data. In order for you to understand my grave concerns about meeting the mandates of No Child Left Behind, consider these facts about the Reading School District. Compared to the other 500 school districts in Pennsylvania, Reading School District ranks in the:

—98th percentile for the percentage of students at or below the poverty line
—99th percentile for the percentage of children who have English as their second language
—100th percentile for mobility (Last year, the Reading School District had 16,280 students. From the time we opened our doors in September, until May 1, we had over 8,000 children either move into or from one of our schools!)
—100th percentile for our drop out rate
—1st percentile for adults in the community with at least a high school diploma
—99th percentile for single parent households

As you can see, indicators suggest we have a needy student population. Although we are a very poor community, our community places a high value on our children's education: The citizens of Reading make the highest local tax effort of the 18 school districts in Berks County and rank 75th, or in the top 15 percent, in Pennsylvania. Yet, we are able to spend $2,000 less per student than either our county or the state average. We have a $106 million general fund budget. If we could spend the average of what our peers spend, we could increase that budget by over $33 million! In truth, if we could spend what our neighboring school district directly to the north spends, we could increase our budget by $70 million. To me, it is unconscionable that, in this country, the quality of a child's education is determined by his zip code. For those who would argue otherwise, I would ask you to consider these facts. Again, compared to the other 500 school districts in Pennsylvania, the Reading School District ranks in the:

—93rd percentile for the number of students per teacher
—92nd percentile for classrooms with 30 or more children
—99th percentile for the number of students per computer
—99.8th for students per administrator (meaning, of course that we have one of the leanest administrative staffs in the state)
—88th percentile for our professional turnover rate (Our starting teacher salaries are approximately $10,000 below both our county and state averages.)

In spite of these numbers, I believe we have an excellent school district. I say that not only as the superintendent, but as a parent whose child is thriving as a junior at Yale, due largely to the educational foundation she received in the Reading School District.

But we have many children with many needs. And, as our teachers and our children are working so hard to close the educational gaps these children have when they enter school, they are now being told that they are failures according to No Child Left Behind.

Members of Congress, we know exactly what needs to be done to give our children the same educational opportunity to succeed as other children across this nation. Given the resources, we would increase the length of the school day and the school year, we would institute all day kindergarten, we would significantly reduce our class size at every level for all children and would assure that children who have English as their second language are in classrooms with not more than 15 children, and are taught by teachers and assisted by aides who both are truly bilingual, so that these children learn English, but not at the expense of their education. We would provide smaller class sizes, more intense interventions and year round school for our special education students. We would use technology as an effective educational tool to meet the varied needs of our students. And that's just the beginning.

Our schools that have been placed in Year One of School Improvement under No Child Left Behind have complied with a mandate under this law and have written school improvement plans. They have written these initiatives into their plans.

But these initiatives will take tens of millions of dollars; money we don't have; money that has not been provided through the enactment of No Child Left Behind. Although our federal funds have grown by about $6 million since 1999, given our

growth in student population, which consistently is between 300 and 350 students a year for the past 15 years, and, given the profile of the children who are entering our school district, we actually are able to spend two dollars less per eligible child using federal funds than in 1999!

I urge Congress to fully fund the mandates of No Child Left Behind, so that our children, all of our children, are given the educational opportunities they deserve.

I urge Congress to reconsider the mandates for the current method of testing special education children and I urge Congress to require that No Child Left Behind mandates are consistent with the mandates of IDEA.

I urge Congress to reconsider the timelines established for the evaluation of children who are limited English proficient and develop evaluation methods for these children that are consistent with bodies of research that speak to the number of years it takes for a child, particularly for a child of poverty, to adequately develop academic vocabulary.

I urge Congress to continue to hold public schools accountable for the achievement of both special education children and children who are limited English proficient by requiring value-added testing, designed to show the academic growth that each of these children makes each year.

Members of Congress, while I speak from the point of view of a superintendent in an urban school district, it is important for you to know that many of my concerns are shared by superintendents of some of the wealthiest, most academically successful school districts in Pennsylvania. Recently, 138 superintendents, from a 14 county region in Pennsylvania, signed their name to a position paper relative to No Child Left Behind, which I have included with my testimony.

I thank you for your time today and I urge you to honor the intent of the No Child Left Behind law by addressing the mandates within this law that will surely undermine its effectiveness.

Senator SPECTER. Thank you, Dr. Jamula.

STATEMENT OF DR. JAMES SCANLON, SUPERINTENDENT OF SCHOOLS, QUAKERTOWN COMMUNITY SCHOOL DISTRICT

Senator SPECTER. Dr. Jim Scanlon, superintendent of schools with the Quakertown Community School District. We'll put your impressive curriculum vitae in the record.

Dr. SCANLON. Yes, thank you very much. I'm here speaking on behalf of the superintendents from 138 school districts representing 14 counties in Pennsylvania, including those suburban counties around Philadelphia and near our capital of Harrisburg.

NO CHILD LEFT BEHIND ACT

It's extremely rare that an issue has the power to galvanize and unite districts so solidly. In fact, I've never known one issue to arouse so much concern and unity. These districts are committed to educational excellence, quality instruction, and accountability for results, all qualities that No Child Left Behind Act strives to promote.

Each of us supports the concepts of high standards, using data for decision-making, creating school profiles and giving information to parents in parent-friendly language, again all goals of the Act. But there are three major concerns we have about this law. One, it's inherently unfair to special education students and conflicts with the Federal law, IDEA, Individuals With Disabilities Education Act. Two, it disregards the needs of students who demonstrate limited English proficiency. And three, it disregards the amount of time, funding, and resources to meet the requirements in the law.

Children with disabilities have to participate in their respective State testing programs. They're not designed for children who have

disabilities. Therefore, these tests do not accurately reflect their academic progress.

NO CHILD LEFT BEHIND ACT AND IDEA

No Child Left Behind and IDEA are two laws that are polarized. That is, IDEA says special education students are entitled to progress at different rates. No Child Left Behind says all students must progress at the same rate. IDEA says special education data sources tailored to a student's capabilities must be used to assess his or her progress, while No Child Left Behind says standardized test data must be used to assess progress. IDEA measures student progress against standards based on current levels of performance. No Child Left Behind measures progress against universal grade-level standards.

Basically, No Child Left Behind has no consideration for the special learning needs of special education students. We're being asked to answer to two completely contradictory Federal laws and our special needs students are caught in the middle.

LIMITED ENGLISH SPEAKING STUDENTS

No Child Left Behind requires non-English-speaking students to be assessed during their first year of attendance in school in the United States. In effect, these limited-English-speaking students are being forced to take a test many of them don't even understand. Research shows it takes 5 to 7 years for students to learn the language proficiently.

COSTS OF NO CHILD LEFT BEHING ACT

Many of our school district budgets receive between 1 and 2 percent of Federal money. Most of it comes in the form of title I funds, which is targeted for early childhood reading and math. No Child Left Behind forces us to spread the title I funds across our entire district, and although title I funds have increased, they have not increased in proportion to the number of children those funds are now supposed to cover. It's like giving someone a queen-sized comforter instead of a sofa throw but now asking them to keep 10 people warm with it instead of two. Someone's going to be left out in the cold.

Districts will also have to incur other costs because of No Child Left Behind. They include hiring and training professionals to meet highly qualified provisions, transportation costs for families exercising school choice options, additional infrastructure and staff for analyzing test scores, the cost of additional teachers and aides to provide remediation. The list goes on and on.

FLEXIBILITY FOR IDEA AND LEP STUDENTS

We're asking you to do the following to help us better educate and change what we firmly believe is destructive rather than constructive legislation. One, allow special education students' progress to be measured by the assessments in their individual education plans protected under the Federal law, IDEA. Essentially, allow IDEA to drive the evaluation of special education students.

Two, provide sufficient time and accommodations for assessing limited-English-speaking students, and I know Secretary Paige has addressed some of that recently. However, we believe one year is not quite enough. Give them more time to learn the language before they're tested.

PREPARED STATEMENT

Fully fund No Child Left Behind to support schools and districts. Study, analyze, collect data, and learn how much this law and its changes will really cost us, and then adequately fund it so that we can fulfill the requirements.

We'll continue to work to provide the best learning environments possible for our students and staff. It's our duty to point out the flaws in this law, and I hope you will work with us, not against us, toward the common goal of educating our children. Thank you for listening and learning with us.

[The statement follows:]

PREPARED STATEMENT OF DR. JAMES R. SCANLON

I am here speaking on behalf of the superintendents from 138 school districts, representing 14 counties in Pennsylvania, including those in suburban Philadelphia and near our capital of Harrisburg.

It is extremely rare that an issue has the power to galvanize and unite districts so solidly—in fact, I've never known one issue to arouse so much concern and unity.

These districts are committed to educational excellence, quality instruction and accountability for results, all qualities that the No Child Left Behind Act strives to promote. Each of us supports the concepts of high standards, using data for decision-making, creating school profiles and giving information to parents in parent-friendly language—again, all goals of the Act. BUT—there are three major concerns we have about this law:

1. It's inherently unfair to special education students and conflicts with the federal law, IDEA (Individuals with Disabilities in Education Act).

2. It disregards the needs of students who demonstrate limited English proficiency.

3. It disregards the amount of time, funding and resources to meet the requirements in the law.

Children with disabilities have to participate in their respective state testing programs—that are NOT designed for children who have disabilities—therefore these tests do not accurately reflect their academic progress.

No Child Left Behind and IDEA are two laws that are polarized—that is, IDEA says special education students are entitled to progress at different rates. No Child Left Behind says all students must progress at the same rate. IDEA says specialized data sources tailored to a student's capabilities must be used to assess his or her progress. No Child Left Behind says standardized data sources must be used to assess progress. IDEA measures student progress against standards based on current levels of performance. No Child Left Behind measures progress against universal grade level standards. Basically, No Child Left Behind has no consideration for the special learning needs of special education students. We are being asked to answer to two completely contradictory federal laws, and our special needs students are caught in the middle.

No Child Left Behind requires non-English speaking students to be assessed during their first year of attendance in school in the United States. In effect, these limited English speaking students are being forced to take a test many of them don't even understand. Research shows it takes five to seven years for students to learn the language proficiently.

Many of our school district budgets receive between one and two percent in federal money—most of it comes in the form of Title One funds, which is targeted for early childhood reading and math. No Child Left Behind forces us to spread the Title One funds across our entire district—and although Title One funds have increased, they have not increased in proportion to the increase in the number of children those funds are now supposed to cover. It's like giving someone a queen-size comforter instead of a sofa throw but now asking them to keep 10 people warm with it instead of two. Someone's going to be left out in the cold.

Districts will also have to incur other costs because of No Child Left Behind. They include: hiring and training paraprofessionals to meet "highly qualified" provisions; transportation costs for families exercising school choice options; additional infrastructure and staff for analyzing test scores; the cost of additional teachers and aides to provide remediation. The list goes on and on.

We are asking you to do the following to help us better educate our children and change what we FIRMLY believe is destructive, rather than constructive legislation:

1. Allow special education students' progress to be measured by the assessments in their individualized education plans, protected under the federal law, IDEA. Essentially, allow IDEA to drive the evaluation of special education students.

2. Provide sufficient time and accommodations for assessing limited English speaking students—essentially, give them more time to learn the language before they are tested.

3. Fully fund No Child Left Behind to support schools and districts—study, analyze, collect data, and learn how much this law and its changes will really cost us—and then adequately fund it—so that we can fulfill the requirements.

We will continue to work to provide the best learning environments possible for our students and staff. It is our duty to point out the flaws in this law, and hope you will work with us, not against us, toward the common goal of educating our children.

Thank you for listening, and learning with us!

Senator SPECTER. Thank you very much, Dr. Scanlon. As I said earlier, Secretary Paige has to leave at this point, but he's very graciously agreed to meet with all of you at 2 p.m. this afternoon in his office. I want to announce that there are others who have come from Pennsylvania—Dr. Jacob Dailey, who's the director of legal and external relations at the Chester County Intermediate Unit; Dr. Mary Lou Folts from the Tredyffrin/Easttown School District; Dr. Melody Wilt from the Chester County Intermediate Unit; and Dr. Mark Dietz from the Wyomissing Area School District. And those folks may be included as well, Secretary Paige.

I'll have one of my staffers take you over. Secretary Paige has to leave at this point, and we're going to interrupt the hearing for just a few minutes and we'll resume with the balance of the witnesses in just a few minutes.

Secretary PAIGE. Can we say thank you very much for your leadership and the opportunity to come and testify before you.

Senator SPECTER. You're very welcome, Mr. Secretary. The issues here are very important and I appreciate your open ear. It's good to have the Secretary's ear and even better to have the Secretary's pen, but you start with his ear. And what we're always doing around here, and you saw a number of Senators wanted to ask more questions, but we have so much time and so many commitments. But you have provided the very good safety valve, Mr. Secretary, by being willing to meet this afternoon, and for the record here, we'll continue to hear from the witnesses after a very brief recess.

I regret the interruption, but I had to address a veterans convention in Harrisburg. There's a great problem when somebody is selected to the Senate and he or she is not twins or triplets.

STATEMENT OF DR. MARIE SLOBOJAN, DIRECTOR OF INSTRUCTION, TREDYFFRIN/EASTTOWN SCHOOL DISTRICT

Senator SPECTER. I return now to Dr. Marie Slobojan, director of instruction, staff development, and planning at the Tredyffrin/Easttown School District. I'm sorry that you don't have the Secretary here, but you have—would you identify yourself for the record?

Mr. SIMON. Yes, I'm Ray Simon. I'm Assistant Secretary for Elementary and Secondary Education.

Senator SPECTER. And this gentleman is right in line with the issues, but you'll have the Secretary's ear, as I said earlier, at 2 p.m. Dr. Slobojan, thank you for joining us and we look forward to your testimony.

Dr. SLOBOJAN. Thank you for inviting us to discuss the impact of the reauthorization of the Elementary and Secondary Act in the Tredyffrin/Easttown School District. As you can see from the district profile that we submitted, Tredyffrin/Easttown School District is a high-performing K–12 district as determined by multiple measures of performance, including scholastic aptitude tests, educational record tests, and advanced placement standardized tests.

We consider the SAT a particularly informative measure of our performance, because typically 100 percent of our students participate in this test. Our average daily attendance is 96.6 percent and we graduate 99.9 percent of our students. We take our responsibility to educate every child very seriously by setting and enforcing strong standards of accountability for our district.

The Pennsylvania School System of Assessment is the single academic measure of performance that defines the district's adequate yearly progress. Students must perform at the proficient or above-proficient level.

TREDYFFRIN/EASTTOWN SCHOOL DISTRICT

The 2002–03 Standard & Poor's report for our district states the following: Statewide, none of Pennsylvania's school districts report a greater proportion of test scores that meet or exceed State standards. Statewide, none of Pennsylvania's school districts report higher proportions of scores in the advanced performance level. Across the State, none of Pennsylvania's districts report a smaller proportion of scores in the below-basic performance level.

In spite of such an extraordinary record of meeting the needs of children, strongly supported by our community, the current version of the Elementary and Secondary Education Act has endangered the public school students in our district.

Point one, all students in our school district are currently experiencing a skewed educational program designed to ensure their success on the Pennsylvania assessments in mathematics and reading. Placing this emphasis on a single high-stakes test detracts from the rich curriculum and creative environment that promotes self-directed, lifelong learning that students in our district have come to expect.

Teachers within the district feel constrained by the narrow parameters suggested in the State curriculum. We believe that our compliance with this initiative results in our providing a regressive educational experience for our students.

Second, our district receives no title I funds. Therefore, any compliance action we take is funded from our local resources. This means that we redirect our funds from existing programs with demonstrated success.

Point three, in the 2002–03 school year, we were audited in our special education program and identified as having exemplary practices for the State of Pennsylvania. This year, we anticipate

that we will placed on the warning list for this special education subgroup. We believe that this will start our 6-year march to privatization in the Tredyffrin/Easttown School District.

NCLB ACT AND THE INDIVIDUALS WITH DISABILITIES ACT

We believe the principles of the No Child Left Behind legislation violate the instructionally sound framework of the Individuals with Disabilities Act. Principle one, children learn at different rates. Principle two, valid student assessment involves multiple data sets. Principle three, effective instruction and assessment is delivered at the student's instructional level. The result is that these students are experiencing stress, fear, and they risk being ostracized due to their inclusion in a federally labeled subgroup.

NCLB ACT AND LIMITED ENGLISH PROFICIENT STUDENTS

Point four, we currently have 111 English language learners speaking 29 different languages. The Federal requirements for testing are inconsistent with the research, which suggests it takes approximately 7 years for non-native speakers of English to acquire proficiency to perform on standardized tests.

During the testing period, students demonstrate anger and frustration. Students who are about to take this test feel as though they are forced to show that they will fail. The sense of failure has made it difficult to encourage students to learn English and to improve their proficiency. In effect, the law is having the exact opposite effect it was designed to promote.

Senator SPECTER. Thirty seconds left.

PREPARED STATEMENT

Dr. SLOBOJAN. I'll just skip to my concluding remarks. In order to effectively assess the progress of our students for the purposes of adequate yearly progress, please include multiple assessments, factor subgroups into an equation that weights their proportion within the school population as a whole, develop appropriate assessments and have comparable tests and standards across all States.

We ask you to amend the legislation to fairly assess the multiple dimensions of human intelligence and to respect the dignity of every student.

[The statement follows:]

PREPARED STATEMENT OF DR. MARIE SLOBOJAN

Honorable Senators: Thank you for inviting us to discuss the impact of the reauthorization of the Elementary and Secondary Education Act in Tredyffrin/Easttown School District.

As you can see from the District profile, Tredyffrin/Easttown is a high-performing K–12 school district, as determined by multiple measures of performance including Scholastic Achievement Tests, Educational Records Bureau tests and Advanced Placement standardized tests. We consider the SAT a particularly informative measure of our performance because typically 100 percent of our students participate in this test. Our average daily attendance is 96.6 percent and we graduate 99.9 percent of our students. We take our responsibility to educate every child very seriously by setting and enforcing strong standards of accountability for our district.

The Pennsylvania School System of Assessment, or PSSA, is the single academic performance measure that defines the district's Adequate Yearly Progress where

students must perform at the proficient or above proficient level. The 2002–03 Standard & Poor's report for our District states the following:

—Statewide, none of Pennsylvania's school districts report a greater proportion of test scores that meet or exceed state standards.

—Statewide, none of Pennsylvania's school districts report higher proportions of scores in the Advance performance level.

—Across the state, none of Pennsylvania's districts report a smaller proportion of scores in the Below Basic performance level than this district.

In spite of such an extraordinary record, of meeting the needs of every child, strongly supported by our community, the current version of the Elementary and Secondary Education Act has endangered the public school students in our district.

POINT 1

All students in our school district are currently experiencing a skewed educational program designed to ensure their success on the Pennsylvania assessments in mathematics and reading. Placing this emphasis on a single high-stakes test detracts from the rich curriculum and creative environment that promotes the self-directed life-long learning that students in our district have come to expect. Teachers within our district feel constrained by the narrow parameters suggested in the state curriculum. We believe that our compliance with this initiative results in our providing a regressive educational program for our students.

POINT 2

Our District receives no Title I funds. Therefore, any compliance action we take is funded from local resources. This means that we redirect funds from existing programs with demonstrated success to programs that provide remediation for state testing.

POINT 3

The 2002–03 school year audit of our Special Education Program identified our District as having exemplary practices. In 2003–04, we anticipate that we will be placed on the warning list for this special education sub-group, thus starting the six-year march to privatization for the Tredyffrin/Easttown School District.

We believe the principles embodied in the No Child Left Behind legislation violate the instructionally sound framework of the Individuals with Disabilities Act.

Principle 1.—Children learn at different rates.

Principle 2.—Valid student assessment involves multiple data sets.

Principle 3.—Effective instruction and assessment is delivered at the student's instructional level.

The result is that these children are experiencing stress and fear and risk being ostracized due to their inclusion in a federally labeled sub-group.

POINT 4

Currently we have 111 students in our English Language Learners program, speaking 29 different languages. The federal law requires that these students be tested in English following three years of tutoring in English. Research indicates that it takes a minimum of 7 years for a nonnative speaker of English to gain the proficiency level that translates into successful performance on most standardized tests.

During the test, students taking the assessment have demonstrated anger and frustration. Going through a test where only the directions were translated made the students feel as though they were forced to demonstrate what they did not know. Currently students who are about to take this test feel that they are forced to participate in an assessment they will fail. This sense of failure has made it difficult to encourage students to learn English and to improve their proficiency. In practice, this law is having the exact opposite effect it was designed to promote.

POINT 5

Pennsylvania's calculation of Adequate Yearly Progress places students in our Commonwealth at a disadvantage to students in other states. This disadvantage occurs because the proficiency in standards across the United States punish students in states where the standards are high. For school districts such as ours, that already meet the state's annual requirements, this concept is regressive. While other school districts have until the year 2014 to meet these goals, the high achievement of our district's students places us on the warning list if we marginally drop from the high standards that we currently achieve.

In order to effectively assess the progress of our students for the purposes of Adequate Yearly Progress we recommend the following changes.

1. Include multiple assessments of academic performance in the Adequate Yearly Progress formula.

2. Factor sub-groups into an equation that weights their proportion within the school population as a whole. In this way sub-groups would not carry the same weight as the entire school population.

3. Develop assessments that are appropriate for students with special needs and those who are English Language Learners. Use those assessments in the Adequate Yearly Progress calculation.

4. Have comparable tests and standards across all states for the calculation of Adequate Yearly Progress.

The Tredyffrin/Easttown community is proud of the public education that it provides for its students. We have always accepted responsibility and demonstrated accountability for the performance results of every student that we serve. We respectfully request amendments to the legislation to fairly assess the multiple dimensions of human intelligence and to respect the dignity of every student that is educated in public school districts across this nation. Thank you for your attention.

Senator SPECTER. Dr. Slobojan, we have your point and we thank you very much. Moving right down the table in sequence, sitting next to Dr. Slobojan is Mr. Samuel Evans. Mr. Evans is the founder of the American Foundation for Negro Affairs, a long list of accomplishments, being appointed by President Roosevelt. Was that Franklin or Theodore, Mr. Evans?

Appointed by President Roosevelt, I know it was FDR, as the coordinator of the U.S. Division of Physical Fitness. President Johnson appointed him as czar of the war on poverty. He's the founder of Youth City, the cooperative education extension service and the family of leaders.

Mr. Evans celebrated his 101st birthday last November. Sam Evans was older than Strom by a full month. Sam Evans is about the only man in America who could—who did refer to Strom Thurmond as one of the young guys.

STATEMENT OF SAMUEL LONDON EVANS, FOUNDER, AMERICAN FOUNDATION FOR NEGRO AFFAIRS

Senator SPECTER. Mr. Evans, we're honored to have you here, and you have wanted to meet with Superintendent Paige for some time. We're going to put your testimony in the record and this afternoon you're going to have a chance to meet with Secretary Paige. It's an honor to have you here, Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman. Let me say right away that I was up this morning around 3:30, 4:00 to be sure I get here because when Senator Specter calls me, I have to go. Let me say right away that I asked President Carter, when he was running for office, to set up the Department of Education. Everywhere I go I hear people talking about education. Nations of the world are rated on three things: what percent of that nation is educated; number two, what percent is economic secure; and number three, what is their behavior pattern and sense of values?

It is right here our behavior pattern and sense of values in education that is destroying America's democracy. America ranked 22 among the nations in science, mathematics, and education. It means then that the United States—21 nations in the world are greater educated than we are. It's because our behavior pattern and sense of values about education is contaminated with colonial concepts.

Every step of the way it is preventive rather than encouraging. Let's take one instance. When you put a power in the hand of an individual today, the success of a student on any level is no further than the pen or pencil of his professor teacher. He has that power. But that awesome power is the control numbers. If you take up the philosophy of education, take it up and study it, you'd be amazed at the—how many individuals understand the American—you see, for instance, goal from K to graduate school, you come out, they will believe in six things, six, and those six will aid the controlling power and harm the other group.

Number one, they believe in war, w-a-r, war. You keep the guns. Now you got population to deal with, we got to cut them up, cut them up into pieces, so therefore, number two, you believe in getting ahead of others rather than getting rid of the others. And number three, you believe in class distinction.

Senator SPECTER. Mr. Evans, you have 1 minute left.

PREPARED STATEMENT

Mr. EVANS. Number four, you believe in authority. I'm sorry that I come here today, but I'd be glad to talk to anyone. I want to end by saying this, that the American educational system must be purified. Thank you.

[The statement follows:]

PREPARED STATEMENT OF SAMUEL LONDON EVANS

The Frontiers Of Knowledge In: Integrated Concepts Of Science, Philosophy And Education Is Eliminated From The Established Schools Of Learning That Propagates Specialization. Therefore, The Curriculum Is Limited To Only "One" Of The Following Subjects:

1. Philosophy Of Education
2. Basic Concepts And Modern Physic
3. Theory Of Values
4. Nature Of Mathematics
5. Anthropology
6. Astronomy
7. Paleontology
8. Stars And Nebulae
9. The World Of Crystal
10. Direct Implicit In The Structure Of Earth
11. Gestalt Psychology
12. The Nature Of Aesthetics
13. Signs Symbols And Personalities
14. Laws Of Density
15. The Nature Of Meteorology
16. The Nature Of Etiquette

In This Connection, Students Who Are Limited To: "Only One," Of The Above Subjects, Are Recognized As "Educated Models," However, The AFNA Program Serves In Two Or More Capacities:

ONE.—"The AFNA Plan," Prepares The Student To Meet The Academic Requirements Of The School He Or She Attends, In Order That They May Pursue Professional Careers In: Medicine, Law, Computer Science, Business And Commerce, To The Humanities.

TWO.—Beyond This, "AFNA Students" Are Privileged To Learn And Study The Entire Basic Structure Of: The Frontiers Of Knowledge, In Integrated Concepts Of: Science, Philosophy And Education.

THREE.—Professors And Educators, Will Lecture In: One Of The Above Subjects . . . In This Connection, The Students Will Receive A Copy Of Each Lecture And Required To Take It Home For Study And Review . . . Students Then, Are Required To: Rewrite The Lecture, With The Cooperation Of Their Parents And Qualified Neighbors, All Assisting The Student . . . "He" Or "She" Will Then Bring A Copy Back To Their Class For Evaluation . . .

Students Will Receive:
—Ten Points For Completion
—Ten Points For Spelling
—Ten Points For Neatness
—Ten Points For Format
—Ten Points For Clarity And Etc.

Means, The Total Experience Will Bring Academic Surroundings Back Into The Home And Made Available To Family And Community, For Study And Review . . . With The Desire To Expand The Concept Of Academic Scholarly Learning in The Home And Community Level.

FOUR.—In This Connection, Students Are Required To Keep Copies Of Each Lecture For Their Files . . . For It Is Hoped That Each Student Will Complete Written Studies Of: "The Sixteen Subjects, From 7th Grade, Through High, College And Graduate School . . ." Indeed, Such An Achievement; Would Place Students On That High Rarefied Academic Platform, That Holds Less Than 7 percent of The World's Scholars.

FIVE.—AFNA Is Not A School, College Or University. AFNA, Is A Supplementary Schooling Institute . . . Working And Preparing Students To Meet Their Academic Qualifications, In Cooperation With Academic Schools Of Learning. Together, AFNA, Universities, And Colleges, Work To Obtain The Needed Funds From: Federal, State, City And Philanthropists; To Eliminate The Dismissal Of Students For Tuition Deficiencies.

The Need To Eliminate, "BAR AND BOARD'S FAILURES," Based On Academic Deficiencies, Of Which The Students Have Already Obtained And Qualified Through Their Graduate Schools Of Learning.

SIX.—Beyond This, AFNA; Requires That Each Student Be Given A Copy Of: "The Declaration Of Independence," For Each To Study, Learn, And Recite . . . For It Represents The Basic Roots And Meaning Of: "The American Form Of Government" . . . Which Has Been Largely Eliminated In Schools Of Learning.

Today, At This Writing 2004; 5th Of January, Humanity Is Divided Into A Multitude Warring Camps . . . With Each Group Fighting For Their Individual Advancement, Based On The Concept Of The Fastest Draw.

Yet, Humanity Is 99.9 percent The Same, The 1 percent Difference Is Environment, Culture And Ethnicity . . . However, "The AFNA Plan," Is Based On The Concept:

"One God And One Humanity" . . .

"Seek Not Advantage Over Others, Seek Equality And Justice For All"

"Therefore, Democracy Is The Key, That Provides For Individuals, Or Groups, To Work Out Their Own Way Of Life, Without Fear, Or Without Hindrances And Without Destructive Attitudes Towards Others."

Therefore, No Race, Political Ideology, Religion, Commercial Enterprise Are Worth Saving, If It Destroys The Democratic Process Of Government.

"The AFNA Model," Students Learning In Cooperation With Parents, Guardians, Relatives, And Friends, Will Join The Other AFNA Graduates . . .
—750 Medical Doctors
—550 Lawyers
—96 PhD's
—4,500 College Graduates
And Many Other Para-Professionals In The Health Fields.

EVALUATION

[Mithras Group Ltd., Aaron N. Katcher, M.D., Chairman And Director, Of The Division Of Behavioral Sciences, University Of Pennsylvania]

Indeed, In Evaluating The AFNA Plan: We List Below The Following From: The Mithras Group Ltd., Aaron N. Katcher, M.D., Chairman And Director, Of The Division Of Behavioral Sciences, University Of Pennsylvania.

EXCERPTS OF THE EVALUATION (MGL) PROCESS

In This Connection, We Know; Doubt Comes From The Thought That You Could Be Doing Better. Well-intended, Even Satisfying Effort Is Not Always Effective . . . Are The Courses In AFNA The Right Ones, Should The AFNA Students Be Spending Their Time In A Laboratory, And Are They The Right Students For The Program?

The Above And The Following Doubts, Are Doubts About "The Model" . . . "The Plan" . . . Is It The Best Mode For A Supplementary Minority Education Program? In Describing, "The Model," We Also Described How We Displayed That Mode To A Succession Of Audiences In Pursuit Of Critical Commentary . . . The Meetings

Of The American Association Of Medical Colleges, The Conferences Of Educators With Interest In Minority Problems, Convened In Philadelphia And New Orleans. The Discussions, With Faculties Of The Participating Medical Colleges, And The Paper Presented To The Association For Higher Education In Chicago.

One.—In All Of These Meetings, "The Model"; Was Exposed For Evaluation, Amendment And Revision. No Substantive Suggestion For Change Were Offered. If There Were Anything Better Or More: The Participants In The Program Should Be Doing, Those Who Should Know, Were Silent About Describing What That "More" Might Be . . .

Two.—The Next Doubt, Was A Question About The Outcome Of The Program . . . That Goes Beyond The Know/edge Of Personall Success Of The Students We Have Known In The Program; The Kind Of Description Of Outcome That Goes Beyond Individuals, To The Abstraction Of Numbers.

The Numbers And Findings Have Been Gathered:

(A) 98 percent Of Those Completing The High School Phase Of The Program Go On To College . . .

(B) College Retention Rate Over All Four Years is 83 percent . . .

(C) 57 percent Of The Students Entering College, Graduate . . .

AND THE IMPORTANT BOTTOM LINE,

(D) 25 percent Of The Students Who Enter College, Go On To Graduate, Or To Medical School . . .

An Evaluation Of The Program Conducted In Cooperation With The Educational Testing Service Of Princeton, Demonstrated, The Program's High Retention And Graduation Rates From High School . . . This Record Was Achieved With Students, Whose SAT Scores Were Well Below The Average Goals For Students In College They Attended.

Therefore, The Evaluation Of "The Model" Presented Herein Has Met Every Test And Goes Over And Beyond The Usual And Previous Analytical Problems Of Leaders. Indeed, "The Model" Has Accomplished Its Purposes.

So In Conclusion, When The AFNA Students Have Reached The Requirement Of Their Profession, They Will First Direct Their Knowledge In:

"Building Security Of: The Family, Mother, Father, Guardian, And Country . . . The Very Roots Of Your Living And Being, To Meet Their Needs In The Sunset Of Their Life."

Indeed, Brothers And Sisters, Under This United Conviction, We:

"WOULD RATHER RIDE IN AN OX-CART, OR A COVERED WAGON IN A DEMOCRACY . . . THAN IN A ROLLS ROYCE, DRIVEN UNDER A DICTATOR."

Senator SPECTER. Thank you very much, Mr. Evans. Thank you for your profound statement.

STATEMENT OF C. DELORES TUCKER, FOUNDER, PHILADELPHIA MARTIN LUTHER KING, JR. ASSOCIATION FOR NON-VIOLENT CHANGE

Senator SPECTER. We turn now to Dr. C. Delores Tucker, founder and national chair of the National Congress of Black Women, also founder and president of the Bethune-DuBois Institute and the Philadelphia Martin Luther—Dr. Martin Luther King, Jr. Association for Non-Violent Change. She served as Pennsylvania's Secretary of State, attended Temple University and the Wharton School of the University of Pennsylvania. Thank you for joining us, Dr. Tucker, and I might add to your regular resume your leadership on education at Cheyney and other educational institutions.

Dr. TUCKER. Thank you so much. I can't say much about you because of the 5-minute rule, but nevertheless, to leave a child behind is to leave a child behind forever. We as a Nation can ill afford to allow ourselves to slip into a second-rate position in any area of global competition. The No Child Left Behind Act must be more than a slogan. It must be a reality.

Outsourcing is one of the problems that we're facing because we have not met up to that position of that child being educated. I'm going to say all of this to get to my time. There is a wealth of undeveloped talent languishing in the urban centers of America, but we

have the will and the vision to really tap into what this Nation needs, a tap into the brain pool of wealth. America would be assured of achieving educational superiority over all nations in this century.

COLLEGE FOR TEENS PROGRAM

The National Congress of Black Women, the Philadelphia Martin Luther King Association, of which you serve on our board with our mayor, Senator Specter, we have tapped into this brain pool of wealth with our College for Teens program, which grew out of our College for Kids program, 9 to 12 years of age, which began at the University of Pennsylvania 10 years ago, and parents said you can't drop them at 12 years of age, that's from 9 to 12. And so I said, what can we do? College for Teens. We approached you, and you recognized the need for training our young people early.

Thirteen months after I met with the president of Cheyney University, we cut the ribbon for 200 students to live on Cheyney's campus in the summer learning the work that they're going to have in the fall and being taught by the Princeton Review national organization, training them to learn the work that they're going to have in the fall, but also geared toward enhancing their SAT scores.

STUDENT PARTICIPANT OF COLLEGE FOR TEENS PROGRAM

I have one of the young persons here now that was a part of the second College for Teens program. We had 246 young people living on campus at Cheyney University this past fall—summer rather. And she's here today, and I want you to stand right here for a minute, quickly please, and tell him what your scores increased to when you went into the school and when you came out of the school.

Ms. DURSEY. When I started I had——

Senator SPECTER. Would you step forward and speak into the microphone? First, if you would identify yourself, please.

Dr. TUCKER. You have 5 minutes too, right? Yeah, 2½, 2½. I'll let the child speak.

Ms. DURSEY. Hi, my name is Nakeisha Dursey. I'm a Philadelphia student at the Philadelphia High School for Girls. When I first started the program my score was 1,140. When I left it was 1,400.

Dr. TUCKER. It was 1,100?

Ms. DURSEY. It was 1,140 when I started.

Dr. TUCKER. And then when you left?

Ms. DURSEY. It was 1,400.

Dr. TUCKER. 1,400. That's what we do. Her parents are here, her mother is here, and we have others that have come, but we just wanted to have a child speak with you today. The first year the Princeton Review provided SAT preparation classes for all program participants whose student achievement—well, I skipped so many pages I'm up to page 6—but the Martin Luther King Association for teens exemplifies your program, Senator Specter, your zeal for student achievement. One hundred percent of all graduating high school seniors from the 202—the 2002 MLK program successfully completed the college application process and were accepted into

college. And this last class, the 246th, we didn't have the money for it but we reached out to do it anyhow.

I'm saying as I close, I got so far down here I'm at the end—with the outsourcing of jobs overseas, education is no longer a domestic issue. It is now a global issue. No Child Left Behind must become the catalyst for success for all of America's students. The law meant to deliver on President Bush's campaign promise to improve public school education with specific regard to the substandard educational opportunities that have been historically offered to poor and minority students.

AFTER SCHOOL AND SATURDAY PROGRAMS

Clearly, Senator Specter, you have maximized the funding opportunities that we needed because this isn't just the summer program. We have an after-school program coupled with this where we make sure they stay ahead and they keep ahead of the courses and they have—they're great students when they go into school and they just say that we're bored now, we don't have everything, everybody wants to tell us—want us to tell them how to do things.

Well, we also have a Saturday program where they come in and enhance their computer skills and we give them a free computer, so we help them in every way, and we just want you to know that this year we hope to have 300 students on that campus and we've started another College for Teens at Capital College, which is right here in Maryland, and the Justice Department has said this is one of the model programs that they have seen in this country. Nowhere else is this program done, but it's a vision that I had because I've been raising and working for children all my life.

CHILDREN WITHOUT HOMES

When I was Secretary of State, I went up to school to get the kids registered. I got the voting age reduced from 21 to 18. I saw the gang coming into the high school. I said why do you travel with gangs? And you know what they said to me? And this is what I want to leave with you. They said, Dr. Tucker, you have to understand, the gang is our family and the street is our home. We wanted Gerard College, because where these children don't have homes, and too many don't, that's where the problem is, that's where the problem is. Those who do not have parents, like the little 6-year-old boy that was living with his mother, she was on drugs, father in jail, mother on drugs, Flint, Michigan, and they took him, put that boy into a home with his relative and that was a crack house. So he went to school one day in Flint, Michigan and killed a student who was 6 years old.

PREPARED STATEMENT

So we need to deal with the children who do not have homes, like Gerard College, and I would like to invite the Senate for you to bring a team up there. That's what Steven Gerard did in the 1800s. He was an orphan, and he said, in order to take these children and train them and make them the best that they are—and when I gave the graduation address there the other day, I cried, because I've never seen so many males walking in a graduation class, be-

cause 15 to 24, 60 percent of that age are in what I call the three-P: prison, parole, probation.

The last point that you always hear, this is a cost. It is not a cost. It is an investment. It's an investment that will take care of itself, and either we are going to educate or the other choice is incarcerate, and that's the cost.

[The statement follows:]

PREPARED STATEMENT OF DR. C. DELORES TUCKER

To leave a child behind now is to leave a child behind forever! We, as a nation, can ill-afford to allow ourselves to slip into a second rate position in any area of global competition. The No Child Left Behind Act must be more than a slogan; it must be a REALITY, if America is to maintain her position of influence and respect in the global community. The greatest power that America can amass at this juncture in history is BRAIN POWER!!! Even as we deliberate here today, many of our blue chip companies are OUTSOURCING jobs that require critical thinking and analytical skills as well as high-tech jobs because it is said that not enough students who graduate from our high schools, colleges, and universities have the academic prowess to perform efficiently and competitively. This is a sad commentary on the most powerful country in the world!

Every day and every week we are reading reports where America is losing its advantage because of a perceived lack of Brain Power on the part of our youth. Conversely, an excellent commentary on the world's leading nation is that congressional appropriations support public schools as well as comprehensive youth development programs that prepare students to succeed in any aspect of the American workforce, that is, congressional appropriations reinforce America's greatness!

I am here today to applaud and praise the Congress for the progress you have made in recognizing how important youth development programs are in maintaining educational excellence in our great nation. There is a wealth of under developed talent languishing in the urban centers of America. If we have the will and vision to really tap into this "Brain Pool of Wealth", America would be assured of achieving educational superiority over all nations, in this century.

The National Congress of Black Women and The Philadelphia Martin Luther King, Jr. Association for Nonviolence have begun, what we believe to be, a very unique program, in Philadelphia, Pennsylvania, to tap into this Brain Pool of Wealth. It is our College For Teens Program, which began in 2001 at Cheyney University, in Pennsylvania. It allowed low-income, first generation, minority students to experience the rigors of a college environment for six weeks. It features a three (3) pronged approach to student achievement:

1. An After-School Tutorial Program that focuses on direct instruction in language arts and mathematics;
2. Saturday Computer classes that bridge the digital divide; and
3. Summer College Residency Program that features a six to eight week college preparation program, where students live on the college campus and prepare for the SAT, receiving academic preparation from The Princeton Review professionals.

Longitudinal data reveal that The SUCCESSES of those students are phenomenal!

The first year The Princeton Review provided SAT preparation classes for all program participants, whose grades represented eighth through twelfth. THE AVERAGE GAIN IN PRE and POST SAT RESULTS WERE 140 points, as measured by The Princeton Review. This success was a direct result of the investment Senator Arlen Specter made in the public school children of Philadelphia.

In 2002, TWO HUNDRED STUDENTS participated in the Philadelphia Martin Luther King, Jr. Association for Nonviolence's College For Teens Program because Senator Specter is committed to early intervention for student success and he wants to close the achievement gap that presently exists between urban and non-urban student populations. Senator Specter is to be commended for raising the level of expectations for all of America's students so that America will bridge the digital divide and the student achievement gap. He has done this by thoroughly examining the tenets of all appropriation requests, ensuring that America's dollars will yield American success.

The MLK Association's College For Teens Program exemplifies Senator Specter's zeal for student achievement.

Examples:

—100 percent of all graduating high school seniors from the 2002 MLK program successfully completed the college application process and were accepted into college;
—School attendance in the targeted middle and high schools increased;
—Parent participation in school activities increased; and
—SAT scores measured average gains of 160 points.
Examples:
—In 2003—246 students were enrolled in the College For Teens Program representing grades seven through twelve;
—80 percent of the student population represented returning students; and
—SAT Scores soared an average of 200 points!

One high school sophomore, who is with me today, increased her 2003 SAT Score by almost 400 points!

Her mother and grandmother comprise 50 percent of the executive committee of her high school PTA, and she has maintained a 3. GPA throughout high school, and until today has a nearly perfect attendance record for the first two years of her high school career.

With the OUT-Sourcing of jobs overseas, education is no longer a domestic issue . . . it is now a global issue! No Child Left Behind must become the catalyst for success for all of America's students! The law was meant to deliver on President Bush's campaign promise to improve public school education, with specific regard to the substandard educational opportunities that have been historically offered to poor and minority children. Clearly, Senator Arlen Specter has maximized his funding resources to advance public education and community development in limited communities in Philadelphia.

In closing, Senators, I say to you, think for a moment what it would mean to America's future to have one million inner-city children involved in a program like this one. We must remember that education is not a cost but a lifetime investment.

Thank you.

Senator SPECTER. Thank you very much, Dr. Tucker.

AMERICAN FOUNDATION FOR NEGRO AFFAIRS

Mr. EVANS. Mr. Chairman, would you permit me to just have read—just mention a word about the AFNA program. I just want Dr. Cooper to come up and read about what AFNA is all about.

Senator SPECTER. Mr. Evans, we're running very late, but how much time would you need?

Mr. EVANS. Well, how much time do you think these kids are worth? What I'm saying is I took my time to come down here.

Senator SPECTER. Go ahead, Mr. Evans.

Mr. EVANS. Well, I'm saying. Wait a minute—where are you at, Cooper? Will you come up here? Are you here? Come over here? Okay, sit down there, Cooper. Let me say this, I want to say this. We are never going to solve a program in a colonial system where you don't permit to present what you're doing. Now, I put in some 75, 80 years in this work and real sincere, and I'm 100 years old and you're going to give me 5 minutes to explain my work.

So let me come here now and say this. I'm a resident of America, I'm an American, and I want to see America work. Now I want Dr. Cooper just to read just what AFNA's doing, read this.

Senator SPECTER. Would you identify yourself for the record at the start please?

Mr. COOPER. Reverend Jason Jerome Cooper, member of the AFNA staff. AFNA national education and research fund, AFNA is and AFNA is not——

Mr. EVANS. Louder.

AFNA NATIONAL EDUCATION AND RESEARCH FUND

Mr. COOPER. AFNA is a scholarship—is not a scholarship or loan-granting organization, a job placement agency, an organization that pays students for participation, a guarantee of admission to college and other professional schools set up to provide students with summer jobs. AFNA is a non-profit organization, national in scope with national headquarters in Philadelphia.

Mr. EVANS. You're reading the wrong thing, Reverend.

Mr. COOPER. Designed to assist students in pursuing professional careers in medicine, law, engineering, computer science, business through the humanities, through advanced academic tutorials and apprenticeships directed and supervised by the professionals. AFNA is working in conjunction with parochial——

Mr. EVANS. Reverend, will you just hold that? You're reading the wrong paper. Read the other paper, the paper about 14 things. You're reading the wrong paper.

Senator SPECTER. Mr. Evans, in another minute or two you'll want to chair this hearing.

Mr. EVANS. Well, I'm just saying that——

Senator SPECTER. You may have him read the other paper if you promise not to run for the Senate, Sam.

Mr. EVANS. We have turned out some 800 medical doctors, 700 lawyers.

Senator SPECTER. Go ahead, sir.

Mr. COOPER. Mr. Chairman, the paper that he's——

Mr. EVANS. You were reading the——

Mr. COOPER. I'm sorry. AFNA national education and research fund is beyond the concepts of specialization and the frontiers of knowledge: integrated concepts, science, philosophy, and education, by Samuel London Evans. The frontiers of knowledge in integrated concepts of science, philosophy, and education is eliminated from the established schools of learning that propagates specialization. Therefore, the curriculum is limited to only one of the following subjects: (1) philosophy of education; (2) basic concepts of modern physics; (3) theory of values; (4) nature of mathematics; (5) anthropology; (6) astronomy; (7) paleontology; (8) stars and nebulae; (9) the world of crystal; (10) direct implicit in the structure of earth; (11) gestalt psychology; (12) the nature of aesthetics; (13) signs, symbols, and personalities; (14) laws of density; (15) the nature of meteorology.

In this connection, Mr. Chairman, students are limited only to one of the above subjects that are recognized as educated models. However, AFNA program serves in two or more capacities. One, the AFNA plan prepares the student to meet the academic requirements of the school he or she attends in order that they may pursue professional careers in medicine, law, computer science, business and commerce, to the humanities.

Two, beyond this AFNA students are privileged to learn and study the entire basic structure of the frontiers of knowledge in integrated concepts of science, philosophy, and education.

Three, professors and educators will lecture on one of the 15 subjects before mentioned, and in this connection the student will receive a copy of each lecture and be required to take it home for

study and review. Students then are required to rewrite the lecture with the cooperation of their parents and qualified neighbors all assisting the student. He or she will then bring copies back to class for evaluation in completion, spelling neatness, and so on.

This means, Mr. Chairman, the total experience will bring academic surroundings back into the home and made available to the family and the community for study and review with the desire to expand the concept of academic scholarly learning in the home and on the community level.

Four, in this connection, students are required to keep copies of each of the 15 lectures for it is hoped that each student will complete written studies of the 15 subjects from 7th grade through high, college, and graduate school. Indeed, such an achievement would place the students on the high rarefied academic platform that holds less than 7 percent of the world's scholars.

Five, AFNA is not a school——

Senator SPECTER. You now have 1 minute left on the time allocated by Chairman Evans.

EVALUATION OF AFNA

Mr. COOPER. Let me then go to evaluation of the program by Dr.—by Dr. Katcher, The Mithras Group, Aaron N. Katcher, University of Pennsylvania. In this connection, we know no doubt—doubt comes from the thought that you could be doing better. Well intended, even satisfying efforts is not always effective. Are the courses in AFNA the right ones? Should AFNA students be spending their time in the laboratory or are they—are they right for the student? Is it the best model for the supplementary minority education program?

In describing the model, we also describe how we displayed that model to a succession of audiences in pursuit of critical commentary. The conference of educators with interest in minority problems convened in Philadelphia and New Orleans, and the Association for Higher Education in Chicago. They discovered at all of these meetings the model was exposed for evaluation. If there were anything better to be added from these various organizations the participants in the program should be doing, none present were able to——

Senator SPECTER. Reverend Jason Cooper, we have to move on. Thank you very, very much.

STATEMENT OF PAUL G. VALLAS, CHIEF EXECUTIVE OFFICER, SCHOOL DISTRICT OF PHILADELPHIA

Senator SPECTER. Dr. Paul Vallas, will you resume your place at the table? Thank you very much. We turn now to the distinguished chief executive officer of the School District of Philadelphia, Mr. Paul Vallas.

Prior to coming to Philadelphia, he was the chief executive officer for the Chicago public schools, and we were very lucky to kidnap him from Chicago. He received his undergraduate and master's degree from Western Illinois University, was in the Philadelphia Inquirer just this morning on the issue of single sex education separating young men and young women, and said he wasn't going to adopt it until he found community support, so that's a sage ap-

proach. Mr. Vallas, you've waited a long time. Now the floor is yours.

Mr. VALLAS. It's always a pleasure to follow my colleagues and, of course, the great Dr. Evans and the great Dr. Tucker. I'll be very quick because we've really covered just about the same territory. First of all, I'm a strong supporter of No Child Left Behind. I think No Child Left Behind is bringing the accountability measures that are long overdue, and I'm not afraid to test and I'm not afraid to disaggregate the data, because I think the disaggregation of data, while it's created a great degree of consternation among many, it's long overdue because it really identifies the underachievement that exists, not only in large urban schools but in rural districts and suburban districts and even some of the more affluent districts. And I think by focusing attention on those who are being underserved, I think it forces us to be held accountable.

NO CHILD LEFT BEHIND

You know, No Child Left Behind has four objectives. One is to provide children with more choices if they're in underperforming schools—oh, sorry about that. Should I start over? Just joking. Two, to provide supplemental education services for children who can have no choices other than their neighborhood school. Three, to reorganize those schools that are consistently academically failing. And four, to make sure you've got certified teachers.

Now, clearly, while all of these goals pose in many respects much greater challenges for smaller districts, particularly districts with only one to two school districts, these goals, at least among the larger districts, are achievable, and rather than to go into how we've worked to comply with those goals, I'll just refer you to my written testimony that I've submitted with the attached materials to the committee.

STANDARDS, CURRICULUM, AND TESTING

I will tell you this, though. In terms of testing and holding children to standards, I've always felt that if you understand what the standards are and your curriculum and instruction is aligned with those standards and the test that you subject your children to, are testing children to those standards, then every day that you deliver quality curriculum instruction, you are in fact teaching to the test.

So, you know, the—our move towards obviously embracing not only standardized tests but our own turnover test in our revamping of our curriculum and our aligning of our curriculum and instructional models to the State standards are increasing the amount of time on tests spent helping children learn to those standards providing supplemental services.

In our data-driven instruction, in which case we evaluate our children's progress every 6 weeks and then we make adjustments in that instruction so that we can do what we need to do to bring them to those standards. You know, I'm very comfortable with that. It certainly is creating a lot of consternation and a lot of anxiety, but, you know, that's good, because for far too long, at least in our school district, there has been so much underachievement and there has been a great degree of neglect.

NCLB ACT AND CHILDREN WITH DISABILITIES

I will say this. Like my colleagues, I share with them the concern over funding. Let me point out that there has been a 36 percent increase in funding, particularly, I believe, title I funding, and our district alone has received over $35 million in additional funding over the past couple of years. Clearly, the mandates—we need to be doing a better job to fully fund the mandates. We clearly need to be doing a better job to fully fund the special education mandate and I certainly think that some modifications are in order when it comes to the students with English language deficiencies, as well as with special education students, because I also agree with my colleagues that IDEA and No Child Left Behind seem to be in conflict, and I think the evaluation of special education children should really be driven by their individualized education plan.

PREPARED STATEMENT

But that said and done, you know, I think the—I think the act is a tool that sets clear, definable objectives, and I think it's an act that demands accountability. Certainly funding is an issue. Funding is always going to be an issue. Obviously that's where I will continue to focus my attentions on, but I do want to thank you for this opportunity to speak and to follow my distinguished colleagues. Thank you so much.

[The statement follows:]

PREPARED STATEMENT OF PAUL G. VALLAS

Good morning. Thank you Chairman Specter, Ranking Member Harkin, and other distinguished members of the subcommittee for this opportunity to appear before you today. When Senator Specter asked me to testify here today on Philadelphia's implementation of the No Child Left Behind Act, I was both honored and humbled to appear. And given Senator Specter's unyielding support of the School District of Philadelphia and of education in general, I was delighted to accept his offer.

Like any broad and sweeping reform of its nature, the No Child Left Behind Act has certainly drawn a great deal of attention recently. Passionate advocates both for and against the Act have filled the airwaves, the newspapers, and sometimes their own backyards with rhetoric espousing its virtues or deriding its failures. While there is certainly room for debate on the pros and cons of the Act, there can be little debate about this fact: there is simply no time to waste when it comes to setting high expectations for our children, providing the needed resources for children to meet these expectations, and holding adults accountable for achieving these expectations. As the head of America's sixth largest school district, it is my belief that the No Child Left Behind Act lays the groundwork for accomplishing these objectives, and I have made every effort to accomplish its mandates.

The chief objective of the Act is closing the achievement gap between majority groups and minority groups. The greatest tool that NCLB provides to achieve this objective—and, I suspect, the greatest object of consternation of some of my colleagues—is the disaggregation of test scores by subgroup. For the first time, we are able to shine a spotlight on groups that have been historically underserved. With this recognition comes our obligation to provide whatever resources we have to correct this historic imbalance, and the structure of the Act provides districts with the opportunity to do so.

The School District of Philadelphia has aggressively implemented all four phases of No Child Left Behind over the past two years. Those four phases are "Expanding Comprehensive School Choice Options," providing "Intensive Supplementary Education Services in Low Performing Schools," "Implementing a Rigorous Corrective Action Plan for Schools Not Making Adequate Yearly Progress," and "Aggressively Recruiting Highly Qualified Teachers." The handout you have been given, entitled "School District of Philadelphia: Programming to Implement No Child Left Behind Legislation" details what we have accomplished under each of these phases, but I would like to draw your attention to a few highlights.

Under "Expanding Comprehensive School Choice Options," you will note that the District has 176 out of our 263 schools identified as low performing schools. With that, over 45,000 students chose to enroll this year in schools outside of their neighborhood schools. But the District went beyond the limits of "choice" as a decision to be made between your neighborhood school and a "higher performing school." In addition to meeting the choice mandates of No Child Left Behind, we have also formed innovative new school-by-school partnerships with universities, museums, private managers, and even companies like Microsoft to manage and assist our lowest performing schools. We have also seeded our schools with magnet programs, International Baccalaureate programs, honors classes, dual credit offerings, and advanced placement courses to provide real choice to our parents. The School District has enacted a 300 percent increase in the number of honors and advanced placement courses, because we believe that closing the "high achievement" gap is just as critical as closing the "remedial" gap for our children.

Under the provision calling for "Intensive Supplementary Education Services in Low Performing Schools," the District has targeted assistance for over 40,000 Grade 1–9 students performing below grade level in reading and mathematics through the implementation of a comprehensive extended day academic program in all district elementary, middle, and comprehensive high schools during the 2003–2004 school year. The District has also implemented a comprehensive mandatory six-week summer school academic program in reading and mathematics for over 58,000 Grade 3–10 students not meeting promotion requirements or performing below grade level. The District has contracted with Voyager, Princeton Review, and Kaplan to provide the curriculum and the professional development for these programs.

The second part of your handout deals specifically with Supplemental Education Services, and I feel it is important to draw your attention to one problematic provision of NCLB here. As the briefing indicates, Pennsylvania has approved, and the School District of Philadelphia has contracted with, 20 providers of Supplemental Education Services. The District's Intermediate Unit (Pennsylvania's version of "Education Service Agencies") has also been approved as a provider, so services to low-achieving students through Voyager and Princeton Review can also receive funding under this provision. I cannot argue with the spirit of a provision that calls for parents to be able to choose between different providers for tutoring and support for their child, and I certainly support a free-market model that has these providers compete to provide the best services. But as the law stands, the price is in essence "fixed" as a percentage of a district's Title I budget, so very little can be done in terms of achieving the most amount of service for the most economical model. To put it simply, I as a superintendent was faced with the prospect of serving 12,000 students for 36 hours of instruction at $1,800 per child or serving 40,000 children for 160 hours of instruction at $300 per child. Wanting to serve the largest number of children, our District pursued the IU-provider model, and given that some of the providers in the Philadelphia area are making 60–70 percent profit on their services, I felt this to be the most prudent course of action.

Under "Implementing a Rigorous Corrective Action Plan for Schools Not Making Adequate Yearly Progress," the District has developed a mandatory, rigorous, and uniform K–12 standards-based curriculum, instructional delivery models, instructional materials, and aligned professional development system for low-performing schools. We have also implemented a uniform district-wide assessment system to complement the results from our state assessment to provide yearly benchmarks for district and school accountability. As your handout indicates, we have provided a number of additional resources to provide support for our schools lagging behind in AYP. This includes changes in the management, structure, and organization of low performing schools that cannot demonstrate improved performance; 49 failing schools in Philadelphia were restructured with private and charter school management, 22 comprehensive high schools have implemented 9th grade academies designed to narrow the achievement gaps of students below grade level in reading and mathematics, and a number of failing middle schools have been converted into neighborhood K–8 magnet and high school programs.

Finally, the District has wholeheartedly embraced the provisions requiring the "Aggressive Recruitment and Retention of Highly Qualified Teachers." Under our Campaign for Human Capital, the District hired over 1200 new teachers this year working with programs like Troops for Teachers, Teach for America, our retired teacher program, and aggressive recruitment and retention practices. Even in spite of a substantive class-size reduction in grades K–3, which necessitated the hiring of an additional 400 teachers, we met our hiring objectives and opened the school year with almost no teacher vacancies.

The School District of Philadelphia has chosen to aggressively implement the No Child Left Behind Act because its tenets are sound and its goals are clear: we must

do all that we can to ensure that all of our children are reaching their full potential. There is certainly room for improvement, however. While no one should deny that meaningful increases in federal education funding have been achieved under No Child Left Behind (a 36 percent increase since 2001), providing more Title I resources, which can be used rather flexibly to support proven successful practices like reduced class size and after school assistance, should be a priority. Providing transportation resources for choice programs, which for Philadelphia has meant more than $7 million in additional costs, would be a welcome assistance. Moving closer to a 40 percent funding of special education versus the current 18 percent funding is critical as disaggregated data shows how woefully inadequate our special education resources are. And complementing a standards and accountability movement such as the No Child Left Behind Act with a desperately needed school construction assistance program would be a smart investment in districts like Philadelphia whose walls have sometimes fallen faster than our test scores in past years.

While we can't shortchange our children by failing to fund reforms, neither can we hold their futures hostage by waiting for a never-ending funding debate to resolve itself. The School District of Philadelphia has demonstrated that substantial education reform can be attained by using existing resources to fund education priorities. In short, our philosophy is about sending all available dollars into the classroom. We will continue to use the tools provided us under the No Child Left Behind Act to accomplish this, and we will not allow excuses to get in the way of achievement. Thank you again for the opportunity to provide comment here today, and I welcome any questions you may have.

SCHOOL DISTRICT OF PHILADELPHIA PROGRAMMING TO IMPLEMENT NO CHILD LEFT BEHIND LEGISLATION

EXPANDING COMPREHENSIVE SCHOOL CHOICE OPTIONS

Expand the opportunities for students attending the 176 identified low performing schools (total number of district schools is 263) to transfer to higher performing schools

Over 45,000 students choose to enroll in schools outside of their neighborhood schools:

—Sent 2003–2004 School Choice notifications to families of 127,499 students via mail; as well as posted information on the district web site, press releases, and public notices to the media.

—Over 3,000 students will transfer from the district's lowest performing, highest poverty schools for the 2003–2004 school year.

—Over 1,000 students transferred as part of a Regional Program for School Choice from the 10 lowest performing/highest poverty elementary schools during the 2002–2003 school year.

—Over 11,000 students participate in the district's voluntary transfer program from 132 racially isolated low performing schools.

—Over 11,000 students are enrolled in district magnet programs in 13 high performing middle and high schools (over the next five years a significant number of magnet programs will be introduced with as many as 15 added during the 2003–2004 school year).

—Over 19,000 students are enrolled in 46 charter schools (four new charter schools have been approved for 2003–2004, and an additional three new charters will open in 2004–2005).

Over 20,000 students are enrolled in the 70 identified new partnership schools (45 privately managed, 21 restructured by the district, and 4 new district charters) as part of the school reform process (over the next five years the number of partnership schools will continue to increase, with 10 additional schools added in 2003–2004).

Within the next five years, 11 new magnet high schools will be constructed (one in each academic region); 14 large middle schools will be converted to small neighborhood magnet high schools (during 2003–2004, 6 middle schools will begin conversions).

—Formed partnerships with universities (Drexel, Eastern, Holy Family, St. Joseph's, and Temple Medical School) to develop new management structures for low performing high schools.

—Formed partnerships with private and public institutions to enroll high school juniors and seniors in high performing college preparatory and school-to-career programs.

Within the next five years, 30 low performing smaller middle schools will be converted into neighborhood K–8 schools with open enrollment for students living in that region.

INTENSIVE SUPPLEMENTARY EDUCATION SERVICES IN LOW PERFORMING SCHOOLS

Expand the opportunities for students attending low performing schools to receive intensified supplementary education services to significantly improve academic achievement

Implemented aggressively a school readiness campaign (Healthy Kids, Healthy Minds) for screening and health care support services for students prior to enrolling in the district's full-day Kindergarten program, and at appropriate grade levels in compliance with Commonwealth of Pennsylvania mandates (during 2002–2003, 75 percent of students screened for vision, 2003–2004 projection: 95 percent; during 2002–2003, 12 percent of students screened for dental, 2003–2004 projection: 75 percent).

Targeted physical and behavioral health care support and case management services for elementary school students who are performing below grade level, i.e., establishment/verification of insurance coverage, medical and dental care homes, behavioral health linkages as needed, and timely resolution of identified health problems (during 2002–2003, 72 percent of students had documented insurance, 2003–2004 projection: 95 percent).

Implemented a rigorous district-wide promotion/graduation policy as a means of identifying and supporting students performing below grade level.

Targeted assistance for approximately 30,000 Grade 3–9 students performing below grade level in reading and mathematics through the implementation of a comprehensive extended school day academic program in all district elementary, middle, and comprehensive high schools during the 2002–2003 school year.

Contracting with PDE approved providers to administer extended school day and summer programs including Voyager, Princeton Review and Kaplan Learning, 21 community based organizations in 11 Beacon School sites (serving over 1,300 students with 8 new sites in development), and 17 private providers (offering tutoring services to 4,538 students).

Implementing a comprehensive mandatory six-week summer school academic program in reading and mathematics for over 58,000 Grade 3–10 students not meeting promotion requirements or performing below grade level (12,000 students participated in 2002).

—Providing summer programs for over 5,000 English Language Learners and Special Education students.

IMPLEMENTING A RIGOROUS CORRECTIVE ACTION PLAN FOR SCHOOLS NOT MAKING ADEQUATE YEARLY PROGRESS

Develop and implement a rigorous accountability system that ensures academic improvement and sustained growth through a system of evaluating, monitoring, and providing assistance to low performing schools

Developed a mandatory, rigorous, and uniform K–12 standards-based curriculum, instructional delivery models, instructional materials, and aligned professional development system for low performing schools.

Implemented a uniform district-wide assessment system to complement the results from the state assessment system (Grades 3, 5, 8, 11 in reading, writing, and mathematics) and provide yearly benchmarks for district and school accountability.

—Over 128,000 Grade 3–10 students were assessed using the TerraNova in reading, mathematics, and science in the fall 2002 to set district, school, and individual student baselines for academic performance.

—Over 157,000 Grade 1–10 students were assessed using the TerraNova in reading, mathematics, and science in the spring 2003 to measure district, school, and individual student progress for academic performance from the fall 2002 baseline.

—Over 58,000 Grade K–3 students were assessed quarterly using the Dynamic Indicators of Basic Early Literacy Skills to measure and track individual student progress in fluency, phonics, and phonemic awareness.

—Over 58,000 Grade K–3 students were assessed quarterly using the Diagnostic Reading Assessment to measure and track individual student progress using running records.

Developed a rigorous district-wide school performance index to complement the state NCLB Accountability Plan by tracking school progress using a variety of indicators including the PSSA, the TerraNova, student mobility (the district average is 35 percent annually for each school), student, attendance, teacher attendance, persistence rates (the percentage of students who do not drop out of school before graduation), and promotion and graduation rates.

Implemented a rigorous school quality review process to evaluate the performance of the district's 85 identified lowest performing schools.

Wrote corrective action plans with mandated timelines and implementation strategies for the district's 85 identified lowest performing schools (this includes privatized, charter, and district restructured school models).

Designed and implemented a uniform process for school improvement planning for the 2002–2003 school year for all the district's 263 schools, based on the findings from the school quality review process.

Developed procedures for changes in the management, structure, and organization of low performing schools that cannot demonstrate improved performance.

Pre qualified up to 5 new private companies to manage additional low performing district schools.

Restructured 49 failing schools by implementing proven privatized and charter school models (over the next five years the number of privatized and charter schools will continue to increase, with 14 additional schools added in 2003–2004).

Restructuring failing middle schools by converting schools into neighborhood magnet K–8 and high school programs (during 2003–2004, 3 middle schools begin conversions).

Restructuring failing high schools by implementing a rigorous reform movement that includes converting schools that do not demonstrate improved performance into neighborhood magnet programs (during 2003–2004, 22 comprehensive high schools will implement 9th grade academies designed to narrow the achievement gaps of students below grade level in reading and mathematics).

Facilitated the implementation of the Accountability Review Council in cooperation with the School Reform Commission to meet the requirements of the district reform partnership agreement between the city and state governments (the ARC will certify the district's reform results and produce annual report cards measuring the progress of reform).

AGGRESSIVE RECRUITMENT OF HIGHLY QUALIFIED TEACHERS

Institute the Campaign for Human Capital, a blueprint for the recruitment, retention, and renewal of a highly qualified teaching staff

Utilizing alternative recruitment strategies including Teach America and Troops to Teachers (resulting in the hiring of 145 new qualified teachers).

Implementing an aggressive strategy to recruit qualified mathematics and science teachers through partnerships with local universities such as Drexel University and the Transition to Teaching Program.

Expanding the Reduced Class Size model from K–2 to K–3 classrooms to increase the district's pool of highly qualified elementary school teachers.

Preparing emergency certified teachers for the Praxis examination by offering classes at Holy Family, Temple, or using an on-line Praxis preparation course.

Expanding the district's pool of highly qualified elementary school teachers by assigning former literacy interns who have become certified to serve as stand alone teachers (it is anticipated that 250 new teachers will come from this pool).

Developing a competency profile made up of characteristics commonly possessed by the highest quality teachers as found by a variety of research methods, including surveys, focus groups, interviews, etc.

Implementing an aggressive marketing campaign to target segmented groups of high need teacher candidates (African-Americans, males, critical needs subject area candidates).

Implementing a training program to build the capacity of the recruitment team by exposing them best practices.

Designing "Leadership for Retention and Renewal" professional development program—that will equip them with the skills and strategies necessary to support all teachers (rookie, novice and veteran) in their schools.

Implementing a tuition reimbursement program for teachers beginning their second year in the district to continue professional development, thus providing an incentive for ongoing professional growth.

Implementing a comprehensive mandated pre-service training program all new teachers must attend to ensure their preparedness for entering our classrooms.

Establishing the position of New Teacher Coach to support newly hired at teachers at a 10:1 ratio.

Expanding the district's current incentive programs to attract highly qualified teachers to include a Teacher Ambassador Program called "Every Teacher, an Ambassador" which will provide a monetary incentive for identifying certified teachers and teachers in hard to staff positions.

Increasing the number of student teachers by offering a series of incentives to the student teacher as well as to the cooperating teacher.

Creating for the 2003–2004 recruitment season a "Roll Out the Red Carpet Campaign" strategy that will attract college juniors and seniors from our regional colleges and universities to learn about the benefits of teaching in our schools and living in Philadelphia.

Testing of all instructional paraprofessionals has begun and will continue until all paraprofessionals meet the requirements of the statute.

SES PROVIDERS

No Child Left Behind guarantees that students from low income families who are attending low performing schools will have access to tutoring services paid for by the School District of Philadelphia. The Intermediate Unit's program was recently approved by the State as one of these supplemental providers.

	Number of hours	Cost	Students served
SES Providers (47 approved by state)	36–40 hours total	$1,815 per student	12,500
Extended Day (using state approved providers)	160 hours	$300 per student	Upwards of 40,000

The District, as required by law, notified parents that they could choose to use the services of an SES provider by letter on October 24. The letter included a list of all the SES providers—as well as their phone numbers—that had submitted their paperwork to the District.

This letter followed up and reinforced an aggressive advertising program launched by the SES providers themselves back in August.

The SES advertising has been ongoing from August until today.

17,000 students improved their performance between the beginning of last year and the beginning of this year so that they have moved out of the bottom quartile, as measured by the Terra Nova. However, these students are still encouraged to take advantage of the District's Extended Day program.

Extended Day is being modified from last year to include an hour of instruction as well as an hour of enrichment activities Monday through Thursday. The curriculum for instruction aligns with state standards and directly supports the new standardized curriculum being taught in all classrooms throughout the District. The second hour, provided in conjunction with community based organizations, is optional.

There are 30,500 3rd through 8th graders in the District that can take advantage of the Extended Day program. In fact, the first hour of Extended Day is mandatory for students in grades 3, 8 or 11 who are scoring in the bottom quartile, as measured by the Terra Nova.

The objective of the District's Extended Day program is to provide high quality supplemental educational services to all the District's children.

To ensure that parents know about that they have this choice, the School District is sending letters home with students in 192 schools. Pursuant to federal law, low income families at the 192 schools qualify for supplemental services.

State approved providers have partnered with the District in order to provide the high quality Extended Day program. The providers include Voyager, Princeton Review and Kaplan.

Extended Day—which began October 17 for grades 3–8 and will begin on December 2 for grades 1, 2 and 9—is able to provide more hours of instruction and enrichment to more students than supplemental service providers can because they cost significantly less. For example, the average cost of Extended Day is about $300 per student for the 20 week program (up to 160 hours), while the law authorizes comparable supplemental services for $1,815 per student.

While the District supports the spirit and intent of the federal No Child Left Behind law, it intends to enforce academic and fiscal accountability. This will ensure that as many children as possible can have access to services.

Educational choice for parents and students is actually reduced when private companies are allowed to make unreasonable profits at the expense of students. Fewer students can be served and the quality of the program invariably diminishes.

Senator SPECTER. Thank you very much, Mr. Vallas. When you said the thing has already been said, that was a commentary of a very famous Congressman, Mo Udall, a Democrat from Arizona. He stood at a speech once after many speakers presented themselves and he said, everything has been said, but not by everybody. And

on Capitol Hill, it doesn't matter that everything has been said until everything has been said by everybody.

This has been a very informative hearing and I want to thank you for coming from Pennsylvania on short notice. When I saw the meeting which you had on March 1, just on Monday, it seemed to me that really ought to attract the attention of the Secretary and his expert in the field, Mr. Ray Simon. And the Secretary will meet with you at 2 p.m. and you'll have a little more time.

Everything that's been said has been transcribed in the record, and although the Senators come and go because they have many other committee assignments, the transcript will be read by staff and your words will be weighed, and I believe that there will be changes to No Child Left Behind. There will be modifications made as we go through the learning curve, and there will be more funding as well.

We have a very tight budget this year, which you all know, but there are many of us here who, as you said, Dr. Tucker, consider education an investment. It is not an expenditure, and when Mr. Evans outlines what he has done for AFNA, we have recognized that on the Federal funding for many, many years, as we have recognized what you have done, Dr. Tucker, and what you are all doing.

So thank you very much for coming. There is no higher priority on the budget than education and this subcommittee will pursue it with great diligence.

Dr. TUCKER. Thank you, Senator, too, for having us here.

STATEMENT OF SENATOR THAD COCHRAN

Senator SPECTER. We have received the prepared statement of Senator Thad Cochran which will be placed in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I want to welcome the Secretary and thank him for coming to testify before the subcommittee today, and for his outstanding service to our nation as Secretary of Education.

I appreciate the Secretary's attention to my state of Mississippi, which is also his home state. He has honored us with several personal visits.

I've visited with our State School Superintendent, and a good number of teachers, principals and parents since the passage of the No Child Left Behind Act. My impression is that our State has embraced the concept of accountability and is utilizing the new flexibility that is built into the programs.

I'm pleased to see the budget proposal for the Department of Education suggests increases of $1 Billion each for title I grants and Special Education grants to states. And, I'm pleased that continued funding is suggested for Ready to Learn Television, Civic Education, Character Education and other areas of importance. There are some areas in the budget proposal that eliminate programs that have been important to individual schools, teachers and assisted the State's efforts in meeting the requirements of No Child Left Behind. In particular, proposed elimination for the National Writing Project, Arts in Education, Gifted Education, STAR Schools, and Foreign Language programs for K–12 schools draw my attention. I'm concerned about those areas, and I know we'll work through the appropriations process and try to meet the needs and interests in my state and across the nation.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. 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

PENNSYLVANIA TITLE I FUNDING

Question. In Pennsylvania 233 of 500 school districts who receive Title I grants will receive less funding in fiscal year 2004 than they did in fiscal year 2001, the year before the No Child Left Behind Act was passed. As a former superintendent, what advice related to carrying out this important law do you have for the 233 districts in Pennsylvania that will receive fewer Title I funds in fiscal year 2004 than they did in fiscal year 2001?

Answer. My advice would be that as important as Title I funding is to local school districts, it is typically a small fraction of overall funding, and that the reforms in No Child Left Behind are specifically designed to leverage education spending from all sources, Federal, State, and local. So the question is not what can or cannot be done with a Title I allocation, which may be smaller or larger than it was the year before, but how can we better allocate all our funding to help ensure that all our students reach challenging State standards.

BUDGET REQUEST AND HIGHLY QUALIFIED TEACHERS

Question. Is the President's budget request for fiscal year 2005 sufficient to meet the requirements of the No Child Left Behind Act, such as to attract, train and retain "highly qualified" teachers, implement additional testing requirements, and provide more public school choice and after-school tutoring, in light of the reduction in Federal funding for these districts?

Answer. We believe Federal funding is more than adequate to meet the requirements of No Child Left Behind programs. As I mentioned earlier, success in meeting those requirements depends not primarily on a particular level of Federal support, but on making better decisions in the use of combined education funding from Federal, State, and local sources. I would add that when it comes to testing, the development and implementation of the additional assessments required by No Child Left Behind is separately funded through a State grant program, and the amount of this funding has been going up every year. In addition, not all districts are required to provide public school choice and supplemental educational services, just those in which schools have been identified for improvement, corrective action, or restructuring.

STUDENTS TRANSFERRING TO SCHOOLS NOT IDENTIFIED FOR IMPROVEMENT UNDER NO CHILD LEFT BEHIND ACT

Question. Based on available information and pending analysis of consolidated State applications and other State-reported data, the Department has reported that 5,000 schools have been identified for improvement and an estimated 2.5 million students are available to transfer to a public school that is not identified for improvement. How many of these students have in fact transferred?

Answer. These data will be included in the Department's forthcoming report on the implementation of key provisions in No Child Left Behind, which is scheduled for completion and submission to the Congress in late spring of this year.

TITLE I SCHOOL CHOICE

Question. What is known about whether eligible students and their parents are choosing to stay in their current school?

Answer. We do not have comprehensive data on this issue, but preliminary studies carried out by education organizations, as well as news reports, suggest that the great majority of students eligible to transfer to another public school do indeed stay in their current school. Sometimes this is because parents and students are more comfortable in their neighborhood schools; in other cases it may be that parents are encouraged by improvement efforts or other special programs at their current school. In still others, it may be that local school officials have not done enough to inform parents about available choices or have not provided that information early enough in the year.

I would add that I see nothing wrong with parents choosing not to move their children, so long as they receive sufficient information on the available choices. The point of the public school choice requirement is that parents and students have op-

tions if they are not happy with their current school, and that no student is forced to remain in a poorly performing school if there is a better alternative.

BARRIERS TO SCHOOL CHOICE

Question. To what extent do real and perceived barriers prevent students from exercising the choice option required by No Child Left Behind?

Answer. I believe it is too early to determine the extent of this problem. Certainly in the first couple of years of implementing No Child Left Behind many districts did not aggressively inform parents of available choice options, and in many cases the fact that options were made available only after the school year had already started discouraged students from transferring. We expect, and have already seen, that such problems diminish over time, as States and districts improve their procedures and more parents become aware of choice options.

Question. What specifically does the fiscal year 2005 budget propose to address these issues?

Answer. Effective implementation of public school choice under No Child Left Behind is not really a budget issue, and our budget does not include any specific proposals in this area. As I mentioned earlier, I believe this is a problem that is being addressed over time. And of course the Department continues to provide guidance and technical assistance on public school choice, and to examine choice implementation as part of its regular Title I monitoring efforts.

REPORT ON NCLB IMPLEMENTATION

Question. The subcommittee understands the Department's report to Congress, including State and local performance related to No Child Left Behind, is expected to be available in late spring of 2004. As soon as it is available, please provide the subcommittee with a copy of the report.

Answer. We expect that the report will be completed and submitted to the Congress in late spring of this year.

COSTS OF SCHOOL IMPROVEMENT AND CHOICE REQUIREMENTS

Question. Based on information derived from State reporting and/or other reliable and appropriate data, what is the Department's estimate of the funding required to meet all of the requirements related to school improvement status—public school choice, supplemental services, school restructuring, etc.—which must be taken with respect to schools that fail to meet adequate yearly progress standards for 2 or more consecutive years?

Answer. There is no reliable way to estimate such costs, primarily because States and districts have great flexibility in developing school improvement plans, and because costs will vary greatly from district to district depending on the extent of the problems that are preventing schools from meeting adequate yearly progress (AYP) standards. Also, it is not necessarily the case that school improvement or restructuring requires additional funding. More often, districts will obtain improved results through better use of existing funding from all sources—Federal, State, and local—rather than merely adding new spending or initiatives that tend to ignore problems in core instructional areas.

Question. Does the fiscal year 2005 budget request provide sufficient funds to pay the costs of such activities?

Answer. We believe the President's budget request, combined with funding made available in earlier years as well as State and local resources, is sufficient to pay for the school improvement requirements of the No Child Left Behind Act.

FUNDS FOR SCHOOL IMPROVEMENT

Question. Mr. Secretary, the Pennsylvania Department of Education has indicated that under the No Child Left Behind law, they will have fewer funds available at the State level for school improvement than they did in fiscal year 2001, while they have almost three times as many schools identified as in need of improvement. How will the Department provide these schools with the additional assistance they need to improve the academic achievement of students, with fewer resources?

Answer. It is possible that State-level resources for school improvement are somewhat lower than under the earlier law, but overall funding for school improvement efforts, which under No Child Left Behind is targeted to the district level, greatly exceeds the funding available for such activities prior to reauthorization. This is because under the old law, States were permitted, but not required, to reserve up to one-half of one percent of their Title I allocations for school improvement efforts. Under No Child Left Behind, beginning in fiscal year 2004, States are required to

reserve 4 percent of their allocations for school improvement, and to distribute 95 percent of such reservations to those school districts with the greatest need for such funds.

To put this change in dollar terms, in fiscal year 2001, States might have reserved as much as $44 million for school improvement. In fiscal year 2005, under the President's request for Title I, they will be required to reserve more than $500 million for this purpose.

Congress did provide, in appropriations language, separate funding for school improvement, including the provision of public school choice options, in fiscal years 2000 and 2001. Even these amounts—$134 million in 2001 and $225 million in 2002—were significantly below the levels provided under No Child Left Behind.

Question. What other resources are proposed in the fiscal year 2005 budget to assist schools trying to improve the academic achievement of all students, particularly those schools identified as in need of improvement or on watch lists?

Answer. There are no specific proposals for additional school improvement-related funding in our budget, both because we believe the Title I reservation is sufficient and because, in a larger sense, all of our programs provide funding that is intended to help schools improve the academic achievement of all students.

SUPPLEMENTAL SERVICE PROVIDERS

Question. Has the Department compiled any evidence that third-party supplemental services providers are more successful than their regular public schools in providing Title I services?

Answer. No, we do not yet have any performance data on supplemental service providers. What we do know is that Title I, as operated by regular public schools over the past four decades, has largely failed to improve achievement for participating students. No Child Left Behind is trying to change this rather unimpressive record, and we believe third-party providers will be able to make a contribution in this effort, particularly for low-income students in schools that consistently do not make adequate yearly progress.

CHOICE AND SUPPLEMENTAL SERVICES

Question. What information is available about the timeliness and effectiveness of communication to parents of affected pupils eligible for public school choice and supplemental services options?

Answer. Preliminary studies and other early evidence suggests a mixed record by districts in communicating No Child Left Behind choice and supplemental service options to parents. In part this reflects the usual difficulties encountered in doing something new, and we have seen districts improve over time. And, unfortunately, it also reflects at least occasional reluctance by districts to fully comply with the requirements or spirit of the new law.

Question. Are parents typically being offered a substantial range of choices?

Answer. Based on the limited information we have, most districts are complying with the law, which requires a choice of more than one school. This is not the same as a "substantial range of choices," but the law and our regulations do give districts some flexibility in this area, in order to take into account geographic limitations and allow LEAs to make efficient use of transportation resources.

Question. Have any localities received waivers from the requirement to provide supplemental services; if so, how many have been provided?

Answer. Such waivers may be approved by State educational agencies only if there are no available service providers and the school district itself is unable to provide services. We do not have data on waivers that SEAs may have granted.

MATHEMATICS AND SCIENCE PARTNERSHIPS

Question. The fiscal year 2005 budget proposes to override the No Child Left Behind Act authorization for the Math and Science Partnerships program in order to administer a new competitive grant competition focusing solely on math instruction for secondary education students. How is this proposal consistent with Goal 2 and objectives 2.2 and 2.3 identified in the Department's fiscal year 2005 Performance Plan related to math and science achievement, when additional funds may only be used for math instruction in secondary schools?

Answer. The Administration believes that it is critical to fund efforts specifically to accelerate mathematics learning at the secondary level by helping secondary students master challenging curricula and by increasing the learning of students who have fallen behind in mathematics. Research indicates that many students who drop out of school lack basic skills in mathematics, and our Nation needs to support these students so that they can catch up to their peers and stay in school.

Question. Where does the Department find any congressional intent for it to run a separate $120 million grant program focusing only on math instruction and reduce State flexibility to target funds to areas of greatest need?

Answer. It is not at all unusual for a President to identify critical educational needs and, in between the periodic congressional reauthorizations of major education laws, propose either modifications to existing programs or even entirely new programs to address such needs. It also is not unusual for both the President and the Congress to emphasize one part of a law over another. In the case at hand, the President believes there is good reason to give priority to improving math instruction. Moreover, he is proposing to use new money to pursue this priority, thus preserving State flexibility in the use of existing funding.

STUDENTS' SCIENCE ACHIEVEMENT

Question. Since annual science assessments will be required under NCLB beginning in the 2007–2008 school year, won't this new grant program designed only to improve math achievement curtail efforts to improve science achievement?

Answer. Since we are proposing to use new money for the President's proposal to improve math instruction, I do not see how this would "curtail" current efforts to improve science achievement. In addition, since mastery of basic mathematics is often a prerequisite for learning most sciences, I believe it is reasonable to argue that the President's proposal may well have the additional benefit of contributing to improved science achievement.

FUNDS FOR ASSESSMENTS REQUIRED BY THE NCLB ACT

Question. To date, the Congress has appropriated more than $1,161 million to assist States with the development and implementation of additional assessments required by the No Child Left Behind Act and the fiscal year 2005 budget request includes $410 million for such authorized activities. The General Accounting Office, National Association of the State Boards of Education and other organizations have developed different estimates for the costs associated with the additional assessment requirements of No Child Left Behind. Is the Department confident that funding provided at the proposed fiscal year 2005 level—in addition to funds already appropriated—would be sufficient to meet the additional assessment requirements of the No Child Left Behind Act? If so, please provide the subcommittee with the specific evidence used by the Department to reach this conclusion.

Answer. We believe that the funding provided under the State Assessment Grant program, in addition to being fully consistent with the congressional authorization level and the "trigger amounts" in the law, is sufficient to pay for the costs of developing and implementing the new assessments required by No Child Left Behind.

These costs vary considerably, of course, depending on such factors as the grades covered by a State's existing assessment system, the number of students tested, and the types of assessments used. This is why the cost estimates developed by differing organizations also vary considerably. Under these circumstances, and particularly in view of the fact that such costs were not separately funded under the previous law, we believe that No Child Left Behind funding for assessments reflects a reasonable and responsible approach to paying for the new assessments.

GRANTS FOR ENHANCED ASSESSMENTS

Question. Within the amount provided for assessments, more than $21 million has been used for activities authorized under the Grants for Enhanced Assessments Instruments program. Specifically, what projects have been funded to assist States with meeting the challenge of developing and implementing appropriate alternate assessments for students with disabilities and for developing and implementing assessments for English language learners?

Answer. So far the Department has made nine grants under this program using approximately $17 million from fiscal year 2002 funds. A competition to award $4 million from fiscal year 2003 closed on April 5, 2004. The Department estimates that it will make 6 grant awards from these funds.

ENHANCEMENT OF ASSESSMENT PROJECTS FOCUS ON STUDENTS WITH DISABILITIES AND STUDENTS WITH LIMITED ENGLISH PROFICIENCY

The nine current projects, which are awarded to States or consortia of States, focus on enhancement of assessments for students with disabilities and students with limited English proficiency. Four projects focus on the assessment of English proficiency, two focus on appropriate test design and accommodations for LEP students, one project examines appropriate accommodations for special education stu-

dents, one aims to improve the technical quality of alternate assessments for students with severe disabilities, and one project will enhance State capacity to evaluate and document the alignment between State standards and State assessments.

Below is a short summary of each Grants for Enhanced Assessments project:

Lead State: Utah Collaborators: Montana, Idaho, New Mexico, Colorado, Oregon, Wyoming, and North Dakota

Grant amount: $1,842,893

Summary: The project aims to develop a series of assessments of English language proficiency at four levels (K–3; 4–6; 7–9; 10–12) to enable teachers to diagnose the proficiency level of English language learners (ELLs).

Lead State: Rhode Island

Collaborators: Maine, New Hampshire, and Vermont

Grant amount: $1,788,356

Summary: The project will build upon an existing collaboration among Maine, New Hampshire, Rhode Island and Vermont and will help compare progress across States and combine resources to develop the highest quality assessments. States will examine the impact of computer-based testing accommodations on the validity of test scores for students with and without special needs, and train teachers to create and use the assessments.

Lead State: South Carolina

Collaborators: American Association for the Advancement of Science, Austin (Texas) Independent School District, The Council of Chief State School Officers, District of Columbia Public Schools, Maryland, and North Carolina

Grant amount: $1,719,821

Summary: The project will help gather valid information about ELLs' academic knowledge and skills, and matching ELL students with the proper accommodations based on their testing needs.

Lead State: Oklahoma

Collaborators: Alabama, California, Delaware, Kansas, Louisiana, Massachusetts, Minnesota, New Jersey, North Carolina, Pennsylvania, South Carolina, Texas, Wyoming, West Virginia, and Wisconsin

Grant amount: $1,442,453

Summary: The project will work to expand and automate a process for judging the alignment of assessments with content standards, serve students with disabilities and help link assessments across grades. The alignment process system will be available on a CD–ROM that can be readily distributed to States to increase the use of the alignment tool in assessment development and verification.

Lead State: Nevada

Collaborators: Indiana, Iowa, Kentucky, Louisiana, Massachusetts, Michigan, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, South Carolina, Texas, and West Virginia

Grant amount: $2,266,506

Summary: The project will help States implement assessments to measure the annual growth of English language development in speaking, listening, reading and writing. The project will produce test forms and an item bank from which States can draw to create test forms that reflect local needs and characteristics, and will help States predict ELLs' readiness for English language assessment.

Lead State: Pennsylvania

Collaborators: Maryland, Michigan, and Tennessee

Grant amount: $1,810,567

Summary: This project is designed to help States assess ELLs by analyzing State standards, establishing content benchmarks and developing standards-based assessments drawn from scientific research. The resulting assessments are to be shared with interested States and districts.

Lead State: Colorado

Collaborators: Iowa, Oregon, Illinois, Missouri, South Carolina, West Virginia, and Wyoming

Grant amount: $1,746,023

Summary: The project will help improve alternative assessments for students with complex disabilities, and the assessment methods will be developed, pilot tested and analyzed during the course of this project.

Lead State: Wisconsin

Collaborators: Alaska, Delaware and Center for Applied Linguistics, Center for Equity and Excellence in Education, Second Language Acquisition, University of Wisconsin, and University of Illinois

Grant amount: $2,338,169

Summary: This project will develop and enhance assessment instruments specially designed to measure ELLs' performance and progress in English proficiency

and literacy skills based on State standards on reading, writing and language arts and alternate assessments to measure their performance in other academic content areas.

Lead State: Minnesota

Collaborators: Nevada, North Carolina, and Wyoming

Grant amount: $2,013,503

Summary: This project will develop new tools to measure the progress of ELLs using technology to pilot language assessment, develop new methods to organize, collect and score student assessment data and combine data from multiple measures to improve the evaluation of student progress over time. Staff development will help teachers use assessment results to improve instruction and the methods will be available to other States.

EFFECTIVENESS OF ASSESSMENTS BEING DEVELOPED

Question. Has the Department disseminated information about the best practices and innovative approaches to high-quality, appropriate assessment tools developed through this funding stream?

Answer. The first awards under this program were made a little over a year ago, and it is too early to assess the effectiveness of the assessments that are under development by the various grantees.

STATEWIDE LONGITUDINAL DATA SYSTEMS

Question. Mr. Secretary, section 208(e) of Public Law 107–279 requires you to "make publicly available a report on the implementation and effectiveness of Federal, State, and local efforts related to the goals of this section, including—identifying and analyzing State practices regarding the development and use of statewide, longitudinal data systems . . ." as well as other required elements, not later than one year after the enactment of the Education Technical Assistance Act of 2002. What is the status of this report?

Answer. The Department currently is not preparing the specific report referenced in section 208(e), but has been pursuing similar efforts—including the analysis of existing State data systems, the identification of weaknesses, and highlighting best practices—as part of our Performance Based Data Management Initiative.

STATEWIDE LONGITUDINAL DATA SYSTEMS NOT REQUIRED BY NCLB

Question. Given the importance of high quality and timely student achievement data as relates to implementation of No Child Left Behind, don't you agree with the critical need to assess State systems and provide evidence of best practices with regard to such statewide systems?

Answer. I agree that reliable student and school performance data are essential to reaching the goals of No Child Left Behind, and we are working with States and school districts on this issue through our Performance Based Data Management Initiative. This initiative is focused on the performance data required by No Child Left Behind, and will consolidate data collection from States, districts, and schools to both improve data quality and reduce paperwork burdens.

However, the reporting requirements of No Child Left Behind are almost exclusively concerned with groups of students, rather than individual students. For this reason, although statewide longitudinal data systems may be very desirable as a tool to support educational reform, they are not required to successfully implement the No Child Left Behind Act.

Moreover, most of the data that would be collected by such longitudinal systems—such as enrollment, annual assessment results for individual students, course completion, and SAT and ACT results—is required for State purposes and not for meeting Federal reporting requirements.

For these reasons, while I applaud efforts to develop statewide longitudinal data systems, I believe such systems are primarily a State and local responsibility.

EDUCATION PROGRAM FUNDS THAT CAN BE USED FOR STATEWIDE LONGITUDINAL STUDENT DATA SYSTEMS

Question. How does the fiscal year 2005 budget request specifically support the goal of ensuring that States and school districts have the knowledge and resources to develop and implement such systems?

Answer. As indicated previously, longitudinal student data systems are not required by the No Child Left Behind Act, and thus have not been targeted for specific support in our fiscal year 2005 budget request. States are free to use Title V, Part A State Grants for Innovative Programs for this purpose, as well as State Assess-

ment Grant funding once they have implemented the full range of assessments required by No Child Left Behind. In addition, the Department is providing $10 million annually to support the integration of statewide data systems as part of our Performance Based Data Management Initiative.

Question. Mr. Secretary, I am informed by the Pennsylvania Department of Education that it needs $12 million over 3 years to implement the required system in Pennsylvania and an additional $1 million per year to maintain it. What Federal funding is available for the Commonwealth to develop the statewide data system required to support effective implementation of the No Child Left Behind Act?

Answer. Again, while Pennsylvania deserves praise for undertaking the development of a statewide longitudinal student data system, such a system goes beyond the data-collection requirements of the No Child Left Behind Act. And since this system would primarily serve the needs of Pennsylvania's school districts and schools, finding $12 million over three years should not be overly daunting for a State that spends more than $16 billion annually on public elementary and secondary education.

However, as I mentioned earlier, Pennsylvania could use Title V, Part A State Grants for Innovative Programs funding, as well as State Assessment Grant funding once it has implemented the assessments required by No Child Left Behind, to support the development and implementation of its statewide longitudinal student data system.

PELL GRANT MAXIMUM

Question. The President's fiscal year 2005 budget proposes to establish $4,050 for the Pell Grant maximum award, the same as fiscal year 2003 and fiscal year 2004. If adopted, this would mean three years, consecutive years at this maximum grant level. According to the College Board, tuition for 4-year private colleges has gone up more than 5 percent for the third year in a row; and for public 4-year universities, tuition has increased by more than 13 percent this year. I would also note that research has demonstrated that low-income students are not as successful in completing their postsecondary education because they often attend school part time, work long hours, and borrow heavily.

Mr. Secretary, doesn't your proposal to maintain the current maximum Pell Grant at $4,050 for fiscal year 2005 mean that students served by the program will lose ground relative to the price of postsecondary education?

Answer. We share your concern about the increasing cost of higher education. Our primary goal, however, must be to secure the financial stability of the Pell Grant program, the cornerstone of Federal student aid. Raising the maximum award without adequate funding would exacerbate the program's funding shortfall, currently estimated at $3.7 billion by the end of award year 2004–05. The Administration's 2005 budget would increase Pell Grant funding by over $800 million to fully fund the cost of maintaining the current $4,050 maximum award. The Administration is committed to working with Congress to eliminate the shortfall and place the program on a firm financial footing.

COLLEGE ENROLLMENT GAP

Question. What other support is proposed in the President's budget to reverse the increasing college enrollment gap between low- and high-income students?

Answer. The Administration's Enhanced Pell Grants for State Scholars proposal is one way the President's budget addresses this issue. Research consistently shows students who complete a rigorous high school curriculum are more successful in pursuing and completing postsecondary education. The Administration's proposal will encourage additional States and their local governments to participate in the State Scholars program, encouraging low-income students to successfully complete these programs.

The Administration also supports strong academic preparation for postsecondary education and training through the Federal TRIO and GEAR UP programs. The Administration is proposing in fiscal year 2005 to spend $1.13 billion dollars for these two programs. In addition, the Administration is doubling support for the Advanced Placement Program. Low-income students who participate in Advanced Placement programs, which give students the opportunity to take college-level courses in high school, are much more likely to enroll and be successful in college than their peers. These programs also serve as a mechanism for upgrading the entire high school curriculum for all students. The Administration is proposing a $28 million increase for the Advanced Placement program authorized in the No Child Left Behind Act, bringing spending on it to nearly $52 million a year.

LEVERAGING EDUCATIONAL ASSISTANCE PARTNERSHIPS

Question. Why does the fiscal year 2005 budget propose to eliminate the $66.2 million in funding for the Leveraging Educational Assistance Partnerships program—which helps States establish and expand need-based student aid programs—despite the fact that it is the only Federal program designed to expand the amount of need-based student aid provided by States?

Answer. When the Leveraging Educational Assistance Partnerships (LEAP) program was first authorized as the SSIG program in 1972, 28 States had undergraduate need-based grant programs. Today all but two States have need-based student grant programs. State grant levels have expanded greatly over the years, and most States significantly exceed the statutory matching requirements. For academic year 2002–2003, for example, estimated State matching funds totaled nearly $1 billion. This is more than $950 million over the level generated by a dollar-for-dollar match, and far more than would be required even under the 2-for-1 match under Special LEAP. This suggests a considerable level of State commitment, regardless of Federal expenditures.

PELL GRANT COST ESTIMATES

Question. The Administration has proposed a budget process reform that would change budget scoring with respect to the Pell Grant program. For the last three fiscal years, what was the difference between program costs (displayed by academic year) for the Pell Grant program as estimated in the President's Budget, and at the time of the Mid-Session Review?

Answer. The requested information is shown in the following table.

Fiscal year	Award year	Max award proposed	Est. program cost President's budget	Est. program cost mid-session review	Difference
2002	2002–03	$3,850	$9,582,000,000	$9,531,000,000	($51,000,000)
2003	2003–04	4,000	10,863,000,000	11,442,000,000	579,000,000
2004	2004–05	4,000	11,410,000,000	12,133,000,000	723,000,000

MID-SESSION REVIEW REESTIMATES OF PELL GRANT PROGRAM COSTS

Question. For the same period, what were the differences between the assumptions used in the President's budget and those available at release of the Mid-Session Review?

Answer. In general, the Administration revises its applicant growth assumptions for Mid-Session Review in June based on updated operational data, including actual information for the current academic year. For the last three years, the Administration adjusted its applicant growth assumptions for Mid-Session Review to account for unanticipated increases in Pell applicants, increasing estimated costs over the President's Budget level. Other technical assumptions used to estimate program cost—such as changes in Federal tax provisions, mandatory updates to the Need Methodology Tables, and proposals to verify applicants' income data with the IRS—were either revised or introduced during this update period. In addition, government-wide economic assumptions used for Mid-Session Review typically differed from those used in the President's Budget.

ACCURACY OF DEPARTMENT'S PELL GRANT COST MODEL

Question. Has the Department ever accurately estimated the program cost of the Pell Grant program?

Answer. Historically, the Department's Pell Grant cost model has been a reasonably accurate predictor of program costs. Over the last 10 years (academic years 1994–95 through 2003–04), the model's estimates were within an average of 4.6 percent of actual costs. A review of annual data indicate the forecasting model is particularly reliable during times of economic stability and less so during other periods. Estimation in this area is particularly challenging due to the lead time necessary to produce the President's budget—up to two full years before the beginning of the funded academic year—and the economic changes occurring during that period.

Question. What actions has the Department taken to improve its ability to more accurately forecast the cost of the Pell Grant program?

Answer. Since one of the key components in forecasting the cost of the Pell Grant program is projecting applicant growth in future years, the Department is working to build better and more robust tools for forecasting applicant growth. Over the past three years, the Department has made ongoing improvements to its primary Pell

Grant cost model by expanding the sample sizes of applicants and recipients, incorporating real-time disbursement data, and by auditing key technical parameters.

INTERNAL REVENUE SERVICE DATA MATCHING

Question. The Administration has again proposed to allow the IRS to match income tax return data against student aid applications, in order to reduce the number of erroneous student aid payments. According to the U.S. Department of Education, this proposal would save the Federal Government $50 million in erroneous payments during the 2005–2006 academic year and substantially more in subsequent years. What is the status of efforts to enact authorizing legislation?

Answer. We have worked closely with the Treasury Department and the Office of Management and Budget in developing this proposal. The Administration's unambiguous support is clearly shown in the August 9, 2002, letter signed by Secretaries Paige and O'Neill and OMB Director Daniels transmitting the proposed legislation to the Congress.

Recently Congressman Johnson introduced H.R. 3613 the "Student Aid Streamlined Disclosure Act of 2003," which was referred to the Subcommittee on Oversight of the Ways and Means Committee. There is general support for the concept, and we are currently working to address specific operational concerns.

STEPS TAKEN TO REDUCE ERRONEOUS FEDERAL STUDENT AID EDUCATION PAYMENTS

Question. What other steps is the Department taking to reduce and eliminate erroneous Federal education payments?

Answer. The Department has implemented a multi-year effort to research the causes of, and to suggest solutions to, incorrect student payments. We have substantially increased the number of student aid applications submitted using FAFSA on the Web. The online student aid application substantially reduces errors and improves services to students. The Department retargeted the verification selection criteria to focus on the Pell Grant program and is encouraging schools to verify all selected applicants. To ensure that verification occurs, the Department is conducting a series of community outreach sessions on student aid application verification processes. Finally, we have taken steps for improving the Department's compliance and monitoring techniques in the Federal Student Aid and Office of Postsecondary Education programs.

NEW PROGRAMS VERSUS PROGRAM ELIMINATIONS

Question. Mr. Secretary, in response to a question I submitted last year, you stated, "the Administration believes it is more effective to deliver scarce Federal education resources to States and school districts through large, flexible formula grant programs rather than small, categorical grant programs mandating particular approaches to educational improvement." I agree with this general proposition. However, I note that you have proposed in the fiscal year 2005 budget, 6 new programs that would provide separate funding through categorical grant programs that support a narrow purpose. At the same time, the fiscal year 2005 budget request proposes to eliminate 38 categorical grant programs funded at more than $1.4 billion last year, ranging from the Smaller Learning Communities program to Arts in Education, because your Department believes that in many instances these programs have a narrow or limited effect.

Will you explain your rationale for requesting funds for new programs proposed in the fiscal year 2005 budget, which have a very narrow purpose, but not those you propose to eliminate because of their limited objectives?

Answer. The Administration does not oppose all categorical grant programs, nor have we proposed to eliminate funding for all of them. We recognize that such programs often serve an important purpose, such as calling attention to unmet needs, stimulating innovation, or demonstrating specific educational strategies. What we have objected to, particularly in the current budget environment, is the continued funding of such programs long after they have achieved their objectives, when they duplicate other funded activities, or when it has become clear that the funded strategies are not an effective use of taxpayer funds.

I believe our 2005 request is entirely consistent with this approach, as reflected in our budget documents, which clearly identify the rationale for a handful of new categorical programs while proposing to terminate separate funding for a much larger number of similar programs that have largely achieved their original purposes. I would add that, in most cases, these latter programs may be funded under broader, more flexible State grant authorities if desired by States and local school districts.

CENTER FOR CIVIC EDUCATION'S WE THE PEOPLE PROGRAMS

Question. Mr. Secretary, the fiscal year 2005 budget proposes funding for the Center for Civic Education's We the People (WTP) programs. These programs have been very effective through the years in providing students with the knowledge, skills, and attitudes they need to be effective citizens, and evaluations continue to testify to the success of these programs. Would you agree the WTP programs can be an antidote to the cynicism and apathy toward politics and government that persists among young people today?

Answer. We agree that civic education programs can play a critical role in equipping young people with the knowledge and skills necessary for effective citizenship. Civic Education is a clear Administration priority. Although the Department has not conducted any evaluations of the Center for Civic Education's We the People programs, recent studies suggest that quality civic education programs may prompt students to understand, care about, and act on core citizenship values. Quality civic education programs can also help schools and communities maintain safe and inclusive learning environments that foster increased social responsibility and tolerance.

INCREASE FOR RESEARCH, DEVELOPMENT, AND DISSEMINATION

Question. The fiscal year 2005 President's budget acknowledges the importance of evidence-based decision making in education, yet proposes to eliminate funding for many of the programs that provide this information to SEAs, LEAs and teachers themselves. On the one hand you ask for an increase in Research, Development and Dissemination. At the same time the fiscal year 2005 budget proposes to eliminate funding for the Regional Educational Labs, the Eisenhower Math and Science Clearinghouse and the Regional Technology in Education Consortia. Can you please comment on these proposals?

Answer. The requested increase for Research, Development, and Dissemination is not an indication that the Administration proposes to shift funds from technical assistance to research. Instead, the Administration recognizes the fact that although the No Child Left Behind Act mentioned scientifically based research 111 times, there are significant gaps in our scientific knowledge in many of the areas in which Congress instructed that funding decisions and practice should adhere to scientifically based research, including math, science, school-wide reform models, early literacy programs in preschools, and professional development of teachers. Our request for increased funding would support rigorous research to give education practitioners the information they need to ground their decisions and practices in strong evidence of what works.

In the conference report accompanying the Consolidated Appropriations Act of 2004, the conferees strongly urged the Department to hold a competition for the new comprehensive centers authorized under sections 203 and 205 of the Education Sciences Reform Act of 2002 (ESRA). In the budget request for fiscal year 2005, the Administration requested funding under the School Improvement account to support a competition for the new comprehensive centers. The new comprehensive centers would provide much-needed training, technical assistance, and professional development in reading, mathematics, and technology to States, local educational agencies, and school in order to improve the academic progress of disadvantaged students, boost teacher quality, and improve English fluency among students with limited English proficiency.

Under section 205 of the Educational Technical Assistance Act of 2002, the Comprehensive Regional Assistance Centers, the Regional Technology in Education Consortia, and the Eisenhower Regional Mathematics and Science Consortia were only authorized to continue until the comprehensive centers authorized under section 203 are established. Since the Department plans to hold a competition for the new comprehensive centers in 2005, there would be no authority under which to request funds to continue awards to the existing technical assistance providers.

REGIONAL EDUCATIONAL LABORATORIES PROGRAM

The Administration did not request funds for the Regional Educational Laboratories program because there is no evidence that the laboratories consistently provide quality research and development products or evidence-based training and technical assistance. Although the Education Sciences Reform Act of 2002 reauthorized the program, the current authority does not enable IES to ensure that all of the laboratories adhere to standards of scientific quality needed to produce evidence with which to inform decisions.

ARTS IN EDUCATION

Question. The No Child Left Behind Act recognizes the arts as a core subject of learning. Studies show that the arts are proven to help close the achievement gap and improve essential academic skills. If arts have been proven to be essential to the learning process, why does the fiscal year 2005 budget propose to eliminate the arts in education program?

Answer. The Administration's fiscal year 2005 budget eliminates 38 small categorical programs that have narrow or limited effect, including the Arts in Education program, to help increase resources for high-priority programs. Districts seeking to implement arts education activities can use funds provided under other Federal programs. For example, districts can use the funds they receive through the State Grants for Innovative Programs to implement arts programs.

In addition, under the Improving Teacher Quality State Grants program, districts may use their funds to implement professional development activities that improve the knowledge of teachers and principals in core academic subjects, including the arts. Also, districts are able to supplement the amount of funding they receive for these two programs by exercising their options under the transferability authority of the State and Local Transferability Act.

21ST CENTURY COMMUNITY LEARNING CENTERS

Question. The fiscal year 2005 President's budget proposes to freeze funding for the 21st Century Community Learning Centers Program. This is a program that enjoys public and bi-partisan congressional support. These programs help working families, provide vital additional academic support to students and provide safe, supervised environments for kids after school. Is there a reason the Department's fiscal year 2005 budget does not support expanding this program beyond its current funding level?

Answer. The Administration is proposing to maintain strong support for the 21st Century Community Learning Centers program by requesting $999.1 million in the 2005 budget. The request recognizes that the program provides a significant opportunity to improve the quality of an estimated 1,800 after-school programs that the program is able to support. At the same time, we need to ensure that the weaknesses in the previous program are not carried into the State-administered program. Preliminary findings from the evaluation of the antecedent program show a need to focus the program on providing more academic content and developing a knowledge base about successful academic interventions.

The request also recognizes that the new grantees funded by States need some time to achieve better outcomes for students, and that national evaluation and technical assistance activities can play a key role in successful implementation. The Department continues to provide technical assistance and intensive outreach to help grantees focus on program improvement. We also continue to fund rigorous evaluation activities that will yield program performance information and assist us in developing new interventions.

NCLB TRANSFERABILITY PROVISIONS

Question. Under the State and Local Transferability Act enacted as part of the No Child Left Behind Act, States and local school districts are provided with additional flexibility to target certain Federal funds to Federal programs that most effectively address the unique needs of States and localities and to transfer Federal funds allocated to certain State grant activities to allocations for certain activities authorized under Title I. How did the Department consider this authority in making its fiscal year 2005 budget request?

Answer. Our 2005 request maintains high levels of funding for the programs that are included in the transferability authority (Improving Teacher Quality State Grants, Educational Technology State Grants, State Grants for Innovative Programs, and Safe and Drug-Free Schools and Communities State Grants programs) to ensure that States and school districts have meaningful flexibility to use Federal funds to address their own priorities. In addition, the flexibility provided by the transferability provisions supported the Administration's proposals to reduce or eliminate funding for small categorical programs, since the transferability provisions make it easier for States or districts to identify alternate sources of funding for such programs, should they wish to continue them.

Question. How will the authority be considered in assessing the relationship between Federal funding provided and the performance outcomes achieved with such funds?

Answer. The Department plans to collect information, through program performance reports and a study of resource allocation, on the amount of funds transferred among programs under the transferability authority. As for the relationship between Federal funding and performance outcomes, we believe that it is often not possible to isolate the separate impact of many Federal programs on student outcomes, due to the fact that federal programs frequently seek to leverage broader State and local improvements in education programs. However, we will also continue to collect and report information on trends in student outcomes in order to assess the overall impact of Federal, State, and local reform efforts on student achievement.

Question. How will this authority shape decisions on future budget requests for affected programs?

Answer. The transferability authority supports the Administration's emphasis on rationalizing and consolidating the delivery of Federal education resources to give States and school districts maximum flexibility in using these resources to meet local needs, and to improve student achievement while reducing administrative, paperwork, and regulatory burdens. As with the 2005 budget request, I expect that we will work to maintain or increase funding for the flexible State grant programs included in the transferability authority, while reducing budget support for smaller categorical programs with limited impact and more complex administrative requirements.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

REPORT ON WRITING BY THE NATIONAL COMMISSION ON WRITING

Question. Mr. Secretary, many teachers in my State, and I know in other States, have benefited from the very economical professional development provided by the network of National Writing Project institutes. Every State is benefiting from the relatively small Federal investment in the National Writing Project. Many schools report data that shows measurable improvement in student success in writing who have been taught by writing project teachers. This is a program that I've worked for more than a dozen years, to keep authorized and keep funded.

This past year, the College Board—this is the organization that administers the college entrance examinations with which we are all familiar, such as the SAT, established the National Commission on Writing. It concluded that, "Writing today is not a frill for the few but an essential skill for the many." Further, it has added to the college entrance examination a writing section, and it proposes a concerted effort on retraining teachers in the teaching of writing, and doing so by increasing the Federal investment in the National Writing Project. I find this recommendation compelling. These were professionals, college presidents, and academicians from all over the country, who looked at the state of student writing and how it was being taught, and concluded that the best thing the Federal Government could do to make a positive contribution to improving this condition, is to increase the funding of the National Writing Project.

Are you aware of the report of the National Commission on Writing?

Answer. Yes, I am familiar with the National Commission on Writing report, and the important recommendations included in this document. I agree that writing is an essential learning skill, and that the ability to write is foundational to other learning areas.

When considering recommendations made in this report, however, it is important to keep in mind that Richard Sterling, the National Writing Project's (NWP) Executive Director, chaired the project's advisory panel. There is no reliable evidence that the NWP is any more or less effective than other professional development activities. No impact evaluations of the NWP have been conducted to date. In recent years, the NWP has sponsored several evaluations of activities supported under their project. Unfortunately, neither evaluation approach employed by NWP was sufficiently rigorous to yield reliable information on the effectiveness of interventions supported through the program. For example, NWP claimed that the latter evaluation shows statistically significant gains from baseline to follow-up for 3rd and 4th grade student participants; however, because the study failed to used control groups or carefully matched comparison groups, it is not possible to draw any reliable conclusions regarding impact on student learning in NWP classrooms relative to other classrooms where writing skills are taught.

ARTS IN EDUCATION

Question. The grants that have been available under the Arts in Education program have provided nationally recognized school reform in my State through the Mississippi Arts Commission's Whole School Program. The Commission received one of the first grants available under this program and this has been successful as well as provided arts in schools that otherwise would have none. The benefit of arts education has been widely reported over the last several years, and I think we need to continue to allow schools to have a resource that goes beyond what States and local governments can supply. The Federal funds that go to States simply do not stretch far enough to allow arts education to be a priority in schools of high poverty. School representatives regularly thank me for my support, and in the same breath, ask for continued funding. This is a difficult situation, but one I hope we can resolve.

Answer. While the Department plays a significant role in certain areas of education, all specific decisions about curricula and other program offerings are made at the State and local levels. Because it is my understanding that most decisions to reduce or eliminate music and art programs are driven by budget concerns, I believe there is little the Department can do in this area, given our relatively small and necessarily focused contribution to overall education spending. New flexibility provisions in the No Child Left Behind Act made it easier for States and districts to support music and arts programs with Federal dollars, but we recognize that there are many needs competing for these resources. I do believe that as States and districts make progress in meeting their proficiency goals for reading and math, they will devote additional attention and resources to other core subjects such as music and art.

FEDERAL SUPPORT FOR FOREIGN LANGUAGE INSTRUCTION

Question. In the area of foreign language instruction, the evidence is that we need to be doing this beginning in elementary schools. It is my understanding that the small grant program we have to provide schools with support for this has many more times the applicants than it can approve. Most schools K–8 do not offer foreign language instruction, and in States where resources are overburdened, even high schools are not able to offer even common foreign languages such as Spanish or French. The point, Mr. Secretary, is that for these schools, the resource they need is direct access to a Federal grant program. These programs make a difference in whether or not certain subjects are taught, and whether or not students have the advantage of a competitive education.

Answer. I share your view that, in general, foreign language instruction is important for students who will pursue careers in an increasingly multicultural world economy. However, both budget constraints and the limited Federal role in education dictate a focus on core priorities, and our core priority in elementary and secondary education lies in helping special populations, such as poor students and students with disabilities, to meet challenging State standards in reading, math, and science, as called for in the No Child Left Behind Act.

I also think that the rebounding economy will permit greater State and local support for programs such as foreign language instruction—as well as art, music, and physical education—that suffered most during the recent recession. Finally, States and school districts may fund foreign language instruction under larger, more flexible Federal authorities like Title V State Grants for Innovative Programs.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

SINGLE SEX EDUCATION

Question. During passage of No Child Left Behind, we reached a bi-partisan agreement on single-sex education. NCLB says that schools may provide single-sex programs as long as they are consistent with "applicable law,"—Title IX and the U.S. Constitution—and requires the Department of Education to provide guidance on that applicable law. The law does not direct the Department of Education to change the Title IX regulations. However, yesterday, you released new proposals to amend 30-year-old Title IX regulations on single sex education.

Current law allows single-sex programs when appropriate, but contains protections against sex discrimination. The proposed regulations would dispense with meaningful anti-discrimination protections and authorize schools to provide alternatives for girls that fall far short of equality. In the press release announcing this

change, you even admit that research on students' performance in single-sex education programs is inconclusive.

Shouldn't you be spending that funding and the efforts of the Department of Education on helping our States implement the No Child Left Behind Act to close the achievement gap instead of throwing out long-standing anti-discrimination laws, potentially broadening the achievement gap for our Nations' girls and boys?

Answer. As required by the new law, we issued guidance on May 8, 2002 on the Title IX requirements related to single-sex schools and classrooms. At the same time, the Department published a notice that the Secretary was planning to propose amendments to the existing Title IX regulations applicable to single-sex education.

The No Child Left Behind Act brought a new emphasis on flexibility and choice in Federal education programs. Consistent with this emphasis, the proposed amendments to the Title IX regulations provide more flexibility to educators to establish single-sex schools and classrooms in elementary and secondary schools. Research indicates that single-sex programs may provide educational benefits to some students, and such programs also offer additional public school choice options to children and their families.

The Department's proposed amendments continue to require school districts to afford substantially equal educational opportunities to both sexes when single-sex classes and schools are offered. Any effort to provide either sex with alternatives that are inferior to those provided the other sex would not be consistent with these amendments.

In addition, the proposed amendments require school districts to ensure that single-sex classes do not rely on overly broad generalizations about the different talents or capacities of female and male students. While we acknowledge that there is a debate among researchers and educators regarding the effectiveness of single-sex education, we believe our proposal makes educational sense and protects both girls and boys from discrimination.

SCHOOL CHOICE AND PELL GRANTS

Question. The President's budget yet again includes funding for vouchers, which were rejected during passage of No Child Left Behind. The Bush budget includes $50 million for the Choice Incentive Fund and another $14 million for the DC voucher program, which the Senate never even voted on.

How can you justify repeatedly abandoning public education by giving just 1,700 students $7,500 to attend schools that are unaccountable to students, their families, or the Department of Education and may not be providing a quality education, when you are not increasing Pell grants for millions of low-income students past $4,050 to attend accredited institutions of higher education? This is especially troubling when so many people are going back to school, particularly community colleges, for education and training to compete in this workforce.

Answer. The President's request would increase Pell Grant funding by over $800 million, to a record $12.8 billion. The Administration believes there is no contradiction between this strong support for the Pell Grant program and our proposed modest funding for educational innovations that expand choice for the parents of elementary and secondary school students. Both proposals are fully consistent with the Department's mission and goals; in fact, vouchers and other choice options are an effort to bring to elementary and secondary education the same accountability mechanism supported by the Pell Grant program: allowing students to attend the school of their choice.

STRIVING READERS INITIATIVE

Question. Your budget proposes $100 million for a new program—Striving Readers—to help improve reading for middle and high school students. I support efforts to improve our high schools and additional resources for high schools, including through my Pathways for All Students to Succeed Act, which provides tools and resources to reform secondary education.

Isn't it true that overall high schools will be net losers in funding? Your budget proposes to cut the Perkins Career and Technical Education program by $300 million, eliminate the $173 million Smaller Learning Communities program designed to provide more individualized attention to high school students, as well as eliminate the $34 school-counseling program. That seems to result in a net loss to high school students of some $300–400 million. What is the rationale behind that?

Answer. I don't believe that it is correct to say that our budget results in a net loss of support for high school students. The Administration has chosen to target scarce resources on programs such as the Title I Grants to Local Educational Agencies (LEAs) and Special Education Grants to States, programs that benefit high

school as well as elementary school students, rather than fund small categorical grant programs with narrow effect, such as the Smaller Learning Communities and School Counseling programs. Our fiscal year 2005 request would provide for an increase of 52 percent for Title I Grants to LEAs and 75 percent for Special Education State Grants since President Bush took office; these programs support our Nation's secondary school students as well as elementary students.

In addition, our proposal to strengthen and modernize the Federal investment in vocational education will help States and communities improve the academic performance of high school students by supporting effective career pathway programs that promote rigorous academic curriculum and build a stronger bridge between high schools and postsecondary and workforce preparation. Further, rather than funding general expenses like equipment purchases and hiring of staff that have little direct impact on student learning as we do now, the proposed "Sec Tec" program would target funds to partnerships between school districts and technical schools, community colleges, and other career pathways programs to ensure that students are being taught the academic and technical skills necessary for further education and training and success in the workforce.

FUNDING FOR NCLB PROGRAMS

Question. Your budget for NCLB provides only a 1.8 percent overall increase. After factoring in inflation and continued enrollment growth that increase would actually result in a cut in funding for schools. Further, instead of providing real funding for programs, including Title I and IDEA, you cut 38 programs and level fund many more.

Since States and schools have been complaining that they need significant additional resources to meet the many requirements of NCLB, do you think a cut in funding in real terms is the right approach?

Answer. Over the past decade, overall spending on elementary and secondary education in the United States has grown from $300 billion to just over $500 billion. Funding for the Elementary and Secondary Education Act has more than kept pace with this increase, nearly tripling from $8.5 billion to $24 billion over the same period. Moreover, these increases occurred in an environment of historically low inflation, resulting in very substantial increases in real terms. I believe these funding levels, along with the President's budget request, are more than sufficient to pay for the changes called for in the No Child Left Behind Act.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Thursday, March 25, in room SD–192. At that time we will hear testimony from the Honorable Tommy Thompson, Secretary, Department of Health and Human Services.

[Whereupon, at 11:55 a.m., Thursday, March 4, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 25.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2005

THURSDAY, MARCH 25, 2004

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

The subcommittee met at 9:35 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Stevens, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. TOMMY G. THOMPSON, SECRETARY

OPENING STATEMENT OF SENATOR ARLEN SPECTER

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

Our witness today is the distinguished Secretary of Health and Human Services, Tommy Thompson. Secretary Thompson served as Governor of Wisconsin from 1987 to the year 2000, the longest tenure of a Governor in Wisconsin's State history, a national leader in welfare reform and expanding healthcare to low-income children and families, served as chairman of the National Governors Association, the Education Commission of the States, and Midwestern Governors Conference, bachelor of law degree from the University of Wisconsin in Madison.

We focus today on the budget of the Department of Health and Human Services, which has been proposed by the administration at $62.9 billion, which is an increase of $974 million over the fiscal year 2004 level, or 1.6 percent. And this is tough year on all accounts, as we know. This budget proposal has a great many question marks in it, one of which is the assumed savings of $767 million, all of which are within the jurisdiction of Finance Committee, but I'm sure Senator Thompson will drop a letter to the Finance Committee and tell them to proceed to save that money for us, right, Secretary?

Secretary THOMPSON. That is correct, sir.

Senator SPECTER. And the reduction and elimination of about a dozen programs, which have a lot of support in the Congress—Article 1 of the Constitution still has that cumbersome provision about congressional authority to appropriate, and some of our colleagues take that very seriously on programs which have been developed over the years. And I take a look at 11 programs which are being zeroed out, and then major cuts.

The Center for Disease Control has a reduction of $116 million, which is a little hard to understand in light of their increased responsibilities. Every time we turn around, there's a major problem on SARS or AIDS or bioterrorist threats. And their building program is in midstream. I visited the Center for Disease Control several years ago, and was shocked to see what was going on down there. Your predecessor, Mr. Secretary, appeared here every year, and never once mentioned the need for capital improvements at the CDC, and it was in dire need. It's gone a fair distance on a billion-and-a-half dollar budget, and I don't know how we can stop it now, but, at the same time, I don't know how we can not stop it now.

The NIH funding is totally inadequate to allow NIH to go forward. I know how important that is in your personal agenda. And I also know you're not the President or the director of OMB, and you don't structure all of the budgets.

But it looks like a tough year ahead for us, Mr. Secretary.

Secretary THOMPSON. It is.

Senator SPECTER. I was hoping to finish before the distinguished ranking member came, so he missed his opening statement.

Just kidding. Just kidding, Senator Harkin.

We have established a unique partnership, I think, that the world knows about, to the detriment of both of us, personally. But when we have changed gavels from time to time, it has been seamless, and we have worked very, very closely together. And I'm delighted to yield to my distinguished colleague today, who has effectively tied up the Senate with an overtime issue on which I agree with his position.

Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. I wish it wouldn't tie up the Senate. I wish we would just vote, that would be the end of it.

Thank you very much——

Senator SPECTER. We—Senator Frist may let you do that. Then what are you going to do?

Senator HARKIN. We vote, and then we move on.

Thank you very much, Mr. Chairman. And, again, I just echo the words that you've said. I've enjoyed our partnership, now going back 14 years, and the changing of the gavel back and forth has been seamless. And I have appreciated your willingness to work together and make this truly a bipartisan subcommittee, in every sense of the word. The issues we deal with, on health and education, medical research, biomedical research, are not really partisan issues at all, and I don't think either one of us have ever looked at them in that regard.

Mr. Secretary, it's always a pleasure to have you appear before this subcommittee, and I look forward to working with you in this

year's budget process. First, I want to commend you for your commitment to two important issues, issues that I know are a top priority for both of us.

The first is the support for programs for persons with disabilities. I appreciate your continued support for the New Freedom Initiative and its goal of removing barriers to community living for people with disabilities. This is extremely important. Now let's work together to get the legislation enacted.

Secretary THOMPSON. Please.

Senator HARKIN. I also want to thank you for including funding for the Real Choice System Change Grants in your fiscal year 2005 budget. I don't think those funds would be there without your personal intervention, and I appreciate that.

Second, I congratulate you on your efforts to make wellness programs a priority. Obesity, lack of physical activity, smoking, and poor nutrition are a grave threat to our country; not just to individuals, but to all of us, as taxpayers. In this country, we spend a trillion dollars a year on healthcare, and the figures show that fully 75 percent of those are spent on chronic diseases, like heart disease, cancer, and diabetes. And what those diseases have in common is that often they're preventable.

So, Mr. Secretary, I know you agree, because I've read your statements. In this country, we fail to make the necessary up-front investments in prevention. I'm absolutely convinced that prevention is an idea whose time has come. And the good news is, this can be and should be a bipartisan initiative. Senator Specter and I are working together on some wellness initiatives that we plan to include in this year's bill. I look forward to working with you on these initiatives.

For one thing, CDC has promised to send me some more pedometers. Ah-ha, you beat me to it. All right, Mr. Secretary, tell you what I'll do. Unscripted, I tell you what, I may issue a challenge, and I'll issue one to my partner here. We'll all put pedometers on, and we'll see who takes the most steps this year.

Secretary THOMPSON. Ten-thousand steps a day, Senator.

Senator HARKIN. How many?

Secretary THOMPSON. Ten-thousand steps a day.

Senator HARKIN. Are you doing that?

Secretary THOMPSON. Uh-huh.

Senator HARKIN. I may take back my challenge.

Good for you. Well, that is a great example, because that's what we've got to be doing here.

We're doing some other things. I've been working with Senator Frist on getting some signs put by the elevators——

Secretary THOMPSON. Uh-huh.

Senator HARKIN [continuing]. Which they've done at NIH. I don't know if you've done your Department the same. If we just go over there a little bit, there's a stairs. If you climb the stairs, it's healthier, and there's a certain calorie type of thing for how many stairs you climb, and stuff like that, to get people climbing stairs. Well, that's just off the record.

But we're going to get the pedometers, and we're going to try to get this thing moving here on the Hill. But, again, I just wanted to commend you for those things. The Freedom Grants Initiative,

the money that you've requested for the Systems Change Grants—please work with us to get that bill through, the New Freedom Initiative. It's most important. And on all the stuff you're doing on wellness and obesity and things like that—I may differ with you slightly—I have this in my questions—in terms of whether or not it should be mandatory or permissive for restaurants and things like that, on the menus and stuff, and we'll have a dialogue with you on the questions on that.

The one last thing that—on a less positive note, I suppose—I'm concerned about recent reports that the chief actuary for the Medicare program was told not to tell Members of Congress that his office had concluded that the Medicare Prescription Drug Program—that would cost upwards of $10 billion more than previously reported. Again, I'll be asking you this during the question-and-answer period.

Again, Mr. Secretary, I look forward to your testimony.

Secretary THOMPSON. Thank you very much.

Senator SPECTER. Thank you very much, Senator Harkin.

Senator Cochran.

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you very much.

Mr. Secretary, we appreciate very much your exemplary service as Secretary of the Department of Health and Human Services. We also note that you've made strong efforts to begin the implementation of the new Medicare Prescription Drug Initiative. I'm pleased to see, also, the aggressive effort in the budget to safeguard the country against bioterrorist threats—$5 million that's included in the budget to help prepare State and local governments to respond to these disease outbreaks is an important step forward.

I also commend the efforts to identify threats before they reach our country, and to prevent the entry of microbes, diseases, adulterated drug products, and all other items that would threaten the safety of our citizens. The budget also provides funding to help improve the health of those who live in small towns and rural communities, such as in my State of Mississippi. Almost half of those served by small-town health centers are in rural areas. The increase of $219 million to provide for health centers and their sustainment was appreciated very much.

It's my hope that special emphasis can also be placed on targeting research to areas of the country that suffer disproportionately from diseases like diabetes, cardiovascular disease, and obesity. Generally speaking, I think, under the pressures of trying to control spending and deal with the problems of the deficit, this is a budget that should encourage those of us who are interested in improving the health and safety of American citizens.

Thank you very much.

Secretary THOMPSON. Thank you, Senator.

Senator SPECTER. Thank you, Senator Cochran.

Just one note, to answer the question which may be on the minds of many, or at least some, about my Halloween mask. I came out of the restaurant in Philadelphia on Saturday night and tripped on a defect in the sidewalk, and landed squarely on my

nose. And I'm pleased to report that my nose was not broken, but where my nose hit the sidewalk, the sidewalk was broken.

Mr. Secretary, the floor is yours.

Secretary THOMPSON. Mr. Chairman, Senator Harkin, Senator Cochran, thank you very much.

I am very happy that the nose was not broken, and I'm glad that you are mending back in good shape. That could have been a very serious fall, and I'm very happy and appreciative that things are——

Senator SPECTER. Mr. Secretary, my colleague in the Philadelphia city race, Tom Gola, a famous basketball star, lost his balance, slipped and hit his head, and he's been in very serious condition ever since, so there are repeated circumstances of people falling, and even fatalities, so I consider myself very fortunate.

Having brought up the subject, I'm reminded there's a famous story, probably apocryphal, about Winston Churchill laying on a veranda one night, and a woman walked by and saw his condition and said, "You're drunk." And he responded, "You're ugly."

She recounted again, "You're drunk." And he said, "You're ugly." And then she said again, "You're drunk." And he said, "Yes, but I'll be sober in the morning."

Next week, I'll be back to my old appearance, however bad that may be.

SUMMARY STATEMENT OF HON. TOMMY G. THOMPSON

Secretary THOMPSON. I want to thank you, Senator Specter, for inviting me, and Senator Harkin, for giving me this opportunity to discuss the President's fiscal year 2005 budget for the Department of Health and Human Services.

In my first 3 years in the Department, I believe we have made tremendous progress in improving the health, the safety, and the independence of the American people. We continue to advance in providing healthcare to seniors and to low-income Americans, and in providing the welfare to children and strengthening families and protecting the homeland. We have re-energized the fight against AIDS at home and abroad. We've increased access to quality healthcare, especially for minorities, the uninsured, and the underinsured.

We're helping smokers—and I know this is a very big concern of yours, Senator Harkin—free themselves of a debilitating habit through a national hotline. We have set it up in the Department, Senator Harkin, without asking the Congress for any money. It'll be up and running by the end of this year. And I want you to know that I pushed this, and I feel as passionate as you do that we've got to reduce the tobacco. And hopefully someday we'll be regulating it.

With your help, 3 months ago President Bush signed the most comprehensive Medicare improvements since it was created, nearly four decades ago. There has been some controversy, and I know there'll be questions about it, and I'm going to answer those questions completely to this particular Committee.

To expand on our achievements, the President proposes $580 billion for HHS for fiscal year 2005, an increase of $32 billion, or 6 percent, over fiscal year 2004. Our discretionary budget authority

is $67 billion, an increase of $819 million, or 1.2 percent, over fiscal year 2004, and an increase of 26 percent since 2001. And I understand, Senator Specter, that there are some gaps, and I want to work with you to see how we might be able to ameliorate the situation.

Of this total, subcommittee is responsible for $63 billion, an increase of $659 million, or 1.1 percent, over fiscal year 2004, or $974 million under current law. In order to strengthen our bioterrorism preparedness and public-health system, we have requested $4.1 billion, up from $300 million in 2001. And I would respectfully—humbly respect—and invite all of you Senators down to take a look at what we have done in the Department. And I think you'll find it very impressive and informative, what we have built, to be able to track diseases and bioterrorism activities all over the world. I've had a lot of people come down, and everybody that walks out of it feels very much relieved that we are very much there. And I would hope that you'd come down and see it.

This investment will improve our preparedness for bioterrorism attack on any kind of bioterrorism attack or for any public-health emergency. We already have seen our investment pay off, in CDC's leadership in fighting the SARS outbreak last year in a coordinated a public-health response to the West Nile virus, and even helped to deal with a particularly hard flu season this past year.

As you all know, I'm a very big proponent of information technology. That's why we will be providing a computer language, called SNOMED, to any proprietor that wants to, at no charge, starting, hopefully, by the 1st of May. We're leading the way in developing standards for electronic medical records. And last month, I announced an FDA rule to prevent medication errors by requiring bar codes on medicine and blood products.

Community health centers, as you have mentioned, Senator Cochran, are absolutely a key element for increasing access to and availability of healthcare for helping the uninsured. We're proposing to provide $1.8 billion for health centers to provide healthcare services to 15 million Americans. I want to thank you, Senator Specter and Senator Harkin, for your leadership on this. We wouldn't be here today if it wouldn't have been for your great leadership.

Through our New Freedom Initiative, Senator Harkin, we're working to help the elderly, the disabled, by promoting home and community-based centers. In my desire to reduce obesity and diabetes, we, along with the help of Congress last September, my Department announced 12 steps to HealthierUS grants totally more than $13 million to some more community initiatives to promote better health and prevent disease. This included 23 communities, including one tribal organization, 15 small cities and rural communities, and seven large cities. These communities are doing some very exciting work in chronic disease prevention and health promotion. For example, in Washington State, health professionals are targeting Latino adults who have diabetes, asthma, or obesity, or have a high risk of getting those conditions.

In Michigan, through the Intertribal Council of Michigan, public-health officials have created a resurgence of interest in passing on traditional wisdom in cultural practices, including consumption of

highly nutritious traditional foods. We're delighted by these activities, and the Department will expand the program this year with the addition of $44 billion, and has requested $125 million for these programs in 2005.

Later today, I'm going to unveil the Medicare improved drug-discount cards. I will also announce that a Pennsylvania company will be among our Medicare-approved drug-discount card sponsors. This company serves 265,000 Pennsylvania seniors, and, all together, Pennsylvania seniors will receive $486 million this year and next.

PREPARED STATEMENT

We look forward, ladies and gentlemen, to working with this committee, the medical community, and all Americans as we build upon our past accomplishments, implement the new Medicare law, and carry out the initiatives that President Bush is proposing to build a healthier, safer, and stronger America. And I want to thank you for your bipartisan support on health issues.

Thank you, once again, for giving me this opportunity to appear in front of you.

[The statement follows:]

PREPARED STATEMENT OF HON. TOMMY G. THOMPSON

Good morning, Chairman Specter and members of the Subcommittee. I am pleased to present to you the President's fiscal year 2005 budget for the Department of Health and Human Services (HHS). I am confident you will find our budget to be a positive solution to improving the health, safety, and well-being of our Nation's citizens. Before I discuss the fiscal year 2005 budget, I would like to thank the Subcommittee for its hard work and dedication to the programs within HHS. I am extremely proud of the manner in which we have worked together effectively, in a bipartisan effort, since I was appointed Secretary. This cooperation should be lauded and the tremendous results for the American people can be seen in our many accomplishments.

This year's budget proposal builds upon past accomplishments in meeting several of the health and social well-being goals established at the beginning of the current Administration. I deeply appreciate the level of support I have received from the Subcommittee during the past on so many issues that have touched American's lives. For example, with your help, the Department has funded 614 new and expanded health centers. This has effectively increased access to health care for an additional 3 million people, of which 64 percent are minorities, increasing the overall number of patients served in health centers by almost 30 percent. In the past three years, your support for protecting our nation from bioterrorism has made the country better prepared and better protected.

Your unwavering commitment in doubling the budget for the National Institutes of Health has supported work by more than 217,000 research personnel affiliated with 2,000 universities, hospitals, and other research facilities across our great nation. This support has led to a constant flow of new scientific discoveries. We have also established the Access to Recovery State Vouchers program, providing 50,000 individuals with needed substance abuse treatment and recovery services. HHS initiated a new Mentoring Children of Prisoners program to provide one-to-one mentoring for approximately 30,000 children with an incarcerated parent and created education and training vouchers for foster care youth, securing funding to provide vouchers of up to $5,000 to 17,400 eligible youth since 2001. Last year, we worked together with Congress to pass the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), adding prescription drug coverage for seniors and modernizing the Medicare program. While I thank you for your support in these and the many other accomplishments to improve the health, safety, and well-being of our citizens, there is still much to be done.

For fiscal year 2005, the President proposes an HHS budget of $580 billion in outlays to enable the Department to continue working with our State and local government partners, as well as with the private and volunteer sectors, to ensure the health, safety, and well-being of our nation. This proposal is a $32 billion increase in outlays over the comparable fiscal year 2004 budget, or an increase of about 6

percent. The mandatory programs in the HHS budget total $513 billion in outlays. Of this $513 billion, Medicare and Medicaid combine to equal about $474 billion, an increase of approximately $29 billion or 6.5 percent over fiscal year 2004. The discretionary programs in the HHS budget totals $67 billion in budget authority. Of this total, this Subcommittee is responsible for approximately $63 billion in budget authority, an increase of approximately $659 million, or 1.1 percent over fiscal year 2004 for proposed law, and an increase of approximately $974 million, or 1.6 percent over fiscal year 2004 for current law.

For fiscal years 2004 and 2005, the MMA appropriated $1.0 billion in start-up funds so that the Centers for Medicare and Medicaid Services (CMS) would have funds available upon enactment to implement the enormous increase in new administrative responsibilities under the legislation. With rare exceptions, however, these administrative costs have typically been categorized in the budget as discretionary. Thus, this year the President's budget classifies the $1 billion for CMS implementation of the MMA as discretionary.

In addition, the budget identifies approximately $500 million in mandatory program savings for this Subcommittee's consideration. These are four legislative proposals that I believe will lead to increased cost effectiveness and reduced waste in the Medicare and Medicaid programs. First, allowing beneficiaries to purchase durable medical equipment after 13 months instead of 15 months is a lower burden for our beneficiaries and a savings for Medicare, and it will improve access to these products while reducing rental payments. Second, requiring the Centers for Medicare and Medicaid Services (CMS) to use the Administration for Children and Family's (ACF) wage database will allow CMS to identify more quickly whether a beneficiary has employer-sponsored insurance and to determine whether Medicare should be the secondary payer, as opposed to the primary payer, to that other health coverage.

Third, we are proposing to eliminate a windfall to the States by reducing Federal reimbursement for Medicaid administrative costs by about $300 million. Most states' TANF Block Grants were based on expenditures that included the costs of determining Medicaid eligibility, but they have also received Federal match for these expenditures through Medicaid since TANF's implementation. Our proposal seeks to eliminate this double payment for fiscal year 2005. Finally, we are proposing to change the enhanced matching rates for administrative activities toward systems' improvements, consistent with other enhanced rates.

EXPANDING ACCESS TO HEALTH CARE FOR AMERICANS

One of the most important issues on which we can continue to work together, is expanding access to quality health care for all Americans. In 2002, the President launched an initiative to expand access to health care by creating 1,200 new or expanded health care sites and serving an additional 6 million people by 2006. Since the initiatives inception, with the strong bi-partisan support of this Subcommittee, the Health Centers program has significantly impacted more than 600 communities, serving over 13 million patients, 3 million more than in 2001, 40 percent of who have no health insurance coverage, and many others for whom coverage is inadequate. In addition, States use Health Insurance Flexibility and Accountability (HIFA) demonstrations to expand health care coverage. As of January 2004, HIFA demonstrations expanded coverage to 175,000 people and another 646,000 were made eligible.

While we have made significant strides in this endeavor, there is still much work to be done. In fiscal year 2005, the President's budget request will continue to expand resources for Health Centers to a level of $1.8 billion, an increase of $219 million over fiscal year 2004. This increase will result in increased services for an additional 1.6 million people in approximately 330 new and expanded sites. This level will provide access to comprehensive preventative and primary care services, at over 3,800 health sites nationwide, for a total of almost 15 million uninsured and underserved individuals, nearly 7 million from rural areas.

ACCESS TO RECOVERY

Mr. Chairman, the fiscal year 2005 budget represents the fourth year of the President's strong commitment in leading our nation's battle against addiction. With your support, we have made significant progress. Current use of illicit drugs among students has declined by 11 percent between 2001 and 2003. However, there continues to be an unmet need for drug treatment services. The fiscal year 2005 budget will provide 100,000 individuals with drug and alcohol treatment benefits by doubling funding to $200 million for the Access to Recovery State Voucher Program. This program will allow individuals seeking clinical treatment and recovery support services

choices among qualified community provider organizations, including those that are faith-based. The program's emphasis is on objective results and is measured by outcomes, including decreased or no substance use, no involvement with the criminal justice system, attainment of employment or enrollment in school, family and living conditions, and social support.

DISEASE DETECTION AND BIOTERRORISM PREPAREDNESS

In the past three years, your support for our bioterrorism efforts has been unwavering, and together we have made tremendous strides in protecting our nation from various threats. While we have made great strides, it is imperative that we remain steadfast in our commitment to protect our nation and the well-being of all its citizens. The fiscal year 2005 request for HHS bioterrorism activities is $4.1 billion, an increase of $155 million above fiscal year 2004, and $3.8 billion above the fiscal year 2001 level.

This work will be coordinated with the Global Disease Detection Initiative at CDC. The Global Disease Detection Initiative (+$27.5 million) will help the United States learn more rapidly about new disease threats that emerge in other Nations. CDC will recognize infectious disease outbreaks abroad faster, and help those nations identify and stop those diseases before they arrive in the United States. In order to accomplish this task, CDC will expand its presence internationally and collaborate with multinational organizations, such as the World Health Organization (WHO) to improve overall global disease detection, control, and surveillance. CDC will also invest an additional $10 million to expand quarantine efforts at ports-of-entry for international travelers.

Funds will be directed to carry out a new interagency bio-surveillance initiative to prepare against a potential bio-terrorist attack. The Centers for Disease Control and Prevention (CDC), in coordination with the Food and Drug Administration (FDA), the Department of Homeland Security, and the Department of Agriculture, will be working to improve the response to bioterrorism through early detection with the BioSense Surveillance Initiative. Through this program, we will improve human health surveillance, strengthen the laboratory response network, and increase the numbers of boarder health and quarantine stations, which will allow us to identify and isolate potential disease outbreaks more rapidly.

We also continue our work in building the Strategic National Stockpile of drugs, vaccines and medical supplies that can be shipped anywhere in the country on short notice, with a request for $400 million in fiscal year 2005. The fiscal year 2005 budget returns the financing of the stockpile to HHS. DHS will continue to have the authority to order deployment of the stockpile in an emergency, along with HHS. The fiscal year 2005 budget includes a three-year financing plan to expand our antibiotic stockpile to be able to provide post-exposure anthrax treatment from 13 million to 60 million people. In fiscal year 2005, we have included a contingency provision that will allow us to transfer up to $70 million to the Stockpile from funds available for State and local preparedness, should the added funds be needed.

Our nation's ability to detect and counter bioterrorism ultimately depends on the state of biomedical science, and the National Institutes of Health (NIH) will continue to ensure full coordination of research activities with other Federal agencies in this battle. The fiscal year 2005 budget includes $1.74 billion for NIH biodefense research efforts, an increase of $120 million, or +7.4 percent. Included within this biodefense total is $150 million to support the construction of Biosafety laboratories for NIH to help develop medical protection from bioterrorism, and to back up State and Federal public health laboratories. Prior to fiscal year 2002, only a few laboratories in the United States were capable of conducting research on potential bio-terrorism agents. The $150 million investment in fiscal year 2005 will fund an additional 20 Biosafety Level 3 laboratories across the country.

The ability to mitigate the health effects of radiation exposure in the potential event of the use of a limited nuclear or radiological device in a terrorist attack presents a critical challenge for which little progress has been made in the last forty years. For fiscal year 2005, $47 million is requested in the budget for the Public Health and Social Services Emergency Fund, to be coordinated and managed by NIH. This new initiative will support targeted research activities needed to develop medical countermeasures to more rapidly and effectively treat nuclear or radiological injuries.

Throughout my time as Secretary, many steps have been taken to allow for improved access to vaccines for those in need and better methods to combat the spread of influenza viruses. The average Medicare reimbursement rate to physicians for the administration of the flu vaccine increased from $3.98 per dose in CY 2002, to $7.72 in CY 2003, an increase of +94 percent. The payment increased again in 2004 to

$8.25 per dose. In fiscal year 2004 and 2005, $40 million per year will be used for creating a stockpile of children's influenza vaccine to ensure this past year's shortages do not reoccur. While these previous measures have improved access to vaccines, we must also look toward future improvements. It is imperative that the United States develops the domestic capacity to produce rapidly the vaccine our nation would need in a pandemic. For that reason, the fiscal year 2005 budget seeks to double to $100 million our investment to ensure a year round production capacity for influenza vaccines to improve our preparedness for an influenza pandemic, as well as develop production technologies that could be scaled-up rapidly to provide surge capacity during a pandemic.

CHILDHOOD VACCINES

The Budget includes two legislative proposals in Vaccines for Children that I believe should be strongly supported by the members of this Subcommittee. This legislation would enable any child who is entitled to receive VFC vaccines to receive them at State and local public health clinics. There are hundreds of thousands of children who are entitled to VFC vaccines, but can receive them only at Community Health Centers and other Federally Qualified Health Centers. The proposal ensures VFC coverage of childhood vaccines for VFC eligible children when they show up for services at a public health clinic. Given the rising cost of childhood vaccines, ensuring access to VFC vaccines for eligible children is especially important. Legislation is also needed to restore tetanus and diphtheria vaccines to the VFC program. The VFC authorization caps prices at such a low level that no manufacturer will bid on a VFC contract. As a result, the vaccines that are provided to VFC children through the public health system have to be financed with scarce discretionary resources. Enactment of the legislation the budget proposes would, at the same time, expand by $55 million the vaccines that are available to children while reducing by $110 million the demand for vaccines financed with discretionary appropriations.

CDC will continue to build a six-month, vendor-managed stockpile of all routinely recommended childhood vaccines. Between fiscal year 2004 and fiscal year 2006, CDC will invest an additional $583 million to meet target quantities needed for a six-month stockpile. Vaccines from the stockpile can be distributed in the event of a disease outbreak and will mitigate the effect of any potential manufacturing supply disruption.

COMPLETION OF THE DOUBLING OF NIH

I commend you, Mr. Chairman, and this Subcommittee, for your commitment in doubling the budget for the National Institutes of Health, consistent with the President's request. Building on the momentum generated by the fulfillment of the President's commitment to complete the five-year doubling of the NIH budget, the fiscal year 2005 request provides $28.8 billion for NIH. This is an increase of $764 million, or +2.7 percent, over the fiscal year 2004 level. In fiscal year 2005, over $24 billion of the funds requested for NIH will flow out to the extramural community, which supports work by more than 217,000 research personnel affiliated with 2,000 university, hospital, and other research facilities across our great nation. These funds will support a record total of nearly 40,000 research project grants in fiscal year 2005, including an estimated 10,393 new and competing awards.

NIH remains the world's largest and most distinguished organization dedicated to maintaining and improving health through the use of medical science. Major advances in scientific knowledge, including the sequencing of the human genome, are opening dramatic new opportunities for biomedical research and providing the foundation for un-imagined results in preventing, treating, and curing disease and disability. Investment in biomedical research by NIH has driven these advances in health care and the quality of life for all Americans, and the fiscal year 2005 budget request seeks to capitalize on the resulting opportunities to improve the health of the nation.

In an effort to target gaps and opportunities that no single NIH institute could solve alone, the fiscal year 2005 budget allocates $237 million for the Roadmap for Medical Research initiative, an increase of $109 million (or +85 percent) over fiscal year 2004. This initiative consists of three core themes of establishing new pathways to discovery, inventing the research teams of the future, and re-engineering the clinical research enterprise.

COMMUNITY AND FAITH-BASED INITIATIVES

In support of the President's Community and Faith-Based Initiative, the fiscal year 2005 budget maintains a commitment toward programs that link community and faith-based organizations with State, local governments, and Federal partners

programs. The initiative creates results by empowering those at the community level, who can best identify the social and health related problems. Those at the community level can then act to produce positive results and be agents of change in the lives of the most needy.

The President's budget requests a total of $100 million for the Compassion Capital Fund, doubling the fiscal year 2004 level. Initiated in fiscal year 2002, the Compassion Capital Fund awards grants to organizations which provide technical assistance to help faith-based and community organizations access funding sources, operate and manage their programs, develop and train staff, expand the reach of programs into the community, and replicate promising programs.

As our nation's prison population continues to rise, another important program that reaches our most vulnerable children is the Mentoring Children of Prisoners program. Studies indicate that children with incarcerated parents have a seven times greater chance of becoming incarcerated themselves and are more likely to succumb to substance abuse, gangs, early childbearing, and delinquency. This budget request includes $50 million, maintaining the fiscal year 2004 level, to provide grants to enable public and private organizations to establish or expand projects that provide mentoring for children of incarcerated parents and those recently released from prison. This activity will give 30,000 adolescent children of prisoners a beacon of hope in their world of despair.

The President's budget includes $10 million for Maternity Groups Homes as part of the Transitional Living program. This will provide pregnant and parenting youth who cannot live safely with their own families access to adult-supervised community-based group homes, and a range of coordinated services including childcare, job training, and counseling.

HEAD START PROGRAM

One of the most fundamental truths in our society today is the necessity for a solid educational background to allow all children the opportunity to succeed. The initial educational experience is the bedrock of our children's healthy growth and development. Mr. Chairman, with the generous support of this Subcommittee, we have made a significant difference in this beginning stage of our children's growth and development. This commitment towards meeting the needs of our most vulnerable citizens is unwavering and remains stronger than ever with the 2005 President's budget request of $6.9 billion for Head Start. This is an increase of $169 million over the fiscal year 2004 level. In fiscal year 2005, 919,000 children will receive Head Start services including 62,000 children in the Early Head Start program.

In fiscal year 2005, we will continue to emphasize the goals of the President's Good Start, Grow Smart Initiative to strengthen Head Start by partnering with States, by providing information on child development and early learning to teachers, caregivers, parents, and grandparents, and close the gap between research and practice in early education. The fiscal year 2005 request includes $45 million to support the President's initiative to improve Head Start by funding nine State pilot projects coordinating State preschool programs, Federal child care grants, and Head Start into a comprehensive system of early childhood programs for low income children. The budget also includes $124 million to maintain competitive salaries for Head Start teachers and to support program enhancements in early literacy and cognitive development.

PREVENTION INITIATIVES

More than 1.7 million Americans die of chronic diseases—such as heart disease, cancer, and diabetes—each year, accounting for 79 percent of all U.S. deaths. Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. The budget includes $915 million for CDC's Chronic Disease Prevention and Health Promotion program, an increase of $62 million over fiscal year 2004.

Within this request is $125 million, an increase of $81 million, for the Steps To A Healthier U.S. Initiative. This increase will fund the State and community grant program initiated this past September to reduce the prevalence of diabetes, obesity, and asthma-related complications, targeting those at high risk. Last year these funds reached 23 communities, including seven large cities, one Tribal consortium, and 15 smaller cities and rural areas, and more areas will benefit during the upcoming year. Also a total of $10 million will be used to expand the Diabetes Detection Initiative, which targets at-risk populations. The aim of this initiative is to reach these populations where they live, work, and play through a customized, tailored approach with the aim of identifying undiagnosed diabetes.

The fiscal year 2005 budget request for the CDC National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is $220 million, an increase of $10 million over fiscal year 2004. This program has helped to increase mammography use by women aged 50 and older by 18 percent since the program's inception in 1991. Efforts are targeted toward low-income women with little or no health insurance and have helped to reduce disparities in screening for women from racial and ethnic minorities. With the requested increase, an additional 32,000 diagnostic and screening services will be provided to women who are hard-to-reach and have never been screened for these cancers.

MENTAL HEALTH TREATMENT

In meeting the President's goal of transforming the mental health system and increasing access to mental health services for some of our most vulnerable citizens, the fiscal year 2005 budget includes $913 million in discretionary funding for mental health services, an increase of $51 million over fiscal year 2004, or +6 percent. As an important step in reshaping this delivery system, the budget proposes $44 million for State Incentive Grants for Transformation. These new grants will support the development of comprehensive State mental health plans to reduce system fragmentation and increase services available to people living with mental illness.

Recent studies have found that 20 percent of individuals experiencing chronic homelessness also have a serious mental illness. This request proposes $10 million for the Samaritan Initiative, an Administration-wide initiative to reduce chronic homelessness, jointly administered with the Departments of Housing and Urban Development and Veterans Affairs. Through this initiative, States and localities will develop processes to better enable access to the full range of services that chronically homeless people need, including housing, outreach, and support services such as mental health services, substance abuse treatment, and primary health care.

FIGHTING HIV /AIDS

HIV is one of the most serious and destructive challenges facing humanity in our world today. No country, whether large or small, rich or poor, can escape the devastation it brings. All have citizens whose lives have been destroyed by this horrible disease, and our commitment to ending this pandemic is both strong and unwavering. No nation in history has ever committed the time, energy, and fiscal resources that the United States has invested in this effort. The fiscal year 2005 total HHS budget will continue this emphasis with the request for HIV/AIDS funding of $15 billion, or +31 percent over fiscal year 2001 for both domestic and global HIV/AIDS prevention, care, treatment, and research activities.

Specifically, the fiscal year 2005 budget includes $784 million for States to purchase medications for persons living with HIV/AIDS. At this level, monthly AIDS Drug Assistance Programs will increase from 93,800 clients in fiscal year 2004 to 100,000 clients in fiscal year 2005. Also included is $53 million for the HIV/AIDS in Minority Communities activities to support innovative approaches to HIV/AIDS prevention and treatment in minority communities.

MARRIAGE AND HEALTHY FAMILY DEVELOPMENT

The President announced an expanded initiative to build on research that there are life-long benefits of growing up in married-parent families. This initiative, comprised of new and existing programs, has four elements: (1) supporting marriage and families; (2) providing tools to parents; (3) teaching values to children; and (4) encouraging community and faith-based organizations to support families.

Within this initiative is $273 million to help parents and communities provide teens with the tools to make responsible choices and abstain from early sexual activity. The budget includes $50 million to support a new program that will assist noncustodial fathers in becoming more involved in their children's lives, and $107 million to nearly double funding for State child abuse programs to reduce the incidence of child abuse and neglect and increase services to those who are victims.

HEALTH CARE INFORMATION TECHNOLOGY

Improvements in the safety, effectiveness, and efficiency of health care, as well as in public health preparedness, can best be achieved by the accelerated use of health information technology (IT). Therefore, the fiscal year 2005 budget requests $50 million in new funding for a Health Care IT initiative. This amount, by funding demonstrations and investing in private sector and public program partnerships, will accelerate the development and utilization of modern IT in both health care and public health. These investments will assist development by the private sector of

needed standards, examine ways the use of IT can be encouraged, coordinate actions across all agencies, and ensure that this investment will further the national health information infrastructure.

These resources will be made available to local, regional, tribal and State data exchange networks and organizations, to provide the infrastructure necessary for exchange of a patient's health information within that area, and with other such organizations nationally. In addition, technical assistance and resources to these networks and information infrastructures will be available. These investments will complement and build upon the Agency for Healthcare Research and Quality's (AHRQ) demonstration grants and other activities to evaluate the effects of IT on the safety and quality of health care—a critical component of assuring that IT's positive benefits are adopted broadly.

MODERNIZATION AND REFORM INITIATIVES

With the enactment of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Department faces many challenges in the coming fiscal year. A top priority for CMS, and all Operating Divisions within HHS, will be the timely implementation of the sweeping changes in the law. As the most significant reform of Medicare since its inception in 1965, the law expands health choices for beneficiaries and adds a prescription drug benefit. MMA will strengthen and improve Medicare, while providing beneficiaries with new benefits and the option of retaining their traditional coverage.

Along with Medicare reform, the President remains fully committed to strengthening and empowering America's families through legislation supporting welfare reform, modernization of Medicaid and SCHIP, increased child support enforcement, and reform of the child welfare system.

MANAGEMENT IMPROVEMENTS

Finally, I would like to update the subcommittee on the Department's efforts to use our resources and the taxpayer's dollars in the most efficient manner. To this end, HHS remains committed to setting measurable performance goals for all HHS programs and holding managers accountable for achieving results. I am pleased to report that HHS is making steady progress. We have made significant strides in streamlining and making performance reporting more relevant to both decision makers and customers. As a result, the Department is better able to use performance results to manage and to improve programs. By raising our standards of success, we will continue to improve efficiency and increase our ability to improve the health of every American citizen.

IMPROVING THE HEALTH, SAFETY, AND WELL-BEING OF OUR NATION

Chairman Specter and members of the Subcommittee, I would like to thank you once again for your passion and support in working with us in this fight to improve the health, safety, and well-being of all Americans. The budget I bring before you contains proposals from many different areas. These programs, from enhancing the building blocks for our youngest and most vulnerable with Head Start, to expanding Health Centers to increase the access to quality health care for minorities, to protecting our nation from the threat of bio-terrorism, all meet vital needs within our communities. All of these proposals, which vary greatly in substance, are put forth with one simple overarching goal of ensuring the health, safety, and well-being of all Americans. I know that this goal is one that we share together, and I look forward to your continued support as we move toward turning our passionate commitment into positive results for the American people.

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

We will now proceed with our customary 5-minute rounds.

PRESCRIPTION DRUG BENEFIT ESTIMATES

Mr. Secretary, the morning news reports are filled with the testimony of Mr. Richard Foster before a House committee yesterday, where he, in his capacity as the Medicare programs chief actuary, told House Members that he gave an analysis last June to the White House and the President's Budget Office which was not shared with the Congress, predicting that prescription drug benefits being drafted on Capitol Hill would cost about $150 billion

more than President Bush said he wanted to spend. And he further reported that unnamed administration officials, or perhaps they are named, threatened to fire him.

I have two questions for you on that. Do you have any personal knowledge that the cost estimate of $150 billion was concealed? And, second, do you have any personal knowledge about the alleged threats?

Secretary THOMPSON. Senator, let me quickly respond, as accurately as I possibly can. Number one, I read in the paper, after the alleged threat by the Administrator of CMS—I had my chief of staff immediately——

Senator SPECTER. The first you knew about it was reading about it in the newspaper?

Secretary THOMPSON. No, no. This was way back in June when this took place. I read about it in the newspaper, I heard about it, and I had my chief of staff call——

Senator SPECTER. And my question is: The first time it came to your attention was when you heard news reports?

Secretary THOMPSON. That is correct. Last June.

Senator SPECTER. Okay.

Secretary THOMPSON. And then I had my chief of staff contact Mr. Foster and tell him, directly from me, that his job was not in jeopardy.

Now, the actuary's assumptions, based upon that, was only for the first section of Senate bill 1, and that was $550 billion. I did not know of that figure. I did know of the assumptions that Rick Foster had projected that we would be having more people participate in Medicare, by 94 percent versus CBO's number of 87 percent that was publicized. The Congress knew about that. The administration knew about that. And that was the big difference.

The second difference on the cost estimates was based upon how much is going to be used by low-income seniors. We assumed that it's going to be a lot more than CBO. CBO scores it at 87 percent. We score it at 94 percent. That is a difference of about a $100 billion of the $134 billion difference between CBO and our actuary. That's based upon assumptions. Those figures were known—not the exact figures. The fact is, is that we knew that they were going to be more, and we made that to be known to the Congress.

Senator SPECTER. Well, focus specifically on what Mr. Foster——

Secretary THOMPSON. Okay.

Senator SPECTER [continuing]. Has said. And that is that he had a figure of $154 billion more than the President's figure, and he did not tell Congress about that $150 billion more.

Secretary THOMPSON. Senator, that was based upon an earlier bill. That was Senate bill 1 that was introduced—that was the chairman's score from the Finance Committee. That was not the bill that was debated on the floor of the Senate or the House of Representatives. Those figures didn't come out until December of this past year, after the bill passed.

Senator SPECTER. So are you saying that his allegation is factually incorrect, that he did not have information about $150 billion excess beyond what the President wanted to spend, and that he did not conceal that from the Congress?

Secretary THOMPSON. I'm saying that the $150 billion difference is based upon an earlier version of the bill, and the final version is $134 billion, and that didn't come out until December 13. And the $150 billion was based upon only the first section of the bill. And there was no—to the best of our knowledge, and we have looked through all the records—there has not been any written record where any Member of Congress has asked for the earlier assumptions or the earlier figures. And that's why I've asked the inspector general of my Department to get all the facts so that we can report it to Congress. I have asked the inspector—have asked the Inspector General to make a detailed report to me and to Congress.

Senator SPECTER. My red light just went on, and I want to observe the time limits, so I'll turn now to Senator Harkin.

Senator HARKIN. Mr. Secretary, I think the record will show here that you might have made a little bit of a misstatement, because I made a note on this. You said you read about this last June in the news reports. You did not read about it last June.

Secretary THOMPSON. Yes, I did.

Senator HARKIN. There was a news report last June——

Secretary THOMPSON. Yes, there was.

Senator HARKIN [continuing]. In the newspapers——

Secretary THOMPSON. Absolutely.

Senator HARKIN [continuing]. Saying that there was this higher estimate?

Secretary THOMPSON. No. No, there was a—the newspaper article that was last June was—is that—it came out, it was reported by AP, that Mr. Foster had been threatened that he was going to lose his job if he didn't send up—and what was requested was the score on the benefits of the particular bill, on premium support.

Senator HARKIN. Premium support, that's——

Secretary THOMPSON. Premium support. And that was what was requested. That was what Tom Scully had told Rick Foster not to send up. That's what was said.

Senator HARKIN. Okay.

Secretary THOMPSON. Then Tom Scully says, "Somebody made the allegation that you're going to get fired if you send it up." When I heard that, I asked my chief of staff to call—which he did—call Mr. Foster and say, "Your job is not in jeopardy at all." Mr. Foster has testified to that.

Senator HARKIN. Okay, then, I still wonder why we were not given those numbers.

Secretary THOMPSON. We've looked at it, Senator Harkin, and we do not believe there has ever been a written request from any Member of Congress—neither the Senate or the House had ever requested for those figures. Those figures were preliminary figures on Senator Grassley's bill, and it was only on the benefit portion, on the drug portion, not the total bill. And that figure was $551 billion. And the last figure that deals with the bill that was passed was $534 billion.

Senator HARKIN. Uh-huh.

Secretary THOMPSON. That's $17 billion difference, and that's—and Rick Foster testified yesterday that the final figures did not come out until the latter part of December, after the bill passed.

Senator HARKIN. That's right. But on June 3, Foster made his higher estimate. That's one. That was $150 billion.

Secretary THOMPSON. That is—but that was on a different bill. That was on——

Senator HARKIN. That was on S. 1.

Secretary THOMPSON [continuing]. S. 1. But that was—that was the chairman's mark, and that was only on the drug benefit. It wasn't on the other seven provisions of the bill, the other seven chapters.

Senator HARKIN. Okay. So then the bill passed in November, but the bill that passed—it was somewhat different than S. 1, obviously.

Secretary THOMPSON. Completely different.

Senator HARKIN. Well, I don't know that it was completely different; it was somewhat different. But are you saying that it made no difference whether or not we knew there was $150 billion more, or what the estimates were by the time the bill passed?

I guess it just seems to me that, you know, who knew what, when, and how they knew it, and all that kind of stuff. It just seems to me that we have a fundamental question here. Do you think it should be the policy of the administration, any administration, that the actuaries officers at CMS provide technical assistance to Members of Congress, as I understand the practice was before this year? Now, I could be mistaken on that. But I understand the practice was that the actuaries office at CMS provided information to the relevant committees.

Secretary THOMPSON. We have looked at that, and that was not the practice, and that's why there was some report language put in, in the Balanced Budget Act, because members of the Republicans were not able to get it from the actuary under the previous administration.

But to answer your question, Senator Harkin, I think that that information should be made available, and I have testified to that previously.

Senator HARKIN. I agree with you, because obviously it was collected at taxpayers' expense. I mean——

Secretary THOMPSON. Yes, sir.

Senator HARKIN [continuing]. This is not some private entity doing this, and that—those figures ought to be available for policymakers. I don't know what the end result is going to be, but I hope it is that we have access to these kind of figures in the future, I hope.

Secretary THOMPSON. I think you should. I think you will. The CBO numbers are the ones that are—and those are the ones—the CBO still says it's $395 billion, not the $534 billion. And there's a logical explanation that I could go into if you would want me to, Senator Harkin.

Senator HARKIN. My time is up. I hope we get a second round, because I did want to ask you about the Wellness Program.

Senator SPECTER. There will be a second round, Senator.

Senator HARKIN. Thank you, Mr. Chairman.

Senator SPECTER. Senator Cochran.

DRUG REIMPORTATION

Senator COCHRAN. Mr. Secretary, we've had some debates and votes on amendments here in the Senate relating to importation of pharmaceutical products from other countries. Are there sufficient funds in this budget request to deal with the problem of counterfeit or unsafe pharmaceutical products that may enter the United States from other countries?

Secretary THOMPSON. I don't think so, Senator. I think it's a growing problem, and I think that we are doing the best job possible. As you know, I requested this Congress, early on when I came on, to get enough inspectors to deal with some things with food. We have increased it. But, overall, I still think that there is a good chance of having counterfeit drugs. And we see that every time we stop. We had, as you know, some inspections at the border not too long ago, one in July and one in September and October of this year, and about 87 percent of the drugs that came in were either mislabeled, mis-packaged—some were counterfeit, some were not certified by FDA, or approved by FDA. So a lot of drugs that come into America are not regulated by the FDA.

Senator COCHRAN. Are you making an effort to bring this to the attention of our friends around the world, and try to get help there in those countries?

Secretary THOMPSON. We are. We have a very strong, aggressive outreach program to other countries, especially to Canada. But Canada has pretty much indicated that it's not their problem, and it's our problem, and that we should address it ourselves. We have started hearings. Last Friday was the first hearing. I set up a commission, headed up by Surgeon General Carmona, to take a look at reimportation, importation, as well as ways in which we can develop it.

We've also set up a task force on counterfeit drugs, and we announced that a couple of weeks ago. We're working with the Federal Trade Commission and the Department of Justice in regards to that.

We're quite aggressive, but your question was, are there enough resources? I don't think there are, because FDA is very strapped with all of its demands. And this is a huge problem, and if, in fact, we are going to have reimportation, we're going to have more resources in order to make sure that this reimportation of drugs are safe.

VACCINES

Senator COCHRAN. In connection with the availability of vaccines to deal with threats to the public health——

Secretary THOMPSON. Yes.

Senator COCHRAN [continuing]. There seems to be a gap between what we should have and what we do have in the way of an inventory of vaccines, being able to locate them, and then mobilize our resources to deliver them where they may be needed in case of an outbreak of a disease or illness. Is there any effort in the budget to deal with that problem by providing funding to the Centers for Disease Control or other agencies that could help move us in the direction to deal with that more effectively?

Secretary THOMPSON. Absolutely, there is, and you've already done a great deal, and I wish you could just come down and see how we track this. We have got the country split up into 12—in 10 regions, but we have 12 strategic locations where we have 600 tons of medical supplies, antibiotics, vaccines that we can strategically deploy to any city in America within 7 hours. It takes nine semi-truck loads or a KC–135 in order to do so. And we track that.

We also have got, at the present time, enough smallpox vaccine, 400 million doses, to vaccinate every man, woman, and child in America. We have enough doxycycline and Cipro, as far as anthrax is concerned, to treat 14 million people in America for 60 days. We have money in here to go to 20 million, which is a huge increase of supplies that we're going to have to put in the supplies depots, but we're going to do that.

We are asking for a BioShield, which is still tied up in Congress, and this is going to allow us to reach out to the pharmaceutical and biological companies to develop new vaccines for tularemia, for the plague, and for hemorrhagic superviruses, and so on.

We're doing a lot, but we can always do more. I'm very satisfied with where we are, but I know that we can improve, and that's what we intend to do.

Senator COCHRAN. Thank you very much for your efforts in this area. It's so important to homeland security and the health and safety of our American citizens.

Secretary THOMPSON. I would hope you'd come down and see us, Senator.

Senator COCHRAN. I'll do that. I need to go to the Center for Disease Control, too. I've never gone down there to take a tour around. I've seen photographs of some of the buildings that need upgrading——

Secretary THOMPSON. Senator Specter's been down there. I'd like you to come down there. It's worth your time to do it. We're only a block away. If you come down, I can get you through in a half an hour, 45 minutes, and I can show you exactly how we track diseases and storms and whatever we've got to face. It's really an educational type of thing, and it's really—I invite you. I'd love to have you come down and host you and get a chance to see it.

Senator COCHRAN. I accept your invitation, with pleasure.

Secretary THOMPSON. Thank you.

ORASURE

Senator SPECTER. Mr. Secretary, a Pennsylvania company, Orasure Technologies, Incorporated, in Bethlehem, has developed a 20-minute HIV test, and I know you're familiar with it.

Secretary THOMPSON. I'm very excited about it, Senator.

Senator SPECTER. On March 10, Orasure met with HHS officials regarding additional purchases through the Substance Abuse and Mental Health Administration, and was led to believe that SAMHSA had committed to a $13 million purchase order; however, SAMHSA has now told staff that no such commitment has been made, and any potential purchase will be less than $5 million. You and I have exchanged correspondence on it. I would be interested to know whether there was any commitment for a $13 million purchase, and what you anticipate by way of a purchase in light of the

remarkable technology at hand and the tremendous need for determining, in Africa and other places, whether the people have HIV/AIDS?

Secretary THOMPSON. I can't answer you specifically as to what was committed by SAMHSA, or if there was a misunderstanding, but I will get an answer to you very quickly. I'm sorry about that, that I don't have it at the top of my head, Senator Specter.

[The information follows:]

ORASURE

We are committed to using new technology to identify undiagnosed HIV-positive individuals, help them reduce risk of transmission, and refer them to care. In fiscal year 2003 CDC bulk-purchased $2 million of rapid tests (250,000 kits), and has placed an additional $2 million order for fiscal year 2004. We have also encouraged our international partners to consider the OraQuick tests in their efforts to identify individuals with HIV/AIDS. The Global Assistance Program countries frequently use OraQuick as a tie breaker when two less expensive tests give different results.

SAMHSA submitted a request to the HIV/AIDS in Minority Communities Fund to purchase HIV rapid test kits for its HIV/AIDS grantees. At this time, no final decision has been made about the level of funding available for this request. The HIV/AIDS in Minority Communities Fund supports innovative approaches to HIV/AIDS prevention and treatment in communities of color. Each year HHS agencies/offices submit proposals for activities to reduce the disproportionate impact of HIV/AIDS on racial and ethnic minorities. In fiscal year 2003, a total of eight agencies/offices received dollars from this fund. It is our hope to reach final decisions on these dollars very shortly.

GLOBAL FUNDS FOR AIDS, MALARIA, AND TUBERCULOSIS

Secretary THOMPSON. In regards to Africa, as you know, I'm chairman of the Global Fund for fighting AIDS, malaria, and tuberculosis. I advised—we just came back from Geneva this past—we had our seventh board meeting, and I advised the board of this new, innovative idea that Orasure has come up with. The problem we have in the Global Fund is that it will use Orasure to be the arbitrator. They don't use it for the basics. I mean, they have a cheaper product. And if there's some question as to the accuracy, then they bring in Orasure to determine for sure. When they came out with this new quick test, I'm hoping to be able to push through the Global Fund to be able to be a bigger user of Orasure's product, because I'm very sold on it, and I'm very—I think the company is doing a tremendous job, and I think it could help save us money in the future.

Senator SPECTER. Well, thank you for that answer and for your assurances that you will take a look to see what commitments——

Secretary THOMPSON. I will.

Senator SPECTER [continuing]. Have been made by SAMHSA or others in your Department.

CDC AND NIH BUDGETS

A two-part question, Mr. Secretary. Your budget document states there is a growing concern that the next public-health emergency could overwhelm current capacities to respond, and would likely overwhelm CDC's current capabilities. How can we realistically cut the CDC budget by $116 million on their overall budget, and almost 180 million on their buildings and facilities, in the light of their mission and the tremendous threats?

The second question I have for you relates to the budget of the National Institutes of Health, where we are facing a situation with the administration request to lead to a drastic curtailment of NIH awards.

If you would respond to those two questions, I would appreciate it.

Secretary THOMPSON. Thank you. And let me quickly respond so I can get to both of them.

In regards to CDC, let me say that I let you down, Senator. I did not sell as effective as I thought I should have been able to, to get a little more money into buildings. That is the big difference in the reduction at CDC. As you all know, and you've been the leader in this, we're trying to get $250 million a year down there, and we came in with a budget of $82 million, of which $40-some million is going to Fort Collins. That is the big difference. A reduction in the VERB program was the other. I gave Director Gerberding, Assistant Secretary Julie Gerberding, an allotment of what she could do. She came in with the best budget she could. I think it's quite good.

In regards to overwhelming the resources, the biggest thing I'm concerned about right now is a pandemic flu, and we have put some additional money in there, $50 million in the CDC, I've got $50 million into my accounts, in order to try and make sure that we are prepared to try and move companies from the egg culture to the cell culture, especially with avian flu that may come or may not come. I am very concerned about that. And avian flu could have the potential for destroying some of the egg stock because it affects chickens, and so we're trying to do something.

In regards to NIH, we still, under our budget, are going to be able to give out more grants. Where we saved the dollars was reducing what was called the cost of increase to the cost of inflation over the 4-year grants, and we reduced that approximately from about 3.3 percent down to about 1.3 percent. But next year, even if our budget—if Congress doesn't put more money into it, there will be more grants out there than there has been before. And since I've been Secretary, thanks to you, the Congress leadership in giving us the dollars, we have gone up by 30 percent in grant applications, in grant requests, in grant approvals, and 42 percent increase in the amount of dollars that those grants have been able to receive.

Senator SPECTER. My red light went on in the middle of your answer, Mr. Secretary. And we will be submitting more detailed questions on NIH——

Secretary THOMPSON. Thank you.

Senator SPECTER [continuing]. For the record.

Secretary THOMPSON. I would be more than happy to answer them, sir.

Senator SPECTER. We've been joined by the distinguished chairman of the full committee.

Senator Stevens.

HEALTHCARE DELIVERY

Senator STEVENS. Thank you, Mr. Chairman. I do have three other areas to stop by—I stopped by here, Mr. Chairman, because

I don't think any person in history has brought more hope to the Alaska native people in the area of healthcare delivery than Secretary Thompson, and I'm——

Secretary THOMPSON. Thank you.

Senator STEVENS [continuing]. Here to thank you very much and, what's more, to invite you back again. Your annual visits really bring great hope to our people.

ALASKA DENTAL ASSOCIATION

You may be interested to know that yesterday, for the first time, the American Dental Association, the Alaska Dental Association, approached me with the idea of trying to interface some dental care into the village health clinics. That has been a total gap, in terms of the care——

Secretary THOMPSON. Huge gap.

Senator STEVENS [continuing]. Of Alaska natives. It's really great news. They came forward on their own, and I look forward to working with you and with your people on trying to partnership with them. They're willing to take on part of the cost. It's a very interesting thing.

POSITRON EMISSION TOMOGRAPHY

I also am grateful to you for what you've done to help us try to move CMS forward to bring about the favorable coverage decision for PET, positron emission tomography. I do believe, Mr. Chairman, that there's no system that holds more hope for dealing with the baby-boom generation than PET, in terms of trying to get a handle on Alzheimer's and those diseases related to dementia. And, clearly, if we follow through in that generation with the amount of Alzheimer's we've had in my generation, the cost is going to be overwhelming. We must find some way to deal with it, and at least PET will give us a chance for our medical researchers going ahead to try and find a cure to slow it down and to provide the opportunity, through the prescription drugs already on the scene, to deal with severe symptoms and to give those seniors with Alzheimer's a chance to have a fairly decent life as they can—into that terminal period. I can't thank you enough for that.

I do have a couple of questions that I would like to submit for the record, if I may, Mr. Chairman. And I thank you for your courtesy.

OBESITY

My last comment would be, keep up the battle against obesity.

Secretary THOMPSON. Thank you.

Senator STEVENS. You know, we're just back on a journey through the Middle East, Mr. Secretary—Jordan, Iraq, Kuwait, Pakistan, Afghanistan, and even into France. We're the only nation that really has this terrible, terrible addiction to obesity, that I saw on that whole trip. Not our military men and women, thank God. They get the discipline when they're fairly young, and I hope it carries through for them. But for our community at large, I think obesity is becoming a number-one challenge to our survival. So I would hope we would all join with him and help him as much as possible.

Thank you for your courtesy.

Secretary THOMPSON. Thank you very much, Senator Stevens, and let me just thank you for your leadership. And, yes, I will be back in Alaska. I told you I'd go back to Alaska every year as long as I'm Secretary, and we've made some progress; not as much as you or I would like, but we're making some, and we'll be back there, and we've still got to work on the water and sewer for Alaska natives, because that is still—it's a huge problem, and I know you're the leader in that that, and I applaud you.

PREPARED STATEMENT

Senator STEVENS. Well, when your nearest neighbor is 500 miles away in every direction, and you have a hundred people, hope is a great thing.

Secretary THOMPSON. Yes, sir.

Senator STEVENS. And you've brought hope to those people, and I want to help you continue that.

Secretary THOMPSON. Thank you very much.

Senator STEVENS. Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TED STEVENS

Thank you Mr. Chairman. Secretary Thompson, it's a pleasure to see you here today. Once again I want to express my appreciation for your leadership on a host of issues that are of vital importance to all Americans. I especially want to thank you for all that you have done for Alaska. We are looking forward to having you visit us again this summer.

I am also very grateful to you for helping get C.M.S. moving forward to a favorable coverage decision for PET scans to help diagnose Alzheimer's disease in Medicare patients at an earlier time than any other diagnostic test. That coverage will give many seniors who discover they have Alzheimer's a chance to slow the progress of the disease with medication before its incapacitating symptoms appear.

Mr. Secretary, I believe we will be facing a crisis of huge proportions when Alzheimer's begins to strike the baby boom generation. I hope our investment in medical research at NIH will produce a cure before that time. But, in the meantime, early diagnosis of Alzheimer's disease, through pet, coupled with currently available prescription drugs begun at a stage before the most severe symptoms appear, will help many seniors continue to lead productive and reasonably healthy lives.

I'm also pleased that you were finally successful in including funding in your fiscal year 2005 budget for the Denali Commission. While it is less than our fiscal year 2004 number, I know that you have worked hard to have those funds included in your budget because you have seen first hand many of the infrastructure projects the commission has funded in remote parts of Alaska.

I am concerned that several programs that fund rural health activities, like the Rural Outreach grants and Rural Hospital Flexibility grants have been eliminated. Both of these programs, while relatively small ones, have benefited remote communities in Alaska and other rural States that need special help to provide needed health services. I know this is a very tight budget, but I urge you to work with the subcommittee to restore funding for these programs.

Another matter of concern to me is our Nation's growing epidemic of obesity. Mr. Secretary, you are to be applauded for your personal leadership in this area, beginning with your putting the Department on a diet and encouraging physical activity. I hope you will continue to push forward, because yours is a message we must heed. A recent report from the CDC tells us that obesity will soon overtake smoking as the Nation's leading cause of preventable death. I will be pleased to work together with you in your efforts to make us a healthier Nation.

Mr. Secretary, again I thank you for your tireless efforts to improve the health and well being of Alaskans and other Americans.

Senator SPECTER. Thank you, Senator Stevens.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

MONEY FOLLOWS THE PERSON INITIATIVE

Mr. Secretary, as I said in my opening statement, I know you've long supported the right of people with disabilities to choose to live in their neighborhoods and communities, rather than nursing homes and institutions. Along with Senators Specter and Smith, we introduced a bill last summer to get the Money Follows the Person Initiative, as it's called, enacted last summer. As I said earlier, you included funds for this initiative in your fiscal year 2005 budget, for which we're very appreciative. I understand the Finance Committee is going to hold hearings on this issue on April 7. Again, these are all good first steps, but we really need your support to get this bill moving through Congress and signed into law.

I haven't really heard of any real opposition to it. It's just, sort of, we've got to get it moving. You know, we hear a lot of talk about the New Freedom Initiative and everything, and we're all very supportive, but nothing seems to happen. I guess I'm just asking if you could really help with the administration and getting this thing moving through Congress this year. That's all I'm asking.

Secretary THOMPSON. Absolutely. I am as passionate about it, hopefully, as you are, Senator. And I want to see it done, because I'm not going to be here next year, and I want to make sure that we get it through before I leave, and then I'm—I have talked to Senator Grassley on it, and he's going to hold a hearing on it. I'm hoping he'll get the bill introduced quickly so we can start getting co-authors on it and start getting bipartisan support. I don't think there's that much—any opposition to it. I think we've just got to get the time to get it through the committee and on the floor and through both houses. And I know the President's going to sign it. So let's work together on a bipartisan basis and make sure it gets completed this year.

Senator HARKIN. Well, I appreciate that, and I just—whatever we can do to help, but you can also be very influential in——

Secretary THOMPSON. Thank you.

Senator HARKIN [continuing]. Move it through. And I know you're passionate about it. And I agree with you, we've got to get it through this year.

FOOD LABELING

The second part of my question is, I had—I said I'm—again, I'm really appreciative of all that you're doing personally, and, through you, your Department, on this issue of obesity and wellness, and personal wellness as, sort of, a thing that we've got to be focusing on. I am somewhat puzzled, however, by the fact that many of the recommendations pertaining to the food industry and the labeling of foods, especially restaurant foods, are voluntary rather than mandatory.

As the FDA report notes, food consumed away from the home has increased from 33 percent of consumers' food budgets in 1970 to 47 percent in 2002. Over the same period, total calories consumed from food purchased outside the home increased from 18 percent to 32 percent. I guess my question is this: Why, then, despite FDA's own assertion that the food labeling required under the original

National Labeling Education Act has been helpful to the consumers, and despite the fact that your focus groups show that consumers would like more labeling in restaurants, why do does the report recommend, quote, "urge" the restaurant industry to launch a nationwide, quote, "voluntary" and point-of-sale information campaign for customers, rather than some sort of mandatory labeling requirement? I guess that's the essence of my question. Why voluntary? Why not have some mandatory labeling requirement for that information?

Secretary THOMPSON. It's a different way to approach the problem. I'm not saying one approach is that much better over the other one. Every month I sit down with a different group of people. I've met with the Restaurant Association now three times. I have asked them to put more information on their menus. Most of them are complying. It was a tough sell in the first meeting. Every meeting since then has been getting better, Senator. And the last one was a very friendly meeting in which they were volunteering many more menu items that are going to be heart-healthy and low carbs and better, and they're going to be more informative.

Number two, I have met with the health insurance companies many times. I met the health insurance, health companies, medical companies, and so on. I do this on a monthly basis. I bring in a different group to talk about prevention. And we continue to do that. We're holding a summit, I believe, next week, in Baltimore, on prevention, and we're having, I believe, 1,200 people that have signed up already to do it. So I'm using the bully pulpit because I believe, like you do, of $1.5 trillion, 75 percent is for chronic illnesses—$155 billion for tobacco-related diseases, 442,000 people die; $135 billion for diabetes, 200 million Americans die; $117 billion on obesity. And I think we can do a lot better job. And I just think right now we can do it by pushing rather than hammering them.

Senator HARKIN. Well, Mr. Secretary, I was here when we pushed through the labeling for packaged goods in grocery stores. We had the same arguments then from the grocery people. The grocery manufacturers—oh, my gosh—"We changed the contents of boxes. We can't be doing this. And it's just going to be awful. It's just going to cost so much money." We went ahead and did it, and, you know, not even a blip. And yet people rely on that today. They go to grocery stores—it's taken some years, but now you look, I think the figures are over 60-some percent in surveys—people go to grocery stores, look at those labels to find out what they're buying.

Now, Ruby Tuesday, I don't know anybody—I don't know Ruby Tuesday—who owns it or who runs it, but I have a feeling they had a lot to do with these people now being more willing to put things on their menus, because Ruby Tuesday voluntarily said they're going to put it all in.

Let me just show—where's my chart? They were saying how onerous it was going to be. Here's a typical menu. And all they did is, they put the calories, the saturated fat, and sodium for each item. It's not a big deal.

Secretary THOMPSON. It is not.

Senator HARKIN. It's not a big deal.

Secretary THOMPSON. And it's very enlightening. And that's what we've got. We're changing the labeling out at FDA. We set up a committee. We're going to have some new labels with more information as to calories, portion size. And that's coming to FDA.

Senator HARKIN. But, again—and I know my time is up—I'm all for volunteerism, but FDA is also in the business of regulation and mandating, and we've been through this before, because it is such a health crisis. I, again, urge you to get the FDA involved in setting down a mandatory—there's legislation here, as you know, to do that, pending in the Senate and the House, to get the FDA to set down regulations on information of fat, calories, sodium on menus in restaurants. Rather than urging them—and you can urge and urge and urge. Some will do it, but not all of them will.

Secretary THOMPSON. I think you're going to see a lot of that kind of information on the labels when we come out later on this summer, Senator.

Senator HARKIN. Well, I hope so.

Secretary THOMPSON. I think you'll be very happy with it.

Senator HARKIN. But, again, I guess my rhetorical response might be, well, should we undo the regulations on the labeling regarding packaged good, and just make that voluntary?

Secretary THOMPSON. No.

Senator HARKIN. Of course not. Of course not. So I think this is, sort of, the next step in that, and I still believe that—I hope voluntarily everybody does it, but then you're going to have—maybe one will voluntarily put this information, someone will put this information.

Secretary THOMPSON. No, we're going to have uniform standards, and I'm going to be rolling those out this summer.

Senator HARKIN. But they'll be voluntary.

Secretary THOMPSON. Most of them will be at this point.

Senator HARKIN. So I won't have to abide by it. I'll put whatever I want to on it. Rather than putting the total calories and what that double-cheese, double-whatever-it-is, and these fries, I might put it on for a 6-ounce portion.

Secretary THOMPSON. I think we're going to be much more successful than you think, Senator.

Senator HARKIN. Well——

Secretary THOMPSON. I hope, anyway.

Senator HARKIN. Well, we can hope. We can hope. But it seems to me they've got to be pretty stringent and straightforward. But if it's voluntarily, you'll get a mismatch of all kinds of different information on stuff, and they will try to confuse people, because we've seen that happen in the past without the kind of things we have on the packaged goods. And we have a problem there, too, a little bit, as you know, because they use different sizes. And the FDA is getting ready to address that, and I applaud that.

Secretary THOMPSON. Yes, we are.

Senator HARKIN. Thank you, Mr. Chairman, for letting me go over my time.

Senator SPECTER. Thank you, Senator Harkin.

HEALTH PROFESSIONS

Mr. Secretary, there are three questions that I would like to state now, and ask you to respond to for the record.

With respect to health professionals, Mr. Secretary, I would like you to answer, for the record, how we can realistically cut the $300 million reduction on those programs in light of the urgent shortage of health professionals, especially in rural areas. Your budget justifies that by an additional $25 million to the National Health Service Corps, which, frankly, I don't see the relationship. But if you would respond for the record, we would appreciate it.

ABSTINENCE EDUCATION

Number two, on the abstinence initiative, this is a program that I think is very meritorious, abstinence education, and we would like a response on the evaluation that your Department is having as to how well these programs are working.

STEM CELL RESEARCH

And, third, as to stem cells, this continues to be a highly controversial subject. Those who oppose embryonic stem-cell research seek to tar those who favor it with the accusation that human cloning is supported, which, of course, is factually untrue. It's totally different, nuclear transplantation. But we would like you to respond as to your evaluation as to the availability of the 63 lines the President referred to on his famous declaration, back on August 9, 2001 in his 9 o'clock speech—the line was expanded to 70—and what has happened there, and how many of those are really usable, untainted with mouse feeder, and what is happening elsewhere. We hear periodic reports, but you are the central figure in the Federal Government. Give us the specifics on what's going on in South Korea or other places, or what Harvard is doing with reported $100 million program, another report about things going on in Minnesota. And I see these periodically in the press, but we really ought to collate all of this in one central repository so we know what is happening on this very important subject, which is the cutting edge of real opportunity to make inroads against the most dreaded maladies of the era. I know your personal thinking on the subject, and I know that—the complexities of the issue, but, at the minimum, as of this time, we ought to have the facts before us as to what is happening there to make a judgement.

Well, thank you very much for coming in, Mr. Secretary.

Secretary THOMPSON. Thank you, Senator.

Senator SPECTER. I'd like to meet with you privately for a moment or two after the hearing.

ADDITIONAL COMMITTEE QUESTIONS

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

HEALTH PROFESSIONS

Question. With respect to health professionals, Mr. Secretary, I would like you to answer, for the record, how we can realistically cut the $300 million reduction on those programs in light of the urgent shortage of health professionals, especially in rural areas?

Answer. Over the past two decades, we have invested over $6 billion on general health professions training grants. However, as we shape future spending, we will concentrate on directly supporting efforts that improve health professions shortages, focus on emerging workforce demands, and meet the needs of the underserved.

The President's budget makes a substantial investment in expanding access to health care to underserved communities through the Health Centers program and the National Health Services Corps. In fiscal year 2005, the Health Centers program is on-track to meet the President's five-year goal to increase access to health care in 1,200 communities with new and significantly expanded health center sites and increase the number of people served by over 6 million. Further, the President's budget supports approximately 2,750 loan repayments and scholarships for health care professionals in the neediest communities through the National Health Services Corps program.

The new rural health care investments created by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) will mean greater access to hospitals, health professionals and other medical services for rural seniors. It is estimated that the major rural provisions of the MMA will increase Medicare spending in rural America by $20 billion over 10 years. In addition to substantially increasing Medicare reimbursement for rural hospitals, a focal point for health care in rural communities, the MMA will also increase reimbursement for physicians, and other health care providers, in rural areas. For example, the Act establishes a new 5 percent incentive payment for physicians practicing in physician scarcity areas which include many rural communities.

ABSTINENCE

Question. On the abstinence initiative, this is a program that I think is very meritorious, abstinence education, and we would like a response on the evaluation that your Department is having as to how well these programs are working.

Answer. The Department is currently funding two independent, rigorous, longitudinal evaluations of abstinence education programs. The first is an on-going evaluation of a select number of State Section 510 abstinence education programs. It is being conducted by Mathematica Policy Research (MPR). The second evaluation effort is currently in design phase. It will examine the effectiveness of community-based abstinence education programs and other approaches to teen pregnancy and STD prevention. Both of these evaluation efforts are overseen by the Office of the Assistant Secretary for Planning and Evaluation (ASPE).

An implementation report from the ongoing MPR evaluation was issued in April 2002. It documented a wide range of abstinence education programs that have been well received. They are innovative in their approach to promoting abstinence as the healthiest choice for youth. These programs incorporate activities that have been shown to be effective: an emphasis on goal setting; developing decision-making skills; getting parents, schools, and communities involved in supporting the healthy development of youth.

The programs are diverse, creative, and offer youth much more than a single message of abstinence. Youth responded positively to program staff who showed a strong and unambiguous commitment to the program message, and programs that used an intensive set of youth development services to enhance and support the abstinence message were very well received. The report showed that addressing peer pressure is difficult, and many programs have struggled to address these issues and engage parents in this process. This report also offered a description of the ways in which programs have partnered with local schools to provide abstinence education, highlighting some of the challenges to creating and sustaining these partnerships.

The MPR evaluation has an end date of September 30, 2006. The original time frame in the statute under which the evaluation project is operating was through September 2001. However, the contractor and others have recognized the need for a longer-term follow-up period in which to examine the program effects on youth. As a result, the contract period has been extended through September 2006.

ASPE is also in the process of designing an evaluation of community-based abstinence education activities and other approaches to teen pregnancy and STD preven-

tion. ASPE contracted Abt Associates to develop evaluation designs for a longitudinal, rigorous impact study, which will help best answer some of the original policy questions that were the impetus for this study. The study will follow adolescents through high school, and will measure the impact of these programs on behavioral outcomes, including the reduction and prevention of out-of-wedlock pregnancies and sexually transmitted diseases (both viral and bacterial). Other key outcome variables of interest include age at first sexual activity and intercourse, frequency of sexual activity and intercourse, and number of individuals who postpone sexual activity or intercourse through adolescence.

STEM CELL RESEARCH

*Question.*What is the status of the human embryonic stem cell (hESC) derivations listed on the NIH Stem Cell Registry? How many are in private hands? How many have been grown on mouse feeder layers? How many are viable?

Answer. All of the derivations listed on the NIH Human Embryonic Stem Cell Registry are privately owned by 15 different companies or academic institutions. The providers indicated by an asterisk (*) below are recipients of the NIH Infrastructure award to develop, characterize and distribute cell lines.

BresaGen, Inc., Athens, Georgia*
—4 derivations
—3 lines available
—The cells in derivation BG04/hESBGN–04 failed to expand into undifferentiated cell cultures.

Cell & Gene Therapy Research Institute (Pochon CHA University), Seoul Korea
—2 derivations
—0 lines available

Cellartis (formerly Cell Therapeutics Scandinavia), Göteborg, Sweden*
—3 derivations
—2 lines available
—Cell line SA03/Salgrenska 3 was withdrawn by donor.

CyThera, Inc., San Diego, California*
—9 derivations
—0 lines available
—The cells failed to expand into undifferentiated cell cultures.

ES Cell International, Melbourne, Australia*
—6 derivations
—6 lines available

Geron Corporation, Menlo Park, California
—7 derivations, all duplicates of Wisconsin Alumni Research Fdn. derivations

Göteborg University, Göteborg, Sweden
—16 derivations, reported to have not been exposed to mouse feeder layers
—0 lines available

Karolinska Institute, Stockholm, Sweden*
—6 derivations
—0 lines available
—The cells failed to expand into undifferentiated cell cultures.

Maria Biotech Co. Ltd.—Maria Infertility Hospital Medical Institute, Seoul, Korea
—3 derivations
—0 lines available

MizMedi Hospital—Seoul National University, Seoul, Korea*
—1 derivation
—1 line available

National Centre for Biological Science/Tata Institute of Fundamental Research, Bangalore, India
—3 derivations
—0 lines available

Reliance Life Sciences, Mumbai, India
—7 derivations
—0 lines available

Technion-Israel Institute of Technology, Haifa, Israel*
—4 derivations
—2 lines available

University of California, San Francisco, California*
—2 derivations
—2 lines available

Wisconsin Alumni Research Foundation, Madison, Wisconsin*
—5 derivations

—5 lines available

Of the 78 entries on the Registry, 71 are from independent embryos and 7 are duplicates located at both WiCell (Wisconsin Alumni Research Fdn.) and Geron. The Geron cell lines are not being widely distributed to the research community.

Of the 71 independent derivations:

—16 have failed to expand into self renewing, pluripotent cell lines (9 at CyThera, 1 at BresaGen, 6 at Karolinska), and 1 line was withdrawn by the donor at Cellartis (formerly Cell Therapeutics Scandinavia, CTS). NIH provided Infrastructure support in failed attempts to expand these 16 derivations into distribution-quality cell lines.

—Of the remaining 54 independent derivations, 21 are available for shipment, after expansion and characterization using NIH Infrastructure grant awards. The 21 that are currently available are:

BresaGen, Inc.—BG01, BG02, BG03
Cellartis—SA01, SA02
ES Cell International—ES01, ES02, ES03, ES04, ES05, ES06 4
MizMedi Hospital—MI01
4Technion-Israel—TE03, TE06
UCSF—UC01, UC06
WiCell—WA01, WA07, WA09, WA13, WA14

—Of the remaining 33 independent derivations, 2 more are at institutions with NIH Infrastructure awards. If these 2 were developed into distribution quality cell lines ready for shipment, there would be 23 independent cell lines available to the research community. The 2 cell lines under development are:

Technion-Israel—TE04, TE07

—The remaining 31 independent derivations are all at institutions located outside of the United States that have not applied for NIH Infrastructure awards to develop their cell lines. Any plans to develop these derivations into cell lines that are available to the research community are unclear at this time. The 31 derivations at institutions that do not have Infrastructure awards are:

Pochon CHA (Korea)—2 derivations
Göteborg Univ. (Sweden)—16 derivations
Maria Biotech (Korea)—3 derivations
National Centre for Biological Sciences (India)—3 derivations
Reliance Life Sciences (India)—7 derivations

As far as we know, all derivations have been exposed to mouse feeder cells, with the exception of the 16 derivations at Göteborg University (Sweden).

Information on the detailed characteristics of each of the derivations is available on the NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov.

Question. What is Happening at Harvard University?

Answer. On March 25, 2004, Harvard University announced the derivation of 17 hESC lines in an article published in the New England Journal of Medicine. Funding for the derivations and distribution of these lines is being provided by the Howard Hughes Medical Institute, Juvenile Diabetes Research Foundation and Harvard University.

On April 23, Harvard University announced the establishment of the Harvard Stem Cell Institute. According to Harvard, the Institute will encourage adult and embryonic stem cell research using both animal and human stem cells. The Institute has two co-directors: Harvard Medical School Professor David Scadden, who also directs Massachusetts General Hospital's Center for Regenerative Medicine and Technology, and Douglas Melton, the Thomas Dudley Cabot Professor of the Natural Sciences and a Howard Hughes Medical Institute investigator.

Research at the Institute will be focused on five areas of disease for which stem cell therapy seems most promising. The diseases all result from some sort of organ or tissue failure and include: diabetes, neurodegenerative diseases, blood diseases, immune diseases, cardiovascular disease, and musculoskeletal diseases.

Although research on the 17 new human embryonic stem cell (hESC) derivations are not eligible for Federal funding, NIH is currently supporting several scientists at Harvard University whose hESC research use lines eligible for Federal funding. Dr. Doug Melton is working to identify the genes involved in hESC self-renewal and differentiation. Dr. George Daley is studying hematopoietic development from hESCs. Dr. Howard Green is working to develop the culture conditions to coax hESCs to become the keratinocytes that make up human skin's epidermis. Dr. Jeffrey Harper is analyzing the signals that control hESC division.

Question. What is Happening in South Korea? What is Happening in Other Countries?

Answer. On February 12, 2004, South Korean researchers published the first scientifically credible report of the creation of a cloned human embryo in the labora-

tory by means of somatic cell nuclear transfer (SCNT) (Science 303: 1669–1674.) These scientists, supported by the South Korean government, then used these cloned embryos to establish a human embryonic stem cell line. They combined the DNA of a woman's ovary cell with her donated egg, from which the nucleus had been removed, and then stimulated the newly combined cell to divide. The resulting very early embryo was then allowed to develop to the blastocyst stage (five to nine days), at which point it was disaggregated and the highly potent stem cells of the inner cell mass were removed. These stem cells were then treated to produce a stem cell line to be used for various kinds of biomedical research. Subsequent to the publication of the SCNT study, the South Korean government voted to ban the creation of cloned human embryos, but might allow cloning for biomedical research on a case-by-case for medical treatment subject to approval by a National Bioethics Advisory Commission. Scientists will be permitted to use spare frozen embryos, left over from infertility treatments and kept in laboratories for at least five years, for limited stem cell research into treatments for hard-to-cure diseases. The regulations banning human cloning are expected to come into effect after President Roh Moohyun signs the bill. The regulations on stem cell research will go into effect in 2005.

Other International Stem Cell Efforts

International Society for Stem Cell Research (ISSCR)

The International Society for Stem Cell Research is an independent, nonprofit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application. Opinions on the legitimacy of experiments using human embryos vary among members of the European Union (EU) according to the different ethical, philosophical and religious principles in which they are grounded. EU member states have taken very different positions on the regulation of human embryonic stem cell research and cloning for biomedical research. More information about the regulations and policies of EU members can be found on the website of the ISSCR at the following link: http://www.isscr.org/scientists/legislative.htm.

The International Stem Cell Forum (ISCF)

The ISCF was founded in January 2003 to encourage international collaboration and funding support for stem cell research, with the overall aim of promoting global good practice and accelerating progress in this vitally important area of biomedical science. The Forum's long-term aim is to help stem cell scientists achieve a range of revolutionary medical advances that will benefit people throughout the world. The ISCF is led by the United Kingdom's Medical Research Council and consists of 14 leading supporters of stem cell research from around the world. Member organizations are based in the United States, Finland, Australia, Canada, Germany, France, Israel, Netherlands, Japan, Singapore, Sweden, Switzerland, and the United Kingdom. Within ISCF, the United States is represented by the NIH. The Juvenile Diabetes Research Foundation International (JDRF) is also a member of the ISCF. One short term goal of the ISCF is to compare different stem cell lines from the member organizations. As part of this goal, NIH's federally approved stem cell lines will be compared to those of other member organizations. Information about the stem cell research efforts of the member organizations can be found on the website: http://mrc.live.tmg.co.uk/.

PREPARED STATEMENT RECEIVED

Senator SPECTER. We have received the prepared statement of Senator Mary L. Landrieu. The statement will be placed in the hearing record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

With the release of the 2005 budget, President Bush emphasized his commitment to reducing the deficit, most of which has been created by his fiscally irresponsible policies, within five years. The overall budget proposed by the President cuts domestic discretionary spending outside of homeland security by $49 billion by 2009, a 12 percent cut in spending. A large portion of the domestic discretionary spending that the Administration proposes to cut from 2005–2009 is administered by the Depart-

ment of Health and Human Services and provides services such as child care, child welfare, and health care to our poorest children, families, and seniors.

Because it is an election year, the Administration has attempted to hide their lack of support for domestic spending by playing a shell game. When questioned about their commitment to important social issues, the Administration touts its minor increases in some programs in the 2005 budget as evidence of their "compassionate conservatism." Yet, if you look closely enough you will see that after this year, these "increases" continue to shrink until they sink below current funding levels by 2009.

Although I am supportive of almost any policy aimed at bringing the economy back into an era of surpluses, as we enjoyed during the Clinton years, I believe the President's method for trying to achieve a reduction in deficits through cuts in spending on our most vulnerable populations is at best, flawed. Because domestic discretionary spending outside of homeland security only accounts for one-sixth of the overall budget, the President's proposed cuts would not significantly reduce the deficit. What they will do, however, is increase financial burdens on states at a time when they are experiencing the worst fiscal crises since WW II. estimates show that states will face deficits of $40 billion or more in 2005. It is predicated that my own state of Louisiana will face a deficit of $500 million this year. Under the decreased federal funding in the President's new budget, Louisiana and other states will be forced to impose deeper cuts on programs such as government subsidized health insurance and child care subsidies for the poor.

In his budget, President Bush does not limit his cuts to discretionary spending but also proposes cuts in entitlement spending for many of these programs. It is unbelievable to me that in a time of a recession, this President proposes to cut support for TANF, child care, child welfare, and other social services by over $2.8 billion.

While his TANF re-authorization calls for increases in the number of hours that fathers and mothers must work, the budget flat funds child care assistance to these families. Over the last year 100,000 children have lost assistance and predictions indicate that at least an additional 200,000 children will lose assistance by 2009 under the current budget proposal. The TANF entitlements funds are also flat-funded, though 8.2 million people are unemployed and more families are at risk of reliance on the welfare system. And although President Bush's policies have contributed greatly to the dire situation many of these families face, he continues to turn his back on them by refusing to provide adequate funding to the government programs that will allow them to survive these difficult times.

The Administration's proposal for health care reflects an equal lack of compassion towards these low-income families. Our country's problem of the uninsured has reached a crisis level, with almost 44 million individuals who are not insured. Predictions show this problem is getting even worse. Yet, the Administration is proposing further cuts in aid to low-income individuals through Medicaid, calling for a reduction in funding for Medicaid by nearly $1 billion in 2005 and by nearly $16 billion over the next ten years. And the President is attempting to unload this crisis onto states by pushing for turning Medicaid into a block grant. The result would be a cap on the amount of money the federal government would spend on this program and a shift of costs to the states, preventing them from being able to respond to the dynamic health care needs of their residents.

President Bush is proposing a similar funding structure for foster care payments to states. Under this proposal, states would be given the option to receive block grants in place of entitlement funding that is typically provided for services to foster children. These block grants would freeze funding to states at a specific level for five years, meaning that the funds would no longer be based on need or the number of eligible children. This cost neutral proposal does not increase funding to a foster care system that is already under-funded. In fact, many programs that have been block-granted in the past have ended up with less funding over time. Although I do support a federal funding structure for child welfare services that allows states the flexibility to be innovative in meeting the challenges of families involved in this system, the President's proposal of block granting will ultimately result in states having less resources to provide necessary services.

Understanding that these families face complex and varying challenges, I support the President's budget proposal that would increase funding for Promoting Safe and Stable Families to $505 million. This program offers flexible funding to states for a range of community-based family support and adoption services. This money can be used for prevention and family preservation services that help to keep children with their biological families and out of the child welfare system. Although I am happy to see that the Administration has recognized the importance of this program by proposing increased funding, I hope that it will modify proposals for other child welfare programs to provide adequate funding to assist families.

Investments in programs that focus on prevention, such as those provided through the Promoting Safe and Stable Families funding, are cost-saving. By investing in these primary services, our government avoids investment in solving problems that could have been prevented. Unfortunately, the President's budget proposal for substance abuse services under the Substance Abuse and Mental Health Administration does not reflect this idea, with over 2½ times the amount of funding proposed for prevention services dedicated to treatment services. I support the increases that President Bush is proposing for these treatment services, for this funding will aid in the healing of individuals and families who suffer from substance abuse issues. However, I further support increases in funding for prevention services, so that we can help families avoid the problems associated with substance abuse.

As lawmakers and appropriators, we have the responsibility to act on the idea that we can always do more to help the people we represent. We cannot be complacent with this budget. Much more can be done for some of our most vulnerable populations that are served through the Department of Health and Human Services than what is outlined in the President's budget. Using my seat on the Appropriations committee, I am committed to seeing valuable programs proposed to receive cuts by the Administration receive the funding that is necessary to meet the needs of those they are intended to serve.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Thursday, April 1, in room SH–216. At that time we will hear testimony from the Honorable Elias Zerhouni, Director, National Institutes of Health.

[Whereupon, at 10:35 a.m., Thursday, March 25, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, April 1.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2005

THURSDAY, APRIL 1, 2004

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

The subcommittee met at 9:30 a.m., in room SH–216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Stevens, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ELIAS A. ZERHOUNI, M.D., DIRECTOR

ACCOMPANIED BY:

RAYNARD KINGTON, M.D., Ph.D., DEPUTY DIRECTOR, OFFICE OF THE DIRECTOR

WILLIAM R. BELDON, DEPUTY ASSISTANT SECRETARY FOR BUDGET

DUANE ALEXANDER, M.D., DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

BARBARA ALVING, M.D., ACTING DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

JAMES F. BATTEY, JR., M.D., Ph.D., NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

JEREMY M. BERG, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

FRANCIS S. COLLINS, M.D., Ph.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

PATRICIA A. GRADY, Ph.D., DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

RICHARD J. HODES, M.D., NATIONAL INSTITUTE OF AGING

SHARON H. HRYNKOW, ACTING DIRECTOR, FOGARTY INTERNATIONAL CENTER

THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

STEPHEN I. KATZ, M.D., Ph.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

STORY C. LANDIS, Ph.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

TING-KAI LI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALCOHOL ABUSE AND ALCOHOLISM
DONALD A.B. LINDBERG, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE
KENNETH OLDEN, Ph.D., S.C.D., L.H.D., DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
RODERIC I. PETTIGREW, Ph.D., M.D., DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING
JOHN RUFFIN, Ph.D., DIRECTOR, NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES
PAUL A. SIEVING, M.D., Ph.D., DIRECTOR, NATIONAL EYE INSTITUTE
ALLEN M. SPIEGEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
STEPHEN E. STRAUS, M.D., NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
LAWRENCE A. TABAK, D.D.S., Ph.D., NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL DISEASES
JUDITH L. VAITUKAITIS, M.D., DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES
NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE
ANDREW C. VON ESCHENBACH, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE
JACK WHITESCARVER, Ph.D., DIRECTOR, OFFICE OF AIDS RESEARCH

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The time is precisely 9:30, which is our starting time, and the Appropriations Subcommittee on Labor, Health, Human Services, and Education will now proceed.

Today we will consider the appropriations process as it applies to the National Institutes of Health. And as I have stated on many occasions, I consider NIH the crown jewel of the Federal Government. It may be the only jewel of the Federal Government.

But medical science and humanity is deeply indebted to the extraordinary work which has come out of medical research from the National Institutes of Health.

The budget process is always complicated and a goal was established to double NIH funding, which we have more than met. When asked what would happen after doubling, as you know, my response was instantaneous and obvious, and it was tripling. It would be too hard to quadruple it before you triple it.

When I took over the chairmanship of this subcommittee in January 1995, I took a look at the priorities and thought this was none higher, really at the top of the list. And Senator Harkin, the ranking member, agrees. We know around here if you want to get something done, you have to cross party lines. Sometimes it gets you into trouble if you have a primary election campaign. My opponent thinks I should not talk to Democrats. But Senator Harkin and I, when we have changed the gavel, it has been seamless and we have proceeded to give tremendous support to NIH.

We have a very tight discretionary budget this year. It is up one-half of 1 percent, and that is very, very, very difficult. The administration has put in a figure of $729 million over the $28.5 billion

budget, and as I am sure you know, we offered an amendment to increase it by $1.3 billion and we were successful, 72 to 24.

But there were some strenuous arguments raised by my colleagues in the Senate that NIH was getting too much funding compared to other important research Departments in the Federal Government. And when one of my colleagues made an impassioned plea, I agreed with him that the other Departments were not getting adequate funding. But that did not bear on not adequately funding NIH. And what it takes is the subcommittee chairmen to pick up those important research projects and take the lead and get them funded.

We have a Federal budget of $2,400,000,000,000. Do you know how much money that is? Well, nobody else does either.

They say if you took a room this size, it would be insufficient to stuff $10,000 bills into it.

We can afford money for research. That is the best investment that we are making beyond any question. But it is a fight.

NIH has its own problems which you know about, challenges on conflicts of interest, which we have addressed in a separate hearing and we will talk about today, the issues about compensation, an issue which I know is being addressed.

NIH is being attacked on an ideological level. The November 28, 2003 edition of Science had an editorial marked Don't Let Ideology Trump Science. An amendment was offered in the House of Representatives to strike four NIH grants because sex was mentioned in the title, peer-reviewed. One of them involved a question of spread of venereal disease at truck stops where truckers are highly vulnerable, long stops, fatigue, away from home, places frequented understandably by prostitutes, and NIH wanted to make a study. And that and three other of your projects were challenged because if you have sex in the title, it makes a good 30-second commercial, if you voted for it, to defeat you. The surprising thing was that in the House of Representatives the amendment almost passed: 212 to 210.

Now, it just happens that the amendment was offered by the fellow who wants to take my seat on the U.S. Senate who has voted against every domestic spending bill, voted against Head Start, voted against Medicare reform, voted against the budget for Labor, Health and Human Services, voted against the budget for NIH. So in this town you have to be prepared to defend yourself against attacks. So if you have one or two, Dr. Zerhouni, do not think you are being discriminated against.

It goes with the territory. I think it is within your pay grade to defend yourself, Dr. Zerhouni, and to prevail, and I think it is within my pay grade to prevail also. But it is a battle.

So much for an opening statement. I read it just like Betty Lou wrote it for me.

Super Senator Taylor. She is not just a regular Senator. She is a super Senator.

Dr. Elias Adam Zerhouni began his tenure as the 15th Director of NIH on May 20, 2000. He had a very distinguished career prior to coming to NIH: executive vice dean of Johns Hopkins University School of Medicine, Chair of the Department of Radiology; Martin Donner Professor of Radiology; medical degree from the University

of Algiers School of Medicine; and residency in diagnostic radiology at Johns Hopkins. Thank you for joining us, Dr. Zerhouni, and we look forward to your testimony.

SUMMARY STATEMENT OF DR. ELIAS ZERHOUNI

Dr. ZERHOUNI. Thank you, Mr. Chairman. It is our pleasure to be here with the 27 institute and center directors of NIH to present our budget, but also to express our thanks and appreciation for your strong leadership on behalf of research and medical research and NIH.

INTRODUCTION OF NEW INSTITUTE DIRECTORS

I would like to start by introducing three of our new directors, and I will ask them to stand up to be introduced to you, Mr. Chairman.

Dr. Story Landis is now the Director of the National Institute of Neurological Diseases. She has been appointed in the past year and has done an outstanding job already working with all aspects of neurological disorders, including collaboration with patient groups in trying to find the best approaches to rising threats of neurological degenerative diseases.

Dr. Nora Volkow is the new Director of the National Institute of Drug Abuse. She has joined us from the Brookhaven National Laboratory in Stony Brook University. She is a leader in imaging of drug addiction and has already changed the strategy of her institute in many appropriate ways.

Dr. Jeremy Berg is the new Director of the National Institute of General Medical Sciences. Dr. Jeremy Berg joined us from Johns Hopkins where he was the Chair of the Basic Science Institute at Johns Hopkins and Chair of the Department of Biophysics.

I also would like to mention two acting Directors, Dr. Barbara Alving, who is the acting Director of NHLBI, and Dr. Sharon Hrynkow, who is the acting Director of the Fogarty International Center.

BREAKTHROUGHS AND ADVANCES

Mr. Chairman, members of the committee, it is my pleasure to actually summarize the written testimony that we submitted to you. What I would like to do is go right away and tell you how important your investment has been in terms of specific breakthroughs and advances between last year and this year.

NIH developed a completely new Ebola vaccine that can protect the population in less than a month. This a real breakthrough in biodefense.

Just 2 days ago, NIAID announced that a new SARS experimental vaccine has been successful in animal experiments and will enter human trials as soon as we can do so. This is less than a year after the SARS epidemics which we knew not the cause of and it took us several weeks to find the cause. A year later, we are ready to fight this disease if it reappears.

We discovered in 2003 several genes, for the first time, associated with schizophrenia. This was ranked as the number two ad-

vanced scientific advance of 2003, following the discovery of dark matter in the universe.

We identified just 3 weeks ago a new master switch gene relating to type 2 diabetes. This is a very important discovery that will help us in discovering how type 2 diabetes develops.

We have changed the practice paradigm of long-term hormone replacement therapy for women because of the landmark studies of the Women's Health Initiative.

Today on the cover of Nature magazine, we are announcing the completion of the rat genome, a very important advance. As you know, by 2005 we were hoping to only have the human genome available to us. We now have the mouse, the rat, and the human genome, and we will be able to do comparative analysis that will advance our understanding of biology and disease.

NIH ROADMAP FOR MEDICAL RESEARCH

All throughout the past 2 years, we have also taken into account the need for new science strategies, and this is what we call the NIH roadmap for medical research. The roadmap is essentially our effort to find ways to accelerate basic research discoveries and speed the translation of those discoveries into clinical practice. It is a dedicated effort to explicitly address roadblocks that slow the pace of medical research in improving the health of the American people.

The major driver for this approach is exemplified on this slide in front of you, and that is that we need to transform medical research in the 21st century. In the 20th century, we treated disease when symptoms appeared and normal function had been lost. Why was that? Because for the past 5,000 years and the 20th century included, we did not understand the molecular and cellular events that led to disease. So we had to wait until the disease was explicit. And this is very expensive in both financial and disability costs.

The paradigm of the 21st century is that we will intervene before symptoms appear and preserve normal function for as long as possible because we do understand much better the genetic events that lead to disease.

We have come up with very bold initiatives. We will integrate all clinical research networks that are under NIH throughout the country and link them to community physicians to form new communities of research that will translate much quicker, much more efficiently than we have in the past the benefits of our fundamental understanding of research.

A good example is juvenile rheumatic diseases, a disease set that affects only 300,000 children in the country. To do good research and have enough understanding of what happens, we need to recruit patients across the Nation, and this will be facilitated by a project of the roadmap called National Clinical Research Networks with trained community physicians in every community linked to academic centers.

We continue to invest across NIH in a combined and coordinated fashion to advance medical research as fast as we can. This year we are requesting $237 million for the roadmap.

STEWARDSHIP

We have continued also to focus on management excellence and stewardship of our resources. Let me point out two very simple statistics. Our funding went up by 141 percent in the past 10 years, almost 2 and a half times, 2.4 times. Our FTE's, the number of people, at NIH needed to manage this portfolio has only increased by 16 percent. Why? Because we have aggressively used modern methods of management using information systems to prevent the need for us to increase our FTE numbers. Our Research Management and Support budget has gone from 4 percent of our budget to 3.5 percent of our budget. So we are doing what you are asking us to do and being very good stewards.

As you said, we will have on May 6 a final meeting of the Advisory Committee to the Director to finalize the recommendations of the Blue Ribbon Panel for conflict of interest and will report back to you as soon as we have that.

FISCAL YEAR 2005 BUDGET REQUEST

Mr. Chairman, we are requesting a budget of $28.607 billion which is $28.527 billion from this committee, and a 2.6 percent increase over 2004. We also have at our program level $47 million for nuclear and radiological countermeasures which are housed in the Public Health Service emergency fund.

PREPARED STATEMENT

We are pleased to be here and will answer any of your questions. Again, we would like to thank the bipartisan support of this committee over the years. Thank you, Mr. Chairman.

[The statements follow:]

PREPARED STATEMENT OF DR. ELIAS A. ZERHOUNI

Good morning, Mr. Chairman and members of the Committee. Let me begin by expressing my deepest appreciation to the Congress, Secretary Thompson, President Bush, and the American people for their generous and bipartisan support of the NIH's efforts to help improve the health of all our citizens. I respect the extraordinary effort of this committee and, Mr. Chairman, your leadership as well. I thank you for it.

The year 2004 marks a sea change for the NIH and its Roadmap for Medical Research. We are refining our basic and clinical research programs to ensure that new discoveries rapidly lead to new and improved diagnostics, treatments and prevention strategies that extend the length and improve the quality of human life.

In my testimony today, I want to cover four areas: first, highlight several key research advances that took place in the last year which represent the critical contributions of NIH intramural researchers and grantees; second, give examples of how the NIH Roadmap effort will help shape our approach to patient-oriented research; third, offer examples of our stewardship; and fourth, present an overview of our budget. In the course of my testimony, I will mention emerging priorities and our plans for responding to the health challenges ahead.

BREAKTHROUGHS & ADVANCES

Each year, the public investment in research yields critical scientific advances. The four I highlight here are just a sample of the many that represent the development of new and improved treatments, diagnostics, or prevention strategies that will affect the health of the entire nation.

Few viruses are feared more than the Ebola, a deadly microbe that causes outbreaks in Africa and Asia and kills up to 90 percent of those it infects. Scientists at the NIH National Institute of Allergy and Infectious Diseases Vaccine Research

Center developed a single dose, fast-acting, experimental Ebola vaccine that successfully protects monkeys after just one month, and human trials are now under way.

This year NIH research further elucidated the role of widely used hormone replacement therapies. The NIH halted the estrogen alone study of the Women's Health Initiative on March 1, 2004 after 5.6 years of follow-up, due to increased risk of stroke. You will recall that NIH, in 2002, stopped the combination hormone trial arm of the Women's Health Initiative early due to an increased risk of invasive breast cancer, coronary heart disease, stroke, and pulmonary embolism in study participants on estrogen plus progestin compared to women taking placebo. It indicated that healthy postmenopausal women taking combination hormone therapy also suffered twice the rate of dementia as those taking a placebo. Together, the results of these clinical studies changed conventional dogma, and provided important new evidenced-based information to women who are deciding whether to begin or how long to continue menopausal hormone therapy. These trials clearly are having a major impact on the health of people we know and love—our wives, our sisters, our daughters and our mothers.

The third advance was the discovery of genes associated with schizophrenia, which is a profoundly disabling disorder that affects one percent of the adult population. It is marked by hallucinations, delusions, social withdrawal, flattened emotions, and loss of social and personal care skills.

Research like this on the genetics of mental illness was named the Number 2 scientific "breakthrough of the year" for 2003 by the prestigious peer-reviewed journal, Science. Most of this work was funded by NIH and included discoveries of candidate genes for schizophrenia, depression, anxiety and bipolar disorders. These discoveries bring us closer to developing new diagnostic tests, strategies for prevention, and targets for the treatment of schizophrenia and other mental disorders.

The fourth advance came only three weeks ago, when NIH announced a major new discovery, the identification of a common variation of a pancreatic "master switch" gene that increases the risk of type 2 diabetes by 30 percent. Type 2 diabetes now affects 17 million people in the United States, and is responsible for enormous health care costs. This gene discovery opens the door to the development of new and more effective methods of prevention and treatment.

NIH ROADMAP

Let me now turn your attention to the NIH Roadmap for Medical Research. I want to tell you why the Roadmap is so important to the future of medical research and to innovations in improving people's health. I also want to give you some examples of how we at NIH expect the Roadmap to change the way we do research and the practice of medicine.

One of the questions we face is how do we successfully do our part in the battle to contain health costs? We need to address the following issues: What are the roadblocks? What are the major challenges? How can we most effectively invest the funds that the American taxpayers entrust to us to fashion the fastest track to discovery as well as translate those discoveries to the patient's bedside or the doctor's office?

In seeking answers to these questions, one thing becomes clear. The traditional paradigm of medical care—when practitioners waited for the disease to cause the patient the loss of some function—must be replaced by a paradigm where health professionals act before the individual loses any function. This has become even more critical since chronic diseases now consume about 75 percent of our fast-growing health care expenditures.

Let me present four examples of how the NIH Roadmap will transform our approach to biomedical research in specific disease areas.

The first example is schizophrenia, a disorder that—as I mentioned earlier—affects one percent of the U.S. population. The peak onset occurs between the ages of 18 and 25. Schizophrenia has the hallmarks of both a neurodevelopmental and a neurodegenerative disease. But after 100 years of neuropathological study, we still lack knowledge of the precise cause of the disorder.

Today, schizophrenia is the fifth leading cause of years lost due to disability among Americans from ages 15–44. Although we can treat the so-called "positive" symptoms, such as hallucinations and delusions, we do not yet have treatments for the "negative" symptoms, like withdrawal and cognitive deficits. And these are the largest source of disability.

Less than 30 percent of people with this illness are currently employed. And people with schizophrenia represent one of the largest groups on atypical antipsychotics as the treatment of choice. In 2001, Medicaid paid for more than 50 percent of the

total spending on atypical antipsychotics, amounting to $2.7 billion, a figure which has been growing at roughly 25 percent a year for the past 3 years.

Today, we lack a diagnostic test or a strategy for preventing schizophrenia. This situation is similar to cardiovascular disease 30 years ago in that we see schizophrenic patients only after their first "heart attack," that is, episode, and we do not have the equivalent of cholesterol as an identifiable risk factor.

However, what we have done recently—and what holds great promise for those who are suffering—is identify 12 genes associated with risk. Our challenge now is to move from the discovery of those genes—most of which have no known function—to understand the role these genes play in the onset and progression of this brain disease—and do something about it.

Our hope is to use these genes to identify what is abnormal in the brains of schizophrenics, identify it early and thus provide the psychiatric equivalent of serum cholesterol. To accomplish this, we must study the protein products of these genes by using molecular tools that can make their function transparent.

It is precisely here that the NIH Roadmap will help accelerate the effort to study protein products through so-called molecular libraries—databases of information on small molecule compounds like aspirin and antihistamines. These libraries will let researchers screen hundreds of thousands of small molecules to yield these tools.

For example, we know that a variation in the neuregulin gene is associated with an increased risk for schizophrenia. To understand how this gene confers risk, we need to find chemicals that mimic or inhibit the gene's function. This would give us a precise description of how alterations in the gene change the activity of brain cells. Molecular libraries will not only yield the tools to study the neuregulin gene but also provide a test for vulnerability to schizophrenia. With such tools and tests, doctors could approach risk for schizophrenia the way we currently approach risk for heart disease.

A second example where the NIH Roadmap offers promise is in pediatric diseases, through the creation of clinical research networks.

Uncommon disorders like the juvenile forms of rheumatic diseases, such as arthritis, lupus and dermatomyositis, affect 300,000 children in the United States. Not one of these diseases is common enough to be studied intensively at any one academic health center. Thus, many such centers as well as community-based pediatricians are needed to collect a sufficient group of patients who can participate in these studies to gather meaningful results.

The development of clinical research networks that focus on chronic childhood diseases—like those already established for childhood cancers—and the potential to include community physicians trained in clinical research methodology in the research process will enable clinical trials to be more efficient and effective.

Using the NIH Roadmap clinical research networks concept, this could occur without building a new, and often very expensive, infrastructure for every new trial. Including community-based pediatricians as full partners in the research will allow us to overcome some of the limitations of patient recruitment that we currently experience and enable more children to participate in these trials, and accelerate the development of new treatments.

The third example is Alzheimer's Disease (AD). We have made considerable progress in understanding Alzheimer's Disease. Fifteen years ago, we knew none of the genes that cause AD and we had only a limited understanding of the biological pathways involved in the development of brain pathology. Ten years ago, we could not model the disease in animals. Five years ago, we were not funding any prevention trials and had no way of identifying persons at high risk for the disease. And, as recently as one year ago, we had no way of imaging AD's characteristic amyloid plaques in a living person.

Today, we can do all of these things. And we are poised to make the discoveries that will transform our understanding of the basic and clinical aspects of AD and enable us to effectively prevent, diagnose, and treat it using several NIH Roadmap initiatives.

Through basic research in Alzheimer's disease, we identified a number of brain pathways that are potential targets for preventive interventions. These range from dysfunction and death of specific neurons to loss of the connections between neurons. Roadmap efforts to improve imaging of small molecules will let us visualize the effects of treatments more rapidly and accurately, which could make effective AD clinical trials smaller, faster and more affordable.

My fourth and final example is cardiovascular disease. One of the greatest public health success stories of the last half century is the dramatic reductions in mortality from cardiovascular diseases. Studies initiated by the NIH—the Framingham Heart Study and the Lipid Research Clinics Coronary Primary Prevention Trial—have been key to that success. They helped not only to identify risk factors that con-

tribute to the development of cardiovascular diseases, but also to demonstrate the efficacy of therapeutic interventions to control them.

Even so, cardiovascular disease remains an enormous health burden, accounting for 38 percent of all deaths in the United States in 2001. Progress in reducing that burden will require continued efforts to refine our understanding of risk factors, such as obesity and high cholesterol, and to identify and evaluate new prevention approaches. This means that large scale population-based studies will remain a critical component of our research effort.

The NIH Roadmap will help fashion the interactive network and involvement of many community-based practitioners. For example, we can make better use of large-scale organizations set up for single studies, such as the recently completed Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). Instead of disbanding it, we can involve many or all of the investigators in other trials addressing not only cardiovascular disease but also other diseases. The National Electronic Clinical Trials and Research (NECTAR) initiative—a critical part of the Roadmap effort to re-engineer clinical research—will enable data sharing and enhance comparison and aggregation of results from multiple trials by using standard definitions of outcomes and adverse events. In the future, patients will know directly from their own community doctors, who will be equipped with the new web-based NECTAR, what medical research can do for them in terms of participation in studies, the best available therapies, and nearby advanced research centers.

STEWARDSHIP

We realize that to advance the NIH scientific agenda, our management and administration must be effective, efficient and productive. By introducing new information technology and business systems and streamlining governance structures, we are placing continuous improvement of management and administrative functions at the forefront of our agency priorities. Let me highlight a few of our efforts.

NIH is making rapid progress to modernize its business and financial systems. An agency-wide information technology system, known as the New Business System (NBS), is integrating such processes as acquisitions, travel, property, and financial management. This effort will reduce the cost and complexity of doing business, enhance the level of service, and improve management controls.

NIH is also improving its peer review system, which is recognized as the cornerstone of NIH's success. The NIH Center for Scientific Review (CSR), the focal point of the NIH peer review system, reviews about 70 percent of the grant applications submitted to NIH. In fiscal year 2003, CSR received a record-breaking 66,000 grant applications.

CSR is in the final stages of crafting new and more flexible review panels organized into 24 scientifically-related clusters. NIH is also incorporating new technologies into the review process through the electronic Research Administration (eRA). The goal is to implement an end-to-end electronic grants administration for NIH research award mechanisms that could reduce the waiting period from submission of an application to a grant award by more than two months—from 9 to 10 months down to 7 months.

Remarkably, because of improvements in productivity over the past ten years, NIH funding has grown 141 percent, while our FTEs have increased by only 16 percent.

The NIH also realizes the need for a more efficient means of trans-NIH coordination. To streamline decision making, we reduced the plethora of NIH administrative committees down to a trans-NIH Steering Committee and 5 working groups. Additionally, as we discussed when I met with the subcommittee in January, all our conflict of interest policies and procedures are under review both to ensure that they meet the highest standards and, most importantly, to preserve the public's trust in the NIH. I will soon receive the report of a Blue Ribbon Panel I created to advise NIH on what changes they think we should make. I will inform you about their conclusions, and mine, once they complete their work next month.

BUDGET

The discretionary fiscal year 2005 budget request for the NIH is $28,607 million ($28,527 million from this subcommittee and $80 million from the VA/HUD subcommittee), an increase of $729 million or 2.6 percent over the fiscal year 2004 Enacted Level. In addition, $47.4 million is included in the budget authority request of the Public Health and Social Services Emergency Fund (PHSSEF), for NIH research in radiological/nuclear countermeasures, and $150 million in mandatory funds was previously appropriated for the Special Type 1 Diabetes Initiative, bring-

ing NIH's program level total to $28,805 million, or a 2.7 percent increase. The budget increases funding for the NIH Roadmap (+$109 million), obesity research (+$40 million), which will thus grow by 10 percent from $400 million in 2004, and biodefense research (+$74 million), an increase of 4.5 percent over fiscal year 2004.

CONCLUSION

In conclusion, I want to reemphasize the NIH commitment to help improve the health of the American people. Although we have had great success in changing acute lethal diseases like AIDS and many cancers and childhood diseases into chronic manageable diseases, there are many challenges ahead. Life expectancy has increased and the diseases of aging and the aging population have become major priorities.

With a shift from acute to chronic diseases, health disparities and pediatric diseases also present challenges, as do emerging and re-emerging diseases, such as SARS. We are confident, as the committee has shown it is, that medical research will make a critical difference in the lives of all Americans.

As the NIH director, I fully understand and embrace my role as the steward of our Nation's investment in medical discovery. And I remain vigilant to ensure that these precious resources—including over 212,000 scientists working at 2,800 institutions in the United States and overseas and the 5,000 scientists at the NIH itself—are used wisely and efficiently and produce not only new knowledge but also tangible benefits that touch the lives of every individual who reaches out for our help.

BUILDINGS AND FACILITIES PROGRAM

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the Buildings and Facilities (B&F) Program for fiscal year 2005, a sum of $99,500,000.

ROLE IN THE RESEARCH MISSION

State-of-the-science research and support facilities are a vital part of the research enterprise. The National Institutes of Health's (NIH) Buildings and Facilities (B&F) program designs, constructs, repairs and improves the agency's portfolio of laboratory, clinical, animal, administrative and support facilities at its six installations in three states. These facilities house researchers from the NIH Institutes' and Centers' (ICs) intramural basic, translational, and clinical research programs; the NIH leadership, and various programs that support agency operations. The fiscal year 2005 B&F budget request supports critically needed and timely investments to keep the agency's facilities and supporting physical infrastructure healthy, safe, secure, and research ready.

The B&F budget request is the product of a comprehensive, corporate capital facilities planning process. This process begins with extensive consultation across the research community and the NIH's professional facilities staff. It works through the Facilities Working Group, an advisory committee to the NIH Steering Committee and the HHS Capital Investment Review Board. The budget request is the current year plan in a rolling five-year facilities plan. Through this process, the real and insistent program demand for more effective and efficient facilities designed to support current and emerging investigative techniques, technologies, and tools is integrated with, and balanced against, the need to repair, renovate, and improve the existing building stock to keep it in service and to optimize its utility.

The fiscal year 2005 request provides the necessary funding support for the ongoing safety, renovation and repair, and related projects that are vital to proper stewardship of the entire portfolio. It provides funds to continue the functional integration of the clinical research components of the existing Building 10 with the new Mark O. Hatfield Clinical Research Center (CRC). Additionally, the request includes funds to: complete the design of the Animal Research Center (ARC) on the Bethesda campus; complete the creation of a security buffer around the Rocky Mountain Laboratories (RML), in Hamilton, MT; and to add another chiller to the NIH's Bethesda campus central utility system that is needed to meet current and anticipated cooling demands.

The fiscal year 2005 B&F budget request is organized among five broad Program Activities: Construction, Essential Safety and Regulatory Compliance, Repairs and Improvements, Renovations, and Equipment/Systems. The fiscal year 2005 request provides funds for specific projects in each of the program areas. The projects and programs enumerated are the end result of the aforementioned NIH facilities planning process and are the NIH's capital facility priorities for fiscal year 2005.

FISCAL YEAR 2005 BUDGET SUMMARY

The fiscal year 2005 budget request for Buildings and Facilities is $99.5 million. The B&F request contains $16.5 million for Construction, including $5 million to complete the design of an Animal Research Center; $9.5 million to complete the creation of a security buffer around the Rocky Mountain Laboratories (RML) in Hamilton, MT; and $2 million for concept development studies of projects proposed in the facilities plan.

There is a total of $6 million for Essential Safety and Regulatory Compliance programs composed of $0.5 million for the phased removal of asbestos from NIH buildings; $2 million for the continuing upgrade of fire and life safety deficiencies of NIH buildings; $1 million to systematically remove existing barriers to persons with disabilities from the interior of NIH buildings; $0.5 million to address indoor air quality concerns and requirements at NIH facilities; and $2 million for the continued support of the rehabilitation of animal research facilities. In addition, the fiscal year 2005 request includes $59.2 million in Repairs and Improvements for the continuing program of repairs, improvements, and maintenance that is the vital means of maintaining the complex research facilities infrastructure of the NIH. The request includes $10.8 million in Renovations to complete the Building 10 Transition Program. Finally, the request includes $7 million in Equipment/Systems for the Chiller 27 project.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. PAUL A. SIEVING

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Eye Institute (NEI) for fiscal year 2005. This budget includes $671.6 million, an increase of $18.8 million over the fiscal year 2004 enacted level of $652.7 million comparable for transfers proposed in the President's request. As the Director of the NEI, it is my privilege to report on the progress laboratory and clinical scientists are making in combating blindness and visual impairment and about the unique opportunities that exist in the field of vision research.

RETINAL DISEASES

Retinal diseases are a diverse set of sight-threatening conditions that include age-related macular degeneration, diabetic retinopathy, retinopathy of prematurity, retinitis pigmentosa, Usher's syndrome, ocular albinism, retinal detachment, uveitis (inflammation), and cancer (choroidal melanoma and retinoblastoma). One of the most tragic retinal diseases, retinopathy of prematurity (ROP), causes severe vision loss in premature, low-birthweight infants. ROP is characterized by excessive growth of abnormal blood vessels in the back of the eye that often hemorrhage and scar the retina. This year, results from an NEI-funded clinical trial, called the Early Treatment of Retinopathy of Prematurity (ETROP), established that early treatment, based on newly developed diagnostic criteria, improves visual outcomes in infants at the greatest risk of developing ROP. The ETROP study also found that these new diagnostic criteria were helpful in select patient subgroups that may not ultimately develop ROP. For these infants, careful observation was found to be the best approach. Results from ETROP will greatly improve visual outcomes for children with ROP.

Age-related macular degeneration (AMD) is a leading cause of blindness in patients over age 60 in the United States and is a major health problem in most other developed countries. More than 9 million Americans have some degree of AMD (Archives of Ophthalmology, In Press). Based on the results of an NEI-funded clinical trial, the Age-Related Eye Diseases Study (AREDS), 1.3 million of these people would develop advanced AMD if no treatment were given to reduce their risk. If these people at risk for development of advanced AMD received the supplements (vitamins C, E, beta-carotene, and zinc) used in AREDS, more than 300,000 of them would avoid advanced AMD and any associated vision loss over the next five years. Delaying the advance of a disease in older-age populations is an essential strategy to reduce the burden and incidence of disease.

Uveitis is an autoimmune inflammatory disease of the eye that accounts for up to 10 percent of blindness in the United States (Ophthalmology 2004; 111:491–500). In collaboration with researchers at the National Cancer Institute, NEI intramural scientists have reported promising results with the use of a monoclonal antibody (daclizumab) in the long term treatment of patients with uveitis. This new therapy seems to have many fewer side effects than existing immunosuppressive therapies,

leading to an improved quality of life. Planning is underway to begin a Phase III study to evaluate the full potential of this therapy.

CORNEAL DISEASES

The cornea is the transparent tissue at the front of the eye. Corneal disease and injuries are the leading cause of visits to eyecare clinicians, and are some of the most painful ocular disorders. In addition, approximately 25 percent of Americans have a refractive error known as myopia or nearsightedness that requires correction to achieve sharp vision; many others are far-sighted or have astigmatism.

NEI intramural scientists found that serum albumin represents up to 13 percent of the total water-soluble protein of the mouse cornea. Humans also have abundant serum albumin in the corneal stroma. Because the serum albumin accumulates in the corneal stroma by diffusion from the blood supply surrounding the cornea, it may provide an improved route of drug delivery to the cornea. Conjugating serum albumin to the drug of choice and injecting the conjugate into the blood stream will not only direct the drug within the cornea, but extend its half-life within this tissue. Future research will evaluate the usefulness of serum albumin as a drug carrier to treat corneal disorders.

NEI intramural scientists recently identified an enzyme called CDK5 that regulates corneal epithelial cell adhesion and migration. Using a model wound healing system, these researchers found that the rate of wound closure was significantly retarded in cells with too much CDK5 and accelerated in cells in which the CDK5 was inactivated. Continuation of this line of research may provide the means to promote rapid healing of corneal tissues that have been damaged by disease or injury.

CATARACT

Cataract, an opacity of the lens of the eye, interferes with vision and is the leading cause of blindness in developing countries. In the United States, cataract is also a major public health problem. The economic burden of cataract will worsen significantly in coming decades as the American population ages.

Age-related cataract formation is believed to result from the complex effects of aging on normal physiological processes. It has long been recognized that lens transparency is a function of a very high concentration of soluble proteins, the crystallins, within the specialized lens fiber cell. In the lens, α-crystallin has a dual function: it accumulates in fiber cells in high concentrations to produce the high refractive index needed for transparency, and it functions as a molecular chaperone to protect against clouding of the lens due to protein aggregation. For some time, scientists have attempted to understand how α-crystallin can continue to perform its chaperone functions over a range of stress conditions encountered by the lens during a lifetime. New data suggest that under low stress, α-crystallin is maintained in a multi-subunit complex. Under conditions of high stress, α-crystallin breaks into smaller sub-units that can protect the clarity of the lens from protein aggregation. It has been hypothesized that this chaperone function decreases with age and leaves the lens more vulnerable to stressful conditions. Improving our understanding of this protective role of α-crystallin may one day lead to the means to prevent cataract.

GLAUCOMA AND OPTIC NEUROPATHIES

Glaucoma is a group of eye disorders that share a distinct type of optic nerve damage, which can lead to blindness. Elevated intraocular pressure (IOP) is frequently, but not always, associated with glaucoma. Glaucoma is a major public health problem and is a leading cause of blindness in African Americans (Archives of Ophthalmology, In Press).

A hallmark of glaucoma is the death of retinal ganglion cells (RGC) in the retina, which can lead to catastrophic vision loss. Previous NEI studies have found evidence that elevated IOP deprives RGCs of brain-derived neurotrophic factor (BDNF), an endogenous protein that is crucial to RGC survival. Ocular injections of BDNF in rodent models of glaucoma have improved RGC survival. However, due to the relatively short half-life of this protein, the need for frequent ocular injections would not bode well in treating a chronic disease like glaucoma. To overcome this hurdle, NEI-supported researchers recently used gene therapy in rodent models of glaucoma to transfect RGCs with the gene that encodes BDNF, providing a lasting and direct supply of this essential protein. Ongoing NEI-supported laboratory work is evaluating whether gene therapy with BDNF provides long-term benefit and whether gene delivery with other neurotrophic agents, alone or in combination with BDNF, improves RGC survival.

STRABISMUS, AMBLYOPIA AND VISUAL PROCESSING

Developmental disorders such as strabismus (misalignment of the eyes) and amblyopia (commonly known as "lazy eye") are among the most common eye conditions that affect the vision of children. In addition, more than three million Americans suffer from visual processing disorders not correctable by glasses or contact lenses (Archives of Ophthalmology 1990; 108:286–290).

Patching the stronger eye has been a mainstay of amblyopia therapy. Unfortunately, there is no specific patching regimen that is widely accepted for treating the disease. To address the clinical issue of the optimal number of patching hours for moderate amblyopia, an NEI-supported clinical trial compared daily patching of two hours versus six hours for children with moderate amblyopia. Results from this clinical trial revealed that patching the unaffected eye of children with moderate amblyopia for only two hours daily is as effective as patching the eye for six hours. This finding should improve treatment compliance as patching can be a socially stigmatizing and uncomfortable practice for young children.

TECHNOLOGICAL INNOVATIONS

The marriage of computer technology and medical science is creating advances in treating even the most intractable diseases. In one such union, specially designed computer chips implanted in the eye may one day make it possible to partially restore visual function to the blind. Ocular neuro-degenerative diseases such as retinitis pigmentosa (RP) and macular degeneration damage and destroy the light-sensitive photoreceptor cells in the retina. The microelectronic retinal prosthesis, a device developed by NEI-supported researchers, mimics the function of photoreceptor nerve cells by turning light into electric signals. In a recently published study, a 74 year-old patient blind with RP was able to see spots of light, detect motion, and recognize simple shapes. Although preliminary, these results are a promising first step in realizing a prosthetic device that can restore ambulatory vision to patients with retinal degenerative diseases, which are a major cause of vision loss in this country.

PROGRAM INITIATIVES

The rapid progress in areas of gene discovery and bioinformatics has created the need for enhanced cooperation and coordination among groups that provide genetic diagnostic information to the clinician and patient, store and provide DNA specimens to researchers, and maintain data banks of genotype-phenotype information. Such groups are underrepresented in the area of human ocular disease. The purpose of this initiative is to explore the establishment of a national central registry and molecular database of securely coded information from a large number of people with ocular diseases caused by genetic mutations. Information will be provided through a network of cooperating groups who provide genetic and diagnostic services to patients and clinicians. Such a registry and database will be of great value in advancing research for these important diseases.

Clinician scientists will play a major role in translating laboratory findings into safe and effective therapies. However, the vision research community has raised concerns about the future of clinician scientists. Declining clinical revenues are making it increasingly difficult for clinicians to find time away from the examination room to get the training they need. However, many of the investigational therapies now being contemplated will be translated by the next generation of clinician scientists. We need to make sure that current clinician scientists have a capable next generation to pass the torch to.

In addition to its existing extramural training and career development grant programs, the NEI is working to increase the ranks of the clinician scientist through a new intramural clinician scientist training program at the NEI. The Clinician Scientist Development Program is designed for board eligible/certified clinicians who seek to develop an independent research program that integrates the field of vision research with the clinical study of patients with ocular disease or disorders.

The NEI recently published its forward looking *National Plan for Eye and Vision Research.* The NEI's ongoing planning process involves the assessment of important areas of progress in eye and vision research and the development of new goals and objectives that address outstanding needs and opportunities for additional progress. The National Plan can be accessed through the NEI website at: http://www.nei.nih.gov/strategicplanning.

NIH ROADMAP

The NIH Roadmap provides a framework for the priorities the NIH as a whole must address in order to optimize its entire research portfolio. The NEI is committed to the initiatives of the Roadmap and is working to meet its goals. I would like to highlight NEI's involvement in two Roadmap Initiatives: "Nanomedicine" and "Re-Engineering the Clinical Research Enterprise."

The NEI and the National Human Genome Research Institute are heading an NIH committee charged with implementing the Nanomedicine Roadmap Initiative. Nanotechnology originated in the fields of engineering and physics and refers to the research and development of materials and devices at the atomic, molecular or macromolecular levels. Nanomedicine integrates nanotechnology with biomolecular processes. The long-term goal of the Nanomedicine Roadmap Initiative is the development of therapeutic nanotechnology interventions for medical diagnosis and the treatment of disease. To meet these goals we are establishing a process to solicit ideas and concepts germane to the development of Nanomedicine Development Centers.

Nanomedicine Development Centers will be designed to achieve an understanding of biological systems at the nanomolecular level.

Over the past decade NEI-supported laboratory research has given rise to an unprecedented number of promising, pre-clinical therapies for eye disease. NEI's continued success depends on building the clinical infrastructure for translational medicine. Consonant with the NIH Roadmap initiative "Re-engineering the Clinical Research Enterprise" the NEI is creating cooperative clinical research groups that will enhance and expand clinical trial infrastructure. Over the last year, the NEI implemented the Diabetic Retinopathy Clinical Research Network. More than 70 clinical centers with the capability to participate in the clinical trials network have been identified. This network joins the highly effective Pediatric Eye Disease Investigator Group as models for future clinical networks the NEI plans to build.

Mr. Chairman that concludes my prepared statement. I would be pleased to respond to any questions you or other members of the committee may have.

PREPARED STATEMENT OF DR. JOHN RUFFIN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center on Minority Health and Health Disparities (NCMHD) for fiscal year 2005, a sum of $196,780,000, which represents an increase of $5,324,000 over the comparable fiscal year 2004 appropriation.

A STRATEGIC APPROACH TO ELIMINATE HEALTH DISPARITIES

Unprecedented scientific advances in biomedical research over the last several decades dramatically improved public health. However, racial and ethnic minorities and other populations that experience disparities in health status have not benefitted equally from our Nation's progress in scientific discovery.

The NIH supports a comprehensive research program to better understand why a broad spectrum of diseases disproportionately impact racial and ethnic minorities and the urban and rural poor. No other scientific area so thoroughly transcends so many diverse areas of science and involves all of the NIH Institutes and Centers (ICs).

The NCMHD plays a key role in framing the NIH health disparities research agenda by conducting and supporting basic, clinical, social sciences, and behavioral health disparities research; developing research infrastructure and training programs; reaching out to and disseminating health information to minority and other health disparity populations; stimulating scientific programs within the NIH ICs to uncover the causes of health disparities and eliminate their impact on society; and developing and updating the NIH Health Disparities Strategic Plan.

This past year, the NCMHD, in collaboration with the NIH Director, every NIH IC, and the National Advisory Council on Minority Health and Health Disparities, completed the first comprehensive NIH Health Disparities Strategic Plan, based on scientific priorities and opportunities that will lead to new therapies and prevention strategies that will ultimately eliminate health disparities in America. This evolving plan will guide future NIH health disparities research efforts.

INNOVATIVE EFFORTS TO COMBAT HEALTH DISPARITIES

The NCMHD has accomplished much since its creation. Today, the NCMHD has 60 Health Disparities Centers of Excellence spread across the nation. These Centers of Excellence, now located in 23 states, the District of Columbia, and Puerto Rico,

support health disparities research, research training, and community involvement to identify factors that contribute to health disparities and to develop and implement new diagnostic, treatment, and prevention strategies.

The NCMHD addresses the national need to develop a diverse, strong, and a culturally competent scientific workforce by eliminating barriers that prevent racial and ethnic minority students and students from disadvantaged backgrounds from pursuing research careers. Currently, the NCMHD supports about 300 researchers from 38 states through its two Loan Repayment Programs, which help to level the playing field and make it possible for under represented individuals to enter the scientific, technological, and engineering workforce. These "Health Disparities Ambassadors" are key to creating the culturally competent health disparities and clinical research workforce of the future.

The NCMHD has also created a one-of-a-kind Research Endowment Program. Unique at the NIH, this program addresses the national need to build research and training capacity in institutions that make significant investments in the education and training of minority and disadvantaged individuals. This program is making it possible for 13 institutions located in 11 states and Puerto Rico to establish health disparities endowed chairs and programs, enhance student recruitment efforts, provide merit-based scholarships, recruit and retain faculty, develop innovative instruction delivery systems in minority and health disparities research areas, and access emerging technologies.

The NCMHD Research Infrastructure in Minority Institutions Program, born out of a partnership between the National Center of Research Resources and the Office of Research on Minority Health, (the predecessor to the NCMHD) is making it possible for institutions to target research efforts on health disparities that exist in the Southwest Border States; in rural communities, such as the Appalachia Region, the Mississippi Delta, and the Frontier States; and in urban centers of the nation. Currently, 11 institutions in eight states benefit from this program.

In addition to using its core programs, the NCMHD strategy to eliminate health disparities also includes leveraging NIH dollars and expertise by creating partnerships with the NIH ICs and other agencies within the Department of Health and Human Services to fund health disparities research, training, and outreach programs. Over the past two years alone, the NCMHD forged many new partnerships, supporting more than 400 research projects to combat health disparities in our nation.

CLOSING THE HEALTH DISPARITY GAP

Racial and ethnic minorities and other health disparity populations experience a disproportionate burden of illness, disability, and premature death due to cancer, cardiovascular disease and stroke, diabetes, HIV/AIDS, infectious diseases, infant mortality, and other diseases. The Department of Health and Human Services, through its "Closing the Gap Initiative," designates these areas as major research priorities. NCMHD programs focus on these priorities and many others. The following initiatives represent a small sampling of the richness and diversity of NCMHD activities.

Cancer

Cancer deaths vary by gender, race, and ethnicity. Certain racial and ethnic groups have lower survival rates than whites for most cancers. Colorectal cancer rates among Alaska Natives are higher than the national average and Asian Americans suffer disproportionately from stomach and liver cancers. African American men have the highest rates of colon, rectum, prostate, and lung cancers (*Healthy People 2010*).

NCMHD Health Disparities Centers of Excellence in 12 states across the nation are bringing to bear their state-of-the-art research and outreach programs to eliminate the impact of cancer on diverse populations. These efforts take place in Alabama, Arizona, California, Colorado, Georgia, Maryland, Mississippi, New York, Pennsylvania, Tennessee, Texas, and Virginia. One example of this intense effort is the American Indian and Alaska Native Health Disparities Center in Colorado, which conducts cancer research to address the needs of Native American and Alaska Native populations.

The NCMHD Research Infrastructure in Minority Institutions program, which focuses on building research capacity at minority serving institutions, also addresses cancer health disparities. The Charles R. Drew University is working to improve the detection and characterization of brain tumors, and researchers at San Francisco University are examining the impact of social support, spirituality, and depression on quality of life among breast cancer survivors from diverse populations.

Forty-five Health Disparities Ambassadors supported by our Loan Repayment programs have also set their sights on combating cancer health disparities in 17 states including Alabama, California, Colorado, Georgia, Illinois, Kansas, Massachusetts, Maryland, Michigan, Minnesota, North Carolina, New York, Pennsylvania, Tennessee, Texas, Virginia, Wisconsin, and in the District of Columbia. Some of the exciting work taking place under this program includes a community-based health promotion project to prevent cervical cancer in Vietnamese-American women; research studies on racial differences and barriers in obtaining breast, cervical, and colon cancer screening; and a population-based study that examines the variation in outcomes of colorectal cancer between African Americans and whites.

Collaboration with the other NIH Institutes and Centers has allowed the NCMHD to extend the reach of its scientific expertise to tackle cancer health disparities in rural populations. For example, the Appalachia Cancer Network, cosponsored by the NCMHD and the National Cancer Institute, addresses cancer in rural and medically underserved Appalachian populations in West Virginia, Kentucky, Tennessee, Virginia, Ohio, Pennsylvania, Maryland, and New York. The goal of this network is to reduce cancer incidence and mortality and to prevent future increases; to increase cancer survival; and to stimulate greater coordination and participation among regional, state, and community cancer control networks throughout Appalachia.

Cardiovascular Disease & Stroke

Cardiovascular disease takes a heavy toll on certain populations. Heart disease rates have been consistently higher in the African American population than in whites (*Healthy People 2010*). Data on stroke risk factors are sparse for most racial and ethnic populations, except for African Americans whose stroke deaths, when adjusted for age, are almost 80 percent higher than in whites (*Healthy People 2010*).

Today, 13 NCMHD Health Disparities Centers of Excellence, located in nine states across the nation including California, Georgia, Hawaii, Maryland, Mississippi, North Carolina, New York, Pennsylvania, and Texas focus on eliminating disparities due to cardiovascular disease. Three Health Disparities Centers of Excellence in Georgia, Mississippi, and New York focus on stroke research. The NCMHD also supports 20 Health Disparities Ambassadors spread across 11 states, including California, Florida, Illinois, Indiana, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, and Texas, who have set their sights on eliminating health disparities due to cardiovascular disease.

The NCMHD Health Disparities Center of Excellence at Jackson State University in Jackson, Mississippi is built on a partnership with the University of Mississippi Medical Center, the University of Pittsburgh, and the Jackson Medical Mall Foundation. This Center's research agenda focuses on cardiovascular disease, stroke, and cancer in the African American population in Mississippi.

The NCMHD also partners with its fellow NIH ICs, in the battle against cardiovascular disease and stroke disparities. The NCMHD partners with the National Heart, Lung, and Blood Institute to support the Jackson Heart Study. This study evaluates the environmental and genetic factors contributing to the disproportionate incidence of cardiovascular disease in African American men and women living in Mississippi. To date, almost 5,000 participants have benefitted from the program by visiting the clinic, with an average of 25 participants per week.

The NCMHD and the National Institute of Neurological Disorders and Stroke partner to support two Specialized Neuroscience Research Programs at the Morehouse School of Medicine and at the University of Texas at San Antonio. This funding allows institutions to develop state-of-the-art neuroscience research programs; strengthen collaborations and resource-sharing between minority medical and graduate schools, community-based organizations, and leading neuroscience laboratories; expand training opportunities for minority students to access and prepare for careers in neuroscience research; and build new stroke research capacity.

Diabetes

Certain communities, including Hispanics, American Indians, African Americans, and certain Pacific Islanders and Asian populations, as well as economically disadvantaged and older people suffer disproportionately from diabetes (*Healthy People 2010*). Diabetes is the target of 27 Health Disparities Centers of Excellence in 17 states including Alabama, Arizona, California, Colorado, Georgia, Hawaii, Illinois, New York, North Carolina, North Dakota, Maryland, Mississippi, Oklahoma, Pennsylvania, South Carolina, Texas, and Wisconsin, as well as the District of Columbia. These programs include the University of Hawaii at Manoa, where efforts are underway to reduce and eliminate the major complications of diabetes in Pacific Islanders. The University of Pennsylvania is developing behavioral strategies for re-

ducing obesity, a major factor contributing to diabetes in Latino and African American communities.

The NCMHD has also deployed 15 Health Disparities Ambassadors to 10 states, including Alabama, California, Florida, Georgia, Illinois, Massachusetts, New Hampshire, New York, Texas, and Virginia in the effort to eliminate diabetes-related health disparities. These individuals are conducting several important projects including reducing obesity in diabetic African American women in the state of Georgia and conducting educational interventions to prevent type 2 diabetes in middle school children in Alabama. Under the NCMHD Research Endowment program, Xavier University of Louisiana is increasing the diabetes research capability of its College of Pharmacy, promoting health disparities research, and increasing the pool of well educated under represented minorities who pursue advanced education in biomedical and behavioral research.

New NCMHD partnerships are also playing a significant role in eliminating diabetes health disparities. The NCMHD and the Indian Health Service recently formed a partnership to develop the Tribal Epidemiology Centers Program to address and eliminate health disparities, including diabetes disparities, experienced by American Indians and Alaska Natives. Recent NCMHD support enabled the creation of a new Northern Plains Tribal Epidemiology Center in Rapid City, South Dakota, continued funding for the other six existing EpiCenters, and the development of a summer training institute for Indian Health professionals. The funding will assist the EpiCenters to carry out their training program for local health staff, and expand their outreach activities to include a community-based research training program.

HIV/AIDS

The disproportionate impact of HIV/AIDS on certain populations underscores the importance of sustained research and prevention efforts. In 2002, the AIDS diagnosis rate among African Americans was almost 11 times the rate among whites. African American women had a 23-times greater diagnosis rate than white women. African American men had almost a nine-times greater rate of AIDS diagnosis than white men. (Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 2003). In 2000, the AIDS incidence among Hispanics was 22.5 per 100,000 population, more then three times the rate for whites (Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 2002:1).

In its fight against HIV/AIDS health disparities, the NCMHD partners with the Centers for Disease Control and Prevention to support the Racial and Ethnic Approaches to Community Health (REACH) Program. REACH serves African American, Asian American, Pacific Islander, Hispanic American, American Indian, and Alaskan Native populations at increased risk for HIV/AIDS, cardiovascular disease, breast and cervical cancer, diabetes and infant mortality. REACH develops, implements, and evaluates innovative community level intervention demonstrations that could be effective in eliminating health disparities by 2010.

With the Agency for Healthcare Research and Quality, the NCMHD supports the EXCEED Program to examine the underlying causes and contributing factors for racial and ethnic disparities in health care and to identify and implement strategies for reducing and eliminating those disparities. Under this initiative, the Medical University of South Carolina is examining strategies to address HIV/AIDS disparities in health status between African Americans and whites, and the Baylor College of Medicine is assessing the extent to which problems in doctor-patient communication contribute to racial and ethnic disparities in health care use.

Infant Mortality

In recent years, infant mortality rates in the United States have steadily declined; yet the rate of Sudden Infant Death Syndrome among African Americans is still twice that of whites. African American women continue to be three to four times more likely than white women to die of pregnancy-related complications. Hispanic women are less likely than whites to enter into early prenatal care. Fetal Alcohol Syndrome disproportionately impacts American Indian, Alaska Native, and African American babies. (*Healthy People 2010*).

The NCMHD has Health Disparities Centers of Excellence in six states including Alabama, Florida, Georgia, Texas, Iowa, and Wisconsin that focus their efforts to improve the health of mothers and their infants. One of these, the "Mexican-American Women's Health Project Center" at the University of Texas, El Paso, partners with established Hispanic health disparities researchers at the University of Arizona. Their research efforts focus on modifying behaviors of Mexican-American women relating to alcohol use; maternal health and nutrition; smoking cessation; and the pursuit of recommended Pap and HPV screening tests. Another Center at

the University of Northern Iowa focuses on maternal and child health disparities to address the special health needs of Iowa's minority groups, which include urban African Americans, members of the Meskwaki Indian Tribe, rural families, growing populations of Latino and East African immigrants, and refugees from Bosnia and the former Soviet Union.

The NCMHD also supports six Health Disparities Ambassadors through its Loan Repayment Programs, who are focusing their attention on infant mortality health disparities. These efforts is take place in Florida, Maryland, Michigan, Missouri, North Carolina, and Pennsylvania. Ongoing efforts include evaluating the link between sexually transmitted diseases and infant mortality; determining leading health indicators for women and girls; and creating logic models for maternal, child, and family health programs.

RURAL HEALTH

Another top priority of the NCMHD is improving rural health across the nation. In pursuit of this goal, the NCMHD established an innovative Health Disparities Center of Excellence partnership between Clemson University and Voorhees College, a Historically Black Institution in South Carolina. This partnership will build capacity for research, training, and outreach to address health disparities in rural Hispanic and African American communities in South Carolina. The Tuskegee University and the University of Alabama, Tuscaloosa Health Disparities Center of Excellence partnership, in conjunction with the University of Alabama Institute for Rural Health Research and community organizations, focuses on adult immunization, infant mortality, cancer, and diabetes.

Over the past year, the NCMHD also created opportunities to include the expertise of other NIH ICs in addressing the needs of rural communities, forming 16 new rural health partnerships with the NCI, NHLBI, NIAAA, NIDA, NIEHS, NIMH, and the NINR. Examples of these new projects include the Appalachia Cancer Network; the Deep South Network for Cancer Control; the Rural Caregiver Telehealth Intervention Trial; and studies on the effects of alcohol and violence on rural women; coronary artery disease in Alaska Natives; migrant worker health and the environment; mental health treatment for rural Mexican Americans, African Americans, women, and the poor; cardiovascular health training and outreach in Latino communities; and substance abuse among Ojibwe children and youth.

CONCLUSION

The diversity of the American population is one of the greatest assets of the nation. One of the greatest challenges facing the nation is reducing and eliminating the profound disparity in health status that exists for many of its populations. Without decisive action now, the health challenges of the 21st century will expand along with the increasing number of racial and ethnic minorities, inhabitants of rural areas, and low socioeconomic populations.

The NCMHD will continue to combat health disparities through our flagship programs. We will explore new opportunities to support academic development for the health disparity researchers of tomorrow. We will seek to create innovative programs to serve as a bridge between NCMHD capacity building programs and an investigator's first independent research effort. Cognizant of the value of engaging communities in the elimination of health disparities, we will lead efforts to conduct effective community-based outreach and research to our numerous constituents. We will continue our legacy of creating and nurturing partnerships to further increase the reach of our activities to eliminate health disparities and we will encourage our fellow NIH ICs to join the core health disparities programs of the NCMHD. The NIH Roadmap Initiative should also provide opportunities for the NCMHD constituent populations and research community to participate in interdisciplinary research, clinical research, and technology.

Our vision of the future is a collective one that is embodied in the NIH Health Disparities Strategic Plan. With leadership, commitment, and strong scientific partnerships the NIH can advance scientific discovery to ensure the health of all Americans. Working together, we can turn the vision of an America where all citizens have an equal opportunity to live long, healthy, and productive lives into reality.

PREPARED STATEMENT OF DR. JUDITH L. VAITUKAITIS

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center for Research Resources (NCRR) for fiscal year 2005, a sum of $1,094,141,000, including support for AIDS research,

which reflects a net decrease of $84,815,000 over the comparable fiscal year 2004 appropriation, due entirely to the phasing out of extramural construction projects for fiscal year 2005.

It is a pleasure once again to have the opportunity to present the accomplishments of NCRR-supported investigators and the future directions for NCRR programs. As a component of the National Institutes of Health, NCRR enables all lines of health-related discovery by supporting the creation and development of critical research resources and technologies. Because significant discoveries can be made at a variety of levels—from molecules to patients, or even patient populations NCRR supports a wide range of research resources across several disciplines. These resources include state-of-the-art clinical research environments, such as the nationwide network of General Clinical Research Centers. The GCRCs facilitate clinical research and protect the safety of participants in research. Each year more than 10,500 NIH-supported investigators conduct nearly 8,000 research projects at the GCRCs, predominantly through more than a half million outpatient research visits.

NCRR also supports research resources that develop and enhance scientific access to advanced technologies, nonhuman models for the study of human diseases, and career development and training. Because of its trans-NIH focus, NCRR is well-positioned to facilitate research by promoting the sharing of research tools and technologies as well as providing the tools for research collaborations so that research teams may address more complex research problems.

TECHNOLOGY AND INSTRUMENTATION

NCRR strives to ensure that neither the lack of research resources nor technology development becomes rate-limiting for research. Two Nobel Prize winners in 2003 can vouch for the importance of having ready access to NCRR-supported resources. Dr. Roderick MacKinnon of Rockefeller University, co-recipient of the Nobel Prize in Chemistry, was honored for his groundbreaking studies of the structures and functions of ion channels, which control the movement of electrically charged atoms across cell membranes. Ion channel malfunctions can trigger a host of human disorders, including irregular heart rhythms and seizure disorders. Dr. MacKinnon noted that his award-winning discoveries depended on having access to the scientific expertise and advanced research instrumentation available at NCRR-supported resources that specialize in mass spectrometry and crystallography of complex molecules.

The challenge for NCRR is to keep pace with the biomedical community's changing needs for research tools and to ensure that tomorrow's research queries have tomorrow's critical instrumentation and technologies in hand. The research resources and tools needed for scientific investigations change dramatically over time as more complex research queries are posed and require new technologies. Many research tools now considered critical to understanding the cause of disease and protecting the health of Americans were unheard of just a few years ago. For instance, the Magnetic Resonance Imagers, or MRIs, now found in hospitals and medical centers across the country were rare and experimental less than 20 years ago. Dr. Paul Lauterbur of the University of Illinois, Urbana-Champaign, depended on NCRR for many of his investigations into magnetic resonance imaging. Dr. Lauterbur was corecipient of the Nobel Prize in Physiology or Medicine for his studies that led to the development of MRI. From 1990 to 2000, Dr. Lauterbur headed an NCRR-funded magnetic resonance research center, which helped to facilitate the evolution of MRI into the invaluable diagnostic and clinical research tool that it is today.

CLINICAL RESEARCH RESOURCES

Just as NCRR technology and instrumentation resources laid the foundation for critical discovery in the basic and applied sciences, NCRR also catalyzes clinical and patient-oriented research through the network of GCRCs. In addition, NCRR develops and supplies investigators with clinical-grade biomaterials, such as vectors for gene therapy and human pancreatic islets for transplantation into patients with type 1 diabetes.

Research on rare diseases is one area where the GCRCs are ideally positioned to catalyze clinical research. Rare disease research is challenging in part because few patients with a particular rare disease can be recruited from any one clinical center. The nationally distributed network of the GCRCs makes them well-suited for enabling multicenter studies of rare conditions. Therefore, NCRR has partnered with the NIH Office of Rare Diseases and other groups to launch a network of Rare Diseases Clinical Research Centers. The network provides researchers with access to sufficient numbers of affected patients for statistically meaningful studies. The net-

work also facilitates collaborations among scientists from multiple disciplines and institutions.

To ensure the safety of human subjects participating in clinical research projects, clinical investigators must adhere to Federal, state and local regulations, policies, and guidelines. Yet these necessary responsibilities place heavy demands on the time of already-busy clinician investigators. To address this issue, NCRR established a new GCRC staff position known as the Research Subject Advocate (RSA). The RSA assists GCRC investigators, nurses, and staff to underscore the safe and ethical conduct of clinical studies and represents the interests of research participants. NCRR plans to extend and strengthen the role of RSA in an approach that complements that undertaken by the host institution.

HEALTH DISPARITIES

NCRR also supports clinical research studies on health disparities, or diseases that disproportionately affect racial and ethnic minority populations. NCRR has joined with the National Institute of Mental Health to establish three Comprehensive Centers on Health Disparities. These Centers will further develop the capacity of Research Centers in Minority Institutions' (RCMI) medical schools to conduct basic and clinical research in type 2 diabetes and cardiovascular disease, both of which disproportionately affect minority populations. The Centers will provide support to further develop the requisite research infrastructure, recruit magnet clinical investigators, recruit and develop promising junior faculty, and facilitate substantial collaboration between the RCMI grantee institutions and more research-intensive universities. NCRR also supports a Stroke Prevention and Intervention Research Program that focuses on minorities, as well as a mentored clinical research career development program to provide clinical research training for doctoral and postdoctoral candidates in minority institutions.

BIOINFORMATICS AND COMPUTER NETWORKS

Whether studying clinical manifestations of disease or the basic biology of cells and tissues, today's biomedical researchers generate vast data sets. This data deluge has increased scientific demand for access to scaleable computation and modern management tools. A related and equally important trend is the fact that biomedical research projects are becoming broader in scope. For example, neuroscientists now want to correlate brain images with events at cellular and molecular levels, including gene expression. These broad research projects require large multidisciplinary teams, gathered from scientists distributed across the country.

To meet the challenges associated with these trends, NCRR supports the development of bioinformatics tools, including the software programs or algorithms that help scientists manage and analyze their data. NCRR also is instrumental in the creation of high-performance computer networks that link laboratories throughout the United States. A few years ago, NCRR joined with the National Science Foundation, Internet2, and investigators from several universities to establish the Biomedical Informatics Research Network (BIRN). The BIRN provides the tools for researchers to pool their data and to use federated databases so that they can oversee the integrity of their data, use bioinformatics tools for data mining, and visualize their data. In fiscal year 2004, NCRR began expanding the number of BIRN sites in order to establish a national infrastructure of bioinformatics tools and provide access to scaleable computing that, in turn, is linked to a nationally distributed network of modern imaging capabilities for studies of degenerative brain disorders.

Other components of the BIRN network will link underserved institutions, such as doctoral degree-granting minority institutions and institutions in states that have received limited NIH research funding because they include very few research trained investigators, otherwise known as Institutional Development Award (IDeA) states. The networks will foster collaborative research and help investigators create a virtual critical mass of investigators. The BIRN also will foster collaborations across institutions located at remote sites. NCRR plans to establish a network for institutions with medical schools that are associated with NCRR's Research Centers in Minority Institutions (RCMI) Program. This electronic network will facilitate their participation in large clinical trials and other research studies and help define the factors contributing to health disparities among minority populations and ways to overcome those factors.

In concert with other NIH components, NCRR participates in many NIH Roadmap initiatives for example, development of a National Electronic Clinical Trials and Research (NECTAR) network, which will form the backbone for all clinical research networks. An important component of NECTAR will be the standardization of patient data collection and storage procedures, which will facilitate data sharing

by investigators. NCRR also supports other trans NIH Roadmap initiatives, including the National Centers for Biomedical Computing, Exploratory Centers for Interdisciplinary Research, and National Technology Centers for Networks and Pathways.

PROTEOMICS

The availability of complete genomes for a variety of organisms provides an important first step in understanding many complicated biological questions, including the molecular basis for disease. The next step in this process will be to develop technologies to quantitate spatiotemporal differences in the levels of gene expression, assess post-translational modifications of proteins, and characterize protein-protein interactions in both healthy and diseased cells.

NCRR will support the development of the necessary technology and infrastructure to advance the science of proteomics. An advanced proteomics center will focus on multiple technologies, including techniques for protein purification, structural techniques, mass spectrometry, and DNA microarray instrumentation along with the necessary bioinformatics.

CONCLUSION

I have today noted two important trends in biomedical research the rapid accumulation of data and the broadening scope of research studies. To these, I must add a third trend namely, the increasingly collaborative nature of biomedical science. Some of today's most pressing questions in biomedical science are so complex, so multifaceted, that they cannot be addressed by a single investigator or even a single research laboratory. In many cases, teams of scientists with diverse skills and backgrounds are needed to get the job done.

It is my belief that this emphasis on interdisciplinary collaborations, as evidenced by the multiple NIH Roadmap initiatives related to this area, will bring about unprecedented gains in biomedical science, and ultimately lead to improved health of all U.S. citizens. Finally, as the research paradigm evolves toward greater complexity, the infrastructure required to support that research must evolve too.

I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. DUANE ALEXANDER

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2005 President's budget request for the National Institute of Child Health and Human Development (NICHD). The fiscal year 2005 budget includes $1,280.9 million, an increase of $39.1 million over the comparable fiscal year 2004 appropriation of $1,241.8 million.

The NIH Roadmap provides the schema to guide the NICHD in achieving its programmatic and research goals.

Today I would like to share with you how the research supported by this committee is improving the lives of children, mothers, adults and families, and helping to reduce health disparities. The NICHD is participating in the trans-NIH obesity initiative identifying how primary care physicians can help children maintain a healthy weight.

ENCOURAGING HEALTHY BIRTH OUTCOMES

Preeclampsia is a condition that affects five out of every hundred women who become pregnant. Preeclampsia can occur suddenly, and without warning, causing women to develop dangerously high blood pressure. In some cases, the condition may progress to eclampsia in which women experience potentially fatal seizures. Infants born to mothers with preeclampsia may be extremely small for their age or may be born prematurely, putting them at risk for a variety of other birth complications. Although a woman's high blood pressure and seizures can be treated, the only cure for preeclampsia is delivery of the baby. In a significant step toward treating preeclampsia, researchers have identified substances in the blood that have the potential to predict who will develop preeclampsia. This knowledge may help us treat women before preeclampsia becomes a serious problem, for them and their infant.

We have also intensified our research in the area of stillbirth, a devastating occurrence that affects far too many families. Health care providers use the term stillbirth to describe the loss of a fetus after the 20th week of pregnancy. Stillbirth can occur before delivery or as a result of complications during labor and delivery. In at least half of all cases, researchers can find no cause for the pregnancy loss. We hope to change that. The NICHD has established the Stillbirth Collaborative Net-

work, which consists of research centers in Texas, Utah, Rhode Island, and Georgia. In each center, a team of specialists, including obstetricians, nurses, statisticians, and even grief counselors will seek to understand the causes of stillbirth and eventually find ways to prevent these deaths.

One way to increase the chances of a healthy pregnancy and healthy birth outcome is to avoid alcohol during pregnancy. Infants born to mothers who drink heavily during pregnancy are known to be at risk for mental retardation and birth defects. They are also at increased risk for Sudden Infant Death Syndrome (SIDS). NICHD researchers have now identified another reason that women should not consume alcohol during pregnancy: exposure to alcohol before birth affects the developing nervous system in the arms and legs.

Recently, scientists in NICHD's Maternal-Fetal Medicine Units Network reported a breakthrough in reducing a major cause of infant mortality and the subsequent long term health problems associated with prematurity. The scientists, working collaboratively in 14 academic health centers across the United States, demonstrated that progesterone administered to women at risk for premature birth could significantly reduce the likelihood of early delivery. This was a very significant discovery and we were delighted that others recognized its importance. A few weeks ago, Parade magazine identified this discovery as one of the ten most significant health advances of the past year.

NEW FRAGILE X CENTERS TO DEVELOP TREATMENT OPTIONS

In 2003, the NICHD funded three new Fragile X research centers. Teams of researchers at each of the centers located in North Carolina, Texas, and Washington state are developing new ways to diagnose both the mild and severe forms of the condition, as well as new treatments. Fragile X syndrome is the most common genetically-inherited form of mental retardation currently known. It occurs in 1 out of every 2,000 males and in 1 in 4,000 females. The syndrome is caused by a mutation in a specific gene, known as FMR1, on the X chromosome. In its fully-mutated form, the FMR1 gene interferes with normal development, resulting in mental retardation. In a partially mutated form, the FMR1 gene can cause fragile X syndrome in the children of a parent who is a carrier. Until recently, it was thought that carriers did not have any symptoms. Researchers have learned that some people with a form of fragile X have mild cognitive and emotional problems. In addition, some female carriers are likely to undergo premature menopause. In older male carriers, the fragile X is associated with a neurological degenerative syndrome. Identifying a means to predict which carriers will develop the symptoms could be a first step toward developing new treatments for these often overlooked symptoms. The Fragile X Research Centers are focusing their research on how the fragile X affects the developing brain and nervous system, how the disorder progresses throughout an individual's life span, and treatments that can improve the behavior and mental functioning of people with fragile X syndrome.

IMPROVING TREATMENT FOR CRITICALLY ILL CHILDREN

Critical care medicine for children is an emerging field where, in general, physicians continue to rely upon adult treatments that have not yet been tested for effectiveness in a young population. To change this situation, the NICHD will help establish a national pediatric critical care research network to develop and evaluate treatments for children with disabling conditions. The initiative will foster collaborations among scientists in many different fields and will support research such as the best approach to care for children with brain injury, the most effective way to transition a critically ill child from an acute care to a rehabilitation setting, and the care of critically ill children in the event of a bioterrorism attack.

CUTTING OBESITY THROUGH RESEARCH AND PROGRAMS

The increase in overweight and obesity among adults and children is a major public health concern. In fact, in a recent analysis of international data, NICHD researchers documented that U.S. teenagers were more overweight than youth in 14 other developed countries. Like many other health conditions that affect adults, the antecedents of adult obesity can be found in childhood. Young children who are overweight are likely to be overweight as adults. There is no single explanation for the increase in childhood overweight and there is no single solution. However, we know we must devise successful interventions that help children maintain a healthy weight. As part of the trans-NIH initiative, the NICHD will lead a major effort to determine whether a weight control program for children and youth led by primary care physicians as part of a comprehensive community-based effort can be successful. Currently, most weight management programs are administered through spe-

cialty clinics. However, there is strong evidence that an appropriate intervention by a physician can have a significant impact on personal behaviors such as tobacco use. Effective weight management programs in a primary care setting would be accessible to large numbers of children and would minimize the geographic, social, and economic barriers that commercial weight management programs can impose.

We are also developing an exciting research-based program that helps to teach young children the fundamentals of good nutrition and physical activity as well as how to make sense of the messages that appear in the media. Three years ago, this committee provided funds to the NICHD and other health agencies to develop programs that encourage young people to engage in healthy behaviors. In response to this directive, the NICHD has developed "Media Smart Youth," an after school program for children between nine and 13 years of age. The program focuses on good nutrition and physical activity. But it also provides skills to young children to interpret the messages about food and snacks they see on television, in magazines, and on the Internet. As part of their activity, the children who take part in Media Smart Youth develop messages about the importance of good nutrition and physical activity for their peers. The program has been tested with youth groups around the country. In fact, the children at P.S. 127 in the Bronx who took part in this program developed a message about physical activity for young people that appeared for 30 minutes on the Panasonic "jumbotron" screen in Times Square.

HELPING YOUNG CHILDREN PREPARE FOR SCHOOL

The preschool years are crucial for learning language, social skills, and developing the intellectual capabilities that set the stage for later success in school. Yet, comparatively little is known about how to help young children obtain the greatest benefit possible from the preschool experience. In December 2003, NICHD joined with two other HHS agencies and the Department of Education, and launched a five year research initiative to find the best ways to help preschoolers at risk for failure in school acquire the skills they need for school success. The initiative provided $7.4 million in funding for the first year. Eight projects were funded to test research-based approaches to preschool curricula, Internet based approaches to training preschool teachers, and the importance of parental involvement for preparing children to enter school. Funds requested for fiscal year 2005 will allow us to expand this effort by funding academic researchers and small businesses to develop and produce more effective measurements of outcomes from preschool interventions.

SIDS RESEARCH SUPPORTS PROGRAM OUTREACH

We have known for more than 10 years that placing infants on their backs to sleep reduces their risk of Sudden Infant Death Syndrome (SIDS). In fact, since the NICHD launched the Back to Sleep SIDS risk reduction campaign in 1994, the rate of SIDS in the United States has declined by more than 50 percent. The NICHD continues a vigorous research program to learn more about the causes and prevention of SIDS. For instance, a team of NICHD-funded researchers in Ohio recently discovered that infants who were placed to sleep on their backs were less likely to develop fevers, get stuffy noses or develop ear infection. Ear infections alone cost the health care system an estimated $5 billion a year. So this simple behavior of placing infants on their backs to sleep not only saves lives, it can save the health care system large sums money by reducing the use of antibiotics to treat ear infections. We also learned that infants who are normally placed to sleep on their backs are at greatly increased risk of SIDS when they are occasionally placed to sleep on their stomachs. New research on SIDS continues to shape our SIDS risk reduction outreach campaign. More recently, a major focus of the campaign has been reducing the risks of SIDS in African American communities.

SIDS rates for African American babies have declined significantly since the NICHD initiated its Back to Sleep campaign ten years ago. Yet, the SIDS rate for African American infants is more than twice that of white infants. To address this health disparity, the NICHD joined forces with three national African American organizations in a unique collaboration to reduce the risks of SIDS in African American communities. The Alpha Kappa Alpha Sorority, the National Coalition of 100 Black Women, and the Women in the NAACP, sponsored three regional summit meetings to raise SIDS awareness and train community leaders to be resources and spokespersons for SIDS risk reduction in their communities. The summit meetings were held in Tuskegee Alabama, Detroit Michigan, and Los Angeles California, and they helped build an infrastructure to involve faith-based, community, and service organizations in reducing the risks of SIDS and in promoting the health of infants. In Detroit, for instance, the summit ended with a "SIDS Sunday," which was held at Hartford Memorial Baptist Church on the Sunday following that summit. After-

wards, other churches across the region held a "SIDS Sunday," where pastors shared SIDS information from their pulpits, in their church bulletins, and with nurses and care givers in their childcare centers and nurseries. The successful collaboration of researchers, government officials, and the community will create a strong foundation for launching other interventions to eliminate health disparities.

MOTHERS LEAVING WELFARE HAD NO EFFECT ON PRESCHOOLERS

A study that received much of its funding from the NICHD demonstrated that when a mother leaves welfare to enter the labor force, it does not seem to have any negative effects on preschoolers or young adolescents. The study was undertaken in response to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, which mandated stricter welfare requirements for all welfare recipients. The researchers theorize that the positive and negative effects of going off welfare and getting a job may cancel each other out. For example, the increase in family income that comes with leaving welfare thought to relieve the stress on a family may make up for the decreased amount of time that mothers spend with their young children. In addition, mother's transition to work had a slightly positive effect on teens, reducing the teens' levels of anxiety. Conversely, teens whose mothers left the job market and went on welfare developed increased anxiety levels.

MICROBICIDES THAT CAN PREVENT SEXUALLY TRANSMITTED INFECTIONS

The NICHD is funding a number of projects to develop microbicidal compounds to prevent the spread of sexually transmitted infections and HIV. These compounds not only have the potential to prevent the spread of disease-causing bacteria and viruses, but may also be effective in preventing pregnancy. One project is a large scale test of the contraceptive effectiveness of Buffergel, a compound that kills the microorganisms that cause sexually transmitted diseases, and shows promise as a contraceptive. Another project is studying a microbicidal spermicide, C31G. The compound's effectiveness will be compared to that of a conventional spermicide preparation. Working with the National Institute of Allergy and Infectious Diseases, the NICHD has funded a new system to test the quality of potential microbicides to determine if they warrant further testing in human beings.

SAFER DRUGS FOR USE WITH CHILDREN

In January 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The law recognizes that drugs may have different effects in children than they do in adults, and seeks testing for drugs given to children. For roughly 75 percent of the drugs approved by the U.S. Food and Drug Administration (FDA) for adults, there is inadequate information available to ensure the safety and effectiveness of the drugs in children. Moreover, there is little or no data to guide physicians in prescribing dosages of these drugs for children. Working in close collaboration, the NICHD and the FDA, as directed by the BPCA, identified several high priority drugs to be tested. The NICHD is currently establishing partnerships with pediatric drug study networks in other NIH Institutes to expedite the study of other clinically important drugs.

Drugs prescribed to pregnant women are also a concern. Although nearly two-thirds of all pregnant women take at least four to five drugs during pregnancy and labor, the effects of these drugs on a pregnant woman and her fetus remain largely unstudied. In addition, little is known about how pregnancy-related changes in cardiac output, blood volume, intestinal absorption, and kidney function may influence drug absorption, distribution, utilization, and elimination. Therefore, the NICHD will establish a new network of Obstetric-Fetal Pharmacology Research Units that will allow investigators to conduct key pharmacologic studies of drug disposition and effect during normal and abnormal pregnancies.

NATIONAL CHILDREN'S STUDY

In a few short years, The National Children's Study has evolved from a concept to an exciting research collaboration poised to answer critical questions about child development. The fiscal year 2005 budget request continues planning dollars for this important project, but does not reflect funding to launch the study itself, since it is still being developed. The National Children's Study plans to examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. The NICHD serves as the lead agency on this ambitious project, working closely with the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency. The

collaboration involves government agencies, the research community, industry, and community groups.

NIH ROADMAP AND CLINICAL RESEARCH

To ensure that the necessary clinical research workforce is available to translate laboratory findings to improved treatments for patients, the NIH Roadmap is strengthening several stages in the career path for these researchers. One new program will provide clinical research experience and didactic training during medical and dental school. Another will train doctorate-level professionals in multi disciplinary collaborative clinical research settings that reflect the diversity of today's clinical research team. To attract community practitioners to clinical research, the NIH plans to create a cadre of National Clinical Research Associates, community practitioners trained in clinical research who will refer patients to large clinical trials to enhance patient recruitment and more rapidly test potential therapies. The NIH is also identifying ways to improve peer review of clinical research grant applications and to enhance promotion and tenure policies in academia for clinical researchers.

PREPARED STATEMENT OF DR. ALLEN M. SPIEGEL

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for fiscal year 2005, a sum of $1,876,196,000, which includes $150 million for the Special Appropriation for Research on Type 1 Diabetes through Sec. 330B of the Public Health Service Act. The NIDDK transfers some of these funds to other institutes of the NIH and to the Centers for Disease Control and Prevention (CDC). Adjusted for mandatory funds, this is an increase of $54,956,000 over the fiscal year 2004 enacted level of $1,821,240,000 comparable for transfers proposed in the President's request.

HIGHLIGHTS OF PROGRAM ENHANCEMENTS

I appreciate the opportunity to testify on behalf of the NIDDK's efforts to combat the wide range of debilitating, chronic health problems within our research mission, many of which are caused directly or indirectly by obesity. Last year, I reported the creation of an NIDDK Office of Obesity Research to intensify the fight against this major public health problem, which is harmful both in its own right and as a driver of type 2 diabetes, especially in minorities and the young. Obesity can also be a contributing factor to nonalcoholic fatty liver disease, gallstones, end-stage kidney disease, and urinary incontinence. According to the CDC, approximately 64 percent of adults and 15 percent of children and teens are considered either overweight or obese. Disturbingly, these rates reflect skyrocketing trends over the past two decades. To accelerate research to combat this epidemic, the NIH Director established the NIH Obesity Research Task Force in April 2003, with co-chairmanship by the Directors of the NIDDK and the National Heart, Lung, and Blood Institute (NHLBI). I am pleased to report that the Task Force has completed a draft Strategic Plan for NIH Obesity Research, with input from external scientific and lay experts. This Plan is posted on a newly established Web site that will alert investigators to NIH obesity research funding opportunities, and also inform the public about NIH efforts. Both the Plan and the Web site are dynamic, and will evolve with changes in science and public health needs. Acting alone, the NIH cannot halt or reverse obesity; however, by generating and disseminating new research knowledge, we can lend a vital scientific dimension to what must truly be a multifaceted national effort.

The Strategic Plan will contribute to the prevention and treatment of obesity by bolstering research in three major avenues: (1) behavioral and environmental approaches to modify lifestyle; (2) pharmacologic, surgical, or other biological/medical approaches; and (3) ways to break the link between obesity and its associated health conditions, known as co-morbidities. Within the goals and strategies outlined in the Plan, the NIDDK will have a major role in three trans-NIH initiatives.

The first is an effort to combat pediatric obesity in site-specific ways—both in primary-care settings, and in other community settings, such as the home, day-care, pre-school, school, and other venues. Researchers will explore effective methods for the primary prevention of inappropriate weight gain among children and adolescents who are not overweight; secondary approaches to prevent further weight gain among those already overweight or obese; and tertiary efforts to prevent co-morbidities. We will build on studies the NIDDK is already pursuing to evaluate the effects of so-called "natural experiments" in which States or localities are chang-

ing the food and lifestyle choices and cues that students encounter in school settings. We will also build on studies to determine the effects of modifying the home environment, such as the influence of T.V.-watching on obesity, eating behavior, and physical activity. Our children are precious, and we should do all we can to spare them the serious health problems that can attend a lifelong struggle with obesity.

A second trans-NIH initiative will focus on the neurobiological basis of obesity, which includes the intricate brain-gut circuits that signal hunger and fullness, and thus are crucial to maintaining the body's energy balance between calories consumed as food and expended in physical activity. I previously reported on several hormones that mediate energy-related signals, such as leptin, adiponectin, and ghrelin. By exploiting these and other findings through innovative collaborations between biomedical and behavioral researchers, we will delineate the many pathways that modulate the control of eating behavior in humans.

In a third trans-NIH initiative, the NIDDK will take the leadership role in creation of an Intramural Obesity Clinical Research Program to capitalize on the unique, collaborative infrastructure of the NIH Clinical Research Center. This Program will foster multidisciplinary approaches to obesity research in areas such as metabolism, endocrinology, nutrition, cardiovascular biology, liver and other digestive diseases, genetics, and the behavioral sciences. A "magnet" approach will draw upon the extensive expertise and resources of the NIH intramural program to frame state-of-the-art clinical investigative strategies and harness emerging technologies.

In addition to these trans-NIH initiatives, the NIDDK will support a range of research, including ancillary studies to maximize the resources already invested in ongoing clinical trials. We will pursue challenging questions about obesity. What factors control where fat is deposited, and the relationship between its location and differences in metabolism, fat-cell regeneration, cell signaling, and associated comorbidities of obesity? What is the relationship between obesity and abnormal levels of circulating and stored lipids, which are a hallmark of metabolic problems? Can we identify biomarkers of change brought on by the obese state? What genetic abnormalities underlie the co-morbidities of obesity? What steps can people take to achieve long-term maintenance of weight loss?

As obesity is escalating in the United States, so is type 2 diabetes. New estimates from the CDC place the number of people with diabetes at 18.2 million, and about 90–95 percent of them have this form of the disease. Disturbingly, about 5.2 million of those affected are unaware. Millions of adults also have a condition called "prediabetes," in which glucose levels are elevated, but not as high as in full-blown diabetes. Because clinical trials have demonstrated that lifestyle and medical interventions can significantly delay or prevent disease onset in those at high risk, it is critical to identify these individuals and underscore the preventive actions they can take. The NIDDK is taking vigorous steps to foster the generation of new laboratory tests to improve diabetes detection, as well as to promote the development of more cost-effective strategies to pinpoint those at risk who can benefit most from early intervention. We are also supporting studies to translate important advances from clinical trials in diabetes prevention and care into medical practice. For example, for a low-income Latino population, we are supporting a clinical trial to compare current translation efforts for type 2 diabetes prevention with a method that incorporates culturally-sensitive strategies. We are also studying an interactive video conferencing system to enable communication between health professionals at a large medical center and diabetes patients in a rural state, with limited access to health care providers. Interventions that are successful in these trials could pave the way to widespread use by communities throughout the country.

Once considered an "adult-onset" disease, type 2 diabetes is being increasingly diagnosed in children and adolescents, especially in minority populations. We are launching a multi-center, school-based trial (STOPP-T2D) to find ways to prevent the development of risk factors for type 2 diabetes in middle-school children. The trial will include school-based programs targeting nutrition, physical activity, and behavior modification. Another multicenter trial (Treatment Options for Type 2 Diabetes in Adolescents and Youth TODAY) will seek the best treatment strategies.

Diabetes can lead to serious complications, such as blindness, irreversible kidney failure, lower limb amputation, and heart disease. We have established an NIDDK Diabetes Complications Working Group, which is charged with seamless integration of these activities across the Institute. The NIDDK also recently convened an international group of clinical and basic researchers to brainstorm research approaches to the urologic complications of diabetes. Because complications can affect many organs, we collaborate with other components of NIH and the Department to benefit from their expertise. For example, studies have shown that the process of new blood vessel formation, called "angiogenesis"—traditionally studied in relation to cancer—is also critically important to vascular changes in diabetes, such as the dangerous

proliferation of blood vessels in the eye that can lead to blindness. Angiogenesis will be the central theme of a new research collaboration involving multiple NIH institutes.

In an aggressive research program on type 1 diabetes, we have established unique, innovative, and collaborative research groups, clinical trial networks, and consortia, with an overarching group to standardize and coordinate their efforts. We are also working to overcome barriers that currently prevent widespread clinical research on islet transplantation to restore normal insulin-producing capacity to patients. In collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), we are establishing a national consortium to step up progress toward general clinical applicability of islet transplantation.

To spur research in digestive diseases, the NIDDK recently established a new Liver Disease Branch within its Division of Digestive Diseases and Nutrition. With expert external input, this Branch is now spearheading the development of a Liver Disease Research Action Plan under the auspices of the Digestive Diseases Interagency Coordinating Committee. As requested by the Congress, the NIDDK is submitting a report on actions taken by the NIH and other HHS components in response to recommendations from a Consensus Conference on hepatitis C. In other research, broad approaches are providing insights into the inflammatory bowel diseases—Crohn's disease and ulcerative colitis. Fundamental studies are shedding light on the development of pathways that control gut motility; integration of pain, motility and behavioral neural circuits; and gut inflammation.

For polycystic kidney disease (PKD), a research consortium has established the value of Magnetic Resonance Imaging for measuring kidney size. This advance portends dramatic improvements in assessing disease progression—a critical step in developing and evaluating new treatments. The HALT-PKD Network is testing a regimen designed to lower blood pressure and slow disease progression—the first of several clinical studies envisioned. A workshop on oxalosis and primary hyperoxaluria—an inherited cause of kidney stone disease—has identified future clinical research directions, which will apply emerging knowledge about underlying metabolic and genetic abnormalities. We have also launched or expanded initiatives on interstitial cystitis, urinary incontinence, and urinary tract infections, consistent with the scientific recommendations of the Strategic Plan of the Bladder Progress Review Group. A recently formed Interstitial Cystitis (IC) Epidemiology Task Force is guiding efforts in that area, as described in a requested report to the Congress.

TRANSLATION RESEARCH AND ROADMAP EFFORTS

Underpinning our disease-focused programs is an emphasis on "translation" research, which benefits patients directly by bringing the fruits of laboratory discoveries into the arena of clinical research, and by propelling the positive results of clinical trials into medical practice. In one promising pilot effort to speed the development of therapies for type 1 diabetes, we are building on an innovative mechanism established by the NCI called "Rapid Access to Intervention Development." We are also pursuing several translational efforts related to the NIH Roadmap for Biomedical Research. These include development of non-invasive methods for diagnosing and monitoring the progression of diabetes, kidney and digestive diseases; harnessing new technologies such as proteomics the study of proteins and their functions; as well as studying stem cells during human development and tissue repair. We are leading an NIH Roadmap initiative in "New Pathways to Discovery" by enhancing metabolomics—the study of networks within the cell, and constituents of the cell, such as carbohydrates, lipids, and amino acids. We are also playing a major role in Roadmap efforts to build "Research Teams of the Future" by spurring interdisciplinary research training. These efforts can benefit programs within the NIDDK mission by bridging scientific disciplines and catalyzing partnerships, such as collaborations between biomedical and behavioral researchers, which are so important to moving obesity research forward.

Today, I have presented a cameo of our many and diverse research efforts and plans. Our research momentum has never been greater, and our commitment to improving health remains clear and strong.

PREPARED STATEMENT OF DR. SHARON H. HRYNKOW

Mr. Chairman and Members of the Committee, I am pleased to present the President's Budget for the Fogarty International Center for fiscal year 2005, a sum of $67,182,000, which reflects an increase of $1,838,000 over the comparable fiscal year 2004 appropriation.

I welcome this opportunity to relate Fogarty's progress over the past year and proposed plans for fiscal year 2005. Programs at Fogarty, developed with the support and guidance of the Administration and this Committee, reflect our nation's enduring commitment to achieve "a healthy America, in a healthier world." These were the words of the late Congressman John E. Fogarty, Chairman of the House Appropriations Subcommittee from 1951 until 1967, and for whom the center is named. He championed research as the one truly global effort in which all nations can and will join as real partners.

The health challenges facing the United States are many. Among the communicable diseases, AIDS and tuberculosis continue to challenge even the most sophisticated public health interventions. SARS emerged in Asia and washed upon our shores, as did West Nile Virus several years ago. And the emergence of avian flu in Asia and the United States is a compelling tale that is a harbinger of probable Asian flu pandemics yet to come. All told, the infectious threats cost our economy dearly. And as chronic disease such as cancer, cardiovascular disease, and mental health disorders increase year after year in the United States and world-wide, both treatment and prevention efforts must be applied. These challenges are shared with communities around the world.

To address these challenges, Fogarty supports a broad range of research and training programs, each designed to tackle particular health problems shared by United States and foreign populations. Our particular focus is on improving the capacity of communities in poor settings to address health challenges. Accordingly, our emphasis has been on working with scientists and health professionals in low- and middle-income nations on shared health problems. Our programs identify research opportunities best addressed through international cooperation. Fogarty's efforts are multidisciplinary, embracing clinical, epidemiological, basic biomedical and social science research. They are multi-sectoral, closely coordinated with our sister institutes at NIH, the Centers for Disease Control and Prevention, and international organizations with health and development missions, including The World Bank and the World Health Organization. Moreover, the programs enhance foreign relations with governments and communities alike, and advance the historic humanitarian role of our nation. And importantly, our programs promote a global culture of science, founded on equal partnerships between scientists working across borders, in a culture of sharing of scientific information, peer review and sound management policies. Fogarty supports over twenty research and training programs in more than 100 countries, involving more than 5,000 scientists in the United States and abroad.

What follows is a selective summary of ongoing and planned Fogarty activities to support NIH international objectives and realize Congressman Fogarty's vision.

THE HIV/AIDS EMERGENCY

HIV/AIDS has exacted a profound human toll in the United States and abroad, reversed gains in child survival in many nations, and threatened the economic stability of emerging markets by reducing the number of working men and women. Reducing the impact of HIV/AIDS in resource-poor countries, which bear the disproportionate burden of this disease, requires a strong national commitment on their part and international research cooperation to develop effective prevention and control strategies. The Fogarty AIDS International Training and Research Program (AITRP), now in its 16th year of operation, has been a major source of support for training a cadre of foreign medical scientists from developing countries needed to combat the global HIV/AIDS pandemic. Working through U.S. universities, Fogarty has supported Masters level, Ph.D., and post-doctoral training for young scientists in countries most affected by the pandemic. These scientists are testing HIV/AIDS vaccines abroad, developing effective public health strategies to reduce transmission, and acquiring new knowledge for treatment for those already infected.

Through the Fogarty AIDS Program, nearly 2,000 foreign researchers from over 100 countries have been trained in the United States, many at senior levels, and over 50,000 have trained in cutting-edge laboratory methodologies through workshops and courses conducted in those countries where HIV/AIDS is most devastating. This large international cadre of trained scientists has facilitated the implementation of new programs such as the Pediatric AIDS Foundation Call-To-Action, the President's initiative on prevention of maternal-to-infant transmission of HIV, and the President's Emergency Plan for AIDS Relief (PEPFAR). In addition, health scientists trained under the program have played vital roles in helping approximately 20 countries receive awards from the Global Fund for AIDS, TB and Malaria. As we work in partnership with colleagues around the world, the benefits of the Fogarty AIDS program accrue also in the United States. Interventions and

strategies developed and tested abroad may have direct relevance to communities in the United States.

Among research accomplishments in the past fiscal year, scientists at the University of North Carolina and the University of Malawi have identified a new and effective means to minimize postpartum transmission of HIV through implementation of an inexpensive two-drug antiretroviral regimen. This is of significance because low-income women in sub-Saharan Africa typically do not obtain medical attention during pregnancy and are usually uninformed of their HIV status until delivery. Effectively deployed, this intervention will mean that more newborn infants will have a chance to grow to be healthy adults, even where the lack of resources and other obstacles to extending medical care limit prenatal care and interventions.

CHANGING MICROBIAL THREATS

HIV/AIDS is a cautionary example. The rapid emergence of new pathogens and re-emergence of infectious disease, believed to have been controlled or contained, presents a disturbing new chapter in the grim evolutionary battle between humans and microbes. This is the result of social and demographic trends, including increases in international travel and trading across borders, and changes in the genetic structure of microbes that increase virulence and transmission, and weaken the efficacy of existing drugs. Among major disease pathogens, malaria has resurged due to resistance of the parasite to available drugs and resistance of mosquitoes to insecticides. Malaria accounts for an estimated 2 million deaths per year with increasing mortality due to drug resistance and HIV-contaminated blood transfusions related to malaria-induced anemia.

Building on the success of the AIDS training program, Fogarty launched in 1996 the International Training and Research in Emerging Infectious Diseases, a training program which builds expertise in microbiology, epidemiology, and laboratory methods as part of a broad effort to combat new and emerging diseases worldwide. Today, that program has been expanded to include other infectious diseases as the Global Infectious Disease Research Training Program, linking U.S. universities with counterparts around the world to advance research projects (through 27 Fogarty awards) and, importantly, to build the next generation of scientists able to combat emerging infections, such as SARS and West Nile Virus. Through this program, Fogarty is helping to address the infectious disease challenges of today while preparing for new pathogens yet to emerge tomorrow, as surely they will.

A powerful new tool for malariologists and other infectious disease researchers concerns the use of sophisticated mathematics to predict the course of an epidemic. Such mathematics, sometimes termed models, can be used to chart the benefits of prevention and control measures. Most recently, mathematical models were used to project the course of the SARS epidemic in Asia, and to develop strategies to limit the spread of the disease. Several years ago, Fogarty established a unit at NIH concerned with the use of mathematical models for control and prevention of several diseases, including malaria. The elements of a malaria prevention program include reducing the population of mosquitoes, treatment of malaria patients, and use of personal protection such as bed nets to prevent mosquito bites. In addition, there is a major effort underway to develop a malaria vaccine. The Fogarty epidemiologists have used mathematical models to determine the best strategy to employ such a vaccine, when it becomes available, along with existing methods of malaria control and prevention. All this must be done within the various complex ecological settings in which malaria occurs. The use of such advanced mathematics in devising the most effective strategies in the study of infectious diseases will surely bring unexpected benefits to human kind. Importantly, through a network of in-house research experts and extramural scientists, Fogarty also employs mathematical models to assist biomedical research and public health policy-makers prepare for and respond to bioterrorism events. In coordination with DHHS, Fogarty has mobilized experts in epidemiology, terrorism-response and public health policy in the context of category A agents including plague, tularemia smallpox and anthrax.

THE EMERGING EPIDEMICS OF CHRONIC DISEASE

By the year 2020, chronic disease is expected to contribute 60 percent of the global disease burden. The toll in the United States is already enormous: for example, obesity has more than doubled from 15 percent during 1976–1980 to 31 percent in 1999–2000, and 65 percent of adults ages 20 to 74 were overweight to obese in 1999–2000. As populations age, and risk exposures shift due to environmental and dietary factors, non-communicable diseases are estimated to become a leading source of disability and premature death in developing nations as well. Tobacco-caused disease and death is a major concern in the United States and globally. In

the United States, while picking up the habit of smoking is on the decline in most groups, in young girls it is on the rise (The World Bank). In low- and middle-income nations, as wealth increases in urban settings, smoking commencement in youth, and particularly in girls, is rising at alarming rates (The World Bank). To address this challenge, Fogarty launched in 2002 its International Tobacco and Health Research and Capacity Building Program. While in its early stages, our expectation is that research will lead to new interventions that will benefit U.S. communities as well as those around the world.

There is a growing awareness of the burden on health inflicted by trauma and injury both in the United States and worldwide. The numbers are startling: more than 1.2 million people are killed in traffic accidents annually, and millions more are injured or disabled. Deaths from all types of injuries, including war and domestic violence, are projected to rise from 5.1 million in 1990 to 8.4 million in 2020, with road traffic injuries as a major cause for this increase, with millions more sustaining injury that results in life-long disability. In response to the growing epidemic of trauma, Fogarty is initiating a new research and training program. Among the features of the program will be training across the range of basic to applied sciences, the epidemiology of risk factors, acute care and survival, rehabilitation, and the long-term mental health consequences. Possible research areas will include development of low-cost synthetic blood products and diagnostic imaging tools, identification of behavioral intervention strategies, particularly in youth and other high-risk groups, and health services research to determine cost-effective measures for emergency care in low-income settings. The new knowledge from the program will benefit not only developing countries but, as low-cost and effective strategies are identified, communities in the United States.

PREPARING THE NEXT GENERATION OF U.S. GLOBAL HEALTH LEADERSHIP

While Fogarty works to build capacity and train young scientists in the developing world, critical steps have been taken to ensure that U.S. investigators at a formative stage in their careers also have opportunities to engage in international research projects. The Center will enhance and expand two programs to bring the next generation of U.S. scientists more fully into the global culture of science. The first of these, the International Research Scientist Development Award (IRSDA) program, provides post-doctoral training for four years, two of which must be spent conducting research in a developing country. Nearly 20 U.S. scientists are now being supported as IRSDA trainees. Addressing an earlier step in the career path, Fogarty has recently teamed with the Ellison Medical Foundation to create a second program, the new pre-doctoral clinical research training program for U.S. medical and public health students. Under this program, students will spend a year in a developing country conducting NIH-sponsored clinical research under the mentorship of an experienced foreign investigator and a collaborating research team. The first students to be selected will begin the program this summer.

ENHANCING OPPORTUNITIES FOR WOMEN IN SCIENCE

NIH's goal to bolster the nation's intellectual capital includes attracting more women to careers in science, both to build a new generation of talented scientists and to ensure that research issues germane to women's health are addressed. Fogarty has extended this important goal to international programs. At an October 2003 colloquium on career path issues facing women in the life sciences, including women in the developing world, Fogarty and its co-sponsors, the NIH Office of Research on Women's Health and the National Institute of Environmental Health Sciences, invited perspectives on opportunities in advancing career issues for women in the life sciences from a community of scientists, administrators and science funding agencies. To follow up on the recommendations, Fogarty and its partners have agreed to: collect data on developing country women in science and their career paths; support workshops to develop skill sets for women scientists in the developing world that will better enable them to take on leadership roles within health research and/or policy settings; and develop and implement strategies to effectively use the Internet and other information technologies to support networking and mentorship.

ADVANCING THE NIH ROADMAP: GLOBAL POSITIONING

Fogarty supports programs linked to each of the three main Roadmap themes—New Pathways to Discovery, Research Teams of the Future, and Re-Engineering the Clinical Research Enterprise. In particular, to improve the clinical research enterprise, Fogarty supports two new programs aimed at training developing country professionals in clinical, operational and health services research. These programs rep-

resent a new approach to enhance clinical research, and pave the way for new partners, namely those in low- and middle-income nations, to work more closely on mental health, and on AIDS and TB with U.S. counterparts. In support of Roadmap themes of new approaches and new pathways to discovery, Fogarty is also supporting studies to identify the impact of environmental degradation on economic development and human health. These programs link social scientists, including mathematicians and economists, with clinicians and medical researchers to provide new insights and strategies to tackle urgent global health challenges.

CONCLUSION

Mr. Chairman, global challenges require a global response. Collective action is not only an economically rational approach to global health research challenges, but a scientific and humanitarian imperative. With the continued support of this Committee, Fogarty will accelerate both research discoveries and applications through international cooperative action to the benefit of the United States and to global communities. "A healthy America in a healthier world" has never been as important as it is today. Thank you.

PREPARED STATEMENT OF DR. RODERIC I. PETTIGREW

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The fiscal year 2005 budget includes $297,647,000, an increase of $8,817,000 over the fiscal year 2004 enacted level of $288,830,000 over the comparable fiscal year 2004 appropriation.

The NIBIB's mission is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and health care. Our vision is to profoundly change healthcare by pushing the frontiers of technology to make the possible a reality.

PROGRESS TOWARDS SUCCESS

Established by law in December 2000, the NIBIB has already demonstrated an impressive track record as a conscientious steward of public funds and has achieved significant milestones. In fiscal year 2003 the NIBIB funded approximately 750 awards, including 300 new awards that received outstanding scores in a highly competitive peer review system. Consistent with our mission, approximately one-third of our new awards were for innovative, high-impact, though high-risk, exploratory studies. These studies addressed the feasibility of a novel avenue of investigation and/or breakthroughs in biomedical imaging and bioengineering within a specific area. The Institute has also been effective at reaching segments of the scientific community that traditionally have not been supported by the NIH, especially those from the engineering and quantitative sciences. Between the first and second years of our grant-making authority, proposals to the NIBIB from first-time NIH applicants increased significantly. In fiscal year 2003, approximately 50 percent of respondents to requests for targeted applications identified themselves as first-time NIH applicants.

The Institute has built a solid research infrastructure through the issuance of numerous basic and applied research solicitations in promising areas of scientific investigation. Responses to the Institute's targeted initiatives far exceeded even the most optimistic estimates based on prior NIH experience. Coupling this to the successful outreach to new applicants and to the science community, it is clear that NIBIB is filling an important need with regard to catalyzing interdisciplinary science and supporting engineering research aimed at translating scientific discoveries to practical applications.

The NIBIB continues to foster successful linkages and collaborations with other NIH Institutes and Centers, Federal agencies, academic institutions, and private industry. We regard input from industry as critical for helping to identify research needs that will result in significant healthcare improvements as well as for translating technologies and research results to patient applications. As a first step in establishing collaboration with the biomedical industry, the NIBIB sponsored a workshop on "Biomedical Industry Research and Training Opportunities" in December 2003. Recommendations from this meeting will be considered in the planning and development of future NIBIB programs.

ADVANCING TOMORROW'S TECHNOLOGIES TODAY

Biomedical imaging and bioengineering are interdisciplinary fields requiring collaborations not only among imagers and engineers, but also with biologists, chemists, mathematicians, computer scientists, and clinicians of all specialties. Today, the imaging and engineering sciences are essential for improved understanding of biological systems, detecting and treating disease, and improving human health. Recent advances in these fields have enabled the diagnosis and treatment of various diseases using increasingly less invasive procedures. Benefits associated with minimally invasive imaging applications include quicker and more accurate diagnoses leading to improved patient outcomes at reduced costs. Minimally invasive image-guided interventions now serve as powerful tools in the operating room and can be applied to surgical procedures in urology, oncology, neurosurgery, ophthalmology, orthopedics, and cardiology.

The quest for faster and more effective minimally invasive surgical interventions has resulted in the introduction of computer-assisted robotic technology, whereby the surgeon works with small tools through small incisions. However, current instrumentation prohibits the surgeon from actually feeling the forces exerted when manipulating tissue. This lack of sensory control can be particularly detrimental in surgery, where the forces applied to sutures are critical in creating knots that are strong enough to hold, but do not damage the tissue. To overcome this problem, NIBIB investigators are developing instruments with three-dimensional sensors designed to give the surgeon a feeling comparable to that of performing the task manually. This research has additional applications as well, including expert-assisted surgery in remote locations.

Magnetic resonance imaging (MRI) has been used successfully for over 15 years to generate soft tissue images of the human body. However, a number of diagnostic MRI applications require further improvements in both imaging speed and spatial resolution. For example, accurate abdominal imaging generally requires a complete image obtained during a single "breath-hold" period, which can take up to 30 seconds. Many patients, especially those with respiratory illnesses, cannot tolerate long breatholds. The NIBIB supports an active research program on optimizing MRI speed and spatial resolution. One new approach under study, called parallel imaging, collects MRI signals from a number of independent coil shaped antennas. The appropriate combination of these signals can provide an order of magnitude improvement in imaging speed or resolution. Enhancements such as this hold promise for greatly enhancing the non-invasive diagnosis and treatment of abdominal and neurological diseases.

Functional magnetic resonance imaging (fMRI) is a relatively new technique that builds on the basic properties of MRI to measure quick and tiny blood flow related metabolic changes that take place in the active brain. Thus, fMRI studies are capable of providing not only an anatomical view of the brain, but a minute-to-minute recording of actual brain activity. This technology is now being used by NIBIB researchers to precisely map functional areas of the normal, diseased, and injured brain and to assess risks associated with surgery or other invasive treatments. Functional MRI can help physicians determine exactly which parts of the brain are responsible for specific crucial functions such as thought, speech, movement, and sensation. This information allows physicians to better plan surgeries and radiation therapies and to guide interventional strategies for a variety of brain disorders.

Molecular imaging provides a way to monitor cellular activities in normal and diseased states. The development of novel imaging technologies, combined with new or enhanced probes that bind to and "highlight" defined cellular targets, will allow this technique to be more broadly applied to biomolecules that are known indicators of a diseased state. For example, NIBIB researchers have developed nanometer sized fluorescent crystals, called quantum dots, that glow and can act as markers for specific cells when bound to certain targeting agents such as cancer cell antibodies. These agents can more precisely pinpoint the location of the sentinel lymph node in breast cancer patients. The sentinel node (SN) is the first node in the body to come into contact with cancer cells as they leave the breast and begin to spread to the rest of the body. Testing for metastatic cancer cells in the SN allows for accurate staging using information from a single lymph node, rather than 10 to 15 axillary nodes, and allows patients to avoid many of the complications and side effects associated with a traditional axillary lymph node dissection.

Advances in bioinformatics have been identified as having great potential for positively impacting medical science and health care. NIBIB researchers are developing and evaluating several innovative technologies designed to help solve the information management problems faced by today's doctors. Concepts enveloped in this system include a medical record architecture designed for portability; a mechanism for

linking laboratory findings with medical problems; and a real-time, context-sensitive visualization of the medical record. Taken together, these concepts form a comprehensive system for facilitating evidence-based medicine in a real-world setting.

NEW BIOMATERIALS FOR TISSUE ENGINEERING

Tissue engineering holds the promise to repair and/or replace damaged organs using biologic materials. For success in this area, a number of scientific and bioengineering challenges must first be met. For example, we must learn to produce, manipulate, and deliver collections of cells not only as building blocks for tissues and organ systems, but as models for studying drug development. Toward this goal, NIBIB researchers have successfully transformed adult rat engineered tissue cells into cells that form cartilage and bone. The two cell types were integrated into separate layers, encapsulated in a gel-like biocompatible material, and shaped into the ball structure of a human jaw joint. Although more work is needed before this tissue-engineered joint can be used in humans, it holds great potential for treating patients with temporomandibular disorders, osteoarthritis, and rheumatoid arthritis. These procedures could also be further refined and adapted for developing artificial knee and hip joints.

Coronary stents are small devices that serve as a scaffold to prop open the inside of an artery and provide vessel support. They are commonly made of stainless steel or nylon mesh and therefore remain as a permanent implant in a blood vessel. Although stents have revolutionized the treatment of coronary artery disease, limitations include an inflammatory reaction and the development of stent closure due to blood clots forming within the device, a process termed restenosis. To address this problem, NIBIB researchers have recently developed a mechanically strong, hemocompatible, and X-ray visible polymer as a noninflammatory fully-degradable coronary stent. While designed as a stent, work continues to refine the device to serve additionally as a drug-delivery vehicle. This may also have application as a drug-delivery mechanism for other diseases, such as cancer.

SENSORS FOR MEDICINE

Biosensors are nanoscale or microscale devices that detect, monitor, and transmit information about a physiological change, or indicate the presence of various chemicals, gases, or biological materials. Laboratory diagnostics used in hematology, clinical chemistry, pathology, and microbiology already employ sensor technologies to perform simultaneous measurements for many substances in urine, blood, saliva, sweat, and interstitial fluids. The Institute has an active research program in sensor technologies and continues to expand this important area. For example, NIBIB researchers are engineering recombinant antibody fragments (recAbs) that will increase the sensitivity and specificity of a type of biosensor called a piezoimmunosensor. Piezoimmunosensors have been proposed for almost 20 years; however, there has been no procedure for providing a sensing layer that is uniform, chemically stable during the measurement process, and contains high numbers of binding sites. By creating tightly packed monolayers of recAbs that will bind to the surface of the sensing unit, researchers are solving this problem while also preventing non-specific interactions with molecules, and thus improving specificity.

Other researchers are focusing on the design and fabrication of miniaturized implantable responsive drug delivery devices that integrate a smart drug delivery system with a biosensor. These drug delivery systems are aimed at providing individualized therapies that monitor the patient's body chemistry and control drug flow as needed.

NIH ROADMAP

To transform the Nation's medical research capabilities and to speed the movement of research discoveries from the bench to the bedside and into medical practice, the NIH has laid out a series of far-reaching initiatives known collectively as the NIH Roadmap for Medical Research. The NIH Roadmap focuses on the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

The NIBIB mission also strongly supports the NIH Roadmap initiative, since the Roadmap goal is to facilitate the development of innovative, novel and multidisciplinary science and technology that has the potential to further advances in health care. For example, the NIBIB is participating in an initiative that will facilitate the formation of collaborative research teams capable of generating novel probes for molecular and cellular imaging. The overall goal is to establish programs to create complete tool sets for the detection of single molecule events in living cells and to gen-

erate new strategies for dramatically increasing the imaging resolution of dynamic cellular processes.

Other areas of immediate interest to and supported by the NIBIB include the development of nanomedicine technologies, new tools for the study of proteomics and metabolic pathways, data and techniques for computational biology, and advances in bioinformatics. The NIBIB also strongly supports the NIH Roadmap theme on research teams of the future through sponsoring multidisciplinary research and interdisciplinary training.

MULTIDISCIPLINARY RESEARCH TEAMS

The value of collaboration among disciplines and organizations has long been recognized as important for developing novel approaches to problems in biology and medicine, and for effectively translating research results to patient applications. We are pleased to report that there have already been some successful "NIBIB partnerships" between biomedical engineers and imaging scientists that have had significant impacts on healthcare. For example, an ongoing Bioengineering Research Partnership team is using fMRI to integrate information on the suspected location of brain seizures with information about surrounding brain function in order to improve surgical outcome and reduce or eliminate seizures. In one early phase study, surgery employing fMRI strategies was used to almost eliminate seizures in a patient who had been suffering from as many as 100 seizures daily.

In conclusion, the NIBIB is dedicated to promoting the development of emerging technologies and interdisciplinary collaborations that drive healthcare advances. I would be pleased to respond to any questions that the Committee may have.

PREPARED STATEMENT OF DR. JACK WHITESCARVER

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the AIDS research programs of the NIH for fiscal year 2005, a sum of $2,930,397,000 an increase of 5,000 above the comparable fiscal year 2004 appropriation.

The NIH represents the largest and most significant public investment in AIDS research in the world a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies. Perhaps no other disease so thoroughly transcends every area of clinical medicine and scientific investigation, crossing the boundaries of the NIH institutes. The Office of AIDS Research (OAR) plays a unique role at the NIH. OAR coordinates the scientific, budgetary, and policy elements of the NIH AIDS program, supported by nearly every Institute and Center; prepares an annual comprehensive trans-NIH plan and budget for all NIH-sponsored AIDS research; facilitates NIH involvement in international AIDS research activities; and identifies and facilitates scientific programs for multi-institute participation in priority areas of research.

WORLDWIDE PANDEMIC

AIDS is the deadliest epidemic of our time. More than 22 million people have already died of AIDS—3 million of them in 2003 alone—the largest number ever. HIV has already infected more than 60 million people around the world, and AIDS has surpassed tuberculosis and malaria as the leading infectious cause of death worldwide.[1]

The United Nations General Assembly's Declaration of Commitment on HIV/AIDS states ". . . the global HIV/AIDS epidemic, through its devastating scale and impact, constitutes a global emergency and one of the most formidable challenges to human life and dignity, as well as to the effective enjoyment of human rights, which undermines social and economic development throughout the world and affects all levels of society national, community, family, and individual."[2] According to a U.N. report, "The epidemic has not only killed people; it has imposed a heavy burden on families, communities and economies. The misery and devastation already caused by HIV/AIDS is enormous, but it is likely that the future impact will be even greater . . . The HIV/AIDS epidemic has erased decades of progress in combating mortality and has seriously compromised the living conditions of current and future generations. The disease has such a staggering impact because it weakens and kills many people in their young adulthood, the most productive years for income genera-

[1] "Report on the Global HIV/AIDS Epidemic: July 2002," (UNAIDS/WHO, Geneva, Switzerland, 2002).

[2] "The Impact of AIDS" (Department of Economic and Social Affairs, United Nations, 2003).

tion and family caregiving. It destroys families, eliminating a whole generation crucial for the survival of the younger and older persons in society." The report also highlights "the long-term damage accruing to human capital, as children's education, nutrition and health suffer directly and indirectly as a consequence of HIV/AIDS. The effects of lowered investment in the human capital of the younger generation will affect economic performance for decades to come, well beyond the timeframe of most economic analysis."[3] Another dimension to the epidemic in Africa was cited in the New York Times: "As a result of HIV, the worst-hit African countries have undergone a social breakdown that is now reaching a new level: African societies' capacity to resist famine is fast eroding. Hunger and disease have begun reinforcing each other."[4]

A recent CIA report estimated that by 2010, five countries of strategic importance to the United States—Nigeria, Ethiopia, Russia, India, and China—collectively will have the largest number of HIV/AIDS cases on earth.[5] Foreign Affairs magazine stated: "The spread of HIV/AIDS through Eurasia, in short, will assuredly qualify as a humanitarian tragedy—but it will be much more than that. The pandemic there stands to affect, and alter, the economic potential—and by extension, the military power—of the region's major states . . . Over the decades ahead, in other words, HIV/AIDS is set to be a factor in the very balance of power within Eurasia—and thus in the relationship between Eurasian states and the rest of the world."[6] Dramatic increases in HIV infection also are occurring in Eastern Europe, Central Asia, Latin America, and the Caribbean.

THE U.S. EPIDEMIC

According to CDC, the decline in death rates observed in the late 1990s, due largely to expanded use of new antiretroviral therapies (ART) that prevent progression of HIV infection to AIDS, has now leveled off; and AIDS incidence increased 2 percent in 2002 (over 2001). This means that the overall epidemic is continuing to expand.[7][8][9] In addition, use of ART has now been associated with a series of side effects and long-term complications that may have a negative impact on mortality rates. HIV infection rates are continuing to climb among women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age.[10] The appearance of multi-drug resistant strains of HIV presents an additional serious public health concern.[11][12][13][14][15] According to CDC reports, approximately one quarter of the HIV-infected population in the United States also is infected with hepatitis C virus (HCV). HIV/HCV co-infection is found in 50 to 90 percent of injecting drug users (IDUs). HCV progresses more rapidly to liver damage in HIV-infected persons and may also impact the course and management of HIV infection, as HIV may change the natural history and treatment of HCV.[16] This expanding and evolving U.S. epidemic presents new and complex scientific challenges.

COMPREHENSIVE AIDS RESEARCH PLAN AND BUDGET

To address these compelling scientific questions, the OAR develops an annual comprehensive trans-NIH AIDS research plan and budget, based on the scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV infection and AIDS. The planning process is inclusive and collaborative, involving the NIH Institutes, as well as eminent non-government experts from aca-

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[3] Ibid.
[4] A. de Waal, "What AIDS Means in a Famine," New York Times, 11/19/02.
[5] "Intelligence Community Assessment: The Next Wave of HIV/AIDS: Nigeria, Ethiopia, Russia, India, and China." (CIA, 2002).
[6] "The Future of AIDS," Foreign Affairs, November/December 2002.
[7] CDC Year-End HIV/AIDS Surveillance Report for 2002 (CDC, 2003).
[8] "Centers for Disease Control and Prevention HIV Prevention Strategic Plan Through 2005," (CDC, 2001).
[9] "HIV/AIDS Update—A Glance at the HIV Epidemic," (CDC, 2001).
[10] "U.S. HIV and AIDS Cases Reported Through June 2000," CDC HIV/AIDS Surveillance Report, Vol. 12 (2002).
[11] N. Loder, Nature 407, 120 (2000).
[12] H. Salomon et al., AIDS 14, 17 (2000).
[13] Y.K. Chow et al., Nature 361, 650 (1993).
[14] M. Waldholz, "Drug Resistant HIV Becomes More Widespread," Wall Street Journal, 2/5/99.
[15] "World Health Report on Infectious Diseases: Overcoming Antimicrobial Resistance," (WHO, Geneva, 2000).
[16] "Frequently Asked Questions and Answers About Coinfection with HIV and Hepatitis C Virus" (CDC, 2002).

demia, industry, foundations, and AIDS community representatives. The Plan serves as the framework for developing the annual AIDS research budget for each Institute and Center, for determining the use of AIDS-designated dollars, and for tracking and monitoring those expenditures. The planning process also serves to monitor and assess scientific progress on an annual basis.

The Plan establishes the NIH AIDS scientific agenda in the areas of: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. In addition, the plan addresses the cross-cutting areas of: Microbicides; Racial and Ethnic Minorities; Women and Girls; Prevention Science; International Research; Training, Infrastructure, and Capacity Building; and Information Dissemination. In consultation with the Director of NIH, the OAR determines the total annual AIDS research budget. Within that total, the OAR establishes the AIDS research budgets for each NIH Institute and Center, in accordance with the priorities and objectives of the Plan, at each step of the budget development process up to the Conference Committee. To accomplish this, OAR consults regularly with the Institute and Center Directors. This process allows the OAR to ensure that NIH AIDS research funds will be provided to the most compelling scientific opportunities, rather than a distribution based solely on a formula.

OAR plays a crucial role in identifying scientific areas that require focused attention and facilitating multi-Institute activities to address those needs. OAR fosters this research through a number of mechanisms, such as designating funds and supplements to jump-start or pilot program areas, sponsoring workshops or conferences to highlight a particular research topic, and sponsoring reviews or evaluations of research program areas to identify research needs.

The overarching priorities that continue to frame the NIH AIDS research agenda are: prevention research to reduce HIV transmission, including development of vaccines, microbicides, and behavioral interventions; therapeutics research to develop simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated illnesses, malignancies, and other complications; international research, particularly to address the critical needs in developing countries; and research targeting the disproportionate impact of AIDS on minority populations in the United States. All of these efforts require a strong foundation of basic science, the bedrock of our research endeavor.

VACCINES AND PREVENTION RESEARCH

Vaccine research remains a critical priority. As a result of increased NIH funding, many new approaches to HIV vaccines are being pursued. Although production of candidate vaccines for clinical study has proceeded slowly, approximately 14 new candidate vaccines will enter Phase I trials in the next 2 years. Several new combinations of products, which are expected to provide better immune responses, also will be tested in Phase I or II trials. The Dale and Betty Bumpers Vaccine Research Center, located on the NIH campus, recently launched the first Phase I clinical trial of a multi-clade, multi-gene vaccine candidate. The development of vaccine candidates also requires sufficient quantities of non-human primates for preclinical testing.

In addition to vaccines, our biomedical prevention research priorities include the development topical microbicides; strategies to prevent mother-to-child transmission, including a better understanding of risk associated with breast-feeding; and management of sexually transmitted diseases (STDs). NIH also supports behavioral research strategies, including interventions related to drug and alcohol use. Efforts continue to identify the most appropriate intervention strategies for different populations and sub-epidemics in the United States and around the world.

NEW CHALLENGES IN THERAPEUTICS RESEARCH

While multiple ART drug combinations continue to successfully reduce viral load and restore immune responses in many HIV-infected individuals, these regimens also can result in serious toxicities and side effects, single- and multiple drug-resistance, and other complications that make them unacceptable for some individuals. These side effects and complications appear to be increasing as HIV-infected individuals continue on drug regimens. More deaths occurring from liver failure, kidney disease, and cardiovascular complications are being observed in this patient population. NIH-sponsored research efforts continue to develop better antiretroviral drugs and treatment regimens that demonstrate less toxicity, activity in viral and cellular reservoirs, reduced development of drug resistant virus, improved pharmacodynamics and pharmacokinetics, easier compliance, and lower cost.

While the incidence of certain opportunistic infections (OIs) and malignancies has decreased with the advent of ART, the number of cases of TB, multiple drug resist-

ant TB, and other coinfections such as Hepatitis B virus and Hepatitis C virus has increased. The development of practical and affordable treatment regimens against HIV coinfections and endemic diseases in developed and developing nations is an NIH priority.

INTERNATIONAL RESEARCH

NIH bears a unique responsibility to address the urgency of the global AIDS epidemic. To meet that need, the OAR established an initiative and strategic plan for global research on HIV/AIDS and has significantly increased research efforts in the past several years to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted, as well as people affected by HIV/AIDS worldwide. Critical to the success of these international studies are foreign scientists who are full and equal partners in the design and conduct of collaborative studies. To that end, NIH also supports international training programs and initiatives that help build infrastructure and laboratory capacity in developing countries where the research is conducted.

WOMEN AND MINORITIES

Women experience HIV/AIDS differently from men. NIH research has demonstrated that women progress to AIDS at lower viral load levels and higher CD4 counts than men. Women also experience different clinical manifestations and complications of HIV disease. These findings may have implications for care and treatment of HIV-infected women, particularly with ART. There are many research questions that remain unanswered about specific characteristics of women and girls that might play a role in transmission, acquisition, or resistance to HIV infection during different stages of the life course.

In many U.S. urban centers, HIV seroprevalence rates mimic those found in some developing nations. These findings, along with the resurgence of STDs and associated high-risk behaviors, demonstrate the need for comprehensive strategies to decrease HIV transmission in affected vulnerable populations, and improve treatment options and treatment outcomes. OAR is directing increased resources toward research to develop new interventions that will have significant impact on these groups. These include interventions that address the 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 will continue to ensure the participation of minorities in AIDS clinical trials, as well as in natural history, epidemiologic, and prevention studies.

SUMMARY

The human and economic toll of the AIDS pandemic is profound, demanding a unique response that is complex, comprehensive, multi-disciplinary, and global. The NIH role in this response is fundamental and unprecedented. The nation's investment in AIDS research is reaping even greater dividends, as AIDS-related research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases. The authorities of the OAR allow NIH to pursue a united research front against the global AIDS epidemic. We are deeply grateful for the continued support the Administration and this Committee have provided to our efforts.

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman, I am pleased to present the President's budget request for the National Human Genome Research Institute for fiscal year 2005, a sum of $492,670,000, which reflects an increase of $13,842,000 over the fiscal year 2004 Final Conference appropriation.

Following the completion of the Human Genome Project last year, the National Human Genome Research Institute (NHGRI) of the National Institutes of Health announced an ambitious plan for applying genomics to human health benefits. *A Vision for the Future of Genomics Research*, the outcome of almost two years of intense discussions with over 600 scientists and members of the public, has three major areas of focus: Genomics to Biology, Genomics to Health, and Genomics to Society. Several ambitious projects are already underway to help achieve this vision includ-

ing the International Haplotype (HapMap) Project, the Encyclopedia of DNA Elements (ENCODE), the NIH Roadmap initiative on Molecular Libraries, and a new Ethical, Legal and Social Implications (ELSI) Center initiative. As we enter the genomic era, the continued support of biomedical research in this area is more vital than ever.

ONGOING NHGRI INITIATIVES

International HapMap Project

To study genetic variation more effectively across the human genome, the NHGRI and a team of partners has launched the International HapMap Project. The goal of the project is to determine the common patterns of DNA sequence variation in the human genome, and to make this information freely available in the public domain. This international consortium is developing a map of these patterns across the genome by determining the genotypes of one million or more sequence variants in DNA samples from populations with ancestry from Africa, Asia, and Europe. When complete, the HapMap will enable the discovery of sequence variants that affect common disease, the development of diagnostic tools, and the ability to choose targets for therapeutic intervention. Detailed information about the HapMap project was published in a landmark article in *Nature*, and updated details can be found on the web at www.hapmap.org.

Comparative Genomics to Understand the Human Genome

One of the most powerful approaches for unlocking the secrets of the human genome is comparative genomics. While the completed sequence of the human genome represents a milestone of historic proportions, a daunting challenge that still lies ahead is to interpret its biological meaning and function. Recently sequenced genomes of the mouse, rat, and a wide variety of other organisms—from yeast to chimpanzees—prove that the genomes of other species are amongst the most powerful tools in advancing understanding of the human genome. The current NHGRI-supported, large-scale sequencing centers have built a prodigious capacity for, and expertise in, sequencing entire genomes. The combined capacity of these centers is expected to yield the equivalent of about 20 additional draft vertebrate genomes in just the next three years. These additional species sequences will provide exciting new insights into the function of the human genome, and will assist genome scientists in translating the basic findings of the Human Genome Project into tangible applications, including the diagnosis, prevention, and treatment of disease.

ENCODE—ENCyclopedia Of DNA Elements

To understand the meaning of the human instruction book, the genome, the identities and precise locations of all functional elements must be determined. Thus, the NHGRI has launched the ENCyclopedia Of DNA Elements (ENCODE) project to identify these elements comprehensively. The ENCODE project seeks to characterize the tools needed for exploring genomic sequence, improve those tools when necessary, and define a clear path for the determination of all of the functional elements in the entire human genome. On October 9, 2003, the NHGRI announced the first ENCODE grants in a three-year, $36 million project (www.genome.gov). ENCODE begins as a pilot effort to evaluate methods for the exhaustive identification and verification of functional sequence elements in a carefully selected 30 million base pairs, or about one percent, of human genomic DNA. This will require access to information, resources, ideas, expertise, and technology beyond the capabilities of any single group. Therefore, a consortium of investigators with diverse backgrounds and expertise will work cooperatively to carry out this project to: (1) evaluate rigorously the relative merits of a varied set of computational and experimental techniques, technologies, and strategies for identifying the functional elements in human genomic sequence, and (2) test the capabilities of such methods to scale up efficiently to allow, ultimately, analysis of all the functional elements encoded in the entire human genome sequence.

Centers Of Excellence In Genomic Science (CEGS)

The NHGRI Centers Of Excellence In Genomic Science (CEGS) program has been in place for four years. This program is a centerpiece of the Institute's effort to stimulate new interdisciplinary approaches to genomic research and technology development. A total of about 10 CEGS grants are ultimately expected to be funded. These will generally be five-year awards of up to $3 million per year. Seven awards have been made to date; each involves multiple investigators and disciplines, and several cut across departments and institutions. A grantee meeting in October 2003 stimulated new collaborations and identified ways to share CEGS grant data and resources with the larger research community.

Clinical Research Activities in the NHGRI Intramural Program

Research efforts of NHGRI Division of Intramural Research (DIR) investigators are aimed at deciphering the genetic contributions to common disorders, to provide a better understanding of diseases such as cancer, diabetes, and heart disease, as well as to a number of less common but equally debilitating afflictions. DIR investigators have been at the forefront of scientific innovation, developing a variety of research approaches that accelerate the understanding of the molecular basis of disease. These include the development of DNA microarray technologies for large-scale molecular analyses, innovative computer software to study fundamental biological problems, animal models critical to the study of human inherited disorders, and the clinical testing of new therapeutic approaches for genetic disease. Three examples of gene discoveries within the past year include the gene responsible for Hutchinson-Gilford progeria syndrome, the disease causative gene for Charcot-Marie-Tooth disease type 2D, and a gene variant that contributes to the risk of type 2 diabetes. These and other advances should ultimately lead to improved diagnostic, prevention, and treatment strategies having a direct impact on human health.

NEW INITIATIVES

The NHGRI is very enthusiastic about the initiatives included in the NIH Roadmap and is deeply involved in implementation plans for several of the projects embodied in the "New Pathways to Discovery" theme.

Molecular Libraries

As part of its *Vision for the Future of Genomics Research*, and in partnership with many other NIH Institutes as part of NIH's new Roadmap for Medical Research, the NHGRI is taking a lead role in providing access to high throughput screens for small organic molecules to public sector researchers. These small molecules can be used as chemical probes to study cellular pathways in great depth and will broadly enable public and private biomedical research into basic biology and accelerate the validation of new therapeutic targets, and thus the discovery of new drugs. For this effort to provide maximal benefits, the library of small molecules must contain a sufficient number of compounds. To build such a library, a network of six national centers will establish a common collection of 500,000 or more chemically diverse small molecules, of both known and unknown activities. Investigators who develop assays suitable for high throughput screening will apply for access to these centers. After peer review, suitable assays will be run through a screen of 500,000 or more compounds, and the positives subjected to a first pass of chemical optimization to generate useful compounds. We anticipate that this new resource will catalyze a genuine paradigm shift, because it will give academic investigators a new and powerful research tool not previously at their disposal.

$1,000 Genome Sequence

Current sequencing costs are too high to collect the quantity and quality of soome sequences optimal for research and clinical applications. Completely sequencing the genomes of many individuals would greatly advance understanding of the role of DNA sequence variation in human health, but using DNA sequence information for care of individuals is not possible at current costs. Thus, NHGRI has launched an aggressive program to develop technologies to lower the cost of DNA sequencing dramatically. The goal for the first five years of this program is to develop the capability to produce a high quality draft sequence for a large, complex (e.g., mammalian) genome for $100,000. The goal of the second phase, which is estimated to take ten years, is producing a genome sequence for $1,000. Once achieved, a $1,000 genome analysis would be of great use to correlate DNA information with health outcomes. This includes determining genes in each individual that predispose that individual to specific diseases, and assessing which drugs are likely to elicit adverse reactions in each individual, so that drugs can be used more effectively and with fewer side effects.

Centers for Excellence in ELSI Research

The NHGRI Ethical Legal and Social Implications (ELSI) research program recently released a Request for Applications inviting proposals for the development of Centers of Excellence in ELSI Research (CEER). The CEER program is designed to support the development of groups that will pursue research questions best approached through intensive and extended collaboration among investigators from multiple disciplines, using diverse methodologies. CEER investigators are encouraged to consider new ways to explore these questions, design innovative and efficient research projects, propose and disseminate health or social policy options based on Center research, and, when feasible, facilitate policy development perti-

nent to a specific issue. Center applicants are particularly encouraged to identify cutting edge research topics and approaches that may lead to high payoff solutions to important ELSI problems.

Intramural Social and Behavioral Research Branch

The NHGRI has formed a new Social and Behavioral Genetics Research Branch within its intramural research program. The main focus of the Branch is to conduct research on the social and behavioral aspects of translating genomic discoveries into improved health. The Branch will also: (1) study innovative ways of applying genetic discoveries to promote health and well-being; (2) apply social, behavioral, and communication theories to understand how to communicate genetic risk effectively; (3) develop and refine evidence-based methods of communicating genetic risk to individuals, families, communities, and populations; (4) seek to understand how social factors influence genetic discoveries and research; and (5) investigate the ethical and public policy implications of genetic research and the use of genetics in clinical practice.

OTHER AREAS OF INTEREST FOR NHGRI

Genetic Discrimination

The NHGRI remains concerned about the risk of genetic discrimination and supports the President's call for federal legislation. Many Americans are worried that insurers and employers may use genetic information to deny, limit, or cancel their health insurance or to discriminate against them in the workplace. A total of 41 States have enacted legislation on discrimination in health insurance and 31 have enacted legislation on workplace genetic discrimination. However, only comprehensive federal legislation can guarantee everyone in the United States protection from genetic discrimination. Last October, the full U.S. Senate voted unanimously (95–0) in favor of the "Genetic Information Nondiscrimination Act of 2003" (S. 1053), which would address this problem. It is hoped that the House will soon take similar steps.

Intellectual Property Rights in Genetics and Genomics Research

NHGRI has long worked on issues of intellectual property related to genetic and genomic data. The NHGRI ELSI program plans soon to issue a new initiative to encourage studies of the role of intellectual property rights in genetics and genomics research, as well as the impact of exclusivity on progress in these fields. The initiative will support legal, economic, political science, and statistical analyses and empirical investigations of theories and practices of rights holders, stakeholders, and researchers in genetics and genomics research and development, with the specific goal of helping build the research base necessary to inform the rational development of future policy options regarding intellectual property in genetics, and genomics.

The NHGRI, with several other NIH Institutes, has recently provided funds for a National Academy of Sciences' study, "Intellectual Property in Genomic and Protein Research and Innovation." This 18-month study, involving experts from law, public policy and genomics, will address such important questions as: What is the impact of intellectual property and licensing on genetic and proteomic research? What policy options should be considered in this area? How have other regions of the world addressed these issues? It is hoped that this study will provide insights on how to address the thorny issues surrounding the interface of intellectual property, biomedical research, and patient care.

Direct-to-Consumer Marketing of Genetic Tests

Marketing of products or services that promise to provide consumers with genetic insights into personal health has proliferated dramatically in recent years. NHGRI's intramural Division of Bioethics has systematically studied this issue. So far, researchers have found that many direct-to-consumer (DTC) advertisements exaggerate the scientific basis of claims made and/or fail to communicate effectively the current limitations of the specific genetic knowledge discussed. In particular, the Internet has provided a powerful medium for the construction of "informational" resources through which DNA analysis is often linked to a claim to individualize consumer profiles for specific products available through the website. Additionally, the first example of a multi-media DTC advertising campaign for a genetic test, the BRCA1/2 test, was piloted in two metropolitan areas in the last year. The NHGRI recently held a workshop to assess DTC marketing of genetic tests, and considered the scope of the practice and possible policy options. The NHGRI will work with the Secretary's Advisory Committee on Genetics Health and Society on this issue.

Trans-NIH Obesity Initiative

The NHGRI Deputy Director represents the Institute on the trans-NIH obesity working group. We believe that this initiative is vitally important, and that the genomic tools produced by the Human Genome Project can be of considerable utility in discerning the role of genes and environment in causing obesity, and in predicting which obese individuals will develop which diseases.

CONCLUSION

With the completion of the human genome sequence, we have fully entered the genomic era. The NHGRI has now spearheaded many specific and innovative initiatives to understand how genetics affects human health, the ultimate motivation for the Human Genome Project. The most interesting and important applications of genomics lie not behind us, but ahead of us. Continued investment by the Congress in genetic/genomic research is vital to our efforts to enhance the health of all.

PREPARED STATEMENT OF DR. RICHARD J. HODES

Mr. Chairman and Members of the Committee: The NIA is requesting an fiscal year 2005 budget of $1,055,666,000, an increase of $31,068,000 or 3 percent over the comparable fiscal year 2004 appropriation.

Thank you for this opportunity to participate in today's hearing. I am Dr. Richard Hodes, Director of the NIA, and I am pleased to be here today to tell you about our progress making and communicating scientific discoveries that will improve the health and well-being of older Americans.

There are today approximately 35 million Americans ages 65 and over, according to the U.S. Bureau of the Census. Thanks to improvements in health care, nutrition, and the overall standard of living, these men and women are more likely than ever before to be healthy, vigorous, and productive: Studies confirm that disability among America's elders has declined steadily over the past decade. More older Americans are able to participate in "instrumental activities of daily living," such as performing household chores and managing their own medications, while fewer are experiencing limitations in basic physical tasks such as walking or climbing stairs.

At the same time, diseases of aging continue to affect many older men and women, seriously compromising the quality of their lives. For example, more than half of all Americans over age 65 show evidence of osteoarthritis in at least one joint. Over half of Americans over age 50 have osteoporosis or low bone mass. Cardiovascular disease, cancer, and diabetes remain common among older Americans. And as many as 4.5 million Americans suffer from Alzheimer's disease (AD), the most common cause of dementia among older persons.

The mission of the National Institute on Aging is to improve the health and well-being of older Americans through research. In support of this mission, the Institute conducts and supports an extensive program of research on all aspects of aging, from the basic cellular and molecular changes that occur as we age, to the prevention and treatment of common age-related conditions, to the behavioral and social aspects of growing older, including the demographic and economic implications of an aging society. In addition, the NIA is the lead federal agency on Alzheimer's disease research; our activities in that area encompass prevention, detection, clinical trials, and caregiver issues. Finally, our education and outreach programs provide vital information to older people across the United States on a wide variety of topics, including living with chronic conditions such as arthritis or diabetes, caring for a loved one with Alzheimer's disease, and maintaining optimal health through exercise.

The NIA works to rapidly translate research findings into practical interventions and information that will benefit older Americans. This may involve enhancing our methods of communicating important research findings to physicians or the public; creating opportunities for patients to benefit from groundbreaking research through participation in clinical trials; or even recognizing the potential of a very basic finding in a mouse, a worm, or a molecule to eventually have a powerful impact on the public health.

For example, recent findings in *C. elegans*, a tiny worm that is frequently used for genetic studies, are providing important insights about fat regulation and storage that may lead to improved understanding of overweight and obesity in humans. NIH-supported researchers used RNA interference (RNAi), a technique in which genes are inactivated one at a time to determine their function, to screen the worm's genome and found some 417 genes involved with fat regulation and storage. Many of the genes they found have human counterparts, a number of which had not been previously implicated in the regulation of fat storage. Overweight and obesity are

widespread in the United States and are associated with an array of health problems, including heart disease, stroke, osteoarthritis, adult-onset diabetes, and certain types of cancer; the genes identified in *C. elegans* may ultimately suggest new targets for treating human obesity and its associated diseases.

Another recent basic discovery, this one in mice, may have profound implications on the field of reproductive biology. Since the 1950s, scientists have believed that women are born with all the oocytes (eggs) they will ever have, and that these eggs die off as a woman ages, with fertility diminishing and, at menopause, disappearing as a result. However, NIH-supported researchers recently found that oocyte-containing follicles continue to develop in the ovaries of adult mice. If this finding is confirmed—and extended to humans—it could lead not only to new treatments for premature ovarian failure (which affects some 250,000 American women under age 40, according to the National Institute of Child Health and Human Development), but also to interventions to delay menopause and extend fertility.

NIA-supported investigators in all fifty states are conducting research that is changing the way we prevent, diagnose, and treat the diseases of aging. NIA also supports networks of centers that focus on specific topics, including demography and the basic biology of aging. There are currently 29 NIA-supported Alzheimer's Disease Centers (ADCs), at which investigators are working to translate research advances into improved care and diagnosis for AD patients while focusing on the program's long-term goal—finding ways to treat and possibly prevent AD. Many ADCs have satellite facilities that offer diagnostic and treatment services and collect research data in underserved, rural, and minority communities. Another type of Center, the Edward R. Roybal Centers for Research on Applied Gerontology, translates behavioral and social research findings into practical outcomes for older adults. Each of the six Roybal Centers addresses one or more central themes (e.g., cognitive influences on physician/patient interaction affecting medical compliance; safe driving behavior; social role adjustment upon retirement).

The NIA also supports a variety of clinical trials, frequently in collaboration with one or more NIH Institutes or other organizations. For example, NIA is currently supporting 25 AD clinical trials, seven of which are large-scale prevention studies. These trials are testing agents such as anti-inflammatory drugs and anti-oxidants for their effects on slowing progress of the disease, delaying AD's onset, or preventing the disease altogether. Other intervention trials are assessing the effects of various compounds on the behavioral symptoms (agitation, aggression, and sleep disorders) of people with AD. In addition to AD, NIA supports clinical trials for a number of other conditions, including cardiovascular disease, Parkinson's disease, and certain types of cancer.

A major clinical trial in which NIA-supported researchers took part is the Diabetes Prevention Program, a multi-institutional study that was initiated by the National Institute on Diabetes and Digestive and Kidney Diseases and was designed to identify interventions that could prevent or delay the development of type 2 diabetes. The researchers found that people who are at high risk for diabetes can sharply reduce their risk by adopting a low-fat diet and moderate exercise regimen. This effect was most pronounced among study participants age 60 and over. Treatment with the drug metformin (Glucophage®) also reduced diabetes risk among study participants, but for unknown reasons was less effective among older participants. With other participating NIH Institutes, we are continuing to follow the study participants to determine long-term effectiveness of these interventions.

The NIA also has a number of ongoing or planned special initiatives on diverse research topics. These include:

Health Disparities.—The NIA's Healthy Aging in Neighborhoods of Diversity Across the Lifespan (HANDLS) project is a community-based study of health disparities among different racial, ethnic, and socioeconomic groups in Baltimore. The purpose of HANDLS is to disentangle the effects of race and socioeconomic status on risk factors for morbidity and mortality, incidence and progression of pre-clinical disease, development and persistence of health disparities, longitudinal health status, and health risks. The pilot phase of the study was completed in December 2001, and the full-scope study is now being planned for implementation in 2004–2005. Unique to the HANDLS study is the use of two fully-equipped mobile research laboratories that enable investigators to collect data directly in the neighborhoods under study, establishing links with the community and increasing both the interest of potential participants and the retention rate.

Neuroimaging.—The NIA is developing an Alzheimer's Disease Neuroimaging Initiative, a longitudinal, prospective, natural history study of normal aging, mild cognitive impairment, and early AD to evaluate neuroimaging techniques such as magnetic resonance imaging (MRI) and positron emission tomography (PET). The study objectives are to:

—Identify the best markers for early diagnosis of AD
—Identify markers for following disease progression and monitoring treatment response
—Develop surrogate endpoints for clinical trials
—Decrease time and expense of drug development
—Establish methods for the collection, processing, and distribution of neuroimaging data in conjunction with other biological, clinical, and neuropsychological data

The initiative is planned as a partnership among the NIA/NIH, academic investigators, the pharmaceutical and imaging equipment industries, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the NIH Foundation, with participation from the Alzheimer's Association and the Institute for the Study of Aging. The clinical, imaging, and biological data and samples will be made available, with appropriate safeguards to ensure participant privacy, to scientific investigators in the academic and industrial research communities.

Testosterone replacement in men.—Levels of circulating testosterone decline as men age, and this decline may be related to decrements in physical and cognitive functioning—for example, recent research suggests that older men with lower levels of free, or unbound, testosterone circulating in their bloodstreams could be at increased risk of developing Alzheimer's disease (AD). Increasingly, middle-aged and older men are turning to testosterone replacement therapy (TRT) to forestall these symptoms: In 2002, over 800,000 men received some form of testosterone replacement. However, as with the use of hormone replacement therapy among women prior to the release of the Women's Health Initiative results demonstrating serious HRT-related risks, men are using TRT in the absence of clear scientific data supporting its use. A multi-disciplinary panel, led by the Institute of Medicine and supported by the NIA and the National Cancer Institute, recently evaluated the pros and cons of conducting clinical trials of testosterone replacement therapy in older men to answer many of the lingering questions about the effects of this hormone in the aging body. The NIA is considering the IOM recommendations very carefully and will act on the recommendations to begin clinical trials to determine the efficacy of testosterone in treating symptomatic older men with low testosterone levels.

Genetics.—The NIA has established a new AD Genetics Initiative, a program to accelerate the pace of AD genetics research by creating a large repository of DNA and cell lines from families with multiple AD cases. The goal of this initiative is to develop strategies for identifying the remaining late-onset AD (LOAD) risk factor genes, associated environmental factors, and the interactions of genes and the environment. The NIA's AD Genetics Initiative will intensify sample collection and encourage data sharing by providing access to the repository to qualified investigators. To date, several well-integrated components of the Genetics Initiative have been launched. Mechanisms to efficiently identify and share large numbers of samples for AD genetic analysis have been developed through the recently-enlarged National Cell Repository for AD (NCRAD), and eighteen of the NIA's Alzheimer's Disease Centers have received supplemental funding to recruit new family members participation. Uniform standards for sample collection have also been developed. As of late January, over 200 families have been evaluated and enrolled, and over 800 blood samples have been logged at NCRAD. A clinical task force has been established which is helping to determine the correct phenotypic data to be included with the biological samples. A major goal is the long-term follow-up of individuals participating in the study.

In order to publicize the initiative, the NIA Office of Communications and Public Liaison, together with its Alzheimer's Disease Education and Referral Center, Columbia University, and NCRAD, partnered with the Alzheimer's Association to conduct focus groups and develop publicity materials to help recruiting efforts. These publicity materials, including a workbook, CD ROM, fact sheet, and brochure were distributed at the a recent meeting of the ADCs and will now be sent to ADCs and Alzheimer's Association chapters to help recruiting efforts.

Longevity.—The NIA has formed a Longevity Consortium to help identify and understand genetic and other factors that predispose to human longevity or protect against multiple age-related conditions, a major goal in aging research. The Consortium is an innovative system for expeditious generation, review, and funding of new projects as opportunities arise, and includes epidemiologists, geneticists, population biologists, statisticians, and others with an interest in the genetic and molecular basis for longevity. Participants can draw on the study populations of 15 of the largest human aging studies, including the Cardiovascular Health Study, the Women's Health Initiative, Health ABC, the Study of Osteoporotic Fractures, the Rotterdam Study, the Honolulu Heart Study, and the New England Centenarian Study. Alto-

gether, Consortium researchers will have access to data on some 200,000 study subjects.

Demography.—As the percentage of Americans over age 65 increases, profound societal changes will likely occur. NIA-supported researchers are exploring the changing demographic, social, and economic characteristics of the older population. Research embraces topics such as: trends in the age-structure of populations; changes in levels of disease and disability; economic costs of disability; cost-effectiveness of interventions; migration and geographic concentrations of the elderly; decision-making about retirement; pensions and savings; the relationship between health and economic status; and health disparities by gender and race. The results of this research often have important implications for public policy. Such research often involves large datasets that are frequently co-sponsored by NIA and other government agencies in the United States and overseas. These include:

—*Health and Retirement Study*, a biennial survey of more than 22,000 Americans over age 50, which provides data for researchers, policy analysts, and program planners who are making major policy decisions that affect retirement, health insurance, saving and economic well-being.

—*National Long-Term Care Study*, which explores trends in the prevalence of self-rated old age disability and physical, cognitive, and sensory limitations.

—*Longitudinal Study of Aging*, a long-term study in which the NIA participates with the National Center for Health Statistics.

—*Panel Study of Income Dynamics*, begun in 1968 and conducted by the National Science Foundation, is a nationally representative longitudinal study that collects information on U.S. households. Notably, the PSID contains information on approximately 5,000 heads of households and spouses who are baby boomers (born 1945–1964)—a cohort not yet represented in the Health and Retirement Study (HRS). Continued data from the PSID will shed light on individual household saving behavior of the baby boom generation and its neighboring age cohorts.

Health Communication.—Communication of research-based health information is another key activity of the NIA, and the Institute uses both traditional and innovative means to disseminate information. In 2003, the Pew Internet and American Life survey found that 22 percent of Americans age 65 or older have access to the Internet, and that 58 percent of these "wired seniors" had used the Internet to look for information about a specific disease. However, NIA-supported research has demonstrated that with age come changes in cognition (such as working memory, perceptual speed, text comprehension) and vision (including loss of ability to detect fine details, less light reaching the retina, and loss of contrast sensitivity) that could hinder the older person's ability to use the Internet easily and effectively. To respond to the unique needs of Internet users over 60, the NIH launched NIHSeniorHealth.gov on October 23, 2003. Developed by the NIA and the National Library of Medicine, and featuring content developed in collaboration with several other NIH Institutes, this web site is easy for older adults to read, understand, remember, and navigate. For example, the site features large print and short, easy-to-read segments of information repeated in a variety of formats—such as open-captioned videos and short quizzes—to increase the likelihood it will be remembered. Consistent page layout and prompts help users move from one place to another on the site without feeling lost or overwhelmed. The site also has a "talking" function, which allows users the option of reading the text or listening to it as it is read to them.

The risk of many diseases increases with age, so the site focuses on health topics or specific diseases that are of particular interest to older people, including Alzheimer's disease, Alzheimer's disease caregiving, arthritis, balance problems, breast cancer, colorectal cancer, exercise for older adults, hearing loss, lung cancer, and prostate cancer. Upcoming and planned topics include complementary and alternative medicine, diabetes, falls, shingles, vision changes, and others. Each topic provides general background information, quizzes, frequently asked questions (FAQs), open-captioned video clips, transcripts for the videos, and photos and illustrations with captions. From its launch in October 2003 through late January, NIHSeniorHealth.gov has received over a million page views and been visited by nearly 118,000 unique visitors.

The NIA also maintains a large selection of lay-language Age Pages, which cover an array of topics relevant to older people and include information on a number of diseases and conditions, suggestions for coping with these conditions, and information on other resources. Most of the Age Pages have been translated into Spanish.

At a March 2002 hearing of this Committee entitled "Bench to Bedside," Chairman Regula recommended that NIA and the Administration on Aging (AoA) work together to disseminate research-based consumer education to the thousands of sen-

iors who participate in the Meals-on-Wheels program across the Nation. In response, NIA staff, with the participation of AoA, have conducted focus groups of program managers from the Meals on Wheels Association of America (MOWAA) to determine the types of information of greatest interest to MOW's clients, as well as the best ways to deliver such information (e.g., meal tray liners printed with key health messages, articles for MOWAA newsletters, or specially crafted Age Pages.) Based on focus group feedback, NIA is currently revising Age Pages on diabetes, alcohol, and depression; these materials will be tested at the upcoming MOWAA meeting in September 2004, and we anticipate that distribution to MOWAA clients will begin shortly thereafter.

The Alzheimer's Disease Education and Referral (ADEAR) Center has been compiling and disseminating information about AD for health professionals, persons with AD and their families, and the public since 1990. NIA is also working to translate research findings into action through its highly successful campaign to encourage older people to exercise. In the last four years, NIA has distributed over 611,000 copies of its exercise guide and 93,000 copies of its companion video to the public. A Spanish-language version of the guide was published in January 2002, and over 33,500 copies have been distributed to date. The NIA's efforts to promote exercise and strength training are conducted in support of the President's "HealthierUS" and the Department of Health and Human Services' "Steps to a HealthierUS" initiatives.

PREPARED STATEMENT OF DR. ANDREW C. VON ESCHENBACH

BUDGET STATEMENT

The fiscal year fiscal year 2005 budget includes $4,870,025,000, an increase of $134,052,000 over the fiscal year 2004 enacted level of $4,735,973,000 comparable for transfers proposed in the President's request.

2015 CHALLENGE GOAL

The Nation's unwavering support of cancer research has enabled the National Cancer Institute (NCI) and our many partners throughout the cancer research community to make enormous strides over the past three decades. Our understanding of cancer as a disease process, and the associated opportunities to prevent, detect early and successfully treat it has improved dramatically. However, even in the face of this progress, the magnitude of the cancer burden means that the disease still affects nearly every family in America. This year, approximately 1.4 million of our citizens will face a cancer diagnosis, and over 560,000 of our citizens—about 1,540 each day—will die from their disease. Furthermore, the fact that cancer occurs primarily in individuals over the age of 50 means that more of our citizens will suffer the terrible burden of this disease in the next 10–20 years due to the aging and changing demographics of our population.

Fortunately, the convergence of science and advanced technologies is changing our perceptions of what is possible. In fact, we are entering a period in biomedical research where progress in cancer research can be exponential—an inflection point. Last year I informed this committee that "our nation's investment in basic research has fueled the engine of discovery, which is rapidly illuminating the cumulative genetic changes and associated molecular mechanisms that ultimately produce cancer." As I said then and I reiterate now "for the first time, we have within our grasp the ability to design target-specific interventions to preempt this process." Based on the current astounding pace of progress in cancer research and the transformational effects of advanced biomedical technologies, I am even more fervent in my belief that we can achieve this vision.

To capitalize on this inflection point, I have set forth an ambitious challenge goal for the NCI, and for the entire cancer research and care community: to eliminate suffering and death from cancer by 2015. This "stretch goal" is intended to unify and focus our thinking, strategies, and actions in new ways that will optimize the use of our resources and accelerate progress against cancer. This challenge also presents new opportunities for the NCI to provide leadership for our Nation's effort to conquer cancer, especially in the development of the new synergies and partnerships needed to achieve this bold vision.

Recent progress across nearly all of biomedical research has set the stage for unimagined progress in biomedicine early in the 21st century. Thanks to research, we now understand that cancer is a disease process—where normal cells are transformed into cancer cells through a series of defined steps that begin with a simple change in the genetic material. If left unchecked, these transformed cells can

progress and spread to cause the suffering and death that we recognize as the horrific burden of cancer. Thankfully, our growing understanding of this process has revealed multiple opportunities to intervene. These new intervention strategies include preventing initiation of the process; detecting it early when it is most amenable to elimination; and arresting the process to stop the spread (metastasis), which is the primary reason that patients suffer unduly and die from their disease. In short, we are rapidly learning how to "preempt" the cancer disease process. We believe in the next few years that new intervention strategies will allow us to prevent and/or eliminate many cancers—and ultimately transform cancer into chronic, manageable diseases that patients live with—not die from.

Scientific advances and major discoveries from areas such as genomics, nanotechnology, proteomics, immunology, and bioinformatics allow us to envision a not too distant future when a patient's genetic, lifestyle, and environmental risk for cancer can be combined with effective prevention and early intervention strategies especially for those at high risk. Serum genomic and proteomic patterns, and advanced imaging technologies, will be employed to detect cancers at the earliest stages. Precise molecular diagnosis and patient-specific prognostic profiling will allow physicians to predict response to specific interventions and provide a rational basis for tailoring therapies. The result will be more efficacious and less toxic, targeted agents delivered to patients. Achieving these outcomes will result in the preemption of a great deal of cancer. I believe that this is no longer a dream but an achievable reality.

To achieve the 2015 challenge we must take the steps necessary to accelerate the pace of progress across the entire cancer research continuum. The basic research which is aimed at discovering the pathways that lead to cancer represents the beginning of a continuum that proceeds through development of new agents and technologies and ultimately to the delivery of these new interventions to patients. Using our ever increasing knowledge of the molecular defects in cancer cells and the biomarkers that define the cancer process will enable the development of the new targeted interventions we need to prevent, detect, and treat cancer.

To achieve this acceleration the NCI has identified six "mission-critical" research areas that we believe will offer significant potential for near term progress against cancer. These include: harnessing the power of the newly emerging science of molecular epidemiology to better identify risk populations; developing an integrative understanding of cancer (systems) biology to discover key biomarkers and targets; facilitating the development of "strategic" cancer interventions for targeted prevention, early detection, and treatment; creating a national integrated clinical trials system to more effectively test these interventions; overcoming health disparities to deliver these advances to those in greatest need; and developing a bioinformatics network to connect the cancer research community and optimize the collection, analysis, and use of the enormous amount of data and knowledge that must be managed and shared.

CANCER BIOMEDICAL INFORMATICS GRID (caBIG)

In this past year's Appropriations Committee Report, NCI was requested to explore ways in which information could be better shared among researchers and cancer care deliverers. In early 2004, the NCI responded by launching an unprecedented program to connect cancer researchers through an advanced technology platform called the Cancer Biomedical Informatics Grid (caBIG). This pilot initiative has the potential to transform the pace of cancer research by providing the tools needed to share information and data. caBIG will be developed by connecting 50 of our NCI-designated cancer centers through an NCI-developed open source system which will in effect become the "World Wide Web" of cancer research. This platform which integrates with the NIH Roadmap informatics initiative will link individual cancer researchers and research institutions across the nation, and around the world, in an open source, federated network that will enable researchers to share tools, standards, data, computing applications, and technologies. This unprecedented bioinformatics system will facilitate the collection, storing, searching, analysis, classification, management, and archiving and retrieval of research data. caBIG will improve the quality of data, provide unimagined access to heretofore limited databases, increase the pace of cancer research and enhance the effectiveness of our investments in cancer research. caBIG has the capability to virtualize cancer research.

caBIG leverages the unique resources and capabilities of NCI's cancer centers to meet the needs of the broad cancer research and care communities. The cancer centers, along with NCI's platforms for translational research, the Specialized Programs of Research Excellence (SPORES), are our partners in this strategic effort to ensure that the fruits of fundamental scientific research can be rapidly captured for

the benefit of cancer patients. This is an example of how the future can be transformed if we can successfully integrate advanced technologies across the discovery, development, and delivery research continuum. In this instance the whole will be a great deal more than the sum of the parts.

NATIONAL ADVANCED BIOMEDICAL TECHNOLOGY INITIATIVE

In developing strategies to optimize progress in NCI's high priority research areas, it became clear that we must proactively identify, develop, and deploy advanced biomedical technologies, such as bioinformatics, across the entire cancer research continuum. This concept represents a critical new element of our overall strategy to achieve the 2015 challenge goal; however, there is clearly a gap between our current level of capabilities in advanced technologies and what is needed. I believe that we now have the opportunity to address this gap through the creation of an unprecedented national advanced biomedical technology initiative that will be transformational for cancer and other diseases.

Achieving our challenge goal will require that we fully integrate advanced "enabling" technologies with the cancer research and care enterprise. Advanced technologies represent those new tools and approaches that enable new approaches to the challenging problems of detecting, controlling, and preventing cancer. Advanced technologies allow cancer researchers to generate, collect, and analyze vast amounts of data, and to pursue innovative approaches that could not be accomplished without these sophisticated tools. As illustrated by our efforts in bioinformatics, the NCI is providing leadership in the development and integration of advanced technologies and we are also building the cross-disciplinary teams needed to implement these new strategies.

Providing advanced technology platforms to scientists working in cancer research is one of our highest priorities at the NCI; and to that end, we have undertaken a cancer-enterprise wide planning effort to develop a national advanced technology initiative for cancer. In planning for this initiative, the NCI has identified (in addition to bioinformatics) multiple areas of advanced technology development that will be crucial in building this national resource. Examples of cross-cutting capabilities, which will support the range of strategic research priorities that we have identified as pivotal areas for progress, include: advanced imaging; biomarkers and proteomics; nanotechnology; and development capabilities such as scale-up for new cancer therapies and prototyping for new diagnostics devices.

We have made significant progress in cancer diagnosis and treatment based on static imaging of the body's organs provided by x-ray, CT, PET, and MRI. The new generation of advanced imaging technologies will target specific molecules and cells. We will be able monitor cellular processes to assess the effectiveness of experimental treatments and to define cancer cells at their earliest stages. Nanotechnology will provide opportunities to develop biosensors that have the capability of detecting changes in cells at the earliest stages of cancer and "report" back on them. This breakthrough technology will also facilitate the design of new technologies to probe cell functions, measure cellular events with unimagined precision, and specifically deliver molecular entities to attack cancer. The combination of advanced imaging and nanotechnology offers the promise of realizing these advances to achieve the exponential progress that is possible at the current inflection point.

The post-genomics era in cancer research has produced vast amounts of information aout the genetic basis of cancer, but perhaps of more importance, we are learning that the functioning of normal and tumor cells is controlled by the proteins that are transcribed from these abnormal genomes. These proteins, along with genes and other indicators of the processes and pathways that distinguish cancer, are called biomarkers. Through the use of advanced technologies NCI is developing innovative strategies to discover and validate biomarkers for use in clinical applications. Biomarkers, along with advanced imaging, nanotechnology, and other advanced technology platforms, will comprise an unprecedented National Advanced Biomedical Technology Initiative for Cancer (NABTIc).

This initiative is a major element of our strategy to achieve NCI's challenge goal to eliminate suffering and death due to cancer by 2015. The NABTIc would leverage and align the capabilities and resources in advanced technology development across the nation—and gain strength from all sectors. Through a network of technology "nodes" it would capitalize on capabilities in our cancer centers and SPORES and optimize the deployment of NCI's existing strengths in advanced technologies that currently exist at our Frederick campus. This initiative is currently being refined and further developed with the aid of our advisors and partners in the extramural community, and a plan to purse this concept is under development.

STRATEGIC PARTNERSHIPS

Finally, to implement many elements of our strategic plan, we will partner broadly With all of the sectors that comprise the cancer community, including other federal agencies and private industry. The NCI is an active partner with many federal agencies, including the Department of Defense, the Veterans Administration, the Centers for Disease Control and Prevention, the Agency on Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services. One partnership that is critically important to optimizing the pace at which laboratory discoveries progress to become new interventions for cancer is our alliance the Food and Drug Administration (FDA). Early last year we created the NCI/FDA Interagency Oncology Task Force to leverage the expertise of both agencies for the expressed purpose of streamlining and accelerating the development of preventive, diagnostic, and therapeutic interventions for cancer. Considerable progress has already been made in the areas of joint training and fellowships, developing markers of clinical benefit, improvement in the overall process of oncology drug development, and creation of a common bioinformatics platform (caBIG) to improve the organization and reporting of data from oncology clinical trials. These partnerships are critical. Each agency, along with the other sectors involved in the development, commercialization, and delivery of the new inventions we desperately need to preempt cancer, is a valued partner who can unite with us to facilitate and speed the overall process.

Last year, I closed by telling members of this committee that we stand at a pivotal crossroads—a defining moment in this nation's effort to prevent and cure cancer. Over the past 12 months we charted the future course forward—through the creation and implementation of innovative strategies—and have undertaken initiatives that will allow us to move rapidly toward a day when cancer will become a chronic disease. What was once a vision is becoming reality through the combined efforts of researchers and leaders from all sectors, patients and their families—and so many others. I believe that together we will realize the economic and human benefits of eliminating the suffering and death due to cancer, and in this quest, inform our efforts to transform our overall health care system.

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) of the National Institutes of Health (NIH). The fiscal year 2005 budget of $4,425,507,000 includes an increase of $122,467,000 over the fiscal year 2004 enacted level of $4,303,040,000, comparable for transfers proposed in the President's request.

NIAID conducts and supports research studies to understand, treat, and prevent infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria, and illness from potential agents of bioterrorism. In addition, the Institute supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies. For 56 years, NIAID-sponsored research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people worldwide. Historically, NIAID has accomplished its mission with a strong commitment to basic and targeted research in immunology, microbiology, and infectious disease, disciplines that are related and complementary. The new initiatives of the NIH Roadmap, and the information, reagents and infrastructure they will produce, will further promote the efficient and effective movement of NIAID discoveries from the laboratory bench to the bedsides of patients.

THE NIAID RESEARCH RESPONSE TO THE THREAT OF BIOTERRORISM

The use of deadly pathogens such as smallpox or anthrax as agents of bioterrorism is a serious threat to the citizens of our nation and the world, and biodefense research to mitigate this threat is a key focus of NIAID research. Since the anthrax attacks of 2001, NIAID has significantly strengthened, accelerated, and expanded our biodefense research program. NIAID-supported biodefense research includes: (a) basic studies of the structure, ecology, and disease-causing mechanisms of microbes that could be used by bioterrorists; (b) the response of the immune system to these pathogens, and; (c) the translation of this knowledge into safe and effective countermeasures—treatments, diagnostics, and vaccines. To achieve our biodefense research goals, NIAID works closely with partners in academia, industry, and other private and public-sector agencies. Research on potential agents of bioterror prom-

ises to enhance not only our preparedness for bioterrorism, but also for naturally occurring endemic and emerging infectious diseases.

Progress in biodefense research has been swift and substantial. More than 50 major NIAID initiatives involving intramural, academic and industrial partners have been undertaken. As part of this effort, the Institute has greatly increased biodefense research capacity. For example, NIAID recently funded eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research. This nationwide network of multidisciplinary academic centers will conduct wide-ranging research on infectious diseases and the development of diagnostics, therapeutics and vaccines. In addition, NIAID is supporting the construction of two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). These high-level biosafety facilities promise to speed the development of effective therapies, vaccines and diagnostics for diseases caused by agents of bioterror as well as for naturally occurring emerging diseases such as SARS and avian influenza.

In addition, NIAID has developed and expanded contracts to screen new drugs; develop new animal models and establish a reagent and specimen repository. NIAID also has made a significant investment in determining the genetic sequences of the genomes of a range of pathogens, which has helped to illuminate the workings of all classes of microorganisms. NIAID-supported researchers and their international colleagues have sequenced genomes representative of all bacteria considered bioterror threats (including multiple strains of the anthrax bacterium), as well as at least one strain of every potential viral and protozoan bioterror pathogen. NIAID also is funding research to better understand the body's own protective mechanisms. A new NIAID program, the Cooperative Centers for Translational Research on Human Immunology and Biodefense, will conduct research to better understand the human immune response to potential agents of bioterror, with the objective of developing new bioterror countermeasures. Another large-scale program is funding sophisticated studies of the human innate system, comprised of the cells that are the "first responders" to infection. Boosting innate immunity holds great promise for developing fast-acting countermeasures to mitigate the effects of bioterror pathogens or toxins.

The ultimate goal of all NIAID biodefense research is the development of medical countermeasures. NIAID-supported scientists have identified: (a) antivirals that may play a role in treating smallpox or the complications of smallpox vaccination; (b) several approaches to blocking the toxins of the anthrax bacterium; as well as (c) antibiotics, antivirals and antitoxins against other major bioterror threats. New and improved vaccines against smallpox, anthrax and other potential agents also are being developed, with the objective of adding them to the Strategic National Stockpile (SNS). For example, NIAID has sponsored the development of a next-generation anthrax vaccine known as rPA, with the goal of adding 75 million doses to the SNS to protect U.S. citizens. Clinical trials of rPA are ongoing; results to date build on similar findings in animal studies and suggest that the vaccine is safe and capable of evoking a robust immune response. Researchers also will test whether the currently recommended course of antibiotic therapy for individuals exposed to anthrax spores can be reduced by vaccinating exposed subjects with rPA.

NIAID-supported researchers also are testing several new smallpox vaccines that may prove at least as effective as the current smallpox vaccine, but with fewer side effects. One of these, modified vaccinia Ankara (MVA), is based on a strain of the vaccinia virus that replicates less robustly than the traditional Dryvax vaccinia virus, and is known to cause fewer side effects than the latter. Human trials of MVA vaccines are underway at NIH and elsewhere. Encouragingly, recent studies by NIAID intramural scientists and their colleagues have shown that MVA protects monkeys and mice from smallpox-like viruses. NIH also has launched the first human trial of a vaccine designed to prevent infection with Ebola virus. The trial vaccine, a type called a DNA vaccine, is similar to other investigational vaccines that hold promise for controlling such diseases as AIDS, influenza, malaria and hepatitis.

HIV/AIDS RESEARCH

Most recent estimates on the scope of the HIV/AIDS pandemic are profoundly sobering. Approximately 40 million people worldwide are living with HIV/AIDS. In 2003 alone, 5 million people worldwide were newly infected with HIV—about 14,000 each day, more than 95 percent of whom live in low and middle income countries. In 2003, 3 million people worldwide with HIV/AIDS died. In the United States, nearly one million people are living with HIV/AIDS, and by the end of 2002, more than 500,000 people with HIV/AIDS had died. As shocking as these numbers are,

they do not begin to adequately reflect the physical and emotional devastation to individuals, families, and communities coping with HIV/AIDS, nor do they capture the huge deleterious impact of HIV/AIDS on the economies and security of nations, and indeed entire regions. Even as the burden of HIV/AIDS continues to grow, recent developments provide some measure of optimism. For example four new antiretroviral drugs were licensed in 2003 by the U.S. Food and Drug Administration (FDA), each of which built on NIAID-sponsored research and/or has been tested in NIAID clinical trials networks. Many other "next-generation" anti-HIV drugs are in clinical trials.

A vaccine that prevents HIV infection—or at least slows the progression of disease—is a critical NIAID priority. Vaccine developers face formidable obstacles, including the genetic diversity of the virus and the lack of a clear understanding of the immune responses that might protect against HIV infection. Nonetheless, NIAID and our academic, industrial, international and philanthropic partners have made significant progress. Numerous HIV vaccine candidates are in various stages of preclinical and clinical development. The new Partnership for AIDS Vaccine Evaluation (PAVE) promises to optimize these efforts. PAVE is a coordinated HIV vaccine research effort that includes the three government agencies most involved in this activity—NIH, the Centers for Disease Control and Prevention (CDC), and the Department of Defense. These agencies will work together to ensure that research protocols, standards, and measures are developed in a coordinated and harmonized manner so that outcomes can be compared across trials in the most cost effective and scientifically efficient manner. International non-government organizations (NGOs) and companies also have expressed interest in joining the partnership. Concurrently, novel approaches to HIV prevention are being studied and validated, including topically applied microbicides that individuals could use to protect themselves from HIV and other sexually transmitted pathogens. As discussed in the new NIAID Strategic Plan for Topical Microbicides, more than 50 candidate agents have shown laboratory activity against HIV and other STDs, and several of these agents have demonstrated safety and efficacy in animal models. In small human studies, several products have proven safe; later this year, NIAID's HIV Prevention Trials Network (HPTN), in conjunction with the National Institute of Child Health and Human Development, will launch a large international study to test two promising products in more than 3,000 women at high risk of acquiring HIV in the United States, five African countries, and India.

RESEARCH ON OTHER EMERGING AND EMERGING INFECTIOUS DISEASES

Infectious diseases have always afflicted humanity, and they will continue to confront us as long as man and microbes co-exist. Unfortunately, the viruses, bacteria, and parasites that cause infectious diseases do not remain static, but continually and dramatically change over time as new pathogens (such as HIV and the SARS coronavirus) emerge and as familiar ones (such as influenza virus and West Nile virus) re-emerge with new properties or in unfamiliar settings.

West Nile virus (WNV) first appeared in the western hemisphere in 1999, and by 2003 had spread to 45 states in the United States. NIAID has moved quickly to address this threat with basic research on the virus and its maintenance in nature, the development of vaccines and treatments, and the provision of reagents and other resources to the research community. NIAID also is supporting the development of three types of vaccines, as well as the screening and testing of WNV therapies. For example, the NIAID-sponsored Collaborative Antiviral Study Group is assessing the safety and efficacy of WNV immunoglobulins in patients with, or at high risk of serious brain diseases caused by WNV.

Severe acute respiratory syndrome (SARS) is a new infectious disease first identified in humans in early 2003. The prompt recognition that SARS is caused by a new type of coronavirus, and the rapid progress in SARS research reflect the dedication of and collaboration by the world's medical researchers and public health experts, including NIAID-sponsored scientists in the United States and abroad. NIAID supports research to understand the epidemiology and biology of the SARS virus and how it spreads, and to develop SARS countermeasures. Several approaches to SARS countermeasures are being pursued by the NIAID Laboratory of Infectious Diseases, the NIAID Vaccine Research Center, and by our contractors and grantees. For example, NIAID is participating in a project to screen up to 100,000 antiviral drugs and other compounds for activity against the SARS virus, and will test the most promising in animal models and human clinical trials. A number of compounds have shown promise in the test tube, including alpha interferon, a drug already approved by the FDA for the treatment of hepatitis B and C infections.

NIAID scientists and grantees are pursuing several parallel approaches in the search for a SARS vaccine. Once these experimental vaccines are ready, NIAID plans to test them in human clinical trials in our network of Vaccine and Treatment Evaluation Units. New research suggests that a SARS vaccine is within reach: NIAID intramural scientists have demonstrated that the mouse immune system develops antibodies capable of single-handedly neutralizing the SARS virus. This discovery affirms that researchers developing vaccines that trigger antibodies to the SARS virus are heading in the right direction. These findings also indicate that drug researchers can use laboratory mice as a model to evaluate whether a drug blocks the SARS virus. Both findings could help lessen the time it takes to develop an effective vaccine or antiviral drugs for SARS.

Influenza is a classic example of a re-emerging disease; it is not a new disease, but it continually changes. Because the replication machinery of the influenza virus is error prone, as the virus multiplies it can mutate to a slightly different form; this is referred to an "antigenic drift." Such viruses might require a slight modification of the yearly influenza vaccine to accommodate these changes. In addition, non-human influenza viruses such as avian influenza, can emerge that may be able to jump species into domestic poultry, farm animals such as pigs, and humans. This type of significant change in the antigenic makeup of the virus is referred to as "antigenic shift." Deadly pandemics associated with antigenic shifts are known to have occurred in 1918, 1957, and 1968. The pandemic that occurred in 1918–1919 after an antigenic shift killed 20–40 million people worldwide, including more than half a million in the United States. This recent history explains the current high level of concern about the appearance of new forms of virulent H5N1 avian influenza viruses in Asia that can adapt themselves by mutation to infect humans as has been the case already in dozens of individuals in Viet Nam and Thailand. Of even greater concern is the possibility that this avian virus can combine or reassort its genes with a human influenza virus and acquire the capability of readily spreading from person to person resulting in a new pandemic. Given the poor condition of public health systems in many underdeveloped regions and the speed of modern air travel, the consequences of such an event, should it result in an influenza pandemic, would be severe.

To address this threat, NIAID supports a broad program to develop more effective approaches to controlling influenza virus infections. Research includes programs to understand the pathogenesis, transmissibility, evolution, epidemiology, and the immune response to influenza viruses, as well as to develop new diagnostics, antiviral drugs and vaccines. NIAID currently supports several research projects to develop vaccines that could be manufactured more rapidly, are more broadly cross-protective, and are more effective than current influenza vaccines. The use of reverse genetics—a tool developed by NIAID grantees—holds the promise for more rapid generation of vaccine candidates that match the anticipated strain expected to circulate during the influenza season. Reverse genetics also can be used to turn highly pathogenic influenza viruses into vaccine candidates more suitable for vaccine manufacturing by removing or modifying certain virulence genes; laboratories around the world are using the technique to prepare vaccine candidates against the H5N1 viruses emerging in Asia. NIAID also is funding the development of new influenza vaccine technologies. Recently, NIAID supported a Phase II clinical trial of a new influenza vaccine produced in a cell culture system as an alternative to manufacturing the vaccine in eggs. Because NIAID has had remarkable success in the past with groundbreaking vaccine research—including advances that led to hepatitis B, *Haemophilus influenzae b,* pneumoccocal pneumonia, and acellular pertussis vaccines—we are confident that one of the approaches that we are pursuing also will lead to a useful, "next-generation" influenza vaccine that can readily be adapted to emerging influenza strains.

RESEARCH ON IMMUNE-MEDIATED DISEASES

Immune-mediated diseases such as autoimmune diseases, allergic diseases, and asthma are important health challenges in the United States and abroad. Autoimmune diseases afflict 5 to 8 percent of the U.S. population; asthma and allergic diseases combined represent the sixth leading cause of chronic illness and disability in the United States, and the leading cause among children. The past two decades of fundamental research in immunology have resulted in a wealth of new information and extraordinary growth in our conceptual understanding of the immune system and the pathogenesis of immune-mediated diseases, which has led to the development of many useful therapies. For instance, we now have powerful treatments that selectively target several of the immune system molecules that cause inflammation, a hallmark of many autoimmune diseases. NIAID-sponsored researchers are

now developing novel ways of selectively blocking inappropriate or destructive immune responses, while leaving protective immune responses intact, an area of research known as tolerance induction. In the Immune Tolerance Network, a consortium of basic and clinical scientists, promising studies are underway using tolerance induction to treat autoimmune diseases, such as rheumatoid arthritis, type 1 diabetes, and multiple sclerosis; asthma and allergic diseases; and the rejection of transplanted organs, tissues, and cells. So-called "tolerogenic" therapies would replace current lifelong non-specific immunosuppressive regimens (and their often debilitating side-effects) with short-term specific regimens that hold the promise of being curative.

Other important research is being conducted by the recently expanded Autoimmunity Centers of Excellence. The nine centers that make up this program conduct basic research and clinical trials on new immune-based therapies for diseases that collectively afflict between 14 and 22 million Americans. The Institute and our collaborators also have significantly bolstered the study of primary immunodeficiency diseases—disorders caused by inherited flaws in the immune system that increase susceptibility to infections—with funding of the Primary Immunodeficiency Research Consortium (PIRC), a coalition of the world's most prominent researchers in the field of primary immunodeficiency diseases.

Another important NIAID research focus is the development of new interventions to reduce the burden of asthma, a significant and growing public health problem in the United States and many nations worldwide. NIAID has long been at the forefront of discoveries leading to the characterization of asthma and allergic diseases and is now vigorously pursing the translation of basic knowledge into more effective treatment and prevention strategies. To develop interventions to prevent the onset of asthma, more information is needed on the events that induce asthma. NIAID's Inner-City Asthma Consortium (ICAC) will soon launch a large study to define and analyze immunological and environmental influences upon the development of childhood asthma in a cohort of urban children followed from birth.

CONCLUSION

With a strong research base, talented investigators in the United States and abroad, and the availability of powerful new research tools, NIAID anticipates that our basic and applied research programs will provide the countermeasures to improve our defenses against those who would attempt to harm us with bioterrorism, will develop new tools in the fights against HIV/AIDS and other infectious diseases, and will improve therapies and management of immune-mediated diseases.

PREPARED STATEMENT OF DR. NORA D. VOLKOW

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Drug Abuse. The fiscal year 2005 budget includes $1.019 billion, an increase of $28.273 million over fiscal year 2004 conference level of $990.787 million comparable for transfers proposed in the President's request.

NIDA: 30 YEARS OF DISCOVERY

As the National Institute on Drug Abuse (NIDA) prepares to celebrate its 30th anniversary this year, I am honored to have this opportunity to tell you about some of our remarkable scientific accomplishments and how these advances are setting the course for a better future. A tomorrow that will bring us even better prevention interventions to deter the initial use of drugs by those at risk before they become one of the more than 180 million people around the world who currently abuse illegal drugs. A future that will also bring us better treatment interventions to help those who have already become addicted, and who may suffer from some of the myriad consequences of drug abuse including HIV/AIDS and comorbid mental illnesses. Research supported by NIDA, the world's largest supporter of research on the health aspects of drug abuse and addiction, may even bring us innovative and improved ways to deal with other major health epidemics impacting our society, such as chronic pain and obesity.

ADDICTION AND OBESITY: COMMON NEUROBIOLOGICAL MECHANISMS

Obesity and addiction are serious National health problems that may have much in common. Both addiction and some forms of obesity represent problems resulting from excessive behaviors and lack of impulse control. Knowledge derived from addiction research shows that the brain circuits involved in compulsive eating and im-

pulse regulation are part of the same brain systems involved in addiction, with the neurotransmitter dopamine playing a prominent role. (See Figure 1.) A better understanding of the role of the dopamine and other systems in the motivation for and salience of food may lead us to the development of better medications and behavioral interventions for obesity, as well as addiction. In addition, medications being developed for obesity may also help to reduce drug use. Because of the commonalities between these disorders, we are able to share knowledge of brain and behavior and combine efforts across institutes to forge new insights and approaches that may result in improved health for all. NIDA is pleased to be a key participant in a trans-NIH initiative that is looking at all aspects of this chronic health problem, from its neurobiological underpinnings to helping people establish healthy behaviors.

THE INTEGRATION OF BRAIN, BEHAVIOR AND HEALTH

Understanding the connections between brain, behavior, and health will be critical to improving the health of ALL Americans. Science is at a point where all the elements of the human brain (genes, proteins, circuits) and its development can now be mapped out.

We did it with the Human Genome and I am confident we can do it with the brain. We are already beginning to unravel how various genes, proteins, brain circuits and pathways interact with each other and the environment to affect all aspects of human behavior. This overarching approach is necessary if we are to make progress in improving the quality of life for individuals who suffer from complex disorders, such as drug addiction, which can start at a young age and continue across the lifespan. Now that advances in medical sciences have increased the lifespan of humans, a major challenge becomes to improve the quality of life of individuals, which hinges on our ability to understand the neurobiological underpinnings of human behavior and the impact and malleability the environment can have on it. This pertains not only to problems such as addiction, but other health problems such as obesity, adherence to medical regimens and with establishing and maintaining healthy life styles.

ADOLESCENCE, THE DEVELOPING BRAIN, AND PREVENTION

Collaborating with other Institutes to map out structural and functional aspects of the brain and how it changes throughout development will help us better understand human behavior, and how we can modify it to improve and extend human life. In particular, understanding the developing adolescent brain will be useful in drug abuse prevention efforts. Research indicates that exposure to drugs of abuse in adolescence, when many changes are occurring in the brain, may be a period of significantly increased vulnerability to drugs' effects. Fortunately, advances in science and NIH-funded studies have now brought us to a point where our researchers can use new animal models, new brain imaging technology and other neurobehavioral assessment tools to probe the development of brain and behavior interactions. These new directions in adolescent research will help to inform us on important aspects of cognition, decision-making, emotional regulation, and risk perception during adolescence, and will help us determine how these play a role in the use and consequences of illicit drugs. Armed with new knowledge about how adolescents make decisions, NIDA will be poised to design interventions that can reduce drug experimentation and addiction. We are making progress in this regard through our National Prevention Research Initiative and through our science education activities like "NIDA Goes Back to School Campaign" where science-based materials were disseminated to teachers and students all across America.

EXCELLENT NEWS: DRUG USE DECLINES

Some of the best news to a NIDA Director came in December 2003 when we released the latest data on teen drug use trends. NIDA's long-standing Monitoring the Future Survey showed an approximately 11 percent decline in illicit drug use over the last 2 years by students in the eighth, tenth, and twelfth grades combined. (See Figure 2.) The use of MDMA or Ecstasy decreased by almost fifty percent for the three grades combined in that same time period Also encouraging was the fact that tobacco use among this population was the lowest in the 28 year history of the survey.

NEWS FOR CONCERN: PRESCRIPTION DRUG ABUSE CONTINUES

There was also some disturbing news last year about youth drug use, showing very high rates of abuse of prescription pain killers (e.g., Vicodin® and OxyContin®). Remarkably, 1 in 10 twelfth graders reported abusing Vicodin last

year, making it the second most widely abused illicit substance after marijuana in this population. Hospitals are also seeing more patients coming to emergency rooms for prescription drug abuse. According to data from SAMHSA, between 1994 and 2001 the number of emergency room mentions for hydrocodone and oxycodone increased 131 percent and 352 percent respectively. When used as prescribed, medications like Vicodin can be very effective, but when used improperly they can have very serious adverse health consequences including death from overdose. More research is needed to prevent, educate, and treat prescription drug abuse. Developing new medications that have no abuse or diversion potential is a high priority for NIDA.

Researchers are making progress in this area. Just last year, researchers developed a compound to selectively affect a cannabinoid receptor that is involved in regulating pain. Unlike many other receptors, this one is not found in the brain. When the compound (AM1241) was given to animals, they were less sensitive to several forms of painful stimulation. Not only does this research open up a new arena for pain medication development, but it also sets the stage for developing new medications that are less likely to be abused. Also, NIDA's investment in the development of buprenorphine/naloxone for treating opioid addiction, for example, provides an alternative medication for pain that has less diversion potential than that of other opiate analgesics, and exemplifies how science can help alleviate our Nation's problems.

RESEARCH ON THE CONSEQUENCES OF MARIJUANA, AND THE DEVELOPMENT OF NEW MEDICATIONS

Research continues to shed new light on the deleterious consequences of marijuana, the most abused illegal drug in the United States. Early exposure to marijuana, for example, has been found to increase the likelihood of a lifetime of subsequent drug problems. A recent study, published in the Journal of the American Medical Association of over 300 fraternal and identical twin pairs, who differed on whether or not they used marijuana before the age of 17, found that those who had used marijuana early had elevated rates of other drug use and drug problems later on, compared to their twin who did not use marijuana before age 17. This study reemphasizes the importance of primary prevention by showing us that early drug initiation is associated with increased risk of later drug problems, and it provides more evidence for why preventing marijuana experimentation during adolescence could have a big impact in preventing addiction.

We are also finding that a lifetime of heavy cannabis use can result in an overall dissatisfaction with oneself and with life for most users. Last year, researchers published data on the impact of long-term cannabis use on life achievement such as educational attainment and income. Significantly fewer of the heavy cannabis users completed college and more had household incomes of less than $30,000 compared to individuals who used marijuana minimally.

It is clear, more research is needed to curtail use of this drug. Although the number of marijuana treatment admissions has increased from 92,414 in 1992 to 255,394 in 2001, there are relatively few treatments that have been shown to be effective specifically for marijuana addiction. NIDA is encouraging researchers, as well as the pharmaceutical industry, to become more active in finding new medications for marijuana and for other drugs of abuse. With the fairly recent discovery of an endogenous cannabinoid system with specific receptors and endogenous ligands, the likelihood of finding new targets for medications development is increased. One form of a cannabinoid receptor antagonist (CB1-receptor) has already been developed by several pharmaceutical companies and is undergoing clinical investigation for the treatment of alcoholism and nicotine addition, as well as obesity. Moreover, preliminary data in humans has shown that it can block the effects of marijuana.

ACCELERATING RESEARCH DISCOVERIES BENCH TO BEDSIDE: BEDSIDE TO COMMUNITY NIH ROADMAP AND OTHER INITIATIVES

For science to be useful in preventing and treating addiction this knowledge has to reach the communities. This is an area where NIDA continues to excel. Over the past few years, NIDA has established and strengthened strong collaborative relationships with a number of government agencies, including the Substance Abuse and Mental Health Services Administration (SAMHSA) to build national infrastructures that can facilitate the flow of research into community practice. NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), which now serves 27 states plus the District of Columbia and Puerto Rico, and the more newly established National Criminal Justice Drug Abuse Treatment Study (CJ-DATS) exemplify

NIDA's commitment to bringing science out of the laboratory and to the community. These initiatives parallel and complement those proposed as part of the NIH Roadmap, including the promotion of interdisciplincary research and the development of improved infrastructures for clinical research, which aim to accelerate the advancement of research discoveries from the bench to the bedside and to the community.

GETTING THE MEDICAL COMMUNITY MORE INVOLVED IN SCREENING AND ADDRESSING HIV/AIDS AND OTHER DRUG ABUSE CONSEQUENCES

Because drug abuse begins in youth and most pediatricians and family physicians typically do not ask questions about drug use, NIDA has launched a Primary Care Outreach Initiative to educate pediatricians and other primary care physicians about the importance of early detection and treatment. The medical community is also being reminded of the need to recognize substance abuse and addiction as disorders that will affect the course of other diseases, including mental illness, cancer, cardiovascular and pulmonary diseases, trauma and infectious diseases. Injection drug use has directly and indirectly accounted for more than one-third (36 percent) of AIDS cases in the United States. Data show that drug abuse treatment can reduce activities related to drug use that increase the risk of getting or transmitting HIV. Also the fact that the health and social consequences of drug abuse, including HIV/AIDS, disproportionately affect racial and ethnic minority populations; for example almost half of HIV/AIDS cases occur in African Americans even though they constitute only 11 percent of the population according to the latest Census data, which highlights the urgency to conduct research that can benefit all populations. (See Figure 3.)

Using our established networks (CTN and CJ-DATS), NIDA is strengthening its commitment to attend to associated health problems like HIV/AIDS, hepatitis and co-morbidity that often accompany substance use. The CTN, for example has a number of treatment protocols underway that address HIV/AIDS and hepatitis. Also, because data suggest that the prevalence of HIV and other infectious diseases is high among drug users in the criminal justice system, with HIV seropositivity rates estimated to be 8–10 times higher than in the general population, NIDA is encouraging more research to prevent and treat the spread of HIV/AIDS and other diseases among individuals in the criminal justice system with substance abuse related problems.

CONCLUSION

Our Nation's investment in drug abuse research is showing reductions in drug abuse rates and its deleterious consequences at the individual, family, and community level. A continued commitment to medical research, and to working with other agencies and sectors, will lead to new advances, technologies and innovations that will result in a healthier population.

Figure 1.

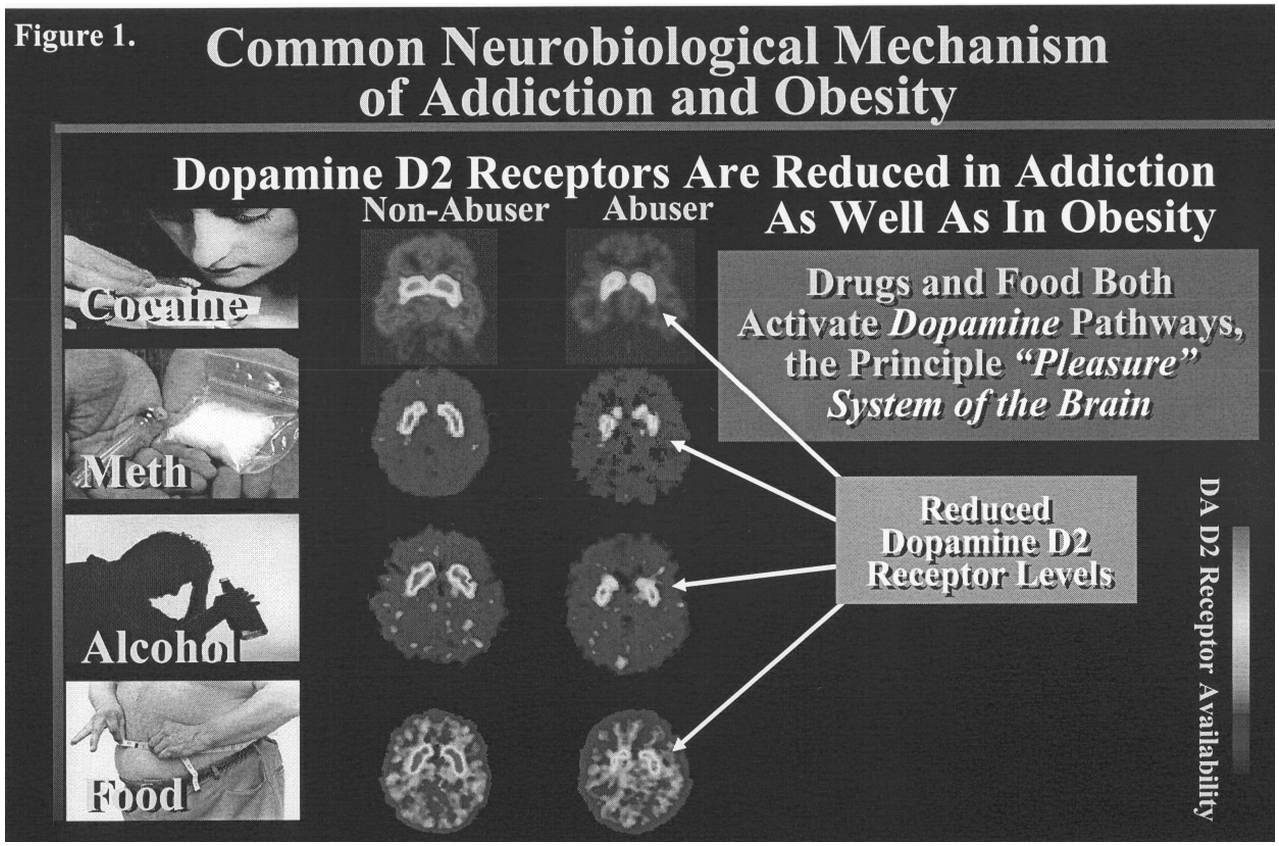

Common Neurobiological Mechanism of Addiction and Obesity
Dopamine D2 Receptors Are Reduced in Addiction As Well As In Obesity
Non-Abuser
Abuser
Cocaine
Meth
Alcohol
Food
Drugs and Food Both Activate Dopamine Pathways, the Principle "Pleasure" System of the Brain
Reduced Dopamine D2 Receptor Levels
DA D2 Receptor Availability

Figure 2.

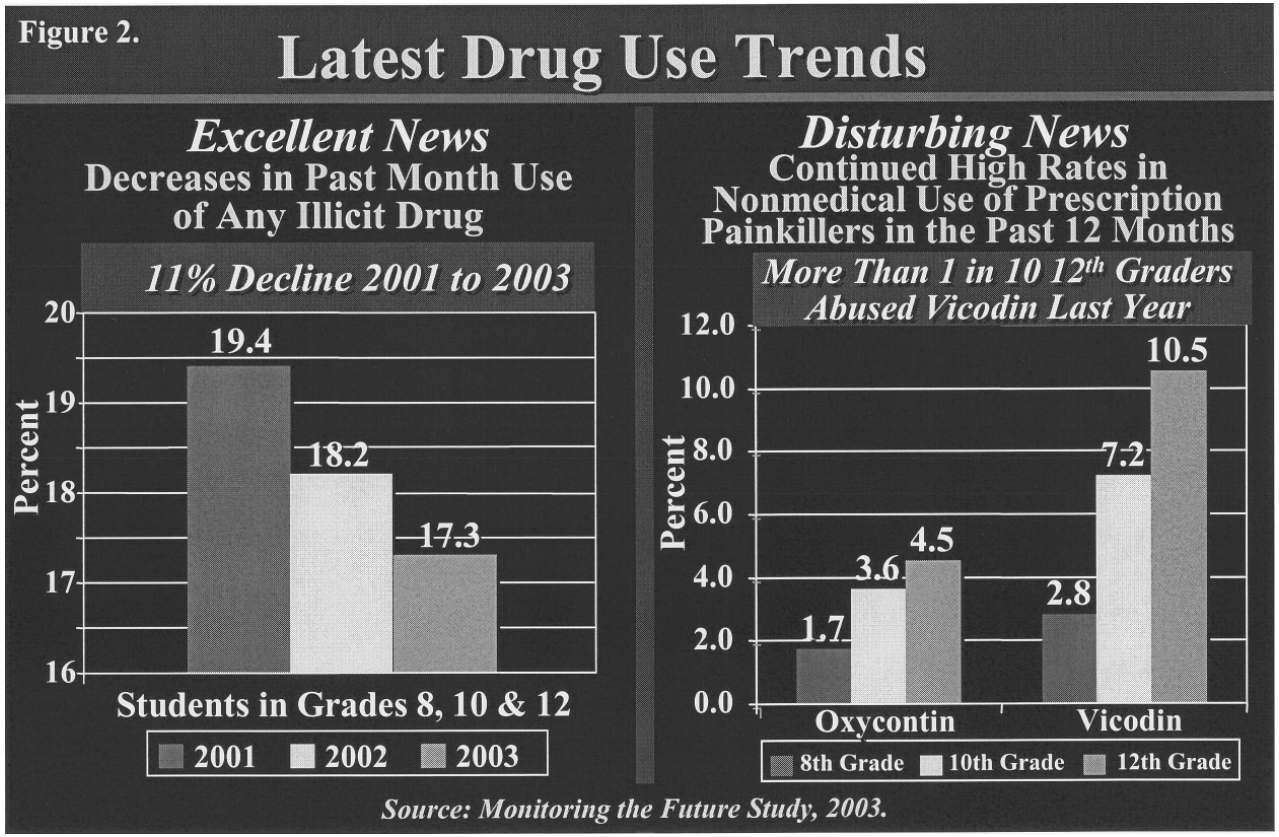
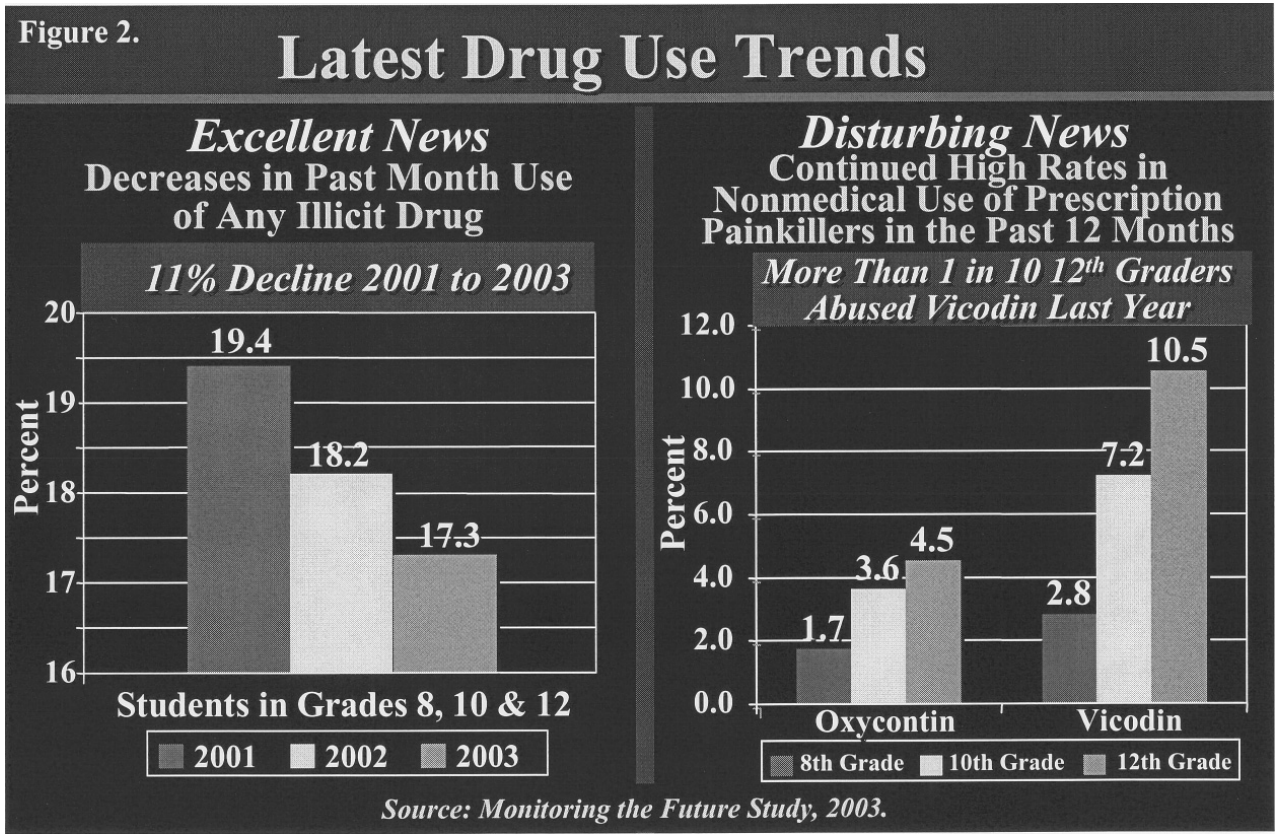

Latest Drug Use Trends
Excellent News
Decreases in Past Month Use of Any Illicit Drug
11% Decline 2001 to 2003
Percent
20
19
18
17
16
19.4
18.2
17.3
Students in Grades 8, 10 & 12
2001
2002
2003
Disturbing News
Continued High Rates in Nonmedical Use of Prescription Painkillers in the Past 12 Months
More Than 1 in 10 12th Graders Abused Vicodin Last Year
Percent
12.0
10.0
8.0
6.0
4.0
2.0
0.0
1.7
3.6
4.5
2.8
7.2
10.5
Oxycontin
Vicodin
8th Grade
10th Grade
12th Grade
Source: Monitoring the Future Study, 2003.

Figure 2.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Source: Monitoring the Future Study, 2003.

PREPARED STATEMENT OF DR. JEREMY M. BERG

Mr. Chairman and Members of the Committee, good morning. I am pleased to present the President's budget request for the National Institute of General Medical Sciences (NIGMS). The fiscal year 2005 budget includes a sum of approximately $1,960 million which reflects an increase of $55 million over the fiscal year 2004 enacted level of $1,905 million.

CROSS-CUTTING AND CUTTING-EDGE RESEARCH

Both before joining NIGMS as its new director last November and since then, I have been tremendously impressed by the Institute's leadership in supporting basic biomedical research—that is, scientific studies into the most fundamental biological processes that govern human health. The kinds of research that we fund are both cross-cutting and cutting-edge. NIGMS-supported studies have shed light on everything from the three-dimensional structures of individual proteins—life's building blocks—to the complex interactions between molecules inside cells. More importantly, by uncovering the previously hidden workings of this cellular machinery, not only do we gain a better understanding of the very basis of human health, but we also gain valuable clues to fixing this machinery when it goes awry. Those clues are essential in helping scientists develop better methods to diagnose, treat, and even prevent a wide range of human diseases.

NIGMS has a successful track record of supporting the nation's brightest minds in basic biomedical science. Perhaps the highest recognition of that success can be seen in the number of Nobel Prizes that NIGMS grantees have won over the past four decades: a remarkable 55 to date. This past year was no exception. Roderick MacKinnon, M.D., a biophysicist at the Rockefeller University and a long-time NIGMS grantee, won the 2003 Nobel Prize in chemistry for discovering the structure and function of membrane ion channels—the "gatekeepers" that control what essential molecules move in and out of cells. MacKinnon's breakthrough provides direct visualization of the basis for the electric circuits that are responsible for the functioning of our brains and the beating of our hearts. The detailed structural information is revealing how local anesthetics work and why some drugs have life-threatening cardiac side effects. The work of literally thousands of other researchers has been redirected in response to his discoveries.

NIGMS' impressive return on investment in basic biomedical research is also evidenced by the many other prestigious awards honoring our grantees. In 2003, Rockefeller researcher C. David Allis, Ph.D., won the third annual Wiley Prize in the Biomedical Sciences for his work on chromatin, the complex of DNA with proteins that packages genetic information inside each cell nucleus. The structure of chromatin is largely responsible for why one cell is a nerve cell while another cell is a muscle cell, even though they contain exactly the same DNA sequence. Allis' studies of the chemical modifications that regulate chromatin hold promise for learning how to control genes that suppress and inhibit the growth of tumors in cancer. The previous year, two other NIGMS grantees—Andrew Z. Fire, Ph.D., of the Stanford University School of Medicine, and Craig C. Mello, Ph.D., of the University of Massachusetts Medical School—were among the winners of the second annual Wiley Prize for their groundbreaking discovery of gene silencing by a mechanism called RNA interference. The phenomenon of RNA interference is the subject of upcoming meetings at both the National Academy of Sciences and NIH because of its potential impact for both basic research and for entirely novel approaches to preventing and treating disease.

Even greater advances in biomedical science are possible in the years to come. Through forward-thinking programs designed to foster innovative research and train the next generation of pioneering scientists, NIGMS is playing a leading role in the NIH Roadmap for Medical Research—the exciting new vision of the future recently launched by NIH director Elias Zerhouni, M.D. I would like to share with you some of the key strategies we have developed to help realize this important vision.

BLAZING A TRAIL FOR THE NIH ROADMAP

Throughout its history, NIGMS has helped push back the frontiers of medical knowledge primarily by funding the most promising research grant applications submitted by both new and established scientists. This so-called investigator-initiated research—supported through the NIH's R01 grant mechanism continues to be the most important instrument NIGMS has to promote experimentally based, hypothesis-driven research—the heart of our nation's scientific mission.

In recent years, NIGMS launched a number of larger, targeted initiatives to address both significant opportunities and critical gaps in biomedical research today. In many ways, programs such as NIGMS' Protein Structure Initiative (PSI), its large-scale collaborative "glue grants," and its new Center for Bioinformatics and Computational Biology have blazed a trail for the NIH Roadmap. Today, NIGMS is well positioned to participate with other NIH institutes in transforming the nation's biomedical research capabilities and accelerating the translation of scientific discoveries from the bench to the bedside.

Structural biology is part of the Roadmap's New Pathways to Discovery theme, and NIGMS is playing a key role in this area. One major activity is the PSI, an ambitious 10-year project launched in 2000. The aim of the PSI is to solve the three-dimensional structures of thousands of proteins experimentally and ultimately produce computer-based tools for modeling the 3-D structure of any protein from its genetic spelling, or sequence. Knowing the structures of proteins helps scientists understand how these molecules function in health and disease and aids in the development of new medicines.

Results from the nine pilot centers set up in the first phase of the PSI are promising, demonstrating that automated protein production "factories" are feasible and are yielding high-resolution data that is already being used by scientists around the world. This year, NIGMS plans to ramp up the PSI in its second phase, with the funding of large-scale centers that will dramatically reduce the time and cost of solving protein structures, as well as specialized centers that will tackle challenging problems such as membrane proteins and protein complexes.

NIGMS is also contributing substantially to Roadmap-related initiatives through its support of research aimed at unraveling the complexities of living systems. In 2003, the Institute awarded its fifth glue grant, bringing together a diverse team of scientists to assemble a complete picture of lipids—fats and oils—inside cells, and the role they play in heart disease, arthritis, and other major illnesses. Other ongoing glue grants awarded since the program started in 2000 include projects aimed at understanding cellular signaling and communication, cell movement, and inflammation and the way the body responds to injury.

Last year, NIGMS also added two new Centers of Excellence in Complex Biomedical Systems Research. At these centers, interdisciplinary teams of researchers from both the biological and physical sciences will focus on the emerging field of "systems biology," which seeks to find hidden patterns of biological interactions at all levels, from individual proteins to entire organisms. The new centers join two others launched the previous year with NIGMS funding.

COMPUTER-BASED SOLUTIONS TO BIOMEDICAL CHALLENGES

Harnessing the power of computers to solve complex problems in biology is another major theme in both the NIH Roadmap and NIGMS' research mission. In 2003, the Institute's recently created Center for Bioinformatics and Computational Biology welcomed its first director, Eric Jakobsson, Ph.D., a leading researcher in the field from the University of Illinois at Urbana-Champaign. Dr. Jakobsson has been instrumental in launching one of the first Roadmap initiatives, a program to fund the creation of NIH National Centers for Biomedical Computing. The centers will bring together computer scientists, biomedical researchers, and experts from the experimental, clinical, and behavioral sciences to tackle such challenges as developing computer simulations that will accurately model the complex inner workings of the human brain and other vital systems.

One of the most exciting prospects for computational biology is the promise of turning the vast amounts of data generated by the Human Genome Project into promising new medical treatments that are tailored to the individual. As Allen D. Roses, M.D., senior vice-president of genetics research at GlaxoSmithKline, recently observed, "The vast majority of drugs—more than 90 percent—only work in 30 to 50 percent of the people." NIGMS is addressing this critical issue through the Pharmacogenetics Research Network, a nationwide collaboration of scientists from academia, government, and industry that the Institute spearheaded in 2000, with additional funding from five other NIH institutes. The network has already produced a key computer-based resource that scientists are now actively using: the Pharmacogenetics and Pharmacogenomics Knowledge Base (PharmGKB). With this and other tools at their disposal, scientists will be able to study the effect of genes on people's responses to a wide variety of medicines including antidepressants, chemotherapy, drugs for asthma and heart disease, and many others. The ultimate goal of pharmacogenetics research is to help tailor medicines to people's unique genetic make-ups, thus making medicines safer and more effective for everyone.

Computational biology is also at the heart of another NIGMS initiative: the Models of Infectious Disease Agent Study (MIDAS). An integral component of the overall NIH biodefense plan, MIDAS is a network of scientists who will produce user-friendly computational models for policymakers, public health workers, and other researchers to assist them in making better-informed decisions about emerging infectious diseases. The first centers funded through the MIDAS initiative will launch this year and are expected to contribute significantly to our ability to prevent, detect, and respond to new infectious diseases, either natural or human-made.

Other NIH Roadmap-related initiatives include NIGMS' program to establish high-quality chemical libraries that provide scientists with powerful tools for discovering potential new drugs, and a portfolio of grants designed to stimulate the development of new molecular imaging technologies that can be harnessed to visualize the actions of individual molecules over time in living cells. The effort to create, distribute, and apply these tools will be tremendously enhanced by initiatives that are part of the Roadmap.

TEAM SCIENCE AND INTERDISCIPLINARY TRAINING

The increasingly complex nature of biomedical research today demands new approaches to carrying out the scientific enterprise. NIGMS has been at the forefront of addressing this issue, especially in its support for "team science"—interdisciplinary research that seeks to combine the skills and expertise of scientists from diverse fields and backgrounds. And now as part of another major theme in the NIH Roadmap—Research Teams of the Future—NIGMS is bringing its own experience to the table to help build successful synergies in large-scale research collaborations, and to help prepare the next generation of biomedical scientists trained in multiple disciplines.

For example, NIGMS has led the way in supporting cross-disciplinary research and training through its Medical Scientist Training Program—which leads to the combined M.D.-Ph.D. degree and produces investigators who can bridge the gap between basic and clinical research. Other NIGMS programs support training in the cellular, biochemical, and molecular sciences; systems and integrative biology; the pharmacological sciences; genetics; molecular biophysics; biotechnology; the chemistry-biology interface; and bioinformatics and computational biology.

Many NIGMS research and training programs combine both the biological sciences—cellular and molecular biology, genetics—and the quantitative sciences—physics, chemistry, engineering, mathematics. Indeed, bringing together these two scientific cultures is essential if we are to continue to make important advances in biomedical research in the 21st century. That growing realization has spurred a flurry of activity in recent years. For example, NIGMS joined forces with the National Science Foundation in 2002 to launch an initiative to encourage the use of mathematical tools and approaches to study biology. NIGMS is also partnering with the NIH Office of Science Education on a program to transform undergraduate biology education by incorporating examples and perspectives from the quantitative sciences into biology courses. This program responds to the National Research Council's Bio2010 report.

NIGMS also has a long-standing commitment to increasing the number of underrepresented minorities engaged in biomedical research. Through our Division of Minority Opportunities in Research, NIGMS takes a leading role at NIH to encourage and prepare minority students to pursue training for scientific careers and to enhance the science curricula and faculty research capabilities at institutions with substantial minority enrollments. Both these programs and the efforts to train and recruit more scientists from the physical sciences into biomedical research are essential if we are going to have the biomedical workforce necessary to solve the challenging problems that lead to human disease and drive up the costs of providing health care.

BALANCING LARGE- AND SMALL-SCALE SCIENCE

As promising and worthwhile as these major initiatives are, we must not lose sight of NIGMS' mainstay over the past four decades: investigator-initiated research. By encouraging the best and brightest basic scientists to pursue new directions in their fields, NIGMS has made tremendous contributions to advancing biomedical science. It is often a single investigator, supported by a single grant, who discovers something that turns out to be the tip of a very important iceberg. And we must continue to support these creative minds in order to sow the seeds for tomorrow's advances.

At the same time, we must recognize the need to invest strategically in targeted, larger-scale research to meet the critical needs of ensuring the nation's health and

well-being, its technological competence and competitiveness, and its security. In short, we need to balance small- and large-scale science in a way that both catalyzes and capitalizes on innovation. With our experience in managing thousands of individual research grants every year along with a growing number of multi-institutional, multidisciplinary research efforts, NIGMS can strike that balance while leaving open the door to future directions that are still beyond our powers of prediction.

Thank you, Mr. Chairman. I would be pleased to answer any questions that you may have.

PREPARED STATEMENT OF DR. STORY C. LANDIS

Mr. Chairman and Members of the Committee, I am Story Landis, Director of the National Institute of Neurological Disorders and Stroke (NINDS). I am pleased to present the President's budget request for NINDS for fiscal year 2005. The fiscal year 2005 budget includes $1,546,623,000, an increase of $44.9 million over the fiscal year 2004 enacted level of $1,500,693,000 comparable for transfers proposed in the President's request.

The mission of the NINDS is to reduce the burden of neurological disorders by finding ways to prevent or to treat these diseases. When I began as Director about six months ago, one of my first priorities was to meet with voluntary groups representing patients and their families. So far, I have met with more than 40 groups, and this remarkable experience has educated me about the extraordinary range of diseases within the NINDS mission, the power of their impact, and the urgency of finding ways to prevent or treat these disorders. These discussions also reinforce the importance of increasing public-private partnerships, which is a goal of our Institute, as well as a major focus of the NIH Roadmap process.

My own research has focused on fundamental questions about how the nervous system develops how genes help wire up connections in the brain, how cells choose to become a particular type, and whether there is any "plasticity" in this process. Issues such as these, long central to basic neuroscience research, are now at the crux of efforts to devise treatments for neurological diseases. I am encouraged by the prevention and treatment strategies emerging from the investment in basic research drugs to home in on the molecules that cause disease, stem cells to repair the damaged nervous system, natural neurotrophic factors to promote survival and growth of brain cells, "vaccines" to prevent stroke, implantable stimulation devices to compensate for brain circuits unbalanced by disease, therapies to turn off, repair or replace defective genes, neural prostheses to read control signals directly from the brain, and behavioral and drug interventions to encourage the "plasticity" of the brain and spinal cord to compensate for damage. The NINDS must continue to support basic research. We must also re-energize our efforts to translate opportunities into practical therapies. Today I will highlight a few of the ways we are working to bring people and resources together to accomplish that.

STEM CELLS

Neural stem cell biology is one area in which basic science and clinical promise are so closely intertwined that it is easy to forget the origins of our understanding of neural stem cells in very basic research. The generation of new neurons in the adult brain was discovered when a basic scientist sought to understand how male canaries learn a new song each spring. This year, NINDS researchers have contributed to advances in identifying and isolating adult neural stem cells, in understanding the signals that control embryonic and adult neural stem cells, and in developing stem cell therapies in animal models that show promise for Parkinson's disease, demyelinating diseases, such as Canavan, Krabbe, or Tay-Sachs, and many other disorders. The NINDS has helped foster research on embryonic and adult stem cells through several initiatives, including training programs in the use of approved human embryonic stem cells, grant supplements to compare these to cells from other sources, and scientific workshops. An NINDS intramural researcher also leads a new NIH facility that is characterizing the approved human embryonic stem cell lines. For the coming year, an initiative targeting collaborative research in stem cell biology, designed to bring together teams of experts from several areas of stem cell biology, is a high priority.

GENES AND THE NERVOUS SYSTEM

Genetics is another neuroscience research area that has made astonishing progress. Overall, researchers have identified more than 200 genes that can cause neurological disorders. Gene findings in the past year are relevant to diseases such

as Parkinson's disease, Charcot-Marie-Tooth disorder, and cerebral cavernous malformations, which can predispose people to strokes. Discoveries such as these lead to improved diagnosis, development of animal models, and the first clues to what underlies disease processes and how to stop them.

Several NINDS efforts bring people and resources together in genetics. Some are simple, but important, such as programs to promote sharing of transgenic mice that are essential models of human diseases. Others are more ambitious, such as the Gene Expression Nervous System Atlas (GENSAT) project, which will map the activity of thousands of genes in the brain and provide genetically engineered mouse strains that allow scientists to study how these genes contribute to health and disease. Microarray screening centers make another new technology and the data arising from it widely available. Microarrays allow scientists to simultaneously monitor the activity of virtually all genes, with wide potential applications to basic and clinical neuroscience; for example, recent studies show micrarrays may predict which patients will respond to approved drugs for multiple sclerosis. The NINDS Human Genetics Resource Center, established this year, makes DNA samples, immortalized cell lines, and accompanying clinical and pedigree data available to all qualified researchers. The repository currently contains samples related to stroke, epilepsy, Parkinson's disease, and motor neuron diseases, including amyotrophic lateral sclerosis (ALS) and spinal muscular atrophy (SMA).

TRANSLATIONAL RESEARCH

"Translational research" encompasses the many steps that are needed to move from basic research insights to a therapy that is ready for human testing in clinical trials, and the NINDS has a long history of programs in this arena. For example, over three decades, the Neural Prosthesis program has supported research on electronic and mechanical devices that help compensate for abilities lost through disease or injury, including pioneering research on direct brain control of prostheses, which has recently become a focus of such forward thinking agencies as the Defense Advanced Research Projects Agency (DARPA). The NINDS has responded to increasing opportunities by developing a comprehensive translational research program that fosters cooperative efforts, provides peer review criteria tailored to the needs of translational research, and utilizes milestone driven funding, which is common in industry. In fiscal year 2003, the Institute funded the first projects in this program, focused on gene and stem cell therapies for Parkinson's disease, neuroprotectants for stroke and trauma, treatments for brain tumor, and drugs for epilepsy, ALS and Huntington's disease.

DRUG DEVELOPMENT FOR NEUROLOGICAL DISORDERS

New and expanding efforts to develop drugs complement the broad translational program. The NINDS has awarded a contract for a high throughput screening (HTS) facility, and solicited proposals for the development of disease-related screening tests. HTS uses robotics to rapidly test large numbers of chemicals to find lead compounds for drug development and use as research tools. Ongoing screening efforts focus on ataxia telangiectasia, ALS, and Parkinson's disease. Several NIH institutes are working together to develop chemical libraries focused on the brain, and the NIH Roadmap "Molecular Libraries" component will directly facilitate screening efforts such as these.

Another NINDS drug development effort is a longstanding public-private partnership. Since 1975, the NINDS Anticonvulsant Screening Project has worked with more than 140 companies and 230 academic institutions to test more than 20,000 compounds for anti-convulsant properties, including several drugs now in clinical use. Guided by the epilepsy benchmarks planning process, the Institute is expanding this program with increased focus on preventing the development of epilepsy and on treatment-resistant epilepsy. The NIH Roadmap "Structural Biology" goals to improve our understanding of membrane proteins, such as ion channels that are implicated in some types of epilepsy and neurotransmitter receptors that are often the targets for drugs, will have an important impact on future efforts to develop drugs for this and many other neurological disorders.

Some drugs developed for epilepsy have shown promise for other diseases, such as chronic pain. To take advantage of that kind of crossover, observed in many areas of medicine, the NINDS worked closely with academia and voluntary disease organizations to develop a consortium of 26 laboratories to screen a set of 1,040 known drugs, mostly approved by the U.S. Food and Drug Administration (FDA) for other uses, for potential use against neurodegenerative diseases. The Consortium is sharing data on 29 laboratory screening tests based on molecules, cells in culture, or

simple organisms. Several promising drugs have moved to further testing in animals, and a few may move soon to clinical trials.

PROGRAM TO ACCELERATE THERAPEUTIC DEVELOPMENT FOR SMA

Valproic acid is one example of a drug, now used for the treatment of epilepsy, that in the past year has shown promise in cell culture for a different disease, spinal muscular atrophy (SMA). SMA is the most common single gene cause of infant mortality. In recent years, scientists have discovered the gene defects that cause SMA, developed animal models that mimic essential aspects of the human disease, and devised plausible strategies for developing therapies. Because of the impact of SMA and the state of the science, the NINDS chose this disease as the focus of an innovative approach, initiated in fiscal year 2003, to expedite the development of therapies. The performance-based contract mechanism accelerates all steps from recognition of a research need, through solicitation and review, to funding of targeted research subprojects, with guidance by an expert steering committee that takes a very active role in driving the process. If successful, this approach might be applied to other diseases.

MUSCULAR DYSTROPHY AND CENTERS PROGRAMS

The muscular dystrophies are another group of inherited disorders that are a high priority for NIH. Researchers, beginning more than a decade ago, have identified defects in several genes that can cause the various kinds of muscular dystrophy. These findings have brought improved understanding of what causes these diseases, better animal models to develop therapies, and some practical benefits for example, a new diagnostic test for Duchenne muscular dystrophy will eliminate the need for painful muscle biopsy in many children, and help identify female carriers of the disease before they pass it on to their sons. Therapies to slow or stop muscular dystrophies have been elusive, but there have been encouraging results recently in animals using drugs, stem cells, and gene therapy approaches. To expedite progress against the muscular dystrophies, the NIH has funded three Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, with the expectation that up to three more will be funded competitively in fiscal year 2005. The NIH is also working together with the broadly representative interagency Muscular Dystrophy Coordinating Committee (MDCC) on developing a muscular dystrophy research and education plan for NIH.

The NINDS, often working with other components of NIH, has several centers programs, such as the Morris K. Udall Parkinson's Disease Centers of Excellence, the Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS), the Studies to Advance Autism Research and Treatment (STAART), and the Specialized Neuroscience Research Program (SNRP), which encourages minority scientists and addresses health disparities in neurological disorders. Other centers focus on disorders such as brain tumor, spinal cord injury, and head trauma.

CLINICAL TRIALS

The NINDS continues to set standards of quality and innovation in clinical trials that evaluate whether potential treatments or preventive measures are safe and effective. One recent example, the Neuroprotection Exploratory Trials in PD (NET-PD), was launched in April 2003 to evaluate drug therapies that might slow the progression of Parkinson's disease. The project rigorously selected candidate drugs from a broad array of potential compounds identified by working with clinicians and researchers throughout academia and industry. The 42 clinical sites have recruited individuals with early, untreated Parkinson's, and early phase trials of four drugs will be completed in early 2005. In the coming year, the NINDS clinical trials program is also working to train researchers to conduct clinical trials and to develop a broad clinical trials network that will encompass the greater community of neurologists. Clinical trials for neurological disorders is another area in which the cross-cutting NIH Roadmap efforts for "Re-engineering the Clinical Research Enterprise" are likely to have a major impact.

INTRAMURAL PROGRAMS

Before becoming the director of NINDS, I led the Institute's intramural program on the NIH campus in Bethesda, MD, which is one of the largest basic and clinical neuroscience programs in the world. In addition to recruiting superb individual scientists in fields such as ion channels, genetic diseases of the nervous system, brain tumors, and stroke, a central focus of the program has been to bring researchers together from disparate fields of science. To this end, the Porter Neuroscience Re-

search Center, opening its first phase in 2004, brings together scientists from eight institutes to "put the brain back together" by overcoming artificial disciplinary boundaries within and across institutes and by setting the standard for collaborative research in neuroscience.

FUTURE COOPERATIVE EFFORTS

I have mentioned a few areas in which the NIH Roadmap efforts will facilitate our efforts against neurological diseases, but the same can be said of virtually every major effort within the Roadmap. Driven by the science, several NIH components that have a major focus on the brain are also increasingly working together to form a "blueprint for the brain," in which cooperative efforts across Institutes can expedite progress. These Institutes already cooperate extensively in areas such as training of researchers, genetics, autism, muscular dystrophy, health disparities, brain tumors, stroke, and pediatric neuroimaging, to name a few examples. I hope to report to you in the future about progress in forming other cooperative ventures aimed at our common goal of finding better ways to prevent or to treat all disorders that affect the brain and other parts of the nervous system.

Thank you, and I would be pleased to answer questions.

PREPARED STATEMENT OF DR. STEPHEN E. STRAUS

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2005 budget request for the National Center for Complementary and Alternative Medicine. The fiscal year 2005 budget includes $121.1 million, an increase of $4.2 million over the comparable fiscal year 2004 appropriation of $116.9 million.

INTRODUCTION

Five years ago, recognizing the increasing public health opportunities of complementary and alternative medicine (CAM) and the challenges to research in this area, Congress elevated the NIH Office of Alternative Medicine to the National Center for Complementary and Alternative Medicine (NCCAM). Several months later, as NCCAM's first Director, I articulated a set of priorities for the Center that emphasized growth in the portfolio of rigorous research project grants, enhanced investments in research training and careers awards to build an effective CAM research collective, creation of an intramural research program (IRP), and commitment of stable funding for research centers. As we embark on planning our second 5 years of work, I am pleased to report that NCCAM has achieved these and many other critical objectives.

NCCAM's success to date is evident in some of its vital statistics:

—Under the President's proposed fiscal year 2005 budget, NCCAM's investment in research project grants will have increased from approximately $10 million in 1999 to almost $76 million, while funding for research training and career awards will have increased from under $1 million in 1999 to approximately $8.8 million.

—In collaboration with other NIH Institutes and Centers (ICs), NCCAM has launched nine multi-center Phase III clinical trials of popular CAM interventions for chronic illnesses that affect so many Americans, including osteoarthritis, dementia, cancer, and coronary artery disease.

—NCCAM established an intramural research program in 2001, which studies CAM approaches to diseases of aging, including arthritis, depression, muscle wasting, cancer, pain, and diabetes.

—Based on a comprehensive external review, NCCAM refined its research centers program to support rigorous investigations at both traditionally research-intensive and CAM institutions. In 2003, NCCAM made its first round of revised center awards in three categories: Centers of Excellence for Research on Complementary and Alternative Medicine, Developmental Centers for Research on Complementary and Alternative Medicine, and Planning Grants for International Centers for Research on Complementary and Alternative Medicine. NCCAM's Centers program will foster capacity in CAM research, catalyze more effective and essential partnerships between CAM institutions and research-intensive universities, and facilitate the integration of effective CAM therapies with conventional medical approaches.

Already, the nearly 800 projects that NCCAM has supported since 1999 have yelded over 700 scientific publications, including some that were published in the most prestigious journals—*Journal of the American Medical Association, New Eng-*

land Journal of Medicine, and *Proceedings of the National Academy of Sciences.* Complementing these research and research training activities are extensive efforts to communicate research results and other critical information about CAM to the public and practitioners. NCCAM's award-winning Web site is visited over 1.5 million times each year for its 90 fact sheets, consumer alerts, news releases, and announcements of new research initiatives. In a partnership with the National Library of Medicine, NCCAM helped create a CAM subset on the reference database *PubMed* that now hosts nearly 400,000 reports about CAM studies, which are available to anyone with Internet access. In the aggregate, the investments made in NCCAM's first 5 years are already informing the health care decisions Americans make at home and in consultation with their practitioners.

In its first 5 successful years, NCCAM has become fully integrated within the NIH, developing a research agenda that is responsive to its mission, fiscally accountable, and supportive of rigorous CAM research. NCCAM's research priorities today encompass six thematic areas in which CAM can have a public health impact: obesity, botanicals, brain-body interactions, acupuncture, neurodegenerative diseases, and HIV/AIDS. The next section highlights some of the advances and activities in three of these priority areas.

ADDRESSING THE OBESITY EPIDEMIC

An alarming 65 percent of American adults,[1] 16 percent of adolescents, and 10 percent of American children are now overweight.[2] Obesity results from complex interactions among human biology, behavior, and the environment and, therefore, requires a multidisciplinary approach to prevent and treat it. NCCAM is contributing to the trans-NIH strategy to address this epidemic by supporting studies of the safety and efficacy of popular, but unsubstantiated, dietary approaches to obesity and its many complications. One of the most popular approaches today is the diet plan championed by the late Dr. Robert Atkins, which emphasizes a low-carbohydrate, high-fat, high-protein regimen.

In fiscal year 2003, NCCAM-sponsored researchers reported in the *New England Journal of Medicine* on a ground breaking 1-year, multi-center trial about the effects of the Atkins diet on weight loss and risk factors for cardiovascular disease. At 6 months, those on the low-carbohydrate diet had lost more weight and had reduced levels of blood lipids more than those on the conventional diet. At the end of 1 year, however, the differences between the two groups of dieters lessened, leading investigators to call for larger and longer-term studies. NCCAM is working with its NIH partners to support a larger and more definitive study.

In its intramural program, NCCAM researchers are testing whether the dietary supplement glucosamine, used by over 4 percent of older Americans for degenerative arthritis, causes resistance to insulin, a condition that predisposes one to diabetes—a disease linked to obesity. Other IRP studies are evaluating carnitine, a nutrient essential for the normal metabolism of fats, to see whether it can reduce abdominal fat content, stimulate weight loss, and improve glucose utilization.

In fiscal year 2005, as part of the overall trans-NIH focus on obesity, NCCAM will cosponsor two major initiatives in obesity research, *Neurobehavioral Basis of Obesity* and *Prevention and Treatment of Pediatric Obesity in Primary Care Settings.* The first seeks to bridge the gap between understanding the molecular and genetic regulation of food intake and behavioral influences on obesity. The pediatric initiative will evaluate preventive and therapeutic strategies for obesity that could be recommended for children and adolescents in primary care settings, such as a physician's office, primary care clinic, or HMO.

EXAMINING THE SAFETY AND EFFECTIVENESS OF BOTANICAL PRODUCTS

Approximately 14 percent of Americans use herbal supplements to prevent disease, maintain wellness, or treat illness or pain.[3] Many of these people also take prescription drugs. NCCAM-supported research is identifying herbal products that interact with drugs and the underlying biochemical mechanisms of these interactions. For example, studies have shown how St. John's wort and PC SPES (a botanical mixture that had been used to treat advanced prostate cancer) induce the

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[1] *Journal of the American Medical Association,* 288 (14): 1723–1727, Flegal *et al*, "Prevalence and trends in obesity among U.S. adults, 1999–2000"

[2] *Journal of the American Medical Association,* 288 (14): 1728–1732, Ogden *et al*, "Prevalence and trends in overweight among U.S. children and adolescents, 1999–2000"

[3] *Journal of the American Medical Association,* 287 (3); 337–344; Kaufman *et al.,* "Recent patterns of medication use in the ambulatory adult population of the United States: the Slone survey."

activity of a key liver enzyme that is responsible for the metabolism of some 80 percent of all drugs. This finding shows how herbal supplements have the potential to either enhance a drug's toxicity or reduce a drug's effectiveness when a patient takes both dietary supplements and prescription medication.

Each year in the United States, an estimated 70,000 people are diagnosed with head and neck cancers, which are typically resistant to multi-drug chemotherapy. In fiscal year 2003, NCCAM-sponsored researchers examined extracts from the root of *Scutellaria baicalensis*, a Chinese herb, for activity against head and neck cancers. The new study is promising because it shows that the herbal extracts strongly inhibit the growth of human head and neck cancer cells *in vitro* as well as in mice with tumors composed of human cells. Future studies will determine the herb's effects on regulating the cell replication cycle and whether it can be translated into a safe and effective intervention for head and neck cancer patients.

While some research studies confirmed the promise of certain botanicals, others have found herbs that do not deliver on their claims. One example is guggulipid, a botanical extracted from the resin of the mukul myrrh tree, that is marketed in the United States as a dietary supplement to help control blood cholesterol levels and maintain a "healthy heart." In an 8-week placebo-controlled study involving over 100 subjects, NCCAM-funded scientists found that neither the standard or even higher doses of guggulipid significantly lowered the levels of the key low-density lipoprotein (LDL) form of cholesterol in people with high blood cholesterol. This study highlights the need to study popular botanicals that the public is using so that individuals can make informed decisions regarding their own care.

In fiscal year 2005, NCCAM will co-sponsor three important initiatives on the use of botanicals as dietary supplements. Through a newly refined Botanical Research Centers Program being mounted with the NIH Office of Dietary Supplements and the National Institute of Environmental Health Sciences, NCCAM will support interdisciplinary studies of botanicals to generate evidence regarding their safety and potential public health benefits. NCCAM also plans to establish a Phase I Resource Center (PRC) to define the pharmacology and optimal dosing of botanical products and functional foods. Finally, in fiscal year 2005, NCCAM plans to initiate *in vitro*, animal, and preliminary clinical studies of *Silybum marianum* (milk thistle) and its derivative silymarin as a treatment for chronic hepatitis and cirrhosis of the liver, conditions that affect millions of Americans for whom, to date, there is no effective treatment.

Through these programs, NCCAM thoughtfully is investing in programs of basic research to discover natural products and food supplements that could open new avenues for prevention and treatment of conditions that affect the health, well being, productivity, and quality of life of millions of Americans.

INVESTIGATING BRAIN-BODY INTERACTIONS

NCCAM scientists are exploring ancient practices such as meditation, Tai Chi, hypnosis, and yoga to understand their abilities to harness the healing effects of the mind on the body. For example, NCCAM grantees are conducting pilot studies of yoga as a behavioral intervention for the management of chronic obstructive lung disease, insomnia, and chronic low back pain, as well as investigating whether one's spirituality and religiosity have a significant influence on immune system functioning.

In 2003, NCCAM-funded researchers reported that a traditional Chinese meditative exercise regimen, Tai Chi, could enhance physical performance and immune responses in older people. As people age, immunity to the virus that causes chicken pox wanes until the infection can reactivate from its dormant state in nerves and develop into the painful condition shingles. The study concluded that older adults who participated in a form of Tai Chi for 15 weeks experienced statistically significant increases both in ellular immune responses to the virus and in physical performance. This is the first scientific study to show that a CAM approach is responsible both for improvements in physical function and in virus-specific immunity and provides the basis for a larger study of Tai Chi currently being supported by NIH.

To further stimulate research in the field of brain-body interactions, NCCAM is a cosponsor of several NIH research initiatives. The first effort, entitled *Mind-Body Interactions and Health: Exploratory/Developmental Research Program*, will foster program development at institutions that have high potential for advancing mind-body and health research. The second initiative, *Research on Mind-Body Interactions and Health*, will support interdisciplinary collaborations and innovations to understanding the underlying processes of mind-body interactions and health and translating basic knowledge into interventions and clinical practices.

LOOKING FORWARD

Five years ago, the discipline of rigorous CAM research was in its infancy. Absent precedents for the field, NCCAM's initial efforts led to supporting an array of studies spanning numerous CAM practices and health conditions. In these first years, NCCAM found that to better ensure that its funds yield compelling results, it needed to encourage studies on mechanisms of action of CAM approaches, well-developed Phase I and II clinical trials as a foundation for future definitive studies, and collaborations between CAM and research-intensive institutions. In the coming years, the Center will refine its research priorities even more, to emphasize those areas and conditions for which CAM can have the greatest health impact. To this end, in 2004, NCCAM began a formal process to seek input from its many stakeholders, including the scientific community, health professionals, and the public to further target its research, training, and communication goals and to craft a long-term plan to guide the way toward its tenth anniversary.

Complementing this strategic planning process are the trans-NIH Roadmap for Medical Research activities in which NCCAM leadership has a significant role. Core themes of the Roadmap resonate strongly with NCCAM because they promise to provide NCCAM grantees access to more sensitive technologies, richer environments for learning and conducting interdisciplinary research, and a re-engineered platform for clinical trials, all in ways that small institutes and centers could never achieve on their own.

In the coming months and years, I look forward to sharing with members of the Committee, the scientific community, practitioners, and the public our second strategic plan and the results of the research and training investments that we have made. Thank you for your interest in NCCAM's progress and plans. I would be pleased to answer any of your questions.

PREPARED STATEMENT OF DR. KENNETH OLDEN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget for the National Institute of Environmental Health Sciences (NIEHS). The fiscal year 2005 budget is $650,027,000, an increase of $18,964,000 over the comparable fiscal year 2004 appropriation.

INTRODUCTION

Most complex diseases arise from the interplay between biology, environment and behavior. It is the NIEHS' mission to understand this interplay as it translates into increased disease risk. Thanks to the rare confluence of technology breakthroughs in analysis of genes and proteins and their recent application to the environmental health sciences, gene-environment interactions can now be investigated with more rigor and specificity. Our new opportunities within the framework of the NIH Roadmap also offer promise for a more rapid understanding and translation of this knowledge into improved public health. I will outline several of the NIEHS' most important efforts.

GENES AND ENVIRONMENT

There are two principal avenues for exploration of the complex interplay between genes and environment. One is to look at the variations of genes themselves, and the other is to examine how genes respond to environmental stressors. In the case of the first approach, NIEHS is conducting the Environmental Genome Project (EGP) an effort to resequence 544 "environmentally responsive" genes—genes which are thought to be involved in an individual's susceptibility to environmental exposures—and to identify alleles or genetic variants associated with these genes. The key objective of the EGP is to discover and characterize these alleles or genetic variants, called polymorphisms, and to define their roles in the pathways by which environmental agents exert their effects on human health and disease.

Last April, the EGP completed the first phase, publishing a catalog of variation in over 200 genes responsible for detoxifying environmental compounds such as pesticides, as well as metabolizing natural biological components such as hormones. Over 17,000 single nucleotide polymorphisms (SNPs) were identified, with more than 1,000 in coding sequences. This information is already being used to make significant scientific discoveries. For example, it was found that people suffering from benzene-induced leukemia lack a certain SNP in the gene responsible for utilizing a vitamin B, folate, that healthy people have. Thus, the ability to metabolize folate might relate to the relative risk of developing leukemia among benzene workers.

To aid in the functional characterization of SNPs in both coding and regulatory sequences of specific genes, NIEHS initiated the Mouse Genetic Variation Mapping Initiative. The mouse is the most widely used mammalian model system for the study of human health and disease for several reasons, including the fact that the genomes of mice and other mammals are highly conserved. Most human genes have counterparts in the mouse genome; thus, cloning of a gene in one species often leads to cloning of the corresponding gene in the other. The mouse also offers well developed toxicological and pathology databases and molecular genetic techniques for construction of gene knockout strains. Data generated using rodent models have been used widely in preparation of environmental regulatory policy and by the pharmaceutical industry.

One of the greatest challenges for comparative toxicogenomics is the integration of the vast amount of genomic information being generated for a variety of model organisms. At present, there are several disparate but complementary databases on genomic sequences. Most of these databases provide data on gene and genome sequences for individual animal species. These databases do not provide a means to link the genome data to specific environmental chemicals or to toxicological and biological endpoints. They also do not enable researchers to compare information about potentially similar genes and biological responses across multiple species.

Integrating the large number of disparate data sets is the goal of the Comparative Toxicogenomics Database (CTD). The CTD was developed through a collaboration of five NIEHS-funded Marine and Freshwater Biomedical Sciences Centers. The goal of the CTD is to develop a comparative database that links sequence information for genes that are relevant to toxicology to information about gene expression, toxicology and biological processes. The primary focus of the CTD is on marine and aquatic organisms as model systems for human diseases. The initial focus is also on genes that have been identified through the NIEHS' EGP as important for toxicology in these model systems. However, the database will eventually merge all gene sequence information generated on all vertebrates and invertebrates, including aquatic organisms, worms, flies, rodents, and people. The CTD provides information about gene curation and annotation (gene synonyms, sets and functions) and links between gene sequence and toxicity data published in the scientific literature. These aspects of the database represent an important advancement for comparative toxicogenomics. Understanding these mechanisms will allow more informed assessment of human risk by extrapolating toxicity data from animal models to people and will provide a mechanism by which members of the research community can share their data and promote fruitful avenues for future toxicological research.

At present, the CTD is the only fully curated, publicly available database of its kind in the world. However, it serves as a prototype database and data resource for more comprehensive efforts ongoing at the NIEHS. The centerpiece for these discoveries is the NIEHS' National Center for Toxicogenomics (NCT), which uses a multidisciplinary approach to identify genes and proteins affected by specific environmental exposures. When a person is exposed to a chemical, physical, or biological agent, cells in the body may respond by switching on some genes and switching off others, potentially changing the proteins that are produced by the cells. The on/off pattern of various genes is different for each specific exposure, creating a characteristic pattern or "signature," which scientists hope will be useful in classifying chemicals by their effects on various cellular processes. By constructing and populating a database of chemical effects on biological systems, the NCT is assisting the field of environmental health research to evolve into an information science in which gene and protein expression datasets are compiled and made readily available to the scientific community. By building on the data infrastructure being developed through the CTD and other databases, NIEHS scientists are developing the sequence-driven and context-documents Chemical Effects in Biological Systems (CEBS) knowledge base. CEBS is planned as a public toxicogenomics knowledge base that combines and integrates scientific data from a multitude of public domain data sources. These data sources include studies of genetic polymorphisms, gene expression and proteomics, metabolism and toxicology. Once sufficient high quality data have been accumulated and assimilated, it will become possible to characterize an unknown environmental exposure by comparing its gene and/or protein expression profile to compendia of expression profiles in the database. Ultimately, the NCT will develop the capacity to use gene expression signatures and other data to facilitate characterization of toxicants and their biological effects. Through the predictive capabilities expected from toxicogenomics, adverse toxicity in clinical trials will be reduced and the efficiency of bringing new therapeutics to the public will be increased; adverse effects from long-term use or from combinations of therapeutic agents will be better understood and reduced. The final payoff for investing in CTD and CEBS will be more rational environmental health policy and an improved un-

derstanding of gene-environment contributions to the major causes of human death and disease.

OBESITY AND ENVIRONMENT

Environment and behavior intersect in fundamental ways, intersecting with our biology but also with each other. In no area of public health is this more apparent than with the problem of obesity. There is a growing body of literature that illustrates the negative physical and mental health effects of unregulated and poor urban, rural, and suburban development and planning. These studies have documented increased rates of obesity, diabetes, depression, anxiety, and heart disease in these poorly developed areas. For example, in sprawling communities, higher dependence on motor vehicles has resulted in polluting the atmosphere with ground-level ozone and particulate matter, contributing to human health problems such as lung and cardiovascular disease. People most affected by air pollution include older adults with pre-existing diseases; children, especially those with asthma; persons with inadequate health care; and even healthy individuals who work and exercise outdoors. Lack of safe sidewalks in growing urban areas has resulted in a reduction in the number of children walking or biking to schools. Today, only 10 percent of children walk or bicycle to school—a 40 percent reduction over the last 20 years (according to researchers in *Urban Land*). Research suggests that inadequate urban planning, such as a lack of bike paths and sidewalks, results in a more sedentary lifestyle of children, which, in turn, may be a factor in the growing rates of childhood obesity. All of these examples demonstrate how the physical or built environment influences choices that ultimately affect health.

The NIEHS is designing a program as part of the trans-NIH obesity initiative which is designed to examine how the built environment affects obesity and the effectiveness of changes in community planning, design, and development in reducing the extent of obesity and associated comorbidities. These intervention research projects will develop tools to characterize and measure individual and population-level indicators of healthful communities—and of residents' lifestyles and behaviors—that prevent or reduce obesity. We hope that not only will studies of interaction between parameters of the built environment and individual lifestyle choices and behaviors help delineate factors that can prevent or reduce obesity, but also that this work will point the way towards new, cost-effective intervention strategies that promote healthful environments and behaviors.

In a related initiative, NIEHS is partnering with the Robert Wood Johnson Foundation to support a program called Active Living by Design, which will provide support to 25 communities across the country to implement active living programs, policies, and communication strategies to improve community development and promote more healthy lifestyles. The NIEHS is providing an evaluation component to the program to determine the efficacy of various policies and promotions in reducing obesity.

It is critical to delineate the role and impact of community design, planning, and development on individual and population health by understanding the contribution of urban/rural planning (i.e., land use decisions), housing structure, transportation issues, and the availability of public and green spaces as determinants of mental health, physical activity, nutrition, and access to healthy foods. In turn, modifying such parameters may reduce the prevalence of obesity in adults and children. This research effort will require integrated, interdisciplinary research teams, including biomedical scientists, behavioral scientists, social scientists, clinicians, epidemiologists, urban planners, developers, and architects, as well as active participation of community members. It is expected that such research will result in a greater understanding of the health benefits of living in communities that promote healthful environments and behaviors and may also impact policy for land use and public health.

TOXICOLOGICAL EVALUATION OF NANOSCALE MATERIALS

Nanoscale materials are a broadly defined set of substances where at least one critical dimension is less than 100 nm. Ultrafine particulate matter, e.g. the very smallest particles of soot from such sources as diesel exhaust, is a well-known example of ambient nanoparticles; however, this initiative will initially focus on manufactured nanomaterials of current or projected commercial importance. Nanoscale materials can in theory be engineered from nearly any chemical substance; semiconductor nanocrystals, organic dendrimers, and carbon fullerenes and carbon nanotubes are a few of the many examples. Nanoscale materials are already appearing in commerce as industrial and consumer products and as novel drug delivery

formulations. Commercial applications and resultant opportunities for human exposure may differ substantially for nanoscale vs. "bulk" materials.

Currently there is very little research focus on the toxicology of manufactured nanomaterials. Studies from the ultrafine particle inhalation toxicology literature hint at the complexity of the topic and suggest that nanoparticle size can impact toxicity equally if not more so than chemical composition. There are indications in the literature that manufactured nanomaterials may distribute in the body in unpredictable ways and that certain nanoparticles have been observed to preferentially accumulate in particular organelles. Surface properties can be changed by coating nanoparticles with different materials, but surface chemistry also is influenced by the size of the particle. This interaction of surface area and particle composition in eliciting biological responses adds an extra dimension of complexity in evaluating potential adverse events that may result from exposure to these materials.

The National Toxicology Program (NTP) is developing a broad-based research program to address potential human health hazards associated with the manufacture and use of nanoscale materials. The intent of the NTP/NIEHS research program is to evaluate the toxicological properties of major nanomaterials classes which represent a cross-section of composition, size, surface coatings, and physico-chemical properties, and use these as model systems to investigate fundamental questions concerning if and how nanomaterials can interact with biological systems. Some of these fundamental questions include: What are the appropriate methods for detection and quantification of nanoscale particles in tissues? How are nanoparticles absorbed, distributed in the body and taken up by cells? Are there novel toxicological interactions?

Discussion and review of efforts in this area has highlighted the need for studies of nanoscale materials that not only apply existing toxicology testing methodologies, but also explore the development of appropriate novel toxicological methods to adequately assess potential human health effects. The NIEHS is looking ahead to be able to supplement our critically inadequate knowledge of this rapidly emerging technology.

PREPARED STATEMENT OF DR. THOMAS R. INSEL

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 2005, a sum of $1,421 million, which reflects an increase of $39 million over the comparable fiscal year 2004 appropriation.

In my statement, I will call to your attention the immense burden on our Nation of mental and behavioral disorders. In addition, in the context of a brief review of our research activities and accomplishments, I will describe some of our efforts, in collaboration with trans-NIH initiatives, to bring new treatments from the laboratory to the clinical research arena and ultimately to widespread practice in the community.

BURDEN OF MENTAL ILLNESS

The National Institute of Mental Health faces an enormous challenge: to reduce the burden of mental and behavioral disorders through research on mind, brain, and behavior. Mental disorders are real illnesses that can be diagnosed and in many cases, treated effectively. The need is vast: 450 million people worldwide suffer from a mental disorder. Mental illnesses account for four of the top six causes of disability among 15–44 year olds in the Western world. By 2020, psychiatric and neurological conditions will have likely increased their share of the total global burden by almost half, from 10.5 percent to 15 percent.

In addition to morbidity, mental illnesses are a substantial source of mortality. Of the 30,000 Americans who die by suicide each year, 90 percent have a mental illness. Deaths from suicide outnumber deaths from homicide (18,000) as well as deaths from AIDS and most forms of cancer. Suicide is high among several ethnic minority groups, though remains highest in older white males. Between 1952 and 1992, the incidence of suicide among adolescents and young adults nearly tripled; currently it is the third leading cause of death in adolescents.

In addition to the emotional costs, the economic costs of mental illness are staggering. According to the recent report from the President's New Freedom Commission on Mental Health, the cost in the United States from both direct (treatment-related) and indirect (productivity loss) expenses may exceed $150 billion per year with rapid annual increases, especially in the drug treatment area. Adding to that, more than three million people are receiving disability benefits due to mental disorders. They constitute nearly 28 percent of disabled workers in the Social Security

Disability Insurance Program, and more than 35 percent of people with disabilities receiving Supplemental Security Income. Together they accounted for an estimated $25 billion dollars in cash benefits in 2001.

SCIENCE TO SERVICE

For many mental disorders, there is some form of treatment, but there is no cure. The report from the President's New Freedom Commission on Mental Health describes the need for transforming the delivery of evidence-based treatment and services to communities where they can directly benefit people with mental illness. To achieve this goal, NIMH recognizes the need for the research enterprise to partner with other organizations such as the Substance Abuse and Mental Health Services Administration (SAMHSA), state governments, and advocacy groups. In one such example, NIMH and SAMHSA recently funded nine one-year grants to state mental health agencies to support planning activities toward the implementation of evidence-based practices. Proposed science to service research activities include devising evidence-based group-focused activities for specific ages (child, adult); managing medication for those with schizophrenia; and providing cognitive behavioral therapy for people with depression. Each grant is expected to result in future research and service development initiatives. Translating scientific breakthroughs into far-ranging clinical care, we believe, is an urgent and achievable task.

PROGRESS IN GENETICS

In addition to applying what we already know, we must continue the scientific efforts required to develop better treatments to bring us closer to our ultimate goals of curing or preventing severe mental health disorders. To attain these ambitious goals, we will need a much larger variety of medications and behavioral therapies than are currently available—treatments that can be tailored to work for all those who need them, not just a small subset. As an initial first step, we must discover how genes and the environment interact to produce the biological variations that can signal vulnerability to disease. This year has been remarkable in its wealth of discoveries of genes as well as gene-environment interactions. In depression, for example, NIH-sponsored researchers found that a variation in the gene that regulates serotonin transmission can make a person more vulnerable to depression when faced with stressful life experiences. Those without the gene variation had no such vulnerability, and appeared to be resilient even in the face of many life stresses. Those with the gene variation were not depressed until and unless they faced major life stressors. This suggests that some of the environmental contributors to illness may only be detected by first identifying variations in genetic risk. Future research could help us apply this information to identify those most at risk, and develop treatments that either target genes or the environment, or both. It also suggests a new model with which to test genetic vulnerability and environmental stresses in other major diseases, such as schizophrenia, anxiety disorders, or eating disorders.

This year we have also seen exceptional progress in research on schizophrenia. Several genes have been found which appear to significantly contribute to the development of schizophrenia, providing at least a partial blueprint for the genetic risk architecture of the disease. While we still need to learn more about how they work, this group of genes should bring us closer to diagnostic tests for early detection, new targets for treatment, and even new strategies for prevention. In other studies, genes have been found which are thought to play a role in obsessive-compulsive disorder, panic disorder, and autism. NIMH researchers have also identified genes involved in memory and information processing, both of which are impaired in schizophrenia and various other disorders. These studies were among those named collectively as the number two scientific "breakthrough of the year" by the prestigious journal Science in December. Most of the studies listed were conducted by intramural or NIMH-funded investigators. Studies this year have also provided new insight into the neural circuitry of anxiety and fear processing, suggesting new targets for drug development to treat anxiety, post-traumatic stress disorder, and various phobia disorders.

SCHIZOPHRENIA TREATMENT INITIATIVE

While the news on schizophrenia has been exciting, we recognize that the road from gene discovery to prevention and treatment is neither simple nor rapid. To accelerate this process, we created a new initiative on schizophrenia research. A primary component is a new intramural interdisciplinary team, ranging from molecular to clinical scientists, who will lead a broad effort to understand how different gene variations alter neural networks and disrupt brain activity, leading to cognitive impairment and psychosis. The team will work to identify the role of these

vulnerability genes, including their individual contributions to risk, severity of the disease, and drug response.

A second component of the initiative is a program that targets cognitive problems for people with schizophrenia. Cognitive deficits, such as trouble with memory, attention, and executive function (capacity to make judgments and control impulses) are major determinants and predictors of long-term disability in schizophrenia. They remain a significant barrier to a productive life for people with the disease, yet the medications currently available provide no relief for cognitive problems. There has been a lack of scientific consensus on which cognitive impairments should be targeted and which tools are best for measuring them. As a result, the FDA has not been able to recognize cognition in schizophrenia as a valid treatment endpoint for drug registration. To address these issues, NIMH launched the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) program. It brings together representatives from academia, industry, and regulatory agencies to develop a comprehensive assessment tool to measure cognitive functioning in people with schizophrenia. The second phase is to develop and test novel compounds designed to enhance cognition.

ROADMAP

For most of our recent genetic discoveries, we lack the molecular tools needed to link the genes to new treatments. The search for new molecular tools for schizophrenia and other mental disorders will be aided greatly by one of the NIH Roadmap initiatives that will establish a repository of diverse organic chemicals. Organic chemicals, commonly referred to as "small molecules," have proven to be extremely important to researchers exploring the functions of the cell at the molecular level. In fact, most medicines, from aspirin to antihistamines, are small molecule compounds. This new "molecular library" will offer researchers access to hundreds of thousands of small organic molecules that can be used as chemical probes to study cellular pathways. These compounds will help validate new targets for drug therapy more rapidly, and will enable other researchers to move them into the drug-development pipeline.

AUTISM

NIMH plays a major role in a broad-based NIH effort to create a network of autism research centers focusing on the biomedical and behavioral aspects of the disease. Five institutes at NIH are coordinating their research efforts in an initiative called the Studies to Advance Autism Research and Treatment (STAART) Centers program. This year, the institutes awarded grants to support six new autism research centers, in addition to the two that were funded last year. NIH expects to spend $65 million over five years for the eight centers.

NIMH is the lead agency for the Interagency Autism Coordinating Committee (IACC), a group charged with coordinating research and other efforts on autism within the Department of Health and Human Services (HHS). NIMH took the lead in organizing the "Autism Summit Conference: Developing a National Agenda," a joint effort of the HHS and the Department of Education, held in November 2003. About 650 people attended the meeting to address three major areas of emphasis: biomedical research, implementing early screening and diagnosis, and improving the accessibility and coordination of services. A key focus of the meeting was the introduction of a 10-year national research agenda, developed by an IACC-appointed expert panel. The research agenda identified roadblocks hindering progress in understanding autism's causes and developing treatment, and provided goals and strategies for the next 10 years to overcome these challenges. These research efforts will be carried out through the centers of excellence within the STAART network.

PRACTICAL CLINICAL TRIALS

To improve human health, scientific discoveries must be translated into practical applications. Such discoveries typically begin at "the bench" with basic research where scientists study the mechanisms and pathogenesis of a disease at a molecular or cellular level—then progress to the clinical level, or the patient's "bedside." Equally important is the translation from bedside to practice. Moving new drugs and therapies more quickly and smoothly out of the research environment and into the hands of clinicians is a key feature of the NIH Roadmap. To achieve this, NIH will promote the creation of better integrated networks of academic centers that work jointly on clinical trials and which include community-based physicians who care for large groups of patients. Implementing this vision will require new ways of organizing the methods in which clinical research information is recorded, defin-

ing new standards for clinical research protocols, and creating new models of cooperation between NIH and patient advocacy alliances.

For its part, NIMH is finishing up four large-scale, longitudinal research studies to compare therapeutic approaches for serious mental illnesses, including schizophrenia, Alzheimer's disease, major depression, and bipolar disorder. These are different than most clinical trials, which are usually of short duration and limited to assessment of clinical symptoms. The NIMH studies are testing the various treatment options currently available for these disorders in diverse community populations, recruiting people from a variety of "real world" practice settings, and expanding outcome measures to include functional status and economic costs. The clinical populations currently enrolled in these NIMH treatment trials are among the largest and best characterized populations with bipolar disorder, schizophrenia, and depression ever studied through clinical trials in mental health. These trials will answer urgent questions about the treatment of adolescents with depression, the use of atypical anti-psychotics in people with schizophrenia and Alzheimer's, and the optimal long-term medication for bipolar patients. When the studies are over within the next two years, we hope to be able to continue utilizing this valuable clinical infrastructure—made up of staff, investigators, federal and state agencies, industry, patients, and patient advocacy groups—to answer other critical public health questions in diverse populations.

PRIORITY-SETTING

Over the past five years, we have witnessed unparalleled advances in the basic sciences relevant to mental health. Genomics, imaging, and many areas of neurobiology are beginning to reveal a new understanding of normal and abnormal behavior. Against this backdrop of scientific progress, we continue to face extraordinary challenges for our patients with mental disorders. Science now yields opportunities that promise to deliver for each of these challenges. To realize this promise, we must define areas of high priority. To assist us, workgroups of our National Advisory Mental Health Council are reviewing the NIMH portfolio initially in two key research areas: clinical trials and basic science. Both workgroups plan to deliver reports by May 2004 and both will define priority areas using the criteria of relevance, traction, and innovation. Both workgroups have done an impressive job in reviewing the hundreds of relevant grants in the portfolio. We look forward to their recommendations, as well as to those of our Outreach Partners in every state, the mental health advocacy community, and the public. We rely on these groups to help us meet our ultimate goal of relieving the profound misery suffered daily by patients and families affected by mental disorders.

PREPARED STATEMENT OF DR. RAYNARD KINGTON

Mr. Chairman, members of the Committee: I am pleased to present the President's budget request for the Office of the Director (OD) for fiscal year 2005, a sum of $359,645,000, which reflects an increase of $32,556,000 over the comparable fiscal year 2004 appropriation. The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD also is responsible for a number of special programs and for management of centralized support services to the operations of the entire NIH.

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.

In addition, 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 request for the OD in greater detail.

NIH ROADMAP

As part of the NIH Roadmap for Medical Research, the NIH has launched initiatives in fiscal year 2004 critical to addressing the roadblocks to the acceleration of science conduct and transfer to the public. These initiatives promise to yield far-reaching dividends in medical knowledge and improved health for the public. Under the theme of New Pathways to Discovery, initiatives are aimed at quantifying and cataloging complex biological systems and in developing a better "tool box" for today's researchers, for research teams of the future, and for re-engineering the clinical research enterprise. Examples of initiatives include the creation of an accessible public library database for chemically diverse small molecules, centers that will create new tools to describe the dynamics of protein interactions, development of novel technologies to study cellular metabolites, creation of national software engineering system that can facilitate the ability of scientists to tap into supercomputing networks and share and analyze complex data, and the early conceptual development of nanomedicine. The NIH Roadmap initiatives also have taken steps to prepare Research Teams of the Future, the second theme, by encouraging scientists and research institutions, including the NIH, to test alternative models for conducting research that take advantage of the scientific advances and complexities. A major focus has been placed on planning and research workforce training for the conduct of interdisciplinary research, that research that spawns new disciplines of science. In addition, a new award—the NIH Director's Pioneer Award—will support a select group of investigators who have the potential for ground-breading discoveries. Ultimately findings from the laboratory must reach the public, and the initiatives under the third them—Re-engineering the Clinical Research Enterprise—are geared to address the roadblocks to the conduct of clinical research and its translation to patients. These initiatives include the exploration of the ability to create and enhance interoperability among clinical trial networks, the testing the feasibility of establishing a National Clinical Research Associations program where community-based clinicians are trained to participate in studies and play a role in augmenting the transfer of research to their patients, and the assessment of patient-reported chronic disease outcomes. Critical work continues in the area of research policy analysis and coordination with an emphasis on harmonization and standardization of policies and requirements pertaining to clinical research. In addition, extension and expansions of clinical research training programs extramurally and intramurally have been initiated.

THE OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. Each year, OAR oversees the development of the comprehensive NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual AIDS research budget for each Institute and Center; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. OAR identifies scientific areas that require focused attention and facilitates multi-institute activities to address those needs. OAR coordinates, monitors and fosters plans for NIH involvement in international AIDS research and training activities. OAR supports a number of initiatives to enhance dissemination of research findings to researchers, physicians, patients and communities. The fiscal year 2005 budget request for OAR is $61,435,000.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH), the focal point for women's health research for the Office of the Director, strengthens, enhances and supports research related to diseases, disorders, and conditions that affect women, and sex/gender studies on differences/similarities between men and women; ensures that women are appropriately represented in biomedical and biobehavioral research stud-

ies supported by the NIH; and, develops opportunities for the advancement of women in biomedical careers and investigators in women's health research. The report, *An Agenda for Research on Women's Health for the 21st Century*, provides a framework for the ORWH to collaborate with the scientific and advocacy communities to address gaps in knowledge about women's health and sex and gender factors in health and disease. The fiscal year 2005 budget request of $41,577,000 includes an increase of $626,000 over the fiscal year 2004 appropriation.

Research priorities for women's health emphasize the importance of interdisciplinary research with collaboration and integration of knowledge from multiple areas of scientific expertise; lifespan issues and the continuum from intrauterine life into elderly years; health disparities/differences and diversity among different populations or subpopulations of women; and, sex/gender differences in health and disease and therapeutic interventions at genetic, molecular, cellular, and functional levels. Areas of research interest for 2005 include: pathogenesis of diseases including prevalence/validation of sex differences in diagnosis/treatment of disorders/diseases; clinical trial methodology; mental health studies; new agents for management of menopausal symptoms; treatments/interventions for diseases that show enhanced clinical features in women; and other specific areas such as CFS, and benign gynecologic disorders including uterine fibroids. Special emphasis areas for women's health research include genetics/pharmacogenomics, and the genetic, molecular and cellular bases for action of pharmacologic agents known to have differential effects in females; and, prevention and treatment, from basic biological factors to effects of risk behaviors or interventions. There is expansion of new research in the ORWH specialized centers of interdisciplinary research in women's health and sex and gender factors, and the unique ORWH interdisciplinary career development program in women's health research that fosters the mentored development of junior faculty and assists them in bridging advanced training towards a goal of research independence. In addition, the ORWH has now implemented a new Intramural Program on Research on Women's Health to focus on NIH intramural women's health and sex and gender comparison research. The ORWH continues to partner with Institutes and Centers to ensure compliance with NIH policies for the inclusion of women and minorities in clinical research, and that analyses by sex/gender are addressed by investigators funded by the NIH.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The NIH has a long history of funding health-related behavioral and social sciences research, and the results of this work have contributed significantly to our understanding, treatment, and prevention of disease. The Office of Behavioral and Social Sciences Research (OBSSR) furthers NIH's ability to capitalize on the scientific opportunities that exist in behavioral and social sciences research by providing leadership in identifying and implementing research programs in behavioral and social sciences that are likely to improve our understanding of the processes underlying health and disease and provide directions for intervention. OBSSR works to integrate a behavioral and social science approach across the programs of the NIH. The fiscal year 2005 OD budget includes $26,321,000 for OBSSR, an increase of $415,000 over the fiscal year 2004 appropriation.

Many exciting scientific developments are occurring at the intersection of behavioral and social science research and biomedical research. It has become apparent that increasingly, scientific advances are being made at the interfaces of traditional disciplines, and that approaches to science are becoming more integrative. OBSSR has begun development of a program to provide interdisciplinary training to postdoctoral fellows in NIH intramural laboratories. This program would provide a mechanism hereby an individual with a PhD in a behavioral or social science discipline might acquire interdisciplinary training that included biomedical research. Alternatively, someone trained in a more traditional biomedical field would receive postdoctoral training that included a behavioral or social science component. In addition to the benefits to be realized by the individual trainees, this program would also show NIH leading, by example, our Roadmap efforts to build interdisciplinary Research Teams of the Future.

OBSSR is also developing an initiative to advance discovery of scientific knowledge about eHealth technologies for health behavior change and chronic disease management. Consumers, patients, and providers are increasingly using eHealth applications, particularly the Internet, to seek health information for themselves or family and friends, communicate with others who have a similar disease or illness, and to communicate with their health care providers. These technologies offer people the ability to obtain health information at relatively low cost, including those with limited or no access to health care professionals or services, and historically

underserved populations. While the use of eHealth interventions is becoming widespread, these techniques have yet to receive much rigorous evaluation. This initiative's goal is to bring together components of NIH, the Robert Wood Johnson Foundation and other public agencies and private foundations in a "meeting of the minds" about the state of eHealth evaluation research for health behavior change and chronic disease management, future directions in the field, and the role of NIH and others in developing a research agenda for this area.

Behavioral and social factors contribute significantly to racial and ethnic health disparities. Consequently, OBSSR is committed to developing better knowledge of specific pathways to health disparities and to finding solutions. In February 2003, OBSSR published in the *American Journal of Public Health* a set of papers presenting scientific evidence of the effects of racial/ethnic bias on health and identifying areas for future research to further explicate the relationship. The papers were the product of an OBSSR meeting of approximately 100 leading scientists held in April 2002. Currently, OBSSR is convening discussions among ICs regarding the role of social and behavioral science in their health disparities research activities and avenues for coordinated initiatives.

An effective way to ensure that results of behavioral and social science improve our society's health involves incorporating these in clinical practice. In order to start this process at an early stage in the training of the next generation of physicians, OBSSR funded the IOM to determine how to improve medical education. The results of this study [April 2004] will inform a training initiative that OBSSR with several ICs will launch this year.

THE OFFICE OF DISEASE PREVENTION

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. There are several other offices within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) has as its mission to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health services to the public. 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 2005, the Office of Dietary Supplements (ODS) within ODP requests a budget of $26,218,000, an increase of $414,000 over the fiscal year 2004 appropriation. In fiscal year 2004, ODS published its 5-year Strategic Plan for 2004–2009, a major component of which is to significantly expand efforts to address the role of dietary supplements in reducing the risk for chronic diseases. It will continue to promote the scientific study of the use of dietary supplements by supporting investigator-initiated research in conjunction with other ICs at NIH and stimulating research through conduct of conferences and through presentations at national and international meetings.

ODS, in collaboration with the National Heart, Lung, and Blood Institute and other NIH ICs, has sponsored a systematic review of the relationship between omega-3 fatty acids and a series of clinical indications, particularly coronary heart disease. Several reports will be published in fiscal year 2004 based upon this review, which will serve as the basis for planning further NIH research on omega-3 fatty acids. Congressional language in recent appropriation reports directed ODS to enhance an ongoing collaboration for the development, validation, and dissemination of analytical methods and reference materials for botanical dietary supplements. ODS works with other partners in the public and private sectors to meet this objective. ODS supports the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics at the Centers for Disease Control and Prevention, in order to provide more information about dietary supplement use in the U.S. population.

This will inform future research about potentially important target populations, such as children, women, and the elderly. Funding is used to create and populate a database of dietary supplements, as well as to support the measurement of blood levels of key metabolites associated with dietary supplement use. ODS collaborates with USDA to develop an analytically-based database of dietary supplement ingredients. ODS collaborates with other federal agencies to develop an approach to assessment of the health effects of bioactive factors in foods and dietary supplements. In its continuing efforts to inform the public about the benefits and risks of dietary supplements, ODS collaborates with USDA on the International Bibliographic Information on Dietary Supplements (IBIDS) database, which now includes a consumer-

oriented search strategy. It has also disseminated a database devoted to federal funding of dietary supplement research, called CARDS, which is currently populated with data about the NIH investment from fiscal year 1999–2002. ODS publishes Fact Sheets about vitamin and mineral dietary supplements in collaboration with the NIH Clinical Center, as well as Fact Sheets about botanical supplements.

Another component of ODP, the Office of Rare Diseases (ORD) was formally established through the Rare Diseases Act of 2002, Public Law 107–280. The purpose of this Act is to increase the national investment in the development of diagnostics and treatments for approximately 25 million patients with more than 6,000 rare diseases. A rare disease is defined as one where fewer than 200,000 persons are affected in the United States. The fiscal year 2005 budget request for ORD is $15,787,600, an increase of $253,000 above the fiscal year 2004 appropriation.

Through its *Extramural Research Program*, the ORD supports a Rare Diseases Clinical Research Network with NIH Institutes and Centers (ICs). The major goals for the network include the systematic collection of clinical information to develop biomarkers and new approaches to diagnosis, treatment, and prevention of rare diseases, and to promote training of new clinical research investigators in rare diseases. ORD funded seven Rare Diseases Clinical Research Consortia and one Data and Technology Resources Coordinating Center. The consortia focus on urea cycle disorders, inborn errors of metabolism, rare neurological channelopathies, idiopathic bone marrow failure states and cytopenias, vasculitides, and defects in steroidogenesis. The patient support organizations are closely integrated into the consortia and the network.

The ORD *Intramural Research Program* promotes training in the areas of clinical and basic research into rare diseases and in biochemical genetics, fosters protocol-based initiatives into rare diseases not currently investigated in the intramural program, assists in the investigation of select, unique disorders of unknown etiology, provides overall research support for diagnostics and therapeutics of rare disorders, and supports five Bench-to-Bedside grants.

In its *Scientific Conferences Program*, in fiscal year 2004, the ORD will cosponsor more than 70 scientific conferences on rare diseases. The 460 conferences sponsored to date since 1995 have been shown to be excellent venues to establish a research agenda for specific rare diseases, take advantage of scientific opportunities, or eliminate barriers to dvancing research.

To provide more comprehensive information, ORD, together with the National Human Genome Research Institute (NHGRI), established *the Genetic and Rare Diseases Information Center* to respond to requests for information about genetic and/or rare disorders. In its third year of operation, the information center broadened its language base to include Spanish in addition to English.

In fiscal year 2004, ORD plans to establish a *Trans-NIH Rare Diseases Working Group* to encourage collaborative research activities, provide opportunities for input as new rare diseases research programs unfold, and gather information about the rare disease research programs supported by the ICs and Offices for mandated annual and biennial reports.

THE OFFICE OF SCIENCE EDUCATION

The Office of Science Education (OSE) plans, develops, and coordinates science education programs to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The office's mission is to help people understand and use new knowledge uncovered by the NIH in pursuit of better health for everyone. The OSE works toward this mission by: creating programs to improve science education in schools (the *NIH Curriculum Supplement Series*); creating programs that stimulate interest in health and medical science careers (*the new LifeWorks Web site*); creating programs to advance public understanding of medical science, research, and careers; promoting NIH educational resources and programs; and advising NIH leadership about science education issues. All office programs target diverse populations including under-served communities, women, and minorities, with a special emphasis on the teachers of students from Kindergarten through grade 12. The OSE works closely with NIH institutes, centers, and offices on science education issues, and maintains the OSE Web site as a source of information about available resources and programs. http://science.education.nih.gov.

The NIH Curriculum Supplements series are National Science Education Standards-based lesson plans that are distributed free to K–12 teachers across the country. They incorporate the best of both science and education communities, and are intended to update science content and allow the teacher to incorporate the latest NIH research into classroom instructions. Life Works is a new OSE Web site cre-

ated as a source of career information for students, teachers, counselors, and parents. The site will allow exploration of the educational requirements, knowledge, skills, and abilities required for over 100 health and medical science careers. The fiscal year 2005 Budget request for OSE is $3,899,000.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAM

The NIH, through the Office of Loan Repayment and Scholarship (OLRS), administers the Loan Repayment and Undergraduate Scholarship Programs. The NIH Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees to biomedical and behavioral research careers by countering the growing economic disincentives to embark on such careers, using as an incentive the repayment of educational loans. There are loan repayment programs designed to attract individuals to clinical research, pediatric research, health disparities research, and contraception and infertility research, and to attract individuals from disadvantaged backgrounds into clinical research. The AIDS, Clinical, and General Research Loan Repayment Programs are designed to attract investigators and physicians to the NIH's intramural research and research training programs. The NIH Undergraduate Scholarship Program (UGSP) is a scholarship program designed to support the training of undergraduate students from disadvantaged backgrounds in biomedical research careers and employment at the NIH. The fiscal year 2005 Budget request for OLRS is $7,250,000.

Thank you for giving me the opportunity to present this statement; I will be pleased to answer questions.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY

Mr. Chairman and Members of the Committee: The fiscal year 2005 budget includes $139.198 million, an increase of $4.497 million over the comparable fiscal year 2004 appropriation level.

I am pleased to be here today to discuss the activities of the National Institute of Nursing Research (NINR). NINR supports research that converges well with NIH's top priorities and activities. Our research emphases are also reflected in the NIH Roadmap, the strategy to accelerate scientific discoveries and take new approaches to make them more rapidly available to patients. NINR's scientific community is excited about the opportunities within the current and future NIH Roadmap initiatives. NINR is already supporting important interdisciplinary research training and interdisciplinary research, including community-based research. NINR's scientific community has been alerted to the procedural changes that need to take place in order to capitalize on the NIH Roadmap initiatives; their enthusiasm predicts a high level of support for the Roadmap.

From its inception, NINR has emphasized interdisciplinary research teamwork and clinical and translational research, which are prominently featured in the Roadmap agenda. Our studies address national health problems head on. We have moved from an acute to a chronic disease focus, with emphasis on older people, who are living longer with illness and want the highest quality of life possible. We promote ethnically and culturally sensitive research and are aggressively pursuing research on health disparities, devoting about 20 percent of our budget to this area of science.

CONTROL OF HIGH BLOOD PRESSURE IN YOUNG INNER-CITY AFRICAN-AMERICAN MEN

A good example of a program of research that improves health care disparities in a vulnerable African-American population is located a short distance from here—East Baltimore. The number of people with hypertension nationally is 40 percent higher for African-Americans than for Caucasians, and there is more severe disease impact among African-Americans that can include heart enlargement and kidney dysfunction. The Johns Hopkins School of Nursing conducted this unique hypertension study, targeting a high-risk population of hypertensive young African-American men between 21 and 54 years of age who are generally considered underserved by the healthcare system. At the study's start, only 17 percent had control of their blood pressure, but after three years, 44 percent of the men receiving the intensive form of a carefully designed community-based intervention attained control of their blood pressure. In some cases, the study represented the first time the study participants experienced formal healthcare. Of special significance is that 90 percent of the young men were retained in the study for the entire three-year period. A key to this success was the culturally appropriate, multidisciplinary research team approach that involved nurse practitioners, community health workers, and physicians.

Among the lessons learned from this research is the need to modify healthcare for vulnerable populations like this one in Baltimore—health care that involves home visits that offer educational and behavioral counseling to supplement visits to the clinics, and addresses factors beyond the disease itself, such as reducing substance abuse and obesity.

HEALTH OF MINORITY, INNER CITY NEWBORNS IMPROVED BY NURSE HOME VISITS

Another example of a health disparity is infant mortality, with rates for African-Americans twice those of Caucasians. Researchers tested a carefully designed intervention tailored to the risks of the populations studied to help close this health disparity gap. Findings after one year of the project indicate that the health outcomes of both mother and infant were improved, and costly health care was avoided. The intervention involved focusing on low-income, pregnant African-American and Mexican-American mothers from the inner city, who received a program of planned prenatal care and post-natal monitoring with teaching and counseling at each encounter. Home visits made by a team of trained community residents and led by a nurse were an important feature, and the mothers received monthly phone calls for a year after their babies were delivered. The effects of the program varied by race and ethnicity. For African-Americans, findings indicated that mothers had more realistic expectations of their parenting role and were able to document the immunization of their infants. Their infants' mental development scores were higher than the control group. Mexican-American mothers showed improved skills in dealing with everyday life and in playing with their infants. This research and previous studies indicate that home visits by a nurse-health advocate team are among the most successful interventions in improving maternal and infant health—even for-inner city, low-income minority families. The key is to implement culturally sensitive interventions that are intensive and adequately staffed and funded.

WOMEN'S EARLY WARNING SIGNS OF HEART ATTACK

Although heart disease is the number one cause of death in both genders, far less is known by physicians and by women themselves about how women experience the disease. Research focusing on women's symptoms prior to heart attack found that women have different early warnings of heart attach than men have. Of note is that most clinicians consider chest pain as the most significant symptom for both sexes. Yet in this study the most prevalent symptom was reported to be unusual fatigue (70 percent), followed by sleep disturbance (48 percent), and shortness of breath (42 percent). Fewer than a third of the women reported chest pain or discomfort. Even during the heart attack, 43 percent did not experience chest pain. Clearly, women's symptoms appear to be different from men's. This underscores the importance of women and clinicians, both, recognizing early warning signs of impending heart attack in women, so that they can prevent it or ease its effects.

CHOLERA REDUCED BY LOW TECH WATER FILTRATION

A growing global problem faced by developing nations is the availability of healthy drinking water, a most basic need for life and health. Cholera is carried by untreated surface water and kills thousands of people around the world by causing severe vomiting and diarrhea. The World Health Organization reports that the number of countries with cholera is increasing. In our own hemisphere, cholera incidence is now increasing in 16 Latin American nations. Researchers in Bangladesh have found a simple preventive technique that works and may be transferable to other countries. Inexpensive and widely available cotton sari cloth, when folded four to eight times, creates a filter small enough to remove most plankton, where cholera bacteria often live. In 65 villages with 133,000 inhabitants, the number of cholera cases was almost cut in half when people filtered their water with the sari cloth. Cultural barriers were not an issue, and about 90 percent of the rural study participants followed the filtering procedure. When cholera did occur, those villagers had drunk unfiltered water at villages not participating in the study. The sari filtering technique could work just as well using other types of inexpensive cloth filters if replicated in countries where cholera is widespread.

THE NINR ROLE IN THE NIH ROADMAP

Last year, NINR developed what we call Research Themes for the Future, which represent NINR priorities over the next five plus years. These themes blend well with the NIH Roadmap overall, especially in two areas—Interdisciplinary Research Teams of the Future, and Re-engineering the Clinical Research Enterprise. In the first area, NINR has considerable experience carrying out interdisciplinary team re-

search projects. In fiscal year 2003, more than half of NINR investigator publications appeared in non-nursing journals. This underscores the promise of future successful interdisciplinary research and practice collaborations. It also indicates that many other disciplines value nursing research findings. In the area of improving the clinical research enterprise, most of NINR's research is clinical in nature and can bring research questions to the laboratory from the clinical researcher's perspective. Investigators also translate research findings into the clinical practice of healthcare providers and develop partnerships with communities to speed new scientific knowledge into mainstream health regimens. Late last year, NINR supported a national conference to promote research-intensive environments in clinical settings, including academic medical centers and those that are nontraditional as far as research is concerned, such as nursing homes and community-level health enterprises. The goal was to create partnerships between academic researchers and potential investigators in these settings to develop resources and ease barriers to innovative research.

To make the Roadmap a reality for nurse researchers, since the Roadmap will not be business as usual, but business as usual plus, NINR recently convened an implementation meeting with interdisciplinary experts from across the country. The meeting addressed ways to intersect NINR's themes and priorities with those of the Roadmap, as well as suggestions for new Roadmap directions that reflect the expertise of nursing research. Since NINR has always stressed interdisciplinary research, we look forward to increased participation in the Roadmap.

INITIATIVES

Looking ahead to our fiscal year 2005 initiatives, reduction of obesity, a major public health issue, is certainly on the NINR agenda. Pediatric and adolescent obesity is particularly disturbing in and of itself, because it forewarns of future poor health. We plan to target minority populations at risk for obesity and children who are underserved—for example, those in rural areas. Research will address biological, behavioral and social science factors leading to or perpetuating obesity.

Our genetics initiative is novel for NINR, since it involves incorporating behavioral, biological and molecular science into nursing research. Our focus will be on the interactions between genes, environment and behavior, including health promotion behavior. We will also assess the results of genetic education and counseling, and the effects of genetic testing on health, including lifestyle changes and the reduction of risks for disease.

Increased attention is required to build the knowledge base for effective end of life care. NINR is the lead Institute at NIH for end-of-life research. The research agenda we have identified for better healthcare management at this final stage of people's lives includes improved methodology, instruments, communication, and interventions that helped making choices. Previously published NINR-funded research findings on symptom management are already being integrated into standards of care. Further study is taking place to develop new behavioral approaches to improve the lives of patients and their caregivers and to devise new techniques to improve management of pain.

Self-management has become the most basic way people can improve their lives when they are living with long-lasting, incurable chronic illness. Successful self-management interventions tested in mainstream populations, such as how to improve coping skills and how to maintain and improve cognitive functioning, will be tested in populations with special needs: the unemployed, homeless, very old, impoverished, disabled, or geographically isolated.

Another initiative involves symptom management. Traditionally, clinical practice treats symptoms one symptom at a time. Yet symptoms rarely occur alone they occur in clusters. NINR plans to support research that will identify and describe groups of symptoms in HIV/AIDS and cancer patients by determining these clusters' effects on the patient, and developing interventions to manage the multiple symptoms. In addition to assisting how one symptom impacts the others in a cluster, we will consider the effects of age, treatment, gender, and type and stage of disease.

NINR will expand on past and current research initiatives that focus on minority and underserved women's health, such as health disparities and reduction of low birth weight among minority women. The new initiative will focus on other aspects of women's health outside of reproduction, which in the past was frequently the central focus of women's health research by investigators of many disciplines.

INCREASING THE NUMBER OF NURSE INVESTIGATORS

The well documented and current shortage of nurses was preceded by a significant shortage of nurse researchers. The shortage of nurse researchers also means fewer nursing faculty to train future nurses and to conduct research that provides

the scientific base for healthcare practice. In confronting this issue, NINR continues to collaborate with universities nationwide to rapidly develop baccalaureate-to-doctoral fast-track programs. This is in response to one of the recommendations of the National Research Council four years ago, which urged preparation of more nurse researchers more quickly. NINR revised the predoctoral training mechanism to enable nurses to enroll in the many fast-track doctoral programs in nursing which accept baccalaureate-to-doctoral students. NINR has been responsive to the National Research Council's recommendation, and the nursing community has also responded by rapidly developing these baccalaureate-to-doctoral programs all over the nation.

NINR supports Developmental and Core Centers to stimulate research and research training opportunities. Creating partnerships and leveraging funds is a hallmark of those Centers. We also initiated 17 Nursing Partnership Centers to Reduce Health Disparities, in collaboration with the National Center on Minority Health and Health Disparities. These Centers partner eight research-intensive universities with nine minority-serving institutions. As a result of this program, we expect health disparities research to expand and the number of minority nurse investigators to increase.

NINR will continue to offer career development awards, and we will make a special effort to train minority investigators through mentored research scientist awards and research supplemental awards. NINR's small but growing intramural research program is initiating a graduate partnership program with universities across the country this year and continues to support postdoctoral training opportunities on the NIH campus.

In closing, the upcoming year contains new opportunities to configure scientific research in new ways. NINR and the nursing research community look forward to participation in the NIH Roadmap initiative and in other research that directly impacts the improvement of people's health.

Thank you, Mr. Chairman. I will be pleased to answer any questions the Committee might have.

PREPARED STATEMENT OF DR. BARBARA ALVING

I am pleased to present testimony before this Committee on behalf of the National Heart, Lung, and Blood Institute (NHLBI).

The NHLBI leads a national program directed at alleviating the burdens of diseases of the heart, blood vessels, lungs, and blood. The Institute also is responsible for research on the clinical uses of blood and its products and the management of blood resources. For more than a decade, the National Center on Sleep Disorders Research has been part of the NHLBI and, since fiscal year 1998, the NIH Women's Health Initiative has been administered by the Institute. Our diseases and the burdens associated with them touch the lives of all Americans.

BASIC AND CLINICAL RESEARCH APPROACHES

The ultimate goal of the NHLBI is to improve the public health through discovery of effective methods to prevent and treat disease. Progress toward this goal depends on the existence of a coordinated program that focuses on clinical investigation as the culmination of basic research to unravel the fundamental processes that govern health and disease. The Institute has fostered and sustained a longstanding commitment to laboratory investigations of relevance to its mandate. Moreover, in recent years it has allocated a significant share of the generous budget increases provided to it to aggressive pursuit of promising, cutting-edge opportunities in such disciplines as genomics, proteomics, and nanotechnology. Advances in these areas promise to enable, among other things, more specific approaches to health promotion based on detailed assessment of individual characteristics rather than on general observations about what does or does not foster good health. Our optimism about the probable yield of these new endeavors cannot be overstated.

However, the health-related outcomes of these basic science endeavors depend greatly on the extent to which laboratory discoveries are translated into approaches applicable to "real-life" health problems. And that, in turn, depends on clinical research. Being a disease-oriented agency, the NHLBI has for many years placed strong emphasis on developing and maintaining a robust clinical research portfolio. Particularly with regard to clinical trials, the Institute has worked to design efficient, less costly research approaches to evaluating therapeutic and preventive strategies. As part of this effort, the NHLBI has developed and refined the "clinical research network" concept and successfully applied it to evaluate new therapeutic approaches to conditions such as pediatric cardiovascular disease, asthma, acute respiratory distress syndrome, and Cooley's anemia. The networks provide an infra-

structure that enables rapid and cost-effective testing of new therapies as they come to light.

THE NIH ROADMAP—CLINICAL RESEARCH

It naturally follows that the NHLBI is an enthusiastic participant in the NIH Roadmap initiative titled Re-Engineering the Clinical Research Enterprise: Feasibility of Integrating and Expanding Clinical Research Networks. This new solicitation seeks to identify ways in which clinical research networks can collaborate to conduct clinical trials and other multicenter clinical research studies more efficiently than the current system allows. We at the NHLBI believe that application of lessons learned from this Roadmap initiative will better position the Institute to accelerate the pace of research and to reduce barriers that prevent research advances from becoming incorporated into clinical practice.

POSTMENOPAUSAL HORMONE THERAPY

Major unexpected findings from the NIH Women's Health Initiative (WHI) illustrate the critical importance of the randomized, controlled clinical trial in determining the risks and benefits of preventive strategies. The study, which assessed the role of estrogen therapy, with or without added progestin, in preventing major causes of death and disability among postmenopausal women, was predicated on strongly suggestive evidence from basic research, observational studies, and smaller clinical trials that often measured so-called surrogate end points (e.g., changes in heart disease risk factors or subclinical manifestations), rather than events such as heart attacks or deaths from coronary disease. Indeed, at the outset of the WHI, much doubt existed regarding the feasibility and ethics of conducting the trial, because "everybody" already "knew" that hormone therapy helped women remain youthful and "feminine forever," by not only relieving troublesome menopausal symptoms but also improving general health. Much to the surprise of researchers, practicing physicians, and women themselves, the trial of estrogen plus progestin last year was halted when it found increased risks of heart attack, stroke, invasive breast cancer, and blood clots among women assigned to take hormones. And quite recently, the estrogen-alone part of the study was discontinued because the hormone did not appear to have the hoped-for beneficial effect on heart disease (or, on the other hand, the feared unfavorable effect on breast cancer), but it did increase risk of stroke. These findings have major public health significance: the conclusion is that postmenopausal hormones, once ranking among the most-prescribed preparations in the United States, should generally be used only for short-term alleviation of menopausal symptoms.

LUNG-VOLUME-REDUCTION SURGERY (LVRS)

Another trial of great practical importance was a rigorous assessment of LVRS, a procedure that was first used to treat emphysema during the 1950s. Although some patients seemed to benefit from this radical and invasive procedure, high mortality and morbidity discouraged its widespread use until the early 1990s, when some surgeons began performing LVRS again and insurance reimbursement became one of several issues demanding resolution. The National Emphysema Treatment Trial (NETT) clarified the short-and long-term risks and benefits of LVRS and identified the characteristics of patients who may be most likely to benefit from LVRS, as well as those who are at greater risk of death and complications from the procedure. The NETT reflects a unique relationship in which the NIH funded and administered the study and the Centers for Medicare and Medicaid Services (CMS), which sought evidence regarding the advisability of providing Medicare reimbursement for LVRS, supported participants' care costs. Additionally, the Agency for Healthcare Research and Quality contributed support for analysis of the cost-effectiveness of LVRS. The study results have provided a scientific basis for reassessment of Medicare coverage for LVRS.

TRIALS OF HYPERTENSION CONTROL AND PREVENTION

Last year, we reported results from the ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial), which found persuasive evidence that traditional diuretics should be the initial treatment of choice for lowering high blood pressure. This is a study that only the NIH would likely have undertaken, as the comparison drugs—a calcium channel blocker and an ACE (angiotensin-converting enzyme) inhibitor—were already established as blood-pressure-lowering agents; it further illustrates the unique role played by the NIH in addressing issues of public health importance. Of additional interest is the observation

that blood pressure control rates among ALLHAT participants increased from 25 percent at the beginning of the ALLHAT to 66 percent after five years of followup. These gains were achieved in a variety of clinical practice settings and in subgroups of people known to experience difficulty with blood-pressure control, such as blacks, the elderly, and diabetic patients. These results offer encouragement that blood pressure control is obtainable, and they challenge us to pursue this goal vigorously.

The ALLHAT findings, in combination with evidence from other research studies, prompted issuance of an updated set of guidelines for hypertension management—the so-called JNC 7, or Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment, of High Blood Pressure. An important feature of the guidelines is a reclassification of blood pressure levels that includes the new category "prehypertension" (120 to 139 mm Hg systolic and/or 80 to 89 mm Hg diastolic blood pressure). Individuals with prehypertension are strongly encouraged to pursue lifestyle changes—losing excess weight, eating a heart-healthy diet, increasing physical activity, quitting smoking—to forestall development of overt hypertension. To date, most behavioral interventions have focused on only one or two lifestyle changes at a time. However, findings from a recent clinical trial indicate that an all-in-one approach to lifestyle changes is feasible and effective in lowering blood pressure. Trial participants who addressed many elements of a healthy lifestyle simultaneously also significantly reduced their weight and became more fit providing even more incentive to undertake such changes.

HYDROXYUREA THERAPY FOR SICKLE CELL DISEASE

A breakthrough for patients occurred in 1995 when the NHLBI announced the results of a major trial of the first treatment for adults with sickle cell disease. The study found that use of the drug hydroxyurea slashed rates of painful crises and acute chest syndrome, and sharply reduced the need for blood transfusions and hospitalizations. A followup study of the trial participants recently reported that hydroxyurea not only protects patients from episodes of severe illness associated with their disease, but also prolongs their lives. Even the sickest patients—those who suffered three or more painful crises a year—benefitted. These results have important implications both for improving patient care and for decreasing health care costs associated with sickle cell disease.

IMPROVING SURVIVAL FOR VICTIMS OF CARDIAC ARREST

Cardiac arrest—in which the heart stops beating effectively, blood does not circulate, no pulse can be felt, and the victim collapses into unconsciousness—is a frequent occurrence in this country. Despite several decades of efforts to train members of the public to perform CPR (cardiopulmonary resuscitation), few victims of out-of-hospital cardiac arrest survive the experience. The NHLBI Public Access Defibrillation trial trained volunteer rescuers to use an automated external defibrillator, a device that shocks the heart back into normal rhythm. It found that use of CPR plus the defibrillator, compared with use of CPR alone, markedly increased survival of people who suffered cardiac arrest in various community settings, and caused no major injuries or serious safety problems. An important next step, currently under way with NHLBI support, is to determine the safety and effectiveness of providing defibrillators to families of heart attack patients for use when a cardiac arrest occurs at home. In addition, the Institute is establishing a research consortium of investigators, hospitals, emergency medical services, and local communities to investigate promising experimental strategies to resuscitate patients who experience out-of-hospital cardiac arrest.

COMBATING THE OBESITY EPIDEMIC

Obesity is a problem of great concern to the NHLBI, as it strongly influences the risk for developing diseases and conditions such as coronary heart disease, hypertension, and diabetes. Thus, the Institute is strongly involved in the overall NIH effort to reverse the U.S obesity epidemic, and I have been especially pleased to serve as cochair of the NIH Obesity Research Task Force.

The NHLBI recently launched a major study that addresses one of the most challenging aspects of weight control—keeping lost pounds off. The Weight Loss Maintenance Trial will initially assist overweight or obese adults participants in making lifestyle changes to reduce their weight and, subsequently, it will test various strategies to help the participants maintain their weight loss over the next several years. The trial focuses on persons who are being treated for high blood pressure or high blood cholesterol and, consequently, have particularly strong reasons to achieve and maintain a healthy weight.

Another new initiative will assess the effectiveness of worksite interventions for preventing or controlling overweight and obesity in adults. Strategies to be considered include implementing environmental and policy changes to increase employees' physical activity (e.g., flextime or fitness-center discounts), offering healthful food choices in cafeterias and vending machines, providing information about nutrient and calorie content of foods at the point of purchase, and enhancing social support from fellow workers to encourage improved diet and physical activity.

A third NHLBI initiative will explore the potential use of bioengineering approaches to address problems of obesity. For example, new methods for imaging body fat content may enable more specific identification of who needs to lose weight and their success in doing so. Bioengineering techniques may also offer a solution to the difficult technical challenge of obtaining precise measurements of energy intake and expenditure. One can envision development of a wristwatch-like gadget from which the wearer could easily determine whether an energy intake goal has been exceeded or an energy expenditure has been met. New approaches might provide accurate, convenient, easily understood, and inexpensive devices that would foster research, improve clinical management of adults and children, and help the public eat less and exercise more.

CONCLUSION

These examples illustrate the extraordinary potential of clinical research, and particularly clinical trials, to address issues of major importance to the public health. The NHLBI will continue its commitment to stimulate and support clinical research, and to ensure that the knowledge thereby gained is rapidly, efficiently, and fully applied to disease treatment and prevention.

BUDGET STATEMENT

The fiscal year 2005 budget includes $2,963.9 million, an increase of $172.1 million over the fiscal year 2004 enacted level of $2,791.8 million.

I would be pleased to answer any questions that the Committee 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 budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD). The fiscal year 2005 budget includes $393,507,000 which reflects an increase of $11,561,000 and a 3 percent increase over the fiscal year 2004 final conference level. Disorders of human communication exact a significant economic, social, and personal cost for many individuals. The NIDCD supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. NIDCD's mission includes the support of research to create assistive devices which substitute for lost and impaired sensory and communication function. Equally important to the NIDCD mission has been the discovery of genetic mutations that affect communication disorders. This work would not have been possible without the completion of the Human Genome project, supported in part by the National Institutes of Health. Enabled by this landmark accomplishment, scientists supported by the NIDCD have been studying the genes responsible for non-syndromic (not associated with any other problem) hereditary hearing impairment. Within the last 8 years, 54 genes have been identified, largely due to the contributions of NIDCD. Scientists are now focusing their efforts on identifying more genes, learning what role the genes have in deafness, and determining which genes affect certain populations of individuals. For example, recent studies have demonstrated that particular ethnic groups carry specific genetic mutations. Studying the genes that cause non-syndromic hereditary deafness will also permit early and more accurate genetic testing and foster the development of innovative intervention and prevention strategies, and more effective treatment methods for individuals with deafness and other communication disorders. My testimony today will primarily focus on the many genetic discoveries that have allowed NIDCD-supported scientists to learn more about the causes of communication disorders, a first step in prevention and treatment.

NEW WAY TO IDENTIFY USHER SYNDROME IN CHILDREN

Usher syndrome Type 1 is an inherited disorder. Children born with this disorder are deaf, suffer balance problems, and gradually lose their vision. Although Usher syndrome affects individuals of other racial and ethnic backgrounds, scientists have recently identified a clear pattern of its inheritance in Ashkenazi Jews, who are de-

scendants of Jews from Germany, Austria and Eastern Europe. In 2003, a NIDCD-supported scientist identified a mutation within the gene known to be responsible for Usher syndrome. The particular mutation seems to be responsible for most of the Usher syndrome seen in Ashkenazi Jews. Because scientists now know which mutation is responsible for this type of Usher syndrome, they can develop genetic tests to detect the mutation in Ashkenazi Jewish children who are born deaf. By identifying children destined to lose their sight, parents and doctors can help them learn to communicate and prepare them for blindness. Some of these children will be appropriate candidates to receive a cochlear implant. Cochlear implants are small electronic devices that enable individuals who are deaf or have severe hearing loss to detect sound. This research will now enable doctors to provide important quality of life improvements for children with Usher syndrome.

GENE REPLACEMENT THERAPY CAN GENERATE NEW HAIR CELLS

The sensory hair cells of the inner ear play an important role in detecting sound. People who lose hair cells due to excess noise, infections, or accidents often lose some or all of their ability to hear. Scientists have determined that many forms of inherited deafness are also due to problems with hair cells. The hair cells of the inner ear act like miniature amplifiers. Sound waves that enter the inner ear are converted into a series of chemical and electrical signals within the cells. These signals are ultimately transmitted to the brain via the auditory nerve and interpreted as sound. In the past, only birds or reptiles were thought to be capable of generating new hair cells. Now, NIDCD-supported scientists have discovered a way to use gene therapy to generate new hair cells in the ears of adult mammals. Scientists used a virus to transfer a gene called Math1 into the ears of guinea pigs. Math1 is expressed in developing hair cells, and its expression is thought to cause the cells to become hair cells, rather than becoming another cell type within the ear. The virus infects cells of the ear and causes them to produce the Math1 protein. Early experiments suggest that when the virus infects cells that do not normally express Math1, some of these cells become hair cells. In addition, the new hair cells also attract fibers of the auditory nerve, suggesting that the new cells may also be able to establish a link to the part of the brain that interprets sound—the auditory cortex. If this work can be duplicated in human beings, it may be the first step towards enabling scientists to use gene therapy to restore hearing to those who have lost it, or to enable deaf individuals to hear.

NEW SHORT ELECTRODE WILL ALLOW GREATER BENEFIT FROM COCHLEAR IMPLANTS

Cochlear implants are commercially available miniature hearing prostheses capable of assisting those who are profoundly deaf or severely hearing impaired. Approximately 60,000 individuals all over the world have received cochlear implants. The implant bypasses damaged or missing hair cells to send electrical signals through an array of electrodes within the cochlea (inner ear). Current cochlear implants send sound information that covers the entire frequency range. In order to send both high and low frequency information, the electrodes of the cochlear implant are inserted as far into the cochlea as possible. Unfortunately, inserting the electrodes into the cochlea compromises any residual (remaining) hearing the individual may have had prior to implantation. Consequently, scientists developed a new shorter electrode to help an additional population of individuals with hearing loss. These individuals have a considerable amount of residual hearing and their primary hearing loss is in sounds in the high frequency range. They are also experienced, yet unsuccessful, adult hearing aid users with severe-to-profound hearing impairment who would not have been conventional cochlear implant candidates. The short electrode is inserted into the base (or bottom) of the cochlea to restore hearing at high frequencies, while preserving low frequency hearing, or residual hearing, in the apex (or top) of the implanted ear.

The preliminary data demonstrates residual hearing can be preserved with this short electrode, and provides evidence that this is most beneficial for understanding speech in a noisy background. Furthermore, the innovative short electrode may be an ideal treatment for those with presbycusis, which is the loss of hearing that gradually occurs in most individuals as they grow older. This new electrode design allows many more people with some degree of hearing loss to benefit from cochlear implant technology.

IDENTIFYING GENES IMPORTANT FOR THE SENSE OF TASTE

The worldwide obesity epidemic is causing health professionals to focus their attention on how people choose which foods to eat. Because taste plays an important role in food choice, scientists are interested in figuring out how taste buds tell the

brain that they have tasted something, and which taste genes are responsible for sensing different food flavors. Vegetables such as broccoli, cauliflower, cabbage, and brussels sprouts contain compounds related to phenylthiocarbamide (PTC). For more than 50 years, scientists thought that the ability to taste PTC and similar compounds was determined by a single gene. If an individual inherited the PTC-tasting version of the gene, then they detected its bitter taste. If the tasting version of the gene was not inherited, the compound had no taste to that individual. Now NIDCD scientists, in collaboration with scientists in California and Utah, have identified a gene that regulates a person's sensitivity to the bitter taste of PTC. This explains why people seem to demonstrate a range of sensitivity to PTC's taste and may even influence whether or not an individual likes to eat broccoli and other vegetables containing PTC-like compounds. Because they determine an individual's sensitivity to a particular taste, inherited genes probably influence food choices. In the future, doctors may now be able to use this knowledge as part of a strategy to prevent and treat obesity and to overcome poor nutrition due to poor food choices. Increased knowledge about how taste cells tell the brain that they have detected a particular flavor may also help doctors restore the sense of taste to those who have lost it due to injury, disease or aging.

VOCAL FOLD PARALYSIS

Vocal fold paralysis is a genetic disorder that can be inherited. The vocal folds are two bands of smooth muscle tissue that lie opposite each other and are located in the larynx or voice box. When at rest, the vocal folds are open to allow an individual to breathe. Voice is produced by vibration of the vocal folds. To produce voice, air from the lungs passes through the folds, causing vibration and thus making sound. The sound from this vibration then travels through the throat, nose, and mouth (resonating cavities). The size and shape of these cavities, along with the size and shape of the vocal folds, help to determine voice quality. Paralysis of the vocal folds impacts voice quality and inhibits an individual's ability to communicate. This disorder can also cause life-threatening breathing difficulties in affected newborn infants.

Intramural scientists at the NIDCD and the National Institute of Neurological Disorders and Stroke are studying a family in which this disorder occurs and have found that vocal fold paralysis is due to degeneration of the nerves involved in movement. Weakness in the muscles of the arms and legs can also accompany this disorder. In the study, genetic analyses were used to locate the site of the causative gene to a section on chromosome 2. Further studies revealed that mutations in the dynactin gene, which resides at this location, are responsible for this disorder. Dynactin is a molecule that helps transport materials within nerve cells, and this research finding suggests that dynactin transport is essential for health and maintenance of at least some motor nerve cells.

This finding allows for a genetic tool for diagnosing vocal fold paralysis, which can aid in the clinical and neonatal management of this disorder. In addition, these findings provide better understanding of motor nerve cells and the molecular mechanisms that cause motor nerve degeneration.

NIH ROADMAP

The NIH Roadmap initiative to support interdisciplinary research and research training will advance the NIDCD mission because it encourages collaboration of scientists from seemingly unrelated disciplines. Interdisciplinary collaborations from a variety of scientific disciplines are necessary for developing assistive communications devices such as hearing aids and cochlear implants. The success of the development of the cochlear implant is a good example of successful interdisciplinary research as it involved the effort of physicists, chemists, material scientists, psychologists otolaryngologists, audiologists, speech-language pathologists, electrical engineers, and biomedical engineers We look forward to expanding upon that type of research in the coming years.

Finally Mr. Chairman, I would like to thank you and Members of this Committee for giving me the opportunity today to speak to you about the exciting recent discoveries from the NIDCD. I am pleased to answer any questions that you have.

PREPARED STATEMENT OF DR. DONALD A.B. LINDBERG

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Library of Medicine (NLM) for fiscal year

2005, a sum of $325,147,000, which reflects an increase of $16,671,000 over the comparable fiscal year 2004 appropriation.

The National Library of Medicine continues to be the premier source of science-based medical information. Just 10 years ago the Library introduced its Web site one of the very first in the federal government and so began a decade of amazing growth in the amount and variety of medical information it made available. Today the Library's Web service not only provides free access to Medline/PubMed, the largest and most reliable database of scientific medical information in the world, but NLM has created information products designed specifically for patients, families, and the public.

Despite its recent successes, NLM believes that the surface has barely been scratched and that the future holds the promise of many more valuable information products for the professions and the public. The Library's communications experts are at the cutting edge of new technology and, as more and more users have access to ever more powerful networks, the Library will put in place sophisticated yet easy to use information services that allow users free access to the world's burgeoning base of science-based health information. For scientists this means access not only to the growing published journal literature, but also electronically to scientific monographs and textbooks and to a variety of genomic information resources through NLM's National Center for Biotechnology Information (NCBI). For the general public, this means making even more consumer health information—from the National Institutes of Health and other reliable sources—available from the NLM's Web site.

The new NIH Roadmap Initiative has the potential to have a profound and positive impact on how American medical research is conducted. The NLM sees itself has having an important role in the Initiative in three areas. Because the Roadmap recognizes that one of the most powerful and unifying concepts of 21st century biology is that of bioinformatics, the computerized bioinformatics databases and analysis tools of the NCBI will become even more central to the research enterprise. Second is the Roadmap's requirement to "re-engineer the national clinical research enterprise." NLM's leadership role in working with biomedical vocabularies the Unified Medical Language System, the recently announced arrangement with the SNOMED clinical vocabulary, and NLM's expanding the NIH clinical trials database are all key aspects of improving clinical research. Finally, the Roadmap articulates NIH's responsibility to communicate research results to improve the quality of life for all people. The Library has a central role in collecting and communicating these results through Web-based information services and online databases. These are described in what follows.

TOOLS FOR SCIENTISTS AND HEALTH PROFESSIONALS

The NLM's Medline/PubMed is the most-used database of peer-reviewed medical information in the world. It contains more than 12 million references and abstracts to the world's medical literature published since the 1960s; an ancillary "OldMedline" extends the coverage back to the early 1950s. Each year millions of scientists and health professionals connect to Medline/PubMed (no registration or fee is required) and search for information they can use in the research or practice. More than a half billion such searches are done every year. The newest system, introduced in 1997, is constantly being improved. Several years ago NLM introduced links between Medline/PubMed references and publisher websites so users could retrieve the full text of articles. Today, more than 4,000 of the database's 4,600 publications have such links.

Another heavily used database is GenBank, the repository of all publicly available DNA sequences sent to the NLM from laboratories around the world. GenBank, and an increasing array of other valuable data resources, is the responsibility of the National Center for Biotechnology Information. The Center, which was created by the Congress in 1988 with the mandate to manage and disseminate genetic data, coordinates closely with the NIH Human Genome Project. GenBank today contains more than 27 million sequence entries totaling 33 billion base pairs from over 130,000 species. NLM, through the Web operations of the NCBI, receives more than a quarter million visitors a day seeking molecular biology information ranging from DNA sequences and protein structures to the related research literature.

A repository for chemical structure and assay data has been suggested as one aspect of NLM's involvement with the NIH Roadmap Initiative on "small molecules" to enhance research and develop new therapies. The NCBI is working on such a repository—called PubChem—which will integrate into one open database, information from existing chemical structure databases at various NIH institutes as well as data supplied from industry and academic centers. By providing chemical structure validation and structure-structure matching and by linking to descriptions of

the compounds in journal articles, PubChem will play an invaluable role in making this information useful to scientists.

PubMedCentral, a digital archive, is an important component of the infrastructure needed to enhance access to the life sciences literature. Publishers electronically submit peer-reviewed research articles, essays, and editorials. NLM guarantees free access to the material; copyright remains with the publisher or the author. Access to PubMedCentral is free and unrestricted. The full text of more than 100 life science journals, some going back decades, is now available, and more are added as they sign on to the system. Digitally archiving the scientific literature and guaranteeing access for future generations is an important NLM responsibility.

INFORMATION SERVICES FOR THE PUBLIC

The National Library of Medicine has become a favorite destination of seekers of health-related information on the Web—people looking for answers to questions about their health or the health of their loved ones. MedlinePlus, the largest of NLM's Web offerings for the general public, now receives about 4 million unique visitors a month. Increasingly, they also find their way on the NLM Web site to other services created specifically for them—NIHSeniorHealth.gov, ClinicalTrials.gov, Genetics Home Reference, Household Products Database, and Tox Town are all recent examples. These Web sites contain or point to information created by NIH components and other reliable noncommercial sources. They require NLM librarians and information specialists to work closely with a wide variety of outside organizations. MedlinePlus, launched in November 1998, today is one of the most heavily trafficked Web sites containing health information for the public. It has more than 650 "health topics," containing, for example, overview information, pertinent clinical trials, alternative medicine, prevention, management, therapies, the latest research, and the latest news from the print media. There are even links to the scientific literature through Medline/PubMed. In addition to the 650 health topics, there are medical dictionaries, encyclopedias, directories of hospitals and providers, and interactive "tutorials" with images and sound. MedlinePlus en español was introduced in 2002 and has grown to virtual parity with the English version. Both scored the highest marks of any Federal Web site in a recent outside evaluation. A new aspect of MedlinePlus is its plan to "Go Local," that is, to link users with community helping services near them. North Carolina is the first MedlinePlus partner to go local.

The National Library of Medicine is collaborating with the American College of Physicians in a unique "Information Rx" project that seeks to encourage practicing physicians who are members of the College to "prescribe" MedlinePlus to their patients who need further information on a medical subject. After test runs in Georgia, Iowa, Virginia, and Florida, the Information Rx program will go nationwide later in 2004.

MedlinePlus is not the only NLM information service directed at the consumer. Another very popular resource is ClinicalTrials.gov, which integrates previously fragmented information on human studies for different conditions into a single, coherent system, providing the public with an easy-to-use and convenient "one-stop" site for comprehensive information on clinical trials. The site, which is used not only by the public but by their health care providers, currently includes information on approximately 8,800 trials for hundreds of diseases and conditions conducted in about 90 countries. ClinicalTrials.gov receives approximately 16,000 visitors daily and over 3 million page views monthly.

Late in 2003 another service for the public was launched: NIHSeniorHealth.gov. This site contains information in a format that is especially usable by seniors. For example, the site features large print and easy-to-read segments of information repeated in a variety of formats—such as open-captioned videos and short quizzes to increase the likelihood it will be remembered. NIHSeniorHealth.gov has a "talking" function, which allows users the option of reading the text or listening to it as it is read to them. Another new NLM consumer service is the Household Products Database. This is a guide that provides easy-to-understand information on the potential health effects of more than 2,000 ingredients contained in more than 4,000 common household products. The database provides information on many of these substances and their potential health effects, in consumer-friendly language. For more technical information, users can launch a search for a product or ingredient from the product's page into NLM's TOXNET, a cluster of databases on toxicology, hazardous chemicals, and related areas.

Another consumer health information resource introduced in 2003 is the Genetics Home Reference. Genetics is a complex subject, and much of the primary data and literature are difficult to understand without formal training. The Genetics Home

Reference Website augments MedlinePlus with summaries of genetics information and an overview of the fundamentals of genetic science. The user can browse by a specific disease/condition or by gene. It also has a geographic list of genetic counselors and information for care-givers. The database has more than 100 condition summaries and 80 gene summaries and new content is being added continuously.

The Library launched Tox Town late in 2002. Tox Town looks at an ordinary town and points out many environmental hazards that might exist there. Users can click on a town location, like the school, and see a colorful dollhouse-style cutaway view of that building. Toxic chemicals that might be found in the school are listed, along with links to selected Internet resources about school environments. There are similar cutaways for offices, factories, parks, and other locations. NLM has plans to add new scenes, such as an urban community and a farming region.

SERVING SPECIAL COMMUNITIES

With all these unique information resources, it becomes more and more important for the Library to engage in outreach to let citizens know what is available. The 5,100-member National Network of Libraries of Medicine is an important partner in these outreach endeavors. Many of the programs are directed at minority populations. For example, there are programs to assist in remedying the disparity in health opportunities experienced by African Americans, Latinos, Native Americans, senior citizens, and rural populations. A new NLM database introduced in 2003 has health information aimed at Asian Americans; 2004 will see a similar database with information about the health concerns of Native Americans.

Under a program with the Historically Black Colleges and Universities (HBCUs), NLM is helping to train people to use information resources in dealing with environmental and chemical hazards. The latest aspect of this outreach effort is NLM's collaboration with the United Negro College Fund Special Programs Corporation to work with the HBCUs in the area of consumer health to encourage the use of reliable electronic health information (such as that provided by the NLM) by the public.

NLM also has been instrumental in reaching out to other countries around the world to help improve their access to scientific medical information. The oldest such program is that involving formal partnerships with major institutions in 20 countries. The NLM helps them obtain computerized access to the literature; the countries in turn help NLM receive the medical literature from that part of the world. The Library is also a key player in the Multilateral Initiative on Malaria, the multiagency effort to improve malaria research in African nations. NLM's role is to establish and maintain the first malaria research communications network, MIMCOM. There are now 19 research sites in 9 countries participating, with full access to the Internet.

SCIENCE ADVANCES

Many scientists believe that molecular biology is the primary driver of medical advances in the 21st century. The rapidly increasing volume of molecular data and the need to decipher its cryptic and subtle patterns has created demanding requirements for computerized databases and analysis tools, special curatorial expertise, and unique physical facilities. The National Center for Biotechnology Information is a key player in ensuring that the outpouring of data from molecular biology laboratories around the world is turned to life-enhancing purposes. GenBank, as noted above, is growing rapidly with contributions received from scientists around the world. Scientists also avail themselves of sophisticated computational tools, such as the BLAST suite of programs, which lets scientists search enormous quantities of data for sequence similarities that will identify genes and genetic features. Another tool, Entrez, allows users to search DNA sequences and literature information with techniques that are fast and easy to use. The newest tool is the "Reference Sequence Collection," which provides a centralized, integrated, non-redundant set of sequences that is integrated with other information for all major research organisms. Using the Reference Sequence Collection, time once spent on having to identify, gather, and analyze data can now be spent effectively on research.

The Center is now also conducting research using the human genome sequence to begin exploring the history of human populations. NCBI researchers, working with other collaborators, first assembled a set of 500,000 high-confidence variations and then compared the distribution of these variations on the genome to that predicted by several models of population history. They found that the data best fit a model in which the human population shrank dramatically about 40,000 years ago, a time when modern humans first appeared in Europe. The model suggests that the population subsequently grew about 30,000 years ago, consistent with archaeological evidence of a population expansion during that period. The results indicate that

databases of genetic variation constructed alongside the human genome project can provide a unique insight into the history of human populations. This insight may also explain how these populations may respond differently to selective pressures such as infectious diseases.

NLM's Lister Hill National Center for Biomedical Communications sponsors high-technology communications research projects in such areas as high quality imagery, medical language processing, high-speed access to biomedical information, developing intelligent database systems, multimedia visualization, data mining, and machine-assisted indexing. One prominent area of research has been the Visible Human Project. The project consists of two enormous (50 gigabytes) data sets, one male and one female, of anatomical MRI, CT, and photographic cryosection images. These data sets are available through a free license agreement to 1,800 individuals and institutions in 47 countries where they are being used in a wide range of educational, diagnostic, treatment planning, virtual reality, artistic, and industrial applications. An "Insight Toolkit" has been developed and makes available a variety of open source image processing algorithms for computing segmentation and registration of medical data. The Visible Human Web site is one of the most popular of all NLM's Web offerings.

NLM's Extramural Programs for more than 20 years has supported the training of medical informaticians at universities across the nation. In the early years the program focused on training of informaticians for clinical care. Today the training programs have added opportunities for training in bioinformatics, the field of biomedical computing for the large datasets characteristic of modern research. At present, NLM provides 18 grants to biomedical informatics training at 26 universities, supporting 250 trainees. NLM also participates in the NIH Roadmap activities, almost all of which have major emphasis on biomedical computing. For example, training is an important requirement of the National Centers for Biomedical Computing, an initiative for which NLM is one of the key leaders. Training as embedded in Roadmap activities is expected to become a significant complement to NLM's traditional support of informatics training.

THE FUTURE

In its role as the world's largest medical library, the NLM will continue to provide free access to the enormous literature of the health sciences, including even priceless historical treasures dating to the 11th century. As to the 21st century, the Library is making major contributions to the NIH Roadmap and is also applying its unparalleled collections and talents to "BIOSHIELD," the Department of Health and Human Services' effort to combat bioterrorism. The ability to apply medical knowledge to make our citizens healthy and safe is to repay the investment of the nation in medical research. In this, the National Library of Medicine can be of great help.

PREPARED STATEMENT OF DR. TING-KAI LI

I am pleased to present the President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for fiscal year 2005, a sum of $441,911,000, which reflects an increase of $13,486,000 over the comparable fiscal year 2004 appropriation.

As the recent NIAAA National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) has shown, most cases of alcoholism are established by age 25, beginning as early as age 18.[1] These new results, which are corroborated by studies not yet published, call for a major refocusing of research on youth as the most important target for preventing alcohol abuse and alcoholism on a public-health scale. We now know that youth and adolescence are the critical window of opportunity. The earlier one drinks in adolescence, the greater the likelihood that he or she will develop alcoholism.

The public-health implications of preventing alcoholism before it becomes established in youth are large, given the magnitude of alcohol misuse and its consequences. The 2002 report of the World Health Organization ranks alcohol third as a preventable risk factor for premature death in developed nations. Only tobacco and cholesterol are greater risk factors.

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[1] NIAAA National Epidemiologic Survey on Alcohol and Related Conditions, 2003, and unpublished data from the Collaborative Studies on the Genetics of Alcoholism.

In the United States, almost 18 million American adults met the clinical diagnostic criteria for alcohol abuse or alcohol dependence in 2002.[2] Annual costs to U.S. society of the consequences of alcohol misuse are about $185 billion.[3]

Heavy alcohol use in the American military is on the rise, with more than 19 percent of male personnel and more than 5 percent of female personnel reporting heavy use.[4] (The Department of Defense defined heavy drinking as five or more drinks on one occasion, at least once a week, in its survey). This pattern of drinking is hazardous to the health and welfare of the individual, the family, and society. In the general population of the United States, alcohol-related illness and injury account for at least 8 percent of all emergency-room visits.[5]

ALCOHOL USE BY YOUTH

Alcohol is the primary psychoactive substance of abuse by American children. As the NIAAA fiscal year 2005 Congressional Budget Justification notes, 78 percent of 12th graders, 67 percent of 10th graders, and 47 percent of 8th graders have used alcohol.

The same source of those statistics, the National Institute on Drug Abuse's *Monitoring the Future* survey, also indicates that youth who report having been drunk at least once include 62 percent of 12th graders, 44 percent of 10th graders, and 21 percent of 8th graders. Roughly half of those percentages say that they drank heavily five or more drinks in a row in the past 2 weeks.

The NESARC data show that most cases of addiction, not only to alcohol, but also to other drugs of abuse, first occur in youth, after which new cases drop off sharply. The same research shows that, by comparison, new cases of depression do not follow this trajectory, instead continuing to rise after adulthood.

REFOCUSING THE RESEARCH

The new finding that youth is the stage of life during which alcoholism is most likely to begin calls for a shift in the emphasis of our research. By focusing even more strongly than we currently do on developing strategies to prevent the onset of alcoholism in this population, we have the potential to dramatically reduce, overall, the occurrence of this common disease.

Likewise, shifting the focus of our medication development program to the early stages of the disease stands to improve the effectiveness of treatment. As with most diseases, early treatment for alcoholism could prevent a host of problems, including the medical sequelae of heavy alcohol use, which are estimated to cost $18.9 billion annually.

Studies show that a combination of factors underlie drinking behaviors. Environmental factors—family and peers, for example—are the dominating influences on whether or not an individual first uses alcohol. Personality and temperament also influence the decision to begin drinking. These factors have a profound effect on youth.

Whether or not drinking continues also is influenced by differences, from individual to individual, in the pharmacological effects (activities of genes, proteins, and metabolic products) that come into play once drinking has begun. When drinking progresses to alcoholism, alcohol's pharmacological effects will have become the dominant influence on drinking behavior.

Identifying the pharmacological effects of alcohol is essential to our ability to design effective prevention and treatment strategies for youth. In childhood and adolescence, the pharmacological effects of alcohol are occurring at a time of rapid structural and physiological change in the brain. One of the major questions before us is how alcohol's pharmacological effects work in ways that specifically promote alcoholism during this vulnerable time of life. Two NIH Roadmap initiatives will be particularly informative in this regard, as follows.

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[2] Grant BF, Dawson DA, Stinson FS, Chou SP, Dufour MC, Pickering RP. The 12-month prevalence and trends in DSM-IV alcohol abuse and dependence: United States, 1991–1992 and 2001–2002. Drug and Alcohol Dependence, in press, 2004.

[3] Harwood, H.; Fountain, D.; and Livermore, G. (2000). The Economic Costs of Alcohol and Drug Abuse in the United States 1992 (updated for 1998). Report prepared for the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Department of Health and Human Services. NIH Publication No. 98–4327. Rockville, MD: National Institutes of Health.

[4] The 2002 Department of Defense Survey of Health Related Behaviors Among Military Personnel.

[5] McDonald III AJ, Wang N, Camargo Jr CA. U.S. Emergency Department Visits for Alcohol-Related Diseases and Injuries Between 1992 and 2000, Archives of Internal Medicine, 2004;164:531–537.

The Roadmap Metabolomics Technology Development Initiative will enhance our ability to identify metabolic processes that contribute to alcohol dependence (and alcohol-related organ damage). People have differences in the genes that regulate their cellular mechanisms, including the enzymes responsible for alcohol metabolism. These differences result in variations in how people respond to alcohol; for example, the choice to drink and the amount of alcohol consumed.

Proteins, such as the receptors and transporters for neurotransmitters, play roles in virtually every step of alcohol's actions in the brain and other organs. Another Roadmap initiative, the National Technology Centers for Networks and Pathways, will remove barriers to defining how these proteins behave in the complex biological systems in which they interact. Such proteins are potential targets for medications, but efforts to alter the actions of proteins with potential medication compounds have thus far met with limited success in preventing and treating alcohol-use disorders in adults. This Roadmap initiative will provide much-needed tools that will help us track the interactions of specific proteins at specific points in time and cellular space an ability that will enable us to develop more precise targets for medications to treat the early stages of alcoholism.

ACTIONS UNDERWAY

Our current research on drinking by youth includes studies of the neurobiological mechanisms of adolescent alcohol abuse; an initiative on preventing alcohol-related problems among college students; expanded testing of preventive interventions, from rural children to children in urban, diverse neighborhoods; and an initiative that is examining risk factors and testing community-based, longitudinal prevention programs among children in rural and small urban areas, in response to fiscal year 2004 House Appropriations Report language.

Included in NIAAA's fiscal year 2005 Congressional Budget Justification is an expansion of the latter initiative among youth in rural and small urban communities, both of whom have high rates of alcohol use. Both biological and environmental studies, as well as studies of prevention strategies, will be included. The Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, the National Institute of Child Health and Human Development, the National Institute of Mental Health, and other NIH Institutes, as well as the Department of Education and other Federal agencies, will be invited to collaborate in this initiative.

In addition to our research, we conduct outreach programs for youth. The Leadership to Keep Children Alcohol-Free has recruited 33 Governors' spouses to spearhead a national prevention campaign. The Task Force on College Drinking has brought together university presidents and researchers, and is making headway in efforts to reduce drinking by college students and in evaluating those efforts.

THE LARGER PICTURE

Alcohol abuse and alcoholism often result in behavioral outcomes such as property damage, legal problems, disrupted family lives, and derailed academic pursuits and professional careers. But its consequences also include medical sequelae. With prolonged, heavy use, it can act as a toxin, damaging virtually any organ in the body. For example, alcohol is a leading cause of liver cirrhosis and contributes to some kinds of cancer. Approximately 77 percent of the annual $185 billion cost of alcohol misuse is health-related, generated by medical consequences and lost productivity associated with illness or death.

Research leading to effective strategies for preventing and treating alcoholism early in life, when it is most likely to begin, can help avert many other costly problems. While we will increase our research on drinking by youth, we will continue our studies of the many other facets of alcohol use, such as fetal alcohol syndrome, as well as our research on the apparent protective effect of moderate drinking against certain chronic diseases.

CONNECTION TO OBESITY

We will also conduct research on alcohol's role in the national obesity epidemic. In addition to acting as a drug, alcohol is a food—a highly caloric food. It has more calories per gram than do carbohydrates or proteins.

In addition, alcohol acts on some of the same neurotransmitter systems that regulate appetite. Some medications that work to reduce appetite may also reduce alcohol intake. One of the highest priorities that NIH lists in its Government Performance and Results Act goals is human testing of the compound rimonabant for its potential to reduce alcohol use.

Among the many neurotransmitter receptors that alcohol affects is the one receptor to which the active ingredient in marijuana binds. Stimulation of this receptor promotes appetite, and NIAAA animal studies show that blocking the receptor with rimonabant has the potential to reduce drinking in humans. NIAAA is preparing a human trial of rimonabant for treatment of alcoholism. Rimonabant made news in March of this year, when a French company announced the medication's effectiveness in reducing both weight and smoking.

The anticonvulsant topiramate also is being tested for its effectiveness in reducing both obesity and alcohol use, through actions on another neurotransmitter system. The neurotransmitter gamma-aminobutyric acid (GABA), among many others, is known to be an important intermediary of alcohol's actions in the brain.

Obesity and alcohol are linked in yet another way, recent studies show. The livers of obese rats undergo more cell death and sustain more injury from heavy, periodic alcohol use than do those of their slimmer counterparts. In humans, liver damage is one of the most prevalent medical consequences of chronic drinking.[6]

IMPLICATIONS

On a large scale, epidemiology tells scientists where the action is. That is the case with our new findings on the stage of life when alcoholism is most likely to develop; that is, by age 25. We are beginning to take steps to greatly increase our focus on this period—on how variations in genetic, biological, and environmental factors unfold to promote establishment of alcoholism during development. Meanwhile, the NIH Roadmap initiatives on metabolomics and proteomics are developing tools that can significantly accelerate our research.

PREPARED STATEMENT OF DR. LAWRENCE A. TABAK

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) for fiscal year 2005. The fiscal year 2005 budget includes $394,080,000, an increase of $11,032,000 over the fiscal year 2004 level of $383,048,000 comparable for transfers proposed in the President's Request.

DELIVERING ON THE PROMISE OF BASIC RESEARCH

Although highly technical in nature, basic research provides the detailed molecular clues that scientists and clinicians can use to develop new strategies that more effectively prevent or treat disease. This year, I would like to highlight how NIDCR's investment in the basic sciences continues to yield important advances in oral and public health. I also would like to mention how NIDCR stands to benefit from the recently launched NIH Roadmap which has the potential to catalyze virtually all areas of oral health research and, most importantly, hasten the development of novel treatments that could greatly improve American oral health.

GENE TRANSFER AND THE SALIVARY GLANDS

A prime example of basic research creating new clinical opportunities is the transfer of replacement genes into the salivary glands for therapeutic purposes. In the early 1990s, a team of NIDCR scientists published their initial paper on the technical feasibility of this approach. Thereafter, they began a unique long-term research interest in transferring replacement genes into the salivary glands of persons with Sjögren's syndrome and cancer patients whose salivary glands were damaged during radiation treatment. The hope was that the replacement genes would increase the production of saliva and eliminate the chronic parched sensation that plagues people with dry mouth conditions.

The NIDCR scientists also began to apply their gene transfer studies to a third and seemingly less obvious therapeutic area: single-protein disorders, such as type I diabetes, human growth hormone deficiency, and erythropoietin-responsive deficiencies. Frequently overlooked in the medical literature, salivary glands not only release saliva into the mouth, they routinely secrete digestive enzymes and other proteins into the circulatory system. As the scientists later would demonstrate, the salivary glands readily accept gene-carrying vehicles, or vectors. Thereafter, with minimal coaxing, the salivary glands act as natural protein factories, dutifully manufacturing the encoded replacement protein and pumping it at steady levels into the circulation. The approach has some built in advantages over gene therapy in other

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[6] Carmiel-Haggai M, Cederbaum AI, Nieto N. Binge ethanol exposure increases liver injury in obese rats. Gastroenterology, 125(6):1818–33. Dec. 2003.

parts of the body, such as the liver. Salivary glands are easily accessible and any potential adverse effects would be non-life threatening. Moreover, salivary gland cells are encapsulated to prevent leakage of the vector into the circulation and to other tissues.

Recently, the group developed a new version of gene-carrying vector that entered the salivary glands of mice and produced the human protein erythropoietin for at least one year, a major step forward in the research. Just as importantly, the vector—a stripped down, bioengineered version of the harmless adeno-associated virus—did not trigger a sustained immune response, a common setback in gene therapy experiments.

Building on this strong basic research base, NIDCR has developed a new initiative to evaluate the safety and efficacy of salivary gland gene transfer techniques in people with systemic single-protein deficiencies. The initiative will consist of three Phase I/II clinical trials. The first clinical trial will involve a prototype systemic single-protein deficiency disorder, adult growth hormone deficiency. As currently proposed, 21 patients will be enrolled in the study, which will be completed in four years. If successful, a second clinical trial will be conducted to treat people with erythropoietin-responsive deficiencies and ultimately a third clinical trial for those with Sjögren's syndrome and/or cancer patients with dry mouth.

PERIODONTAL DISEASE AND PRETERM BIRTH

Another outstanding example of basic research creating new clinical opportunities is in the area of preterm pregnancy. In the United States, about one in eight babies is born prematurely,[1] which is defined as a birth that occurs three or more weeks earlier than the expected due date. As all too many parents have tragically experienced, extremely preterm babies can be so small and underdeveloped that they must remain hospitalized for months and, if they survive, spend years battling chronic health problems.

This serious and common problem has spurred scientists to identify "risk factors" associated with premature births. These risk factors—which now include smoking, low-income status, hypertension, diabetes, alcohol use, genitourinary tract infections—allow doctors to identify women who are more likely to deliver prematurely and thereby tailor their prenatal care to control or eliminate the risk factors.

However, the list of risk factors remains a work in progress. An estimated one in four preterm births occur without any known explanation, and that has left scientists searching for additional susceptibility factors to help more mothers and reduce the estimated $13.6 billion per year spent in the United States on hospital stays for infants with a diagnosis of prematurity.[2]

In the mid 1980s, scientists began to suspect that periodontal disease might be one of these elusive risk factors. These NIDCR grantees and colleagues monitored women with more serious periodontal disease and found they were more likely to deliver early than those with mild or non-existent disease. They also have developed a plausible biological explanation to explain the possible association. Based on animal studies, the scientists hypothesized that certain bacteria from severe periodontal infections, most notably *Porphyroma gingivalis,* enter the bloodstream and eventually circulate to the womb. There, the oral pathogens colonize and irritate the uterine wall. This causes inflammation of the uterus and a rise in prostaglandins and other infection-signaling chemicals, which can induce early contractions and trigger premature labor.

Left unanswered is whether treating women for periodontal disease during pregnancy will help them give birth to full term babies. The NIDCR recently launched two large randomized clinical trials to answer this important public health question. These national studies, which merge the disciplines of dentistry and obstetrics, will involve over 2,600 women of various racial, ethnic, and economic backgrounds. What is unique about these clinical trials is there will be a yes-or-no outcome for each woman within 37 to 40 weeks, or the completion of the pregnancy. Women will not need to be tracked at great expense for 10 or 20 years to get the final answer, as is often the case in clinical research. Once all the data are compiled and analyzed, which could take an estimated five years to assemble and analyze, researchers anticipate that they will have sufficient clinical data to offer sound scientific advice one way or the other on this critical public health issue.

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[1] March of Dimes Defects Foundation. http://peristats.modimes.org. Access on March 15, 2003.
[2] March of Dimes, PeriStats.

PAIN RESEARCH

In another example of the potential payoff from basic research, scientists are mapping in greater detail the multiple routes, or pathways, that sensory signals travel en route to the spinal cord and brain. This work has resulted in several new leads in how to more effectively manage pain. One of the most promising new leads stems from work conducted at the NIDCR. Our scientists found that an ultrapotent compound selectively eliminated an entire class of pain-sensing neurons from the peripheral nervous system of a living organism. The compound, called resiniferatoxin (RTX), killed the neurons, blocking inflammatory pain, thermal pain sensation, and reducing hypersensitivity to pain. Importantly, the animals maintained their ability to sense pain, in this case from a pinch, and they remained well coordinated, an indication that RTX did not affect sensory nerves in the muscles and joints. Since these initial reports, the investigators have assembled additional preclinical data and are moving rapidly toward evaluating RTX in human clinical trials.

In order to seed additional discoveries in pain research and to help more Americans effectively manage pain, the NIDCR will begin an initiative to define the proteins and protein networks involved in processing pain-signal information in the orofacial region. This initiative encourages interdisciplinary studies that employ genomic and proteomic approaches, imaging technology, and computational biology to clarify the molecular events involved in chronic orofacial pain disorders.

PUTTING RESEARCH INTO PRACTICE

To achieve our goal of improved oral health for all people, NIDCR must ensure that research advances are translated and adopted into clinical practice. Many of the unique questions faced by dental health professionals on a daily basis are most appropriately addressed in dental practice settings, among unselected patient populations. Practice-based research networks can generate important and timely information to guide the delivery of health care and improve patient outcomes. The NIDCR will launch an initiative to create dental Practice-Based Research Networks (PBRNs) to conduct clinical research. In time, linking the oral health practice-based research networks with existing medical networks will provide additional patients, professional expertise, and integration of resources for conducting research across a broad spectrum of health care specialties. By connecting practitioners with experienced clinical investigators, PBRNs will enhance clinical research supported by the NIDCR and produce findings that are immediately relevant to practitioners and their patients. The networks can support a variety of clinical studies with clear and easily defined outcome measures, and they typically draw on the experience and insight of practicing clinicians to help identify and frame the questions. Because research is conducted in the real-world environment of dental practice, the results are more likely to be readily adopted by practitioners.

NIH ROADMAP

The NIH Roadmap provides several additional opportunities to the oral-health research community. For example the goals of the initiative *Building Blocks, Biological Pathways and Networks*—are closely linked to NIDCR's molecular anatomy efforts to identify the full complement of genes, proteins and protein networks that are expressed in both oral cancer and periodontal disease. Advances in proteomic analysis platforms will be crucial for NIDCR to achieve its goal of defining the salivary proteome—a critical step in the Institute's long-term goal to exploit the salivary secretions for diagnostic purposes. The *Molecular Libraries and Molecular Imaging* initiative holds great promise for accelerating NIDCR's progress in defining the molecular pathways of pain reception and in elucidating new therapeutic targets to manage chronic pain. In addition, the initiative *Research Teams of the Future* will enable NIDCR's ongoing inter- and multi-disciplinary efforts to further expand and develop new ways to approach research questions. Finally, the integration of dentists into the new clinical research infrastructure that will be created by the Roadmap is key given that overall health and oral health are interrelated and that certain systemic conditions such as diabetes, Sjögren's syndrome, HIV/AIDS and osteoporosis have important oral symptoms, manifestations or complications.

NIDCR envisions a clear path ahead for oral and craniofacial research. Many exciting new leads that have been reported in recent years makes it easy to imagine that the next wave of research advances will have a more profound and far reaching effect on oral health than ever before.

Senator SPECTER. Thank you very much, Dr. Zerhouni.

We have been joined by two members of the Appropriations Committee. Let me turn first to the distinguished chairman of the full committee, Senator Stevens.

Senator STEVENS. Well, Mr. Chairman, I am late. So I will just ask to put my statement in the record. I do greet our friends at the table and look forward to the comments and questions.

Senator SPECTER. Without objection, the statement will be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TED STEVENS

Thank you Mr. Chairman. It's a pleasure to welcome Dr. Zerhouni and his distinguished colleagues who head up the Institutes at NIH here today.

I'd also like to thank Dr. Andy von Eschenbach. Andy, I understand from my good friend Dr. Mike Phelps that you gave an excellent speech this past Sunday to the Academy of Molecular Imaging meeting in Orlando. As you know, PET and Molecular Imaging are special interests of mine.

I must be brief since I have three other hearings where I must make an appearance. However, I want to commend Dr. Zerhouni for his efforts to develop the "Roadmap" initiative.

That initiative aims to focus NIH's resources on several broad categories of medical research and to bring together different disciplines to make real, rapid and visible progress to determine the true basis of many diseases and then to treat them. The Roadmap, with its focus in the Director's office is important because no single NIH Institute can address these problems alone.

I'm particularly pleased that you have chosen to focus early efforts of the Roadmap on the integration of nanotechnology, systems biology, and molecular imaging. By combining these three disciplines we hope to discover the molecular basis of diseases like cancers and then to develop targeted molecular therapies to arrest the progress of the disease and cure it.

In the fiscal year 2004 appropriations legislation I sponsored an amendment to give the Director of NIH new authority to put together innovative collaborative approaches to medical research to help speed up the process. I hope that you, Dr. Zerhouni, will use that authority to take bold and visionary steps to help us find these cures.

I've been a longtime supporter of large increases in funding for medical research. I continue that support, but I must warn you that it will be more and more difficult to sustain increases for medical research unless you do pursue bold new approaches such as nanosystems biology that have the potential to show real results that the American taxpayer can see. We must begin to show a return on our investment in order to continue it.

Once again, I commend Dr. Zerhouni and the directors of the NIH Institutes for their leadership and efforts on behalf of all people.

Senator SPECTER. Senator Cochran, do you have an opening statement?

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you very much. I have submitted a statement as well and hope it will be included in the record.

I want to commend the Director and his associates who are here today for the fine work that you are doing. I am particularly impressed with the work in health disparities and some of the research that is being undertaken now and funded by the National Institutes of Health.

PREPARED STATEMENT

I notice an increase in the budget request for the National Center for Minority Health and Health Disparities. I think that is the entity that is supporting the Jackson Heart Study in my State

where very meaningful work is being done in conjunction with the University of Mississippi Medical Center and Jackson State University and other educational institutions in our State to try to get at the bottom of some of the questions of why there is such a disparity in some kinds of heart diseases. This is being done in conjunction with the National Heart, Lung, and Blood Institute as well. But I think the need for more research, conducted in the places where we are experiencing health disparities or high incidences of chronic diseases, is something that is overdue, and I congratulate you for taking this initiative.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Dr. Zerhouni, thank you for joining us today to discuss the budget for the National Institutes of Health. We have had great success in increasing NIH funding. It is my hope that we continue to support high quality research, and focus this research on the most pressing health issues of our country. Our goal should be to make sure NIH research benefits all Americans.

I know you are familiar with the Jackson Heart Study, which looks at the reasons why African-Americans suffer disproportionately from heart disease. I hope the NIH will continue to take an active role in making sure research like this reaches underserved areas of our country. This relatively small investment has made a tremendous impact on my state. I am encouraged by the progress made by institutes, like the National Center for Minority Health and Health Disparities. I am pleased to support NIH in these efforts.

Senator SPECTER. Thank you, Senator Cochran.

We will now proceed with 5-minute rounds of questioning, as is the custom of the subcommittee.

FISCAL YEAR 2005 BUDGET REQUEST

Dr. Zerhouni, your proposed budget will permit grant increases by only 1.3 percent instead of the inflationary increase of 3.5 percent. If NIH applied its usual policy of providing an average grant increase equal to the rate of inflation, it is my understanding that about 640 fewer competing grants would be funded than in 2004.

First of all, is that accurate?

Dr. ZERHOUNI. That is accurate, Senator.

Senator SPECTER. After the increases which we have provided over the last 5 years, do you think the proposed budget is sufficient to maintain the momentum and bring discoveries from the laboratory to the doctor's office?

A subset of that is, how much additional funding would be required to restore the usual NIH average cost policy, assuming the same number of grants which are now in the budget?

Dr. ZERHOUNI. Ideally, Mr. Chairman, you would like to be sure not to fall behind inflation. However, this year, because of the very difficult budget environment, we had to make some difficult choices. We elected to maintain the number of grants to be able to provide as many scientists the opportunity to succeed in applying and made some sacrifices on the cost increases.

If we had $220 million more—the number is $220 million—we could satisfy both conditions: have enough grants and inflationary increases.

Senator SPECTER. If the Congress is willing to appropriate the additional $1.3 billion, what new research initiatives would NIH be able to conduct with these additional funds?

Dr. ZERHOUNI. As you know, because of the doubling and the opportunities offered by the doubling, many of our institutes, if not all of them, have opportunities in translation in clinical research. This is the area of research generally that is difficult to undertake in a budget that is the budget that we are requesting.

So when you look at the priorities that we would have to fulfill, if we had more resources, the first one would be to keep up with inflation. The second would be to continue our analysis and the framework for the Roadmap for medical research, accelerate that. We have some programs like the extramural construction programs, the IDeA program, that we would like to enhance over time, including training stipends. But the most important report from all the institutes is that there are some clinical trials in translational research that will have to be slowed down.

Senator SPECTER. Well, I would like to have a more detailed answer for the record on what the impact will be on the administration's request contrasted with what the impact would be on an additional $1.3 billion. So we have specific information as to how many grants there would be, what will happen to the clinical programs.

Let me turn now to the issue of stem cell research. You and I have discussed this at some length and the President made his famous statement back on August 9th of 2001 about certain stem cell lines being added. Some of those stem cell lines are contaminated with mouse feeder cells. Some of those stem cell lines are owned other places. We see Harvard with a $100 million allocation, which is wonderful but nothing compared to the $28 billion you have. We see South Korea taking the lead. We see scientists leaving the United States because ideology is conflicting with medical research.

[The information follows:]

RESEARCH THAT NIH COULD FUND WITH AN ADDITIONAL $1.3 BILLION

The fiscal year 2005 President's Budget requests an additional $764 million for NIH, a significant increase to the program level given the competing priorities within the Federal budget. An additional $1.3 billion over the request would provide $30.057 billion, an increase of 7.2 percent over fiscal year 2004. With this additional funding, NIH would fund a larger share of the great research ideas that scientists submit to us. We would be able to fund about 700 more research project grants, increasing chances of a scientist's application being funded and increasing the currently expected "success rate" from the 27 percent in the President's Budget to 29 percent. Additional priorities would include:

—Accelerating implementation of Roadmap initiatives;
—Implementing an interdisciplinary approach to neuroscience research by completing the phase 2 of the Porter Neurosciences Building;
—Providing average cost increases equal to biomedical inflation and finance the committed levels for competing continuation grants;
—Increasing support for research training awards; and
—Increasing the amounts NIH pays on career awards.

Examples of the new research initiatives and significant expansions of ongoing programs that NIH would conduct with these additional funds follow:

TRANSDISCIPLINARY RESEARCH ON ENERGETICS AND CANCER (TREC) (NCI)

—Novel initiative involving scientists from multiple disciplines and encompassing projects spanning the biology and genetics of energy balance to behavioral, sociocultural, and environmental influences upon nutrition, physical activity, weight, energy balance and energetics.
—The TREC Centers would foster collaboration among transdisciplinary teams of scientists with the goal of accelerating progress towards reducing cancer inci-

dence, morbidity and mortality associated with obesity, low levels of physical activity and poor diet.
—Centers would also provide training opportunities for new and established scientists who can carry out integrative research on energetics, energy balance and its consequences.

CANCER BIOMEDICAL INFORMATICS GRID (CABIG) (NCI)

—Cancer research platform with common standards to expedite progress by creating a network that links organizations, institutions, and individuals to enable the sharing of cancer research infrastructure, data, and tools.
—All cancer researchers would have access to a common research infrastructure that creates a plethora of opportunities to not only make important new findings but to do so more quickly and efficiently than ever before.
—This new system would offer a library of tools and resources—from clinical trial management systems to tissue bank and pathology tools—that are all built to common standards and are interoperable with other existing systems.
—Study population data would be far more robust and researchers will be able to mine data in a way that simply isn't possible at the moment.
—Joins the various fields of cancer research—from etiologic research to prevention, early detection and treatment.

UNDERSTUDIED CANCERS OF HIGH LETHALITY (NCI)

—A key element to the elimination of death from cancer by 2015 would be to focus on malignancies which are highly fatal, such as pancreatic, esophageal, and liver cancers.
—When these cancers are found, relatively little prolonging of life or quality of life follows.
—Understanding gene-environment interactions is important in learning who is at elevated risk, and how that risk is regulated.
—Discoveries in these areas would lead to more accurate and cost-effective public health interventions aimed at eliminating mortality.

PATIENT NAVIGATION RESEARCH PROGRAM: ELIMINATING BARRIERS TO TIMELY DELIVERY OF CANCER DIAGNOSIS AND TREATMENT SERVICES (NCI)

—A major disconnect or gap exists between cancer *Discovery* and *Development* research and *Delivery* for many Americans. *Discovery* and *Development* research results in beneficial procedures for cancer prevention, early detection, diagnosis, and treatment that are intended for all Americans. Health disparities arise when the *Delivery* system does not provide access to timely, standard cancer care to everyone in the nation. NCI has established the goal of eliminating suffering and death due to cancer by 2015.
—The NCI is challenging principal investigators to develop effective patient navigation interventions. These interventions would address access barriers to quality, standard cancer care. The purpose of the *Patient Navigation Research Program* (PNRP) would be to develop interventions to reduce the time to delivery of standard cancer care services after identifying a cancer-related abnormal finding.
—The patient navigator could assist patients and their families through the cancer care continuum.
—The research hypotheses are that navigated patients would: (1) receive timelier, definitive diagnosis following screening and abnormal finding; (2) receive more timely treatment following positive diagnosis; (3) improve their satisfaction with the health care system experience.

STUDY TO IDENTIFY RISK FACTORS FOR CORONARY HEART DISEASE (CHD) IN HISPANIC POPULATIONS (NHLBI)

—The nation's largest minority group.
—Involve four community-based cohorts of adults, one each of majority Cuban, Puerto Rican, Mexican American, and Central American origin.
—Examine the role of acculturation in the development of risk factors and determine if any play a uniquely harmful role in the development of CHD in Hispanics.
—Include a closely integrated community and professional education component to return the benefits of research results to the participating communities.

FIVE-YEAR RANDOMIZED CLINICAL TRIAL OF CHRONIC OXYGEN USE IN MODERATE TO SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS (NHLBI)

—COPD is the fourth most common cause of death in the United States.
—Oxygen therapy is known to extend the life of patients with severe COPD and hypoxemia.
—Billions of dollars are spent in the United States each year to provide oxygen for patients with moderate or severe COPD without good evidence as to who benefits.
—The trial would determine the effects of oxygen therapy on life expectancy, hospitalization rates, independent living, and quality of life.

MULTI-CENTER CLINICAL TRIAL TO EVALUATE NEW TREATMENT APPROACHES FOR SARCOIDOSIS (NHLBI)

—Sacroidosis is a multisystem disease that usually affects the lungs, and is more common in black Americans.
—Current treatment, which is based mainly on corticosteroids and cytotoxic agents, is non-specific and has many dangerous side effects.
—An NHLBI Sarcoidosis Research Working Group and several patient advocacy groups recommended support for a trial to test new agents for sarcoidosis.

IDENTIFY AND TEST APPROACHES TO REDUCING CARDIOVASCULAR DISEASE THAT ARE SPECIFIC TO AMERICAN INDIAN AND ALASKA NATIVE POPULATIONS (NHLBI)

—Such an initiative would test approaches to reducing cardiovascular disease (CVD) risk factors in American Indian/Alaska Native (AI/AN) populations that can be incorporated into clinical programs of community health care systems or delivered through other public health approaches in native communities.
—Many AI/AN communities bear a heavy burden of CVD and modifiable CVD risk factors.
—AI/AN communities are concerned that few intervention studies have been launched to test possible solutions.

PRACTICE BASED RESEARCH NETWORKS OF DENTAL SPECIALISTS (NIDCR)

—NIDCR's Practice Based Research Networks (PBRN) initiative would otherwise be limited to networks of general dental practitioners.
—Networks provide an infrastructure for conducting multiple, collaborative clinical trials and observational studies relating to dental practice and oral health care.
—Linkage of the oral health PBRNs with existing medical PBRNs would provide additional patients, professional expertise, and integration of resources for conducting clinical research across a broad spectrum of health care specialties.

REGENERATIVE DENTAL MEDICINE (NIDCR)

—Diseases and injuries that damage orofacial tissues have a serious impact on quality of life.
—Human stem cells would be utilized in combination with new bio-inspired materials to regenerate the complex structures of the orofacial system.
—Researchers would develop and test a number of stem cells and biomaterial structures that mimic the multi-dimensional architecture/function of tooth structures.

PROSPECTIVE STUDIES ON CRANIOFACIAL PAIN & DYSFUNCTION (NIDCR)

—Participants enrolled in this study would be followed over time to identify risk factors associated with or predictive of the onset of craniofacial pain and dysfunction.
—Temporomandibular joint (TMJ) dysfunction is a condition of particular interest.

CLINICAL RESEARCH TRAINING (NIDCR)

—In the "post-genomic era," translational and clinical research plays an important role in bringing laboratory observations into the clinical setting.
—NIDCR's new program announcement would foster clinical research training in multidisciplinary research settings for all members of the clinical research team.

FULL-SCALE CLINICAL TRIAL OF PRIMARY INTERVENTIONS TO PREVENT OR DELAY TYPE 2 DIABETES IN CHILDREN AND ADOLESCENTS (NIDDK)

—Cases of type 2 diabetes are increasing in the pediatric population, especially among adolescents and in certain minority groups.
—A school-based intervention approach may be an effective way to prevent risk factors for type 2 diabetes in children and adolescents.
—Pilot studies for a multi-site, multi-component, school-based intervention trial employing both environmental and behavioral changes are under way; could launch the trial in fiscal year 2005.

IMPROVE CLINICAL TRIALS FOR TREATMENT OF INFLAMMATORY BOWEL DISEASE (IBD) (NIDDK)

—The conduct of new clinical trials in IBD is hampered by the current need to rely on indirect diagnostic tests and nonspecific clinical features.
—The conduct of clinical trials and development of safer, more effective treatments would be accelerated by research in proteomics, to discover new biomarkers, and in molecular imaging, to discover new non-invasive diagnostic imaging tests.

STUDY THE ROLE OF THE INTRAUTERINE AND POSTNATAL ENVIRONMENTS IN THE DEVELOPMENT OF OBESITY (NIDDK)

—A better understanding of aspects of the intrauterine environment and a mother's medical status that contribute to future overweight and obesity in offspring could lead to more effective interventions before, during, or shortly after pregnancy.
—Strategies to prevent or treat obesity could also greatly benefit from research on the impact of diet and other environmental factors on the early development of brain pathways regulating calorie intake and energy expenditure, and the permanence of these effects in adulthood.
—Tools are available to conduct these studies in appropriate animal models, including primates.

EXPAND FEASIBILITY TRIAL OF DAILY DIALYSIS TO DETERMINE EFFECTS OF NEW, MORE INTENSIVE DIALYSIS MODALITIES ON MORTALITY AND CARDIOVASCULAR DISEASE (NIDDK)

—Clinical studies are needed to determine whether life expectancy of persons with end-stage renal disease (ESRD), or chronic kidney failure, can be improved by modifying standard dialysis regimens.
—Clinical centers have been established to test the feasibility of a randomized clinical trial of more frequent dialysis.
—The current frequent dialysis trial is limited by size and design to measuring intermediate outcomes, such as blood pressure, anemia, and quality-of-life.
—An expansion of the trial could enable assessment of the effect(s) of any change in dialysis regimen on hospitalization rate and mortality, and on cardiovascular events—e.g., stroke, myocardial infarction and heart failure—which often complicate ESRD.

INITIATE THE VERY LARGE PHASE III CLINICAL TRIALS FOR PARKINSON'S DISEASE (NINDS)

—Necessary to adequately test one or more of the neuroprotective drugs for Parkinson's disease (minocycline, creatine, coenzyme Q10 and GPI–1485) that are being tested in pilot trials.

CONDUCT A PHASE III CLINICAL TRIAL OF CEPHALOSPORIN FOR THE TREATMENT OF ALS (LOU GEHRIG'S DISEASE) (NINDS)

—A screen of 1,040 drugs for potential use against neurodegenerative diseases revealed one that may be particularly helpful for ALS—the antibiotic cephalosporin.

LAUNCH CHEMICAL COUNTERTERRORISM RESEARCH TO COMBAT NERVE AGENTS (NINDS)

—A number of chemical agents and toxins that have served or could serve as terrorist weapons that target the nervous system.
—Research initiatives would focus on ameliorating the acute neurologic responses to these chemical weapons as well as alleviating any chronic neurodegenerative effects.

EXPAND THE SPECIALIZED PROGRAMS OF TRANSLATIONAL RESEARCH IN ACUTE STROKE (SPOTRIAS) (NINDS)

—From four to eight centers.
—Would accelerate translation of basic research findings into clinical practice in acute ischemic and hemorrhagic stroke.

INITIATIVE FOR PANDEMIC INFLUENZA (NIAID)

—Accelerate the development of next generation influenza antiviral drugs and the production and clinical testing of up to four pilot lots of candidate vaccines by up to one year or more.
—Influenza routinely causes 36,000 deaths per year in the United States; however, the ability of flu viruses to occasionally jump from animals to humans poses an imminent threat of a pandemic affecting millions of people—over 20 million people worldwide is estimated to have died during the flu pandemic of 1918.
—Research would also expand surveillance of emerging flu strains in Asian animals to support development of new vaccines against influenza strains with pandemic potential.

CLINICAL TRIALS OF HIV/AIDS VACCINE CANDIDATES (NIAID)

—Expand clinical trials to accelerate by one or more years clinical evaluation of six promising HIV vaccine candidates.
—Forty million people were estimated to have HIV/AIDS as of December 2003, with five million new infections occurring in 2003. Another three million people died of the AIDS pandemic in 2003, including 500,000 children, with a total of 70 million people projected to die of the disease by 2020 if the current trends continue.
—As with other pandemic infectious diseases, a key component to preventing the spread of HIV/AIDS, and to mitigating the long-range impact of the AIDS pandemic, is the development of an effective HIV/AIDS vaccine. Critical challenges to developing an effective vaccine include the need to clinically evaluate a large number of promising HIV vaccine candidates in humans as rapidly as possible to determine the toxicity and effectiveness of the vaccine candidates. Factors contributing to the need to clinically evaluate a large number of the most promising vaccine candidates include the multitude of different HIV/AID virus strains in existence and the frequency at which the virus mutates and the fact that the virus infects and destroys the immune system.

CLINICAL TRIALS IN ORGAN TRANSPLANTATION (NIAID)

—Expand and accelerate clinical trials to develop therapeutic strategies to reduce the immune-mediated morbidity and mortality of organ transplantation.
—Over 25,000 people receive organ transplants each year. Although the one-year survival for single-organ transplantation has improved over the last 15 years to a level approaching or exceeding 90 percent, there has been little success in reversing the decline in long-term graft-vs-host disease and patient survival (13 percent to 55 percent at 10 years, dependant upon organ).
—Studies would support both children and adults and will address the barriers to short- and long-term success of transplant procedures, including incompatibility between donor and recipient, acute and chronic rejection, and complications of long-term pharmacologic immune suppression.

CLINICAL TRIALS OF TOPICAL MICROBICIDES (NIAID)

—Expand existing support of clinical trials to accelerate the clinical evaluation of four promising microbicide candidates that have unique mechanisms of action to potentially protect against sexually transmitted diseases (STD), including HIV/AIDS.
—Topical microbicides are creams, gels or foams that can be applied to the vagina or rectum and prevent STD-causing microbes, including HIV, from invading the host. Pharmaceutical companies have been reluctant to invest in research on microbicides primarily because not enough data has been gathered through large clinical studies in humans to provide a "proof of concept" of any microbicide product.
—A partially effective microbicide could avert more than 2 million HIV infections over a 3-year span; also, microbicides could play a critical role in reducing STD transmission from mother to infant during childbirth.

DETERMINE THREE-DIMENSIONAL STRUCTURES OF PROTEINS (NIGMS)

—Partner with other Institutes.
—Includes those related to cancer and emerging infectious diseases.
—Would be useful for the design of new antibiotics or anti-cancer agents.

RESEARCH RELATED TO DETERMINING WHY DIFFERENT INDIVIDUALS RESPOND DIFFERENTLY UPON TREATMENT WITH THE SAME DRUGS (NIGMS)

—Would help physicians customize treatment to individual patients and may guide the development of new drugs that are more predictively effective in most people.

DEVELOPMENT OF TOOLS FOR INVESTIGATING MODEL ORGANISMS (NIGMS)

—Model organisms such as fruit flies, mice, and roundworms have provided great insights into fundamental biological mechanisms and into human disease.

INNOVATIVE METHODS OF NEWBORN SCREENING (NICHD)

—While ensuring protection of privacy and providing ethical safeguards, the NIH could proceed with efforts to identify, at birth, hundreds of genetic defects associated with mental retardation, primary immunodeficiency diseases, and other potentially disabling and fatal conditions.
—Technologies generated by the Human Genome Project are available to screen for hundreds of genetic diseases in newborns.
—A database in rare genetic diseases could be developed to enable scientists to identify unrecognized genetic defects in newborns, to study currently untreatable disorders, and to develop new therapeutics.
—New screening techniques could allow clinical and preventive interventions for currently treatable genetic disorders, such as Severe Combined Immunodeficiency Disease (SCID), in time to prevent or mitigate risks of early death or life-long disability.

GENOMIC AND PROTEOMIC RESOURCES FOR PREMATURE BIRTH (NICHD)

—The NIH could establish a major consortium to create high-quality data on human gene and protein expression, and to make this information available on a publicly-accessible database that will be dedicated to prematurity research. Investigators could mine the database to advance their own research into the causes of and ways to prevent premature birth.
—Premature birth causes almost 70 percent of neonatal deaths and reducing prematurity would reduce wide racial disparities in infant mortality.
—The depth and accessibility of the new genomic and proteomic database could enable scientists to discover biomarkers for premature birth and ultimately to develop early diagnostic and effective treatment interventions.

RESEARCH BASE TO ASSESS EARLY CHILDHOOD LEARNING AND SCHOOL READINESS (NICHD)

—The NIH could develop, refine, validate, and scale-up tests to assess how well preschool programs help young children—especially those at risk of school failure—to achieve "school readiness," cognitively, socially, and behaviorally.
—Significant academic, public, and political attention is focused on the educational achievement of all children, beginning with preschoolers, with certain federal funds tied to school systems' performance.
—Preschool programs need scientifically-based tests to measure accurately how well they prepare young children for later school success. The programs especially need tests to measure their performance with non-English speaking, ethnically diverse, and educationally at-risk preschoolers. For the most part, such tests do not exist, leaving preschool programs unable to measure their performance for purposes of federal funding.
—The NIH is the primary research agency with the basic and applied scientific expertise to produce these tests, which are now lacking.

THE NATIONAL CHILDREN'S STUDY (NICHD)

—The first two vanguard centers could be established for this ground-breaking, congressionally-authorized, longitudinal study of children's health and development. (There would be significantly larger out-year costs.)

—Extensive planning and selected feasibility studies enable vanguard centers, for this large and complex research effort, to investigate how environmental factors, broadly defined, may influence children's health and development.
—Primary care pediatric practices and other types of clinical sites could become vanguard sites.

NEW INTERVENTIONS TO IMPROVE PREGNANCY OUTCOMES (NICHD)

—The NIH could proceed with clinical trials and related studies to prevent preterm births and improve neonatal outcomes.
—An NIH research network recently discovered the first effective intervention—progesterone treatment of high-risk women during pregnancy—to prevent recurrent preterm birth. The new treatment cannot be approved by the FDA until researchers study children of mothers who received the experimental treatment to detect any later-emerging adverse effect in the children.
—A clinical trial is needed to affirm preliminary findings that a nutritional supplement during pregnancy (an Omega-3 (n-3) polyunsaturated fatty acid) is particularly efficacious in preventing recurrent preterm birth in African American women, for whom the experimental progesterone treatment was less effective.
—A clinical trial is needed to affirm preliminary findings that a single, simple injection of tin mesoporphyrin can successfully prevent complications of hyperbilirubinemia that can result in severe, life-long disabilities. If not diagnosed and treated, hyperbilirubinemia can lead to jaundice, brain injury and kernicterus (a condition of severe neural symptoms, associated with high levels of bilirubin in the blood).

CLINICAL TRIAL FOR THE TREATMENT OF INFLAMMATORY EYE DISEASE (NEI)

—Would be able to begin a clinical trial to evaluate a treatment for uveitis that will greatly enhance patients' quality of life.
—Uveitis is a group of ocular inflammatory disorders that represent a major cause of vision loss and blindness in the United States.
—This new monoclonal antibody therapy could mean fewer side effects than current therapies that require systemic, immuno-suppressive drugs, leading to an improved quality of life.

CLINICAL TRIALS NETWORK FOR THE TREATMENT OF AGE RELATED MACULAR DEGENERATION (AMD) (NEI)

—Could launch a clinical trials network to test promising new therapies for age-related macular degeneration.
—A clinical trials network is needed to test a variety of new treatment approaches targeting the full range of disease forms and levels of severity of age-related macular degeneration.
—Age-related macular degeneration is the leading cause of vision loss among Americans over 65 years of age, the fastest growing segment of the U.S. population.

ROBUST PROGRAM TO EVALUATE THE TOXICOLOGY OF NANOSCALE MATERIALS (NIEHS)

—Nanoscale materials are already appearing in commerce as industrial and consumer products and as novel drug delivery formulations. Commercial applications and resultant opportunities for human exposure may differ substantially for nanoscale vs. "bulk" materials.
—Currently there is very little research focus on the toxicology of manufactured nanomaterials. There are indications in the literature that manufactured nanomaterials may distribute in the body in unpredictable ways and that certain nanoparticles have been observed to preferentially accumulate in particular organelles.
—The NTP/NIEHS research program would evaluate the toxicological properties of major nanomaterials classes which represent a cross-section of composition, size, surface coatings, and physico-chemical properties, and use these as model systems to investigate fundamental questions concerning if and how nanomaterials can interact with biological systems.

USE OF METABOLOMICS TECHNOLOGIES FOR PREDICTING TOXICOLOGICAL RESPONSES (NIEHS)

—Assessment of exposure and of risks from exposure could be greatly improved by using metabolic indicators such as changes in gene, protein or metabolite expression.

—Research supported by this initiative would focus on the application of metabolomics technologies to identify predictive markers of exposure, toxicity and disease in animal and human populations; link metabolic profiles with biological pathways and mechanisms of environmentally-related exposures and diseases; and develop computational and modeling approaches for assessment and integration of metabolomics data in predictive toxicology research.
—This program would be a critically important application of the basic methodology development work being undertaken as part of the NIH Roadmap initiative on Metabolomics Technology Development.

PREVENTION TRIALS TO ASSESS THE POTENTIAL ABILITY OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND A COMBINATION OF ANTI-OXIDANT VITAMINS (NIA)

—Prevent Alzheimer's disease and age-associated cognitive decline.

DEVELOPMENT OF A CLINICAL TRIALS CONSORTIUM (NIA)

—Test testosterone therapy for older men with low testosterone levels who experience weakness, frailty, or a specific disability that may be related to low testosterone.

NEW INTERVENTIONS FOR PREVENTION AND CONTROL OF HEART FAILURE IN PERSONS AGED 65 AND OLDER (NIA)

—Fully develop and validate new interventions through clinical trials.

MULTIDISCIPLINARY IMAGING RESEARCH PARTNERSHIPS FOR ADDRESSING IMPORTANT BIOLOGICAL OR MEDICAL RESEARCH PROBLEMS OF SKELETAL MUSCLE AND ASSOCIATED SOFT TISSUE (NIAMS)

—Improved imaging techniques provide a non-invasive way to monitor changes in muscle (including muscular dystrophy and other muscle diseases) and soft tissue.
—Multidisciplinary imaging research partnerships would stimulate the development of novel imaging technologies that will help us understand the genetic and molecular bases of musculoskeletal soft tissue function, disease, and injury processes.
—Improved visualization of skeletal muscle and associated soft tissue would enable researchers to more accurately measure change during treatment or recovery from injury.

PURSUE THE RESEARCH NEEDS AND OPPORTUNITIES IDENTIFIED AT THE RECENT NIH CONSENSUS DEVELOPMENT CONFERENCE ON TOTAL KNEE REPLACEMENT (NIAMS)

—Approximately 300,000 total knee replacements are performed each year in the United States for end-stage arthritis of the knee joint, and the rate of total knee replacement procedures increases each year.
—While these replacements have shown outstanding success, controversies still exist regarding implant designs and treatment. Research studies suggest that there are particular challenges that must be addressed in patients with Parkinson's disease, rheumatoid arthritis, and diabetes mellitus, as well as total knee replacements in younger patients.

INCREASE SUPPORT FOR TRANSLATIONAL RESEARCH—MAXIMIZING THE RESULTS OF BASIC RESEARCH TO IMPROVE PUBLIC HEALTH (NIAMS)

—To enhance and expand translational research, a new centers program is currently being or would be created called centers of research translation.
—These centers would pair basic and clinical projects in investigator-initiated and directed research that is centered around particular diseases. Different diseases might require different translation mechanisms and strategies.
—The goal of the centers is the application of powerful tools and knowledge from basic research to clinical research to improve human health.

ADDITIONAL STUDIES ON INNOVATIVE THERAPIES FOR RHEUMATIC AND SKIN DISEASES (NIAMS)

—Would expand a successful program that the NIAMS instituted in fiscal year 1999.
—Would solicit investigator-initiated proposals for clinical trials of innovative therapies or approaches for the treatment of rheumatic and skin disease.

—The previous program has produced a number of ongoing clinical trials that form the cornerstone of NIAMS-funded trials in rheumatic diseases.
—It is anticipated that the trials may identify new therapies for rheumatic and skin diseases.

OTITIS MEDIA (NIDCD)

—Would initiate Phase One trials of vaccine candidates.

INITIATE A DEFINITIVE EPIDEMIOLOGICAL STUDY (NIDCD)

—Would establish the role of prenatal exposure to cytomegalovirus in progressive hearing loss during childhood.

COMMUNICATION DISORDERS (NIDCD)

—Would expand research to identify the hereditary basis.

HAIR CELL DEGENERATION AND REGENERATION IN THE INNER EAR (NIDCD)

—Would initiate new research to define the molecular basis.

ENHANCE CAPACITY FOR DISASTER/TERRORISM MENTAL HEALTH RESEARCH (NIMH)

—Could enlarge this currently small program to establish emergency research protocols in conjunction with local public health authorities and develop critically needed measures for use in emergency/disaster research studies.

RESEARCH INITIATIVE ON PEDIATRIC BRAIN-BEHAVIOR DEVELOPMENT VITAL TO DIAGNOSING AND TREATING CHILD MENTAL DISORDERS (NIMH)

—This initiative would result in the first-ever identification of neuroimaging markers of specific child mental disorders which will lead to improved diagnostics and potential for new treatments in pediatric mental illnesses.

USE NIMH CLINICAL TRIAL NETWORKS TO LAUNCH TRIALS ON SIMULTANEOUS USE OF MULTIPLE PSYCHIATRIC MEDICATIONS FOR THE SEVERELY MENTALLY ILL (NIMH)

—Multiple medications is a widespread practice, but there is limited scientific data about its health effects and implications.

ANOREXIA AND BULIMIA (NIMH)

—Would expand research on understanding eating disorders.

MORE RESEARCH USING BRAIN IMAGING TECHNIQUES (NIDA)

—Would study how exposure to drugs of abuse can affect the developing human brain.
—Understanding precisely how brain changes relate to behavior, especially during childhood and adolescence, is critical to designing effective strategies for reducing drug use in the United States.
—Better treatment strategies targeting children and adolescents would be developed through these efforts.

COLLABORATIONS OF ESTABLISHED CLINICAL TRIALS NETWORK (CTN) WITH OTHER ESTABLISHED NETWORKS AT NIH (NIDA)

—NIDA CTN staff and staff from NCI's Community Clinical Oncology Program have discussed the possibility of jointly supporting a smoking cessation study. This study would bring these two NIH clinical research networks together in a synergistic collaboration and test the networks' interoperability.
—CTN has also had discussions with NICHD to link the CTN to a Network at NICHD that is studying adolescents and comorbidity.

ENHANCE OUR UNDERSTANDING OF THE GENETIC OR HERITABLE RISK FACTORS ASSOCIATED WITH DRUG ABUSE USING THE CTN AS A VALUABLE RESOURCE (NIDA)

—The CTN could serve as a resource to acquire genetic information on participants in clinical trials and to better characterize different phenotypes associated with addiction.
—As gene variants are identified in association with drug addiction, research could be conducted to determine how this genetic information can be used to tailor medications to an individual's genetic needs. This knowledge could be incorporated into ongoing medications trials in the CTN.

EXPAND RESEARCH ON PREVENTING DRINKING BY YOUTH IN RURAL/SMALL URBAN AREAS (NIAAA)

—Note: Partnerships have been formed with academic health centers, abbreviated "AHC," to conduct this research. AHC have in place the disciplines required, as well as extensive service networks in rural and small urban regions.
—Would expand the number of AHC sites that would conduct the research.
—Would collect data on psychological and physical development, and environmental/community circumstances, that are not routinely collected in medical settings. A variety of biomedical, psychosocial, and environmental factors act in concert to lead to adverse outcomes, such as alcohol-related problems. We must understand what all of these factors are and how they interact, if we are to make real advances in preventing and treating adverse outcomes of alcohol use among youth.

EXPAND RESEARCH AIMED AT DEVELOPING MEDICATIONS FOR ALCOHOLISM (NIAAA)

—Would develop animal models of response to alcohol that closely predict efficacy of compounds to be tested in humans.
—Would create a clinical-trials network for early Phase II human trials. These trials could yield relatively quick results and can indicate which compounds are worth the resources required for IND approval and Phase III trials. Partnerships would be sought with pharmaceutical companies interested in compounds found to be successful in NIAAA early Phase II human trials.

EXPAND RESEARCH ON ALCOHOL METABOLISM (NIAAA)

—Alcohol metabolism plays a crucial role in alcohol dependence and in alcohol-induced organ damage.
—Would form a bioinformatics data base, including data on gene expression, proteomics, and metabolomics involved in alcohol metabolism. This would be very important to our understanding of which genes and proteins are involved in addictive behavior and alcohol-induced organ damage, including cancer.
—In human clinical studies, use metabolomics and proteomics to generate information on biomarkers of early/late tissue damage, and identify targets for medication development.
—Using imaging technology, would determine if alcohol metabolism occurs in the brain and, if so, determine what enzymes are involved.
—Would identify all adducts (especially those that promote autoimmune reactions) that result from alcohol metabolism, and their roles in addictive behavior and organ damage.
—Would understand the interactions of alcohol metabolism with comorbid conditions, such as obesity and diabetes.

TISSUE ENGINEERED HUMAN MODEL SYSTEMS (NIBIB)

—Would stimulate research and development in three-dimensional human tissue model systems; engineered tissues for drug development; and cell-based sensors for clinical diagnosis and treatment.
—Tissue engineering holds the promise to repair and/or replace damaged organs.
—Tissue engineering strategies focusing on cell-based therapies, or treatment modalities that rely on cells as the agents for the treatment of diseases, have the potential to revolutionize human therapeutics in the 21st century.

MINIMALLY-INVASIVE, IMAGE-GUIDED SURGERY (NIBIB)

—Would support research needed to rapidly develop computer-assisted, image-guided microsurgery, which could replace traditional surgery.
—Image-guided, minimally-invasive surgical procedures involve less patient risk and pain and result in reduced hospital stays and shorter recovery periods.
—Advances in surgical robots and microsurgical techniques could enhance a surgeon's ability to perform complex tasks that cannot be performed by hand.
—Could support: integration of existing technologies and development of new technologies to navigate human anatomy, obtain diagnostic tissues, localize and treat human disease and injury, and monitor responses to surgical interventions.

CHEMISTRY OF IMAGING AGENTS AND MOLECULAR PROBES (NIBIB)

—Could support exploratory projects for the synthesis, physical characterization, and initial demonstration of feasibility for clinical imaging agents for physiological, anatomical, and molecular imaging.
—The ability to image molecular processes and cell function in vivo provides an opportunity to understand biological processes as they occur in their environment.
—Knowledge gained may be used to advance early-stage disease detection and individually-tailored therapeutic interventions.
—The development of new clinical imaging agents requires focused efforts by chemists and molecular biologists to discover new compounds and materials suitable for in vivo imaging.

BRAIN-COMMUNICATION INTERFACE (NIBIB)

—Could develop technologies to create a more functional and convenient system for restoring movement to paralyzed individuals.
—Investigators have been successful in making Function Electrical Stimulation (FES) a practical solution for restoring some movement to paralyzed individuals.
—Current systems allow individuals with spinal cord injuries to stand and breathe, and can restore functional hand grasp and arm movement to some individuals with severe spinal cord injuries.
—Recent developments in the technology of microelectrode design and neurophysiological signal analysis open the possibility of restoring greater control of motor function naturally—by thinking about moving, a technique referred to as direct brain-communication interface.

SUPPORT PLANNING GRANTS TO DEVELOP AND OPTIMIZE MODELS FOR DEPARTMENTS OF CLINICAL RESEARCH WITHIN SCHOOLS OF MEDICINE (NCRR)

—Would provide tools to develop and test models.

RESTORE THE EXTRAMURAL RESEARCH FACILITIES IMPROVEMENT PROGRAM (RFIP) FUNDS (NCRR)

—Would support construction and renovation projects at National Primate Research Centers, animal research facilities and for modem research laboratories at smaller institutions and institutions within IDeA states.

ADDRESS THE SHORTAGE OF ADVANCED INSTRUMENTATION NEEDED TO PURSUE CUTTING-EDGE BIOMEDICAL RESEARCH (NCRR)

—The High End Instrumentation program is the only NIH program that provides support for research equipment that costs at least $750,000; awards may be up to $2 million.

INTEGRATE TECHNOLOGY DEVELOPED THROUGH THE BIOMEDICAL INFORMATICS RESEARCH NETWORK (BIRN) INTO CLINICAL RESEARCH AND OTHER NEW DOMAINS OUTSIDE OF NEUROSCIENCE (NCRR)

—Some BIRN bioinformatics tools would be distributed and other tools developed; hands-on workshops to inform investigators how to use the tools for their research.
—Information technologies would be critical for scientific discovery.

NCMHD COULD STRENGTHEN AND EXPAND ITS PROGRAMS (NCMHD)

—Loan Repayment Program
—Centers of Excellence Program
—Research Endowment Program

NCMHD COULD FULLY LAUNCH ITS COMMUNITY-BASED RESEARCH PROGRAM (NCMHD)

—Would fulfill this Congressional requirement.

TRAUMA AND INJURY (FIC)

—Would initiate a new program to support research training to address the growing global burden of morbidity and mortality due to trauma and injury related to road traffic accidents, suicide and drowning, mental health consequences of

war and civil disorders, lack of emergency care and blood products and other related conditions.
—Training supported by the new program would lead to prevention strategies and interventions in wound healing, development of synthetic blood products, development of low-cost imaging technologies, mental health strategies, and epidemiology to assess risk factors as well as other activities to reduce the impact of trauma and injury to individuals, families and communities.
—Would support the establishment of a global network of highly meritorious research training centers to mitigate the impact of trauma and injury.

BRAIN DISORDERS IN THE DEVELOPING WORLD: RESEARCH ACROSS THE LIFESPAN (FIC)

—This program was begun through short term planning grants in fiscal year 2003 with the intention to grow to full research project grants in fiscal year 2005.
—The program supports collaborative research and capacity building projects on brain disorders throughout life relevant to low- and middle-income nations. Brain disorders represent a fast growing proportion of the global burden of disease.

DEVELOP THE NEXT GENERATION OF INTERNATIONAL RESEACHERS (FIC)

—It is imperative that the U.S. scientific community be prepared to tackle new threats while at the same time be positioned to work in partnership with colleagues around the world on shared problems.
—Would increase support to train U.S. medical students, graduate students and post-doctoral students in methodologies needed to tackle global health challenges.
—Would extend and intensify efforts in resource-limited nations to provide clinically appropriate, cost-effective, and sustainable care of direct health and economic benefits for the global community and mitigate the threat of disease crossing borders to affect the U.S. population.

COULD SIGNIFICANTLY EXPAND CAPABILITY TO ANALYZE, ANNOTATE, AND CLASSIFY MASSIVE AMOUNTS OF RAW SEQUENCE AND PROTEIN DATA TO MAKE IT READILY USABLE BY RESEARCHERS (NLM)

—Molecular biology is generating an unprecedented amount of genomic data that have the potential to overwhelm researchers by sheer volume.
—The protein classification project provides a valuable method to deduce the function of newly discovered proteins, greatly accelerating research in the molecular basis of disease and therapy.
—The unique and comprehensive Reference Sequence Collection would assist in studying the function of single genes and performing large-scale comparative analyses of genes across multiple organisms.

COULD ACCELERATE PROGRESS TOWARD DEVELOPMENT AND IMPLEMENTATION OF CLINICAL VOCABULARY STANDARDS THAT ARE CRITICAL TO RE-ENGINEERING THE CLINICAL RESEARCH ENTERPRISE (NLM)

—The inability to share clinical data across systems impedes clinical research and is responsible for a significant number of medical errors.
—An interlocking set of clinical vocabulary standards must be developed that incorporate robust mappings between multiple vocabularies used in clinical research and health care.
—Research, testing, and demonstration projects would help to determine best practices for incorporating vocabulary standards into clinical research, health care, and public health.

COULD WORK WITH OTHERS TO DEVELOP COMMON SOFTWARE PLATFORMS FOR ADVANCED CLINICAL AND EDUCATIONAL APPLICATIONS OF THE VISIBLE HUMAN AND OTHER IMAGE DATA SETS (NLM)

—Investments in building a Visible Human Functional Atlas of the Head and Neck and associated public software tools establish a strong foundation for developing applications software, including simulation and modeling, useful in medical training and treatment.
—Further research and testing would fully integrate the data, software, and other technology in the teaching of embryology and anatomy courses.

DEVELOP AND SUPPORT WOMEN'S HEALTH INTERDISCIPLINARY RESEARCH CENTERS ESPECIALLY IN THE AREAS OF: (OD—OFFICE OF RESEARCH ON WOMEN'S HEALTH)

—Pharmacogenetic research that focuses on sex differences in drug metabolism and biological pathways involved in the treatment of diseases such as cancer, cardiovascular disease to provide the much needed information to improve clinical outcomes, including a better understanding of the impact of pregnancy or depression on pharmacokinetics, pharmacodynamics, drug efficacy and adverse effects of therapeutic agents.

DEVELOP AND SUPPORT A CLINICAL TRIAL TO TEST A PROMISING INNOVATIVE TECHNIQUE THAT COULD REDUCE THE SIZE OF UTERINE FIBROIDS (OD—OFFICE OF RESEARCH ON WOMEN'S HEALTH)

—Could result in less morbidity for the women who face potential surgery or infertility as a result of this condition.

LAUNCH A TRANS-NIH INITIATIVE TO LEARN WHETHER eHEALTH TECHNOLOGIES ARE EFFECTIVE IN ENHANCING HEALTH BEHAVIOR CHANGE AND CHRONIC DISEASE MANAGEMENT (OD—OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH)

—Consumers, patients and providers are increasingly using eHealth applications for making health care decisions, and for obtaining and dispensing services.
—These technologies offer a potentially low cost health delivery system for underserved populations, as well as a means of supporting provider adherence to evidence-based care.

Senator SPECTER. I want to finish this question before my red light goes on to stay within the time limits. What is the status and availability and adequacy of stem cell lines for adequate stem cell research?

STEM CELL RESEARCH

Dr. ZERHOUNI. We have 17 cell lines now available. As you know, we have worked aggressively in providing infrastructure funding to all the sources that we knew were eligible for Federal funding. NIH has done every effort to expand the availability of lines. We have spent intramurally dollars to create a characterization lab. We have gone from one laboratory 2 years ago to nine laboratories doing research. So we are also realizing that training of scientists in these very difficult methods is very important. So we are doing everything we can to advance the field. So 17 lines are available to date, Senator.

Senator SPECTER. Well, I am going to violate the red light for just one question. That is not enough, is it? Those are not enough, are they? It is a leading question.

Are they?

Dr. ZERHOUNI. Well, we have a Stem Cell Task Force and Dr. Battey really works very hard with the entire community to look at what is the impact of what we need to do today of the number of cell lines. The reports that we have is that we are learning tremendously at a very high pace what are the advantages and limitations. We are looking, for example, at these issues of genetic stability and genetic diversity.

The Stem Cell Task Force at this point feels that we can do a lot of research with what we have. Can we do all of the research that will need to be done over the entire future of stem cell research? No one can say that that would be the case.

Senator SPECTER. Well, I will pursue that with Dr. Battey. I do not consider that an adequate answer, Dr. Zerhouni. It is not often

where I say your answer is not adequate, but I do not believe that is an adequate answer.

We have been joined by the distinguished ranking member, and I will yield to him at this time for 5 minutes for an opening statement or questions or however he chooses to use his time.

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

Senator SPECTER. We will have second rounds, but we have Senator Stevens and Senator Cochran who are here.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Well, thank you very much, Mr. Chairman. I apologize for being late. Some mornings you have to leave about 5:00 in the morning to get here because of the traffic.

It has been a privilege, Mr. Chairman, to work with you over the last 14, almost 15 years, on behalf of supporting, as you have said so many times, the crown jewel of our Federal Government, which is the National Institutes of Health. I want to thank you again for that working relationship, and I want to thank you for your great leadership, Mr. Chairman, in doubling the funding for NIH over that short period of time. It was a pleasure to work with you to do that and to continue to work with you on these crucial issues that impact the health and welfare of all of our people.

Now, unfortunately, the budget we have submitted this year is a far cry from the doubling years. I am concerned what it means for the future health of NIH. We did not double the funding for NIH to then fall off a cliff. But that is a real possibility if we continue on with this kind of budget that we have.

I want to welcome Dr. Zerhouni and the dozens of other NIH leaders who have joined us. I do not always get the time to hear from each of you, but I appreciate your being here and all the work that you do.

All of you were involved in developing the NIH Roadmap. I want to commend you for that effort. The initiative should help break down the walls between the institutes and unite everybody at NIH behind common goals. And, Dr. Zerhouni, I thank you for your leadership in encouraging that and also for your leadership in encouraging more risk-taking in the kind of applications that NIH funds. We always have to be open to new ideas. To the extent that I can, I hope to back you up. People may say, well, why are you funding some of these far-out things? Well, because sometimes we want to take a look at them. And I really applaud you for doing that.

I just got here to hear a little bit about the stem cell issue. We have discussed that many times before here. We know that this research offers enormous potential to help ease the suffering of people with Parkinson's and juvenile diabetes, ALS, Alzheimer's.

I just had the occasion last evening to meet an old friend of mine who I had not seen in several years. I found out that he has Lou Gehrig's disease. It was just a startling thing for me to see that last evening. His words to me were, you have got to put more research into the stem cell research and find out what is going on here. To see someone that you have known for a long time and then you lost contact with him and then you see him and you know

they are not going to be around very much longer and they are in middle stages of Lou Gehrig's disease, it is a tough thing to see.

I am just concerned that the restrictive policies in this research are delaying the day when these diseases could be cured. Under the President's guidelines only those cell lines generated before the arbitrary date of August 9, 2001 at 9 p.m.—not 9:30, not 8:45, but at 9 p.m., very arbitrary—can be approved for federally approved research. The President said then there were more than 60 eligible lines. Later we heard there were 78. Now I just think I heard from you there were 17 that are available to researchers. Well, I will ask some questions about this during my period of time.

These 17 were also grown on mouse feeder cells, all of them, which raises questions whether or not they can ever be used for any kind of human therapies.

Meanwhile, scientists in other countries are moving ahead, but we cannot fund those. We cannot fund any of that kind of research because those lines were developed after August 9, 2001 at 9 p.m. So again, I will get into that in my question and answer period.

I thank you for letting me make my opening statement, and whenever I can get a chance to ask questions, I will——

Senator SPECTER. Thank you, Senator Harkin. We will come back to another round.

Senator Stevens.

Senator STEVENS. Thank you very much.

Dr. Zerhouni, it is nice to see you here. I do not think we have ever had an opportunity to put visuals on all of these people that you have brought here with you today. So I want to thank you for coming and apologize to them for taking their time. I do not know of another group that is more important to the future of our country than maybe now the intelligence community might be that would have a similar impact in the long range, but this long-range impact of you and your colleagues is just staggering.

I heard the comments of my friend, Senator Harkin. Senator Connie Mack came to me and urged me to support a concept of doubling the NIH budget, and we have done that, Senator. So the real question I think we have to do one of these days is analyze what have we achieved with that money. I do think that that is something that you and your assembled colleagues could help us on. We are currently looking to increase other areas now, the National Science Foundation for one and the intelligence community for another. So the doubling of those budgets in the next 5 years will take precedence I think because of the circumstances that exist in the country.

PROSTATE CANCER

I am glad to see Dr. von Eschenbach here. My good friend, Mike Phelps, reported you gave a tremendous speech at the molecular imaging meeting in Orlando. Several of you know my continuing interest in PET and its application to various areas of your institutes. I do hope that we can be able to be very aggressive in the use of that, the total molecular imaging concepts, to Alzheimer's, which I believe is becoming a great problem as the baby boom generation reaches retirement age.

But I have one specific question. Prostate cancer is also a personal interest. I am a survivor now for 12 years. I would be interested if Dr. von Eschenbach would comment upon finasteride and what's going to happen to that clinical trial. I understand the clinical trial was canceled and there were some problems. Was the FDA a problem or was it that the high rate of tumor growth in those taking the drug? What happened, Doctor?

Dr. VON ESCHENBACH. Well, thank you, Senator, for that important question because I think it really underscores and points out not only the tremendous progress that we are making, but also how the investment that you have been responsible for in biomedical research is really now making it possible for us to solve problems that before we did not even understand.

The issue with regard to the prevention trial of prostate cancer using finasteride demonstrated that in fact the drug did reduce the number of men who developed prostate cancer. So in that regard, we stopped the trial because the endpoint had been achieved. We in fact did get the answer and got the answer earlier than we had hoped or anticipated and demonstrated the protective effect of finasteride for a number of men who were susceptible to prostate cancer.

What we also recognized in that trial was that although fewer men developed prostate cancer on finasteride, the kind of prostate cancer that they developed appeared to be more virulent and more aggressive, and perhaps could even increase their risk of progression or dying from prostate cancer.

So in addition to demonstrating the protective effect, what we have now launched into is a subsequent set of studies to understand the mechanisms of action and to determine the impact on virulence. That is now an ongoing part of our research investigation.

Senator STEVENS. Thank you very much on that.

Mr. Chairman, I do have, unfortunately, on the schedule several other subcommittees meeting. Again, I want to thank you for bringing all of the directors of these institutes here. I urge you to let them go quickly so they can go back to work.

Senator SPECTER. That concludes the hearing.

Senator STEVENS. It concludes my time too. Thank you all very much.

Senator SPECTER. Thank you very much, Senator Stevens.

I am going to step out for a moment down the hall to the Judiciary Committee to see if I am needed for a quorum there. I hope to return within the time allotted to Senator Cochran, but if I do not, we will turn to Senator Harkin. Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you.

Dr. Zerhouni, we are very pleased with the fact that you are exploring research possibilities in areas that have previously been, I think, relegated to a fairly low priority. Fundamental challenges such as understanding obesity, its effect on health, what can be done to both treat those symptoms and, more importantly, prevent that condition should be the subject of research. I wonder what emphasis is placed in the budget request with regard to research in this area.

OBESITY RESEARCH

Dr. ZERHOUNI. This is a very important topic to us. Actually I would like to point out that NIH has been working on obesity for over 10 years. I actually have a little graph here that you could see whereby our investments started in 1996 because already at that time, NIH had predicted that the obesity crisis will hit, and it became one of the top 10 topics of research.

However, as you know, the rate of increase of obesity is actually greater than what we expected, so we are increasing our funding at the same level. In fiscal year 1996, we had $86 million. Next year we will have $440 million funding. Last year I established a trans-NIH Obesity Task Force, led by Dr. Allen Spiegel and Dr. Barbara Alving. They have come up with a new strategic research plan for obesity, and despite the difficult budget environment, we are going to increase our funding from $400 million to $440 million in obesity research by $10 million. So we have almost quadrupled our investment in obesity research while the rest of the NIH doubled to show you our commitment to it and also our ability to see proactively where research needs to be.

Senator COCHRAN. I hope you will take into account the importance of concentrating some of this funding in areas that suffer from this in a disproportionate way compared to the rest of the country.

Dr. ZERHOUNI. Actually, Senator, this is one of the priorities of the new plan. We are going to focus on childhood obesity which affects rural areas and minority areas to a much greater degree than other communities. So we will have an implementation to be able to study that pattern early on in life.

ROLE OF THE NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Senator COCHRAN. One new phenomenon I know is the fact that millions of Americans are using dietary supplements and herbal products today. The National Center for Complementary and Alternative Medicine is playing a role in understanding the efficacy and the effects of these products. What are your plans for research with respect to these products?

Dr. ZERHOUNI. If you allow me, I would like Dr. Stephen Straus, who is the Director of the National Center for Complementary and Alternative Medicine, to answer that. He has very definite plans and great strategies for that.

Dr. STRAUS. Thank you. Mr. Cochran, our goal is to characterize the complementary and alternative medicine (CAM) products that Americans are using, understand why they have the activities they do, and then prove whether they are safe and effective. We are doing this in a multi-tiered approach, much of which is conducted in partnership with the other NIH Institutes and Centers because of their strong areas of thematic expertise.

We are doing this with products that are used for neurodegeneration such as ginko biloba. In that regard, we have already enrolled, in partnership with the National Institute of Aging, the National Heart, Lung and Blood Institute and the National Institute of Neurological Disorders and Stroke, over 3,000 patients in

the largest study ever mounted of an herbal product, and at that time the largest preventative study conducted for dementia. The goal is to prevent the onset of Alzheimer's disease in otherwise healthy, aging Americans.

At the same time we are studying mechanism, and in your own State, we have funded outstanding investigators at the University of Southern Mississippi who are showing us several different chemical constituents in ginko that prevent the death of neuronal cells in the brain. These are our strategies.

Senator COCHRAN. Thank you very much.

THE NATIONAL INSTITUTE FOR BIOMEDICAL IMAGING AND BIOENGINEERING

I appreciate also the NIH's recognition of the role for new technologies in the detection and treatment of disease. The National Institute for Biomedical Imaging and Bioengineering was created specifically to enhance research in this area. Has this investment begun to show results, Dr. Zerhouni?

Dr. ZERHOUNI. I think so. One of the most important meetings that the institute has had was actually organized at the University of Mississippi. It was a national strategic meeting to try to see where the direction of the field would go. Dr. Pettigrew is really a great leader and I would like him to comment, if you do not mind, Senator.

Senator COCHRAN. Thank you.

Dr. PETTIGREW. Thank you, Senator, and I appreciate having the opportunity to respond to that question.

There are many problems that physicians alone cannot solve. There are problems that also require the input of quantitative scientists. These would be scientists, which include not only imagers and physicists but also mathematicians and computer scientists.

We have been very successful, I am pleased to report, in bringing physicians and quantitative scientists together to translate the fundamental discoveries from the technologically-based scientists into meaningful clinical applications for patients. That is certainly our goal and we work very hard to achieve that.

The progress to date has been quite remarkable given our short history of only 2 years. I would like to tell you about two examples in this area.

NIBIB'S PROGRESS

The first is the development of a new technology called quantum dots. These are small nano crystals that are able to identify specific cells of interest in the body, for example, cancer cells in lymphnodes. Quantum dots could also be used to identify the deposition of plaque in arteries.

We have also seen progress in an area that many people in the audience might appreciate. No doubt people here have had MRI scans. This is a marvelous technology, in fact, the subject of the Nobel Prize in Medicine this year. But some of our researchers have tackled one of the problems, which is the speed with which these scans can be made. These researchers have improved the speed of acquisition of images 10-fold. Studies that used to take several minutes to acquire can now be acquired in a matter of sec-

onds. The value of this is not only in improved patient comfort, but also in opening up additional applications such as image-guided surgery where speed would be very important.

These are examples of some of the technological innovations that we have been pursuing and have begun to bring to fruition for the benefit of us all.

Senator COCHRAN [presiding]. Thank you. Thank you very much, Mr. Chairman.

Senator Harkin, do you have questions?

Senator HARKIN. If you want to have a follow-up.

Senator COCHRAN. No. Go ahead. I am trying to carry out the chairman's 5-minute rule here. No, go ahead, please proceed.

Senator HARKIN. Okay, thanks.

STEM CELL LINES

I would like to get back to the stem cell issue, if I could, and I would like to direct some questions to Dr. Battey. I believe you are heading the Stem Cell Task Force.

Dr. BATTEY. That is correct.

Senator HARKIN. Correct me if I am wrong, but I think you have said that under the best case scenario, only 23 lines will be available to federally funded scientists. Is it 23 or is it 17? I am a little confused there.

Be that as it may, even if it is 23, my question basically is will 23 be enough to realize the full potential of stem cell research?

Dr. BATTEY. Let me begin by addressing the numbers issue that you have raised.

The number 17 refers to the number of cell lines that are available today for Federal funding that can be widely disseminated across the research community, cells that—if you had a laboratory—you could order and get in your laboratory for experiments. There are six additional derivations located at institutions that hold NIH infrastructure awards for the purpose of developing such cell lines, expanding them, getting them ready to be distributed, going from a derivation to a useful cell line that can be distributed. And we are hopeful that all six of these will become distribution quality cell lines. When you add 17 and 6, one arrives at the figure 23.

Now, there are 31 derivations located in five institutions in Korea, India, and Sweden that are eligible for Federal funding that are on the registry, but they have not sought an NIH infrastructure award to develop such cell lines. So we do not know the status of these derivations. They are privately held and we are not privy to that information.

Senator HARKIN. Let me get to my question there, Dr. Battey. Will 23 or 17 be enough to realize the full potential of stem cell research?

Dr. BATTEY. I do not know the answer to that question, but there are reasons to be concerned. For example, there was a published paper in December showing that when some of the cell lines, some of the 17, are grown in some people's hands and passaged for prolong periods of time, they develop karyotypic abnormalities, chromosomal abnormalities. These abnormalities are some of the same abnormalities that are seen on occasion in teratocarcinomas, which

are tumors of cells like embryonic stem cells. That is an issue of great concern and will need to be followed very carefully.

While I have to say I do not know whether or not we will be able to do everything possible with either 17 or 23 or 46 or 98 or 321 cell lines, I do know that if there is additional functional diversity it is difficult to imagine that more cell lines would be detrimental to research progress.

MOUSE FEEDER CELL LINES

Senator HARKIN. Could any of these 23 lines ever be used in human therapy since they have all been developed on mouse feeder cells?

Dr. BATTEY. We have discussed this issue at great length with the Food and Drug Administration, who would be the organization overseeing the safety and efficacy of any clinical studies that were done with these cells, were these cells to ever be returned to patients in transplantation in an effort to treat some of these awful disorders like ALS that you have spoken about. When we talk to the FDA about this, they say that the mouse feeder cell layer is an issue and the issue of whether or not a retrovirus or some other bad thing might have been transferred from the feeder cell layer to the human embryonic stem cells is an issue that must be explored.

It is not, however, a prohibitive issue. It is one of many issues, including the history of the cells, where they have been cultured, what kind of medium they have been cultured in, if there have been any serum or other biological additives, what the state and purity of those are. So there is no question the feeder cell layer is a safety issue, but it is one of many safety issues and I do not think should necessarily be drawn out of that context.

Would it be preferable to have cells that were not growing on mouse feeder cell layers? I think the answer to that question is yes. Would it be preferable to have cells that were grown in a medium that had nothing but completely defined substances, purified additives? Absolutely. That would be better. In fact, the NIH is funding investigators to try to develop better culture conditions for human embryonic stem cells with the goal of ultimately moving the cell lines into an environment that poses less questions about biological safety.

ACCESS TO ADDITIONAL LINES

Senator HARKIN. The other question I had was basically would federally funded scientists benefit from having access to additional lines. I think you basically answered that. Obviously, the more you have and the more involved, I would assume the better the research would be. You would have just more lines out there to look at.

Dr. BATTEY. We will understand much better what the significance of number of cell lines is when we have explored to a greater degree what we can do with the cells that are available and widely distributed for Federal funding. But as I said before, it is difficult to argue that a greater number with more potential functional diversity would be detrimental to the research effort.

Senator HARKIN. If they had access to additional lines—lead me on. I just want to get a better understanding. How would this be not detrimental if they had more?

Dr. BATTEY. Well, the problem here and the reason why I cannot be more specific in answering this question is that we are just at the beginning of exploring what we can do with the cell lines that are eligible for Federal funding. We are just beginning to learn the master switches that keep these cells in a pluripotent state and allow them to replicate indefinitely in the laboratory. We are just beginning to get our hands around the growth factors and gene expression profiles that are associated with differentiation towards a cell type that might be interesting for a therapeutic application such as a dopamine-producing neuron that might be lost in a patient with Parkinson's disease or a motor neuron that will be lost by your friend with ALS. We are only beginning to understand, and until we know more about what we can do with the cells we have, what their limitations are, what their possibilities are, it is hard for me as a scientist in a fact-based manner to give you a better answer than the one I have given, as much as I would like to do that.

STEM CELL POLICY

Senator HARKIN. Is it time to reevaluate the policy that has been in effect since August 2001?

Dr. BATTEY. I think it is very important for there to be a continued dialogue between scientists, the National Institutes of Health, your subcommittee, and the administration about what the state of the science is. The decision to evaluate a presidential policy is a decision that is made at the level of the White House. Our role in this process, as I understand it, is to provide facts and information for the people who make policy, and we have a regular dialogue with individuals in the administration, as well as individuals on some of your staff about the state of the science in human embryonic stem cells. Just on a personal note, I am happy to come and talk to anybody who has questions or wants to know more about the state of the science in what I consider to be one of the most exciting areas of science for the future of biomedical research.

Senator HARKIN. Thank you very much, Dr. Battey.

Senator SPECTER [presiding]. Thank you, Senator Harkin.

Dr. Battey, the Congress also has a constitutional role in setting national policy and that starts with this subcommittee. Dr. Zerhouni and Dr. Battey, as the area of responsibility may fall, we would like to have a comprehensive report on what has happened to the original 60-some stem cell lines announced by the President back in August of 2001 and what has happened to them, how many are in private hands, how many of them are tainted with mouse feeders, how many of them can be used, what is happening at Harvard, what is happening in South Korea, what is happening in other countries so we can make an evaluation as to what the policy ought to be.

[The information follows:]

STEM CELL RESEARCH

Question. What is the status of human embryonic stem cell (hESC) derivations listed on the NIH Stem Cell Registry? How many are in private hands? How many have been grown on mouse feeder layers? How many are viable?

Answer. All of the derivations listed on the NIH Human Embryonic Stem Cell Registry are privately owned by 15 different companies or academic institutions. The providers indicated by an asterisk (*) below are recipients of the NIH Infrastructure award to develop, characterize and distribute cell lines.

*BresaGen, Inc., Athens, Georgia**

4 derivations
3 lines available
The cells in derivation BG04/hESBGN–04 failed to expand into undifferentiated cell cultures.

Cell & Gene Therapy Research Institute (Pochon CHA University), Seoul Korea

2 derivations
0 lines available

*Cellartis (formerly Cell Therapeutics Scandinavia), Göteborg, Sweden**

3 derivations
2 lines available
Cell line SA03/Salgrenska 3 was withdrawn by donor.

*CyThera, Inc., San Diego, California**

9 derivations
0 lines available
The cells failed to expand into undifferentiated cell cultures.

*ES Cell International, Melbourne, Australia**

6 derivations
6 lines available

Geron Corporation, Menlo Park, California

7 derivations, all duplicates of Wisconsin Alumni Research Fdn. derivations

*Göteborg University, Göteborg, Sweden**

16 derivations, reported to have not been exposed to mouse feeder layers
0 lines available

*Karolinska Institute, Stockholm, Sweden**

6 derivations
0 lines available
The cells failed to expand into undifferentiated cell cultures.

Maria Biotech Co. Ltd.—Maria Infertility Hospital Medical Institute, Seoul, Korea

3 derivations
0 lines available

*MizMedi Hospital—Seoul National University, Seoul, Korea**

1 derivation
1 line available

National Centre for Biological Science/Tata Institute of Fundamental Research, Bangalore, India

3 derivations
0 lines available

Reliance Life Sciences, Mumbai, India

7 derivations
0 lines available

*Technion-Israel Institute of Technology, Haifa, Israel**

4 derivations
2 lines available

*University of California, San Francisco, California**

2 derivations
2 lines available

*Wisconsin Alumni Research Foundation, Madison, Wisconsin**

5 derivations
5 lines available

Of the 78 entries on the Registry, 71 are from independent embryos and 7 are duplicates located at both WiCell (Wisconsin Alumni Research Fdn.) and Geron. The Geron cell lines are not being widely distributed to the research community.

Of the 71 independent derivations:

—16 have failed to expand into self renewing, pluripotent cell lines (9 at CyThera, 1 at BresaGen, 6 at Karolinska), and 1 line was withdrawn by the donor at Cellartis (formerly Cell Therapeutics Scandinavia, CTS). NIH provided Infrastructure support in failed attempts to expand these 16 derivations into distribution-quality cell lines.

—Of the remaining 54 independent derivations, 21 are available for shipment, after expansion and characterization using NIH Infrastructure grant awards. The 21 that are currently available are:

BresaGen, Inc.—BG01, BG02, BG03
Cellartis—SA01, SA02
ES Cell International—ES01, ES02, ES03, ES04, ES05, ES06
MizMedi Hospital—MI01
Technion-Israel—TE03, TE06
UCSF—UC01, UC06
WiCell—WA01, WA07, WA09, WA13, WA14

—Of the remaining 33 independent derivations, 2 more are at institutions with NIH Infrastructure awards. If these 2 were developed into distribution quality cell lines ready for shipment, there would be 23 independent cell lines available to the research community. The 2 cell lines under development are:

Technion-Israel—TE04, TE07

—The remaining 31 independent derivations are all at institutions located outside of the United States that have not applied for NIH Infrastructure awards to develop their cell lines. Any plans to develop these derivations into cell lines that are available to the research community are unclear at this time. The 31 derivations at institutions that do not have Infrastructure awards are:

Pochon CHA (Korea)—2 derivations
Göteborg Univ. (Sweden)—16 derivations
Maria Biotech (Korea)—3 derivations
National Centre for Biological Sciences (India)—3 derivations
Reliance Life Sciences (India)—7 derivations

As far as we know, all derivations have been exposed to mouse feeder cells, with the exception of the 16 derivations at Göteborg University (Sweden).

Information on the detailed characteristics of each of the derivations is available on the NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov.

Question. What is Happening at Harvard University?

Answer. On March 25, 2004, Harvard University announced the derivation of 17 hESC lines in an article published in the New England Journal of Medicine. Funding for the derivations and distribution of these lines is being provided by the Howard Hughes Medical Institute, Juvenile Diabetes Research Foundation and Harvard University.

On April 23, Harvard University announced the establishment of the Harvard Stem Cell Institute. According to Harvard, the Institute will encourage adult and embryonic stem cell research using both animal and human stem cells. The Institute has two co-directors: Harvard Medical School Professor David Scadden, who also directs Massachusetts General Hospital's Center for Regenerative Medicine and Technology, and Douglas Melton, the Thomas Dudley Cabot Professor of the Natural Sciences and a Howard Hughes Medical Institute investigator.

Research at the Institute will be focused on five areas of disease for which stem cell therapy seems most promising. The diseases all result from some sort of organ or tissue failure and include: diabetes, neurodegenerative diseases, blood diseases, immune diseases, cardiovascular disease, and musculoskeletal diseases.

Although research on the 17 new human embryonic stem cell (hESC) derivations are not eligible for Federal funding, NIH is currently supporting several scientists at Harvard University whose hESC research use lines eligible for Federal funding. Dr. Doug Melton is working to identify the genes involved in hESC self-renewal and differentiation. Dr. George Daley is studying hematopoietic development from hESCs. Dr. Howard Green is working to develop the culture conditions to coax

hESCs to become the keratinocytes that make up human skin(s epidermis. Dr. Jeffrey Harper is analyzing the signals that control hESC division.

Question. What is Happening in South Korea? What is Happening in Other Countries?

Answer. On February 12, 2004, South Korean researchers published the first scientifically credible report of the creation of a cloned human embryo in the laboratory by means of somatic cell nuclear transfer (SCNT) (Science 303: 1669–1674.) These scientists, supported by the South Korean government, then used these cloned embryos to establish a human embryonic stem cell line. They combined the DNA of a woman's ovary cell with her donated egg, from which the nucleus had been removed, and then stimulated the newly combined cell to divide. The resulting very early embryo was then allowed to develop to the blastocyst stage (five to nine days), at which point it was disaggregated and the highly potent stem cells of the inner cell mass were removed. These stem cells were then treated to produce a stem cell line to be used for various kinds of biomedical research. Subsequent to the publication of the SCNT study, the South Korean government voted to ban the creation of cloned human embryos, but might allow cloning for biomedical research on a case-by-case for medical treatment subject to approval by a National Bioethics Advisory Commission. Scientists will be permitted to use spare frozen embryos, left over from infertility treatments and kept in laboratories for at least five years, for limited stem cell research into treatments for hard-to-cure diseases. The regulations banning human cloning are expected to come into effect after President Roh Moohyun signs the bill. The regulations on stem cell research will go into effect in 2005.

OTHER INTERNATIONAL STEM CELL EFFORTS

International Society for Stem Cell Research (ISSCR).—The International Society for Stem Cell Research is an independent, nonprofit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application. Opinions on the legitimacy of experiments using human embryos vary among members of the European Union (EU) according to the different ethical, philosophical and religious principles in which they are grounded. EU member states have taken very different positions on the regulation of human embryonic stem cell research and cloning for biomedical research. More information about the regulations and policies of EU members can be found on the website of the ISSCR at the following link: http://www.isscr.org/scientists/legislative.htm.

The International Stem Cell Forum (ISCF).—The ISCF was founded in January 2003 to encourage international collaboration and funding support for stem cell research, with the overall aim of promoting global good practice and accelerating progress in this vitally important area of biomedical science. The Forum's long-term aim is to help stem cell scientists achieve a range of revolutionary medical advances that will benefit people throughout the world. The ISCF is led by the United Kingdom's Medical Research Council and consists of 14 leading supporters of stem cell research from around the world. Member organizations are based in the United States, Finland, Australia, Canada, Germany, France, Israel, Netherlands, Japan, Singapore, Sweden, Switzerland, and the United Kingdom. Within ISCF, the United States is represented by the NIH. The Juvenile Diabetes Research Foundation International (JDRF) is also a member of the ISCF. One short term goal of the ISCF is to compare different stem cell lines from the member organizations. As part of this goal, NIH's federally approved stem cell lines will be compared to those of other member organizations. Information about the stem cell research efforts of the member organizations can be found on the website: http://mrc.live.tmg.co.uk/.

Senator SPECTER I have discussed it with the President and he has a view on it. The facts are very important in formulating all of our views. So let us proceed to bring all the facts to this subcommittee.

Dr. ZERHOUNI. You have my commitment to do so, Senator.

BIODEFENSE AGENTS

Senator SPECTER. Thank you very much.

On the issue of biodefense, the concerns about another attack are with us imminently as we sit here. We have seen an acceleration of the venom and hatred from Wahabes and Islam fundamentalism

and we have a long chronology of attacks going back to 1983 when 283 Marines were killed in Lebanon, what happened in Mogadishu, what happened in Africa in August 1998, what happened with the Cole, what happened on 9/11. We have to be prepared.

Dr. Fauci, you and I have discussed this on other occasions. This year's request includes $1.7 billion toward biodefense research activities. What are the principal bioweapons that we are working to defend against?

Dr. FAUCI. The principal bioterror agents that we are involved in pursuing from the standpoint of developing countermeasures remain the category A agents that we have discussed before this committee on several occasions. High among those are still smallpox, anthrax, botulism toxin, tularemia plague, and the hemorrhagic fevers including Ebola. We are pleased to report, as Dr. Zerhouni mentioned in his opening statement, that over the past year with the resources that this committee has generously given us, we have made extraordinary progress in having available, either already in the stockpile or in contract on its way either in phase I/II or purchase, countermeasures in the form of vaccines for smallpox, anthrax, and soon Ebola.

Senator SPECTER. If there was to be an attack on anthrax, how well prepared are we?

Dr. FAUCI. We are extraordinarily better prepared today than we were in the anthrax attacks in the fall of 2001 with the following issues. A, the stockpile of antibiotics right now to treat prophylactically for the entire 60-day period with ciprofloxacin or doxycycline is now able to meet a substantial attack, God forbid that were to occur. And also, we are now well into the development of the second generation of a recombinant protective antigen anthrax vaccine that could be used to vaccinate people who would go in to clean up, the hazmat people, health workers, and those who would be required to have an extended period of antibiotics. So the anthrax situation is dramatically different than it was in this building a year and a half, 2 years ago.

Senator SPECTER. Adequate?

Dr. FAUCI. I believe adequate. I think we still have a ways to go on every issue, but the progress that is being made particularly in the arena of anthrax is striking.

Senator SPECTER. My red light is about to go on. So I would like you to supplement in writing the details as to the other threats, what we have done, whether it is adequate, and what more needs to be done.

Dr. FAUCI. I would be happy to do that.

Senator SPECTER. This is something we have to address forcefully and promptly.

Dr. FAUCI. Will do.

[The information follows:]

RESEARCH IN MEDICAL COUNTERMEASURES AGAINST CATEGORY A BIOLOGICAL AGENTS

The accompanying table provides a summary on the status of research and development of medical countermeasures for Category A biological agents. These biological agents and the countermeasures that are currently available for them are identified in the first two columns. Recent NIAID accomplishments are identified in column three (complete details of these and additional accomplishments can be found

in the *NIAID Biodefense Research Agenda for CDC Category A Agents Progress Report)*.[1] Candidate countermeasures that are at an advanced research stage where rapid development of the countermeasures is scientifically feasible are identified in the fourth column. Finally, many of the countermeasures that are the focus of early research efforts are identified in the last column.

I would like to add that we continue to support a national, comprehensive biodefense research and development program. It includes the development of other biodefense countermeasures to combat Categories B and C biological agents, as well as a broad range of basic research activities.

[1] See http://www2.niaid.nih.gov/Newsroom/Releases/biodefensereport2003.htm for a detailed report on research progress made to date for CDC Category A Agents.

STATUS OF NIAID RESEARCH IN MEDICAL COUNTERMEASURES AGAINST CATEGORY A BIOLOGICAL AGENTS

Organism	Countermeasures Currently Available	Recent NIAID Accomplishments	Current Product Development Efforts	Focus of Early Research Efforts
Bacillus anthracis (Anthrax)	• Several antibiotics, useful if begun very early after infection • Limited quantities of Anthrax Vaccine Absorbed (AVA) available from DoD and CDC for use under IND • Supportive care	• Initiated advanced development of anthrax rPA vaccine • Completed computer model examining the optimum duration of antibiotic prophylaxis after anthrax exposure • Continued the evaluation of antibiotics currently licensed for other infections	• Recombinant Protective Antigen (rPA) vaccine • Antibiotics licensed for other infections	• Alternate/next generation vaccines • New/better antitoxins and antimicrobials • Basic pathogenesis studies to better understand potential targets for genetically engineered resistance
Clostridium botulinum (Botulism)	• Very limited quantities of polyclonal antibodies available from DHS and CDC for use under IND • Supportive care	• Discovered a cocktail of 3 monoclonal antibodies that potently neutralize botulinum neurotoxin types A1 and A2 in small animal models	• Monoclonal Antibodies • Recombinant botulinum vaccine active against 3 serotypes	• Alternate/next generation vaccines (recombinant toxin fragment) • New/better antitoxins; small molecule inhbitors and other novel synthetic molecules • Exploring toxin stability in the environment
Yersinia pestis (Plague)	• Several antibiotics, useful if begun very early after infection • Supportive care	• Developed mouse model of plague to be used for evaluating new vaccines • Continued the evaluation of antibiotics currently licensed for other infections	• Protein subunit vaccines (FY04 NIAID initiative) • Antibiotics licensed for other infections	• Basic pathogenesis studies to better understand potential targets for genetically engineered resistance • 2nd generation vaccines • New/better antimicrobials
Variola virus (Smallpox)	• Wyeth (Dryvax) vaccine • Aventis Pasteur vaccine • Acambis cell cultured vaccine • Cidofovir for treatment of smallpox and vaccine side effects for use under IND • VIG for vaccine side effects • Supportive care	• Initiated development of MVA vaccine • Screened >950 compounds *in vitro* for activity against poxviruses; tested ≈40 active drugs in animals • Developed IND for cidofovir as primary treatment for smallpox or complications with vaccination • Continued to develop two monkey smallpox models to evaluate drugs/vaccines (with USAMRIID and CDC)	• Advanced development of MVA vaccine – safer alternative; could be used in immunocompromised population (3rd generation) (FY04 NIAID initiative) • Licensed antivirals and antivirals against other viral infections currently under development by industry • Development of oral derivative of Cidofovir	• Easily administered, antiviral drugs • Safer vaccines • Monoclonal antibodies to replace VIG
Francisella tularensis (Tularemia)	• Several antibiotics, useful if begun very early after infection • Supportive care	• Initiated collaboration with DoD to further develop candidate tularemia vaccine (live vaccine strain - LVS)	• Live attenuated and sub-unit vaccine candidates (FY04/05 NIAID initiatives)	• Antimicrobials and immune-based therapies with novel mechanisms of action • Antibiotics licensed for other infections
Viral Hemorrhagic Fevers (note this includes several families of viruses)	• Limited quantities of partially effective, unlicensed vaccines for Junin and Rift Valley Fever viruses available from DoD for use under INDs • Ribavirin effective in the treatment of some viral infections (e.g. Hantavirus and Lassa) • Supportive care	• Demonstrated that fast-acting vaccine protects monkeys from Ebola (with USAMRIID) • Initiated first human trial of DNA-based vaccine for Ebola • Methods developed to study individual proteins from these viruses in regular, low containment laboratories.	• Ebola vaccine • Rift Valley Fever vaccine (preclinical studies) • Marburg vaccine (preclinical) • Lassa vaccine (preclinical) • Dengue vaccine (preclinical)	• Broad spectrum antiviral drugs • Immune-based therapies • Vaccines against the major threat agents • Combination vaccines which are broadly protective

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

FUNDING OF RESEARCH GRANTS

Dr. Zerhouni, our staff has brought to our attention this issue of the number of research grants that we are funding this year. It is a question we always ask. What are we doing in terms of the number of grants and the funding for these grants?

I have found—and you correct me if I am wrong on this—that fiscal year 2004 marked the first time in 8 years that the number of new competing grants went down. It dropped from 10,393 in fiscal year 2003 to 10,135 in fiscal year 2004. That is the bad news. We might say, well, but the good news is the President's 2005 budget calls for raising that number back to the 2003 level of 10,393. So I said, okay. How do we do that?

As you know, when researchers get approved for NIH grants, for the second, third, fourth years, there is an automatic 3 percent increase. Well, what I found out is that this longstanding commitment by NIH to these researchers is necessary so that they can pay their staff and give them their annual salary increases or get new equipment and so forth in the second, third, and fourth years. Now, that is 3 percent. And this year's budget calls for an increase of 1.9 percent to the second, third, and fourth year researchers. As a result, the researchers will receive less money than what NIH committed to providing them.

I am wondering about the effect this is going to have. Could it force them to change the scope of their work in midstream?

Now, again, I think that you and all of us are opposed to breaking NIH's commitment to its grantees. Once you make a commitment, you make a commitment. And I am concerned that this budget is changing this policy, and I am wondering why are we changing this policy. Why are we going to 1.9 percent rather than 3 percent?

Dr. ZERHOUNI. These are very important questions and those are the questions we have grappled with in a very difficult budget environment and we had to make tough choices.

But let me address your first question which was that a decrease between 2003 and 2004 and then recovery in 2005 in numbers of grants. Fiscal year 2003 was the last year of the doubling of the budget.

Senator HARKIN. Right.

Dr. ZERHOUNI. We actually gave more grants in 2003 than we planned to do so that is why the number in 2003 was higher. In 2004, we were planning on keeping that level or even go up a little bit, but certain budgetary events occurred.

One, was the .59 percent cut across the board. That was in conference.

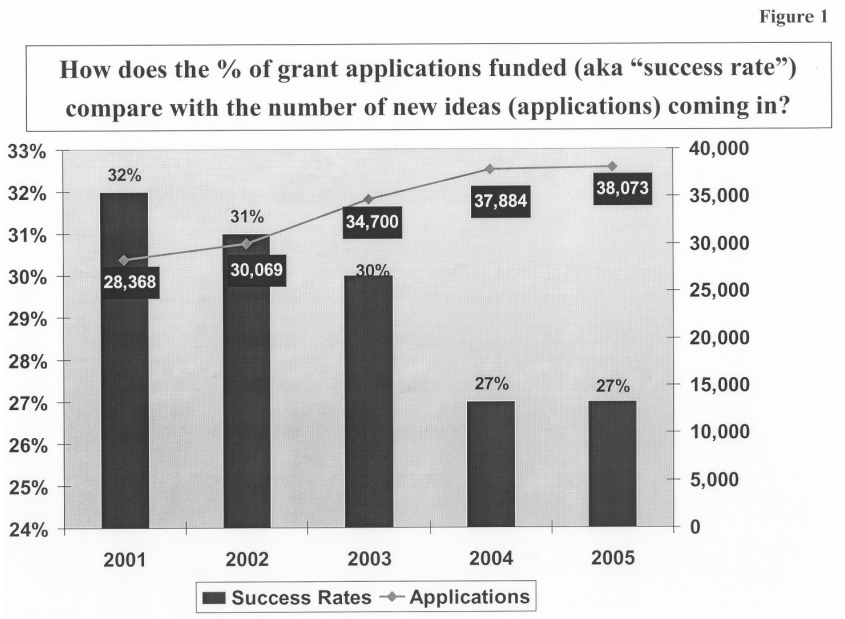
Second was the reshifting of extramural construction, $119 million we had not requested. It was then put back into the extramural construction.

Last but not least was what we call the planning and evaluation tap, 2.2 percent of the NIH budget is used to fund AHRQ, for example. So all of these elements decreased the funds available for the grant pool in 2004.

Now we come to this year and we have a budget envelope of 2.6 percent. So we had to make tough choices.

I agree with your policy principle. This is something that I have told all the Institute and center directors—that our word is our bond. We should really commit to maintaining research grants at least at an inflationary level so that they do not lose the ability to purchase research, if you will.

Figure 1



SUCCESS RATES

But on the other hand, we also have a marked increase in terms of applications and new scientists are coming to us asking for grants. So we had to make a tough decision. I have the information here to show you on the screen. If you looked at our success rate at the beginning of the doubling, our success rate was 32 percent here. The number of applications we received in 2001 was 28,000. Senator, the number of applications we are receiving is now 38,000. This year alone our Center for Scientific Review will receive 66,000 applications for all types of grants for NIH as well as some from CDC, AHRQ, FDA, and SAMHSA.

Senator HARKIN. Excuse me, Dr. Zerhouni, but that 38,000 and the 37,000 and the 34,000 I see, are those the ones that actually make it through the peer review process?

Dr. ZERHOUNI. Those are the ones that are applied for. They are new and competing in that year. Only one-third of them will get funded.

So, for example, if you go back to 2001, Senator, we had 28,000 grants. Thirty-two percent of those were funded. Then we had 30,000 applicants. Thirty-one percent of those were funded. And then in 2003, we had 34,700 applications.

So from my standpoint, as you look at the budget and you look at the number of scientists out there who are coming up with great ideas, we had to make a choice. Can we shave the cost increases to allow more of these increasing numbers of scientists to apply and be successful? So those are the tensions, Senator, that I had to deal with in making the tough decisions.

Senator HARKIN. Well, I understand the dilemma you were faced with. I guess under the budget we have got a choice, either increase the number of new grants and cut back on the increases for those that are already approved, or keep the increases in and not have new grants.

Dr. ZERHOUNI. That's right.

Senator HARKIN. That seems to be the dilemma.

Well, I do not know. Maybe we made the right decision, but I just think we all ought to be aware, Mr. Chairman, of the tradeoff that we have made with this budget. Now, I am preaching to the choir here because this person right next to me here keeps going on the floor trying to get our budget up for NIH and I have backed him every time we have tried to do that. But because of this budget, you have had to make almost a devil's choice here in terms of the tradeoff. As you say, you want to keep your word. You want to keep your commitment to these researchers. But then the President's budget—it is his budget—wants to have all these new starts, so then you have to trade that off. I think that is why we need to actually get this budget back up again so that that does not happen.

PROJECTING OUT-YEAR BUDGETS

Now, I am particularly concerned, as I said in my opening statement, about the years ahead. According to OMB, NIH's budget is expected to drop in actual dollars by 2 percent in fiscal year 2006. If that goes through, do we have any idea what that is going to mean in the number of grants and this dilemma we are facing right now? What is that going to mean?

Dr. ZERHOUNI. At this point I heard the same thing that you heard. So we queried and we asked are there decisions made in our out-year budgets. To this moment, I am not told of any formal decisions that were made by OMB that would imply those cuts in the NIH budget.

Senator HARKIN. I got it from OMB.

Dr. ZERHOUNI. I understand. There were projections, but from the standpoint of our interactions with OMB, we are told that those are projections and estimates that were made, not policy decisions.

Senator HARKIN. Well, I know they are projections. This is what OMB is projecting. I have got the figures right here, a 2 percent cut in fiscal year 2006. That is next year. That is what we are going to be confronting next year, and we are going to be here next year.

So, again, I am just asking. We need some information. What would this mean if OMB's projection goes through and we have this 2 percent cut in fiscal year 2006 and we are confronting that, what does it mean for grants, commitments to researchers, size of

grants? I mean, we need to know what the impact of that is going to be.

Dr. ZERHOUNI. We definitely are willing to provide you with those projections from the standpoint of the agency, and I will provide that to you for the record.

Senator HARKIN. I do not need them right now, but we are going to need them sometime because we are going to start getting into this sometime this year. But we should have some handle on that as to what that might mean, so that we can at least, as we have been saying here, get the facts out as to what this would mean. Before the budget actually comes out is what I am saying, we ought to have this out there so people that are devising the budget know what it is going to mean.

Dr. ZERHOUNI. But again, we checked and those figures are not decisional figures. They are not decisions made. They are projections.

Senator HARKIN. I understand that, but we have got to know what those projections mean in real terms if in fact they follow through on them.

Dr. ZERHOUNI. Definitely.

[The information follows:]

2 PERCENT DECREASE IN FISCAL YEAR 2006

As indicated, while there are mechanically calculated numbers in the OMB computer system that reflect the Administration's overall budget targets in the outyears, no specific funding decisions have been made for NIH or most other domestic programs. In answer to your question, if the NIH budget were to decrease by 2 percent in fiscal year 2006 from the fiscal year 2005 Budget Request, the number of competing research projects grants (RPGs) would decrease by an estimated 2,000 to 2,500 depending on the average cost assumptions used.

Senator HARKIN. Thank you, Dr. Zerhouni. Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

OBESITY RESEARCH

Dr. Zerhouni, the issue of obesity is one of enormous importance. In 15 years, obesity has increased by over 50 percent among adults; in 20 years, 100 percent among children and adolescents. We would like a written response as to what can be done by NIH, how this subcommittee might be effective on diet or education. We have both Health and Human Services and Education to try to confront this growing problem.

[The information follows:]

OBESITY RESEARCH

The NIH Obesity Research Task Force, which was established in April 2003 to accelerate research on this escalating health problem, has developed a Strategic Plan for NIH Obesity Research in broad consultation with external scientific and lay experts. We believe that implementation of this Plan is the best way that the NIH can contribute to arresting the obesity epidemic. Combating obesity must be a broad national effort to which the NIH can contribute new and important scientific insights. As noted, the fiscal year 2005 President's Budget request for the NIH reflects a 10 percent increase for obesity research, which would bring total NIH funding for this area to $440 million. The proposed 10 percent increase includes additional new funding to begin implementation of obesity research in specific areas identified in the Strategic Plan because of their scientific opportunity and public health challenge. With respect to your specific reference to diet and education, the

NIH has also recently created a new obesity research website http://www.obesityresearch.nih.gov), which contains links to science-based information generated by many of the NIH Institutes and Centers for the public, patients, and providers. Two helpful programs are the NIDDK's Weight Control Information Network and the NHLBI's Obesity Education Initiative.

MEDICATION TO LOWER PLASMA LIPOPROTEIN (A) [LP(A)]

Senator SPECTER. Last year I asked Dr. Lenfant about research on medication to lower Lp(a). Dr. Alving of the Heart, Lung and Blood Institute, is there anything new that you can inform the subcommittee about on the status of research toward a medication to lower Lp(a)?

Dr. ALVING. Yes. Thank you very much.

Since the past year, there has been no really new information on Lp(a). It is still defined as an emerging risk factor. But there has been certainly very new information on the importance of lowering LDL, even below the guidelines of less than 100 milligrams per deciliter.

Senator SPECTER. We see the LDL research all the time on the front pages.

Dr. ALVING. Yes.

Senator SPECTER. But how about Lp(a)? That has been identified as a very problemsome factor. We have asked you about it repeatedly. What efforts are you making to identify what can be done about it?

Dr. ALVING. The efforts to identify it have been in terms of our ATP III Guidelines Committee, which has been reviewing all of the literature and has been closely focused on the latest guidelines and the latest research.

Senator SPECTER. Aside from reviewing literature, is there active research being undertaken in the field?

Dr. ALVING. There are R01 grants that include Lp(a), but it has not really been able to be classified as a true risk factor. But what I would like to do——

Senator SPECTER. How many grants?

Dr. ALVING. What I would like to do is reply for the record with an actual listing of the R01 grants so that I can give you very specific information about all of our research.

Senator SPECTER. That would be fine. We would appreciate it if you would specify the grants, what they are doing, what their success has been, what more you need to do.

Dr. ALVING. Yes. I will be happy to do that, Senator.

[The information follows:]

RESEARCH ACTIVITIES ON LP(A)

The NHLBI supports a variety of grants and contracts related to the cardiovascular disease (CVD) risks associated with elevated concentrations of Lp(a), factors that influence Lp(a) levels, mechanisms by which Lp(a) may affect CVD, and Lp(a) metabolism. Beginning in 2005, the NHLBI will support measurement of Lp(a) in the next four years of the National Health and Nutrition Examination Survey.

The NHLBI supports the following R01 grants related to Lp(a):

—APEX: Adiposity Prevention by Exercise in Black Girls *(Medical College of Georgia).*

—Biology of Proteolytic Derivatives of Lp(a) *(University of Chicago).*

—Epidemiology of Coronary Artery Calcification *(University of Michigan at Ann Arbor).*

—Genetic Determinants of Lp(a) Concentration *(University of Texas Southwestern Medical Center).*
—Genetic Epidemiology of Blood Lipids and Obesity *(University of Pittsburgh).*
—Lifestyle, Adiposity, and Cardiovascular Health in Youths *(Medical College of Georgia).*
—Macronutrients and Cardiovascular Risk *(Johns Hopkins).*
—Regulation of Lp(a) Metabolism in Humans *(University of California-Davis).*

The Institute also supports a K08 clinical investigator development award for a project on Lp(a), Homocysteine, and Cardiovascular Risk in End-Stage Renal Disease *(Johns Hopkins).*

Lp(a) is a subject in several epidemiologic studies supported through NHLBI contracts:

—Atherosclerosis Risk in Communities Study (ARIC) *(Baylor College of Medicine, Johns Hopkins, Mississippi Medical Center, University of Minnesota—Twin Cities, University of Texas Health Sciences Center, University of North Carolina at Chapel Hill).*
—Cardiovascular Health Study (CHS) *(Johns Hopkins, University of Washington, University of Vermont, University of Pittsburgh, University of California—Davis, University of Wisconsin, Wake Forest University).*
—Coronary Artery Risk Development in Young Adults Study (CARDIA) *(Harbor-UCLA Research and Education Institute, Kaiser Permanente Division of Research, Northwestern University, University of Minnesota—Twin Cities, University of Alabama at Birmingham, University of California—Irvine).*
—Framingham Heart Study *(Boston University Medical Center).*
—Jackson Heart Study *(Jackson State University, Mississippi Medical Center, Tougaloo College).*

Two NHLBI-supported cooperative agreements related to cardiovascular disease risk factors in Alaska Natives and Native Americans also include Lp(a) measurements:

—Genetics of Coronary Artery Disease in Alaska Natives (GOCADAN) *(MedStar Research Institute).*
—Strong Heart Study *(MedStar Research Institute, Missouri Breaks Research Inc., Southwest Foundation for Biomedical Research, University of Oklahoma Health Sciences Center, Weill Medical College of Cornell University).*

In 1998, the NHLBI initiated a 4-year Lp(a) Standardization Program to enable accurate and consistent measurement that may help to reconcile various findings. Following completion of the program, a workshop was held to present the new results, evaluate current understanding of Lp(a) as a risk factor for CVD, and design future studies. The workshop report was published in the journal *Clinical Chemistry* in November 2003.

In summary, the following statements can be made with respect to Lp(a).

—In general, research has found only a modest association between Lp(a) levels and CVD risk.
—Compared with plasma LDL, Lp(a) concentrations are relatively resistant to alteration by pharmacologic and lifestyle interventions.
—Lp(a) is a complex and heterogeneous protein, and measurement challenges have created difficulties in comparing data from different sources or assessing the impact of findings on the severity of disease.
—Measurement of Lp(a) is not currently recommended as part of CVD risk assessment in patients.

Senator SPECTER. We are going to try to bring this hearing to a close, following Senator Stevens' admonition. We are keeping a lot of scientists away from their laboratories here and there is a lot of work to be done.

SPINAL MUSCULAR ATROPHY

Dr. Landis, on the issue of spinal muscular atrophy therapeutics, could you bring us up to date on when that will be ready for clinical trials?

Dr. LANDIS. We are actually running three pilot clinical trials right now based on previous data. This is a network that is set up by Susan Iannaccone. In addition, the new project looking at additional compounds is well underway. The advisory committee has created a flow plan, and the first set of awards to come up with

an animal model that would be used for preclinical studies will be awarded in the next week or 2.

In addition, two further solicitations have been put out, one that would that would look for cell culture models again being used to solicit better mechanisms to look at therapeutic molecules, and the second to come up with a satisfactory way to measure the protein that is missing. So I think, between what pilot trials are ongoing and this new therapeutics initiative, we are making significant progress.

Senator SPECTER. Would you supplement your answer with a written report about how you project activities of NIH to proceed in this line looking toward some ultimate answer?

Dr. LANDIS. I would absolutely be pleased to do so.

[The information follows:]

SPINAL MUSCULAR ATROPHY

The NINDS has developed a new program, called the SMA Project, to accelerate the development of therapies for this disease. The SMA Project uses a performance-based, milestone driven, contract mechanism to shorten the cycle time from recognition of a need or opportunity for research to getting research underway on those issues and finding answers. We awarded the primary contract in September 2003. This is an extremely ambitious project in a very challenging area of medical science, and scientific progress is not predictable. However, we have explicitly designed the SMA Project to respond quickly to unanticipated obstacles and to emerging opportunities, in the hopes of achieving our goal of identifying a therapeutic candidate for SMA, and completing the required preclinical research and development by late 2007.

One very important aspect of this program is that we are coordinating the research centrally, calling for targeted research projects to meet specific needs identified by an overall plan, and carefully monitoring progress. The program is guided by a superb Steering Committee, with scientists from academia, industry, the Food and Drug Administration, and the intramural and extramural programs at the NINDS. The Committee has already developed a plan and a sample timeline showing all of the steps necessary to meet the goal of bringing a candidate therapeutic to investigational new drug (IND) status that is necessary for clinical trials, within four years. The sample timeline and other detailed information about this program are available to the public on a website at http://smaproject.org.

A crucial aspect of the SMA Project is the rapid turnaround from identifying a research opportunity or need, to solicitation for research proposals, to funding. The first targeted solicitation for research subprojects, focused on mouse models for testing therapies, was issued in December of 2003. These applications have been reviewed, and expect awards to be issued by June 1, 2004. Two further solicitations were issued in March, on cell culture models and on measuring the crucial protein that is lacking in SMA. Full length proposals are due in May, notification of subcontract awards is scheduled for June and funding for July. These initial proposals have been focused on generating the necessary research tools to identify a candidate treatment that has the highest probability of success in the clinic. Future solicitations will be aimed at stimulating new drug identification; the development of gene therapy; and establishing centralized testing facilities to conduct the activities required in the flow plan, such as evaluating compounds in animal and cellular models of SMA.

In addition to the contract-based SMA therapeutics development project, we are currently supporting the short term, open label pilot clinical trials, being conducted by Dr. Iannaccone, of three drugs that have shown promise either in patients or in models of SMA. We will be looking to see if these results warrant larger trials. We are also planning a workshop on clinical trials for SMA to be held later this year. This workshop is intended to ready the SMA clinical community to test interventions that result from the SMA Project, by promoting collaboration and high quality trial design. In preparation, we are moving forward to work with the community on identifying and evaluating drugs now available that may slow the progression of SMA and be ready for testing in clinical trials.

So, we are exploiting the best existing opportunities in the short term for slowing the disease, and at the same time we are developing the best possible treatments for the future through the SMA Project. Finally, I want to emphasize that the SMA

Project is not replacing our traditional investigator-initiated grant programs and our intramural program on SMA; we are continuing to support this research as well. We also have extensive research programs in cross-cutting areas such as gene therapy, drug screening, and stem cells that may ultimately have an impact on SMA.

Senator SPECTER. Thank you. Dr. Spiegel, in your field we had a high visibility attention-getter when NBA basketball star Alonzo Mourning was seeking a kidney transplant and was forced to retire early on glomerular disease that damages filters in the kidney that cleanse the blood. We were asked to hold a separate hearing which was just too much to do. Could you give us an update on where that stands?

Dr. SPIEGEL. Yes, Senator, I would be happy to do that.

The glomeruli are tiny units that cleanse the blood in the kidney and they are comprised of kidney membranes and small capillary blood vessels. There are really two types of injuries that occur. One is glomerulonephritis, which is caused by the immune system. Many institutes at NIH work together to direct attention to preventing kidney failure from glomerulonephritis.

The form that you are referring to, focal segmental glomerulosclerosis, affects children, and as you implied in the case of Alonzo Mourning, can affect African Americans disproportionately. We have intensive research efforts together with patient advocacy groups such as the NephCure Foundation. In fact, we have launched a clinical trial directed at new and more effective therapies for this important disorder, and we are hopeful that from that trial, new, safer, and more effective medication will emerge. But at the same time, we are also reinforcing our basic research to understand the basis for the injury that occurs in glomerulosclerosis.

Senator SPECTER. Thank you very much.

AGE-RELATED MACULAR DEGENERATION (AMD)

Dr. Sieving, with respect to macular degeneration, how are you moving ahead on the clinical trial networks for advancing AMD research?

Dr. SIEVING. AMD is a leading cause of vision loss and, in fact, one of the leading causes of disability in the elderly. It is a neurodegenerative disease. A part of the mission of the institute is to form alliances, scientific alliances and communication related to other neurodegenerations, including Parkinson's and Alzheimer's disease, because there are some common features that mutually these two multiple areas can learn.

Now, the AMD network specifically is going to tackle the opportunities presented by existing and new compounds to modify the effects of and the course of AMD. One such opportunity—it is not actually a network, but one recent success came from the finding reported about a year ago that antioxidant nutrients and zinc can decrease the risk of progressing to end-stage vision loss. That is a very important finding in the aggregate for the American population. Now it is our task to take that bedside finding back to the bench to help understand on a molecular and cell biological basis why this is happening.

Back on the AMD networks, we are proceeding with that. Applications are coming in, will be reviewed, and we hope that we will be able to successfully fund this venture.

AUTISM RESEARCH

Senator SPECTER. Dr. Insel, with respect to autism, could you bring us up to date on the research activities of your department and what success you have had and what your projection is for the future?

Dr. INSEL. I would be happy to, Senator.

We have in the past year launched a total of eight STAART centers. These are interdisciplinary centers to bring both a research effort and an intervention effort to autism. This is a program that will go over the next 4 to 5 years. It involves five of the institutes that are here today. It is, we think, a great national effort that will, by coordinating efforts across many different sites, lead to some very new insights into this troubling and still very mysterious illness.

Senator SPECTER. We have quite a number of questions for the record. We very much appreciate your coming. We appreciate even more the outstanding work you are doing. We are committed to doing our utmost to help you on the funding. When the other research entities come forward with their requests, it continues to be my view that it is a very, very solid capital investment for the United States and we will continue to push on all lines.

Anything further, Senator?

SPINAL MUSCULAR ATROPHY (SMA)

Senator HARKIN. Yes, just one thing, Mr. Chairman.

Dr. Landis, on the SMA issue and what you are sending up to us, I tried to listen to your answer, but would you also look ahead as to how soon we might be going to clinical trials, and what the—I hate to use the word "Roadmap" but what that time line might be?

Dr. LANDIS. We would be pleased to do that. The projection is 4 years for this new initiative to come to fruition with optimally selected compounds, but I will certainly give you a detailed answer.

Senator HARKIN. I will take a look at that.

TRANS-NIH OBESITY TASK FORCE

Back on the issue of obesity, I met with Dr. Gerberding last week at CDC. They have said that now it may be surpassing tobacco usage as the biggest health menace that we face as Americans. Again, I am wondering how, Dr. Zerhouni, you are approaching this in terms of NIH's role in looking at obesity.

Again, it always seems to me that it is easier for people who have never been obese to not be obese than it is for someone who becomes obese to lose weight and hold it down. That is just the facts.

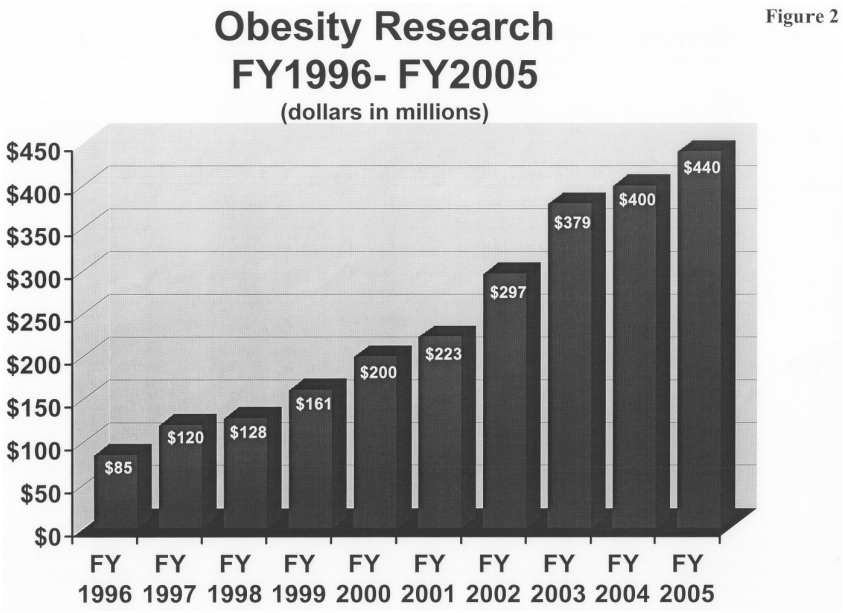
So how do we prevent it in the first place? It seems to me that one of the links in child health, Dr. Alexander, as kids develop and as they learn and grow—it seems to me some research ought to be done on that, what hkids eat and how they develop. And there may be some genetic problems too. I do not know. Dr. Collins could be involved in that.

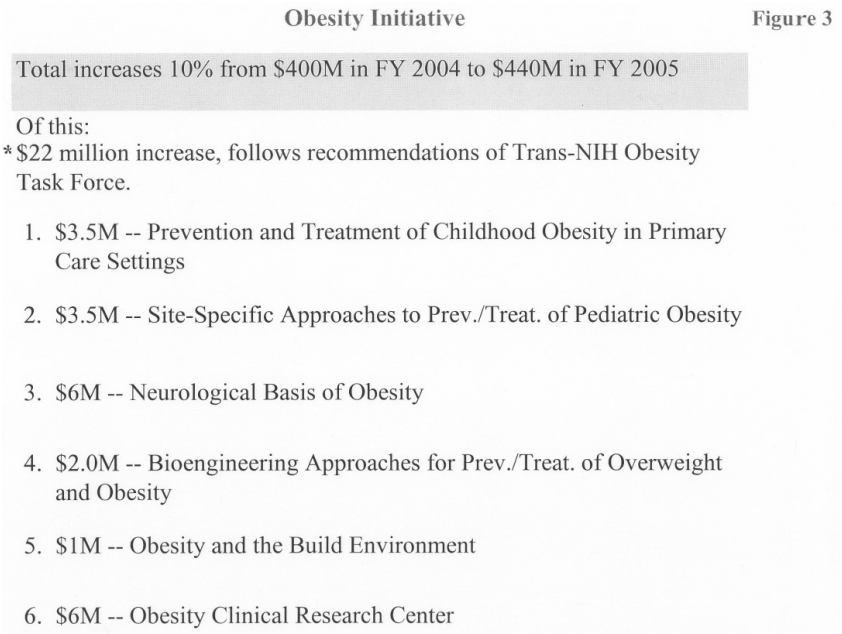
I guess what I am getting at is this seems to lend itself to some kind of an inter-institute kind of task force to look at how we get

to the prevention end of it, not just to the cure, but what are some of the forces that might go into preventing this in the first place.

Dr. ZERHOUNI. You are absolutely correct, Senator. As I indicated to you in the past through this graph, NIH started investing in obesity 10 years ago. But more importantly is the relevancy of the question you are asking. Last year I asked that we form a trans-NIH Obesity Task Force that is led by Dr. Spiegel. This year we are going to increase funding in obesity research by 10 percent. Here on the screen I can actually show you what that 10 percent is going to be related to [see figure 3]: $3.5 million will be the prevention and treatment of childhood obesity in primary care settings; $3.5 million will be site-specific approaches to prevent and treat pediatric obesity.

Figure 2





In a nutshell, we are going to focus on the aspects of prevention and understanding the evidence that we need to, in fact, stop the leading edge of the epidemic which is, we agree, in childhood. The earlier we intervene, the more likely we are to dampen the epidemic as we see it. So we are focusing those efforts exactly on that. We are widening our portfolio. We have quadrupled our investment on obesity research because we knew already a while back that it would become a public health problem.

In addition to that, the other part of the new plan, which is on the web site, is receiving public comment, which is related to exactly what you are asking, this trans-NIH view, the other end of the spectrum is most of the diseases that are developed because of obesity are what we call comorbidities, diabetes, hypertension. Those are the ones that really hit the patients hard. Those do not occur to the same degree at every level of overweight. They occur disproportionately in the very morbid, high obesity patient with a BMI index of 33, 34, 35. So the other component of our strategy is to look at the front end, children, and look at those who are very likely to develop the co-morbidities and understand how you stop obesity from giving diabetes to patients and what is the relationship there, what is the relationship with hypertension, and so on.

Dr. Spiegel, who is leading the trans-NIH task force, will be happy to provide you more detailed information. But we agree with you. It is a multi-prong strategy that we need to implement across all Federal Departments and NIH needs to attack now the leading edge and the trailing edge of what we know are the most important points of action that we should take.

Senator HARKIN. Well, I appreciate it. From my own standpoint, it is the leading edge is where you ought to focus. I hope what I am not hearing, Mr. Chairman, is that somehow or other we are

going to do research into finding out how you can be obese, but we can have some kind of blockers to keep you from getting diabetes. I think more research ought to be into the front end to keep you from getting obese in the first place. That is my unscientific statement on that.

Thank you.

Dr. ZERHOUNI. Thank you, Senator.

Senator SPECTER. Thank you, Senator Harkin. Thank you all very much.

PREPARED STATEMENT RECEIVED

We have received the prepared statement of Senator Mary L. Landrieu which will be placed in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Thank you, Mr. Chairman. Thank you, Dr. Zerhouni, for joining us today to discuss the National Institutes of Health (NIH) and its 2005 budget, as proposed by the President. The National Institutes of Health are an integral component to our nation's health and safety. Within the twenty-seven Institutes and Centers at the National Institutes of Health, research is being conducted and studies are beginning to show, new and exciting ways to prevent, detect, diagnose, and treat the diseases and disabilities which plague our country and the world. Fostering communication and collaboration, the National Institutes of Health provide grant and research opportunities to universities, medical schools, hospitals, and other research institutes in addition to conducting their own federal research. Through these collaborations, the National Institutes of Health position themselves as the world's foremost medical research center and the focal point for domestic medical research.

The President's fiscal year 2005 budget request provides $28.8 billion for the National Institutes of Health. This number represents an increase of $764 million, or 2.7 percent, over fiscal year 2004 levels. As a member of the Senate Appropriations Subcommittee on Labor, Health, Human Services and Education, I was proud to lend my support to doubling the National Institutes of Health budget in just five years. By steadfastly keeping the National Institutes of Health funding on track, my colleagues and I enabled the National Institutes of Health to support far more promising research than it was ever able to before, and to advance into new areas of science. While I am very proud of this aggressive increase and commitment to funding, we must not fall back on our commitment to medical research.

Research at the National Institutes of Health has a real and direct impact on my state of Louisiana. The Centers for Disease Control and Prevention (CDC) reports that 9,306 people have been affected by the West Nile Virus in the United States this year. 240 of those infected have died. Of those cases, the state of Louisiana has reported 123 cases and 8 deaths this year. Mosquito-borne diseases, such as the West Nile Virus, represent one of the most serious and preventable public health threats for many states. With the recent outbreak of the West Nile Virus in the United States, the National Institute of Allergy and Infectious Diseases at the National Institutes of Health have accelerated their research efforts into the West Nile Virus, possible vaccines, and treatment options. We have not yet developed a vaccine to combat the West Nile Virus but with the proper funding, researchers at NIH are committed to finding one.

In addition to West Nile, Louisianians also find themselves battling another deadly epidemic, obesity. Currently in the United States there are 127 million adults that are overweight, 60 million of whom are obese, and 9 million who are severely obese. For children ages 6–11, 30.3 percent are overweight and 15.3 percent are obese. These numbers have more than doubled in the last thirty years. This epidemic threatens the health of our Nation and increases the incidence of type 2 diabetes, fatty liver disease, kidney failure, as well as many other diseases. I am pleased to learn that the fiscal year 2005 budget for the National Institutes of Health supports an expansion of $40 million to its obesity research portfolio but this is not nearly enough to reverse a trend of this magnitude. I hope that we can do more in the near future to end this epidemic. It is imperative that we work to understand the neurobiological, genetic, behavioral, and environmental basis of obesity and develop strategies to maintain healthy weight in adults and children.

In conclusion, I would like to speak briefly about the flu epidemic that has recently taken a toll on our country and the global community. The CDC estimates that 10–20 percent of Americans come down with the flu each year. Of these numbers, more than 100,000 people are hospitalized and approximately 36,000 Americans die from the flu and its complications each year. While we have not experienced a flu pandemic since 1968, each fall and winter brings with it a new strain of the flu. Research institutions and health departments around the world are cooperating to track flu outbreaks and to determine the many different types, strains, and causes. The National Institute of Allergy and Infectious Diseases (NIAID) at NIH currently supports research into how the flu virus works and into developing better vaccines to prevent and treat the infection. By supporting this research at NIH we can hope to better track the development of flu strains and arm ourselves with the proper vaccines and treatments that will prevent deadly outbreaks.

While these are but a few examples of the impact of NIH research on the state of Louisiana, I think they make it clear that the research being funded through the National Institutes of Health has a real and immediate impact on the citizens of our country. By wisely investing in medical research that advances the prevention and treatment of diseases, we in fact are saving money that would otherwise have to be used to diagnose and treat these diseases. I know that my colleagues agree that funding a cure is perhaps the best use of government resources there is. It is my hope that we will continue to increase the National Institutes of Health budget so that our children and grandchildren can truly benefit from the cures and medical advances made every day at NIH.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. 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 HERB KOHL

OBESITY

Question. Dr. Crawford, both USDA and FDA have recently announced new efforts to combat the increasing problem of obesity. FDA announced the "Calories Count" program, and USDA has money in several programs, including WIC, to help battle this problem. However, for all of the government's efforts, all of the money being put into this effort pales in comparison to the food industry's billions of dollars worth of advertising. How can the government successfully get its message out when, at first glance, its efforts appear to be dwarfed by the food industry? How do your agencies compete with that?

Answer. In support of the President's Healthier U.S. initiative, the DHHS established a complementary initiative, Steps to a Healthier U.S., which emphasizes personal responsibility for the choices Americans make for healthy behaviors. One aspect of this initiative focuses on reducing the major health burden created by obesity and other chronic diseases. Following DHHS' July 2003 Roundtable on Obesity and Nutrition, on August 11, 2003, FDA established an Obesity Working Group, or OWG, to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. This report was released on March 12, 2004.

There is no simple answer to the problem of obesity. Achieving success in reducing and avoiding obesity will occur only as a result of efforts over time by individuals as well as various sectors of our society. It should be noted, however, that most associations, agencies, and organizations believe that diet and physical activity should be addressed together in the fight against overweight and obesity.

The OWG report provides a range of short and long-term recommendations to address the obesity epidemic with a focus on a "calories count" emphasis for FDA actions. These recommendations are based on sound science and address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; establishing educational strategies and partnerships to support appropriate messages and teach people, particularly children, how to lead healthier lives through better nutrition; developing initiatives to improve the labeling of packaged foods with respect to caloric and other nutrition information; encouraging and enlisting

restaurants in efforts to combat obesity and provide nutrition information to consumers, including information on calories, at the point-of-sale; developing new therapeutics for the treatment of obesity; designing and conducting effective research in the fight against obesity; and continuing to involve stakeholders in the process.

Regarding food labeling, the OWG report contains several recommendations based on sound science. I will provide these recommendations for the record.

[The information follows:]

Publish an advance notice of proposed rulemaking, or ANPRM, to seek comment on the following:

—How to give more prominence to calories on the food label, for example, increasing the font size for calories, including a column in the Nutrition Facts panel of food labels for percent Daily Value for total calories, and eliminating the listing for calories from fat;

—Whether to authorize health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of a health claim for a "reduced" or "low" calorie food might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers."

—Whether to require additional columns on the Nutrition Facts panel to list quantitative amounts and percent Daily Value of an entire package on those products and package sizes that can reasonably be consumed at one eating occasion—or declare quantitative amounts and percent Daily Value of the whole package as a single serving if it can reasonably be consumed at a single eating occasion; and,

—Which, if any, reference amounts customarily consumed of food categories appear to have changed the most over the past decade and hence require updating.

In addition, FDA will file and respond in a timely way to petitions the agency has received that ask FDA to define terms such as "low," "reduced," and "free" carbohydrate; and provide guidance for the use of the term "net" in relation to carbohydrate content of food—these petitions were filed on March 11, 2004.

FDA will also encourage manufacturers to use dietary guidance statements, an example of which would be, "To manage your weight, balance the calories you eat with your physical activity." In addition, the Agency will encourage manufacturers to take advantage of the flexibility in current regulations on serving sizes to label as a single-serving those food packages where the entire contents of the package can reasonably be consumed at a single eating occasion and encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions.

FDA believes that if the report's recommendations are implemented they will make a worthy contribution to confronting the nation's obesity epidemic and helping consumers' lead healthier lives through better nutrition.

FDA also believes that the regulatory scheme for claims in food labeling, whether health claims, nutrient content claims, or other types of claims, are science based, and we continue to consider modifications to our regulations to keep up with recent scientific developments. A benefit of standardized, science-based terminology, as with other terms that FDA has defined that consumers may use to make health-based dietary choices—e.g., terminology concerning fat content—is that it allows consumers to compare across products and it encourages manufacturers to compete based on the nutritional value of the food. However, FDA does not regulate television and other media marketing of food products. Some of the modifications FDA is currently considering are described above in the list of topics to be covered by the ANPRM the agency intends to issue.

With respect to conveying the report's messages to the public, FDA believes that all parties, including the packaged food industry, restaurants, academia, and other private and public sector organizations in addition to government agencies at all levels, have an essential role to play. On April 22, 2004, FDA's Science Board focused on specific recommendations from the OWG report. These recommendations call on FDA to work through a third-party facilitator to engage all involved stakeholders in a dialogue on how best to construct and convey obesity messages in the restaurant setting and in the area of pediatric obesity education.

This approach is one example of how the Agency intends, by means of public and private partnerships, to leverage its ability to convey appropriate messages on obesity to the public with the goal of changing behavior and ultimately reversing obesity trends in the United States.

IMPORT INSPECTIONS

Question. Dr. Crawford, the FDA budget this year includes a $7 million increase to fund 97,000 food import examinations. This is a big increase in inspections over any previous year—still, however, less than one percent of all of the food imported into this country will be inspected. How would you respond to charges that you still aren't inspecting nearly enough imported food, especially in light of events during the past year where bad food has gotten in and people have died? How do we ensure consumers that their food is indeed safe?

Answer. FDA is appreciative of the additional funding we have received for the inspection of domestic firms and for inspections of imported foods. FDA believes it is more effective to focus our resources in a risk-based manner than to focus simply on increasing the percentage of imported food shipments that are physically inspected. It is important to note that every shipment of FDA-regulated food which is entered through Customs and Border Protection as a consumption entry is electronically reviewed by FDA's Operational and Administrative System for Import Support to determine if it meets identified criteria for further evaluation by FDA reviewers and physical examination and/or sampling and analysis or refusal. This electronic screening allows FDA to concentrate its limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

Due to constantly changing environments of operation, e.g., counterterrorism and BSE, our domestic inspection and import strategy cannot be defined in terms of a percentage of coverage through inspections, physical examinations and sample analyses. It needs to be a flexible blend of the use of people, technology, information and partnerships to help protect Americans from unsafe imported products. Accordingly, the Agency is developing and using strategies for mitigating risks prior to importation through partnerships and initiatives based on best practices and other science based factors relevant to the import life cycle, i.e., from foreign manufacturer to the U.S. consumer. Recently this principle has been applied in the "Canadian Facility Voluntary Best Management Practices for Expediting Shipments of Canadian Grains, Oilseeds and Products to the United States" implemented February 24, 2004, and designed to mitigate the potential of mammalian protein prohibited from being fed to cattle or other ruminants under BSE-prevention regulations promulgated by CFIA and FDA.

Another piece of the long term solution to a higher level of confidence in the security and safety of food products lies in information technology that will merge information on products and producers with intelligence on anticipated risks to target products for physical and laboratory examination or refusal. This strategy would rely on data integrity activities that reduce the opportunity for products to be incorrectly identified at ports. It would also rely on cooperation from producers so that FDA can identify sources that are unlikely to need physical testing. However, even with such targeting, improvements are limited by the available methodologies for assessing threat agents and our ability to predict which tests ought to be used.

We are ramping up our food inspections, but we recognize that we also need to inspect smarter, not just inspect more. That is why FDA is making significant investments in technology and information resources such as the development of the Mission Accomplishment and Regulatory Compliance Services System, MARCS. MARCS is a comprehensive redesign and reengineering of two core mission critical systems at FDA: FACTS and the Operational and Administrative System for Import Support, OASIS. OASIS supports the review and decision making process of products for which entry is sought into the United States. We are using funds to work to further improve targeting and using force multipliers such as IT.

FDA also has a proof of concept project, called "Predict," with New Mexico State University under a Department of Defencse contract which is being designed to enhance agency capability to rapidly assess and identify import entries based on risk using relevant information from various sources including regulated industry, trade, other federal, State, and local entities, and foreign industry and governments. This project, if successful, will greatly enhance FDA's capability to be smarter in directing field activities on products of greater risk to public health and safety. The proof of concept project is projected to be completed in the Fall of 2004. The relentless growth in the volume of domestic as well as imported food products, which are increasingly in "ready for consumer sale packaging." Food imports are now growing at 19 percent per year. FDA needs to use all the potential tools available to improve its efficiency in food security and safety coverage.

In addition, FDA has several strategic initiatives to enhance safety. One of these is "Agency Initiatives to Improve Coverage," which includes the creation of the Southwest Import District to better coordinate import activities on the southern border. Another is reciprocal FDA and U.S. Customs and Border Protection training to

improve product integrity of goods offered for import and increase enforcement actions by Customs to deter willful violations of U.S. laws and regulations. While foreign inspections and border operations provide some assurance that imported foods are safe, the agency continues to work to foster international agreements and harmonize regulatory systems. For instance, we actively participate in the Canada/U.S./Mexico Compliance Information Group, which shares information on regulatory systems and the regulatory compliance status of international firms to protect and promote human health.

It is very important that American consumers trust the safety of the food supply. FDA has made fundamental changes in how we implement our mission of protecting the food supply, so that all Americans can have confidence that their food has been handled under secure conditions that provide assurance of its safety.

FDA FOIA POLICIES

Question. Dr. Crawford, my office has been working with a non-profit patient advocacy group, the TMJ Association, in their efforts to have two FOIA requests that are well over a year old responded to. Their original FOIA request was made on November 1, 2002 (request number 02017071), more than 17 months ago, and the subsequent request was made on March 25, 2003 (request number 03004361). They have not yet received the information requested, and have been unable to get a date commitment by FDA as to when the information will be provided. It is my understanding that they have been informed that FOIA requests are severely backlogged, and the FDA has no idea when they will be able to process their request. What is the current backlog for FOIA requests?

Answer. As of April 28, 2004, FDA has 19,369 pending FOIA requests—17,555 have been pending more than 20 days and 1,814 have been pending 20 days or less. The Denver District Office is responsible for responding to the two requests from the TMJ Association. As of April 28, 2004, Denver District Office has 369 pending FOIA requests—357 requests have been pending more than 20 days, and 12 requests have been pending 20 days or less.

Question. How many FDA staff are responsible for handling these requests? Is this their sole responsibility, or do they have other responsibilities as well?

Answer. For fiscal year 2003 the total number of personnel responsible for processing FOIA requests was 91 FTE, 75 full time employees, and 16 FTE work years representing personnel with part-time FOIA duties in addition to other responsibilities.

Question. Does FDA need additional staff or resources in order to process these requests on a timely basis?

Answer. In some agency components FOIA is a collateral duty. For example, in most FDA field offices, Compliance Officers whose primary responsibilities are related to the Agency's regulatory enforcement activities also perform FOIA duties as permitted by time and regulatory workload. Additional staff devoted to FOIA could shorten the amount of time for processing requests.

Question. What do you believe is a reasonable length of time for a group to wait for an information request to be processed and responded to?

Answer. Requests are processed by the agency component that maintains the requested records. There are a number of factors that must be considered in order to predict a reasonable amount of time for a request to be processed. Those factors include the volume of requests received by the component, the complexity of requests received, the amount of time required to search for records, the amount of time require to review the records to determine whether information is releasable under FOIA, and the resources available to process requests.

Question. What is the average length of time it takes to process a FOIA request? Can you please explain the severe delay in processing this specific one, which has taken over two years and apparently has no end in sight? Can you please provide me a timeframe within which the FDA will respond to these two particular FOIA requests?

Answer. Under the Electronic Freedom of Act Amendments of 1996, agencies are permitted to establish multiple tracks for processing FOIA requests based on the complexity of the requests and the amount of work and time required to process requests. Some FDA components have established multiple processing tracks. Requests are processed on a first in, first out basis within each track. The median number of days to process requests in the simple processing track is 19 days. The median number of days to process requests in the complex processing track, for more complicated requests, is 363 days. For requests that are not processed in multiple processing tracks, the median number of days to process is 44 days.

Due to a heavy load of regulatory cases in the Denver District Office that must be handled by the Compliance Officers in addition to staff shortages, FOIA work in the Denver District is being performed by one individual on a part-time basis. This has resulted in a significant backlog of FOIA requests. The Denver District Office expects to fill request 02–17071 from the TMJ Association in six months, and request 03–4361 in one month.

Question. What additional efforts can this group undertake in order to speed up their request?

Answer. The Denver District Office expects to fill request 02–17071 from the TMJ Association in six months, and request 03–4361 in one month.

In addition, the Denver District is reviewing and evaluating its FOIA workload and will develop a strategy aimed at reducing the backlog of FOIA requests.

Question. What is the FDA's policy on charging for FOIA requests made by non-profit patient advocacy groups?

Answer. The FOIA sets forth criteria that agencies must follow with respect to charging for processing FOIA requests. Non-profit organizations are considered Category III requesters. Such requesters receive 100 pages of duplication and two hours of search at no charge. If the number of pages exceed 100 and/or if the amount of search time exceeds two hours, Category III requesters are charged based on the FOIA fee schedule of the Department of Health and Human Services. The fee for duplication is $.10 per page, and the fee for search is based on the grade level of the individual who processes the request. I will be happy to provide the current grade rates for the record.

[The information follows:]

CURRENT GRADE RATES

GS–1 through 8—$18.00 per hour
GS–9 through 14—$36.00 per hour
GS–15 and above—$64.00 per hour

In addition, requesters may make a request for waiver or reduction of fees if their request meets the following criteria: disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and, disclosure is not primarily in the commercial interest of the requester.

IMPLICIT PRE-EMPTION

Question. Adverse reactions to prescription drugs and other medicines take the lives of more than 100,000 Americans each year, and millions more are seriously injured. For many years, state tort laws have enabled some victims to receive compensation for their injuries. It has been brought to my attention that the Food and Drug Administration (FDA) has stepped in to protect drug companies from liability in some of these lawsuits, potentially robbing individuals of their only means of compensation. FDA's actions are even more troubling when you consider that these lawsuits have other important purposes, such as deterring future bad behavior and providing the American public with access to important health and safety information. How many times has the FDA interfered in lawsuits, arguing that implicit preemption prohibits a plaintiff from receiving compensation for their injuries? In how many of these cases has a court held that the plaintiff's tort claim was implicitly pre-empted by federal law?

Answer. In the past several years, the Department of Justice (DOJ) has represented the United States in four cases involving state-law challenges to the adequacy of FDA-approved risk information disseminated for FDA-approved new drugs.[1] In each case, DOJ contended that the state-law claim was preempted by federal law. In addition, in some cases, DOJ argued that the state-law claim was not properly before the court by operation of the doctrine of primary jurisdiction.[2]

The legal basis for preemption in these cases is FDA's careful control over drug safety, effectiveness, and labeling according to the agency's comprehensive authority under the FDCA and FDA implementing regulations. If state authorities, including judges and juries applying state law, were permitted to reach conclusions about the

[1] FDA also periodically becomes involved, through the Department of Justice, in cases involving preemption of state-law requirements under the medical device provisions of the FDCA, which include an express preemption provision, 21 U.S.C. 360k(a).

[2] Primary jurisdiction allows a court to refer a matter to an administrative agency for an initial determination where the matter involves technical questions of fact and policy within the agency's jurisdiction. See, e.g., *Israel* v. *Baxter Labs., Inc.*, 466 F.2d 272, 283 (D.C. Cir. 1972); see also 21 CFR 10.60.

safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and statutory mandate, the federal system for regulation of drugs would be disrupted. I will be happy to include information on the four cases for the record.

[The information follows:]

Bernhardt

In 2000, two individual plaintiffs filed product liability actions in a New York court against Pfizer, Inc., seeking a court order requiring the company to send emergency notices to users of the prescription antihypertensive drug CARDURA (doxazosin mesylate) and their physicians. The notices would have described the results of a study by a component of the National Institutes of Health (NIH) that, the plaintiffs alleged, demonstrated that Cardura was less effective in preventing heart failure than a widely used diuretic. FDA had not invoked its authority to send "Dear Doctor" letters or otherwise disseminate information regarding a drug that the agency has determined creates an "imminent danger to health or gross deception of the consumer." (21 U.S.C. 375(b).) The plaintiffs, nevertheless, filed a lawsuit under state common law seeking relief that, if awarded, would have pressured the sponsor to disseminate risk information that FDA itself had not disseminated pursuant to its statutory authority.

FDA's views were submitted to the federal district court in the form of a Statement of Interest.[3] The Statement relied on the doctrine of primary jurisdiction. The Statement also took the position that the plaintiffs' request for a court order requiring the dissemination of information about NIH study results to users and prescribers of CARDURA was impliedly preempted. According to the Statement, the court order "would frustrate the FDA's ability effectively to regulate prescription drugs by having the Court substitute its judgment for the FDA's scientific expertise." The Statement also noted that, if the court granted the requested order, a direct conflict would be created between the information required to be disseminated by the court and the information required to be disseminated by FDA under the FDCA (in the form of the FDA-approved labeling).

The Statement contended that state law could not provide a basis for requiring a drug manufacturer to issue drug information that FDA had authority to, but did not, require. Importantly, the submission did not argue that the state-law claim was preempted because FDA had reached a determination that directly conflicted with the plaintiff's view. Nor did it assert that FDA had specifically determined that the information on the NIH study requested by the plaintiffs was unsubstantiated, false, or misleading. In this sense, the Statement of Interest in Bernhardt was the most aggressive, from a legal perspective, than the three subsequent DOJ submissions on FDA's behalf in preemption cases made during the present Administration.

The United States District Court for the Southern District of New York accepted the primary jurisdiction argument made on FDA's behalf. (*Bernhardt* v. *Pfizer, Inc.*, 2000 U.S. Dist. LEXIS 16963, *9 (whether the additional warnings sought by the plaintiffs were appropriate "is a decision that has been squarely placed within the FDA's informed expert discretion")). It did not address the preemption issue. The case was voluntarily dismissed on April 22, 2003.

Dowhal

In 1998, an individual plaintiff in California asked that State's attorney general to initiate an enforcement action against SmithKline Beecham and other firms marketing OTC nicotine replacement therapy products in California. (These products are marketed pursuant to an approved new drug application.) The plaintiff contended that the FDA-approved warnings for the defendants' products did not meet the requirements of a state statute called the Safe Drinking Water and Toxic Enforcement Act (Cal. Health & Safety Code § 25249.5 et seq.), also known as Proposition 65. From 1996 through 2001, FDA had repeatedly advised the defendants that they could be liable under the FDCA for selling misbranded products if they deviated from the FDA-approved warning labeling for their products. FDA also advised the state attorney general in writing in 1998 that the defendants' warning in the labeling clearly and accurately identified the risks associated with the products and, therefore, met FDA requirements under the FDCA. After receiving the letter, the attorney general declined to initiate enforcement action.

Nevertheless, in 1999, the individual plaintiff initiated a lawsuit of his own in California state court under Proposition 65's "bounty-hunter" provision, which em-

[3] Statement of Interest of the United States; Preliminary Statement, *Bernhardt* v. *Pfizer, Inc.*, Case No. 00 Civ. 4042 (LMM) (S.D.N.Y. filed Nov. 13, 2000).

powers individuals to file enforcement actions under that statute on behalf of the people of the State of California. The lawsuit asked the court to award civil money penalties and restitution, and to issue an injunction requiring the defendants to disseminate warnings for their products that differed from the warnings required by FDA. In 2000, the plaintiff filed a citizen petition with FDA requesting that the agency require the defendants to change their warnings to reflect the language sought by the plaintiff in the lawsuit. FDA rejected the proposed language, determining that it lacked sufficient support in scientific evidence and presented a risk of mischaracterizing the risk-benefit profile of the products in a way that threatened the public health. Although the trial court found for the defendant, the California Court of Appeal rejected the defendant's contention that the plaintiff's claim was preempted under the FDCA, and allowed the lawsuit to proceed. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare,* 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002), argued, Case No. S–109306 (Cal. Feb. 9, 2004).)

FDA's views were presented to the Court of Appeal of California in an amicus curiae ("friend of the court") brief and to the Supreme Court of California in a letter brief and an *amicus* brief.[4] All three documents explained that the warning language sought by the plaintiffs had been specifically considered and rejected by FDA as scientifically unsubstantiated and misleading. Including the language would, therefore, misbrand those products and cause the defendants to violate the FDCA. The documents explained, further, that principles of conflict preemption applied to the plaintiffs' claim because it was impossible for defendants to comply with both federal and state law and because the state law posed an obstacle to the accomplishment of the full purposes and objectives of the FDCA.

The California Court of Appeal rejected the preemption argument. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare,* 2002 Cal. App. LEXIS 4384, ***16–17 (Cal. Ct. App. 2002) (reversing trial court decision granting summary judgment for defendants on preemption grounds)). On April 15, 2004, the California Supreme Court reversed the appeals court decision, finding a direct conflict between FDA requirements and the state-law warning requirement advocated by the plaintiff. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare,* 2004 Cal. LEXIS 3040.)

Motus

Also in 2000, an individual plaintiff sued Pfizer in a California court alleging, among other things, that the company had failed to fulfill its state common law duty to warn against the risk of suicide the plaintiff alleged was presented by ZOLOFT (sertraline HCl), an FDA-approved drug in the selective serotonin reuptake inhibitor (SSRI) class indicated to treat depression (among other things). On numerous occasions, FDA had specifically considered and rejected such language for SSRIs as scientifically unsupportable and inconsistent with FDA determinations as to the safety and effectiveness of the products.

The United States District Court for the Central District of California (to which the case had been removed on the ground of diversity) rejected the defendant's preemption argument, allowing the lawsuit to proceed. (*Motus* v. *Pfizer Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000).) The court later granted the defendant's motion for summary judgment on non-preemption grounds (196 F. Supp. 2d 984, 986 (C.D. Cal. 2001)), and the plaintiff appealed. DOJ submitted an amicus curiae brief to the United States Court of Appeals for the Ninth Circuit on FDA's behalf.[5] The brief's arguments were essentially the same as the arguments advanced in *Bernhardt.* In contrast to the situation in *Bernhardt,* however, in Motus, FDA had specifically considered, and rejected, the language requested by the plaintiff under state law. The appeals court affirmed the trial court's decision earlier this year (2004 U.S. App. LEXIS 1944 (9th Cir. February 9, 2004)).

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[4] Letter from Robert D. McCallum, Jr., Ass't Attorney General, *et al.*, to Frederick K. Ohlrich, Supreme Court Clerk/Administrator, Dowhal v. SmithKline Beecham Consumer Healthcare LP, *et al.*, Case No. S–109306 (Cal. filed Sept. 12, 2002); Amicus Curiae Brief of the United States of America in Support of Defendants/Respondents SmithKline Beecham Consumer Healthcare LP, *et al.*, *Dowhal* v. *SmithKline Beecham,* Case No. A094460 (Cal. Ct. App. filed Mar. 22, 2002); Amicus Curiae Brief of the United States of America in Support of Defendants/Appellants SmithKline Beecham Consumer Healthcare LP, et al., *Dowhal* v. *SmithKline Beecham,* Case No. S109306 (Cal. filed July 31, 2003).

[5] Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus* v. *Pfizer,* Case Nos. 02–55372 & 02–55498 (9th Cir. filed Sept. 3, 2002).

In re PAXIL

In 2001, individuals filed suit in a California court on behalf of past or current users of PAXIL (paroxetine HCl) against the drug's manufacturer, GlaxoSmithKline (GSK), alleging that the company's direct-to-consumer (DTC) broadcast advertisements for the drug failed adequately to warn about the consequences of discontinuing the drug. In reviewing the new drug application for the drug, FDA had found no evidence that it was habit-forming and did not require GSK to address that risk in FDA-approved labeling. FDA did, however, require GSK to include in labeling statements regarding discontinuation syndrome, and the labeling consequently recommends that doctors gradually reduce dosages and monitor patients for syndrome symptoms. FDA reviewed proposed DTC advertisements GSK had submitted for Paxil that said that the drug was not habit-forming. The agency at no time determined that this statement was misleading. In August 2002, notwithstanding FDA's determination, the court issued a preliminary injunction prohibiting GSK from running DTC advertisements stating that Paxil is not habit-forming. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 16221 (C.D. Cal. Aug. 16, 2002))

On reconsideration, the court declared that the preliminary injunction challenged only "FDA's . . . determination that the public is not likely to equate the words not habit forming' as used in direct[-]to[-]consumer advertisements with no withdrawal symptoms.'" According to the court, "The question of how members of the general public are likely to interpret (or misinterpret) a statement is within one of the courts' core competencies." Declaring itself "unwilling to blindly accept FDA's ultimate determination here," the court rejected the defendants' preemption and primary jurisdiction arguments. It nevertheless denied the injunction on the ground that the plaintiff was not likely to succeed in demonstrating that "non-habit forming" statement in the advertisement is misleading. Thus, although the court ultimately declined to award the injunctive relief sought by the plaintiff, it continued to distinguish between FDA's determinations as to the adequacy of drug warnings under federal law, and its own view of warnings adequacy under state common law. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 24621 (C.D. Cal. Oct. 16, 2002).)

DOJ submitted to the court a Statement of Interest and a brief asserting preemption.[6] The Statement of Interest contended that a court order requiring GSK to remove the "non-habit-forming" claim from its advertisements for Paxil would be inconsistent with FDA's determination that the company's advertisements were proper and that Paxil is not, in fact, "habit-forming." The brief contended that the court should find the plaintiff's state-law request for a court order preempted because it poses an obstacle to achievement of the full objectives of Congress "by attempting to substitute th[e] Court's judgment for FDA's scientific expertise." As the brief pointed out, FDA had specifically reviewed the advertisements, made suggestions concerning the proper manner of presenting information relating to whether Paxil is "habit-forming," and, in the exercise of its scientific and medical expertise, found the advertisements acceptable. The brief also included a primary jurisdiction argument. The court reversed its earlier award of an injunction prohibiting the manufacturer from running advertisements that had been reviewed and approved by FDA, but the reversal was based on a ground other than preemption. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 24621 (C.D. Cal. 2002).)[7]

Conclusion

As these cases illustrate, courts entertaining lawsuits filed under state law do not always defer to FDA on matters that Congress has placed squarely within the agency's authority. In FDA regulatory areas characterized by comprehensive regulation and requiring a careful and expert evaluation of scientific data and public health issues, state coregulation can stand as an obstacle to or directly conflict with the agency's administration of its statutory mandate. Preemption is the constitutionally prescribed mechanism for resolving these conflicts.

The practice of citing preemption and primary jurisdiction under the FDCA in litigation in which the United States is not a party is well-established and substantially predates the current Administration. DOJ and FDA participation in these cases is unusual. In the current Administration, DOJ has participated in private state-law actions on FDA's behalf only following a judicial finding that the action should proceed, and only to address a state-law finding that, left undisturbed, would

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[6] Statement of Interest of the United States of America, *In re PAXIL Litigation,* Case No. CV 01–07937 MRP (CWx) (C.D. Cal. filed August 20, 2002); Brief of the United States of America, *In re PAXIL Litigation,* Case No. CV 01–07937 MRP (CWx) (C.D. Cal. filed Sept. 4, 2002).

[7] In December 2003 (296 F. Supp. 2d 1374), the litigation, consisting of twelve action in eleven federal judicial districts, was centralized for pretrial proceedings in the United States District Court for the Central District of California.

undermine FDA's execution of its statutory mission or directly conflict with federal law. Responsibility for making final decisions whether to make submissions in private lawsuits, on preemption, primary jurisdiction, or any other issue, rests with the Department of Justice—not FDA itself.

Question. These arguments conflict with long-standing FDA policy. The law appears to contradict what the FDA has argued. What motivated FDA to change its policy?

Answer. The Government's participation in cases arising under state-law and presenting preemption issues is consistent with past FDA practice and with the pertinent law.

The principal enabling statute of the Food and Drug Administration is the Federal Food, Drug, and Cosmetic Act, FDCA. Under this statute, FDA has broad authority to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled, and that drugs and medical products are safe and effective. (See 21 U.S.C. § 393(b)(2)(A)–(C).) By operation of the Supremacy Clause of the United States Constitution (U.S. Const. Art. VI, clause 2), the FDCA nullifies conflicting requirements established by the States in legislation, regulations, or common law. (See *Gibbons* v. *Ogden,* 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.).)

In the past, FDA has addressed conflicting state requirements in the context of rulemaking. In 1982, for example, FDA promulgated regulations requiring tamper-resistant packaging for over-the-counter drugs. In the preamble accompanying the regulations, FDA stated its intention that the regulations preempt any state or local requirements that were "not identical to . . . [the rule] in all respects." (47 FR 50442, 50447; Nov. 5, 1982.) Similarly, in 1986, FDA issued regulations requiring aspirin manufacturers to include in labeling a warning against use in treating chicken pox or flu symptoms in children due to the risk of Reye's Syndrome. In the accompanying preamble, FDA said the regulations preempted "State and local packaging requirements that are not identical to it with respect to OTC aspirin-containing products for human use." (51 FR 8180, 8181; Mar. 7, 1986.) In 1994, FDA amended 21 CFR 20.63 to preempt state requirements for the disclosure of adverse event-related information treated as confidential under FDA regulations. (59 FR 3944; Jan. 27, 1994.)

In addition, for many years, conflicting state requirements have been addressed by FDA through case-by-case participation in selected lawsuits to which the United States has not been a party. Because FDA lacks independent litigating authority, this participation has been by the Department of Justice (DOJ) on FDA's behalf. The practice of addressing conflicting state requirements through participation in litigation dates back many years. For example, DOJ participated on FDA's behalf in favor of preemption in both *Jones* v. *Rath Packing Company,* 430 U.S. 519 (1977), and *Grocery Manufacturers of America, Inc.* v. *Gerace,* 755 F.2d 993 (2d Cir. 1985). In addition, as discussed in our response to the previous question on preemption, FDA has recently participated in several cases involving state-law requirements for the communication of risk information for prescription drugs. Of note, the first—and most aggressive, from a legal perspective—of these submissions occurred during the previous Administration—Bernhardt case included in materials for the record.

NARMS

Question. What is the total amount of funding for NARMS, and from what account does it come?

Answer. The total amount of funding for NARMS in fiscal year 2004 is $7.634 million. This funding is located in the Salaries and Expenses, or S&E, account.

Question. How much is FDA giving to USDA and CDC in fiscal year 2005? How does that compare to fiscal year 2004? Please describe what factors are used to determine the division of funds.

Answer. At this time, FDA has not determined the exact funding for CDC and USDA for NARMS for fiscal year 2005 but plans to make decisions by Fall 2004. In fiscal year 2004, FDA funding on NARMS will be reduced due to government-wide rescissions. In fiscal year 2004, FDA provided funds of approximately $1.6 million to USDA and $2 million to CDC. It is important to point out that a large portion of the funds provided to CDC is given to the states for the collection, isolation and identification of bacterial isolates, which are then shipped to CDC and the Food and Drug Administration's Center for Veterinary Medicine—NARMS retail arm—for susceptibility testing. In determining the funds provided to CDC and USDA, we analyze the entire NARMS program, including the retail food arm of NARMS, and strive to fill in data gaps and avoid duplication of organisms to be tested.

Question. How much NARMS money is currently being spent in foreign countries, specifically Mexico? How is this money being used?

Answer. FDA is not spending any current year NARMS funding in Mexico or other foreign countries.

Question. Does USDA or CDC spend any of their NARMS money in foreign countries?

Answer. In fiscal year 2004 FDA is providing USDA and CDC, $1.6 million and $2 million respectively. FDA does not keep detailed records of USDA and CDC funding for NARMS.

COUNTERFEIT DRUGS

Question. In February, FDA released a report on combating counterfeit drugs. Several new technologies were mentioned that could be used to this effect, including Radiofrequency Identification tagging, color shifting inks, and holograms. Specifically regarding color shifting inks, which I understand are currently available, has FDA taken any action, or do you have any plans to pursue this option?

Answer. It is true that color shifting ink technology is currently available for use on drug packaging and labeling. However, we heard uniformly from all stakeholders that this technology is expensive and requires significant investment of resources and time prior to implementation. Due to the wide variety of products, packaging, and labeling on the market, we heard from manufacturers, wholesalers, and retailers that the decision to use color shifting inks, or any other authentication technology, should be made by the manufacturer after a manufacturer initiated product risk assessment. Without such an analysis, use of color-shifting ink, or other authentication technology, could lead to an unnecessary increase in the cost of drugs to consumers. For example, we heard that color-shifting ink could be appropriate for use on a very expensive, high volume brand name drug product that is likely to be counterfeited, but not on a generic or low volume drug product that is less likely to be counterfeited.

Based on our discussions with manufacturers, we estimate that it would take a minimum of six to twelve months to implement a technology such as color shifting ink from the time a decision is made to use the authentication technology on the packaging and/or labeling of a drug product. It could take longer if the technology, e.g., color-shifting ink, is used on the product itself because safety studies might have to be performed to ensure that the technology, e.g., the ink, does not affect the safety or stability of the product.

ANIMAL DRUG COMPOUNDING

Question. Dr. Crawford, on February 10, I submitted a letter to Dr. McClellan regarding FDA's new Compliance Policy Guidelines, issued July 14, 2003, regarding animal drug compounding. I received a response from FDA on March 31st, and I thank you for that. However, I do have a few more questions in light of the response.

First, the letter stated that FDA issued the CPG for immediate implementation because of the "urgent need to explain how it intended to exercise its enforcement discretion regarding compounded drugs for animal use in light of *Thompson* v. *Western States Medical Center*." However, this case dealt only with compounding in human drugs, not animal drugs. How does this create an urgent need to deal with animal drugs?

Answer. After the *Western States* decision, FDA revised its enforcement policy on pharmacy compounding of human drugs. FDA was concerned that without updated guidance regarding compounding of animal drugs, the public would remain uncertain about whether and how FDA would change its enforcement policy with respect to compounded animal drugs. In addition, agency staff would lack clear guidance on enforcement matters.

As FDA stated in its letter, although prior public comment was not sought in this case, pursuant to the good guidance practices regulations the public was invited to comment on the CPG when it was issued and may comment on it at any time (68 FR 41591 (July 14, 2003)). FDA has been reviewing those comments and will revise the guidance as appropriate upon completion of our review.

Question. Second, the response states that two federal appeals court decisions have held that "the Federal Drug & Cosmetic Act does not permit veterinarians to compound unapproved finished drugs from bulk substances, unless the finished drug is not a new animal drug. These cases support FDA's position that new animal drugs that are compounded from bulk substances are adulterated under the FD&C Act and may be subject to regulatory action." I have been informed that the cases cited deal only with veterinarians compounding drugs, not pharmacists. Why do you limit pharmacists as well as veterinarians? Is this supported by any congressionally-enacted statutory authority, legislative history or case law?

Answer. The principle established by the courts applies equally to compounding by pharmacists and veterinarians.

Veterinary medicine has not traditionally utilized the services of compounding pharmacies to the extent that they have been utilized within human medicine. The increasing activities and presence of compounding pharmacies in veterinary medicine is a relatively recent development.

The Federal Food Drug and Cosmetic Act, or "the Act", and its implementing regulations do not exempt veterinarians or pharmacists from the approval requirements in the new animal drug provisions of the Act, 21 U.S.C. Section 360b. In the absence of an approved new animal drug application, the compounding of a new animal drug from any unapproved drug or from bulk drug substances results in an adulterated new animal drug within the meaning of section 21 U.S.C. Section 351(a)(5). The compounding of a new animal drug from an approved human or animal drug also results in an adulterated new animal drug within the meaning of 21 U.S.C. Section 351(a)(5), unless the conditions set forth in 21 CFR 530.13(b) relating to extralable use are met.

FDA is concerned about veterinarians and pharmacists that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act—such as compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product.

Pharmacists and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.

Question. Finally, the final paragraph of the FDA response states "Accordingly, the regulations that implement AMDUCA provide that extralabel use by compounding applies only to compounding of a product from approved drugs, and that nothing in the regulations is to be construed as permitting compounding from bulk drugs." Is there in the agency's view anything in AMDUCA's regulations or the Act that is to be construed as not permitting compounding from bulk substances?

Answer. As previously noted, under the Federal Food, Drug and Cosmetic Act, in the absence of an approved new animal drug application, the compounding of a new animal drug from a bulk substance results in a new animal drug that is adulterated as a matter of law. This has been FDA's longstanding position, which is supported by two federal appeals court decisions, *United States* v. *Algon Chemical Inc.*, 879 F.2d 1154 (3d Cir. 1989) and *United States* v. *9/1 Kg. Containers,* 854 F.2d 173 (7th Cir. 1988).

CONCLUSION OF HEARINGS

Senator SPECTER. Thank you all very much for being here. That concludes our hearings.

[Whereupon, at 10:48 a.m., Thursday, April 1, 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 2005

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

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

DEPARTMENT OF LABOR

PREPARED STATEMENT OF THE ASSOCIATION OF FARMWORKER OPPORTUNITY PROGRAMS

Good morning Chairman Specter and members of the subcommittee. My name is David Strauss and I represent the 50 nonprofit and public agencies that provide job training and related services to our nation's migrant and seasonal farmworkers.

About 3 million people labor in the fields and farms of America, from Hawaii to Florida and Puerto Rico, from Maine to California. Estimates are that 85 percent of the fruits and vegetables we eat are hand harvested by farmworkers. The pay is extremely low: most farmworkers earn less than $12,000 per year. Few farmworkers receive the job-related benefits, such as health insurance and sick pay, which we all take for granted. In most states, agricultural workers are not even eligible for unemployment compensation. They live a tough life. Many workers travel hundreds, sometimes thousands of miles in search of work. They get paid only when they perform the work: if the weather is bad or the crop is not as plentiful as the farmer had hoped, they simply do not receive wages. They typically cannot afford decent housing. Their children have to struggle mightily to even complete their public school education. The dropout rate for farmworker youth, especially those who migrate with their parents, is enormous.

For over 33 years the federal government has made and kept a commitment to these hardworking people. Special federal programs were created to recognize the reality that farmworkers often cross state lines to work and live. Thus, we have migrant head start, migrant health, migrant education, and the job training effort called the National Farmworker Jobs Program. These all are federally funded and have guidelines that acknowledge that Governors should not be placed in a position of deciding whether or not agricultural workers qualify for these services under state residency or other localized requirements.

Today, I want to talk with you about the last program I mentioned: the National Farmworker Jobs Program, referred to in the budget as the migrant and seasonal farmworker job-training program. This program serves about 25,000 farmworkers each year, a very small percentage of the eligible total. Most of the customers are Hispanic; all must be American citizens or possess valid work authorization documents.

It is an extraordinary program on several counts: it is the most successful program that the Department of Labor funds. In its most recent national report, this program outperformed all others, including the Job Corps, the Dislocated Workers program, the Older Americans program, and so on. The program is operated by non-

profit and public organizations that typically have to serve an entire state with ever-diminishing funds. In fact, they have to compete for the grants.

Yet, they are able to hire staff who are bilingual, are culturally sensitive, and are skilled at serving people with significant barriers to career advancement. Characteristics such as low English proficiency, low education levels, and extreme poverty present significant challenges to case managers who must help farmworkers find a path to a more stable and better paying career. And they do. Staff of the National Farmworker Jobs Program reach out to farm laborers in camps, fields, churches, community centers: wherever necessary to meet the needs of these hardworking people. The hours they work and the locations in which they provide services must be flexible, for during a harvest, farmworkers may toil from sunup to after sundown.

The results are excellent: over 83 percent of farmworkers who wanted training and a new job got one, and their average wage gains exceeded $4,400 per year. That data comes from the Department of Labor, not from our Association. Despite this excellent performance, despite the incredible efforts of dedicated staff and despite the commitment of program operators to achieve their goals with diminishing resources, the Department of Labor (DOL) seeks to eliminate this program in its budget request for 2005. DOL contends that the program is ineffective, that it duplicates the services available to farmworkers in the One Stop Career Centers, and that it spends too much time and money on supportive services. They are incorrect.

Now, DOL stated the same rationale in its 2003 and the 2004 budget requests, and you rejected it. Instead, you funded the program at just under the 2002 level in those years. Members of the Association of Farmworker Opportunity Programs and I have met with Department leaders on several occasions to educate them on how the program works and to explain how effective it is. Now we have DOL's own report that illustrates that it is their best job-training program. Yet they continue to resist your instruction to maintain the National Farmworker Jobs Program.

Since I can only speculate on why the Department persists in this stance, I will answer their three claims. First, as I said earlier the program is amazingly effective, especially when you also consider that many programs operate in counties with some of the highest unemployment rates in the country. I would like to submit relevant portions of the Workforce System Results as of September 30, 2003 issued in mid-January of this year as proof of our success.

Secondly, this program does not duplicate services in the One Stop Career Centers. The One Stop system created in the Workforce Investment Act of 1998 represents an improvement in training and placement services for job seekers. In fact, NFJP agencies are mandated partners in that system. Labor Secretary Elaine Chao may not be aware that most of our members have memoranda of agreement with their state's workforce boards, and participate in the One Stop Centers. But many rural areas do not have One Stop centers that are easily accessible to those who work in the fields. Further, these centers seldom operate outside normal business hours, and they have no program of outreach to hard to serve agricultural workers. One Stops are held to program measures that work against serving people with less than 10th grade educations. And many rural One Stop Centers simply do not have staff who can converse in Spanish, Creole, Vietnamese or other languages that farmworkers in particular areas may speak. It would be a great mistake to assume that removing the NFJP agency from the One Stop partnership would improve services to farmworkers, as DOL has suggested. In fact, ending the NFJP would, I am certain, end job-training services to farmworkers in most of this nation. And that would be a great tragedy, for this program represents access to the American Dream for migrant and seasonal farmworkers. Whether they choose to build their careers in agriculture or in another industry, they deserve the opportunity to achieve a better life through training and job placement.

Finally, DOL claims that our members spend too much time and money on what we call related assistance—services that help a farmworker prepare for training or stabilize their economic situation while they continue to work in agriculture. First, the data: last year, about 8.5 percent of grant funds were spent on related assistance, while over 81 percent went for job training and placement services. Now, it is true that a majority of the farmworkers nationwide who participated in our program received such assistance and no training. However, in states such as California, Texas, Washington, and Arizona you will find that a healthy majority of customers received job training and placement. In states to which farmworkers migrate and work for relatively brief periods, they tend to receive more life-sustaining services such as emergency shelter, car repair vouchers, or food. Again, I remind the committee that farmworkers do not have the same safety net as the rest of us: no unemployment insurance, for example. And when they migrate, they are often in places that have residency requirements for assistance.

I dwell on this point because this seems to me to be a particularly cruel and insensitive criticism of our members' activities—they are charged by the Section 167 of the Workforce Investment Act with providing related assistance, and for good reason. And I think members of the agricultural industry would be unpleasantly surprised to learn that DOL thinks it is wrong to help a worker who plans to harvest a crop. Sometimes that help prevents homelessness. Sometimes the help consists of English language training so the farmworker can better understand the job he/she must perform. Sometimes it consists of pesticide safety training, which enables farmers to legally employ people who must be certified in such safety before they can work amidst dangerous chemicals.

The Office of Management and Budget has issued an "analysis" of the NFJP that is as flawed as the Department of Labor's statements. Rather than going into it in detail today, I will instead ask you to accept our analysis and rebuttal of their Performance Assessment Rating Tool.

In closing, I reiterate: the National Farmworker Jobs Program does an excellent job by the Department's own assessment. More importantly, the program operators are keeping faith with the charge that you gave them when you enacted the Workforce Investment Act in 1998. This program represents a path to the American Dream for our country's lowest paid and hardest working people. Please don't let them down. Maintain the National Farmworker Jobs Program in the appropriation for the Department of Labor for 2005. Thank you for this opportunity to present testimony today.

For more information contact: David Strauss, AFOP, 4350 N. Fairfax Drive, Suite 410, Arlington, VA 22203 Telephone: 703–528–4141, ext. 101 email: strauss@afop.org

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PREPARED STATEMENT OF RURAL OPPORTUNITIES INC.

Honorable Chairman, Senator Arlen Specter, and Honorable Committee Members: I would like to sincerely thank you for this opportunity to present testimony to the Senate Appropriations Subcommittee for Labor, Health and Human Services, and Education.

I am submitting this testimony on behalf of Rural Opportunities Inc., provider of the National Farmworker Jobs Program (NFJP) services to Migrant and Seasonal Farmworkers in Pennsylvania, New York, New Jersey and Ohio. NFJP is funded under Section 167 of the Workforce Investment Act (WIA). I am requesting that the Subcommittee recommend full restoration of funding for this initiative at $80 million for Federal fiscal year 2005.

Historically, Congress has recognized the need for a nationally-administered program to serve Migrant and Seasonal Farmworkers. The mobility and unique socioeconomic characteristics of these workers leave them unserved or under-served by any other workforce program convention. This fact is clearly evident, as each Congress since 1973 has passed an Act designating specific programs to serve Farmworkers: the Comprehensive Employment and Training Act (CETA), the Job Training Partnership Act (JTPA) and most recently, the Workforce Investment Act (WIA). WIA was passed as a direct result of the work done by you and your colleagues, and we thank you.

Today, although almost 6 years have passed since WIA was implemented, nothing has changed that should alter the intent demonstrated by the establishment and continuation of this program effort to serve the Farmworkers of this nation. Unfortunately, as grantees—and foremost as advocates—for Farmworkers and their needs, we have found ourselves continuously defending the Farmworker program and advocating for adequate funding. We also have recognized that, although Congress has clearly demonstrated its wishes in EVERY jobs program since 1973, the U.S. Department of Labor continues to zero out funding for this vital program, while at the same time hailing it as one of their most successful.[1]

Although it may seem cliché in 2004, we are still forced to ask the question: "Are Farmworkers better served today than they would be if no program existed?" The answer is an unqualified "Yes." NFJP nationally had an 84.6 percent successful placement rate (Entered Employment Rate) for Farmworkers who entered training in PY 2002 (July 2002 to June 2003).[2] According to USDOL statistics as of 30 September 2003, ROI—across our entire service area—had a 100 percent success rate in placing Farmworkers in jobs after training.

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[1] Workforce System Results, www.dol.gov, page 6.

[2] PY 2002 Preliminary Grantee performance for the NFJP, wdsc.doleta.gov/msfwPY02.

Why does the Office of Management and Budget in their program analysis question the actions of Congress in establishing emergency and supportive services? We are directed by Section 167 of the Workforce Investment Act to provide emergency and supportive services to stabilize the agriculture workforce. Ensuring that our nation's agricultural employers continue to have access to a stable agricultural workforce required less than 9 percent of the total funds appropriated for the NFJP. Agricultural stabilization services that meet the short term emergency needs of Farmworkers enable them to be available for work in our nation's fields at peak harvest times.

With regard to the impact of NFJP job placement, ROI statistics[3] for PY 2002 show an average wage gain of $5,611 in Pennsylvania, $4,372 in New York, $6,519 in New Jersey and $3,925 in Ohio. The national average across all NFJP programs for the same wage measure is $4,413.[4] Ironically, the average wage gain reported by the One Stop system for the same period was only $3,094,[5] while serving a population confronted by far fewer barriers to employment.

As compelling as this economic information is, nothing speaks louder than the words of the participants, your constituents, who have begun to experience the American dream. I have requested and received permission from some of our participants to use their stories in this testimony.

To set the background for these stories, let me describe the typical Farmworkers served in the NFJP programs Rural Opportunities Inc. operates. The average participant is a young Hispanic male or female. Of those served in PY 2002, 91.6 percent were Hispanic, 64.7 percent were 21–44 years old, 71.5 percent had limited English speaking skills and 84.8 percent dropped out during or before high school. Most were members of families who had been working in agriculture since their birth. In fact, over 69 percent knew agriculture as their only work experience. These are the very characteristics that would preclude our program participants from being served by the local One Stop.

Ofelia Carmona is an Hispanic woman aged 41. She was born into a Farmworker family. At age 6, she began working in the fields with her 13 brothers and sisters. Married at age 14, Ofelia dropped out of school and began migrating with her husband, and soon children, to the fields and orchards of the Northeast. While pregnant with her 4th child, she and her husband decided they wanted more for their children. With the help of Rural Opportunities Inc., Ofelia pursued her GED. She attended GED class in the morning and work experience at a Migrant Health Clinic each afternoon. After completing her GED, Ofelia was hired full-time by the Clinic. But she was not through with her efforts; Ofelia returned to Community College and, while continuing her full-time employment, obtained a Nursing Assistant Associates Degree. Today, Ofelia is the Director of a Migrant Head Start Center and is working to achieve a Bachelors Degree in Early Childhood Education.

Juan Luna's story is not unlike that of Ofelia; Juan is a 36-year-old Hispanic male. He dropped out prior to completing high school, had limited English speaking skills and no transportation, and his only work experience had been as a migrant following the crops. He was not in a position to enter the traditional job market. ROI began by helping Juan access English as a Second Language classes. Then, when his English skills had begun to improve, ROI assisted him in entering Occupational Skills Training at the Metal Working Institute, where he learned the skills to become a Machinist. Today, Juan is employed with the Hauser Corporation as a machine operator and will soon complete his second year on the job.

Cipriano Rodriguez migrated from Mexico 12 years ago to pick apples. Discouraged by the poor pay, he finally left farm work after many years for a factory job, although his interest in agriculture remained strong. Learning of the services provided by Rural Opportunities, Inc., he established the goal of obtaining his Commercial Driver License and returning to agriculture—and his love for the land. He completed training and passed the required tests, and was able to obtain year-round employment at a large farm in the Hudson Valley, driving produce to processing and storage facilities. Four years ago, he became a United States citizen.

Ofelia, Juan, Cipriano . . . these are not the customers of the traditional One Stop system. These are the customers of the National Farmworker Jobs Program grantees. They are not unlike the 328 participants ROI assisted to gain full-time, year-around employment in PY 2002.[6]

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[3] Rural Opportunities Inc. Management Information System, PY 2002.
[4] Workforce System Results, www.dol.gov, page 6.
[5] Workforce System Results, www.dol.gov, page 7.
[6] www.workforceatm.org

NFJP program served 5,612 Farmworkers in PY 2002 nationwide.[7] Without NFJP, who would serve these individuals? The One Stop system? The same system that served less than 1 percent of this population in PY 2002? The One Stop system does not have language or culturally appropriate staff and cannot be expected to develop appropriate staffing in a few short months. The One Stop system does not do outreach to overcome Farmworkers' barriers to services, such as lack of transportation, isolation, and sunrise to sunset workdays. Nor can Farmworkers, if they somehow manage to access the One Stop system, be expected to use a computerized system for job search assistance and labor market information—a system targeting high school graduates, an education level far beyond that attained by the average Farmworker.

Throughout our history, Rural Opportunities Inc. has always sought to assist Farmworkers in achieving their dreams by placing them in jobs of their choosing—within or outside of agriculture. Often Farmworkers wish to upgrade skills to stay on the farm and find a full-time job in agriculture or an agriculture-related industry. In PY 2002, agricultural upgrades accounted for 30 percent of all of the jobs in which ROI assisted Farmworkers to find placements. In Pennsylvania, we have achieved significant success in the past by working with the Mushroom Industry to design and implement job training. In New York, we have done the same with the Dairy Industry. ROI continues to experience high demand from Farmworkers for training in welding and in obtaining Class I Licenses, both of which secure higher paying year-round employment on the farms. Ironically, a concern we often hear from those in Agriculture and Ag-related Industries is that their interests are not met by the primarily urban or village-based One Stop System. Although as a case management and individual skills-based effort NFJP does not train as many Farmworkers for skilled farm positions as the Industry would like, NFJP does address the Industry's needs.

In his March 2004 presentation to the ROI Board of Directors, George Lamont, a New York State Grower and Executive Director of the New York State Horticultural Association, presented his hierarchy of needs for the Farmworkers he employs: Job Skills Training and English as a Second Language were two of the top three.

The One Stop Delivery System often has recognized how under-equipped it is to meet the needs of the Farmworker population and supports the continuation of the National Farmworker Jobs Program, as evidenced in the following excerpts:

—Your agency's interaction with migrant and seasonal farmworkers, a population that is traditionally underserved by other agencies, is integral to their well-being.[8]

—We realize that without the services provided by the NFJP, farmworkers would not have access to training and job placement outside of agriculture due to the multi-barriers many of them possess. The removal of these barriers requires staff that has the skills and cultural sensitivity to assist this special population as well as those who can provide services evenings and weekends to meet the critical demand of migrant and seasonal farmworkers.[9]

—You have provided these services and truly changed the lives of hundreds of farmworkers by providing needed tools that lead to self-sufficiency for them and their families.[10]

—Your agency staff has the needed skills and cultural sensitivity to assist this population to overcome barriers pertaining to self-sufficiency for themselves and their families.[11]

The National Farmworker Jobs Program grantees have developed a sophisticated service delivery infrastructure in the past 30+ years, capable of meeting farmworkers' needs and generating high levels of success. As an NFJP grantee, Rural Opportunities Inc. has built a support structure of additional resources that allows us to leverage NFJP dollars—for every $1 provided by NFJP, we can bring an additional $3 to bear on the host of problems faced by Farmworkers in each state we serve. The NFJP is more successful because of this and the Farmworker population

[7] www.workforceatm.org

[8] Joseph Kuchere, Workforce Investment Board Chair, Niagara County Workforce Investment Board, letter of support, 2003.

[9] Ana Maria Murabito, Council of Industry of Southeast New York, letter of support, 2003.

[10] Ibid.

[11] Glenn L. Decker, Commissioner of Social Services, Ulster County, letter of support, 2003.

is far better served. ROI has been recognized for the fact that 96 cents of every funding dollar go to client services.[12]

In closing, ROI requests that the Subcommittee recommend an appropriation of $80,000,000—restoring the NFJP program to full funding and recognizing the enormous potential of the NFJP program grantees. Though this appropriation will not ensure that every eligible Farmworker receives the services needed, it will enable the program to hold its ground in providing high quality, culturally appropriate services to this population so desperately in need.

PREPARED STATEMENT OF THE CALIFORNIA WORKFORCE INVESTMENT BOARD

My name is Morgan Clayton, Chairman of the Kern County California Workforce Investment Board. I whole-heartedly support the continued funding of the National Farmworkers Jobs Program, as authorized in section 167 of the Workforce Investment Board (WIA). While our Board represents a Grantee for this program, we also serve as the Local Area for the WIA formula-funded programs in the California counties of Kern, Inyo and Mono. From this unique perspective we have come to appreciate the need for the National Farmworker Jobs program and urge its continued full funding in fiscal year 2005 and beyond.

In providing services to both Farmworkers and the general population for more than 20 years, it has become clear that the farm workers have unique needs in the areas of basic skills, Vocational English-as-a-Second Language, job training and access to available services. A separate program ensures that these needs continue to be addressed. While we continue to enjoy many successes in serving farm workers through our network of rural one-stop career centers, those one-stops simply could not exist without a serious commitment of federal funding to targeted rural workers, especially farm workers.

On behalf of the Workforce Invest Board of Kern County, I am adding our support for the continued, full funding of the National Farmworker Jobs Program.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE WORKFORCE AGENCIES

Chairman Specter, Senator Harkin, and distinguished Members of the Subcommittee. On behalf of the National Association of State Workforce Agencies, I thank the Subcommittee for the opportunity to share information on the contributions our members provide in strengthening our nation's economy by linking workers and jobs. The members of our association constitute state leaders of the publicly-funded workforce investment system vital to meeting the employment needs of business and workers. It is the funding you appropriate that makes much of the workforce system services and infrastructure possible.

Mr. Chairman, the nation's publicly-funded workforce system continues to build on the critical link between businesses in need of employees and workers in need of employment. The state agencies administering job training and employment assistance programs throughout our country are cognizant of the need to provide effective services. We recognize it is no longer enough to wait for a dislocated worker to walk through the door of our one-stop offices, or for the phone to ring from a prospective employer in need of skilled workers. Instead, the workforce system is transforming its operations to meet employer demands for skilled workers in the 21st century.

One can look at the latest Workforce System Results report published by the Employment and Training Administration (ETA) for evidence of our workforce system's performance and continued improvement. This report shows state workforce programs "are either meeting their Government Performance and Results Act (GPRA) goals, or have improved their performance from the previous year." These results were achieved while our nation's economy continues its recovery with sustained high demand on our system. Although the system continues to improve, we are concerned the upward trend in performance might level off in the near future if it does not obtain sufficient resources to meet an ever-growing demand.

A recent survey of state workforce agency administrators yields a consistent concern that the infrastructure needed to maintain services business and workers have come to expect is aging and in need of repair. We are becoming increasingly aware of limitations to the expectation that we can do more with less and the effect of level

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[12] Rochester Business Journal, Non-profit Agencies Vary Widely in Outlay for Overhead Expenses. January 4, 2002; Volume17; Number 40.

or reduced funding on the quality and quantity of our services. Although we strive to continue improving our service levels regardless of our annual appropriations, under funding of our programs makes state decision-making harder and ultimately can lesson the quality and quantity of services we will be able to provide.

STATE UNEMPLOYMENT INSURANCE ADMINISTRATION GRANTS

The Social Security Act requires the Secretary of Labor to allocate grants to states that are necessary for proper and efficient administration of their unemployment insurance programs. However, the President's budget has not proposed sufficient amounts and Congress has often appropriated less than the President's insufficient request for many years. The result is states often receive less than is necessary for proper and efficient administration of their unemployment compensation programs.

Insufficient funding has forced many states to delay indefinitely technological upgrades. Many states are unable to automate their aging benefits and tax systems. The inability to improve infrastructure hampers states ability to combat fraud, such as identity theft and unemployment tax evasion.

NASWA's request for state administration of unemployment compensation in fiscal year 2005 exceeds the Administration's request by $439 million, totaling $3.140 billion. This amount is estimated to be necessary for the states to operate their unemployment compensation programs properly. We believe this amount is necessary because a new budget formulation and allocation system, known as the Resource Justification Model (RJM), provides estimates of the amounts states need for proper and efficient administration of the UI program.

NASWA also requests Congress enact an immediate transfer of $9 billion as a special Reed Act distribution to state trust fund accounts to improve trust fund solvency, avoid employer tax hikes, and improve UI administration, employment services and unemployment benefits. Unemployment trust fund solvency has continued declining during the past year. State unemployment trust fund balances fell from $51.57 billion on September 30, 2001 to $28.13 billion on September 30, 2003. Benefits increased from $27.35 billion in fiscal year 2001 to $41.8 billion in fiscal year 2003. Six months ago, one state borrowed to maintain trust fund solvency. Today eight states are borrowing. Many other states are planning to borrow or substantially increase state unemployment taxes or cut unemployment benefits to maintain trust fund solvency.

If a transfer of $9 billion as a Reed Act distribution does not occur in the next five months, many states will be forced to borrow, cut benefits, or collect additional revenue through state unemployment payroll taxes on employers. Collection of additional employer taxes is unnecessary given the $19.9 billion balance credited to the federal unemployment trust fund accounts. Using already-paid employer unemployment taxes for the UI and ES programs is a far better purpose during this period of high unemployment than merely maintaining balances in federal trust fund accounts.

Mr. Chairman, as you know the workforce system received an $8 billion Reed Act distribution in 2002. Some in Congress and the Administration have said states are "sitting" on these funds, not using them in valuable ways. We can assure you that this is not the case. A recent survey of NASWA members found states have used all of the 2002 distribution for economic stimulus, improved UI benefits and administration and employment services. The $8 billion allowed states to cut unemployment payroll taxes for employers by more than $4 billion and improve state unemployment trust fund solvency, unemployment insurance administration and employment services. A Reed Act distribution in 2004 would stimulate further the economy by allowing many states to avoid raising employer taxes that will increase the cost of hiring new employees and slow the rate of job creation.

WORKFORCE INVESTMENT ACT & EMPLOYMENT SERVICE PROGRAMS

ETA Assistant Secretary DeRocco recently said in her testimony before this subcommittee, the WIA programs that are delivered by the state and local workforce partners continue to meet or substantially meet the majority of their established performance targets this past year. Some 83 percent of adults and 89 percent of dislocated workers were still working in the third quarter following receiving services against respective GPRA targets of 80 percent and 88 percent respectively. After receiving services, adults increased their annual earnings on average by $3,030 and dislocated workers averaged 88 percent of their pre-dislocation earnings.

For older youth ages 19 to 21 receiving services by the publicly-funded workforce system, 70 percent were employed in the first quarter after receiving services. Sixty-three percent of younger youth (ages 14 to 18) who entered the program without

a high school diploma or equivalent, attained a diploma or equivalent by the first quarter after receiving services.

In order to meet the needs of both workers and businesses over the coming year, NASWA recommends the following funding levels for WIA programs for fiscal year 2005: $1.5 billion for dislocated worker state allocations; $950 million for adult training; and $1.128 billion for youth training activities. These amounts represent the funding levels allocated for the system in fiscal year 2002.

Our members are concerned about the Administration's proposed funding cut of $91 million to Employment Service (ES) programs and the elimination of the $35 million for Reemployment Services. Funding for employment services has not been increased in over 8 years. However, most states have supplemented their budget with state or Reed Act funds. While NASWA members can support funding for new initiatives proposed by the Administration ($250 million for Community Colleges, $50 million for piloting Personal Reemployment Accounts, and $35 million for the Prisoner Reentry Initiative), they are concerned about reductions to existing programs.

NASWA requests $330.5 million more than was requested by the Administration for fiscal year 2005 employment service state allotments for a total of $991.7 million. In many parts of the country, the one-stop career centers are built on the ES program. The Administration, state workforce agencies, and local One-Stop centers have accepted a new focus on the business customer. The majority of services provided to the business community have been provided with ES funds. During the period ending December 31, 2003, the ES provided service to 9.2 million applicants.

TRADE ACT FUNDING

Each year, many states deal with a shortfall of funding for worker training benefits under the Trade Act. States have been forced to freeze spending and turn many workers away. Turning workers away has become especially prevalent over the past few years as the number of trade impacted workers rises. We look forward to working with Congress on finding sufficient spending levels for trade programs in fiscal year 2005.

LABOR MARKET INFORMATION

NASWA supports a return to ETA's earlier investment levels of $150 million for one-stop/America's Labor Market Information System (ALMIS) funding. The importance of adequate funding to state agencies for labor market information has intensified as states attempt to work with the Administration on its new "high growth job training initiative." State and local labor market information and high quality employment projections are critical to the identification of industry sectors and occupations where the employment growth will occur and ensure that training dollars are wisely invested.

NASWA also calls for the Administration's leadership and support for funding of the new collaborative effort between the Bureau of Labor Statistics and the Bureau of Census to develop a unified wage record program. This new effort will afford better measurement of program performance and improved understanding of the labor market.

VETERANS EMPLOYMENT AND TRAINING PROGRAMS

Two year's ago, Congress approved the Jobs for Veterans Act, giving states greater flexibility to serve their veteran populations. NASWA supported many provisions in this legislation, especially those that gave states more flexibility in integrating the veterans' employment and training programs into the one-stop career center system.

The Jobs for Veterans Act requires states to submit to the Secretary of Labor, "a plan that describes the manner in which the state shall furnish employment, training, and placement services required under this chapter for the program year." NASWA members believe the annual plan required by the Jobs for Veterans Act will be greatly improved by moving the funding for these programs from a fiscal year to a program year funding cycle. By transitioning funding to a program year (July 1 to June 30) and aligning it with most other employment and training programs, the plans that state workforce agencies submit to the Department will reflect future program year services based on established budget outlays. Program year funding supports integrating VETS-funded programs into WIA one-stop career center systems and planning and performing on the same cycle as other one-stop partners. The workforce system looks forward to another year of high performance and improvement. NASWA greatly appreciates your support. Thank you for considering our request.

PREPARED STATEMENT OF THE NATIONAL YOUTH EMPLOYMENT COALITION

On behalf of the National Youth Employment Coalition (NYEC) and its more than 270 members, I am writing to thank you for being the champion for the Department of Labor's Reintegration of Young Offenders program. If not for your heroic efforts, this small, yet important program would have ceased to exist years ago.

As you know, the Administration's fiscal year 2005 budget proposes to supplant the $49 million Reintegration of Young Offenders program with a new $90 million Prisoner Reentry Program. While NYEC applauds the Administration for its commitment to helping adult prisoners successfully return to society, details are still vague about how or whether this new program would involve young offenders. Additional resources to help reintegrate adult prisoners to society should not come at the expense of existing programs that help reintegrate incarcerated youth and prevent other court-involved youth from recidivating and being incarcerated.

According to the Bureau of Justice Statistics, approximately 120,000 youth under the age of 18 are currently incarcerated in juvenile detention centers, state prisons, and local jails. Most will be released in the next few years. While youth in general are being hard hit by the sluggish economy, court-involved youth face additional barriers to employment. There is a growing consensus among youth development experts that youth who come under court supervision have multiple issues that must be addressed in comprehensive and coordinated ways, if they are to attain employment at wages that will sustain a constructive life path. DOL's Youth Offenders Demonstration grantees provide coordinated services to young offenders, gang-involved youth, and at-risk youth to help them find employment, reduce dependency, and break the cycle of crime and recidivism. Court-involved youth who are at-risk of being incarcerated, and youth already in secure facilities receive training and employment opportunities in addition to education; substance abuse treatment as needed; mental health services; aftercare; housing assistance and family support services; and juvenile justice supervision. Several of our members have received competitive grants through the Reintegration of Young Offenders program in the past and many others plan to apply when the Department of Labor announces that funds are available for the fiscal year 2003 grant cycle.

We must sustain our national investment in services and support for court-involved youth to enable these youth to positively contribute to their communities. Without resources such as the Responsible Reintegration of Young Offenders program, many more will fail to successfully transition into productive employment and instead will join the more than 2 million people currently incarcerated.

Again, thank you so much for your long-standing commitment to court-involved youth.

PREPARED STATEMENT OF THE NATIONAL YOUTH EMPLOYMENT COALITION

The National Youth Employment Coalition (NYEC) is a network of over 270 youth employment, education, and development organizations dedicated to promoting policies and initiatives that help young people succeed in becoming lifelong learners, productive workers and self-sufficient citizens. We urge you to increase federal funding for youth employment/development programs under the Workforce Investment Act (WIA). In addition, we urge you to restore funding for the Reintegration for Young Offenders Program to its fiscal year 2003 level of $54 million, and ensure that these funds continue to be targeted at helping reintegrate incarcerated young offenders and prevent court-involved youth from recidivating or being incarcerated.

We understand that this year's federal budget is particularly tight and we face a historically large deficit. However, our nation is facing a silent crisis—hundreds of thousands of youth are not being provided the opportunities they need to develop the academic and job skills they need to succeed in the 21st century workplace. We continue to hear reports that youth are having difficulty finding jobs in this sluggish economy because many employers are hiring adults for jobs for which they would hire youth in a tighter labor market. These reports are confirmed by the Bureau of Labor Statistics' January 2004 data, which shows that youth (age 16 to 19) have lost more than one million jobs since January 2000; and only 34 percent of youth were employed (part- or full-time) in January 2004—marking the lowest youth employment rate for the month of January since 1965.

Despite record levels of youth joblessness, combined federal funding for the WIA youth formula and the Youth Opportunity Grant Program has been cut by more than 26 percent—from $1.352 billion in fiscal year 2002 to $995 million in fiscal year 2004. The Administration's fiscal year 2005 budget proposes a slight increase to $1.001 billion for the WIA youth formula; however, the House WIA reauthorization bill and the President's reauthorization plan propose using 25 percent of the

formula funds to launch a new National Challenge Grant program. While we support new programs that help youth prepare for jobs and careers and prevent them from dropping out of school, funding for such a new program should not come at the expense of current programs that are already stretched to the breaking point.

We cannot afford to allow our nation's youth development/employment system to erode further. Therefore we were very pleased to learn that the Senate's fiscal year 2005 budget resolution includes an amendment, sponsored by Senators Enzi (R-WY) and Cantwell (D-WA), that would increase WIA funding by $250 million in fiscal year 2005. We urge you this year to begin increasing funds for the WIA youth formula to restore funding to the $1.4 billion level. An additional $250 million should be provided in the event that the new National Challenge Grant program is authorized as a result of WIA reauthorization.

The Administration's fiscal year 2005 budget also proposes to supplant the $49-million Young Offenders program with a new $90-million Prisoner Reentry Program. While NYEC applauds the Administration for its commitment to helping prisoners successfully return to society, details are still vague about how or whether this new program would involve youth. Additional resources to help reintegrate adult prisoners to society should not come at the expense of existing programs that help reintegrate incarcerated young offenders and prevent court-involved youth from recidivating or being incarcerated. At minimum, funds currently targeted at court-involved youth under the Reintegration for Young Offenders Program should be maintained to fiscal year 2003 levels ($54 million) and set aside for young offenders within the structure of the new prisoner reentry program.

According to the Bureau of Justice Statistics, approximately 120,000 youth under the age of 18 are currently incarcerated in juvenile detention centers, state prisons, and local jails. Most will be released in the next few years. While youth in general are being hard hit by the sluggish economy, court-involved youth face additional barriers to employment. There is a growing consensus among youth development experts that youth who come under court supervision have multiple issues that must be addressed in comprehensive and coordinated ways, if they are to attain employment at wages that will sustain a constructive life path. DOL's Youth Offenders Demonstration grantees provide coordinated services to young offenders, gang-involved youth, and at-risk youth to help them find employment, reduce dependency, and break the cycle of crime and recidivism. Court-involved youth who are at-risk of being incarcerated, and youth already in secure facilities receive training and employment opportunities in addition to education; substance abuse treatment as needed; mental health services; aftercare; housing assistance and family support services; and juvenile justice supervision.

We understand that you face difficult decisions this year as you seek to spread limited federal resources for a range of national needs. Yet we must sustain our national investment in services and support disadvantaged youth to enable these young people to positively contribute to their communities. Without resources such as the WIA youth formula and the Responsible Reintegration of Young Offenders program, many more will fail to successfully transition into productive employment.

We thank the Committee for its attention to these important programs for our youth and our emerging workforce.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR HOMELESS VETERANS

INTRODUCTION

The National Coalition for Homeless Veterans appreciates the opportunity to submit recommendations on fiscal year 2005 appropriations for and program management issues related to the U.S. Department of Labor (DOL).

The National Coalition for Homeless Veterans (NCHV), established in 1990, is a nonprofit organization with the mission of ending homelessness among veterans by shaping public policy, promoting collaboration, and building the capacity of service providers. NCHV's nearly 250 member organizations in 42 states and the District of Columbia provide housing and supportive services to homeless veterans and their families, such as street outreach, drop-in centers, emergency shelter, transitional housing, permanent housing, recuperative care, hospice care, food and clothing, primary health care, addiction and mental health services, employment supports, educational assistance, legal aid and benefit advocacy.

The VA estimates that more than 299,000 veterans are homeless on any given night; more than 500,000 experience homelessness over the course of a year. Conservatively, one of every three homeless adult males sleeping in a doorway, alley, box, car, barn or other location not fit for human habitation in our urban, suburban,

and rural communities has served our nation in the Armed Forces. Homeless veterans are mostly males (2 percent are females); 54 percent are people of color. The vast majority are single, although service providers are reporting an increased number of veterans with children seeking their assistance; 45 percent have a mental illness; 50 percent have an addiction.

America's homeless veterans have served in World War II, Korea, the cold war, Vietnam, Grenada, Panama, Lebanon, anti-drug cultivation efforts in South America, Afghanistan, and Iraq. 47 percent of homeless veterans served during the Vietnam Era. More than 67 percent served our nation for at least 3 years and 33 percent were stationed in a war zone.

Male veterans are twice as likely to become homeless as their non-veteran counterparts, and female veterans are about four times as likely to become homeless as their non-veteran counterparts. Like their non-veteran counterparts, veterans are at high risk of homelessness due to extremely low or no income, dismal living conditions in cheap hotels or in overcrowded or substandard housing, and lack of access to health care. In addition to these shared factors, a large number of at-risk veterans live with post traumatic stress disorders and addictions acquired during or exacerbated by their military service. In addition, their family and social networks are fractured due to lengthy periods away from their communities of origin. These problems are directly traceable to their experience in military service or to their return to civilian society without appropriate transitional supports.

Contrary to the perceptions that our nation's veterans are well-supported, in fact many go without the services they require and are eligible to receive. One and a half million veterans have incomes that fall below the federal poverty level. Neither the VA, state or county departments of veteran affairs, nor community-based and faith-based service providers are adequately resourced to respond to these veterans' health, housing, and supportive services needs. The VA plays only a limited role in providing employment services to veterans, administering just one small supported employment program for veterans with serious disabilities.

The U.S. Department of Labor and state and local workforce agencies bear primary responsibility for ensuring that veterans are provided opportunities to prepare for and obtain productive employment. Accordingly, we urge Congress to provide full funding for the programs of the Department of Labor Veterans Employment and Training Service (VETS) in order to ensure that our nation's workforce services system is equipped to fulfill their obligations to our nation's veterans.

FISCAL YEAR 2005 APPROPRIATION RECOMMENDATION—HOMELESS VETERAN REINTEGRATION PROGRAM

The Homeless Veterans Reintegration Program (HVRP), within the Department of Labor's Veterans Employment and Training Service (VETS), provides competitive grants to community-based, faith-based, and public organizations to offer outreach, job placement and supportive services to homeless veterans. HVRP is the primary employment services program accessible by homeless veterans and the only targeted employment program for any homeless subpopulation. Homeless veterans have many additional barriers to employment than non-homeless veterans due to their lack of housing. HVRP grantees remove those barriers through specialized supports unavailable through other employment services programs. Grantees are able to place HVRP participants into employment for $2,100 per placement, a tiny investment for moving a veteran out of homelessness, and off of dependency on public programs.

DOL estimates that 16,800 homeless veterans will be served through HVRP at the fiscal year 2004 appropriation level of $19 million. This figure represents just 3 percent of the overall homeless veteran population, which the Department of Veterans Affairs estimates numbers more than 500,000 over the course of a year. An appropriation at the authorized level of $50 million would enable HVRP grantees to reach approximately 44,000 homeless veterans.

HVRP grants are funded on a 3-year cycle. DOL representatives have indicated that if funding is not increased for the program this year, it is unlikely there would be a competition for new start grants in fiscal year 2005. Additionally, HVRP is being used as the account to fund a joint Department of Labor and Department of Veterans Affairs initiative authorized by Congress to assist veterans incarcerated in their reentry to the community. This decision essentially adds a new purpose to the HVRP program, for which additional funds are needed.

We urge Congress to appropriate at least $50 million for HVRP in fiscal year 2005 Labor-HHS-Education appropriations legislation.

[In millions of dollars]

	Fiscal year			
	2003	2004	2005 administration	2005 NCHV
Funding for Homeless Veterans Reintegration Program	18.2	19.0	19.0	50.0

FISCAL YEAR 2005 APPROPRIATION RECOMMENDATION—VETERANS WORKFORCE INVESTMENT PROGRAM

The Veterans Workforce Investment Program (VWIP), within the Department of Labor's Veterans Employment and Training Service (VETS), provides grants to states and community-based, faith-based, and local public organizations to offer workforce services targeted to veterans with service connected disabilities, with active duty experience in a war or campaign, recently separated from the service, or facing significant barriers to employment (including homelessness). VWIP grants last for twelve months and currently have a limit of $255,000. The fiscal year 2004 appropriation for VWIP is $7.5 million.

At least 80 percent of total VWIP funds is distributed via competition. State governments have traditionally been the exclusive eligible applicant for competitive funds. The states then publish requests for proposals, to which local governments, workforce investment boards, and community organizations may respond. The states monitor the projects and frequently provide matching funds to increase opportunities. While matching funds are not required, applicants can gain up to ten points on their application if they demonstrate effective leveraging. In 2003, VWIP competitive funds were awarded to state agencies in AL, CA, HI, IN, ME, MA, PA, TN, and TX.

VETS may reserve 20 percent of total VWIP funds for discretionary grants. VETS uses discretionary funds for studies, demonstration projects, and additional funding to supplement competitive grants. Discretionary grant applications are accepted directly from local governments, workforce investment boards, community-based, and faith-based organizations. In 2003, VWIP discretionary funds were awarded to organizations in CA, DC, FL, MS, NY, SC, OH, PA, and VA.

Both those agencies that receive VWIP funds and those hoping to apply face the problem of resource scarcity. Due to funding limitations, agencies and organizations receive VWIP funds in only 16 states. The need for the type of targeted assistance that VWIP offers is clearly needed in all states. Additionally, caps on the size of grant awards make it difficult for existing grantees to recruit and retain staff. This limits program effectiveness and the collaborative process.

We urge Congress to appropriate at least $33.5 million for VWIP in fiscal year 2005 Labor-HHS-Education appropriations legislation.

[In millions of dollars]

	Fiscal year			
	2003	2004	2005 administration	2005 NCHV
Funding for Veterans Workforce Investment Program	7.5	7.5	7.5	33.5

PROGRAM MANAGEMENT RECOMMENDATION—PRIORITY OF SERVICE FOR VETERANS IN DOL JOB TRAINING PROGRAMS

The Jobs for Veterans Act (Public Law 107–288) establishes a priority of service for veterans in the receipt of employment, training, and placement services provided under qualified job training programs of the Department of Labor. We request the Committee's assistance in ensuring that qualified job training programs fully extend priority of service for veterans as required by this law.

We recommend that the Committee, through report language, urge the Secretary of Labor to ensure that states, localities, and nonprofit organizations receiving workforce investment funds from the Department of Labor screen all applicants for services for military service status and implement the priority for those qualified. Further, we recommend that the Committee urge the Secretary of Labor to develop and disseminate a guide for veterans in accessing workforce investment services.

In addition, we recommend that the Committee encourage the Secretary to develop and disseminate a guide for assisting veterans service organizations and homeless veteran service providers in accessing workforce investment funds and workforce investment planning processes. Also, we recommend that the Committee

encourage the Secretary to develop and disseminate a technical assistance guide to inform state and local workforce systems on the workforce services needs of veterans, the current limitations of veteran-specific programs in meeting those needs, and the responsibility of mainstream workforce systems to prioritize veterans for services and to collaborate with homeless veteran service providers and veterans service organizations.

Finally, we recommend that the Committee urge the Secretary to compel state workforce agencies to increase their outstationing of disabled veterans outreach program specialists and local veterans employment representatives in locations where homeless veterans congregate, including grantees under the homeless provider grant and per diem program and the homeless veterans reintegration program.

TRANSITION ASSISTANCE PROGRAM

Individuals leaving the military are at high risk of homelessness due to a lack of job skills transferable to the civilian sector, disrupted or dissolved family and social support networks, and other risk factors that preceded their military service. Separating service members must be made aware of the factors that contribute to homelessness and receive information about sources of preventive assistance before they exit the military. The Transition Assistance Program (TAP) has been established to ease the transition of separating service members to the civilian sector. We are concerned that the TAP curriculum, which is developed and administered by the Department of Labor, does not currently include a component on homelessness.

We urge the Committee, through report language, to instruct the Secretary of Labor to ensure that a module on homelessness prevention be added to the TAP curriculum. The module should include a presentation on risk factors for homelessness, a self-assessment of risk factors, and contact information for preventative assistance associated with homelessness.

CONCLUSION

The National Coalition for Homeless Veterans appreciates the opportunity to submit recommendations to Congress regarding the resources and activities of the U.S. Department of Labor. We look forward to continuing to work with the Appropriations Committee in ensuring that our federal government does everything within its grasp to prevent and end homelessness among our nation's veterans. They have served our nation well. It is beyond time for us to repay the debt.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF HOME BUILDERS

On behalf of the over 215,000 members of the National Association of Home Builders (NAHB), as well as our workforce development arm, the Home Builders Institute (HBI), we thank you for the opportunity to submit this statement for the record on the Responsible Reintegration of Youth Offenders program, as well as the newly-proposed Prisoner Re-entry Initiative.

NAHB members are involved in home building, remodeling, multifamily construction, property management, subcontracting, design, housing finance, building product manufacturing and other aspects of residential and light commercial construction. Known as "the voice of the housing industry," NAHB is affiliated with more than 800 state and local home builder associations around the country. NAHB's builder members will construct about 80 percent of the more than 1.6 million new housing units projected for 2004, making housing one of the largest engines of economic growth in the country.

One of the most pressing problems confronting our industry has been a shortage of skilled workers. Record numbers in the construction of new homes, retirements and lackluster interest in the construction trades by younger generations, compounded by insufficient training opportunities for those interested in construction, are among the many factors contributing to the shortages. According to the Bureau of Labor Statistics, some 240,000 workers are needed each year to meet the nation's demand for housing.

HOME BUILDERS INSTITUTE (HBI) PROGRAM BACKGROUND

Each year, the Home Builders Institute (HBI) works through various programs to train and place several hundred youth in residential construction jobs. Through real-life, hands-on training, some of our nation's most at-risk youth learn a skill, and a second chance at a productive and successful life and career. Since 1994, HBI has focused a significant portion of its effort and resources on one particular targeted population, adjudicated youth, through its Project CRAFT (Community Res-

titution Apprenticeship-Focused Training) program. Project CRAFT is targeted solely to adjudicated youth and was piloted in 1994 through a Department of Labor demonstration grant. This program has successfully combined employers, the juvenile justice system, workforce development and other systems, in one overall approach, and has been implemented at 12 sites in nine states (Colorado, Ohio, Florida, Maryland, New Jersey, North Dakota, South Carolina, Tennessee, and Texas). Funding for HBI's work on this program has come largely through funds provided under the Responsible Reintegration of Youth Offenders budget line.

Project CRAFT incorporates the apprenticeship concept of hands-on training and academic instruction, utilizing its Pre-Apprenticeship Certificate Training (PACT), numeracy, literacy and employability skills curricula. Under the supervision of journey-level trade instructors, students learn residential construction skills while completing community service construction projects. More than 90 percent of Project CRAFT graduates achieve success through industry jobs each year. Since 1994, Project CRAFT has helped more than 2,000 high-risk youth, and in addition to offering adjudicated youth trade skills and job placement, community service projects by students saved taxpayers more than $225,000 in labor costs alone in 2002–2003. During 2002, Project CRAFT graduates were placed in jobs with an average wage of $8.29/hour, and performed over 28,000 hours of community service. Recidivism rates for Project CRAFT have averaged between 10–15 percent, with the Nashville, Tennessee program and Orlando, Florida programs experiencing impressive recidivism rates of 9 percent and 6 percent respectively. Additionally, students in the program tend to evidence one grade level of improvement in math and language skills attributable largely to the formal education component that includes contextual learning. Math and communication skills are continually reinforced as students are challenged to apply these skills to everyday situations in the field and in the classroom.

Project CRAFT efforts were recognized by the Department of Labor and the National Youth Employment Coalition when in September 2002, the program received a PEPNet (Promising and Effective Practices Network) Award. We are also grateful to the Senate Subcommittee on Labor, Health and Human Services and Education for its acknowledgement of Project CRAFT in fiscal year 2004 Report Language, and its years of dedicated support for the Responsible Reintegration of Youth Offenders program.

RESPONSIBLE REINTEGRATION OF YOUTH OFFENDERS PROGRAM

NAHB and HBI's encouraging experience with Project CRAFT is an example of the enormous success of the Responsible Reintegration of Youth Offenders pilot program, and the reason why we very strongly support the continuation of funding for a youth-focused program targeting adjudicated youth with training that provides this at-risk population with important job- and life-skills. The Responsible Reintegration of Youth Offenders Program has helped to bring together industry and government in a partnership with tangible positive outcomes. Since 1994 the program has earned a reputation as a worthwhile investment of taxpayer dollars, a significant and important resource to the nation's building industry, and a major contributor to the future success of hundreds of young people. It is a demonstration model that works, and as such deserves to be touted and replicated. We hope that its proven success and recognition as a model intervention will help enable it to receive continued funding.

PRISONER RE-ENTRY PROGRAM

In its fiscal year 2005 budget proposal, the White House introduced a new program called the "Prisoner Re-entry Initiative," with a stated focus to "support activities to help individuals exiting prison make a successful transition to community life and long-term employment." (See fiscal year 2005 Budget Appendix, page 706) This program appears to have a focus only on adult offenders, and the budget does not clearly state whether youth-focused programs would be eligible to participate in the Prisoner Re-entry Program.

NAHB and HBI support goals of the Prisoner Re-entry program, and agree that there is undoubtedly enormous potential for successful programming targeting adult offenders. However, we also strongly believe that it would be short-sighted policy to exclude adjudicated youth from the Department's workforce development efforts, and ill-advised to bring its notable successes such as Project CRAFT to an end. We believe that any funding targeted to training those who are re-entering society must include a component targeted to the youth offender population. We believe that the Prisoner Re-entry program, as laid out by the Department of Labor, has failed to

clarify whether youth and youth-focused programs would be eligible for participation in the new program.

As we have stated, the president's newly proposed Prisoner Re-entry program has significant potential for helping the adult offender community receive important training and job skills. And we believe that HBI is well-positioned to participate in an adult-focused program through its Project TRADE (Training, Restitution, Apprenticeship, Development and Education) program—which is the sister program to the youth-focused Project CRAFT. Designed to train and place adult offenders in employment in the home building industry, TRADE is currently being implemented in Colorado Springs. Project TRADE has trained over 500 adult offenders in the residential construction trade since 1995 through programs in Maryland, North Carolina, Oregon, Pennsylvania, Virginia, Washington, Tennessee and Colorado. We believe that Project TRADE's emphasis on adult offenders complements the work done by Project CRAFT's emphasis on youth offenders.

CONCLUSION

NAHB and HBI continue to strongly support the goals of the Responsible Reintegration of Youth Offenders program. We also support the Department of Labor's interest in targeting a program to adult offenders. However, we are concerned that the Department of Labor has not clearly laid out which populations would be served by the new program. Our own effort to secure from DOL a definitive understanding of the eligible populations has resulted in differing opinions and further confusion over the program's goals and targets. We believe that the Responsible Reintegration of Youth Offenders demonstration program has been highly successful, as evidenced by our own success with Project CRAFT, and we fervently hope that any proposal supported by congressional appropriators will take into account the needs of both the youth and adult ex-offender populations, and will clearly lay out congressional intent to continue serving the youth ex-offender population. We believe it would be an error to overlook the tremendous success achieved by the Responsible Reintegration of Youth Offenders program, and while we hope that such a move is not the intent of the Department of Labor, we urge appropriators to clarify the goals of the Prisoner Re-entry program, and to continue supporting those programs that target adjudicated youth.

Again, we thank the subcommittee for this opportunity to share our views on the Responsible Reintegration of Youth Offenders program, and Prisoner Re-entry Initiative, and look forward to working with you to promote training programs that help America's at-risk youth acquire the skills they need for successful and productive careers.

PREPARED STATEMENT OF THE SOUTHERN CALIFORNIA ELDERLY NUTRITION PARTNERSHIP

Chairman Specter, Ranking Member Harkin, Members of the Subcommittee: The Southern California Elderly Nutrition Partnership (SOCALENP) is submitting this written testimony in support of a 5 percent increase in funding for the Older Americans Act Nutrition Programs as part of the fiscal year 2005 appropriations bill for the Departments of Labor and Health and Human Services.

SOCALENP is a regional partnership formed by six major providers of elderly services in southern California, which serve nearly 2,500,000 meals annually to 80,000 seniors. We are funded by a grant from the Altria Corporation. We came together to strengthen our advocacy voice not only on behalf of the seniors we serve in Southern California but also for all seniors who benefit from the Older Americans Act nutrition programs. It is important to note that these programs are more than a meal. They provide an essential link between seniors and their communities.

California has not only the highest population in the nation but also the largest number of older citizens of any state. For example, California has 10 percent of all persons in the United States over the age of 65. California serves the second highest number of both congregate and home delivered meals of any state in the nation.

The President's budget for fiscal year 2005, while providing a $3 million increase for the nutrition programs, represents only a .2 percent increase from fiscal year 2004. This means that funding did not even come close to keeping up with inflation. In fact, this is a chronic problem facing the nutrition programs. Whereas inflation has increased by more than 45 percent since 1990, funding for the elderly nutrition programs has increased by only 23.8 percent with an especially woeful 9 percent increase for the congregate nutrition program in that time.

Furthermore, data for fiscal year 2002 indicates that the programs, while serving more seniors, are serving them fewer meals. This defeats a primary purpose of the

program, which is to be able to provide these seniors with one third or more of their RDA's through the program. Data provided by AARP indicates that without any adjustment in the President's budget just over 5 million congregate and home delivered meals nationwide would have to be eliminated in fiscal year 2005. Since the underlying Older Americans Act calls for services to be targeted to the elderly especially those with the greatest economic need, the loss of a meal for this sector of seniors is far more devastating.

We seek this modest increase primarily to ensure that we and other service providers can maintain our commitments to eligible seniors and avoid adding to waiting lists either in the congregate or home delivered meals program.

Each member of this Subcommittee knows of Older Americans Act nutrition programs operating in their state. They probably have taken time to visit one of the sites where meals are served, which we are sure left a lasting memory of the need for these services. This program has enjoyed tremendous success over more than 30 years. It is a value-added proposition providing essential services to seniors and doing so in an efficient and localized manner. These highly leveraged federal dollars are invested in maintaining the nutritional health and independence of our nation's seniors, which helps to reduce institutionalization, shorten hospital stays, and allow seniors to remain active in their communities.

We hope you can commit the necessary $30 million to allow this 5 percent increase to be achieved in fiscal year 2005. We believe our request is modest and fiscally responsible when one considers the return on these funds both in terms of its preventive value to the seniors and the ability of service provider to leverage other support for the programs. These programs are truly more than a meal.

PREPARED STATEMENT OF THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

Thank you for this opportunity to submit testimony on behalf of the Association for Professionals in Infection Control and Epidemiology (APIC).

All of us will at some point be admitted to a hospital—or will visit our loved ones while they receive care at a health care facility. Our hospitals, the very institutions we depend upon to save our lives, are fighting for their survival. In recent years, only the highest risk patients are admitted—those individuals that require the highest level of care. Unfortunately, many facilities are facing severe nursing shortages; we have patients waiting for days in Emergency Departments . . . not for lack of beds, but for lack of personnel to staff the beds.

At the very same time, we are being asked to prepare for the unthinkable—not just natural disasters but intentional terrorist acts against our citizens. As a partner in public health preparedness, we are dedicating resources to create the capacity to respond effectively. At the very time we are working with our public health partners at the local, state and federal levels, we are also being asked—or rather, required—to use our extremely limited and precious resources to meet unproven, unnecessary regulatory mandates. The most flagrant, and one that we thought we had proven had no scientific merit is the recent decision by the Administrator of the Occupational Safety and Health Administration (OSHA) to enforce the General Industry Respiratory Protection Standard (or GIRPS) for potential exposures to patients with Mycobacterium tuberculosis (MTB).

On December 31, 2003, New Years Eve, Assistant Secretary Henshaw placed two notices in the Federal Register. The first notice stated that due to the fact that TB is at the lowest incidence level in recorded history, thanks to CDC guidelines and public health efforts, OSHA was withdrawing the proposed rule for preventing occupational exposure to tuberculosis. We commended the agency for this decision.

The second notice stated, however, that OSHA intended to apply the General Industry Respiratory Protection Standard to exposure to patients with potentially infectious M. tuberculosis.

OSHA altered its normal course of rulemaking by effecting significant regulatory changes without providing any opportunity for public review and comment. This decision was not necessary, nor was it precipitated by any preexisting requirement. It appears to have been done completely at the discretion of the OSHA Administrator.

It has never been understood or assumed by the health care community that the General Industry Respiratory Protection Standard would apply to exposure to patients with potentially infectious TB. In fact, when the GIRPS was revised in 1998, the language in the standard specifically stated that these requirements did not apply to health care or to exposure to TB. The health care community therefore re-

lied upon the proposed TB rulemaking for public comment regarding respiratory protection, instead of commenting on the revision of the GIRPS.

Assistant Secretary Henshaw contends that he cannot reopen a final rule for comment, as we are requesting. It is our understanding that the OSHA Administrator can, at any time, choose to reopen a rule for further consideration, regardless of whether that rule is proposed or final. In fact, Secretary Henshaw chose to open the rule on December 31, 2003, by announcing his decision to include exposure to TB under this regulation. It therefore stands to reason that he can open the rule again, to allow for public review and comment, as is the normal course of action.

APIC respectfully requests that OSHA delay application and enforcement of this standard for occupational exposure to patients with potentially infectious TB until at least January 2005, and meanwhile pursue avenues to open the rule for public review and comment. It is vital that OSHA ensure that its decisions are based on sound scientific evidence, and allow for the affected parties to voice their concerns about the implications of these actions. We hope the Subcommittee will assist us by confronting OSHA on this decision, and require the agency to reopen the rule for adequate public consideration and comment.

We thank you for this opportunity to provide testimony to the Subcommittee.

PREPARED STATEMENT OF THE MEXICAN-AMERICAN OPPORTUNITY FOUNDATION AND THE CAREER SERVICES CENTER, KERN COUNTY, CA

In Jalisco, Mexico in the year 1976, Roberto and Maria Sanchez had a little girl they named Maria. When I was 4 years old my dad brought our family of twelve to the USA where they worked as farmworkers to support us while my oldest brother took care of us. A year later I started kindergarten. I remember my first day. My sister took me to school. I grabbed her leg because I didn't want to stay. I attended Carl Clemens Elementary School, then Thomas Jefferson Junior High School for 3 years. I graduated from there in 1991 and went on to Wasco Union High School where I graduated in 1995.

Three days after I graduated, I married Francisco Yerena. I thought, now with my new name, life will be different. In 1999, I gave birth to a boy. I named him Francisco. Everything seemed perfect. Being a young couple it was hard financially. My husband struggled as a seasonal farm worker trying to provide for us. I tried to attend Bakersfield College, but due to financial hardship, I had to quit school and get a job. I remember when I had my first job at Richland pre-school as a substitute teacher's aide and my husband left for Mexico to see about his papers. This made it harder for me and my son to survive. I knew something had to change.

I decided to go to the Career Services Center to get a better job. I went to my appointment and they gave me a basic skills test. Dinorah Castro of Employers' Training Resource called me back about a work experience program at the Mexican-American Opportunity Foundation training center. I worked there as a receptionist for four months. During these four months it was hard on us financially. I traveled everyday from Wasco to Bakersfield. At the end of my work day, I picked up my son from the babysitter and by the time I got home, it was very late. I fixed dinner and spent what time I had with my son. My husband finally returned after being gone for eight months and he had to find employment which only took him a couple of days.

I was so happy that the Mexican-American Opportunity Foundation's Administrator, Magda Menendez, referred me to the Mexican-American Opportunity Foundation pre-school for an interview. It was very exciting for me and I was so nervous waiting to hear from them. On February 9, 2004, they hired me as a substitute teacher and while I am working full time, I also attend Bakersfield College so I can get my teaching degree.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT OF THE BLUE CROSS AND BLUE SHIELD ASSOCIATION

The Blue Cross and Blue Shield Association (BCBSA), which represents 41 independent, locally operated Blue Cross and Blue Shield Plans throughout the nation, is pleased to submit written testimony to the subcommittee on fiscal year 2005 funding for Medicare contractors.

Blue Cross and Blue Shield Plans play a leading role in administering the Medicare program. Many Plans contract with the federal government to run much of the daily work of paying Medicare claims accurately and timely. Blue Cross and Blue

Shield Plans serve as Part A Fiscal Intermediaries (FIs) and/or Part B carriers and collectively process most Medicare claims.

This testimony focuses on three areas:

I. Background, including a description of Medicare contractor functions;

II. Current financial challenges facing Medicare contractors; and

III. BCBSA recommendations for Medicare contractor fiscal year 2005 funding.

I. BACKGROUND

Blue Cross and Blue Shield Medicare contractors are proud of their role as Medicare administrators. While workloads have soared, operating costs—on a unit cost basis—have declined about two-thirds from 1975 to 2004. In fact, contractors' administrative costs represent less than 1 percent of total Medicare benefits.

Medicare contractors have four major areas of responsibility:

1. *Paying Claims*.—Medicare contractors process all the bills for the traditional Medicare fee-for-service program. In fiscal year 2005, it is estimated that contractors will process over 1.1 billion claims, nearly 4 million every working day.

2. *Providing Beneficiary and Provider Customer Services*.—Contractors are the main points of routine contact with Medicare for both beneficiaries and providers. Contractors educate beneficiaries and providers about Medicare and respond to over 50 million inquiries annually.

3. *Handling Hearings and Appeals*.—Beneficiaries and providers are entitled by law to appeal the initial payment determination made by carriers and FIs. These contractors handle nearly 8 million annual hearings and appeals.

4. *Special Initiatives to Fight Medicare Fraud, Waste, and Abuse*.—All contractors have separate fraud and abuse departments dedicated to assuring that Medicare payments are made properly. Few government expenditures produce the documented, tangible savings of taxpayers' dollars generated by Medicare anti-fraud and abuse activities. For every $1 spent fighting fraud and abuse, Medicare contractors save the government $14.

II. CURRENT FINANCIAL CHALLENGES

Of utmost importance to attaining outstanding performance is an adequate budget. Medicare contractors have been underfunded since the early 1990's, however, and the largest portion of the contractor budget—Medicare operations—faces particularly severe funding pressures. Medicare operations activities include claims processing, beneficiary and provider education and communications, hearings and appeals of claims initially denied, and systems maintenance and security.

The underfunding of CMS and its Medicare contractors has gotten even more acute since the passage of the Health Insurance Portability and Accountability Act (HIPAA) and other legislation that places new responsibilities on contractors, without sufficient resources to perform those duties. For example, between 1992 and 2002, Medicare benefits outlays increased 97 percent; claims volume increased 50 percent; yet Medicare operations funding increased a mere 26 percent. Contractor staffing only increased by 6 percent during this time even though many new responsibilities were added and claims volume continued to rise. Clearly funding has not kept pace with additional work. In addition, the recently enacted Medicare reform legislation includes significant changes that will require additional resources for contractors to implement.

Whenever possible, contractors respond to reduced funding by achieving significant efficiencies in claims processing, but it is not enough to keep pace with rising Medicare claims volume and diminishing funding levels. It should be noted that contractors are already extremely efficient. Currently, contractors' administrative costs represent less than 1 percent of total Medicare benefits.

Inadequate budgets for Medicare operations also impact Medicare's fight against fraud and abuse. While many think of Medicare operations activities as simply paying claims, these activities are Medicare's first line of defense against fraud and abuse and are critically linked to activities under the separately-funded Medicare Integrity Program (MIP). As an example, many of the front-end computer edits (e.g., preventing duplicate payments and detecting inaccurately coded claims or claims requiring additional screening) are funded through Medicare operations.

Inadequate funding impacts different functions at different times, but always disrupts the integration of all the functional components needed to "get things right the first time." It thus results in inefficiency and higher costs.

III. BCBSA FISCAL YEAR 2005 FUNDING RECOMMENDATIONS FOR MEDICARE CONTRACTORS

BCBSA is pleased that many Members of this subcommittee recognize the need for adequate administrative resources at CMS. We are concerned the Administration's fiscal year 2005 budget does not appropriately reflect the expected costs to cover Medicare contractor workloads and it relies on a proposal for $205 million in new user fees from providers. BCBSA urges Congress to take the following steps to allow Medicare contractors to meet increased workloads as well as beneficiary and provider needs:

A. Increase Medicare Contractor Operations Funding to $1.81 Billion for Fiscal Year 2005

Medicare contractors continue to face increases in Medicare claims volume. Further reductions in administrative costs, as proposed in the President's budget, would seriously jeopardize contractors' ability to administer Medicare. BCBSA recommends:

1. Claims processing funding must be maintained

The President's budget would decrease Part B claims processing costs by $0.02 per claim to $0.63 under the assumption that standardized electronic transactions under HIPAA will provide savings. Part A claims payment remains the same at $0.87. Available contractor data through the first quarter of fiscal year 2004 show the HIPAA transactions rule has not resulted in lower claims processing costs. In fact the average cost for contractors to process a Part B claim is $0.73, and over $1 for a Part A claim. Medicare electronic claims submission rates were already high prior to HIPAA implementation—98 percent of Medicare Part A and 84 percent of Medicare Part B. The current unit costs for processing Medicare Part B claims must be maintained in fiscal year 2005, requiring an additional $15.4 million.

2. Appeals funding must be enhanced

The President's budget provides no increase to handle ongoing appeals, even though CMS projects the appeals volume will rise in fiscal year 2005. Adequate funding is imperative for contractors to sufficiently handle the nearly 8 million appeals that providers and beneficiaries are expected to submit. BCBSA recommends an additional $5.5 million for these important activities.

B. Increase Medicare Integrity Program (MIP) Funding to $740 Million

Congress created Medicare Integrity Program (MIP) under HIPAA to provide a permanent, stable funding authority for the portion of the Medicare contractor budget that is explicitly designated as fraud and abuse detection activities. Funding was capped at $720 million for fiscal year 2003 and subsequent years, however, despite continuing increases in claims volume (15 percent increase in claims is projected in fiscal years 2004–2005). This freeze in funding concurrent with increases in workload seriously erodes contractors' ability to fight fraud and abuse and ensure the accuracy and appropriateness of Medicare payments.

Contractors' enhanced anti-fraud and abuse efforts due to MIP funding have contributed to the significant decline in improper claims and deficient documentation submitted by providers. In addition, MIP saves money. HHS data shows a $14:1 return on the investment.

1. MIP Funding Should Be Increased

BCBSA urges Congress to authorize an immediate increase in the MIP appropriation to $740 million for fiscal year 2005, with provision for automatic increases in future years. Medicare contractors need these resources to effectively combat Medicare waste, fraud and abuse and to keep pace with rising workloads. MIP contributes to the decline in improper claims submissions and it saves Medicare money. HHS data show a $14:1 return on the investment.

C. Reject New User Fees

BCBSA is very concerned that once again CMS recommends new user fees of $205 million from doctors, hospitals and other providers to support contractor operations. History has shown user fees to be an unpredictable stream of funding. In order for contractors to maintain performance, funds must be consistent and reliable.

Congress has consistently rejected user fees similar to those recommended in the President's budget. Congress should reject them again and provide $1.81 billion in appropriated funds for Medicare contractors and $740 million for MIP.

MEDICARE CONTRACTOR BUDGET

[In millions of dollars]

	Fiscal year		
	2004	2005 administration recommendation	2005 BCBSA recommendation
Medicare Operations	1,701	1,704	1,814.7
Medicare Integrity Program	720	720	740.0
Total Contractor Budget	2,421	2,514	2,555.0

PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

Thank you for the opportunity to submit testimony on the important issue of funding the diabetes program at the Centers for Disease Control and Prevention (CDC) and diabetes research at the National Institutes of Health (NIH). Our government needs to significantly increase diabetes funding at these agencies not only for the 18 million Americans who currently have diabetes, but also for the 40 million who are at high risk for developing diabetes in the immediate future.

The Association is aware that the Subcommittee is in a particularly difficult economic position this year. For that reason, the Association is asking the Subcommittee to adopt one request that is feasible even under the proposed budget numbers: the American Diabetes Association strongly urges the Subcommittee to add an additional $10 million to the budget of the Division of Diabetes Translation at CDC.

Diabetes is a serious disease, and is a contributing and underlying cause of many of the diseases on which the federal government spends the most health care dollars. Diabetes is a significant cause of heart disease (which costs our nation $183.1 billion each year), a significant cause of stroke ($43.3 billion each year), the leading cause of kidney disease ($40.3 billion). Diabetes is also the leading cause of adult-onset blindness and lower limb amputations. Additionally, aside from all of these related conditions, diabetes alone costs our nation $132 billion a year.

Approximately 42,000 people suffering from diabetes live in each congressional district. The following illustrates how diabetes affects your district in realistic terms:

—177 of your constituents will develop heart disease this year because of diabetes.
—154 of your constituents will develop end stage renal disease this year because of diabetes.
—129 of your constituents will lose a foot or leg this year because of diabetes.
—55 of your constituents will go blind this year because of diabetes.

Given the systemic damage diabetes imposes throughout the body, it is no surprise that the life expectancy of a person with the disease averages 10–15 years less than that of the general population.

Unfortunately, the spread of diabetes will only get worse in the coming years unless we see a significantly larger funding commitment by the federal government. Indeed, a CDC report issued in January of this year finds that the prevalence of diabetes nationwide increased by over 60 percent between 1990 and 2001. If diabetes keeps increasing at this rate, its prevalence will double in just over 15 years.

The Association hopes that an additional $10 million this year for the Division of Diabetes Translation—a request strongly supported by the Congressional Diabetes Caucus, comprised of 280 Members of Congress—would simply be the first step in a 5-year effort to double to budget of the Division. Although the medical research community has made tremendous strides in the area of diabetes over the past two decades, the benefits of this research have not been fully realized by a majority of the Americans affected by this disease. The federal government must commit more resources to ensure that important research findings are effectively and adequately translated into public health interventions. To this end, we believe strongly in the work funded by the Division of Diabetes Translation.

However, the Division's fiscal year 2004 budget of $67 million—and the President's $67 million request for fiscal year 2005—represents a miniscule commitment to diabetes prevention and control. Indeed, for every $1 that diabetes costs this country, the federal government currently invests less than $.01 to help Americans prevent and manage this deadly disease.

In 2003 the Division provided support for more than 50 state- and territorial-based diabetes control programs to reduce the complications associated with diabetes. However, funding constraints required the Division to provide severely limited support to 26 states, 8 territories, and D.C. for capacity-building diabetes programs. Slightly more substantive support was provided to the other 24 states for basic implementation programs. Although every state and territory has at least a capacity-building program, unfortunately these programs do not even come close to addressing the needs statewide. Instead, they simply serve as a rudimentary framework upon which a more comprehensive program can be built.

CDC also conducts other activities to help people currently living with diabetes. For example, CDC works with NIH to jointly sponsor the National Diabetes Education Program (NDEP), which seeks to improve the treatment and outcomes of people with diabetes, promote early detection, and prevent the onset of diabetes. In addition, CDC funds work at the National Diabetes Laboratory to support scientific studies that will improve the lives of people with diabetes.

Even while the Division of Diabetes Translation conducts a number of activities to help people with diabetes, it suffers a similar problem as its NIH counterpart, NIDDK. Compared to other diseases, diabetes remains significantly underfunded at CDC. If adequately funded, the Division would be able to fund a basic implementation program in every state as well as conduct and fund additional projects to assist people with diabetes. Without fully-funded diabetes programs and projects in all parts of the country, it will be exceedingly difficult—if not impossible—to control the escalating costs associated with diabetic complications and to stem the epidemic rise in diabetes rates.

The American Diabetes Association supports the President's support for the Steps to a Healthier U.S. Initiative, and is encouraged that this program focuses—among other things—on obesity and diabetes. We strongly believe, though, that funds made available for this new Initiative should not take away from funds that would otherwise be made available to the Division of Diabetes Translation. State Diabetes Prevention and Control Programs—when provided with enough funding—are proven commodities that have been extremely successful in helping Americans prevent and manage their diabetes. Americans in every state should have access to such quality programs.

Chronic diseases, including diabetes, account for nearly 70 percent of all health care costs as well as 70 percent of all deaths annually. However, less than $1.25 per person is directed toward public health interventions focused on preventing the debilitating effects associated with chronic diseases, demonstrating that federal investment in chronic disease prevention remains grossly inadequate. We cannot ignore those Americans who are currently living with diabetes and other diseases.

RECENT FUNDING INCREASES

The American Diabetes Association appreciates that Congress has begun to give greater attention to diabetes research at NIH in recent years and that the current Administration has proposed an overall increase in the NIH budget. However, during much of the past decade, diabetes funding has stagnated even while the burden has grown significantly. Indeed, from 1987–2001, appropriated diabetes funding as a share of the overall NIH budget has dropped by more than 20 percent (from 3.9 percent to 2.9 percent) while the death rate due to diabetes has increased by more than 40 percent. Thankfully, the past 4 years have brought larger increases in diabetes funding than we had seen over the majority of the decade. Only over these years did the growth in diabetes research funding finally keep pace with the growth of the overall NIH budget. At a time when diabetes is exploding across our nation, it remains essential that we increase the research funding levels for diabetes.

Mr. Chairman, we appreciate the increases of the last few years. Congress should be proud of the bi-partisan support for the effort to double the NIH budget. But this should not equate to an automatic institute-by-institute doubling.

Some institute budgets are larger not only due to scientific opportunities, but due to special consideration in years past. Unfortunately, across-the-board percentage increases make it difficult, if not impossible, to address funding shortfalls for diseases that now have promising scientific opportunities. Diseases like diabetes that have not received funding commensurate with their national burden, as well as with existing scientific opportunities, continue to fall behind as a result of this funding strategy.

Across-the-board increases for all institutes simply do not allow the Congress, or the nation, to deal with the serious problem of diabetes anytime soon. While on the surface across-the-board increases appear equitable to everyone, it actually perpetuates inequity in absolute dollar terms. In reality, a 15 percent increase means

much more for diseases and institutes with large budgets, and far less for diseases and institutes with small budgets.

Continuing with an across-the-board approach for Institute funding means that these discrepancies in funding will continue to grow. This is not inherently bad so long as the difference accurately reflects the scientific opportunities and health impact of disease on the nation. But in the case of diabetes at least, it does not.

The net effect of an across-the-board approach is that past funding legacies still affect the funding priorities at NIH to this day. By not constantly making an honest assessment of the health challenges faced by our nation and by not looking harder at the scientific opportunities facing the research community, NIH has perpetuated an inequality in funding based on decisions made many years before.

CONCLUSION

I firmly believe that we could rapidly move toward curing, preventing, and managing this disease by increasing funding for diabetes programs and research both at CDC and NIH. Your leadership can help accomplish this goal.

The American Diabetes Association strongly urges the committee and Congress increase the budget of the Division of Diabetes Translation by $10 million in fiscal year 2005 as the first step in a 5-year doubling plan. A doubling of the Division's budget would allow the Division to finally implement a Basic Implementation Diabetes Prevention and Control Program in every state and territory, thus moving the government in the direction of truly helping all Americans with diabetes. Additionally, we urge the Subcommittee to increase funding at NIH for diabetes research as much as possible in these strict economic times.

Speaking on behalf of the 18 million Americans with diabetes—a disease that crosses gender, race, ethnicity and political party; a disease that is among the most costly, debilitating, deadly and prevalent in our nation; and a disease that is exploding throughout our nation—I appreciate the opportunity to submit this testimony. The American Diabetes Association is prepared to answer any questions you might have on these important issues.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM), the largest single life science society with 43,000 members, is pleased to submit testimony on the fiscal year 2005 budget for the Centers for Disease Control and Prevention (CDC). The CDC is the nation's lead agency for protecting the health and safety of the public, both nationally and globally. Threats to public health and security have steadily increased in number and complexity over time, despite medical successes and technical innovation. The work of the CDC is of unprecedented importance in safeguarding public health.

The ASM is concerned that funding for CDC is not keeping pace with its growing responsibilities to address new health threats. The $6.9 billion fiscal year 2005 request for the CDC is a 2.8 percent reduction below last year's $7.1 billion. The ASM endorses the CDC Coalition's recommendation of $8.1 billion in fiscal year 2005 for CDC, followed by annual increases to achieve $15 billion for the agency by fiscal year 2008. Increased support is crucial to the CDC's primary goals for protecting public health: surveillance and response, basic and applied research, training and education, and prevention and control.

The CDC's ability to mobilize rapidly to prevent or contain disease is an urgently needed line of defense against the economic and social havoc that can result from public health threats. In 2003, the CDC was essential in identifying the cause of the Severe Acute Respiratory Syndrome (SARS) epidemic in Asia and the first case of human monkeypox in the United States. Agency personnel also trained approximately 8,800 U.S. clinical laboratory staff in terrorism preparedness and response, while others investigated numerous outbreaks of infectious and food-borne diseases, as well as chronic disease diagnoses among diverse populations. Proposed cuts to a number of CDC programs could jeopardize the agency's activities to address health threats.

The ASM is concerned that the proposed fiscal year 2005 budget represents no or only slight increases in CDC programs such as emerging and re-emerging infectious diseases, antimicrobial resistance and domestic HIV/AIDS programs. The ASM also recommends that new bioterrorism preparedness initiatives be funded without redirecting resources from needed on-going state and local programs, as proposed in the fiscal year 2005 budget. By adequately enlarging the CDC appropriation, Congress would strengthen significantly our defenses against naturally and intentionally caused disease in the United States and elsewhere.

INFECTIOUS DISEASES AND PUBLIC HEALTH

The National Center for Infectious Diseases (NCID) supports programs to prevent and control endemic, new and reemerging infectious diseases in the United States and abroad. The proposed fiscal year 2005 budget for the CDC includes $400.8 million for infectious diseases, an increase of $31.3 million over fiscal year 2004 funding. Most of the increase benefits two CDC programs: $27.5 million to expand the CDC's Global Disease Detection Initiative to $51 million, and $2 million to increase West Nile virus (WNV) research as well as state and local health department WNV surveillance and response capabilities. Because of increased world trade and travel, nations can no longer ignore any type of infectious disease and global strategies have become fundamental to CDC's public health activities. The ASM supports the budgetary increases proposed for these two programs, but is concerned that critical components of the CDC infectious diseases mission also need additional resources in the fiscal year 2005 budget.

In 2003 the Institute of Medicine (IOM) released a strongly worded, cautionary report on Microbial Threats to Health. The IOM report points out that infectious disease public health needs have been and will continue to increase. Between 1973 and 2003, more than three dozen newly emerging diseases were identified. Most recently, hantavirus, West Nile virus, SARS, bovine spongiform encephalopathy (BSE), and monkeypox became known enemies to public health in the United States. In the 1990s, the CDC revitalized its infectious disease programs to better reflect the emergence of new infectious diseases. By investing in partnerships with local and state health departments, academic research and teaching institutions, private industries, other federal agencies, world health organizations, and health agencies and researchers in other nations, the CDC expanded its ability to detect and contain infectious disease, as it intensified its own research and training programs. The vital need for CDC programs was emphasized dramatically last year with the SARS epidemic and hundreds of human WNV infections. The need remains as urgent today with concern about BSE and avian flu now in the United States.

Experts predict a major pandemic during this century and the most likely source remains influenza. A hallmark of pandemics and many small scale emerging infectious diseases is that they are zoonoses. Zoonotic diseases, infections which are naturally transmitted between animals and man, represent one of the leading causes of illness and death from infectious diseases and nearly all emergent episodes of the past 10 years have involved zoonotic infectious agents. In the United States alone, an influenza pandemic could cause an estimated 89,000 to 207,000 deaths and cost the nation from $71–167 billion in health care costs and lost productivity. Additional budgetary resources are needed to address issues such as zoonoses and influenza, which were highlighted in the IOM report. CDC infectious diseases should be increased by an additional $50 million.We recognize that significant investment will be required to enhance efforts to address the threat of pandemic influenza in order to develop a newer generation influenza vaccine that can be quickly produced and deployed, to strengthen the public health infrastructure at the state and local levels, and to ensure needed vaccines and antiviral medicines are readily available. We recommend that the Department of Health and Human Services (DHHS) assess the needs for resources to address pandemic flu within the NIH, CDC and FDA and coordinate the planning activities.

The goal of the CDC's new Global Disease Detection Initiative within its epidemic services and infectious disease control programs is to work faster and better in recognizing and controlling any infectious disease threatening public health. The CDC operates in a global arena, establishing myriad programs and collaborations beyond the nation's borders and sending quick-response assessment teams around the world. It recently funded five university schools of public health and three non-government organizations to assist malaria-endemic African countries, where the disease kills and disables millions. CDC personnel provide consistent epidemiological expertise and lab support to nations under siege, most recently the Congo (Marburg virus disease), Uganda and Gabon (Ebola hemorrhagic fever), Saudi Arabia and Yemen (Rift Valley fever), and more. CDC programs will be expanded in five countries including Brazil and China and new sites will be created in six others, most of them in Africa. The CDC also will continue to be a major implementing agency for the U.S. Department of State's Mother to Child HIV Prevention Initiative inaugurated last year. The new Global Disease Detection initiative includes improvement of the existing international surveillance network for influenza, to bolster the early warning system for identifying more uncommon viruses.

The multi-faceted network of disease surveillance in the United States expands and changes annually. The CDC last year enhanced its surveillance of prion diseases and responded to the first confirmed U.S. case of BSE in cattle. Food-borne

illness surveillance has grown into one of the most extensively used networks: 76 million Americans suffer from contaminated foods each year at an estimated cost of over $1 billion. The CDC's PulseNet is credited with revolutionizing food-borne surveillance in this country and overseas; recently it was expanded to incorporate a total of 21 participating countries. In 2003, it was critical in identifying U.S. outbreaks of salmonellosis from tomatoes and eggs, E. coli O157 infection from beef, and listeriosis from raw milk cheese. The CDC coordinates U.S. influenza surveillance and recently expanded its sentinel surveillance sites through one of many data-collecting networks. The 891 influenza sites will not only alert officials to impending flu epidemics, but also to other respiratory diseases.

Effective as surveillance networks are in preventing further spread of disease, protecting the public must stress prevention through effective education and science-based efforts. For instance, the CDC supplies funding to most states to promote appropriate use of antibiotics and thus limit the rising medical costs associated with antibiotic resistance. The agency has implemented a National Hepatitis C Prevention Strategy by establishing coordinators in all 50 state health departments. It developed guidelines for the prevention of perinatal group B streptococcal disease that have resulted in a 70 percent reduction since 1993. An initiative begun last year expects to increase HIV testing in this country and enhance prevention, in recognition that the rate of new infections (about 40,000 each year) has remained stable despite education efforts over the past two decades. The "Advancing HIV Prevention" approach shifts strategies to reduce even further the barriers to early HIV diagnosis and quality medical care.

In response to the 2001 Public Health Action Plan to Combat Antimicrobial Resistance (AR), the CDC announced a new extramural applied research grant program in 2003, to fund research in the areas of mechanisms of dissemination of AR genes, resistance in specific human pathogens of public health concern and the characterization of strains of community-associated methicillin-resistant Staphylococcus aureus (MRSA). The goal of the applied research program is to prevent and control the emergence and spread of antimicrobial resistance in the United States. Approximately $25 million is being requested for antimicrobial resistance research, surveillance, prevention and control activities. Considering the magnitude of the problem of antimicrobial resistance, additional new funding should be provided in the CDC budget to address the alarming issue of antimicrobial resistance.

Each year about 48,000 Americans die from vaccine-preventable diseases; worldwide, these diseases cause an estimated 2.4 million childhood deaths. The fiscal year 2005 CDC budget request includes $1.9 billion for a number of significant vaccination programs. Some, like a stockpile of all routinely recommended childhood vaccines, already are in progress. Others are new, like an inventory of childhood influenza vaccine. The immunization budget will continue to provide global immunization activities ($151 million), including the goal of global polio eradication by 2005.

NATIONAL SECURITY AND BIODEFENSE

Intentional release of biological weapons troubled the CDC well before events of 2001, but the enormity of those attacks brought home the grave potential of bioterrorism. The attacks also forced the CDC to shift much of its mission focus to bioterrorism preparedness, in collaborations with other federal, state, and local health organizations. The agency quickly formed emergency response teams, established extensive state-of-the-art communication systems, and concentrated on basic and applied research related to possible bioweapons. The fiscal year 2005 request of $1.1 billion would continue CDC efforts related to terrorism preparedness and emergency response at a funding level identical to that implemented so effectively in fiscal year 2004. The ASM recognizes the dire consequences of bioterrorism and supports extensive funding of CDC preparedness programs. However, the programmatic impact of removing $105 million from state/local programs and $25 million from internal CDC activities to subsidize CDC's component in a new cross-agency Biosurveillance initiative deserves evaluation.

The new Biosurveillance Initiative was designed by a coalition of federal agencies after the Homeland Security Council identified early bioattack warning and surveillance as top priority areas in need of improvement. The CDC's contribution, funded at $130 million in the proposed fiscal year 2005 budget, includes three new program activities, the BioSense surveillance system ($100 million), real-time laboratory reporting ($20 million), and expanded border health inspection and quarantine capability ($10 million). The BioSense program represents a new and largely untested generation of infectious disease surveillance that does not rely upon mandatory or voluntary case reporting from healthcare providers. Instead, sets of anonymous health data will be automatically and electronically gathered from pre-determined

sources like over-the-counter retail sales of home health remedies and visits to emergency rooms. This system is intended to provide public health officials with "a near real-time sense" of the community's health status and to reduce the time needed to detect threats from days or weeks to hours.

The ASM strongly supports two programs of the new initiative which build on the importance of trained personnel who respond locally but work together within the national goal of preventing bioterrorist attacks. One program will expand the CDC's existing Laboratory Response Network (LRN) by adding animal diagnostics and food safety capabilities to public health, clinical, and private commercial laboratories. The other program recognizes that every day more than 2 million people travel to or through this country by air, sea or land, and that each year, more than 350,000 new immigrants arrive. It adds new, strategically placed quarantine stations and creates multidisciplinary teams able to respond to infectious disease emergencies at U.S. seaports, border crossings, and airports.

By the end of fiscal year 2004, over $3 billion will have been allocated by the CDC to upgrade state and local health departments since the 2001 terrorist attacks. Supporting this nationwide community of anti-terrorism capability extends the CDC's own efforts and provides a greater return on funding investments. CDC support also comes from the many wide-ranging communication networks used by the CDC to disseminate new scientific information, health risk alerts, and population- or disease-specific updates. An example is the Epidemic Information Exchange, Epi-X, which provides swift exchange of information among more than 2,000 key public health officials nationwide. The Public Health Information Network sends health alerts and advisory messages to one million recipients, including 90 percent of all county public health departments. The Laboratory Response Network, to be expanded under the new Biosurveillance Initiative, already includes 113 members in the United States and elsewhere; an increasing number of these labs could confirm the presence of anthrax, tularemia, and smallpox, and more than half are qualified to handle some of the most dangerous pathogens.

The complex CDC infrastructure used to prevent bioterrorism also incorporates the training of specialized personnel, the stockpiling of crucial supplies needed in mass emergencies, and the careful monitoring of pathogens and other toxic agents used in research. Management of the Strategic National Stockpile has been returned to the HHS from the Department of Homeland Security, as a source of smallpox vaccine and other medical supplies shippable to any scene of mass trauma in the United States. The Epidemic Intelligence Service grew from 148 officers in 2001, to 167 in 2003; 49 of these first-line responders are assigned to local or state health departments. With the U.S. Department of Agriculture, this year the CDC will inspect 300 laboratories using potential bioagents in research, through the Select Agent Program that controls the possession and transfer of infectious agents. The SAP program should have adequate resources.

BUILDINGS AND FACILITIES

A total of $81.5 million is proposed in the fiscal year 2005 budget for CDC buildings and facilities. CDC is undertaking and has made substantial progress in a 10-year effort to rebuild its physical infrastructure and replace and upgrade decrepit out-dated buildings and facilities. State of the art, safe and secure laboratories and facilities, as well as modern equipment, are essential to an effective CDC response to the broad range of public health threats facing the country and the world. The ASM recommends that Congress appropriate $250 million for CDC's critical infrastructure needs.

PREPARED STATEMENT OF THE INTERTRIBAL BISON COOPERATIVE

INTRODUCTION AND BACKGROUND

My name is Ervin Carlson, a Tribal Council member of the Blackfeet Tribe of Montana and President of the InterTribal Bison Cooperative. Please accept my sincere appreciation for this opportunity to submit testimony to the honorable members of the Appropriations Subcommittee on Labor, Health and Human Services and Education. The InterTribal Bison Cooperative (ITBC) is a Native American nonprofit organization, headquartered in Rapid City, South Dakota, comprised of fifty-three (53) federally recognized Indian Tribes located within 18 States across the United States.

Buffalo thrived in abundance on the plains of the United States for many centuries before they were hunted to near extinction in the 1800s. During this period of history, buffalo were critical to survival of the American Indian. Buffalo provided

food, shelter, clothing and essential tools for Indian people and insured continuance of their subsistence way of life. Naturally, Indian people developed a strong spiritual and cultural respect for buffalo that has not diminished with the passage of time.

Numerous tribes that were committed to preserving the sacred relationship between Indian people and buffalo established the ITBC as an effort to restore buffalo to Indian lands. ITBC focused upon raising buffalo on Indian Reservation lands that did not sustain other economic or agricultural projects. Significant portions of Indian Reservations consist of poor quality lands for farming or raising livestock. However, these wholly unproductive Reservation lands were and still are suitable for buffalo. ITBC began actively restoring buffalo to Indian lands after receiving funding in 1992 as an initiative of the Bush Administration.

Upon the successful restoration of buffalo to Indian lands, opportunities arose for Tribes to utilize buffalo for tribal economic development efforts. ITBC is now focused on efforts to assure that tribal buffalo projects are economically sustainable. Federal appropriations have allowed ITBC to successfully restore buffalo the tribal lands, thereby preserving the sacred relationship between Indian people and buffalo. The respect that Indian tribes have maintained for buffalo has fostered a serious commitment by ITBC member Tribes for successful buffalo herd development. The successful promotion of buffalo as a healthy food source will allow Tribes to utilize a culturally relevant resource as a means to achieve self-sufficiency.

FUNDING REQUEST FOR PREVENTATIVE HEALTH CARE INITIATIVE

The InterTribal Bison Cooperative respectfully requests an appropriation for fiscal year 2005 in the amount of $3,000,000 in the form of an earmark to the Department of Health and Human Service Department's budget. ITBC intends to utilize the funds to conduct a national demonstration project focused on the delivery of bison meat to Native Americans suffering from diet related diseases.

The Native American population currently suffers from the highest rates of Type 2 diabetes. The Indian population further suffers from high rates of cardio vascular disease and various other diet related diseases. Studies indicate that Type 2 diabetes commonly emerges when a population undergoes radical diet changes. Native Americans have been forced to abandon traditional diets rich in wild game, buffalo and plants and now have diets similar in composition to average American diets. More studies are needed on the traditional diets of Native Americans versus their modern day diets in relation to diabetes rates. However, based upon the current data available, it is safe to assume that disease rates of Native Americans are directly impacted by a genetic inability to effectively metabolize modern foods. More specifically, it is well accepted that the changing diet of Indians is a major factor in the diabetes epidemic in Indian Country.

Approximately 65–70 percent of Indians living on Indian Reservations receive foods provided by the USDA Food Distribution Program on Indian Reservation (FDPIR) or from the USDA Food Stamp Program. The FDPIR food package is composed of approximately 58 percent carbohydrates, 14 percent proteins and 28 percent fats. Studies have shown that the FDPIR food package has not been compatible with the genetic compositions of Native Americans and has been a major factor in the high incidence of diet-related disease among Native Americans. Indians utilizing Food Stamps generally select a grain based diet and poorer quality protein sources such as high fat meats based upon economic reasons and the unavailability of higher quality protein food sources.

Buffalo meat is low in fat and cholesterol and is compatible to the genetics of Indian people. ITBC intends to develop a health care initiative that would educate Indian Reservation families of the benefits of incorporating buffalo meat into their diets. In conjunction with educating Reservation families on the benefits of buffalo meat, ITBC intends to develop methods to make buffalo meat accessible for Indian families and to promote incorporation of buffalo into their diets. ITBC intends to coordinate with Reservation health care providers in nutritional studies of Reservation populations that incorporate buffalo meat into diet packages.

ITBC believes that incorporating buffalo meat will positively impact the diets of Indian people living on Reservations. A healthy diet for Indian people that results in a lower incidence of diabetes and other diet related illnesses will reduce Indian Reservation health care costs and result in a savings for taxpayers.

FUNDING REQUEST FOR ITBC TRAINING AND LABOR PROGRAM

The InterTribal Bison Cooperative respectfully requests an appropriation for fiscal year 2005 in the amount of $500,000. This amount is $400,000 above the fiscal year 2004 appropriation for ITBC and is critical to maintain last years funding level and to develop ITBC's training and labor program.

In fiscal year 2004, the ITBC and its member Tribes were funded at $100,000, a decrease of $200,000 from the previous year. ITBC is now requesting $500,000 for fiscal year 2005 for job training as part of ITBC's labor initiative. To insure the success of ITBC's buffalo restoration efforts to Indian lands, training for the various jobs related to the buffalo projects is essential. Most member Tribes of ITBC have reservation unemployment rates of 72 percent. Jobs opportunities on most Indian Reservations are limited, low-paying, and often seasonal and temporary. The jobs created by buffalo restoration to Indian lands will positively impact Tribal unemployment rates and the overall Reservation poverty levels. Raising buffalo as an economic development effort requires skilled labor in permanent employment. ITBC has developed a job training program incorporating on-the-job training and work experience for youth that specifically addresses the unique needs of managing and maintaining buffalo. ITBC's training program further focuses on strengthening the economic development opportunities of buffalo restoration with training specific to meat processing, veterinary science, wildlife and biological services, infrastructure development, business and management training, and the overall development of a skilled workforce.

Sufficient funding for job training is critical to the success of the buffalo restoration projects. The increase in funding will ensure that ITBC can provide job training, job growth training to ITBC member tribes. Without funding at the requested level, the buffalo restoration projects have less assurance of success.

ITBC GOALS AND INITIATIVES

In addition to developing a preventative health care initiative, ITBC intends to continue with buffalo restoration efforts and the Tribal buffalo marketing initiative.

In 1991, seven Indian Tribes had small buffalo herds, with a combined total of 1,500 animals. The herds were not utilized for economic development but were often maintained as wildlife only. During ITBC's relatively short 10-year tenure, it has been highly successful at developing existing buffalo herds and restoring buffalo to Indian lands that had no buffalo prior to 1991. Today, through the efforts of ITBC, over 35 Indian Tribes are engaged in raising over 15,000 buffalo. All buffalo operations are owned and managed by Tribes and many programs are close to achieving self-sufficiency and profit generation. ITBC's technical assistance is critical to ensure that the current Tribal buffalo projects gain self-sufficiency and become profit-generating. Further, ITBC's assistance is critical to those Tribes seeking to start a buffalo restoration effort.

Through the efforts of ITBC, a new industry has developed on Indian reservations utilizing a culturally relevant resource. Hundreds of new jobs directly and indirectly revolving around the buffalo industry have been created. Tribal economies have benefited from the thousands of dollars generated and circulated on Indian Reservations.

ITBC has also been strategizing to overcome marketing obstacles for Tribally raised buffalo. ITBC is presently assisting the Assiniboine and Gros Ventre Tribes of the Fort Belknap Reservation, who recently purchased an USDA approved meat-processing plant, with a coordination scheme to accommodate the processing of range-fed Tribally raised buffalo.

CONCLUSION

ITBC has proven highly successful since its establishment to restore buffalo to Indian Reservation lands to revive and protect the sacred relationship between buffalo and Indian Tribes. Further, ITBC has successfully promoted the utilization of a culturally significant resource for viable economic development.

ITBC has assisted Tribes with the creation of new jobs, on-the-job training and job growth in the buffalo industry resulting in the generation of new money for tribal economies. ITBC is also actively developing strategies for marketing Tribally owned buffalo. Finally, and most critically for Tribal populations, ITBC is developing a preventive health care initiative to utilize buffalo meat as a healthy addition to Tribal family diets to reduce the incidence of diet-related illnesses.

ITBC strongly urges you to support its request for a $3,000,000 earmark to the Department of Health and Human Service Department's budget to develop the critically needed preventative health care initiative utilizing Tribally produced buffalo.

PREPARED STATEMENT OF THE MEDICARE PAYMENT ADVISORY COMMISSION

The Medicare Payment Advisory Commission (MedPAC) was created by the Congress to provide it with independent policy advice and technical assistance con-

cerning the Medicare program and other aspects of the health care system. To carry out its responsibilities MedPAC requests a budget appropriation of $9.905 million for fiscal year 2005. This request for a $605,000 increase over the Commission's fiscal year 2004 appropriation reflects the expanded responsibilities assigned to the Commission by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173), including 16 additional reports and the requirement to advise the Congress on the new prescription drug benefit. The most significant increases in MedPAC's fiscal year 2005 budget will fund data analysis and research contracts to meet those requirements.

WHO WE ARE

MedPAC is a federal advisory commission authorized under section 1805 of the Social Security Act (42 U.S.C. 1395 b-6), as added by section 4022 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33). Broadly defined by statute, the Commission's responsibilities are to:

—consider Medicare payment policies for private plans and traditional fee-for-service Medicare,
—determine the effects of Medicare payment policies on the delivery of health care services, and
—analyze the implications for Medicare of changes in the broader health care system.

MedPAC is a small efficient operation. The Commission consists of 17 Commissioners, appointed by the Comptroller General of the General Accounting Office, who possess expertise in biomedical, health services, and health economics research and who draw on their experiences as consumers, providers, employers, and payers. The Commission meets publicly throughout the year as it develops its recommendations. An executive director, analytic and administrative personnel staff the Commission. Staff are highly trained health policy analysts and economists. The Commission has less than 40 staff and outsources 40 percent of its budget for tasks such as data analysis, programming, printing, editorial work, and selected research projects to maintain efficiencies. We have also achieved efficiencies by migrating data analysis to personal computers and moving from printed to electronic reports.

The MMA requires that the expertise of the Commission's membership be expanded to include pharmaceuticals, and we expect that to occur when new commissioners are appointed in 2004. Over the coming fiscal year, MedPAC will make a significant investment in resources to be able to provide advice on the implementation of the prescription drug benefit and other program changes introduced by the MMA. Judging from our experience during consideration of the legislation, we also anticipate a significant use of resources to respond to Congressional inquiries about the new benefit and program changes.

WHAT WE DO

Each year, our annual appropriations provide the resources necessary to complete the Commission's required activities, including:

—March report to the Congress. Delivered on March 1 of each year, this report includes recommendations on the appropriate levels of payment for Medicare providers and policies to address the distribution of payments within each payment sector.
—June report to the Congress. Delivered on June 15 of each year, these reports have addressed issues such as Medicare in rural America, innovations and variations in the Medicare program, and a variety of other topics.
—Reports required by other legislation. The new Medicare legislation requires MedPAC to issues 16 reports on a variety of topics—12 of which are due during fiscal year 2005.
—Comments on administrative actions. MedPAC is required to comment on payment-related reports that the Secretary submits to the Congress and other proposed rules issued by the Centers for Medicare & Medicaid Services (CMS).

To support the Congress, MedPAC also anticipates Congressional requests for the following projects not specifically mandated by law:

—Policy briefs on topics of interest, including issues such as a primer on prescription drug formularies, descriptive information on beneficiaries eligible for both Medicare and Medicaid, information about employer-sponsored insurance benefits, and other issues that generate interest throughout the year.
—A Medicare data chartbook in June 2004, similar to the one produced in 2003 in response to requests by health committee staff.
—Requests for data and analysis from the health committee staff (more than 100 last year).

MEDPAC REPORTS PROVIDE INFORMATION AND RECOMMENDATIONS

MedPAC's fiscal year 2003 reports informed the Congress on wide range of Medicare issues. During the past year, the Commission completed our annually mandated March and June reports, eight reports mandated under the BBRA and BIPA, and other reports and studies as requested by the Congress. In addition, six reports were developed for MedPAC by external contractors and issued during 2003, and the Commission has submitted written comments to the Secretary of the Department of Health and Human Services on nine proposed rules.

In a program that spends $272 billion, MedPAC's payment update recommendations have important implications for the beneficiaries, the medical delivery system, and the federal budget. The March 2004 report focuses on payment policies and presents recommendations to Congress on updating payments to hospitals, physicians, and other providers, as well as refinements to their payment systems. It also includes refinements to the payments for private plans as well as recommendations to add quality incentives to the payment systems for end-stage renal disease patients and private plan enrollees.

The June 2004 report will address a range of issues of importance to the Congress as it considers both future legislation and CMS implementation of the MMA. The report will address a broad range of policy issues, including disease management, the dual eligible population, information technology, and an overview of issues surrounding implementation of the new drug benefit. It will also include analyses of long-term care hospitals, innovations in purchasing, and hospices.

We anticipate production and submission of a Medicare data chartbook in June 2004, similar to the one produced in 2003 and as requested by health committee staff—although publication will depend upon our assessment of those resources we must commit to studies mandated by the MMA.

During the rest of fiscal year 2004 and into 2005, MedPAC will also be working on the 16 studies mandated by the MMA. These reports cover issues such as the effect of new provisions to aid rural hospitals, analysis of the volume of physician services, changes in use of Part B drugs by oncology patients, and beneficiary cost sharing in plans. In addition, the Institute of Medicine is required to consult with the Commission on a study about quality incentives in the payment system, and GAO and CMS will collaborate with us on an analysis of specialty hospitals.

MedPAC will also comment on CMS administrative actions and review new payment systems for providers such as long-term care hospitals and inpatient rehabilitation facilities. The MMA assigned the Secretary more than 30 reports on which MedPAC will comment. Given the volume of rules and reports the Secretary must promulgate in the coming year to implement the new drug benefit and other MMA provisions, we anticipate that reviewing those actions will require a substantial amount of resources.

MEDPAC PROVIDES TESTIMONY, BRIEFINGS, AND ASSISTANCE TO HILL STAFF

During calendar year 2003, the Commission testified before three Congressional committees. The Commission chair testified before the House Ways & Means, Subcommittee on Health, on the Commission's March Report to the Congress (March 6, 2003) and on Medicare cost-sharing and supplemental insurance (May 1, 2003). The Commission's executive director testified before the Senate Special Committee on Aging on disease management in traditional Medicare (November 4, 2003). In March 2004, the Commission chair testified on improving quality through Medicare payment policy before the House Ways & Means, Subcommittee on Health.

The Commission has provided additional support to the Congress. From February through April 2003, the Commission briefed the Senate Committee on Finance on selected payment systems. On separate occasions, the executive director also briefed the members of the House Energy and Commerce Committee and the House Rural Caucus. In addition, the executive director briefed staff of the rural health caucus on rural Medicare provider payments.

MedPAC staff regularly brief the health committee staff on ongoing work by the Commission. This includes a series of conference calls and face-to-face meetings prior to each public meeting to discuss research, gather feedback, and provide information about Commission deliberations and upcoming recommendations. Commission staff has also responded, both orally and in writing, to numerous requests from Congressional staff on a wide variety of topics. Not including minor requests, Commission staff has filled over 100 direct requests for information from Congressional staff, involving providing data and other substantive analyses or explanations. Staff have also had more than 20 meetings with or briefings for Congressional staff on related topics.

We anticipate our level of support to the Congress including testimony, briefings, and technical assistance will increase in the next year as issues concerning the implementation and implications of new provisions in the MMA become more apparent.

OUTREACH

During 2003, as in previous years, MedPAC has exchanged information and advice with other government entities involved in crafting and assessing Medicare policy. We have met and conferred with staff from the General Accounting Office, the Centers for Medicare & Medicaid Services, the Congressional Budget Office, the Congressional Research Service, the Agency for Healthcare Research and Quality, and the Assistant Secretary for Planning and Evaluation. Exchanges with these government entities will continue so that we coordinate our work and minimize redundancy.

As in past years, MedPAC has continued to gather input to its policy deliberations through meetings with outside groups. Members of the Commission and staff will continue to meet with outside interest groups in order to gather information for MedPAC's findings and recommendations. In addition, in order to increase our understanding of the health care market and the impact of Medicare payment policy on providers, staff have made site visits to gather information. Such efforts will continue this year.

During 2003, Commission staff extended its public outreach through speaking at a number of conferences. Another venue for public outreach has been staff publication of original articles based on Commission research. Members of the staff will continue to reach out to external groups through attendance at and presentations to academic and professional conferences, as well as publication of articles based on work at the Commission. Such efforts increase staff knowledge of the broader Medicare policy context and expand public understanding of the work of the Commission.

MEDPAC RECOMMENDATIONS HAVE BEEN ADOPTED

The Congress and CMS have adopted MedPAC's recommendations on a range of issues. For example, the MMA reflected several of the Commission's recent recommendations on dialysis payments, the update for home health services, the home health rural add-on, updates to payments for services provided at ambulatory surgical centers, increases for physician services, and inpatient hospital payments.

OUR APPROPRIATION REQUEST FOR FISCAL YEAR 2005

For fiscal year 2005, MedPAC requests $9,905,000, which is $605,000 more than the amount requested for fiscal year 2004. Medicare, a more than $270 billion program, represents one of the Congress' highest priorities. The requested budget of just over $9.9 million to better understand the policy concerns for this vital program is both justifiable and reasonable. This amount is necessary not only to maintain but to increase the current level of analysis, hold Commission meetings, develop data, and meet our mandated responsibilities to the Congress.

Our fiscal year 2005 request is driven by several factors. As required by our authorizing legislation, during fiscal year 2005 we will submit our March and June reports. In addition, we will complete a significant number of new tasks, including:

—Complete 12 mandated reports included in the MMA. In addition, MedPAC is required to consult with the IOM, GAO, and CMS on other reports mandated in the legislation.

—Respond to more than 30 payment-related reports submitted to the Congress by the Secretary.

—Increase the analytic scope of the commission to include prescription drugs.

The majority of the increase in MedPAC's budget is for research contracts, computer programming, and commercial contracts to accomplish these new tasks. External research contracts enhance our efficiency by providing access to areas of expertise and additional work force on an as-needed basis. Because of MedPAC's increasing workload, access to external research contractors is critical to providing timely advice to Congress on key Medicare policy issues.

The increased funding will also enable us to respond to the growing volume of informal Congressional requests for information. In addition, it has become increasingly clear that the data available to assess the Medicare program is inadequate and that we must strive to expand data sources and analysis. Fulfilling Congressional requests and expanding data sources requires increased staff time and increased computer costs for data analysis.

While we do have significant increases in the expenses discussed above, MedPAC has achieved certain economies. We have significantly decreased spending on main-

frame computer costs by moving data to personal computers. In addition, continued migration away from printed to electronic reports and internet-based resources has saved a significant amount of money for printing and reproduction. We anticipate these expenses will decline even further in fiscal year 2005 even though we will be delivering 12 additional reports to the Congress during the fiscal year.

More reports, more requests for information, and more timely data lead to an increase in our budget request. Small size, efficient operations, and increased economies enable us to take on increased responsibilities within, what is by any measure, a small budget in relation to the increased leverage it gives the Congress on the Medicare program.

PREPARED STATEMENT OF RESEARCH TO PREVENTION

Since June 2003, the Centers for Disease Control and Prevention (CDC) has undertaken a strategic planning effort to prepare the agency to address the health challenges of the 21st century. The Futures Initiative has involved gathering information from thousands of partners, stakeholders and the public regarding CDC's organization, scope and reach. Key findings include a need to strengthen CDC's role in health promotion and prevention of disease, disability, and injury. To accomplish this, one overarching goal was identified—"All people will achieve their optimal lifespan with the best possible quality of health in every stage of life."

Research to Prevention, a national coalition committed to improving the nation's health through prevention, wholeheartedly concurs with this goal and urges Congress to provide sufficient resources to permit CDC to maximize its chronic disease prevention efforts throughout the country. The coalition's members include the nation's premier voluntary health organizations and health provider organizations, including: the American Association of Diabetes Educators, the American Cancer Society, the American Diabetes Association, the American Heart Association, the Arthritis Foundation, the Chronic Disease Directors, the Epilepsy Foundation, the Lance Armstrong Foundation, Partnership for Prevention, Prevent Blindness America and the National Health Council.

Research to Prevention aims to make prevention and control of chronic diseases and disability a national policy and funding priority by educating policymakers and advocating for vital funding increases for comprehensive public health programs that address the nation's leading causes of death and disability. Research to Prevention is seeking a $340 million increase in funding in fiscal year 2004 for State-based chronic disease prevention and control programs at the Centers for Disease Control and Prevention (CDC). We also support an increase in funding for the Youth Media Campaign, Racial and Ethnic Approaches to Community Health (REACH), the Preventive Health and Health Services Block Grant, as well as Secretary Thompson's Steps to a Healthier U.S. initiative. The attached chart provides detail on the specific requested funding levels.

Chronic diseases are responsible for more than 70 percent of all U.S. deaths and more than 75 percent of all health care expenditures in the United States. The number of deaths alone, however, fails to convey the full picture of the toll of chronic disease. More than 125 million Americans live with some form of chronic disease, and millions of new cases are diagnosed each year. These serious conditions are often treatable but not always curable. Thus, an even greater burden befalls Americans from the disability and diminished quality of life resulting from chronic disease.

One-third, or approximately $300 billion, of the nation's health care budget is spent on older Americans who often have preventable or controllable chronic diseases and conditions. Much of the disability in old age can be delayed or prevented altogether, potentially improving quality of life and saving the nation billions of dollars in health care expenditures and the costs of long-term care.

Chronic disease is not just an issue among older adults. One-third of the years of potential life lost before age 65 is due to chronic disease. The obesity epidemic in this country is taking its toll on young people. Since 1980, obesity rates have doubled among children and tripled among adolescents. Unhealthy diet and physical inactivity play an important role in many chronic diseases and conditions. As our lead prevention agency, CDC needs additional resources to work with states, schools and local communities to implement promising approaches for preventing obesity.

To curb the excessive burden of chronic diseases, both in human and economic terms, the nation must ensure that research advances are applied, evaluated and implemented at the state and local level with comprehensive, sustainable prevention programs. CDC plays an essential role in translating and delivering at the community level what is learned from research—especially ensuring that those populations

disproportionately affected by chronic disease and disabilities receive the benefits of our nation's investment in medical research. Effective interventions need to be developed and implemented to reduce the disabling consequences of these diseases, including blindness, kidney failure, paralysis, fractures, joint deterioration, and limb loss.

Research to Prevention stands ready to work with the Members of this Subcommittee to help make it possible for every state in the nation to develop and deliver health promotion, health education and disease prevention programs to address chronic diseases and disability. By committing a minimum increase of $340 million in fiscal year 2005 for state-based chronic disease programs, we can work to make this a reality.

All states need and deserve statewide implementation grants for the leading causes of death and disability (heart disease and stroke, diabetes, cancer and arthritis) and their risk factors (physical activity, nutrition, obesity, and tobacco use). Emerging chronic conditions, such as epilepsy and complications associated with chronic disease, such as vision loss and oral disease must also be addressed. States also need to track progress statewide through disease registries and behavioral surveys, including the stroke and cancer registries and the Behavioral Risk Factor Surveillance System (BRFSS). The BRFSS information is essential for planning, conducting and evaluating public health programs at the national, state and local levels. Additionally, private organizations rely on the survey data to develop health promotion programs to reduce the prevalence of unhealthy behaviors and to document their effectiveness.

YOUTH MEDIA CAMPAIGN

Research to Prevention supports a $89 million increase above fiscal year 2004 to restores funding to its $125 million level in fiscal year 2001. This campaign—known as VERB—is designed to give kids a positive advertising message about being physically active through paid media, partnerships, and community efforts. In February 2004, the CDC released the first survey results that indicate physical activity among the nation's youth is increasing as a result of the VERB campaign. A 34 percent increase in weekly free-time physical activity sessions among 8.6 million children ages 9–10 in the United States. R2P believes that VERB should be expanded so that even more children will be exposed to healthy messages and increase their chances of becoming more physically active.

REACH

Research to Prevention supports a $12.7 million increase in the REACH program for a total of $50 million in fiscal year 2005. Launched in 1999, the REACH 2010 is the cornerstone of CDC's efforts to eliminate racial and ethnic disparities in health. This project is designed to eliminate health disparities in cardiovascular disease, immunizations, breast and cervical cancer screening and management, diabetes, HIV infections/AIDS, and infant mortality. The racial and ethnic groups targeted by REACH 2010 are African Americans, American Indians, Alaska Natives, Asian Americans, Hispanic Americans, and Pacific Islanders. REACH 2010 is unique because it works across public and private sectors to conduct community-based prevention research to identify the causes of health disparities. Culturally appropriate, community-driven programs are critical for eliminating racial and ethnic disparities in health. A $50 million allocation would support expansion of community-driven programs and evaluation of successful efforts to build capacity; target action; conduct community/systems change; eliminate health disparities; and translate and disseminate results.

PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Research to Prevention supports an increase of $76.7 million to additional clinical services, preventive screening, laboratory research, outbreak control, workforce training, public education, data surveillance, and program evaluation. The funds are used to target the 265 national health objectives in Healthy People 2010 which address cardiovascular disease, cancer, diabetes, emergency medical services, injury and violence, infectious disease, environmental health, community fluoridation, and sex offenses. Because of the allowed flexibility in the use of the funds, states allocate their block grant resources to address areas of greatest need and target populations. A strong emphasis is placed on programs for adolescents, communities with limited health care services, and disadvantaged populations. Since so many states lack funding to address many of the chronic diseases, states have used much of their block grant money to address the leading killers. This program facilitates coordination between states and their local governments since approximately 43 percent of

PHHS block grant funds were distributed by the states to meet county and local public health needs.

THE ADMINISTRATION'S HEALTHY STEPS INITIATIVE

Research to Prevention supports the Secretary's goals of reducing the burden of chronic diseases and applauds him for his continuing commitment to chronic disease prevention. The requested increase of $81.3 million to support the Steps to a Healthier U.S. Initiative can assist the states, local governments and community organizations to increase their efforts to improve health and well being. While the states already distribute approximately 75 percent of their CDC resources directly to community programs, they still lack the resources necessary to reach many of their communities. States are the engine to reach those communities and the Secretary's Steps Initiative provides the gas for the engine. State-based chronic disease funding and the Steps Initiative need to advance together if we are to reduce death and disability and enhance quality of life.

Research to Prevention thanks the Subcommittee for the opportunity to submit testimony and stands ready to work with all Members to reduce and prevent the economic and social burden of chronic disease on our nation.

RESEARCH TO PREVENTION MEMBERS

American Association of Diabetes Educators; American Cancer Society; American College of Preventive Medicine; American Dental Association; American Diabetes Association; American Heart Association; American Public Health Association; American School Health Association; Arthritis Foundation; Association of State and Territorial Chronic Disease Program Directors; Association of State and Territorial Directors of Health Promotion and Public Health Education; Coalition of National Health Education Associations; Center for Science in the Public Interest; Eli Lilly and Company; Epilepsy Foundation; Lance Armstrong Foundation; Missouri Primary Care Association; National Health Council; National Kidney Foundation, Inc.; Oncology Nursing Society; Partnership for Prevention; Prevent Blindness America; Society for Public Health Education; and YMCA of the USA.

CDC CHRONIC DISEASE PROGRAMS—FISCAL YEAR 2005 RECOMMENDATIONS

[In millions of dollars]

	Fiscal year			Increase over fiscal year 2004
	2003 enacted	2004 enacted	2005 R2P targets	
NATIONAL CENTER CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION	963.1	1,024.4	1,613.5	589.0
Chronic Disease Line	790.5	853.8	1,353.5	499.6
Arthritis	15.6	15.8	25.0	9.2
Lupus	1.0	1.0	.....	.....
Cancer Prevention and Control	287.8	313.6	410.0	96.4
B&C Mort Prev	199.4	209.5	250.0	40.5
WISEWOMAN	14.0	14.0	20.0	6.0
Comprehensive Cancer	9.4	11.9	25.0	13.1
Ovarian	4.4	4.9	10.0	5.1
Prostate	14.0	15.5	20.0	4.5
Colorectal	13.4	14.9	25.0	10.1
Skin	1.6	2.2	10.0	7.8
Registries	45.6	49.7	65.0	15.3
Community Health Promotion	22.1	24.0	37.3	13.3
BRFSS	6.9	8.1	18.0	10.0
Com Health Promotion	8.9	8.3	8.3	.....
Compl/Alt Med	1.7	1.8	2.0	0.2
Glaucoma/Vision Screening	4.7	5.8	9.0	3.2
Diabetes	63.3	66.9	150.0	83.1
Epilepsy	7.5	8.2	13.2	5.0
Heart Disease and Stroke	43.0	45.7	80.0	34.3
Paul Coverdell Stroke Registry	5.0	5.0	5.0	.....
Nutrition/Phys Activity/Obesity	34.1	44.7	75.0	30.3
Micronutrients	5.0	0.4	.....	.....
Iron Overload	0.4	0.4	.....	.....
Oral Health	11.7	12.4	20.0	7.6
Prevention Research Centers	26.8	26.7	26.7	.....
Safe Motherhood /Infant Health	54.0	53.9	53.9	.....

CDC CHRONIC DISEASE PROGRAMS—FISCAL YEAR 2005 RECOMMENDATIONS—Continued

[In millions of dollars]

	Fiscal year			Increase over fiscal year 2004
	2003 enacted	2004 enacted	2005 R2P targets	
School Health	57.8	62.4	82.4	20.0
Coordinated School Health	10.8	15.7	35.7	20.0
HIV	47.0	46.7	46.7	.....
Tobacco	99.9	99.7	130.0	30.3
ADDITIONAL TARGETS:				
STEPS	15.4	43.7	125.0	81.3
Youth Media Campaign	51.0	35.8	5.0	89.2
PHHS BLOCK GRANT	135.0	133.3	210.0	76.7
REACH	37.6	37.3	50.0	12.7

PREPARED STATEMENT OF THE ASSOCIATION OF UNIVERSITY PROGRAMS IN OCCUPATIONAL HEALTH AND SAFETY

Thank you for the opportunity to present testimony to the Subcommittee in support of funding for the National Institute for Occupational Safety and Health (NIOSH) and for the NIOSH-funded Education and Research Centers (ERCs). My name is Jackie Agnew, and I am the Director of the Education and Research Center at Johns Hopkins University Bloomberg School of Public Health.

I am testifying on behalf of the Association of University Programs in Occupational Health and Safety (AUPOHS), the organization that represents 16 multi-disciplinary, NIOSH-supported, university-based Education and Research Centers (ERCs). The ERCs are regional resources for all parties involved with occupational health and safety—industry, labor, government, academia, and the general public. The ERCs play the following roles in helping the nation reduce losses associated with work-related illnesses and injuries:

—*Prevention Research*.—Developing the basic knowledge and associated technologies to prevent work-related illnesses and injuries.

—*Professional Training*.—Graduate degree programs in Occupational Medicine, Occupational Health Nursing, Safety Engineering, and Industrial Hygiene to provide qualified professionals in essential disciplines.

—*Research Training*.—Preparing doctoral-trained scientists who will respond to future research challenges and who will prepare the next generation of occupational health and safety professionals.

—*Continuing Education*.—Short courses designed to enhance professional skills and maintain professional certification in occupational health and safety disciplines. These courses are delivered on-campus at the 16 ERCs as well as through distance learning technologies.

—*Regional Outreach*.—Responding to specific requests from local employers and workers on issues related to occupational health and safety.

THE SCOPE OF THE PROBLEM OF OCCUPATIONAL INJURY AND ILLNESSES

The many causes of occupational injury and illness represent a striking burden on America's health and well-being. Yet, despite significant improvements in workplace safety and health over the last several decades:

—There were 5,524 occupational fatalities in 2002, for an average of 15 workers per day who died from work-related injuries; and

—More than 4.7 million workers sustained work-related injuries and illnesses in the private sector alone in that same year.

—The economic toll of work-related illness and injury on the nation's employers, workers and their families, and society overall reached an estimated $45.8 billion in 2001, with $137.4 to $229 billion more in indirect costs.

This is an especially tragic situation because most work-related fatalities, injuries and illnesses are preventable with effective, professionally directed, health and safety programs. Although our nation has made tremendous progress in reducing occupational illnesses and injuries during the past 30 years, leading to a decline in the rate of total recordable cases from 11.0 to 7.1 cases per 100 full-time workers between 1973 to 1997, the burden of occupational illnesses and injuries remains unacceptably high.

Furthermore, we do not live in a static environment. The rapidly changing workplace continues to present new health risks to American workers that need to be addressed through occupational safety and health research. For example, by the year 2005, an estimated 33 percent of the U.S. workforce will be 45 years or older. Work-injury fatality rates begin increasing at age 45, with rates for workers 65 years and older nearly three times as high as the average for all workers. Despite being the primary federal agency for occupational disease and injury prevention in the nation, NIOSH receives only about $1 per worker per year for its mission of research, professional education, and outreach.

HOMELAND SECURITY

The heightened awareness of terrorist threats, and the increased responsibilities of first responders and other homeland security professionals, illustrates the need for strengthened workplace health and safety in the ongoing war on terror. The NIOSH ERCs play a crucial role in preparing Occupational Safety and Health (OSH) professionals to identify and ameliorate vulnerabilities to terrorist attacks and other workplace hazards and increase readiness to respond to biological, chemical, or radiological attacks.

Thanks to the Subcommittee's support for occupational health and safety research, NIOSH developed more effective methods to test for anthrax contamination in congressional offices. These procedures were quickly adopted by the Coast Guard, the FBI, and government building contractors.

In addition, occupational health and safety professionals have worked for several years with emergency response teams to minimize losses in the event of a disaster. NIOSH took a lead role in protecting the safety of emergency responders in New York City and Virginia, with ERC-trained professionals applying their technical expertise to meet immediate protective needs and conducting ongoing activities to safeguard the health of clean-up workers.

In the face of the growing concerns surrounding homeland security, ERCs have rapidly upgraded research coordination and expanded training opportunities, including sponsoring national and regional forums on response to bioterrorism and other disasters.

THE NEED FOR OCCUPATIONAL SAFETY AND HEALTH MANPOWER

The NIOSH ERCs were reviewed by the DHHS Office of the Inspector General in 1995. The resulting report affirmed the efficacy of the ERCs in producing graduates who pursue careers in occupational safety and health. Since the ERCs are regional, they are ready to respond to various trends in industries throughout the country. And because they provide training that is multi-disciplinary, ERCs graduate professionals who can protect workers in virtually every walk of life. Despite the recognized success of the ERCs in training qualified occupational health and safety professionals, the country continues to have ongoing shortages. The manpower needs are especially acute for doctoral-level trained professionals who can conduct research and help in implementing the National Occupational Research Agenda.

In May 2000, the Institute of Medicine issued its final report on the education and training needs for occupational safety and health (OSH) professionals in the United States. This report concluded that "the continuing burden of largely preventable occupational diseases and injuries and the lack of adequate OSH services in most small and many larger workplaces indicate a clear need for more OSH professionals at all levels." Specific needs identified by the IOM report include:

—An insufficient number of doctoral-level graduates in occupational safety, thus limiting the nation's capacity to perform essential research and training in traumatic injury prevention.

—An inability to attract physicians and nurses into formal OSH academic training programs, thus limiting the resources needed to deliver occupational health services.

NEW NIOSH INITIATIVE: MOVING RESEARCH INTO PRACTICE

The health of the U.S. economy depends upon a healthy and productive workforce. Through its targeted research and prevention programs, as well as its programs of tracking diseases, injuries, and hazards; capacity building; and rapid dissemination of useful information, NIOSH contributes to the nation's progress in reducing workplace injuries and illnesses and enhancing the health and safety of U.S. workers.

In 1996, NIOSH established the National Occupational Research Agenda (NORA), a framework to guide and promote occupational safety and health research through a consensus-building process with more than 500 outside organizations and individ-

uals. The NORA process identified the top 21 research priorities for occupational safety and health for the nation.

NIOSH has long been committed to translating research results into practical recommendations and disseminating them through its publications. For example, "Alerts" help employers and workers identify and respond to work-related health hazards, and "Workplace Solutions" provide practical advice on hazard control. NIOSH is now building even further on these efforts by launching Research to Practice, or r2p, a new initiative to transfer research findings, technologies, and information into effective prevention practices and products and to promote their adoption in workplaces.

The goal of the NIOSH r2p initiative will be to increase the use in the workplace of effective NIOSH and NIOSH-funded research findings. NIOSH will achieve this goal by translating its research findings into practice as quickly as possible, targeting its dissemination efforts, and evaluating and demonstrating the effectiveness of these efforts in improving worker health and safety. ERCs will play a prominent role in this process.

In addition, in coordination with the HHS Secretary's *Steps to a HealthierUS* initiative, NIOSH is introducing *Steps to a HealthierUS Workforce* to encourage workplace health programs that effectively integrate or coordinate efforts to promote both personal health and workplace health. Through NORA, r2p, and *Steps to a HealthierUS Workforce*, NIOSH will continue to work to achieve its goal of preventing work-related illnesses and injuries. These efforts will continue to be enhanced through partnerships, outreach, and capacity-building to enable NIOSH to leverage resources and expertise.

RECOMMENDATION FOR FISCAL YEAR 2005

AUPOHS requests an increase of $5 million for ERCs, and we are supporting a $30 million total increase over the $277 million appropriated in fiscal year 2004 for NIOSH.—This would provide $307 million for NIOSH and $24.7 million for ERCs in fiscal year 2005. Given that much of NIOSH's extramural research program is carried out by our institutions, sustaining the academic infrastructure provided by the ERCs is essential to the success of NORA, r2p, and *Steps to a HealthierUS Workforce.* Our recommendation would ensure that our nation's universities have the capacity and manpower to implement these initiatives and expand training programs to improve the health and productivity of American workers.

Funding for NIOSH and the ERCs would reduce the staggering burden of occupational illnesses and injury on the American economy, recently estimated at $240 billion. To put this number in perspective, these costs dwarf the $33 billion for AIDS and the $67 billion for Alzheimer's disease, and they are greater than the $164 billion economic cost for all circulatory diseases and the $171 billion cost of cancer. Yet federal support for occupational safety and health research pales in comparison—for example, cancer research receives 17 times as much federal funding.

Thank you for the opportunity to report the great need for research and training in occupational safety and health.

NIOSH-SUPPORTED EDUCATION AND RESEARCH CENTERS (ERCS)

Deep South ERC (University of Alabama at Birmingham and Auburn University); Harvard University; Johns Hopkins University; New York /New Jersey ERC (Mt. Sinai Medical Center and Hunter College); Northern California ERC (UC Berkeley, UCSF); Southern California ERC (UCLA and UC Irvine); Texas ERC (University of Texas and Texas A&M University); University of Cincinnati; University of Illinois at Chicago; University of Iowa; University of Michigan; University of Minnesota; University of North Carolina at Chapel Hill; University of South Florida; University of Utah; and University of Washington.

PREPARED STATEMENT OF ROTARY INTERNATIONAL

Chairman Specter, Senator Harkin, members of the Subcommittee, Rotary International appreciates this opportunity to submit testimony in support of the polio eradication activities of the U.S. Centers for Disease Control and Prevention (CDC). The effort to eradicate polio has been likened to a race—a race to reach the last child. This race requires the dedication to make the sacrifices necessary to achieve success. Like some great relay team, the major partners in the global polio eradication effort have joined with national governments around the world in an unprecedented demonstration of commitment to cross the finish line of this historic public health goal. We cannot allow the great distance we have traveled to diminish our

resolve. Though we may be weary, our adversary is weakening. The victory over polio is closer than ever!

PROGRESS IN THE GLOBAL PROGRAM TO ERADICATE POLIO

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 CDC's polio eradication activities, the battle against polio would be impossible. Thanks to your leadership in appropriating funds, the international effort to eradicate polio has made tremendous progress.

—The number of polio cases has fallen from an estimated 350,000 in 1988 to less than 800 in 2003—a more than 99 percent decline in reported cases (see Exhibit A). More than 200 countries and territories are polio-free, including 4 of the 5 most populous countries in the world (China, United States, Indonesia, and Brazil).

—Transmission of the poliovirus has never been more geographically confined. The Western Hemisphere, the Western Pacific and the European regions are certified polio-free. Wild poliovirus transmission is confined to a limited number of polio "hot-spots" within six countries.

—More than 2 billion children worldwide have been immunized during NIDs in the last 5 years, including more than 150 million in a single day in India.

—All polio-endemic countries in the world have conducted NIDs and established high quality surveillance of Acute Flaccid Paralysis (AFP). The eradication of polio in the Democratic Republic of Congo, Sudan, and Somalia shows that polio eradication strategies are successful even in countries affected by civil unrest.

From the launch of the global initiative in 1988, to the eradication target date of 2005, 5 million people who would otherwise have been paralyzed will be walking because they have been immunized against polio. Tens of thousands of public health workers have been trained to investigate cases of acute flaccid paralysis and manage massive immunization programs. Cold chain, transport and communications systems for immunization have been strengthened. A network of 147 polio laboratories has been established to analyze suspected cases of polio and monitor transmission of polio. This network will continue to support the surveillance of other diseases long after polio has been eradicated.

Give the tremendous progress that has been made in reducing the incidence of polio and diminishing the areas in which the virus circulates, the world currently faces an unprecedented opportunity to stop the transmission of wild poliovirus. However, significant challenges remain as obstacles to the ultimate achievement of our goal of a polio-free world. In 2003, Nigeria surpassed India to become the country with the highest number of polio cases. The surge in polio cases in Nigeria also resulted in importations of cases into several of the countries that neighbor Nigeria. The risk of importations into west and central African countries, and around the world, is magnified by financial constraints that limit the scope of immunization activities.

Continued political commitment is essential in all polio endemic countries, to support the acceleration of eradication activities. The ongoing support of donor countries is essential to assure the necessary human and financial resources are made available to polio-endemic countries. Access to children is needed, particularly in Nigeria, where political and financial differences between key states and the federal government were unexpectedly given voice in the form of untrue rumors about the safety of the oral polio vaccine. As a result, immunization activities in the states that need them most were delayed and/or suspended during the effort to address local concerns. Polio-free countries must maintain high levels of routine polio immunization and surveillance. The continued leadership of the United States is critical to ensure we meet these challenges.

THE ROLE OF ROTARY INTERNATIONAL

Since 1985, Rotary International, a global association of more than 30,000 Rotary clubs, with a membership of over 1.2 million business and professional leaders in 166 countries, has been committed to battling this crippling disease. In the United States today there are nearly 7,700 Rotary clubs with some 400,000 members. All of our clubs work to promote humanitarian service, high ethical standards in all vocations, and international understanding. Rotary International stands hand-in-hand with the United States Government and governments around the world to fight polio through local volunteer support of National Immunization Days, raising awareness about polio eradication, and providing financial support for the initiative. In 2003, members of Rotary clubs around the world announced the results of their second polio eradication fundraising campaign. Rotarians far exceeded the U.S. $80

million goal they had set by raising U.S. $119 million in cash and commitments. Rotary firmly believes that the vision of a world without polio can be realized and that the time for action is now. By the time the world is certified polio-free, Rotary's contribution to the global polio eradication effort will exceed U.S. $600 million.

Rotary International's commitment to the global polio eradication represents the largest contribution by an international service organization to a public health initiative ever. These funds have been allocated for polio vaccine, operational costs, laboratory surveillance, cold chain, training and social mobilization in 122 countries. More importantly, tens of thousands of Rotarians have been mobilized to work together with their national ministries of health, UNICEF and WHO, and with health providers at the grassroots level in thousands of communities.

In the United States, Rotary has formed and leads the United States Coalition for the Eradication of Polio, a group of committed child health advocates that includes Rotary, the March of Dimes Birth Defects Foundation, the American Academy of Pediatrics, the Task Force for Child Survival and Development, the United Nations Foundation, and the U.S. Fund for UNICEF. These organizations join us in expressing our gratitude to you for your staunch support of the international program to eradicate polio. For fiscal year 2004, you appropriated a total of $106.4 million for the polio eradication efforts of the CDC. This investment has helped to make the United States the leader among donor nations in the drive to eradicate this crippling disease.

FISCAL YEAR 2005 BUDGET REQUEST

For fiscal year 2005, we respectfully request that you maintain the level of funding that was provided in fiscal year 2004 ($106.4 million) for the targeted polio eradication efforts of the Centers for Disease Control and Prevention. It is important to meet this level of funding due to the increased costs of the accelerated eradication program, and to respond to the increase in supplementary immunization activities in endemic countries, the need to maintain immunity in polio-free areas and maintain certification standard surveillance. This will ensure that we protect the substantial investment we have made to protect the children of the world from this crippling disease by enabling us to conduct the necessary eradication activities to eliminate polio in its final strongholds—the Indian sub-continent and sub-Saharan Africa.

THE ROLE OF THE U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Rotary commends CDC for its leadership in the global polio eradication effort, and greatly appreciates the Subcommittee's support of CDC's polio eradication activities. For fiscal year 2004, the Subcommittee appropriated a total of $106.4 million for the CDC's global polio eradication activities. Due to Congress' unwavering support, in 2004 CDC is able to:

—Support the international assignment of more than 200 long-term epidemiologists, virologists, and technical officers to assist the World Health Organization and polio-endemic countries to implement polio eradication strategies, and 16 technical staff to assist UNICEF and polio-endemic countries. This includes 19 CDC staff on direct assignment to WHO and UNICEF.

—Provide $50 million to UNICEF for approximately 540 million doses of polio vaccine and $9 million for operational costs for NIDs in all polio-endemic countries and other high-risk countries in Asia, the Middle East and Africa. Most of these NIDs would not take place without the assurance of CDC's support.

—Provide over $18 million to WHO for surveillance, technical staff and NIDs' operational costs, primarily in Africa. As successful NIDs take place, surveillance is critical to determine where polio cases continue to occur. Effective 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.

—Train virologists from all over the world in advanced poliovirus research and public health laboratory support. CDC's Atlanta laboratories serve as a global reference center and training facility.

—Provide the largest volume of both operational (poliovirus isolation) and technologically sophisticated (genetic sequencing of polio viruses) lab support to the 147 laboratories of the global polio laboratory network. CDC has the leading specialized polio reference lab in the world.

—Serve as the primary technical support agency to WHO on scientific and programmatic research regarding: (1) laboratory containment of wild poliovirus stocks following polio eradication, and (2) when and how to stop or modify 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 all 47 countries of the Americas are free of indigenous measles, due in part to improvements in the public health infrastructure implemented during the war on polio. The disease surveillance system—the network of laboratories and trained personnel established during the Polio Eradication Initiative—is now being used to track measles, rubella, yellow fever, meningitis, and other deadly infectious diseases. NIDs for polio have been used as an opportunity to give children essential vitamin A, which, like polio, is administered orally, saving the lives of 1.25 million children since 1998. The campaign to eliminate polio from communities has led to an 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. Additionally, the unprecedented cooperation between the public and private sectors serves as a model for other public health initiatives. Polio eradication is a cost-effective public health investment, as its benefits accrue forever.

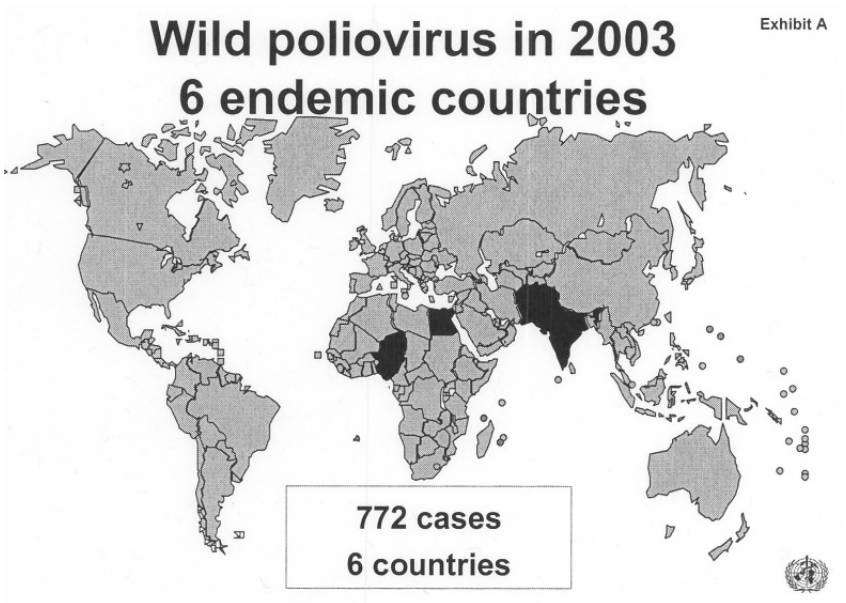
RESOURCES NEEDED TO FINISH THE JOB OF POLIO ERADICATION

The World Health Organization estimates that $765 million is needed from donors for the period 2004–2005 to help polio-endemic countries complete the polio eradication strategy. In the Americas, some 80 percent of the cost of polio eradication efforts was 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 ask the United States to continue its financial leadership in order to see this initiative to its successful conclusion as quickly as possible.

The United States' commitment to polio eradication has stimulated other countries to increase their support. Other countries that have followed America's lead and made special grants for the global Polio Eradication Initiative include the United Kingdom ($425 million), the Netherlands ($112 million), and Canada ($85 million). Japan, which has contributed $231 million, recently expanded its support to polio eradication efforts in Africa. Even the tiny country of Luxembourg has invested in global polio eradication by contributing $4.2 million. In both 2002 and 2003 the members of the G8 committed to provide sufficient resources to eradicate polio as part of its Africa Action Plan. In addition to the ongoing contributions made by historic donors such as United States, the United Kingdom, and Canada, new commitments of $37 million and $4 million were made by France and Russia in response to the G8 pledge.

Intense political commitment on the part of endemic nations is also essential to ensuring polio eradication is achieved. In January 2004, health ministers of the six remaining endemic countries (Afghanistan, Egypt, India, Niger, Nigeria, and Pakistan) gathered at a meeting convened at WHO in Geneva to declare their commitment to supporting intensified supplementary immunization activities in the "Geneva Declaration for the Eradication of Poliomyelitis." In addition, resolutions supporting polio eradication were taken by the African Union and the Organization of the Islamic Conference. Each of these resolutions encourages member states to place a high priority on completing the job of polio eradication.

Your discipline, commitment and endurance have brought us to the brink of victory in the great race against this ancient scourge. Polio cripples and kills. It deprives our children of the capacity to run, walk and play. Other great health crises loom on the horizon. Your continued support for this initiative helps ensure that today's children possess the strength and vitality to grow up and fight against the health threats of future generations.



PREPARED STATEMENT OF THE NATIONAL COUNCIL ON FOLIC ACID

The National Council on Folic Acid (NCFA) is a partnership of over 80 national organizations and associations, state folic acid councils and government agencies whose mission is to improve health by promoting the benefits and consumption of folic acid. Our goals are to reduce folic acid preventable birth defects by recommending that women of childbearing age take 400 micrograms of synthetic folic acid daily, from fortified foods and/or supplements, in addition to consuming food folate from a varied diet and to communicate and promote emerging and new science on folic acid, especially that relate to maternal and child health. The undersigned members of NCFA respectfully recommend that at least $5 million be appropriated in fiscal year 2005 for the Centers for Disease Control and Prevention's Folic Acid Education Campaign.

FOLIC ACID AND BIRTH DEFECTS

Folic acid, a B-vitamin, is critical for proper cell division and growth. It is especially important during the early weeks of pregnancy when the embryonic neural tube, which later becomes the brain and central nervous system, is forming and closing. Defects in closure of the neural tube result in the development of a group of birth defects commonly referred to as neural tube defects (NTDs). The two most common NTDs are spina bifida and anencephaly. Closure of the neural tube occurs early in the development, before most women know that they are pregnant. The consumption of only 400 micrograms of folic acid daily taken prior to conception and early in gestation can prevent as many as 70 percent of NTDs.

The birth defects such as anencephaly and spina bifida, have a great social and economic impact on our nation. The average total lifetime cost to society for each infant born with spina bifida is approximately $532 thousand, while estimated annual medical and surgical costs for persons living with spina bifida in the United States exceed $200 million.[1] Fortification of the grain supply is a significant factor in the 32 percent decline in the rates of spina bifida. In order to continue this trend, however, considerable effort is still needed to increase the number of reproductive aged women who consume 400 micrograms of folic acid each day. But, due to the growing popularity of low-carbohydrate diets many women are abandoning bread and other grains, thereby reducing their intake of folic acid.

[1] Centers for Disease Control and Prevention, MMWR, 1989.

FOLIC ACID AWARENESS AND COUNSELING

Only 20 percent of women know that folic acid can prevent birth defects.[2] Consequently, women generally are low consumers of folic acid, with only 30 percent of all women consuming a vitamin supplement with folic acid every day. Of those who take a daily multi-vitamin, 25 percent forget to take it every day.

We know that health care providers should screen women of childbearing age for folic acid consumption in an effort to promote taking a daily multi-vitamin and to prevent neural tube defects. We also know that 53 percent of women not taking a daily multi-vitamin indicated that they would likely do so if their health provider simply encouraged them.[3]

Following that logic, the undersigned NCFA members recommend that at least $5 million be appropriated to fund the Centers for Disease Control and Prevention's Folic Acid Education Campaign, which is housed with the National Center on Birth Defects and Developmental Disabilities. This funding is necessary to continue the Center's programming devoted on raising folic acid public awareness and training of health professionals on how to discuss folic acid consumption with their patients.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 93,700-member American Academy of Family Physicians submits this statement for the record in support of the Section 747 Primary Care Medicine and Dentistry Cluster. The Academy also supports the Agency for Healthcare Research and Quality (AHRQ) and rural health programs.

Section 747 is the only national program that funds family physician training and includes dollars for general internal medicine/general pediatrics; physician assistants and general/pediatric dentistry. The fiscal year 2004 spending bill provides only $82 million to Section 747, a figure that is $10 million below the fiscal year 2003 levels. The Congressionally established Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) recommends $198 million for Section 747.

SECTION 747 PRIMARY CARE MEDICINE AND DENTISTRY CLUSTER

Background

Section 747 supports family medicine training programs in medical school and in residency programs. It is specifically designed to meet two goals: increase the number of primary care physicians, and boost the number of people who will provide care to the underserved. The Institute of Medicine defines primary care physicians as family physicians, general internists and general pediatricians.

Family physicians provide comprehensive, coordinated and continuing care to patients of both genders and all ages and ethnicities, regardless of medical condition. These residency-trained, primary care specialists treat babies with ear infections, adolescents who are obese, adults with depression and seniors with multiple, chronic illnesses. And because they focus on prevention, primary care, and integrating care for patients, they are able to treat illnesses early; cost-effectively and when necessary, help patients navigate our complex health system and find the right subspecialists.

Section 747 funding has led thousands of physicians to go into primary care and family medicine and serve millions of patients. A study by the Robert Graham Center for Policy Studies showed that medical schools that received Section 747 family medicine funds produced more medical students who:

—Practiced in family medicine or primary care;
—Practiced in a rural area; or
—Practiced in a whole county Primary Care Health Professions Shortage Area (HPSAs) (i.e., counties with inadequate numbers of family physicians, general pediatricians, general internists or obstetrician/gynecologists).

The study showed that continued funding during the years of medical school training had more of a positive impact than intermittent funding.

Another Graham Center report revealed that more Americans depend on family physicians than any other medical specialty: without family physicians, the majority of U.S. counties would become Primary Care Health Professions Shortage Areas. Of the 3,142 counties in the United States, 1,184 (38 percent) are full or partial county HPSAs, which includes more than 41 million Americans.

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[2] March of Dimes, June 2002.
[3] March of Dimes, June 2002.

Funding for Programs Historically Under Threat

However, the health professions programs have been under fire for many years, and, as a result, funding has been threatened during several fiscal cycles. For example, the Administration's fiscal year 2005 budget would eliminate funding for Section 747 and cuts funding severely for Title VII. Reasons differ for these cutbacks, but center mainly around disagreements regarding the long-term role of the federal government in training physicians, and uncertainty about program outcomes and effectiveness.

Most recently, the Office of Management and Budget (OMB) attempted to express these arguments in the 2003 Program Assessment Rating Tool (PART). In that document, OMB criticized all of the Title VII Health Professions programs as lacking a focused objective. However, Section 747, in particular, has a clear purpose and has been successful in achieving its goals. The OMB evaluation lumps all of the programs together and does not evaluate them individually. By definition, these programs will have different goals, different levels of effectiveness and different histories, making the PART evaluation unsophisticated, at best. Additionally, since the federal government has been struggling with a budget shortfall, programs with the slightest amount of negative attention have been tempting targets for budget cutbacks.

Nonetheless, these training programs still enjoy a great deal of support from members of the Appropriations Committees in both the Senate and House, which the Academy appreciates. And, with the exception of the fiscal year 2004 spending bill, Congress has consistently restored funding for these programs.

The Academy strongly believes that the federal government must maintain appropriate funding for Section 747 family medicine training programs. The rationale for this comes from two sources: the steady reliance on family physicians in the current U.S. healthcare system and the Academy's new proposal to restructure future Section 747 family medicine training programs for the coming healthcare system. In short, family physicians are key to a modern healthcare system and more money is needed to modernize their training.

Preserve the U.S. Health Care Safety Net

The Academy supports the Administration's commitment to funding increases to build more Community Health Centers (CHC) and supplement the National Health Service Corps (NHSC). However, we believe that increasing funding for CHCs and the NHSC is only a partial solution. Without support for family physician training, there will be fewer of the physicians who work in these centers or practice in underserved areas. Thousands of family physicians will be needed if the growth in the number of CHCs sites and NHSC staff is to be realized.

Specifically, nearly half of the physicians who staff the nation's Community Health Centers are family physicians. And, since 1971, the National Health Service Corps has placed more than 18,000 health care providers in underserved areas: almost half of the NHSC doctors were family physicians. Finally, according to data from the National Association of Community Health Centers, in 2002, the majority of CHC employees were primary care physicians who were responsible for almost 22 million patient visits.

Invest in Cost-Effective, Quality Care

Unlike all other developed countries, the United States does not have a primary care-based health care system. While other developed countries have about equal numbers of primary care doctors and subspecialists, less than one-third of the U.S. physician workforce is primary care doctors (including family physicians). As a result, about two thirds of the U.S. physician workforce is made up of subspecialists.

In addition, compared to those in other developed countries, we spend the most per capita on healthcare but have the worst healthcare outcomes. More than 20 years of evidence have shown that a primary care-based health system produces greater health and economic benefits. Boosting support for Section 747, which funds training for family physicians and for other primary care disciplines, could allow patients in the United States to enjoy those benefits.

Specifically, research reveals that primary care is effective: leading to reduced all-cause mortality and mortality due to cardiovascular and pulmonary diseases; less emergency department and hospital use; better preventive care; better detection of breast cancer, and reduced incidence and mortality due to colon and cervical cancer. Studies have also shown proof of efficiency: fewer tests; higher patient satisfaction; lower medication use and lower care-related costs. Finally, the data indicates that primary care promotes equity among different populations: health disparities are reduced, particularly for areas with the highest income inequality, resulting in improved vision, more complete immunization, better blood pressure control, and bet-

ter oral health. Supporting Section 747 family medicine training would produce more family physicians, physicians who are cost-effective and provide high quality care.

AGENCY FOR HEALTHCARE, RESEARCH AND QUALITY

The Academy recommends $443 million for the Agency for Healthcare, Research and Quality (AHRQ). AHRQ conducts primary care and health services research geared to physician practices, health plans and policymakers that helps the American population as a whole. In short, the agency translates research findings from basic science entities like the National Institutes of Health (NIH) into information that doctors can use every day in their practices. Another key function of the agency is to support research on the conditions that affect most Americans.

AHRQ Translates Research into Everyday Practice

Congress has provided billions of dollars to the National Institutes of Health, which has resulted in important insights in preventing and curing major diseases. AHRQ takes this basic science and produces information that physicians can use every day in their practices. AHRQ also distributes this information throughout the health care system. In short, AHRQ is the link between research and the patient care that Americans receive.

For example, research shows that that beta blockers reduce mortality. AHRQ supported research to help physicians determine which patients with heart attacks would benefit from this medication.

AHRQ Supports Research on Conditions Affecting Most Americans

Most typical Americans get their medical care in doctors' offices and clinics. However, most medical research comes from the study of extremely ill patients in hospitals

AHRQ studies and supports research on the types of illness that trouble most people. In brief, AHRQ looks at the problems that bring people to their doctors every day—not the problems that send them to the hospital.

For example, AHRQ supported research that found older antidepressant drugs are as effective as new antidepressant medications in treating depression, a condition that affects millions of Americans.

Provisions in the Medicare Modernization Act

In addition, the new Medicare law also directs the agency to study the "clinical effectiveness and appropriateness of specified health services and treatments." While the law authorizes $50 million for this effort, the Academy supports the $75 million figure that is included in the Senate budget resolution.

Moreover, the law asks the agency to establish a new "Citizens' Health Care Working Group," to initiate a nationwide public debate about improving the health care system with the goal of providing every America high quality and affordable health care coverage. The AAFP also supports funding for this new commission.

RURAL HEALTH PROGRAMS

Continued funding for rural programs is vital to provide adequate health care services to America's rural citizens. We support the Federal Office of Rural Health Policy; Area Health Education Centers; the Community and Migrant Health Center Program; and the NHSC. State rural health offices, funded through the National Health Services Corps budget, help states implement these programs so that rural residents benefit as much as urban patients.

CONCLUSION

The Academy urges Congress to increase funding for Section 747 family medicine training (the Advisory Committee on Training in Primary Care Medicine and Dentistry $198 million for Section 747); $443 million for AHRQ and support for rural health programs. Federal support is vital to sustain and improve America's health care system.

PREPARED STATEMENT OF THE TRI-COUNCIL FOR NURSING

The Tri-Council for Nursing appreciates the opportunity to comment on fiscal year 2005 appropriations for nursing programs. The Tri-Council for Nursing is an alliance of four national nursing organizations—the American Association of Colleges of Nursing (AACN), the American Nurses Association (ANA), the American Organization of Nurse Executives (AONE), and the National League for Nursing (NLN).

The Tri-Council is focused on leadership and excellence in nursing. Together, we represent the breadth and scope of nursing; including practicing nurses, nurse executives, nurse educators, and nurse researchers.

The Tri-Council gratefully acknowledges this Subcommittee's support for nursing education and research. We appreciate your continued recognition of the important role nurses play in the delivery of health care services and the increased need to fund nursing education programs, nursing research, and innovative practice models. Unfortunately, the nursing shortage continues to worsen, therefore we are again urging you to invest in nursing.

Today, the burgeoning nursing shortage is impacting health care delivery throughout the nation. The increasing health care demands of the aging U.S. population and changes in the nurse workforce have combined to create a shortage unlike any other. A fundamental shift has occurred in the registered nurse (RN) workforce over the last two decades. As occupational opportunities for young women have expanded, and the changing health care environment has increased stresses on nursing, the number of young people entering nursing has declined. The lack of young people in nursing has resulted in a steady and dramatic increase in the average age of the U.S. nurse. Today, the average working RN is over 43 years old. The average nurse educator is over 50 years old.

This shortage is growing just as the need for nursing services is mounting. America's demand for nursing care is expected to balloon over the next 20 years as a result of the aging of the population, advances in technology, and various economic and policy factors. On February 11, 2004, the Bureau of Labor Statistics reported that registered nursing will have the greatest job growth of all U.S. professions in the time period spanning 2002–2012. During this ten-year period, health care facilities will need to fill more than 1.1 million RN job openings. The Division of Nursing at the Health Resources and Services Administration projects that, absent aggressive intervention, the supply of nurses in America will fall 29 percent below requirements by the year 2020.

The nursing shortage is already having a detrimental impact on the health care system. Numerous recent studies have shown that nursing shortages contribute to medical errors, poor patient outcomes, and increased mortality rates. A study published in the May 30, 2002, *New England Journal of Medicine* reported that higher levels of nursing care correlate with better patient care. And a Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) study published in 2002 shows that nearly one-quarter of all unanticipated deaths or injuries result from nurse shortages. Another study published in the October 23, 2002 Journal of the American Medical Association found that among the surgical patients studied, there was a pronounced correlation between nursing shortages and both patient mortality and failure to rescue.

This growing nursing shortage has effects well beyond domestic health care. Nurses are integral in everything from adequate terrorism preparedness, to veterans' health delivery, to disaster response. In addition, the activation of military reserves is drawing nurses out of the domestic labor market. Therefore, this shortage threatens our very strength as a nation.

NURSING WORKFORCE DEVELOPMENT

Federal support for Nursing Workforce Development in Title VIII of the Public Health Service Act (PHSA) is unduplicated and essential. Recognizing the impact of the nursing shortage, the 107th Congress took the visionary step of passing the Nurse Reinvestment Act (Public Law 107–205). This law improved the programs of Title VIII to meet the unique characteristics of today's shortage. It contained public service announcements, geriatric training grants, and a nurse faculty loan repayment program. It also expanded existing programs in Title VIII to include a scholarship program, career ladder programs, and retention grants for enhancing patient care delivery systems.

In fiscal year 2004, the hard work of this Subcommittee resulted in $142 million in funding for Title VIII programs. We strongly urge you to increase funding for Title VIII programs by at least $63 million to a total of $205 million in fiscal year 2005. The Tri-Council believes that the need for this increase is borne out by the HRSA information for 2003 indicating that only 2 percent of the applications for nursing scholarships were funded, and a mere 8 percent of the nurse education loan repayments were funded.

The Title VIII authorities are:

Nurse Education, Practice, and Retention Grants

This section, formerly known as the Basic Nurse Education and Practice, was expanded and reorganized by the Nurse Reinvestment Act. Education grant areas

were reorganized to include: expanding enrollments in baccalaureate nursing programs; developing internship and residency programs to enhance mentoring and specialty training; and providing new technologies in education including distance learning.

Practice grant areas include: expanding practice arrangements in non-institutional settings to improve primary health care in medically underserved communities; providing care for underserved populations such as the elderly, HIV/AIDS patients, substance abusers, homeless, and domestic abuse victims; providing skills necessary to practice in existing and emerging health systems; and developing cultural competencies.

Retention grant areas include career ladders and improved patient care delivery systems. The career ladders program supports education programs designed to assist individuals in obtaining clinical and theoretical education required to enter the profession, and to promote career advancement within nursing. In fiscal year 2003, HRSA received 301 applications for career ladder grants. Unfortunately, funding levels allowed HRSA to award a total of 12 grants.

Enhancing patient care delivery system grants encourage nurses to remain in patient care by providing grants to facilities to enhance collaboration and communication among nurses and other health care professionals, and to promote nurse involvement in the organizational and clinical decision-making processes of a health care facility. Best practices for these nurse administration programs have been identified by the American Nurse Credentialing Center's Magnet Recognition Program. These best practices have been shown to double nurse retention rates, increase nurse satisfaction, and improve patient care. In fiscal year 2003, HRSA received 122 applications for enhanced patient care delivery systems; HRSA was able to fund 14.

Nurse Education, Practice, and Retention Grants received $31.8 million in fiscal year 2004 appropriations.

National Nurse Service Corps

The nurse service corps is comprised of a loan repayment program and a scholarship program, the Secretary of HHS has the authority to allocate funds between the two areas. The Nurse Education Loan Repayment Program (NELRP) repays nursing student loans in return for at least 2 years of practice in a facility with a critical nursing shortage. For the first 2 years of service, the NELRP will repay 60 percent of the RN's student loan balance. If the nurse elects to stay for another year, an additional 25 percent of the loan will be repaid. Within 3 years, a nurse can pay off 85 percent of his/her student loans.

The NELRP has benefited from the support of this Subcommittee, as well as the administration. It boasts a proven track record of delivering nurses to facilities hardest hit by the nursing shortage. HRSA has given NELRP funding preference to skilled nursing facilities, disproportionate share hospitals, and departments of public health. However, lack of funding has hindered the full implementation of this program. In fiscal year 2003, HRSA received more than 8,300 applications for the NELRP. Due to lack of funding, only 602 loan repayments were awarded. Therefore, 92 percent of the nurses willing to immediately begin practicing in facilities hardest hit by the shortage were turned away from this program.

The nursing scholarship program offers funds to nursing students who, upon graduation, agree to work for at least 2 years in a health care facility with a critical shortage of nurses. Preference is given to students with the greatest financial need. Like the loan repayment program, the nursing scholarship program as been stunted by a lack of funding. For fiscal year 2003, HRSA received more than 4,500 applications for the nursing scholarship. Due to lack of funding, a mere 94 scholarships were awarded. Therefore, 98 percent of the nursing students willing to work in facilities with a critical shortage of nurses were also denied access to the corps.

The National Nurse Service Corps received $26.7 million in fiscal year 2004 appropriations.

Nurse Faculty Loan Program

This program establishes a loan repayment fund within schools of nursing to increase the number of qualified nurse faculty. Nurses may pursue a master's or doctoral degree. They must agree to teach at a school of nursing in exchange for cancellation of up to 85 percent of their educational loans, plus interest, over a 4-year period. Loans may cover the costs of tuition, fees, books, laboratory expenses, and other reasonable education expenses.

This program is critical given the worsening shortage of nursing faculty. Last year, schools of nursing were forced to turn away tens of thousands of qualified applicants due largely to the lack of faculty. In fiscal year 2003, HRSA awarded 55 nurse faculty loan repayments.

The Nurse Faculty Loan Program received $4.9 million in fiscal year 2004 appropriations.

Nursing Workforce Diversity

This program provides funds to enhance diversity in nursing education and practice. It supports projects to increase nursing education opportunities for individuals from disadvantaged backgrounds—including racial and ethnic minorities, as well as individuals who are economically disadvantaged. Racial and ethnic minorities currently comprise more than 25 percent of the nation's population and will comprise nearly 40 percent by the year 2020. Only 12 percent of the RNs in the United States come from diverse backgrounds. Increasing the number of RNs from diverse races and cultures allows them to address the prevention, treatment, and rehabilitation needs of an increasingly diverse population. For fiscal year 2003, HRSA received 122 submissions for nursing workforce diversity grants. HRSA was only able to fund 20.

Nursing Workforce Diversity received $16.4 million in fiscal year 2004 appropriations.

Advanced Nurse Education

Advanced practice registered nurses (APRNs) are registered nurses (RNs) who have attained advanced expertise in the clinical management of health conditions. Typically, an APRN holds a master's degree with advanced didactic and clinical preparation beyond that of the RN. Most have practice experience as RNs prior to entering graduate school. Practice areas include, but are not limited to: anesthesiology, family medicine, gerontology, pediatrics, mental health, midwifery, neonatology, and women's & adult health. Title VIII grants have supported the development of virtually all initial state and regional outreach models using distance learning methodologies to provide advanced study opportunities for nurses in rural and remote areas.

These grants also provide traineeships for masters and doctoral students. Title VIII funds more than 60 percent of U.S. nurse practitioner (NP) education programs and assists 83 percent of nurse midwifery programs. Over 45 percent of advanced nursing graduates go on to practice in medically underserved communities, and in areas with large Medicaid populations. Many provide care to minority or disadvantaged patients. In fiscal year 2003, HRSA funded 35 advanced education nursing grants, 335 advanced education nursing traineeships, and 69 nurse anesthetist traineeships.

Advanced Education Nursing received $58.6 million in fiscal year 2004 appropriations.

Comprehensive Geriatric Education Grants

This authority awards grants to train and educate nurses in providing health care to the elderly. Funds are used to train individuals who provide direct care for the elderly, to develop and disseminate geriatric nursing curriculum, to train faculty members in geriatrics, and to provide continuing education to nurses who provide geriatric care. The growing number of elderly Americans and the impending health care needs of the baby boom generation make this program critically important. In fiscal year 2003, HRSA received 92 applications for the comprehensive geriatric training program, 17 grants were funded.

Comprehensive Geriatric Education Grants received $3.5 million in fiscal year 2004 appropriations.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

The Tri-Council also urges the Subcommittee to increase funding for the NINR, one of the institutes at the National Institutes of Health (NIH). Nursing research is an integral part of the effectiveness of nursing care. Advances in nursing care arising from nursing and other biomedical research improves the quality of patient care and has shown excellent progress in reducing health care costs. Research programs supported by the NINR address a number of critical public health and patient care questions. The research is driven by real and immediate problems encountered by patients and families. Study results offer the clear prospect of improving health, reducing morbidity and mortality, and lowering costs and demand for health care.

Recent studies have focused on the effects of hospital restructuring, such as changes in nurse staffing, on patient care; the incidence and risk factors for uterine rupture in pregnancies following cesarean section; and the means to help family caregivers provide high-quality long, term care for loved ones with chronic health care needs. In addition, NINR is leading the NIH research on end-of-life and pallia-

tive care. The NINR is the second-lowest funded institute at NIH and provides vital health care research for the nursing community. The Tri-Council recommends increasing funding for the NINR in fiscal year 2005.

CONCLUSION

While the Tri-Council is encouraged by a recent resurgence of interest in the nursing profession, we are concerned by the fact that Title VIII funding levels have not been sufficient to assist qualified students enter the nursing profession. The nursing shortage will continue to worsen if significant investments are not made in nursing workforce development programs. Recent efforts have shown that aggressive and innovative recruitment efforts can help avert the impending nursing shortage—if they are adequately funded.

Thirty one years ago, this committee invested $153.6 million in the fiscal year 1974 programs of Title VIII. Inflated to today's dollars, this long-ago appropriation would equal $574 million (more than four times the fiscal year 2004 appropriation). Today's shortage is more dire and systemic than that of the 1970's. The Tri-Council asks you to meet today's shortage with a relatively modest investment of $205 million in Title VIII programs. Additionally, an investment in the NINR will help assure that these nurses are equipped with the information needed to provide the best care possible.

PREPARED STATEMENT OF THE NATIONAL AREA HEALTH EDUCATION CENTERS ORGANIZATION

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Increase funding for the health professions and nursing education programs under Title VII and Title VIII of the Public Health Service Act to at least $550 million for fiscal year 2005.
—Restore funding for Area Health Education Centers (AHECs) to fiscal year 2003 level of $33.1 million.
—Restore funding for Health Education Training Centers (HETCs) to fiscal year 2003 level of $4.3 million.

Mr. Chairman, and members of the subcommittee, I am pleased to present this testimony on behalf of the National AHEC Organization (NAO).

By way of brief introduction, my name is Linda Kanzleiter. I am an Assistant Professor at the Pennsylvania State University College of Medicine and the Associate Director for the dual state Pennsylvania-Delaware Area Health Education Center Program (PA-DEL AHEC).

As a member of NAO, the professional organization representing the national network of Area Health Education Center Programs (AHECs) and Health Education Center Programs (HETCs), I come to you today to demonstrate the AHEC/HETC network as a well-established national system of community and academic partnerships that increases access to quality health care services for our nation, especially the growing number of uninsured and underinsured populations by improving the supply and distribution of our health professions workforce.

Three essential strategies were developed: the Neighborhood Health Centers, later to be named Community Health Centers (1964); the National Health Service Corps (NHSC) established in 1970; and the Carnegie Commissions Report establishing the AHEC program (1970) and HETC program, established for Border and non-border areas (1989). The three programs were created in different acts and at different times, but were brought together within the Public Health Service within a 3-year period.

The Community Health Centers are dedicated to providing preventative and ambulatory health care to the most uninsured and underinsured populations by placing point-of-service facilities in these areas; and the NHSC is committed to placing health professionals to the areas which have the most difficult time recruiting and retaining health professionals. However, it is the AHEC & HETC organization that recruits, trains and retains a health professions workforce committed to working with the underserved. This goal is accomplished through bridging the resources of academia to communities.

THE NATIONAL AHEC AND HETC ORGANIZATION

The effectiveness of the AHEC & HETC organization rests with its community and academic leadership, collaborative practices and committed partnerships of numerous community-based organizations representing 48 AHEC & HETC programs, which direct 180 centers housed in 43 states.

Fundamental to the health care infrastructure of the nation is the recruitment and retention of a qualified health professions workforce. The strategic functions of the AHEC & HETC programs is to facilitate the recruitment and retention of the current and future health care professions workforce as a means to increase access to health care services, and to provide a vehicle to access community-based and academic-based health professionals integral to the promotion, development, dissemination and management of public and community health issues. Claude Earl Fox, former Administrator of HRSA, said it so well: "AHEC programs are a catalyst in both the communities they bridge—spurring the academic enterprise to attend to the needs of the underserved people—and sparking the community of people served to involve themselves in the training of health professionals. This is a necessary first step in addressing the health needs of any community."

The strength of the national AHEC & HETC organization is their cultural diversity and scope of work. The key functions of the AHEC & HETC network rests with access and building capacity, which:

—Creates community-based education and training networks that are developed through linking health professionals and their practices in underserved areas with academic centers and programs to create clinical training experiences for primary care residents, medical students, dental medicine students, nurse practitioners, physician assistants, nurses and other allied health students.

—Recruits practitioners from the incumbent health professions workforce to medically underserved communities through established recruitment programs and special placement opportunities. Special re-entry programs offered to retrain nurses and other health careers for return to the workforce, and job re-training offered to adult learners interested in developing a career ladder or career change.

—Retains practitioners working with disenfranchised populations and medically underserved communities through innovative and traditional continuing medical education programs, building linkages between the community practitioners and academic centers, providing telemedicine initiatives and self directed educational modules to maintain knowledge and skills of health professionals, and fostering telemedicine programs for clinical consultation in some areas.

—Prepares interested primary and secondary students from rural, urban and cultural diverse communities for college and/or career programs in the health professions through academic readiness programs. With a cultural and ethnic diversity blending the nation, emphasis is placed on preparing under-represented minority students into the health careers through science, math, and English preparatory programs.

—Retains the commitment of high school students, medical students, health professions students and residents through the pipeline of health professions education and training through selective mentoring, shadowing and special interest programs.

—Builds capacity within the health care community to address community and public health issues such as bioterrorism, Healthy People 2010 objectives.

THE PA-DE AHEC PROGRAM

The PA-DE AHEC Program is celebrating its 10th Anniversary this year. Although Delaware is new to the Commonwealth's and national AHEC organization, the leadership of the Delaware region brings an in-depth understanding of its state's health professions needs and a commitment to the mission of the national organization and Pennsylvania AHEC program.

The PA-DE AHEC Program houses an innovative dual state system that integrates and bridges academic centers with communities to strengthen and increase access:

—To health care services, especially in underserved communities,

—To communities and health care personnel integral to the public health infrastructure,

—To the academic and community-based health professions workforce,

—To the vital educational resources required to maintain the skills and knowledge of those vested with safe-guarding the health of Pennsylvania and Delaware,

—To the primary and secondary educational systems fostering interests in health careers, especially for cultural and ethically diverse schools students,

—To the medical, dental and mental health practice communities facilitating and responding to community and public concerns.

THE PA-DE AHEC ORGANIZATION

The PA-DE AHEC Program has developed a dual state infrastructure that includes: the University of Pittsburgh Schools of Medicine, Nursing, Dentistry, Pharmacy and Public Health; the Pennsylvania State University College of Medicine, School of Nursing and Agromedicine Program; the Philadelphia College of Osteopathic Medicine; Temple University Schools of Medicine, Pharmacy, Nursing and Dentistry; Thomas Jefferson University, Jefferson Medical College and College of Nursing; Drexel University School of Medicine, University of Pennsylvania School of Dental Medicine and Midwifery Program, and Delaware University, School of Nursing.

Our medical education and training infrastructure also includes over 90 health science institutions, and a community-based teaching network of over 1,000 physicians and health professionals representing 12 medical, oral and public health disciplines, and numerous community organizations inclusive of Pennsylvania's 67 counties and Delaware's three counties.

About Pennsylvania and Delaware

Pennsylvania and Delaware, like the rest of the nation, share the problem of maldistribution of health care providers and limited access to essential health care services. Pennsylvania houses a population of over 12 million people within a geographic range of 46,000 square miles, and supports one of the largest aging populations in the nation. Traditional market forces have not been very effective in making health care available to rural and inner city residents. It is estimated that 21 percent or greater have no health care coverage and a significant proportion remain underinsured. Primary care access and provider shortage in the state have resulted in areas of 55 of 67 counties being designated as Health Professional Shortage Areas (HPSA), Medically Underserved Areas (MUA) or both. Dental Health Professions Shortage Areas and Mental Health Shortage Areas are representative of an increased number of counties without oral and mental health services.

Increasing Access to Health Care

The PA-DE AHEC has facilitated placement of over 31,000 students, representing 78,500 clinical training weeks. These students are primarily recruited to train in underserved communities. Working with 51 community health centers, federally qualified centers, and NHSC designated centers, the PA-DE AHEC fosters clinical training experiences that teach students the rewards and challenges of working with at-risk populations and the special knowledge and skills required to provide quality health care in communities with limited resources.

HEALTH PROFESSIONS RECRUITMENT AND RETENTION

Promoting the NHSC and State Loan Repayment and Scholarship programs are important first steps to introducing providers to Pennsylvania and Delaware. Developing and implementing math, science and English programs for students in disadvantaged school districts facilitates entrance into the health careers through a Grow Your Own approach to the health professions crisis. Special initiatives are also promoted in areas of nursing with re-entry programs (refresher courses for licensed nurses not practicing for five or more years), retraining programs that offer promotional and career advancement, and remedial programs that are targeted to the special adult learner seeking admission to the health careers. All AHEC regions look to facilitate nursing programs focused on recruitment, re-entry, retraining and retention initiatives.

In addition, the PA-DE AHEC Program provides self-directed study programs as way for practitioners to access continuing professional education programs in respect to the increasing professional and practice demands of their office and community. For example the most recent program, PA-DE AHEC is offering a self-directed learning program on the screening, diagnosing and treatment of endocrine disease, psychiatric disorders and co-morbidity. Web-based learning in areas of tobacco cessation and tobacco cessation pharmacopeias are also venues of self directed programs. In addition, statewide satellite broadcasts with capabilities to over 520 down link sites within the system add another venue for continuing professional education.

PUBLIC HEALTH INFRASTRUCTURE

Responding to the national, state and local needs of preparedness teams and public health workers, the PA-DE AHEC Program is an integral partner to the emerging public health infrastructure. The PA-DE AHEC provides, through its academic and community partnerships, program development as well as critical access to com-

munities, at-risk populations and the health professions workforce for emerging public health issues, such as bioterrorism preparedness training to health professionals, especially to agricultural and migrant communities. In addition we work with public health officials in areas of health promotion and disease prevention programs, which focus on minority health disparities and cultural sensitivity training for safety net providers. Many community and public health programs are also delivered to respond to the Healthy People 2010 objectives.

CRITICAL WORKFORCE ISSUES

Regardless of the 30 years of well-intended efforts by countless health professionals and policy makers, the nation's health care "safety net" program is not able to meet the growing health care needs of the country's uninsured and underinsured populations. Young adults no longer see clinical nursing as an acceptable career path, In fact, other health professions are at-risk; pharmacy is another example. Rural hospitals and health systems are also closing frequently; which adds another dimension to limiting access to health care services. The impact of hospital and system closures contributes to the unemployment rate in local communities and decreases the economic base. This fractured health care system looks to address the health care needs of an aging nation, which requires much of its health professions workforce.

Pennsylvania and Delaware are faced with similar concerns. Only 13 percent of Pennsylvania primary care physician workforce practice in rural areas. Furthermore, 25 percent of primary care physicians in the Commonwealth are 55 or older indicating a large number of potential retirees. Equally troublesome is documentation indicating that 20 percent will leave primary care practice in the state because of lack of practice coverage, reimbursement issues, lack of technology in rural areas, and professional isolation. Time is of the essence, and the important message is that AHEC is the foundation for recruiting, retaining and distributing a health professions workforce for the nation.

Mr. Chairman, I respectfully ask the Subcommittee to support our recommendation to increase funding for the Health Professions and Nursing Education programs under Title VII and Title VIII of the Public Health Service Act to a minimum of $550 million for fiscal year 2005. Our recommendations are consistent with those of the Health Professions and Nursing Coalition.

PREPARED STATEMENT OF THE NATIONAL LEAGUE FOR NURSING

The National League for Nursing (NLN)—representing more than 1,300 schools of nursing, 14,000 faculty and individual members, and 18 constituent leagues—appreciates the Subcommittee's past support for nursing education and your continued recognition of the important role nurses play in the delivery of our nation's health care services. NLN is concerned, however, that the advancements made by Congress to help alleviate the nursing shortage will be lost during the fiscal year 2005 appropriations process unless additional resources are expended. We urge your continued support for Title VIII—Nursing Workforce Development Programs by ensuring that these programs are funded at a minimum level of $205 million for fiscal year 2005.

Today's nursing shortage is very real and very different from any experienced in the past. The new nursing shortage is evidenced by an aging workforce; acute nursing shortages in certain geographic areas; and a shortage of nurses and nurse educators adequately prepared to meet patient need in a changing health care environment. As a result, the supply of appropriately prepared nurses and nursing faculty is inadequate to meet the needs of a diverse population. This shortfall will grow more serious over the next 5 years.

Congress did an admirable job of passing the Nurse Reinvestment Act in 2002. The new monies used to fund loans and scholarships are appreciated. However, it has become abundantly clear that significantly more funding is required to meet the existing need. In fiscal year 2003, for example, only 55 nurse faculty loans were awarded. Yet last year, schools of nursing were forced to turn away 29,284 qualified nursing students because of a lack of prepared nurse educators to teach them. This number is significantly greater than the 18,476 students who were turned away in 2002.

Schools of nursing are suffering from a continuing and growing shortage of faculty, which prevents these institutions from admitting many qualified students who are applying to their programs. NLN's 2002 Faculty Survey concludes that not enough qualified nurse educators exist to teach the number of nurses needed to ameliorate the nursing shortage. According to the Survey, this situation is not ex-

pected to improve in the near future, since an adequate number of nurse educators are currently not in the education pipeline.

The NLN Survey found three trends impacting the future of nursing education over the next decade:

The aging of the nurse faculty population

An average of 1.3 full-time faculty members per program left their positions in nursing education in 2002. About half the Survey respondents had at least one unfilled budgeted full-time faculty position and some have as many as 15 such positions.

Approximately 1,800 full-time faculty members leave their positions each year. About 10,000 master's level nurses graduate per year, 15 percent of whom would have to go into teaching just to maintain the status quo. Since this is highly unlikely, the gap between unfilled positions and the candidate pool will widen significantly.

The increasing number of part-time faculty

The number of part-time faculty has increased since 1996—nearly 17 percent in baccalaureate programs and 14 percent in associate degree programs. Approximately 23 percent of the estimated number of faculty FTEs is now provided by part-time faculty.

Part time employees are often not an integral part of the design, implementation, and evaluation of the overall nursing education program. Many may hold other positions that often limit their availability to students. Further, many part-time faculty have not been prepared for the faculty role.

The large number of nursing faculty who are not prepared at the doctoral level

Approximately half the full-time faculty in baccalaureate and higher degree programs holds a doctoral degree. In associate degree programs, doctorally-prepared faculty account for only 6.6 percent and the number is slightly more than 5 percent in diploma programs. Only 350 to 400 nursing students receive doctoral degrees each year and the pool of doctorally-prepared candidates for full-time nursing professorships is very limited.

Educators without doctoral degrees may lack credibility within a university setting and have limited opportunities to assume leadership positions. Institutions with low numbers of doctorally-prepared educators may be less likely to get funds to support research or educational innovations.

As important as educational incentives for future practicing nurses are the scholarships for doctoral students, who will instruct the next generation of nurses. Please do not allow us to lose ground in the fight against the nursing shortage—fund Title VIII nursing programs at a level commensurate with the severity of the health care crisis facing the nation today.

Your support will help ensure that nurses exist in the future who are prepared and qualified to take care of you, your family, and all those in this country who will need our care. If you have any questions about NLN's position or we can be of further assistance to you, please feel free to contact Kathleen Ream, NLN Manager of Government Affairs, at 703–241–3974.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS

The National Association of Children's Hospitals (N.A.C.H.) is pleased to have the opportunity to submit the following statement for the hearing record in support of the Children's Hospitals' Graduate Medical Education (CHGME) Payment Program in the Health Resources and Services Administration (HRSA).

On behalf of the nation's 60 independent children's teaching hospitals, we thank the Subcommittee for the remarkable achievement that Congress made last year in continuing to provide full, equitable GME funding for these hospitals, giving them a level of federal support for their teaching programs that is comparable to what all other teaching hospitals receive through Medicare. We urge the Subcommittee to continue to provide equitable funding for Children's Hospitals GME in fiscal year 2005 so that these institutions will have the resources to train and educate the nation's pediatric workforce.

N.A.C.H. is a not-for-profit trade association, representing more than 120 children's hospitals across the country. Its members include independent acute care children's hospitals, acute care children's hospitals organized within larger medical centers, and independent children's specialty and rehabilitation hospitals.

N.A.C.H. seeks to serve its member hospitals' ability to fulfill their four-fold missions of clinical care, education, research, and advocacy devoted to the health and

well being of all of the children in their communities. Children's hospitals are regional and national centers of excellence for children with serious and complex conditions. They are centers of biomedical and health services research for children, and they serve as the major training centers for future pediatric researchers, as well as a significant number of our children's doctors. These institutions are major safety net providers, serving a disproportionate share of children of low-income families, and they are also advocates for the public health of all children.

BACKGROUND: THE NEED FOR CHILDREN'S HOSPITALS GME

While they account for less than 1 percent of all hospitals, the independent children's hospitals train nearly 30 percent of all pediatricians, half of all pediatric specialists, and a majority of future pediatric researchers. They also provide required pediatric rotations for many other residents. They train about 4,000 residents annually, and the need for these programs is even more heightened by the growing evidence of shortages of pediatric specialists around the country.

Prior to initial funding of the CHGME program for fiscal year 2000, these hospitals were facing enormous challenges to their ability to maintain their training programs. The increasingly price competitive medical marketplace was resulting in more and more payers not covering the costs of care, including the costs associated with teaching.

The independent children's hospitals were essentially left out of what had become the one major source of GME financing for other teaching hospitals—Medicare—because they see few if any Medicare patients. They received only 1/200th (or less than 0.5 percent) of the federal support that all other teaching hospitals received under Medicare. This lack of GME financing, combined with the financial challenges stemming from their other missions, was threatening their teaching programs, as well as other important services.

In addition to their teaching missions, the independent children's hospitals are a significant part of the health care safety net for low-income children. On average, they devote nearly half of their patient care to children who are assisted by Medicaid or are uninsured. More than 40 percent of their care is for children assisted by Medicaid, and Medicaid covers only about 84 percent of the cost of that care. Without the Medicaid disproportionate share hospital (DSH) payments, Medicaid would cover only about 76 percent of children's hospitals' patient care costs. Further, these hospitals provide many important services from dental care to child abuse programs that are either uncovered or very underpaid.

The independent children's hospitals also are essential to the provision of care for seriously and chronically ill children in this country. They devote more than 75 percent of their care for children with one or more chronic or congenital conditions. They provide more than 40 percent to 75 percent of the inpatient care to children with many serious illnesses—from children with cancer or cerebral palsy, for example, to children needing heart surgery or organ transplants. In some regions, they are the only source of pediatric specialty care. The severity and complexity of illness and the services and resources that these institutions must maintain to assure access to this quality care for all children are also often inadequately reimbursed.

The CHGME program, and its relatively quick progress to full funding in fiscal year 2002, came at a critical time. Between 1997 and 2000, independent children's hospitals on average experienced declining operating margins and total margins. By fiscal year 2000 more than a quarter of the hospitals were not able to cover their operating costs with operating revenues, and nearly 20 percent were not able to cover their total costs with total revenues. Thanks to the CHGME program, these hospitals have been able to maintain and strengthen their training programs.

Continuing this critical CHGME funding is more important for these hospitals than ever in light of state budget shortfalls in many states and the resulting pressures for significant reductions in state Medicaid programs. Because children's hospitals devote such a substantial portion of their care to children of low-income families, they are especially affected by cutbacks in state Medicaid programs.

The pediatric community, including the American Academy of Pediatrics, Association of Medical School Pediatric Department Chairs, and others, has recognized the critical importance of the GME programs of the independent children's teaching hospitals, not only to the future of the individual hospitals and their essential services but also to the future of the nation's pediatric workforce and the provision of children's health care and advancements in pediatric medicine overall.

Lastly, many of the independent children's hospitals are a vital part of the emergency and critical care services in their communities and regions. They are part of the emergency response system that must be in place for bioterrorism other public

health emergencies. Expenses associated with preparedness will add to their continuing costs in meeting children's needs.

CONGRESSIONAL RESPONSE

In the absence of any movement towards broader GME financing reform, Congress in 1999 authorized the Children's Hospitals' GME discretionary grant program to address the existing inequity in GME financing for the independent children's hospitals and ensure that these institutions could receive equitable federal support to sustain their teaching programs. The legislation was reauthorized in 2000 through fiscal year 2005 and provided for $285 million through fiscal year 2001 and such sums as may be necessary in the years beyond.[1] Congress passed both the initial authorization (as part of the "Healthcare Research and Quality Act of 1999") and the reauthorization (as part of the "Children's Health Act of 2000").

With the support of this Subcommittee, Congress appropriated initial funding for the program in fiscal year 2000, before the enactment of its authorization. Following that enactment, Congress moved substantially toward full funding for the program in fiscal year 2001 and completed that goal, providing $285 million in fiscal year 2002, $290 million in fiscal year 2003, and $303 million in fiscal year 2004. This represents an extraordinary achievement for the future of children's health care as well as for the nation's independent children's teaching hospitals.

The $285 million appropriated in fiscal year 2002 was distributed at the end of the fiscal year through HRSA to 59 children's hospitals according to a formula based on the number and type of full-time equivalent (FTE) residents trained, in accordance with Medicare rules as well as the complexity of care and intensity of teaching the hospitals provide. Consistent with the authorizing legislation, HRSA allocates the annual appropriation in bi-weekly periodic payments to eligible independent children's hospitals.

FISCAL YEAR 2005 REQUEST

N.A.C.H. respectfully requests that the Subcommittee continue equitable GME funding for the independent children's hospitals by providing $303 million for the program in fiscal year 2005—the level of funding requested by President Bush and equal to the fiscal year 2004 appropriation enacted in January 2004. We are grateful for the administration's recognition of the significance of the CHGME program.

Adequate, equitable funding for CHGME is an ongoing need. Children's hospitals continue to train new pediatric residents and researchers every year. Children's hospitals have appreciated very much the congressional support they have received, including the attainment of the program's authorization in fiscal year 2002 and continuation of full funding with an inflation adjustment in fiscal year 2003 and fiscal year 2004. Now, N.A.C.H. asks Congress to maintain this progress by enactment of the President's request.

Support for a strong investment in GME at independent children's teaching hospitals is consistent with the repeated concern the Subcommittee has expressed for the health and well being of our nation's children—through education, health, and social welfare programs. It also is consistent with the Subcommittee's repeated emphasis on the importance of enhanced investment in the National Institutes of Health (NIH) overall, and in NIH support for pediatric research in particular, for which we are very grateful.

The CHGME funding has been essential to the ability of the independent children's hospitals to sustain their GME programs. At the same time, it has enabled them to do so without sacrificing support for other critically important services that also rely on hospital subsidy, such as many specialty and critical care services, child abuse prevention and treatment services, poison control centers, services to low-income children who have inadequate or no coverage, mental health and dental services, and community advocacy, such as immunization and motor vehicle safety campaigns.

In recommending an fiscal year 2005 appropriation of $303 million for CHGME, the Bush administration specifically cited the both the program's clear purpose and its impact on the financial health of children's hospitals.

In conclusion, the Children's Hospitals GME Payment Program is an invaluable investment in children's health. The future of the pediatric workforce and children's access to quality pediatric care, including specialty and critical care services, could

[1] The Lewin Group, an independent health policy analysis firm calculated in 1998 that independent children's teaching hospitals should receive approximately $285 million in federal GME support for nearly 60 institutions to achieve parity with the financial compensation provided through Medicare for GME support to other teaching hospitals.

not be assured without it. Again, N.A.C.H. thanks this Subcommittee and Congress for your continuing leadership and support.

For further information, please contact Peters D. Willson, vice president for public policy, N.A.C.H., at 703/797–6006 or pwillson@nachri.org.

PREPARED STATEMENT OF THE COMMUNITY MEDICAL CENTERS, FRESNO, CA

With over 43 million people in the United States lacking health insurance, the situation is reaching a crisis. National polls of Americans have ranked affordable health care as a leading concern behind the economy and jobs, and national security and terrorism. The issue is of greater concern for those of us who live in the Central San Joaquin Valley in California.

In the San Joaquin Valley, we face even greater challenges with the delivery of health care. While the national average for uninsured hovers around 15 percent, the Central San Joaquin Valleys sees a figure closer to 20 percent. As the region poises itself to address the chronic double-digit unemployment (from 14 percent-17 percent) and an equally high rate of poverty (20 percent-30 percent) through aggressive economic development and work force training initiatives, we cannot ignore the need for accessible health care for the uninsured.

The health statistics also point to the need to develop a pro-active and aggressive approach to the situation. They are:

—The third highest asthma mortality rate in the nation
—The highest incidence of diabetes among the Hispanic population
—The highest rates of teen pregnancy in the state
—The lowest immunization rates in the nation (62 percent at age 2 vs. 79 percent nationally)
—Late or no prenatal care for pregnant women

Community Medical Centers is a $574 million locally owned, not-for-profit health care corporation based in Fresno, California and is committed to improving accessibility to health care in the area. As a result of a landmark decision by the Fresno County Board of Supervisors in 1996, the County of Fresno and Community Medical Centers embarked upon a 30-year partnership obligating Community to provide care to the uninsured and underinsured residents of Fresno County.

Community, along with other health care providers such as Sequoia Community Health Foundation, a Federally Qualified Health Center, has been committed to developing a network of outpatient clinics throughout the county with a hub facility to be located on the campus of the Regional Medical Center in downtown Fresno. This outpatient clinic is to be adjacent to the UCSF Fresno Medical Education and Research Center, which is currently under construction, and in-patient hospital services as well. It is only by enhancing access to health care through multiple primary care sites can we begin to address the many health care needs of a burgeoning population, both young and old.

This Outpatient Care Clinic will serve as a hub to a network of clinics throughout the County of Fresno housing primary and specialty care including a children's clinic, a women's clinic focusing on obstetrical and gynecological needs, asthma treatment and education, diabetes treatment and education as well as surgical follow-up.

We would like to ask for your assistance in securing $1 million in funding for the purposes of constructing an outpatient care clinic on the campus of the Regional Medical Center in Fresno. We understand that this request would require a special earmark under the Health Resources Services Administration account in the Labor/Health and Human Services appropriations bill. We are also aggressively pursuing funding through multiple private foundations to secure the bulk of the funding for this $24 million facility. We believe that this facility and a comprehensive approach to addressing the need for health care services in our region is the best option to improve the quality of life in the Central San Joaquin Valley.

PREPARED STATEMENT OF THE AMERICAN MUSEUM OF NATURAL HISTORY

ABOUT THE AMERICAN MUSEUM OF NATURAL HISTORY

The American Museum of Natural History [AMNH] is one of the nation's preeminent institutions for scientific research and public education. Since its founding in 1869, the Museum has pursued its mission to "discover, interpret, and disseminate—through scientific research and education—knowledge about human cultures, the natural world, and the universe." It is renowned for its exhibitions and collections, and with nearly four million annual visitors—approximately half of them chil-

dren—its audience is one of the largest, fastest growing, and most diverse of any museum in the country. Museum scientists conduct groundbreaking research in fields ranging from all branches of zoology, comparative genomics, and informatics to earth, space, and environmental sciences and biodiversity conservation.

Today more than 200 Museum scientists with internationally recognized expertise, led by 46 curators, conduct laboratory and collections-based research programs as well as fieldwork and training. Scientists in five divisions (Anthropology; Earth, Planetary, and Space Sciences; Invertebrate Zoology; Paleontology; and Vertebrate Zoology) are documenting changes in the environment, making new discoveries in the fossil record, and describing human culture in all its variety. In the Museum's Institute for Comparative Genomics, established in 2001, researchers are mapping the genomes of non-human organisms as well as creating new computational tools to retrace the evolutionary tree.

The Museum is also a distinguished training institution, which serves up to 80 undergraduates, doctoral, and postdoctoral trainees annually. These training programs support doctoral and postdoctoral scientists with highly competitive research fellowships, and offer talented undergraduates an opportunity to work with Museum scientists. The Museum's doctoral and post-doctoral training program, dating from 1908, is the oldest and largest of any such program at a scientific museum. The Museum currently has collaborative programs with Yale University, Columbia University, Cornell University, New York University, and CUNY. The training encompasses the entire range of science covered in the Museum's mission, which includes astrophysics, earth sciences, evolutionary biology, zoology, paleontology, comparative genomics, biodiversity sciences, and anthropology.

The AMNH collections of some 32 million natural specimens and cultural artifacts are a major scientific resource, providing the foundation for the Museum's interrelated research, education, and exhibition missions. 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 biological collections are many spectacular individual collections, including the world's most comprehensive collections of dinosaurs, fossil mammals, North American butterflies, spiders, Australian and Chinese amphibians, reptiles, fishes, and one of the world's most important bird collections. Collections such as these provide vital data for Museum scientists as well as for more than 250 national and international visiting scientists each year.

The Museum interprets the work of its scientists, highlights its collections, addresses current scientific and cultural issues, and promotes public understanding of science through its renowned permanent and temporary exhibits (such as the *Genomic Revolution* in 2001) as well as its comprehensive education programs. These programs attract more than 400,000 students and teachers and more than 5,000 educators for professional development opportunities. The Museum also takes its resources beyond its walls through the National Center for Science Literacy, Education, and Technology, launched in 1997 in partnership with NASA.

COMPARATIVE GENOMICS RESOURCES

The American Museum shares with DHHS a fundamental commitment to improving the nation's health and education and advancing the research, training, facilities, and technology that support them. The Museum is deeply engaged in the area of comparative genomics; a partnership between the Museum and DHHS/HRSA would further mutual goals for improving the nation's health and welfare through research and training in genomic science.

Genomic Science and Training Resources

DHHS leads the nation's health-related research and genome science, advanced sequencing technologies, instrumentation, and facilities. The American Museum, in turn, is home to a preeminent molecular biology research and training program and leads science education and outreach efforts. In the era of genomics, museum collections have become critical baseline resources for the assessment of genetic diversity of natural populations; studying genomic data in a natural history context makes it possible to more fully understand the impacts of new discoveries in genomics and molecular biology. Genomes of the simplest organisms provide a window into the fundamental mechanics of life, and understanding their natural capabilities can help solve challenges in biodefense, medicine, and health care. In the Museum's molecular laboratories, in operation now for 11 years, more than 40 researchers in molecular systematics, conservation genetics, and developmental biology conduct genetic research on a variety of study organisms. The labs also nourish the Museum's distinguished training programs that serve up to 80 undergraduates, doctoral, and postdoctoral trainees annually.

Frozen Tissue Collection

The Museum offers unique resources in support of its molecular program. These include an expansion of its collections to include biological tissues and isolated DNA preserved in a super-cold storage facility. Because this collection preserves genetic material and gene products from rare and endangered organisms that may become extinct before science fully exploits their potential, it is an invaluable resource for research in many fields including genetics, comparative genomics, and biodefense. Capable of housing 1 million specimens, it will be the largest super-cold tissue collection of its kind. In the past 3 years, 22,000 specimens not available at any other institute or facility have already been accessioned. At the same time, the Museum is pioneering the development of collection and storage protocols for such collections. To maximize use and utility of the facility for researchers worldwide, the Museum is also developing a sophisticated website and online database that includes collection information and digitized images.

Cluster Computing

The Museum also has exceptional capacity in parallel computing, an essential enabling technology for phylogenetic (evolutionary) analysis and intensive, efficient sampling of a wide array of study organisms. Museum scientists have constructed an in-house 700-processor computing cluster—the fastest parallel computing cluster in an evolutionary biology laboratory and one of the fastest installed in a non-defense environment.

Museum investigators have taken a leadership role in developing and applying new computational approaches to deciphering evolutionary relationships through time and across species; their pioneering efforts in cluster computing, algorithm development, and evolutionary theory have been widely recognized and commended for their broad applicability for biology as a whole. The bioinformatics tools Museum scientists are creating will not only help to generate evolutionary scenarios, but will also inform and make more efficient large genome sequencing efforts. Many of the parallel algorithms and implementations (especially cluster-based) will be applicable in other informatics contexts such as annotation and assembly, breakpoint analysis, and non-genomic areas of evolutionary biology as well as in other disciplines.

COMPARATIVE GENOMICS RESEARCH AND TRAINING INITIATIVE

Building on these unique strengths in comparative genomics, and in concert with the health, education, and training goals of DHHS, in 2001 the Museum launched an ambitious initiative—*The Institute of Comparative Genomics.* Equipped with the parallel computing facility, molecular labs with DNA sequencers, ultra-cold storage units, vast biological collections, and researchers with expertise in the methods of comparative biology, as described above, the Institute is positioned to be one of the world's premier facilities for mapping the genome across a comprehensive spectrum of life forms.

The Institute is establishing a distinguished research and training record. Museum scientists have pioneered theoretical and analytical approaches and are leading major new international research projects in assembling the "tree of life." They have developed efficient software for the interpretation of microarray data, which can be used to support more accurate diagnosis of pathogens, and novel methodologies and algorithms for analyzing genomic, chromosomal, and other data to discern evolutionary relationships among organisms. Current projects include sequencing pathogens and, with NIH and DOE support, tracing the evolution of pathogenicity and transfer of disease-causing genes over time and between species.

The Museum is also successfully promoting public understanding of genomic science. The landmark exhibition, *The Genomic Revolution,* seen by approximately 500,000 visitors in New York and now touring nationally, examined the revolution taking place in molecular biology and its impact on modern science and technology, natural history, biodiversity, and our everyday lives. The Museum has also hosted several conferences on important topics related to genomics: *Sequencing the Human Genome: New Frontiers in Science and Technology,* an international conference featuring leading scientists and policymakers in Fall 2000; *Conservation Genetics in the Age of Genomics* in Spring 2001; and *New Directions in Cluster Computing* in June 2001, which explored how parallel computing enables genomic science and other fields. In June 2002, the Museum hosted an international conference examining current knowledge of life's history, *Assembling the Tree of Life: Science, Relevance, and Challenges.*

As it moves forward, the Institute, working in cooperation with New York's outstanding biomedical research and educational institutions, is focusing on molecular and microbial systematics, on constructing large genomic databases, and on expand-

ing our understanding of the evolution of life on earth and the evolution of critical organismal form and function through analysis of the genomes of selected microbes and other non-human organisms. Development of Institute activities entails expanding expertise in microbial systematics and the molecular laboratory program that now trains dozens of graduate students every year; utilizing the latest sequencing technologies; employing parallel computing applications that allow scientists to solve combinatorially complex problems involving large real world datasets; and continuing to advance public understanding of genomic science through educational materials, scientific conferences, and exhibits.

So as to contribute its unique capacities to the nation's genomics research and training efforts, the Museum seeks to partner with DHHS/HRSA in a facilities/instrumentation initiative. We request $1 million to equip our National Research and Training Laboratory for Comparative and Microbial Genomics, a state-of-the-art molecular laboratory. When equipped, the expanded facility will provide up-to-date instrumentation for graduate and postdoctoral trainees as well as for senior scientists. The Museum will contribute its participatory share to this project with funds from nonfederal as well as federal sources.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the more than 51,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants (AAPA) is pleased to submit comments on fiscal year 2005 appropriations for Physician Assistant (PA) education programs that are authorized through Title VII of the Public Health Service Act.

A member of the Health Professions and Nursing Education Coalition (HPNEC), the American Academy of Physician Assistants supports the HPNEC recommendation to provide at least $550 million to support the Titles VII and VIII programs in fiscal year 2005, including $18 million to support PA educational programs, as recommended by the Advisory Committee on Primary Care Medicine and Dentistry.

The Academy believes that the recommended 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 with the Administration's proposal to eliminate funding for most Title VII programs, including zero funding for training in primary care medicine and dentistry. As Members of the Subcommittee are aware, these programs are designed to help meet the health care delivery needs of the nation's Health Professional Shortage Areas (HPSAs). By definition, the nation's more than 3,800 HPSAs experience shortages in the primary care workforce that the market alone can't address. 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 2005.

OVERVIEW OF PHYSICIAN ASSISTANT (PA) EDUCATION

PA programs provide students with a primary care education that prepares them to practice medicine with physician supervision. Physician assistant programs are located at schools of medicine or health sciences, universities, teaching hospitals, and the Armed Services. All PA educational programs are intensive education programs that are accredited by the Accreditation Review Commission on Education for the Physician Assistant.

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 2-year cycle and reregister every 2 years. Also to maintain certification, PAs must take a recertification exam every 6 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, 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. Forty-seven 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. Nineteen percent of all PAs practice in non-metropolitan areas where they may be the only full-time providers of care (state laws stipulate the conditions for remote supervision by a physician). Approximately 41 percent of PAs work in urban and inner city areas. Approximately 44 percent of PAs are in primary care. Nearly one-quarter practice in surgical specialties. Roughly 80 percent of PAs practice in outpatient settings. In 2003, an estimated 192 million patient visits were made to PAs and approximately 236 million medications were prescribed or recommended by PAs.

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 44 million today. Simultaneously, the number of medically underserved communities continues to rise, from 1,949 in 1986 to more than 3,800 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.

Furthermore, now that there is compelling evidence that race and ethnicity correlate with persistent, and often increasing, health disparities among U.S. populations, increasing the diversity of health care professionals is essential. Title VII programs are unique in that they seek to recruit providers from a variety of backgrounds. This is particularly important, as studies have found that those from disadvantaged regions of the country are 3 to 5 times more likely to return to those underserved areas to provide care versus other areas.

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.

Publi 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 1990–2002 reveals that students graduating from PA programs supported by Title VII are 84 percent more likely to be from underrepresented minority backgrounds and 32 percent more likely to practice in underserved settings, than students graduating from PA programs that were not supported by Title VII.

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 underserved areas, including new sites in border communities, and to establish non-clinical rural rotations to help students understand the challenges faced by rural communities. One Texas program uses Title VII funds for the development of web based and distant learning technology and methodologies so students can remain at clinical practice sites. A PA program in New York, where over 90 percent of the students are ethnic minorities, uses Title VII funding to focus on primary care training for underserved urban populations by linking with community health centers, which expands the pool of qualified minority role models that engage in clinical teaching, mentoring, and preceptorship for PA students. 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 sufficient 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. Currently, 36 percent of PAs met their first clinical employer through their clinical rotations.

Changes in the health care marketplace reflect a growing reliance on PAs as part of the health care team. Currently, 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 supply. Additionally, the Bureau of Labor Statistics projects that the number of available PA jobs will increase 49 percent between 2002 and 2012. Title VII funding has provided, and continues to provide, a crucial pipeline of trained PAs to underserved areas. One way to assure an adequate supply of physician assistants, especially PAs likely to practice in underserved areas, is to continue offering financial incentives, such as funding preferences, to PA programs that emphasize recruitment and placement of people interested in primary health care in medically underserved communities.

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. Nor has the Title VII support for PA education kept pace with increases in the cost of educating PAs. A review of PA program budgets from 1984 through 2002 indicates an average annual increase of 6.5 percent, a total increase of 218 percent over the past 18 years; yet, federal support has remained relatively static.

RECOMMENDATIONS ON FISCAL YEAR 2005 FUNDING

A recent report by the Advisory Committee on Training in Primary Care Medicine and Dentistry quotes a study in the Journal of Rural Health: "In 1997, Title VII funded programs increased the rates of graduates entering health profession shortage areas (HPSAs), resulting in 1,357 providers . . . Doubling the funding of these programs . . . could decrease the time for HPSAs elimination to as little as 6 years." The Advisory Committee concluded that ". . . Title VII remains a modest investment, but, as has been demonstrated, one with substantial future payoffs in terms of system quality, access to care, and a culturally competent system of care for the entire population."

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 2005. 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 or bioterrorist attack, 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.

Furthermore, while the Academy applauds the Administration's proposal to strengthen national security by increasing support for health emergency preparedness initiatives, it should not do so at the expense of Title VII programs. Training is the key to preparedness, and Title VII, section 747, is an ideal mechanism for educating primary care providers in public health competencies, facilitating population based and community-based skills and training, and increasing the alliance between public health and primary care providers. This is particularly important for our Nation's most disadvantaged and underserved populations, because they are the most vulnerable during medical emergencies because of a lack of resources and access to care.

The Academy respectfully requests that the Title VII and VIII health professions programs receive $550 million in funding for fiscal year 2005, including $18 million to support PA educational programs, as recommended by the Advisory Committee on Primary Care Medicine and Dentistry.

Thank you for the opportunity to present the American Academy of Physician Assistants' views on fiscal year 2005 appropriations.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR THE MENTALLY ILL

Chairman Specter, Senator Harkin and members of the Subcommittee, I am Margaret Stout of Johnson, Iowa. I current serve as President of the National Alliance for the Mentally Ill (NAMI) and Executive Director of NAMI's statewide Iowa affiliate. I am pleased to offer NAMI's view on the Subcommittee's fiscal year 2005 bill.

NAMI is the nation's largest grassroots advocacy organization, 220,000 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.

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 peo-

ple with these brain disorders through pioneering research that has uncovered both a biological basis for these brain disorders and treatments that work.

The cost of mental illness to our nation is enormous. President Bush's White House Mental Health Commission—which completed its work in 2003—found that the direct treatment cost exceeds $71 billion annually. This does not include the $79 billion in estimated indirect costs of benefits and social services (including 35 percent of SSI benefits and 28 percent of SSDI benefits). These direct and indirect costs do not measure the substantial and growing burden that is imposed on "default" systems that are too often responsible for serving children and adults with mental illness who lack access to treatment. These costs fall most heavily on the criminal justice and corrections systems, emergency rooms, schools, families and homeless shelters. Moreover, these costs are not only financial, but also human in terms of lost productivity, lives lost to suicide and broken families. Investment in mental illness research and services are—in NAMI's view—the highest priority for our nation and this Subcommittee.

FUNDING FOR SERVICES PROGRAMS AT SAMHSA & CMHS

The Center for Mental Health Services (CMHS)—part of the Substance Abuse and Mental Health Services Administration (SAMHSA)—is the principal federal agency engaged in support for state and local public mental health systems. Through its programs CMHS provides flexible funding for the states and conducts service demonstrations to help states move toward adoption of evidence-based practices. Funding for all SAMHSA and CMHS programs is part of the Fiscal Year 2005 Labor-HHS-Education Appropriations bill that Congress will soon consider.

CMHS Programs and the Crisis Confronting the Public Mental Health System

During the recent economic downturn and resulting crisis the state budgets are facing, we are witnessing widening of gaps in the public mental illness treatment system in many states. This is resulting in unprecedented cuts being enacted by states in both direct spending on mental illness treatment and supportive services, and in Medicaid funding of such services. Deep cuts to front-line clinics and providers in the public mental health system, curbs on access to newer more effective medications and closure of acute care beds in the community are just a few of the misguided strategies that states are employing to close their widening budget gaps. 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: increased risk of suicide, the growing number of chronic homeless adults and the growing trend of "criminalization" of mental illness and the stress it is placing on state and local jails and prisons.

The Need to Focus on Recovery-Oriented Evidence-Based Practices

As states continue to cut funding for mental illness treatment and supportive services, CMHS programs are becoming an increasingly important source of funding for the states. First and foremost, states should be encouraged to use their CMHS Block Grant funds to prevent further cuts in services for children and adults with severe mental illnesses. NAMI also supports targeting of CMHS dollars toward investment in evidence-based, outreach-oriented service delivery models for persons with severe mental illness in the community. The need to focus limited resources on evidence-based models (such as Programs of Assertive Community Treatment (PACT) and integrated treatment for co-occurring disorders) was recommended in 2003 by the President's "New Freedom Initiative" Mental Health Commission Report. This landmark report called for a reform of the public mental health system to eliminate system fragmentation and better reflect the priorities of recovery and community integration.

NAMI Supports the Bush Administration's Request for a "Mental Health System Transformation" Initiative

The President's fiscal year 2005 budget includes a request for $44 million at CMHS for a new state incentive grant program for "Mental Health System Transformation." This initiative is intended to help states follow through on the July 2003 recommendations in the White House "New Freedom Initiative" Mental Health Commission report. Under the proposal, funds would be allocated to states on a competitive basis to support the development of comprehensive state mental health plans to reduce system fragmentation and increase access to evidence-based services that promote recovery from mental illnesses. States would be required to use funds to develop plans that cut across multiple systems such as housing, criminal justice, child welfare, employment and education. In subsequent years, up to 85 percent of funds could be used to support community-based programs, with the remaining 15

percent available for state planning and coordination. NAMI strongly supports this proposal as critical to the effort to reform our nation's fragmented and underfunded public mental health system and bridge the gap between scientific advances and practice.

NAMI Supports the "Samaritan" and "ELHSI" Initiatives to End Chronic Homelessness

The President's fiscal year 2005 budget proposes $70 million to continue the "Samaritan Initiative" to end chronic homelessness over the next decade, with funding spread across SAMHSA, HUD and the VA. In addition, the Bush Administration is seeking a $5 million increase for the Projects for Assistance in Transition from Homelessness (PATH) program—boosting fiscal year 2005 funding to $55 million. PATH is a formula grant program to the states that funds outreach and engagement services for homeless individuals with severe mental illnesses. CMHS estimates that this increase in the PATH program will result in 154,000 homeless individuals with severe mental illnesses being served by state and local PATH grantees. NAMI also urges additional funding in fiscal year 2005 for the PATH program to address inequities in the program's interstate funding formula that have the allocation for many smaller rural states frozen since the mid-1990s.

NAMI urges full funding of the "Samaritan Initiative" in fiscal year 2005 and the proposed increase for PATH. Individuals with severe mental illnesses and co-occurring substance abuse disorders make up the largest share of the more than 150,000 people who experience chronic homelessness—those who stay homeless for a year or more. In addition to supporting the Administration's Samaritan Initiative and the recommended increases for PATH, NAMI also supports funding for the Ending Long-Term Homeless Services Initiative (ELHSI) program at SAMHSA to assist states and localities in funding services for new permanent supportive housing being developed through HUD's McKinney-Vento program. Funding at SAMHSA for Samaritan and ELHSI is critical to producing and sustaining 150,000 units of permanent supportive housing that will all but eliminate chronic homelessness. Ending chronic homelessness through permanent supportive housing will pay for itself, as communities save hundreds of millions of dollars in that communities are relieved of the costs related to keeping people homeless—including those associated with shelters, emergency rooms and jails.

Funding for CMHS Programs in the President's fiscal year 2005 Budget

In addition to the initiatives noted above, NAMI also supports ongoing activities at CMHS:

—*Mental Health Block Grant*.—CMHS's largest program, the Mental Health Block Grant (state formula grant program), would receive a $2 million increase under the President's fiscal year 2005 budget proposal (boosting funding to $436 million).

—*Children's Mental Health program at CMHS*.—The President is requesting a $4 million increase for the Children's Mental Health program, increasing funding to $106 million.

—*Programs of Regional and National Significance*.—CMHS's own discretionary budget—known as Programs of Regional and National Significance (PRNS)—would increase under the President's budget to $271 million. This includes the $44 million mental health system transformation initiative noted above.

—*Co-Occurring Disorders*.—The request for fiscal year 2005 for the PRNS program includes $15.2 million in ongoing and new funding for best practices and targeted capacity expansion grants to foster increased access to integrated treatment for individuals with co-occurring mental illness and substance abuse disorders. SAMHSA has an important leadership role to play on this issue. NAMI strongly urges this Subcommittee to support expansion of SAMHSA's activities on this critical priority.

—*Jail Diversion*.—NAMI is disappointed that the President's budget does not request continued funding for the $7 million Jail Diversion program at CMHS. NAMI strongly supports the Jail Diversion program and urges continuation of funding in fiscal year 2005.

—*Suicide Prevention*.—NAMI strongly supports continuation and expansion of CMHS's best practices grants and contracts to support suicide prevention. The President's "New Freedom Initiative" Mental Health Commission report contains important recommendations on making suicide prevention a national priority. NAMI supports these recommendations as critical to addressing the estimated 30,000 suicides that occur every year in our country—90 percent of which involve a victim with a mental disorder.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH) RESEARCH FUNDING

The National Institute of Mental Health (NIMH) is the only federal agency with the main objective of funding biomedical research into serious mental illnesses. Increased funding and focus is needed to achieve the promise of exciting gains in understanding the brain in upcoming years.

NIMH—Smallest Proposed Increase in 8 Years

For fiscal year 2005, the President is proposing a $1.421 billion budget for the NIMH. This is a $39 million increase—2.2 percent—over the amount Congress appropriated for NIMH for fiscal year 2004 ($1.39 billion). While this exceeds the average 0.5 percent increase for all domestic discretionary spending, it is below the 2.7 percent increase proposed for all of the National Institutes of Health (NIH)—which would increase to $28.805 billion under the President's budget. In addition, this proposed increase for NIMH for fiscal year 2005 is below the 3.6 percent increase that Congress enacted for fiscal year 2004 and far below the 8 percent and 9 percent annual increases that were achieved between fiscal year 1998 and 2003.

This minimal budget increase is expected to have a serious impact on the ability of NIMH to sustain ongoing multi-year research grants that have been initiated over the past 3–4 years and fund new grant proposals relevant to serious mental illness. This is especially the case if Congress accepts a proposal being floated by NIH to limit annual "cost of doing research" adjustments to individual grants to 1 percent per year. NAMI remains very concerned that this coming fall-off in budget increases for NIH does not wipe out the new research that has been undertaken at NIMH in recent years, and take advantage of the significant opportunities to advance treatments and cures for serious mental disorders.

Mr. Chairman, NAMI is deeply grateful for your leadership on this Subcommittee in seeking a strong budget for NIH and NIMH. The bipartisan commitment to scientific research that you and Senator Harkin continue to demonstrate is an example to your colleagues in Congress and in the Administration. We commend you for your amendment on the Senate floor during debate on the fiscal year 2005 budget resolution to increase NIH funding above the President's request. NAMI urges you and your colleagues to make every effort to fund in NIMH at the "professional judgment" recommendation for fiscal year 2005—$1.555 billion, or $172.8 million above the fiscal year 2004 level.

"Roadmap to Recovery and Cure"—NAMI's Advocacy Goals and Strategies on Mental Illness Research

This month, the NAMI Policy Research Institute is releasing a new report, Roadmap to Recovery and Cure, urging significant increases in the NIMH budget for basic, clinical and health services research focused on serious mental illness. The reality is that dramatic improvements in the lives of individuals with mental illness can be achieved over the next decade if research is expanded and the treatment system reformed and brought into closer alignment with research.

Among the conclusions in *Roadmap to Recovery and Cure* are that serious mental illness research has been underfunded, compared to other chronic, disabling illnesses, and is insufficiently prioritized at NIMH. The task force also found that psychiatric research has only begun to enter the modern era of biomedical research and requires the development of a strong base of basic and interdisciplinary research, large, policy-relevant clinical trials and services research directly tied to service delivery. It is important to note that all of these are integral to the Bush Administration's Roadmap to Medical Research initiative that is currently driving research priorities at NIH.

Among the recommendations in this report are:

—Significant and accountable increases in NIMH funding of basic, clinical and services research focused on serious mental illness—$1 billion over 5 years,

—Increased application of the NIH's Roadmap to Medical Research initiative to serious mental illness,

—Continuation and expansion of clinical trials focused on serious mental illness,

—Coordination of serious mental illness research, dissemination, and service system policy efforts by the federal government, and

—Increased training and support of researchers and mental health care providers.

The Case for Increased Federal Investment in Mental Illness Research

Further research is imperative if we are to prevent the next generation from suffering. Much has to be learned. The causes and mechanisms of diseases such as schizophrenia and bipolar disorder are mostly unknown. We do not yet have laboratory tests that can diagnose these illnesses. There are no side-effect free treatments. And, of course, there is no primary preventive measure or cure currently available.

Treatment is imperfect; it does not work well for all individuals living with these brain diseases. There are no cures for severe mental illnesses, and existing treatments and services shown to be effective are all too often not available to the people who need and deserve them. While steady research-funding gains have been achieved, NAMI believes that severe mental illness research, from the most basic to services research, remains underfunded, given the tremendous scientific opportunities that exist and the severe burden that these diseases present to the public as well as to our families.

The public health burden associated with severe mental illness is enormous, accounting for a large percentage of costs imposed by all illnesses in the United States. An independent study by the World Bank and World Health Organization (DALY: Disability Adjusted Life Years) found that four of the top ten causes of disability worldwide are severe mental illnesses: major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder, accounting for 25 percent of the total disability resulting from all diseases and injuries.

Where Should Funding at NIMH Be Directed?

Greater Focus & Accountability on Severe Mental Illness.—NAMI believes that more focus is needed at NIMH on severe mental illness research. NAMI therefore urges Congress to require NIMH to provide an accounting of new and existing research grants broken down by specific illnesses.

Basic Neuroscience.—NIMH needs to continue progress that has been made in unraveling the mysteries of molecules, genes, and brain interconnections related to higher brain functioning in brain health and serious disease.

Treatment Research.—Currently there is a lack of understanding about which treatments work best for which patients, in what combination, and with what risks and costs. NIMH has invested in significant research to improve this understanding and it should be continued and expanded in the current budget. Importantly, new treatments must be developed as well.

Services Implementation.—There are many important, even crucial research questions relevant to the treatment system that serves individuals with severe mental illnesses—ranging from improving the provision of evidence-based care to identifying exactly how much public monies are being spent on a treatment system that more often than not is failing.

Consumer and Family Involvement in Research.—All of these efforts at NIMH must be done with a greater involvement with and accountability to those patients with severe illnesses and their families. Recent efforts at NIMH have moved in this direction, but more needs to be done to integrate families and patients into annual reporting and strategic planning on research investments and accomplishments.

CONCLUSION

Chairman Specter, Senator Harkin and members of the Subcommittee, thank you for the opportunity to offer NAMI's views on your fiscal year 2005 bill.

PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS

Mr. Chairman and members of the subcommittee, the Association of Maternal and Child Health Programs (AMCHP) is pleased to submit testimony on the Maternal and Child Health Services Block Grant as you consider the fiscal year 2005 funding request for the Department of Health and Human Services. AMCHP is a national non-profit organization representing the leaders of state public health programs for maternal and child health, and children with special health care needs in all 50 states, the District of Columbia, and eight additional jurisdictions. AMCHP appreciates the subcommittee's continued support of the MCHBG, the common source of funding for our members.

I urge you to provide $807 million for the Maternal and Child Health Services Block Grant (MCHBG) in fiscal year 2005. This funding level is necessary to maintain at least fiscal year 2003 levels of service in every state. Additionally, continued funding ($5 million) within the Special Projects of Regional and National Significance (SPRANS) set-aside for MCH oral health grant activities is critical. As I will explain below, these funds are needed to help state MCH programs that have been hit hard by state budget cuts, rising demand for services, and years of federal flat funding.

Maternal and child health programs help to increase immunization and newborn screening rates, reduce infant mortality, prevent childhood accidents and injuries, and reduce adolescent pregnancy. Each year, more than 27 million women, infants,

children and adolescents, including those with special health care needs, are served by MCH Block Grant funds. Half of the 4 million women who give birth annually receive some prenatal or postnatal services made possible by the MCHBG.

State maternal and child health programs need strong financial support to meet the challenges ahead. Unfortunately, this year 31 states (Alabama, Arkansas, Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, Wisconsin, Wyoming) receive less in MCH block grant funding than in fiscal year 2003. These cuts range from a few thousand dollars to over $1.6 million. Please see the chart at the end of this testimony.

The President's fiscal year 2005 budget flat funds the MCH Block Grant at $730 million again. The President also proposes to add the Universal Newborn Hearing Screening/Trauma Programs to the MCHBG without the $13 million that the programs received in fiscal year 2003. This would force states to cut other worthy MCH programs in order to continue important hearing screening activities or to scale back their hearing screening activities. According to a recent report, thanks to the HRSA funding, the number of infants screened for hearing loss at birth rose almost 20 percent in 2003. Today, 86 percent of infants born in hospitals nationwide are screened for hearing loss, up from 25 percent in 1999.

The need for increased funding is clear and I urge you to provide $807 million for the Maternal and Child Health Services Block Grant in fiscal year 2005. This increase assures that every state receive at least the amount that they received from the MCH Block Grant in fiscal year 2003. Without this funding, states' ability to serve the millions of American women, children, and their families who rely on these programs (approximately 27 million in 2002) would be jeopardized. In every state, Title V is a safety net program for low-income women and children, often the payor of last resort for needed medical services when other sources of payment (either public or private) are not available.

State programs funded through the MCH Block Grant make a difference. Without sufficient funding, over 18 million children will be without the vital health care they need, over 2 million pregnant women will not receive prenatal and postnatal care and have a healthy pregnancy, and almost 1 million children with special health care need will have to battle a fragmented health care system on their own to get the services they require.

Below are specific examples of how reductions at the state and federal levels have affected state maternal and child health programs. Please keep in mind that the actual effect of the cuts will not be fully felt until fiscal year 2005. That's why it is important that you provide sufficient funding in the fiscal year 2005 for the Maternal and Child Health Services Block Grant.

OHIO

Ohio received one of the steepest cuts in aid, losing $1.5 million (or 6 percent) between fiscal year 2003 and fiscal year 2004 in federal MCH funding. Combined with a $7.5 million decline in the state funds available to support MCH, the ability for the program to maintain services to the 266,000 women, infants, and children who received services in 2002 has been severely compromised. Ohio's Children with Special Health Care Needs (CSHCN) program, because of both state cuts and cuts in the Ohio MCH Block Grant, has had to decrease the number of diagnoses covered by the CSHCN Treatment Program and to change the eligibility rules to reduce the services provided. Three diagnosed conditions (Tonsils/adenoids, Serous otitis media, Hernias—except diaphragmatic) were eliminated from the list of those eligible to receive services, affecting almost 600 children.

Other changes may reduce, by as much as 25 percent, the 5,000 children who rely on the program. Co-payments are increased for families. Children with special health care needs require more frequent office visits. Raising co-payments can significantly impact the financial and physical health of these families and their children if they are unable to pay them. These families turn to Title V when insurance (either private or public) cannot provide the services. The Ohio Specialty Field Clinic Program received a 20 percent decrease in MCH block grant and other funding support. The Specialty Clinic Program provides access to pediatric specialists for children in Ohio. The number of clinics will be cut, all in rural Ohio where the greatest need for services are. This will affect the access to care for 300 children in Ohio's rural areas. Cardiac Specialty Clinics will be closed as of July 1, 2004. Funding reductions also slow the ability to respond to emerging issues, such as an increase in Ohio's infant mortality rate.

ALABAMA

Alabama lost $450,000 in federal funding. Combined with state cuts, the MCH program has had to significantly cut back services and staff. Funding for the Monsky Developmental Clinic was slashed by 50 percent. The Monsky Developmental Clinic provides developmental assessments of children with suspected or documented developmental delay (primarily for children from low income families). The clinic maintains a highly specialized multi-disciplined staff of professionals. Monsky is one of two clinics in Alabama that provides this service for children with special health care needs and serves the South Alabama region. The MCH program is the largest financial supporter of the clinic. MCH also lost a public health nurse position that had been working to engage the growing Hispanic community. Without funding to fill the position, it will be difficult to pro-actively address perinatal issues in the growing Hispanic/Latino population in Alabama. There were 2,630 live births to Hispanic/Latino Alabama residents in CY 2002: a 14.7 percent increase over the number in CY 2001.

IOWA

Iowa lost approximately $355,000 in fiscal year 2004. These cuts forced the Iowa Children with Special Health Care Needs program (Iowa Health Specialty Clinics program at the University of Iowa) to cut nutrition services to all children with special needs across Iowa, close the regional specialty clinic in Waterloo, cut the Dubuque clinic by 80 percent, and cut two other clinics by 20 percent. Scores of parents, teachers and educators who teach children who receive services through these clinics have written letters to the CSHCN program protesting the closures and/or reductions at these sites citing the devastating effect on those in need of the services.

TEXAS

Texas received a reduction of $753,000 (3 percent) in federal MCH funds. That reduction along with a reduction in state funds for MCH in 2004–2005 will drastically increase the unmet needs of the MCH population in Texas. Currently, the MCH program addresses less than 10 percent of the MCH population-in-need. For example, Title V MCH fiscal year 2004 contracts funding for population-based services (i.e., initiatives directed toward teen pregnancy, childhood obesity, immunization, etc) was decreased by 33 percent and by 13 percent for direct services (prenatal care, child well-check visits, dental, family planning, etc.). In 2001, the Texas Children with Special Health Care Needs program instituted a waiting list that has grown to 1,200 families and is expected to continue to increase.

WISCONSIN

Wisconsin loses $776,600 (or 6 percent). Options being considered to address this shortfall include applying an across-the-board cut to local projects as well as at the state and regional offices. A reduction to local projects translates to less activities and services received by the maternal and child health population. This will translate to children and families not receiving necessary services. In light of these cuts and the many more that I am unable to include in this testimony, I strongly urge you to provide states increased resources through the MCH block grant in fiscal year 2005 to protect services to low income pregnant women, infants, children with special health care needs and their families. $807 million in fiscal year 2005 does just that.

Again, thank you for this opportunity to testify.

State	Fiscal year		Difference
	2003 actual	2004 conference	
Alabama	$12,866,149	$12,415,309	−$450,840
Alaska	1,146,370	1,180,409	34,039
Arizona	7,406,094	7,842,357	436,263
Arkansas	7,785,008	7,524,664	−260,344
California	44,341,423	48,441,501	4,100,078
Colorado	7,794,869	7,603,353	−191,516
Connecticut	4,946,958	4,998,766	51,808
Delaware	1,982,247	2,034,791	52,544
District of Columbia	7,050,811	7,170,736	119,925
Florida	20,017,388	20,994,684	977,296
Georgia	17,316,887	17,348,033	31,146

State	Fiscal year		Difference
	2003 actual	2004 conference	
Hawaii	2,281,433	2,392,416	110,983
Idaho	3,373,874	3,387,761	13,887
Illinois	23,969,437	23,027,020	−942,417
Indiana	12,665,552	12,318,758	−346,794
Iowa	7,115,676	6,760,133	−355,543
Kansas	5,151,370	4,963,545	−187,825
Kentucky	12,553,023	11,948,246	−604,777
Louisiana	15,533,194	14,293,453	−1,239,741
Maine	3,546,787	3,518,418	−28,369
Maryland	12,212,800	12,367,885	155,085
Massachusetts	12,046,095	11,968,951	−77,144
Michigan	21,596,187	19,903,294	−1,692,893
Minnesota	9,845,406	9,427,666	−417,740
Mississippi	11,169,460	10,337,878	−831,582
Missouri	13,318,533	13,030,039	−288,494
Montana	2,609,133	2,560,004	−49,129
Nebraska	4,270,142	4,183,264	−86,878
Nevada	1,581,541	1,996,035	414,494
New Hampshire	2,023,344	2,071,712	48,368
New Jersey	12,102,033	12,348,050	246,017
New Mexico	4,798,959	4,723,796	−75,163
New York	42,726,728	43,708,310	981,582
North Carolina	17,183,075	17,522,028	338,953
North Dakota	2,007,580	1,882,687	−124,893
Ohio	24,889,019	23,310,577	−1,578,442
Oklahoma	8,041,242	7,791,761	−249,481
Oregon	6,484,811	6,579,878	95,067
Pennsylvania	26,051,877	25,621,198	−430,679
Rhode Island	1,768,713	1,890,246	121,533
South Carolina	12,151,811	11,952,796	−199,015
South Dakota	2,469,092	2,357,003	−112,089
Tennessee	12,693,368	12,419,315	−274,053
Texas	38,661,981	37,908,796	−753,185
Utah	6,336,960	6,222,721	−114,239
Vermont	1,746,907	1,742,951	3,956
Virginia	12,947,026	13,001,114	54,088
Washington	9,364,663	9,613,745	249,082
West Virginia	7,058,712	6,712,857	−345,855
Wisconsin	11,916,084	11,261,938	−654,146
Wyoming	1,333,642	1,309,374	−24,268
Subtotal	572,251,474	567,892,222	−4,359,252

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). NTEU represents more than 150,000 federal employees across 29 agencies and departments of the federal government, including employees in a number of divisions of the Department of Health and Human Services.

NTEU represents employees in the following divisions of the Department of Health and Human Services: the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Administration for Children and Families (ACF), Administration on Aging (AoA), Office of the Secretary (OS), Office for Civil Rights (OCR), Program Support Center (PSC) and the National Center for Health Statistics (NCHS). NTEU also represents employees in the Social Security Administration's Office of Hearings and Appeals (OHA).

As the Chairman knows, for several years now, most federal agencies have struggled to accomplish their missions to the best of their abilities within tight fiscal constraints. Many federal agencies have not had the necessary funds to adequately train their employees, others have been forced to downsize to the point where they are not staffed appropriately for their missions and still other agencies have not had

the resources to use the tools at their disposal to attract and retain the workforces they know they need for the future. These tools include recruitment and retention bonuses as well as the ability to help employees with student loan expenses—tools that the private sector knows are imperative to attracting and retaining the best employees.

The federal government faces an unprecedented recruitment and retention crisis. In addition to adequately funding agencies to perform their missions, NTEU believes that a major step toward making the federal government an employer of choice is a commitment by Congress and the Administration to establish a fair process for setting federal salaries. As you know, Mr. Chairman, for 2 years in a row now, despite a bipartisan and bicameral commitment to pay parity between the Nation's military and civilian employees, the President has chosen to implement a smaller pay raise for civilian employees only to see that raise overturned by subsequent Congressional action.

The message this sends federal employees is that they are not as important as their military counterparts, that they are somehow not as deserving of a fair pay raise. Here it is March 2004 and the pay raise these employees should have received the first pay period in January has still not reached their paychecks. While the full 4.1 percent pay raise is retroactive to January, agencies are still struggling to update their payroll systems and implement the full amount of the pay raise. We are told it may be several more months before all federal employees receive the full pay raise Congress approved.

Adequate and stable agency funding coupled with appropriate federal pay and benefits are the keys to ensuring that the government is able to attract and retain the federal employees it requires. The need for the federal government to hire and maintain a highly skilled workforce has never been more clear. Federal employees protect our Nation's medical supplies, they help secure our borders and they provide important services and information to their fellow taxpaying citizens every day.

The Administration's fiscal year 2005 budget request continues to hold federal agencies to unrealistic funding levels. We cannot continue to ask our agencies to do more while ignoring their requests for appropriate funding.

The Administration's fiscal year 2005 request for program management funding at the Health Resources and Services Administration (HRSA) is $158 million. Although this figure represents a $3 million increase in administrative funds over the fiscal year 2004 funding level, it is important to remember that HRSA's 2004 funding level represented a reduction of $9 million from the prior year. For an agency charged with insuring access to quality health care, especially to underserved populations—services that are in desperate need of expansion—a considerably larger increase in program management funding is called for. HRSA cannot effectively accomplish its mission without additional resources.

The President's budget proposes a substantial increase in funding for the National Center for Health Statistics (NCHS) for fiscal year 2005, a budget increase that is long overdue. As you know, the work NCHS undertakes is critical to ensuring that national health care initiatives are effective and the agency has been held to unrealistic funding levels for too many years now. NTEU hopes the fiscal year 2005 budget request will be enacted for NCHS.

The budget request for program management funds in 2005 at the Substance Abuse and Mental Health Services Administration (SAMHSA) is $92 million, the same as the agency's funding level for fiscal year 2004. SAMHSA is the federal agency charged with improving the quality and availability of treatment and intervention programs for those suffering from substance abuse and mental illness. It is discouraging to see this important agency held to an unrealistic funding level for the coming fiscal year and I am hopeful that program management funding for SAMHSA in fiscal year 2005 can be increased.

The President's budget proposal for fiscal year 2005 for the Administration for Children and Families (ACF), represents an increase of $12 million for federal administration of the programs ACF oversees. Funding restrictions in past years have hampered this agency's ability to accomplish its missions and NTEU strongly supports increased funding for the federal administration of ACF programs.

However, at the same time, we must continue to state our strong opposition to legislation pending in Congress to reauthorize the Head Start Program. As you know, the Head Start Program allows many children from low-income families to access a package of educational and social services that supplement the student's learning. Under the direction of the federal government, the Head Start Program has enhanced the opportunities of millions of American children since its inception. Legislation that seeks to limit the involvement of the federal government with the Head Start Program, such as H.R. 2210, is shortsighted and threatens to move the program in the wrong direction. Similarly, S. 1940, which encourages contracting

out the oversight of the Head Start Program to profit-driven firms in the private sector, must be reconsidered. I hope that the Committee will carefully review the Head Start reauthorization legislation before it is voted on by the full House and Senate.

The President's budget recommends only a slight improvement in funding for program administration for the Administration on Aging (AoA), holding the agency's program administration funding level to $18 million for 2005. With our country's rapidly growing older population, this is particularly troublesome. The Administration on Aging helps older Americans remain independent and productive and offers nutrition, caregiver support and preventive health programs. These are precisely the type of programs desperately in need of expansion, yet the fiscal year 2005 budget proposal, like the 2004 budget before it offers little in the way of new funding for these critical areas. The AoA funding level, too, requires the careful scrutiny of this Subcommittee.

The Office of the Secretary (OS) of the Department of Health and Human Services is slated to receive increased funding in fiscal year 2005. Federal employees working in the Office of the Secretary help administer all of the programs operated by the Department of Health and Human Services. It is critical that this office be effectively funded and NTEU is pleased to see a significant funding increase for this division. We urge the Committee to approve this request.

The President's budget recommends a small increase in program funding for the Office for Civil Rights (OCR). The recommendation would increase this agency's resources from their 2004 funding level of $34 million to $35 million in 2005. The HHS Office for Civil Rights helps to ensure that all individuals have proper access to the services and programs the Department offers. Moreover, this agency helps promote the privacy of medical information. In past years, OCR has been woefully under funded and NTEU urges this body to carefully review their funding needs for 2005.

The Department of Health and Human Services' Program Support Center (PSC) offers a range of administrative services both to HHS agencies and other federal departments that seek out its services. The President's fiscal year 2005 budget, which requests an increase in expenses for this key agency over their fiscal year 2004 funding level, deserves to be adopted by this body.

NTEU also represents employees in the Office of Hearing and Appeals (OHA) of the Social Security Administration. As the Chairman knows very well, OHA's mission is to assist those claimants who have been found ineligible for Social Security disability benefits by providing a due process hearing on their cases. The continuing backlog of cases before OHA prevents a fair and timely hearing for the thousands of individuals whose disability cases must be heard there. One of the problems facing OHA is that it lacks sufficient decision makers to handle its continuing and rapidly growing workload.

For almost a decade, SSA's disability program has been in crisis. In 1995, SSA introduced a program called the Senior Attorney Program that was instrumental in reducing the backlog and improving processing times. The agency's experienced staff attorneys were given the authority to decide and issue fully favorable decisions—without the time and expense of a full hearing—in those cases where the evidence clearly identified an individual as disabled. In every respect, the Senior Attorney Program was a success. Unfortunately, SSA chose to terminate this innovative program as it undertook its Hearings Process Improvement (HPI) plan, a plan SSA now admits was unsuccessful.

On a more positive note, current Social Security Commissioner Barnhart has undertaken an objective review of the entire disability system. Finally, senior SSA officials truly understand the strengths and deficiencies of the current system. This insight combined with the Commissioner's commitment to create a process which serves the needs of the public rather than the dictates of the bureaucracy, have led her to propose a plan for implementing fundamental process changes that will provide a level of service of which we all can be proud.

The plan is comprehensive and involves extensive changes such as the eventual replacement of paper folders with electronic folders, elimination of the Reconsideration Determination, elimination of the Appeals Council, a completely revamped quality assurance system, and the creation of the Reviewing Official position to provide an intermediate step between the State Agency and the ALJ. NTEU is convinced that this plan, if implemented, will result in an efficient, effective, and most importantly, a fair adjudicatory process.

In a particularly important initiative proposed by the Commissioner, a Reviewing Official, or RO position, will be created. This individual will be an attorney and will apply the same adjudicatory standards to the disability determination process, as will the Administrative Law Judges. Past experience from the Senior Attorney Pro-

gram indicates that the creation of this position in conjunction with the other improvements the Commissioner seeks to put in place will result in many disabled claimants being awarded benefits in as little as 30 days.

The President has recognized the importance of providing SSA with sufficient resources to enable SSA to implement the Commissioner's plan to improve the Social Security disability program. NTEU asks that the Congress approve the budget requests of the President regarding the funding of the Commissioner's Approach to Disability Adjudication.

However, as good as the Commissioner's plan is, it does not provide immediate relief for those currently waiting for a disability decision. Unfortunately, it will be October 2005 at the earliest before the Commissioner's recommendations can be implemented. In the meantime, the backlog will continue to grow.

Given the present state of resources, the current workload, and the direction that the Commissioner's Approach is taking the Agency, the Commissioner should immediately reinstate the original Senior Attorney Program. In addition to making a positive, immediate, and effective impact on the backlog, it would act as a good transition to the Reviewing Official. All qualified OHA Attorney Advisors should be empowered to issue fully favorable on-the-record decisions. During the period from 1995 to 1999 Senior Attorneys issued over 220,000 fully favorable on-the-record decisions, and the cases pending at OHA hearing offices fell from over 550,000 cases to 311,000 cases. A well designed and well managed Senior Attorney program should be able to process at least 60,000 fully favorable reversals in a year without reducing the number of ALJ decisions or affecting the overall reversal rate at OHA.

Implementing the original Senior Attorney Program would require limited new hiring and the impact on the backlog would be swift and striking. I strongly recommend that this Committee both carefully review and embrace the Commissioner's new disability plan and also encourage SSA to implement the original Senior Attorney Program once again without delay.

Thank you very much for your attention to these issues. I very much appreciate the opportunity to share this testimony with you.

PREPARED STATEMENT OF THE ONCOLOGY NURSING SOCIETY

The Oncology Nursing Society (ONS) appreciates the opportunity to submit written comments for the record regarding funding for cancer and nursing related programs in fiscal year 2005. ONS, the largest professional oncology group in the United States composed of more than 30,000 nurses and other health professionals, exists to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer. As part of its mission, the Society honors and maintains nursing's historical and essential commitment to advocacy for the public good.

This year more than 1.3 million Americans will be diagnosed with cancer and more than 560,000 will lose their battle with this terrible disease. Despite these grim statistics, significant gains in the War Against Cancer have been made through our nation's investment in cancer research and its application. Research holds the key to improved cancer prevention, early detection, diagnosis, and treatment but such breakthroughs are meaningless unless we can deliver them to all Americans in need. One barrier to ensuring that all people benefit from breakthroughs in cancer research is that recent studies have reported 126,000 registered nurse vacancies in hospitals and 13,900 registered nurse vacancies in nursing homes.

To ensure that all people with cancer have access to the comprehensive, quality care they need and deserve, ONS advocates ongoing and significant federal funding for cancer research and application, as well as programs to help ensure an adequate oncology nursing workforce to care for people with cancer. The Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer and sustain and strengthen the nation's nursing workforce.

SECURING AND MAINTAINING AN ADEQUATE ONCOLOGY NURSING WORKFORCE

Over the last 10 years, the setting in which treatment for cancer is provided has changed dramatically. An estimated 80 percent of all Americans receive cancer care in community settings including cancer centers, physicians' offices, and hospital outpatient departments. Treatment regimens are as complex, if not more so, than regimens given in the inpatient setting a few short years ago. Oncology nurses are on the front lines in the provision of quality cancer care for individuals with cancer—administering chemotherapy, managing patient therapies and side-effects, working

with insurance companies to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, and engaging in myriad other activities on behalf of people with cancer and their families.

Overall, age is the number one risk factor for developing cancer. Approximately 77 percent of all cancers are diagnosed at age 55 and older. Currently, Medicare beneficiaries account for more than 50 percent of all cancer diagnoses and 64 percent of cancer deaths. Of serious concern is that over the next 10 to 15 years the number of Medicare beneficiaries with cancer is estimated to double while more than 1.1 million registered nurse job openings will need to be filled by 2012 to meet growing patient demand and replace retiring nurses. With an increasing number of people with cancer needing high quality health care coupled with an inadequate nursing workforce, our nation could quickly face a cancer care crisis of serious proportion with limited access to quality cancer care, particularly in traditionally underserved areas. A study in the New England Journal of Medicine found that nursing shortages in hospitals are associated with a higher risk of complications—such as urinary infections and pneumonia, longer hospital stays, and even patient death. Without an adequate supply of nurses, there will not be enough qualified oncology nurses to provide the quality cancer care to a growing population of people in need and patient health and well being could suffer.

Further, of additional concern is that our nation also will have a shortage of nurses available and able to conduct cancer research and clinical trials. With a shortage of nurses in cancer research, our war against cancer will take longer because of unfulfilled staffing needs coupled with the reality that in some practices and cancer centers resources could be funneled away from cancer research to pay for the hiring and retention of oncology nurses to provide direct patient care. Without a sufficient supply of trained, educated, and experienced oncology nurses, our nation will falter in its delivery—or application—of the benefits from our federal investment in research.

ONS has joined with others in the nursing community in advocating $205 million as the fiscal year 2005 funding level necessary to support implementation of the Nurse Reinvestment Act and the range of nursing workforce programs housed at the U.S. Health Resources and Services Administration (HRSA). Enacted in 2002, the Nurse Reinvestment Act included new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our nation's nursing workforce. For example, in fiscal year 2003 HRSA received 8,321 applications for the Nurse Education Loan Repayment Program but only had funding to award 602—a rate of 7.2 percent. Also in fiscal year 2003, the agency received 4,512 applications for the Nursing Scholarship Program but only could fund 94—a rate of 2.1 percent. Further exacerbating the current situation is that nursing programs turned away more than 11,000 qualified students last fall, in part due to a shortage of faculty. If funded sufficiently, the components and programs of the Nurse Reinvestment Act would help address the multiple factors contributing to the nationwide nursing shortage, including the shortage of faculty, decline in nursing student enrollments, and poor public perception of nursing as a viable and worthwhile profession.

ONS strongly urges Congress to provide HRSA with a minimum of $205 million in fiscal year 2005 to ensure that the agency has the resources necessary to fund a higher rate of Nurse Education Loan Repayment and Nursing Scholarship applications as well as implement other essential endeavors to sustain and boost our nation's nursing workforce. Nurses—along with patients, family members, hospitals, and others—have joined together in calling upon Congress to provide this essential level of funding. One Voice Against Cancer (OVAC)—a collaboration of more than 50 national nonprofit organizations representing millions of Americans—has added a request of $205 million for the Nurse Reinvestment Act funding to its fiscal year 2005 appropriations advocacy agenda. ONS and its allies have serious concerns that without full funding, the "Nurse Reinvestment Act" will prove an empty promise; the current and expected nursing shortage will worsen and people will not be have access to the quality cancer care they need and deserve.

BOOST OUR NATION'S INVESTMENT IN CANCER PREVENTION, EARLY DETECTION, AND AWARENESS

Approximately two-thirds of cancer cases are preventable through lifestyle and behavioral factors and improved practice of cancer screening. Although the potential for reducing the human, economic, and social costs of cancer by focusing on prevention and early detection efforts remains great, our nation does not invest sufficiently

in these strategies. While as a nation we spend almost $1 trillion a year on our health care system, we only allocate about 1 percent of that amount for population-based prevention. By the year 2020, cancer and other chronic disease expenditures will reach $1 trillion or 80 percent of health care costs. The nation must make significant and unprecedented federal investments today to address the burden of cancer and other chronic diseases and to reduce the demand on the healthcare system and diminish suffering in our nation both for today and tomorrow.

As the nation's leading prevention agency, the Centers for Disease Control and Prevention (CDC) plays an important role in translating and delivering at the community level what is learned from research—especially ensuring that those populations disproportionately affected by cancer receive the benefits of our nation's investment in medical research. Therefore, ONS joins with our partners in the cancer community—including One Voice Against Cancer—in calling on Congress to provide additional resources for physical activity, nutrition, and tobacco control programs and other cancer-related screening, prevention, and public health education efforts supported through the CDC to support and expand much-needed and proven effective cancer prevention, early detection, and risk reduction efforts. Specifically, ONS advocates:

—$250 million for the National Breast and Cervical Cancer Early Detection Program;
—$65 million for the National Cancer Registries Program:
—$25 million for the Colorectal Cancer Prevention and Control Initiative;
—$25 million for the Comprehensive Cancer Control Initiative;
—$20 million for the Prostate Cancer Control Initiative;
—$10 million for the National Skin Cancer Prevention Education Program;
—$9 million for the Ovarian Cancer Control Initiative;
—$5 million for the Geraldine Ferraro Blood Cancer Program;
—$130 million for the National Tobacco Control Program; and
—$70 million for the Nutrition, Physical Activity, and Obesity Program.

SUSTAIN AND SEIZE CANCER RESEARCH OPPORTUNITIES

Our nation has benefited immensely from our past federal investment in biomedical research at the National Institutes of Health (NIH). ONS has joined with the rest of the cancer community in advocating $30.19 billion for the NIH in fiscal year 2005. This increase of 8.5 percent over fiscal year 2004 funding will allow NIH to sustain and build on its research progress resulting from the recent NIH budget doubling effort while avoiding the severe disruption to that progress that would result from a minimal increase.

Cancer research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. We have seen extraordinary advances in cancer research resulting from our national investment that have produced effective prevention, early detection and treatment methods for many cancers. To that end, ONS calls upon Congress to allocate $6.2 billion to the National Cancer Institute (NCI) in fiscal year 2005 as recommended by the NCI Director in the Bypass Budget submitted to Congress annually under the requirements of the National Cancer Act of 1971. The NCI Bypass Budget represents the best estimation of the scientific community regarding the resources needed to continue our battle against cancer.

The National Institute of Nursing Research (NINR) supports basic and clinical research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery to the reduction of risks for disease and disability and the promotion of healthy lifestyles. These efforts are crucial in translating scientific advances into cost-effective health care that does not compromise quality of care for patients. Additionally, NINR fosters collaborations with many other disciplines in areas of mutual interest such as long-term care for older people, the special needs of women across the life span, bioethical issues associated with genetic testing and counseling, and the impact of environmental influences on risk factors for chronic illnesses such as cancer. ONS joins with the nursing community in advocating an allocation of $160 million for NINR in fiscal year 2005.

CONCLUSION

ONS stands ready to work with policymakers to advance policies and support programs that will reduce and prevent suffering from cancer this year and sustain and strengthen our nation's nursing workforce. Moreover, ONS maintains a strong commitment to working with Members of Congress, other nursing societies, patient organizations, and other stakeholders to ensure that the oncology nurses of today con-

tinue to practice tomorrow and that we recruit and retain new oncology nurses to meet the unfortunate growing demand that we will face as the baby boom generation ages. We thank you for this opportunity to discuss the funding levels necessary to ensure that our nation has a sufficient nursing workforce to care for the patients of today and tomorrow and that our nation continues to make gains in our fight against cancer.

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 2005 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 admire your consistent support.

GROWING NURSING SHORTAGE

AWHONN supports the advancement of quality care through an adequate nurse workforce. Data from the Bureau of Health Professions, Division of Nursing's National Sample Survey of Registered Nurses—February 2002, confirm that of the approximate 2.7 million registered nurses in the nation, only about 82 percent of these nurses were working full-time or part-time in nursing. The increase in the number of licensed RNs that was reported from 1996–2000 was the lowest increase reported in previous national surveys. In addition to the shrinking pipeline of nurses coming into the program, the dominant factor in this shortage is the impending retirement of up to 40 percent of the workforce by 2010 or soon thereafter. This will occur at the same time that the needs of the aging baby boomer population will markedly increase demand for health care services and the services of registered nurses.

This critical demand is reinforced by the fact that in February 2004, the U.S. Bureau of Labor released statistics detailing how registered nurses have the largest projected 10-year job growth in the United States. Labor projects a need for 2.9 million nurses in 2012, up from 2.3 million actively working nurses that was projected in 2002. As a result, it will take long-term planning and innovative initiatives at the local, state and federal level to assure an adequate supply of a qualified nurse workforce for the nation.

Nurse Workforce Development Programs

AWHONN recommends a total of $205 million for fiscal year 2005 to fund the Nurse Workforce Development programs in Title VIII

The Nurse Education Act (Public Health Service Act, Title VIII), enacted in 1964, represents the only comprehensive federal legislation to provide funds for nursing education. The programs authorized in this portion of Public Law 105–392 help 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 2002 Congress enacted the Nurse Reinvestment Act which provides funding for new and expanded programs. These programs include scholarships, career ladders, internships and residencies, retention programs and faculty loans designed to encourage students to consider nursing, keep nurses in nursing and ensure that nurse educators are plentiful enough to educate future nurses that we desperately need. The new programs received an initial appropriation of $20 million in fiscal year 2003. This appropriation was in addition to $93 million in funding provided for existing Title VIII programming. Unfortunately, due to limited funding in the first 2 years of the new authorization the loans and scholarships programs have not been successful in providing support to students in nursing schools. In the first year, only 574 loan repay-

ment contracts were made nationally, averaging roughly 11 loan repayment agreements per state and less than 2 percent of all scholarship applicants were funded.

The shortage of registered nurses and the effect of the shortage on nurse staffing and patient safety demand a significant increase in funding for these nurse education programs. Nursing is the largest health profession with over 2.7 million nurses, yet only one-tenth of 1 percent of the federal health funding of the nation is directed to nursing education. A significant increase in funding for these programs would lay the groundwork to expand the nursing workforce, through education, clinical training and retention programs, in order to address some of the serious nursing shortage issues. This investment in nursing education and retention will ultimately benefit us all through improved patient care and health outcomes.

The nursing shortage is not confined solely to care providers; there is also a growing, significant shortage of nurse faculty. The American Association of Colleges of Nursing (AACN) reports that the average age of nursing professors is 52, and for associate professors the average age is 49. The impending retirement of these seasoned educators will impact the ability of our schools and universities to meet the educational health care needs of the nation. In addition, each year nearly 1,800 full-time faculty members leave their positions while only 350 to 400 nursing students receive doctoral degrees. According to AACN, U.S. nursing schools turned away over 11,000 qualified applicants to baccalaureate nursing programs in 2003 due to insufficient faculty, clinical sites, classroom space, and budget constraints. While the capacity to implement faculty development is currently available through Section 811 and Section 831, adequate funding and direction is needed to ensure that these programs are fully operational. Options to provide support for full-time doctoral study are essential to rapidly prepare the nurse educators of the future. AWHONN suggests that a portion of the funds be allocated for faculty development and mentoring. Further, AWHONN recognizes the importance of appropriate investments in advanced practice nursing programs. As in other professions the advanced degree has become a necessary achievement for career advancement and registered nurses who pursue the MSN degree are a part of the cadre of nurses who go on to become faculty. Our nation does need more nurses with basic training to enter the field, but focusing only on these nurses only addresses half the problem. The nursing shortage encompasses nursing faculty—advanced practice nursing and basic nursing must both receive additional funding, but not one at the expense of the other.

Maternal and Child Health Bureau

AWHONN recommends $850 million in funding in fiscal year 2005 for the Maternal and Child Health Bureau

This program provides comprehensive, preventive care for mothers and young children, as well as an array of coordinated services for children with special needs. In fact, the Maternal Child Health Block Grant (MCH) serves over 80 percent of all infants in the United States, half of all pregnant women, and 20 percent of all children.

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, in NINR research, to improve the prenatal health-related behavior of women and reduce rates of child abuse and neglect as well as maternal welfare dependence.

Indian Health Service

AWHONN recommends an fiscal year 2005 appropriation of $5.54 billion for IHS.

The Indian Health Service (IHS) is the principal Federal health care provider and health advocate for Indian people with the goal of "ensur[ing] that comprehensive, culturally acceptable personal and public health services are available and accessible to all American Indian and Alaska Native people." IHS is tasked with an enormous responsibility in providing care to over half of the American Indian population.

The American Indian and Alaska Native people have long experienced lower health status when compared with other Americans. Lower life expectancy and the disproportionate disease burden exist perhaps because of inadequate education, disproportionate poverty, discrimination in the delivery of health services, and cultural

differences. These are broad quality of life issues rooted in economic adversity and poor social conditions.

A recent study of federal health care spending per capita found that the United States spends $3,803 per year per federal prisoner, while spending about half that amount per year, per Native American: $1,914. per capita health care spending for the U.S. general population is $5,065 per year. A significant increase in funding over fiscal year 2004 spending levels is necessary for the Federal government to fulfill its responsibility to Indian Country and achieve its stated goals.

While the nursing shortage continues nationwide, IHS has been disproportionately impacted by the lack of RNs. IHS nurses are older, with an average age of 48 and nearly 80 percent of RNs are over the age of 40, and the average vacancy rate for RNs is 14 percent. IHS administers three interrelated scholarship programs designed to meet the health professional staffing needs of IHS and other health programs serving Indian people. These programs are severely under-funded. Targeted resources need to be invested in the IHS health professions programs in order to recruit and retain registered nurses in Indian Country.

Additionally, Section 112 of the Indian Health Care Improvement Act, Public Law 94–437, authorizes grants to public or private schools of nursing, tribally-controlled community colleges and tribally-controlled post secondary vocational institutions for the purpose of recruiting, training and increasing the number of professional nurses who deliver health care services to Indian people. On average, Section 112 programs provide five undergraduate scholarships per year and two master's program scholarships. This important program should be expanded to provide many more scholarships, both at the undergraduate and graduate levels, in an effort to offer meaningful relief to the nursing shortage for IHS healthcare providers and the patients they serve.

National Institute of Nursing Research (NINR)

AWHONN recommends an increase of $25 million over fiscal year 2004 funding levels for the NINR, resulting in an fiscal year 2005 appropriation of $160 million

NINR engages in significant research affecting areas such as: health disparities in ethnic groups, training opportunities for management of patient care and recovery, and telehealth interventions in rural/underserved populations. These research programs directly help patients and families and contribute to decreased medical costs and increased quality of patient care. This research allows us to refine the practice and provide quality patient care in its current challenging environment.

NINR research improves health outcomes for women. Recent public awareness campaigns target differences in the manifestation of cardiovascular disease between men and women. The differing symptoms are the source of many missed diagnostic opportunities among women suffering from the disease, which is the primary killer of American women. In a study funded by NINR, researchers were able to qualitatively analyze the intensity of pain and limitation of activity experienced by women suffering from angina, both of which were found to be of greater intensity than that experienced by men. The study concluded that the gender variation could significantly impact diagnosis and treatment of female patients suffering from related cardiovascular problems.

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 a 10 percent increase in funding for NICHD for fiscal year 2005, bringing the appropriation to $1.315 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.

Recently NICHD announced the publication of research that led to the finding of predictors of preeclampsia, a life-threatening complication impacting 5 percent of all pregnancies. Abnormal levels of two molecules found in the blood, soluble fms-like tyrosine kinase 1 (sFlt–1) and placental growth factor (PlGF), seemed to predict the development of preeclampsia. This finding has been touted as the most promising lead yet discovered in the effort to prevent and cure preeclampsia.

National Institutes of Environmental Health Sciences (NIEHS)

AWHONN supports an 8 percent increase in funding for NIEHS for fiscal year 2005, bringing the appropriation to $680 million

Research conducted by the NIEHS plays a critical role in what we know about the relationship between our environmental exposures and disease onset. Through the research sponsored by this Institute, we know that Parkinson's disease, breast cancer, birth defects, miscarriage, delayed or diminished cognitive function, infertility, asthma and many other diseases and ailments have confirmed environmental triggers. Our expanded knowledge, as a result, allows both policy makers and the general public to make important decisions about how to reduce toxin exposure and reduce the risk of disease and other negative health outcomes.

One impressive collaborative research project spearheaded by the NIEHS is the recent development of Breast Cancer and the Environment Research Centers. These centers, co-funded by the National Cancer Institute, will study the prenatal-to-adult environmental exposures that may predispose a woman to breast cancer. Recognizing that one in eight women in the United States can expect to have breast cancer in her lifetime, and that the causes of most of these cases are not known; the centers will enroll different ethnic groups of young girls and study their life exposures to a wide variety of environmental, nutritional and social factors that impact puberty.

Centers for Disease Control and Prevention (CDC)

AWHONN recommends an fiscal year 2005 appropriation of $7.9 billion for the CDC

For nearly 60 years, the Centers for Disease Control and Prevention (CDC) has evolved to assume responsibility for programs in infectious disease surveillance, control and prevention, injury control, health in the workplace, prevention of heart disease, cancer, stroke, obesity and other chronic diseases, improvements in nutrition and immunization, environmental effects on health, prevention of birth defects, laboratory analyses, outbreak investigation and epidemiology training, and data collection and analysis on a host of vital statistics and other health indicators. Now more than ever, CDC's role in protecting the nation's health through prevention has become evident as we address issues of terrorism, emergency preparedness and health system capacity and infrastructure. Increased funding for CDC is critical.

For over 30 years, CDC has been deeply involved in the prevention of birth defects through programs like the Folic Acid Education Campaign and the new National Center on Birth Defects and Developmental Disabilities (NCBDDD). The public health impact of birth defects is tremendous. Of the 4 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. CDC funds several programs critical to reducing the number of children born with birth defects.

Heart disease and stroke are the first and third leading causes of death in the United States, causing one death every 33 seconds and $298 billion a year in healthcare costs and lost productivity, according to CDC estimates. Women are most commonly misdiagnosed for cardiovascular disease and nearly 8 million women are currently living with cardiovascular disease. Cardiovascular disease kills nearly half of all American women. Additionally, 61 percent of American adults are overweight or obese and nearly 14 percent of children and adolescents are overweight. Obesity is considered a major public health problem because it serves as the gateway disease for many other illnesses including but not limited to: depression, type 2 diabetes, hypertension, congestive heart failure, stroke, poor female reproductive health and pregnancy complications. These are but two examples of illnesses with pro-

[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.

grammatic public health funding through CDC. Any cuts to these programs will potentially leave millions of Americans without primary prevention programs that ultimately save lives and money. We respectfully request that you provide CDC chronic disease prevention and health promotion programs with $1.1 billion to ensure that these programs have the resources necessary to translate preventive health research into practice. This investment will save lives and billions in health care costs and productivity.

Please find below a summary of AWHONN formal funding recommendations for these and other federal health programs.

Programmatic area	Final fiscal year 2004	President's budget fiscal year 2005	AWHONN's request
Nurse Workforce Development Programs	$142,763,000	$147,000,000	$205,000,000
Maternal & Child Health Block Grant	730,000,000	730,000,000	850,000,000
Indian Health Service	3,671,000,000	3,356,000,000	5,540,000,000
Title X—Family Planning	278,000,000	278,000,000	350,000,000
Newborn Hearing Screening	13,000,000	.....	13,000,000
AHRQ	305,000,000	305,000,000	443,000,000
NIH	28,041,000,000	28,805,000,000	31,685,500,000
NINR	135,000,000	139,000,000	160,000,000
NICHD	1,242,000,000	1,281,000,000	1,315,000,000
NIEHS	631,000,000	650,000,000	680,000,000
CDC	6,972,000,000	6,859,000,000	7,900,000,000

Thank you for the opportunity to submit testimony on these critical areas of funding.

Contact: Lisa M. Greenhill, MPA, Legislative Manager Department of Public Affairs Association of Women's Health, Obstetric and Neonatal Nurses 2000 L St. NW, Suite 740, Washington, DC 20036 (202) 261–2402 lisag@awhonn.org

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PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Heart disease, stroke and other cardiovascular diseases kill more Americans each year than the next 5 leading causes of death combined, putting people of all ages at risk. Cardiovascular diseases remain our nation's No. 1 killer and a major cause of disability. We are concerned that our government is still not devoting sufficient resources for research and prevention to America's No. 1 killer—heart disease—and to our country's No. 3 killer—stroke.

STILL NO. 1—AN UNHAPPY DISTINCTION

Cardiovascular diseases represent a continuing crisis of pandemic proportions. More than 64 million Americans suffer from these diseases, and risk factors are on the rise. While smoking is the top preventable cause of death, the obesity epidemic is catching up. Obesity rates are rising in adults and in children. Also, an estimated 50 million Americans have high blood pressure, 37 million adults have high cholesterol, and more than 11 million have diagnosed diabetes. Also, cardiovascular diseases cost Americans more than any other disease—an estimated $368 billion in medical expenses and lost productivity in 2004. Heart disease is the major cause of premature, permanent disability of American workers, accounting for about 20 percent of Social Security disability payments. Stroke is a main cause of disability. Heart defects are the most common birth defect and cause more infant deaths than any other birth defect.

YOU ARE PART OF THE SOLUTION

Now is the time to capitalize on progress in understanding heart disease, stroke and other cardiovascular diseases. Promising, cost-effective breakthroughs in treatment and prevention are on the horizon. A continued, sustained investment in the NIH and appropriate funding for NIH heart disease and stroke will support promising and critically needed new initiatives and the translation of that research into useful clinical and state programs. For fiscal year 2005, we urge you to:

Appropriate $30.6 billion for the National Institutes of Health (NIH)—to provide a continued, sustained investment in life-saving medical research

NIH research provides new treatment and prevention strategies, creates jobs, and maintains America's status as the world leader in the biotechnology and pharmaceutical industries.

Provide $2.5 billion for NIH heart research and $410 million for NIH stroke research

Researchers are on the brink of advances to enhance prevention and to provide new treatments so you and your loved ones can be spared the pain and suffering of heart disease and stroke.

Allot $80 million for Heart Disease and Stroke for the CDC to expand, intensify and coordinate prevention like expanding the State Heart Disease and Stroke Prevention Program and augmenting the Paul Coverdell National Acute Stroke Registry

Science must be translated into state programs that hearten Americans to make healthy lifestyle choices to avert and control heart disease and stroke and track and improve stroke care delivery.

Support $45 million to continue to help our communities treat cardiac arrest in time to save victims' lives by initiating automated external defibrillator (AEDs) programs

The Rural Access to Emergency Devices Act (part of Public Law 106–505) and the Community Access to Emergency Defibrillation Act (part of Public Law 107–188) help communities purchase AEDs and train emergency and lay responders in their use.

HEART AND STROKE RESEARCH BENEFITS ALL AMERICANS

The doubling of the NIH budget has led to new breakthroughs in treating heart disease and stroke patients and their risk factors for these diseases. Several examples follow.

High Blood Pressure.—A clinical trial concluded that customary diuretic drugs should be the first treatment for lowering blood pressure. The diuretic tested as well or better than some newer types of drugs in preventing high blood pressure complications, including fatal and non-fatal heart attacks, strokes and heart failure. The cost implications are significant because diuretics cost a fraction of the price of the newer drugs.

Hormone Replacement Therapy.—Researchers concluded that long-term estrogen plus progestin therapy risks outweigh its protective benefits. Women study participants taking estrogen plus progestin had increased risks of heart attack, stroke, breast cancer and blood clots.

Heart Attack.—More than 5 million patients with chest pain visit emergency departments each year, but only about 40 percent can be immediately diagnosed with heart attack using standard diagnostic tests. Results from a collaborative study using advanced, non-invasive magnetic resonance imaging showed that MRI can detect a heart attack in emergency room patients with chest pain more accurately and faster than standard diagnostic tests. Since patients can be scanned in under 40 minutes, MRI technology will save lives and reduce disability among survivors by allowing doctors to diagnose heart attacks and start treatment faster.

Recurrent Stroke Prevention.—Results of two clinical trials showed that aspirin was just as effective in preventing recurrent strokes as expensive drugs. Outcomes of the first trial indicated that aspirin appears to be as effective as warfarin in preventing a second stroke, when heart conditions such as atrial fibrillation, a common heart rhythm and rate problem, are not present. Results from the second study showed that aspirin is as effective as ticlopidine, a type of clot inhibitor, in preventing a second stroke in African-Americans who have twice the risk of suffering or dying from a stroke, compared to whites. These results will dramatically change physician care in preventing second strokes in the general public and in African-Americans. Given the lower cost, ease of administration and reduced side effects, compared to warfarin and ticlopidine, aspirin will be a cost-effective method in preventing subsequent strokes.

We join other members of the research community in advocating for an fiscal year 2005 appropriation of $30.6 billion for the NIH to provide a continued, sustained investment in life-saving medical research and support investigation into new therapies. The NIH budget for heart disease and stroke remains disproportionately under funded compared to the enormous burden of these diseases and the numerous promising scientific opportunities that could advance the fight against these disorders. Heart disease, stroke and other cardiovascular diseases meet the NIH's criteria for priority setting (public health needs, scientific quality research, scientific progress potential, portfolio diversification and adequate infrastructure support), but the NIH still invests only 7 percent of its budget on heart research and a mere 1 percent on stroke research. We have a particular interest in individual NIH components that relate directly to our mission. Our funding recommendations for these Institutes follow.

HEART RESEARCH CHALLENGES AND OPPORTUNITIES FOR NHLBI

Advances have been made by more than 50 years of American Heart Association-funded research and more than a half-century of investment by Congress in the National Heart, Lung, and Blood Institute. While more people are surviving heart disease and stroke, they can cause permanent disability, requiring costly medical care and loss of productivity and quality of life.

We urge this Committee to appropriate funding for the NHLBI and for its heart disease and stroke-related efforts to support and expand current activities and to invest in promising and critically needed new initiatives to aggressively advance the battle against heart disease and stroke. To accomplish this goal, we advocate an appropriation of $3.5 billion for the NHLBI, including $2.1 billion for heart disease and stroke. This added investment is needed to focus on heart disease and stroke challenges and opportunities. Several of these follow.

Heart Failure Management.—Heart failure is a major cause of hospitalization and readmission. Medicare recipients represent about 65 percent of repeat hospitalizations within 1 year. Yet, perhaps 50 percent of these hospitalizations are avoidable. Additional funding would allow the NHLBI to initiate a planned multi-center, randomized trial to evaluate management strategies for heart failure patients in terms of their ability to prevent death or hospital readmission. Costs, quality of life, physician compliance, and patient adherence to prescribed treatment will also be assessed. This clinical trial will identify and disseminate useful and effective tools for translation of proven therapies for heart failure into patient care.

Tissue Engineered Blood Vessel Replacement and Repair.—A need exists to develop alternatives to natural blood vessels for adults who endure heart artery bypass surgery and for children born with complex heart defects who need multiple blood vessel grafts. With increased funding, this planned initiative will complement exiting tissue engineered research programs to stimulate efforts to "grow" small-diameter, functional blood vessels.

Cardiovascular Health Study.—Initiated in 1987 to determine risk factors for development and progression of cardiovascular diseases in nearly 6,000 Americans age 65 and older, the Cardiovascular Health Study (CHS) is scheduled to end in 2005. The wide variety and complexity of data and samples collected in the CHS represent an unique national research resource. With increased funding, this planned proposal will stimulate innovative use of CHS data and material, provide opportunities for open and efficient use of the information for the entire scientific community; and continue follow-up of study participants.

Community-Responsive Interventions to Reduce Cardiovascular Risk in American Indians and Alaskan Natives.—American Indian and Alaska Native communities bear a disproportionate burden of heart disease, stroke and other cardiovascular diseases. But, few preventive interventions have been tested. Tribal leaders have urged that research in their communities focus on finding solutions for the most serious issues these populations face, including cardiovascular diseases. To address the concerns of the tribal leaders, with increased funding, researchers will evaluate approaches to reducing behavioral cardiovascular disease risk factors in American Indian and Alaskan Native populations. A central part of this planned initiative will be the development of interventions that can be incorporated into community patient care programs or delivered through other public health avenues in native communities.

STROKE RESEARCH CHALLENGES AND OPPORTUNITIES FOR NINDS

Stroke is the No. 3 killer of Americans and a major cause of permanent disability. Many of America's 4.8 million stroke survivors face debilitating physical and mental impairment, emotional distress and huge medical costs. About 1 in 4 stroke survivors is permanently disabled. An estimated 700,000 Americans will suffer a stroke this year, and nearly 164,000 will die. In addition to the elderly, stroke also strikes newborns, children and young adults.

We urge you to provide sufficient funding for the NINDS to support and expand current activities and to invest in promising and critically needed new initiatives to aggressively prevent stroke, protect the brain during stroke and enhance rehabilitation. To accomplish this goal, we advocate for an fiscal year 2005 appropriation of $1.8 billion for the NINDS, including $204 million for stroke. Some challenges and opportunities follow:

Strategic Stroke Research Plan.—As a result of congressional report language during the fiscal year 2001 appropriations process, the NINDS convened a Stroke Progress Review Group. Their report serves as a blueprint for a long-range strategic stroke research plan. They identified serious gaps in stroke knowledge and outlined

5 research priorities and 7 resource priorities that would spur stroke research. But, more funding is needed to continue to implement this plan.

Emerging Stroke Risk Factors.—Although more Americans are controlling major stroke risk factors, such as high blood pressure and smoking, the number of stroke victims continues to rise. Scientists are defining new risk factors, re-examining existing ones and reconsidering the long-held belief that no difference exists in risk between young and older patients with similar risk factors. Researchers are studying heart valve disease, irregular heartbeats, the role of inflammation in damaging arteries, and the long-term effects of high blood pressure. Increased funding to study these areas may lead to new ways to prevent stroke.

Therapeutic Strategies for Stroke.—Several major clinical trials have identified new methods for preventing and treating stroke in high-risk populations. But, with the increased number of strokes, and with the disparities in stroke treatment, new ways to prevent strokes, to raise awareness, and to better treat strokes need to be developed and evaluated. Funding for new clinical studies is vital for developing cutting-edge stroke treatment and prevention.

Stroke Education.—Less than 5 percent of patients eligible for tPA—the only FDA approved emergency treatment for clot-based stroke—receive it. As a member of the Brain Attack Coalition, a group of organizations devoted to fighting stroke, we work with the NINDS to increase public awareness of stroke symptoms and the need to call 9–1–1. Together, we launched a public education campaign, Know Stroke, Know the Signs. Act in Time, and we are striving to develop systems to make tPA available to appropriate patients. When these measures are implemented, stroke treatment will change from supportive care to early brain-saving intervention. More funding is needed to educate the public and health providers about stroke.

RESEARCH IN OTHER NIH INSTITUTES BENEFIT HEART DISEASE AND STROKE

Research seeking to prevent and find better treatments for heart disease, stroke and other cardiovascular diseases is supported by other NIH entities like the National Institute on Aging, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Nursing Research and the National Center for Research Resources. It is important to provide sufficient additional resources for these entities to continue and expand their critical work.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The AHRQ acts as a "science partner" with public and private health care sectors in improving health care quality, reducing health care costs and broadening access to essential services. They help develop evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. We join with the Friends of AHRQ in advocating for an appropriation of $443 million for the AHRQ to advance health care quality, cut medical errors and expand the availability of health outcomes information.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Prevention is the best way to protect Americans' health and ease the financial burden of disease. Resources must be made available to bring research to places where heart disease and stroke strike—our towns and neighborhoods. Setting the pace on prevention, the CDC builds a bridge between what we learn in the lab and translates findings into programs in the communities where we live. We advocate an fiscal year 2005 appropriation of $8.1 billion for the CDC, with a $340.5 million increase for state-based chronic disease prevention and health promotion programs.

Within that figure, we support an appropriation of $80 million for the CDC's Heart Disease and Stroke line to better expand, intensify and coordinate prevention activities against these diseases such as enhancing the State Heart Disease and Stroke Prevention Program, and the Paul Coverdell National Acute Stroke Registry. It will also allow the CDC to start a heart attack and stroke signs health communications campaign, public and health care provider education, and invest in standardized methodology on lipid and other measurements. A Heart and Stroke Division, with ample resources and capacity, would heighten CDC's efforts on these diseases.

Thanks to this Committee's support since fiscal year 1998, the CDC's State Heart Disease and Stroke Prevention Program covers 33 states. But, only 11 states receive funding to actually implement programs to help prevent and control heart disease and stroke. The remaining 22 states have completed program planning and are prepared and waiting to implement a state-tailored program. This initiative allows states to design and/or implement programs to meet state specific needs to prevent heart disease, stroke and other cardiovascular diseases. Since cardiovascular diseases remain the No. 1 killer in every state, each state needs funding for basic im-

plementation of a State Heart Disease and Stroke Prevention Program. With fiscal year 2004 funding, the CDC can only elevate one state from planning to program implementation.

An appropriation of $80 million would allow the CDC to expand the number of states participating in this State Heart Disease and Stroke Prevention Program by 5 states to conduct a state-tailored heart disease and stroke prevention plan, and elevate 10 more states from the planning stage to program implementation and support the other currently funded states. Also, the CDC would enlarge the Paul Coverdell National Acute Stroke Registry. This registry tracks and improves delivery of acute stroke care—care that can mean the difference between a fairly normal life and long-term disability. The CDC developed and conducted registry prototypes from 2001–2003 and will begin to fund three state registries in fiscal year 2004.

We recommend the following fiscal year 2005 funding levels for the following CDC programs:

—$210 million for the Preventive Health and Health Services Block Grant;
—$70 million for the Nutrition, Physical Activity and Obesity Program;
—$125 million for the Youth Media Campaign;
—$82.4 million for the School Health Education Program; and
—$130 million for the Office of Smoking and Health.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

About 340,000 Americans die each year from sudden cardiac arrest. About 95 percent of the victims die before reaching a hospital. AEDs are small, easy-to-use devices that can shock a heart back into normal rhythm and restore life. The Rural Access to Emergency Devices Act and the Community Access to Emergency Defibrillation Act authorize funds for state and local governments to start AED programs. States, cities and towns nationwide eagerly await funds from these vital public health service grant awards, with available funds far below state requests. An appropriation of $45 million is required to support these authorized programs.

DEPARTMENT OF EDUCATION

Physical inactivity is a key risk factor for heart disease and stroke. Yet, our youth have fewer chances for physical education. Congress has been appropriating money for the Carol M. White Physical Education for Progress (PEP) Act to provide funding for school-based physical education programs, which teach life-long physical activity habits and thus prevents diseases, like heart disease and stroke. We advocate for an appropriation of $100 million for PEP.

ACTION NEEDED

Increasing funding for research, prevention and treatment programs will allow continued strides in the battle against heart disease, stroke and other cardiovascular diseases. Our government's response to this challenge will help define the health and well being of Americans for decades.

PREPARED STATEMENT OF LIVING CITIES: THE NATIONAL COMMUNITY DEVELOPMENT INITIATIVE

Thank you, Senator Specter and Subcommittee members, for the opportunity to share with you the views of Living Cities: The National Community Development Initiative on the administration's fiscal year 2005 budget request for the Office of Community Services within the U.S. Department of Health and Human Services (HHS.)

Living Cities is a nonprofit consortium of 15 major financial and philanthropic organizations working to increase the vitality of cities and improve the lives of people in distressed urban neighborhoods. These organizations are AXA Community Investment Program, Bank of America, the Annie E. Casey Foundation, J.P. Morgan Chase & Company, Deutsche Bank, Fannie Mae Foundation, Robert Wood Johnson Foundation, W.K. Kellogg Foundation, John S. and James L. Knight Foundation, John D. and Catherine T. MacArthur Foundation, the McKnight Foundation, Metropolitan Life Insurance Company, Prudential Financial, the Rockefeller Foundation, and Surdna Foundation.

In addition, HHS and the U.S. Department of Housing and Urban Development (HUD) are investment partners in Living Cities. HHS and HUD representatives attend Living Cities meetings, but are not voting members of the organization. Neither HUD nor HHS had any involvement in the preparation of this testimony, and the testimony does not represent either agency's views in any way. This testimony

also does not represent the views of individual member organizations in Living Cities. This testimony is entirely and exclusively on behalf of Living Cities, a stand-alone charitable organization.

Started as NCDI in 1991, Living Cities has worked with the Local Initiatives Support Corporation (LISC) and The Enterprise Foundation to make strategic investments in the work of nonprofit community development corporations (CDCs) in 23 cities—Atlanta, Baltimore, Boston, Chicago, Cleveland, Columbus, Dallas, Denver, Detroit, Indianapolis, Kansas City, Los Angeles, Miami, Minneapolis-St. Paul, Newark, New York City, Philadelphia, Phoenix, Portland, Oregon, San Antonio, San Francisco Bay Area, Seattle, and Washington, D.C.

The results are tangible. Improvements can be seen in transformed neighborhoods—new homes, places of employment, and the visible presence of stronger community organizations. The Living Cities investment of $254 million has directly supported the creation of almost 20,000 affordable housing units and 1.7 million square feet of commercial, industrial and community facilities developed by CDCs, and has leveraged $2.2 billion, a leverage ratio of nearly 9:1. The federal investment in the Living Cities initiative over the first decade was $36 million, achieving a leverage ratio of 61:1 for these federal dollars.

Based upon our experience, we find that urban neighborhoods have the workers, purchasing power, and physical assets ready to be tapped through a combination of public and private investments. That is why our collaborative is doubling our commitments in the current decade, increasing our investments by an additional half-billion dollars between 2001 and 2011.

IMPORTANCE OF ACCOUNTABILITY

We believe that lessons can be drawn from Living Cities' experience of investing in distressed urban neighborhoods, useful lessons for policy and funding decisions to strengthen distressed communities nationwide. Like this Subcommittee, we demand individual accountability and results from the entities that receive Living Cities resources. Since our inception, we have engaged outside experts to take a hard look at what CDCs are achieving. We are glad to share the results of these studies with the Subcommittee.

Beyond our own research, two federal agencies, the General Accounting Office and the Office of Management and Budget, this year applauded the successful use of federal NCDI/Section 4 funds to strengthen CDCs by improving their internal management, increasing their capacity, and widening their impact.

HHS/OCS: A VITAL PARTNER IN COMMUNITY REVITALIZATION

The history of CDCs is well known. CDCs began forming in the 1960s to address the failure of mainstream government and market structures to provide decent housing, safe neighborhoods, good jobs, and resident participation in planning for their own future. From the outset of the CDC movement, communities that were served ranged from a few square blocks in a single urban neighborhood to multi-county rural areas. Target populations have been equally diverse—including all races and ethnic groups, farmers, immigrants, welfare recipients, small business owners, juveniles, the homeless. What has been consistent among CDCs is that each one has come from and represents a community, and each one has harnessed resources from both the public and private sectors of the economy.

Different administrations have lent their support to CDCs over the decades. During the 1960s, CDCs were viewed as complementary to government. Their role was to encourage neighborhood development, promote anti-poverty strategies, and deliver social services—with generous federal support provided to fuel them. During the Reagan years, CDCs came to be seen by some as alternatives to government. CDCs developed stronger alliances with state and local governments and with private sector partners. These alliances expanded the impact of CDCs. By the 1990s, CDCs were viewed as playing a dual role—as complementary to government and as enhancements to markets.

As you know, the Department of Health and Human Services, Office of Community Services, Community Services Block Grant Act Secretary's Discretionary Fund for Community Economic Development is a significant program of federal assistance to CDCs. This program has been a resource that is critical to the success of community development, a resource that needs to continue.

We focus here on the Discretionary Grant Program of the Office of Community Services, because this program has stood the test of time and has proven to be very successful in using federal dollars to leverage private sector investments to create jobs through economic development projects sponsored by CDCs. This success is il-

lustrated by the following examples of economic development projects selected from some of the CDCs and cities in which Living Cities invests.

Asociacion de Puertorriquenos en Marcha, Inc. in Philadelphia

Received a $500,000 grant from the Office of Community Services that leveraged investment to support $5,100,000 in total development costs for the Gateway Plaza in Philadelphia.

The OCS grant created 125 jobs.

Abyssinian Development Corporation in New York City

Received a $500,000 grant from the Office of Community Services that leveraged investment to support $16,000,000 in total development costs for the Pathmark Supercenter.

The OCS grant created 275 jobs.

Northeast Neighborhood Development in Cleveland

Received a predevelopment grant of $75,000 to perform market and business studies on the potential for improving the retail climate of a key intersection in its community.

While the program is still underway, the OCS grant has already created 10–15 jobs.

Vermont Slauson Economic Development Corporation in Los Angeles

Received a $450,000 grant from the Office of Community Services that leveraged investment to support $1,200,000 in total development costs for the Ranch Markets project.

The OCS grant created 70 jobs.

Bethel New Life in Chicago

Received a $700,000 grant from the Office of Community Services that leveraged investment to support $3,225,000 in total development costs for the Material Recovery Facility project.

The OCS grant created 145 jobs.

Jane Addams Resource Corporation in Chicago

Received a $250,000 grant from the Office of Community Services that leveraged investment to support $1,100,000 in total development costs for the 4422–36 North Ravenswood project and a $300,000 OCS grant that leveraged investment to support $1,000,000 in total development costs for the 4410 North Ravenswood project.

These OCS grants together created 55 jobs.

In order to build on such successful public and private investments in distressed urban neighborhoods, Living Cities finds it to be critically important to continue investment in job creation for low-income people and to continue funding at the highest possible level for programs that have a long history of success. As we have committed to doubling our investment in the current decade, we urge the Subcommittee to support a commensurate increase in funding for the OCS Discretionary Grants Program. We also offer to work with the Subcommittee to explore ways in which the OCS grants can foster further public/private cooperation so as to leverage additional private investment by Living Cities.

The work that has been done over the past decade to strengthen CDCs has increased their capacity to participate in the OCS Discretionary Grants Program. CDCs are providing the infrastructure to achieve economic and social redevelopment of low-income neighborhoods. CDCs take the risks as early investors, providing seed money and working capital for community development projects that become catalysts for further private investment. They encourage the participation of residents in the redevelopment of their communities, prepare the workforce for employment, develop local businesses and provide capital and technical support to other businesses in their target areas. CDCs secure funding for these activities from government, financial institutions, corporations, foundations and other individual funders

Living Cities is supporting CDCs in these activities through our investments in their work and by supporting research on urban markets, including the collection of data on which business and investment decisions are based. Based upon our experience, we see that even very troubled neighborhoods can revive when community leaders, government, and the private sector work together.

We are optimistic about the future of America's cities, given the very real progress we see. In the past decade, the population of the nation's largest 50 cities grew by nearly 10 percent. This was accompanied by a rise in city incomes that outpaced the national average (7 percent versus 4 percent, respectively) and an increase in housing units, homeownership and mortgage lending. At the same time, in certain

urban areas concentrated poverty fell 24 percent in the last decade and urban crime decreased. Inner cities have become hubs of economic activity, with annual retail spending power of $85 billion or the equivalent of 7 percent of U.S. retail spending. Business investment has returned to some urban markets, bringing goods, services and job opportunities. This progress bodes well for the economic strength of cities, their regions, and the nation, economic strength that we believe depends upon strong economies in urban neighborhoods.

PILOT CITIES INITIATIVE

Now in the second decade, Living Cities funders have challenged themselves to do more. First, we have committed to investing an additional $500,000,000 in the current decade. We also are building on the successes of the first 10 years by creating a new investment model, the Pilot Cities Initiative in Baltimore, Chicago, Miami and the Twin Cities of Minneapolis and St. Paul. This initiative is creating new ways for Living Cities investment partners and other funders to align resources over a sustained period of time in order to have a greater positive impact in distressed communities.

Through this new, more powerful model, funders will engage in collaborative efforts to develop healthier neighborhoods by enhancing the linkages between inner city neighborhoods and their residents and the larger economies of their cities and their regions. This initiative also will encourage CDCs to develop new relationships with philanthropy and to expand the impact of economic development by working more closely with other institutions that are serving the same neighborhoods.

CONCLUSION

Despite the significant gains made in Living Cities communities during the first decade and our ambitious plans for the next, we have learned that future gains will be severely limited without additional federal investment. We respectfully request that the Subcommittee consider:

—Increasing the current funding level for the OCS Discretionary Grants Program by an amount that Living Cities will match;
—Encouraging the use of grants to attract further private investment and foster more public/private partnerships; and
—Allowing funding dollars to be used to collect data that document the opportunities in the workforce and the purchasing power of lower-income communities, with OCS serving as the lead federal agency in gathering and making information accessible to people who make business and investment decisions.

It will take a concentrated national effort, but we are determined to see cities across the country reach and sustain healthy status in our time, a level that is worthy of the richest society in the history of humankind. With the support of private and public resources, including the OCS Discretionary Grants Program, CDCs can continue their significant work towards the goal of economic well-being, a goal that includes job opportunities for low-income people.

Thank you for this opportunity to present our views regarding this important program to the Subcommittee.

PREPARED STATEMENT OF THE AMERICAN PUBLIC TRANSPORTATION ASSOCIATION

INTRODUCTION

Mr. Chairman, thank you for the opportunity to submit a statement for the record to the Subcommittee on Labor, Health and Human Services and Education regarding the fiscal year 2005 Labor, Health and Human Services and Education Appropriations Bill.

We submit our views to the Subcommittee to make the point that not only can public transportation make a critical difference in how people get to jobs, health care, training and other social services, but can also provide significant cost efficiencies in the process. It is our hope to work with committee staff in developing report language to highlight this important issue.

ABOUT APTA

The American Public Transportation Association (APTA) is a nonprofit international association of over 1,500 public and private member organizations including transit systems and commuter rail operators; planning, design construction and finance firms; product and service providers; academic institutions; transit associations and state departments of transportation. APTA members serve the public in-

terest by providing safe, efficient and economical transit services and products. Over 90 percent of persons using public transportation in the United States and Canada are served by APTA members.

THE EFFICIENCIES OF TRANSPORTATION COORDINATION ARE RECEIVING GREAT ATTENTION FROM CONGRESS AND THE ADMINISTRATION

Mr. Chairman, the current budgetary climate and the emphasis it has brought on doing more with limited resources provides a fitting context for our focus on of transportation coordination. We believe that relatively minor legislative changes based on simplicity and common sense can provide for necessary consistencies across programs to make transportation coordination work.

Recognizing the efficiencies and additional riders and resources that are possible through improved coordination, APTA has long believed in the potential of greater coordination between human service providers and transportation providers. We have long seen the potential for coordinated transportation to lower the costs of services to taxpayers, enhance the scope and quality of service to customers, and to avoid the duplicate purchase and use of equipment.

In May 2003, the House Committee on Transportation and Infrastructure and the House Committee on Education and the Workforce held a joint hearing to examine both the potential of and the obstacles to coordination. One Member at that hearing noted that enhancing the coordination of human services and transportation had been a topic of interest to Congress since the 1970s. But, when all was said and done, much more was said than done.

The joint House hearing heard from the General Accounting Office (GAO) that there are some 62 federal programs that spend money on transportation. The GAO also found that leadership on coordination was lacking in that coordination seemed to be on everyone's list of things to do but nowhere near the top of anyone's list. There was a Federal Coordinating Council but it rarely met. The situation at the federal level was replicated at the state level. Where states had leadership on coordination through coordinating councils often created by the governors, coordination was often impressive. Where that was not the case, coordination was simply not happening. Like the tango, it takes more than one state or federal agency to coordinate. Those who took coordination seriously often found they were "playing catch with themselves."

In our observation, Congress and the Administration are now taking coordination seriously. Department of Transportation Secretary Norman Mineta and Federal Transit Administrator Jennifer Dorn are reaching out with some success to get more federal agencies on the dance floor. With the launching of the Department of Transportation's "United We Ride" initiative, the Department of Health and Human Services, the Department of Labor, the Department of Education, and other federal agencies are beginning to recognize best practices at the state level and make resources available to enhance state performance. President Bush, to his great credit, has issued an Executive Order calling on federal agencies to assess their roles in coordination and report back to the White House in 1 year on progress they are making to enhance the coordination of transportation programs.

CONGRESS IS ADDRESSING TRANSPORTATION COORDINATION ON SEVERAL FRONTS

Several pending bills contain language that would bolster the coordination of federal transportation programs. APTA is supportive of these efforts.

Pending bills to reauthorize the Federal Transportation Equity Act for the 21st Century (TEA 21) contain numerous provisions that will enhance transportation coordination, including allowing funding from human service programs to be used as a match for FTA programs so long as programs are coordinated, broadening the eligibility guidelines for Job Access and Reverse Commute (JARC) funding, recognizing Mobility Management as an eligible program expense, and requiring local certification plans for the New Freedom, JARC, and Elderly and Disabled programs.

As part of the pending welfare reform legislation, the Senate Finance Committee has approved an amendment supported by APTA calling upon states that use Temporary Assistance for Needy Families (TANF) funds for transportation purposes to certify that they have consulted with transportation agencies in the provision of such services. It seems to be a simple common sense matter, but it often doesn't happen. Such certification will make a requirement of what is now often an afterthought. The House-passed welfare reform bill (H.R. 4) contains an important provision in its TANF program that would treat transportation subsidies as "nonassistance" for purposes of the Act and therefore need not be discontinued when a person exhausts their eligibility for public assistance. Like childcare support, transportation

aid is essential to those who not only want to get a job, but also those striving to retain their job.

Similarly, there are provisions in the Senate's version of the Workforce Investment Act that call on state and local workforce planners to account for how people are to get to training and available jobs. It makes as much sense to coordinate training with available transportation as it does to link training to available employment. Along with childcare, the ability to get to a job efficiently is often the factor that determines whether a person can get and retain employment.

It is APTA's hope that significant progress can be made in the next year as both Congress and the Executive Branch focus attention on replacing old habits with new habits.

PUBLIC TRANSPORTATION PROVIDES AFFORDABLE AND EFFICIENT ACCESS TO HEALTH CARE

Following the old adage, "follow the money," we note that the GAO identified a major source of transportation spending in the Medicaid program. Close to $1 billion is spent on transportation to assist Medicaid clients. APTA members in Connecticut and Florida have had some success offering mainline transit service to those for whom it is appropriate through a Medicaid Pass Program. Medicaid clients see their transportation options enhanced at the same time the Medicaid program sees its costs lowered. Transit operators experience an increase in ridership while being reimbursed by the Medicaid program. Such programs can be a win/win/win situation for those who need services, those who pay for them, and those who provide the service.

Public transportation has already demonstrated its ability to effectively provide non-emergency transportation to health care services when given a chance. In 1997, the Healthcare Financing Administration estimated it was losing $1.2 billion annually in non-emergency medical transportation subsequently states began to coordinate services with local transit systems and by 2000 20 percent of the nation's Medicaid rides were on public transit.

While lack of coordination between providers of transportation assistance programs for the elderly and disabled and public transportation systems is not a new problem, the need for these services will continue to grow. According to a recent FTA study, 32 million senior citizens rely on transit as their driving ability decreases; 27 million Americans with disabilities depend on transit to maintain their independence; and 37 million people who live below the poverty line and cannot afford to drive rely on transit to get to work. The population of elderly transit users is expected to rise, growing nearly four times faster than the general population between 2010 and 2030; yet according to the AARP, more elderly people now live in suburban settings that lack transit options than ever before.

Public transportation has worked hard to improve its service. Between 1990 and 1999, the percentage of wheelchair accessible buses has increased dramatically. Systems continue to update their vehicles, including trains and buses, to ensure that individuals with disabilities can use their service. With access available to populations served by HHS and other social programs across the country, public transportation is clearly in a position to help these people and save taxpayer dollars right now.

PUBLIC TRANSPORTATION DELIVERS PEOPLE FROM WELFARE TO WORK

Similar to its success in helping the elderly and disabled, public transportation is already at work helping the population of low-income workers and job seekers such as TANF clients by providing low-cost, efficient transportation services.

Many welfare recipients do not own cars and must rely on public transportation to get to work. And while most welfare recipients live in central cities, most newly created jobs are in the suburbs. Public transportation has been successful in many cases in providing transportation options to these job seekers, especially under the JARC program, but barriers remain. For instance, Fort Worth's transportation authority, The T, has noted that it has difficulty coordinating various sources of funding to provide transportation service that gets workers from the central city to the suburbs because local service providers are required to track separate data from both the Department of Labor and the Department of Housing and Urban Development.

CONCLUSION

Mr. Chairman, the public transportation community stands ready to provide a cost efficient, easy-to-use and effective solution to the increased demand for transportation options for communities served by federal programs such as TANF. The

U.S. Department of Transportation is already required to coordinate with HHS, but it needs to improve coordination with HHS as well as with other agencies at all levels of government. Many states and local governments are excelling at this process. Millions of additional federal dollars could be saved by requiring all states to follow their lead.

Enabling effective coordination between all federal agencies and the DOT requires statutory changes to provide the Coordinating Council with authority to require recipients of federal funds at all levels to work together. Taking advantage of the TEA 21 and TANF reauthorizations to require state and local governments that receive TANF and JARC funds to coordinate their services would be an excellent first step. This will put the experience and resources of transit to use to effectively serve our disadvantaged populations.

Mr. Chairman and Members of the Committees, we urge you to take public transportation service and the cost efficiencies it provides into consideration as you mark up your fiscal year 2005 appropriations bill. We would be pleased to work with your staff in developing report language in that regard.

In closing, APTA would like to urge this Subcommittee to remain vigilant as you monitor the progress of executive agencies and the Coordinating Council in the next year. Progress is being made but there is much more to do.

Thank you.

PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

The Coalition of Northeastern Governors (CONEG) is pleased to provide this testimony for the record to the Senate Subcommittee on Labor, Health and Human Services, and Education regarding fiscal year 2005 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The Governors appreciate the Subcommittee's consistent support for the LIHEAP program, and we recognize the difficult decisions facing the Subcommittee in this time of severe fiscal constraints. However, in light of sharply higher home energy prices, we request the Subcommittee to provide $3 billion for LIHEAP in regular fiscal year 2005 funding and $3 billion in advance appropriations for fiscal year 2006.

LIHEAP is a vital tool in making home energy more affordable for almost 5 million of the nation's very low-income households—the elderly and disabled on fixed incomes and families with young children. Recent survey data compiled by the National Energy Assistance Directors' Association (NEADA) provide a glimpse of the difficult choices made by low-income households and the strong, ongoing need for LIHEAP assistance. The percentage of income spent on total home energy by these low-income households can be four times higher than average households. For many of these households, annual income is simply not sufficient to pay high winter heating bills, even in periods of economic growth. Even after taking constructive actions to reduce their home energy use, too many low-income residents are forced to make dangerous choices between heating their homes, paying the full rent or mortgage, seeking medical attention, or purchasing food or vital medications. The NEADA survey found that an estimated 38 percent of LIHEAP recipients went without medical or dental care; approximately 28 percent did not make a rent or mortgage obligation; 30 percent did not fill a prescription or take the full dosage; and 21 percent became sick because the home was too cold.

The rise in winter heating fuel prices hits these vulnerable citizens especially hard. The Northeast is heavily dependent on deliverable home heating fuels such as home heating oil, kerosene, and propane. Price volatility in these fuels adversely affects the low-income households who, without the disposable income to purchase fuels off-season, typically enter the market when both the demand for and price of fuels are high.

Rapidly rising energy prices, the very cold winter conditions in many parts of the country, and the continued high unemployment among low-wage workers continue to put heightened demand on the states' already stretched LIHEAP programs. In fiscal year 2004, states expect to serve an estimated 4.8 million low-income households with LIHEAP assistance, an increase of 6 percent over the 2002–2003 period. However, the number of low-income households eligible for LIHEAP assistance increased by a similar 6 percent—to approximately 34.6 million households. In short, in spite of the welcomed increase in LIHEAP funding, only a fraction—approximately 15 percent of eligible households—continue to be served at current LIHEAP funding.

An increase in the regular LIHEAP appropriation to $3 billion for fiscal years 2005 and 2006 will enable states across the nation to reach more of those vulnerable citizens in need of assistance and more fully implement cost-effective measures to

meet their continuing energy needs. Today, most winter heating programs have exhausted their program resources at the end of the heating season, leaving little or no resources for cooling programs this summer; or they have limited ability to assist families who, in arrears on heating bills, face the prospect of having their home heating source cut off. In addition, without funds to carryforward to the new heating season, state LIHEAP programs lack the capability to undertake the "pre-buy" programs that help stabilize heating fuel prices for low-income households and expand the reach of limited program funds. An increased federal appropriation, and advance funding, would allow states to manage the program resources in a manner to better take advantage of market opportunities.

Enactment of advance funding is vital to the states' program planning activities for the coming heating season. In the Northeast, where the heating season begins in early October, states generally spend up to 70 percent of the LIHEAP funds during the first two quarters of the fiscal year. Therefore, states must begin to plan and do program outreach in the spring and summer if they are to begin their LIHEAP program as soon as the new fiscal year starts. Advance funding helps ensure that states have the necessary funds to open their programs and provide timely assistance to low-income families who lack the financial resources to bear the initial costs of deliverable home heating fuels.

The current uncertainty of world energy markets underscores the importance of states being able to prepare for the potential of volatile energy prices. These preparedness activities, while critical, cannot fully shield our lowest-income citizens from the impacts of higher heating fuel prices. Your support for fiscal year 2005 LIHEAP appropriations at the $3 billion level and the enactment of advance fiscal year 2006 appropriations is urgently needed to enable our states to help mitigate the potential life-threatening emergencies and economic hardship that confront the region's most vulnerable citizens.

We thank the Subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast.

PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) is the national service organization representing the interests of over 2,000 municipal and other state and locally owned utilities in 49 of the 50 states (all but Hawaii). Collectively, public power utilities deliver electricity to one of every seven electric consumers (approximately 40 million people), serving some of the nation's largest cities. However, the vast majority of APPA's members serve communities with populations of 10,000 people or less.

We appreciate the opportunity to submit this statement supporting funding for the Low-Income Home Energy Production Assistance Program (LIHEAP).

APPA has consistently supported an increase in the authorization level for LIHEAP to $3.4 billion annually—an increase that was embodied in the stalled Energy Policy Act and has also been advanced more recently in the Senate's version of the Poverty Prevention and Reduction Act, a bill that has not yet been considered in the House. In the absence of final action on an increased authorization level for the program, the Administration's request of $2 billion for fiscal year 2005 ($1.8 billion in state block grant funding and $200 million in emergency funding) is a good start. However, APPA believes that the Subcommittee should consider appropriating the $3.4 billion necessary in fiscal year 2005 to more fully meet the energy needs of low-income households.

APPA is proud of the commitment that its members have made to their low-income customers. Many public power systems have low-income energy assistance programs based on community resources and needs. Our members realize the importance of having in place a well-designed low-income customer assistance program combined with energy efficiency and weatherization programs in order to help consumers minimize their energy bills and lower their requirements for assistance. While highly successful, these local initiatives must be coupled with a strong LIHEAP program to meet the growing needs of low-income customers. In the last several years, volatile home-heating oil and natural gas prices, severe winters, high utility bills as a result of the western electricity crisis, and the effects of the economic downturn have all contributed to an increased reliance on LIHEAP funds.

Also when considering LIHEAP appropriations this year, we encourage the Subcommittee to provide advanced funding for the program so that shortfalls do not occur in the winter months during the transition from one fiscal year to another. LIHEAP is one of the outstanding examples of a state-operated program with mini-

mal requirements imposed by the federal government. Advanced funding for LIHEAP is critical to enabling states to optimally administer the program.

Thank you again for this opportunity to relay our support for increased LIHEAP funding for fiscal year 2005. We look forward to a favorable outcome.

PREPARED STATEMENT OF THE MEALS ON WHEELS ASSOCIATION OF AMERICA

Mr. Chairman and Members of the Subcommittee, we are Enid A. Borden and Margaret B. Ingraham, Chief Executive Officer and Director of Policy and Legislation, respectively, of The Meals On Wheels Association of America (MOWAA). The Association represents local community-based meal programs from every state that provide congregate and home-delivered meals and other nutrition services to older persons in need. It is on behalf of MOWAA, its member programs, and the literally hundreds of thousands of frail, elderly and at-risk individuals that they serve that we present this testimony.

As part of the appropriations process in which this subcommittee engages every year, you doubtless hear from hundreds, probably thousands of individuals and organizations representing programs funded through the enormous bill under your purview. Each comes to advocate for a specific project or program and to make the case as to why that program merits a particular level of federal financial support in the next fiscal year. In that regard, MOWAA is no different from the others from whom you have heard. But in other ways—significant ones that we will enumerate briefly—MOWAA, or rather the senior meal programs that are our members—are significantly different.

Please allow us the opportunity to put our request in an historical and human perspective. In 1972 when it reauthorized the Older Americans Act, Congress included senior nutrition programs among the services funded under the Act. Today, "Meals On Wheels," as those programs have come to be popularly called, are perhaps the most widely recognized and universally lauded of Older Americans Act programs. It should come as no surprise to you that we also believe they are the most important. Why? The answer is simple. Because food is fundamental to life and health and psychological and emotional well-being. There is no arguing that fact. All of us eat regularly, generally 21 meals per week and we even may sneak a snack here or there when we get hungry. But many of America's most vulnerable citizens, the frail and at-risk elderly, have no ability to shop for or to prepare meals for themselves. For them, home-delivered meal programs are a virtual lifeline. In some cases, they are the only source of nutritious food that a senior has; and even then, most programs have the resources to provide only five meals each week.

Last year, according to the Administration on Aging over 253 million meals were served with Older Americans Act funds. That is impressive indeed. But the sad reality on the underside of that success is that hundreds of thousands of equally needy seniors were not served. A conservative estimate is that 4 out of every 10 home-delivered meal programs have waiting lists. And currently, the old-old age group (defined as 85 and older) is the fastest growing cohort in the U.S. population. So, simply stated, if appropriations levels are not increased, and increased substantially, the unspeakable will occur. That is, even larger numbers or frailer individuals will be going hungry. Mr. Chairman and members of the subcommittee, we believe that is unacceptable in this the wealthiest nation on the planet.

Earlier we mentioned historical context. Let me return to that. In fiscal year 1992, 20 years after the establishment of OAA nutrition programs, the federal financial commitment was just over $607 million. (That figure represents the sum of Title III C–1, III C–2 and NSIP (then called USDA/NPE)). For fiscal year 2004, the President has requested $719 million. Yes, that is an increase; but it is a grossly inadequate one. For during the intervening years since 1992, other important factors have changed. First, there is inflation. Then there is the population shift, which has dramatically increased the number of individuals needing assistance with nutrition services. In 1992 there were 42.7 million individuals age 60 and older in the United States, and approximately 3.3 million of those were 85+. In this year (2004) the number of those 85+ is over 4.7 million. That, by any standard, is astounding growth. And it is growth that has gone largely uncompensated. Here is what we mean by that.

We asked one of this country's most distinguished actuaries to look at these numbers, to look at population growth and inflation (by applying the annual CPI-U) and then to produce an "equivalent" appropriation level. That is, we asked him to calculate what the federal commitment to each elder was in fiscal year 1992 and then to determine what funding levels these senior meal programs should have received in fiscal year 2004 to ensure parity with 1992. Why parity? Because we know that

you agree that today's elders are just as important a part of our society today as they were 12 years ago. Today's elders—your parents and grandparents and perhaps even siblings and neighbors, certainly your constituents—are as deserving as those who came before them of receiving senior nutrition program services when they can no longer provide meals for themselves. Had you provided parity in 2004 with 1992, based on the changes in the CPI-U and the 85+ population alone, the funding level would have been approximately $1.158 billion, an almost 61 percent increase over the $719 million being requested by the Administration for the next fiscal year. This year's request, in fact, is less than the 1992 enacted level for Nutrition Services Incentive Program (NSIP, formerly USDA); it is less than the 2002 enacted level for Title III C–1; and it is the same level as the fiscal year 2003 enacted level for Title III C–2. In other words, overall the request is much less than adequate for us to keep faith with the older population that depends on local community-based meal programs in every State in this great country. We are not so unrealistic as to believe that we can achieve parity in 1 year, although we do believe our case has merit. Mr. Chairman and members of the subcommittee, the Meals On Wheels Association of America does urgently and sincerely request that you increase funding for senior meal programs by no less than 10 percent for each line item over last year's levels, to approximately $786 million combined.

The year 2005 will mark the 40th Anniversary of the Older Americans Act, and we can think of no more fitting way to recognize the invaluable contribution that OAA programs have made in the lives of older Americans and to demonstrate Congress' continued commitment to elders than by adopting funding levels that will help local programs serve those in need.

Before we close we do want to make one more point, that is often overlooked when it comes to senior nutrition programs. These senior meal programs that receive funding through the Older Americans Act exemplify how effectively public-private partnerships can serve citizens in need. For that is what these programs are: public-private partnerships that reflect the unique needs and characteristics of the communities in which they operate and that rely on a number of funding sources. Federal dollars are only a portion of the funds on which these programs rely in order to operate. But they are a critical part, for they enable programs to leverage money from a variety of other sources, such as States and local governments, foundations, corporations and individuals. In the home-delivered program, for example, each $1 in federal funds leverages $3.35 from other sources. So even a modest increase in funding of 10 percent could assist in a major way in meeting unmet need.

As you consider our request, you may want to keep in mind in whose behalf MOWAA is making it. Each and every one of these "frail, homebound individuals" is unique, just as you and I, so it is impossible to give you a description that covers them all. But here is a simple profile: the average Meals On Wheels recipient is an elderly woman in her very late seventies or eighties; she is more than twice as likely as her contemporaries to live alone, apart from family and friends. She is likely to be functionally impaired (have trouble walking, for example) and have three or more diagnosed chronic health conditions. In addition, she probably has an income below 200 percent of poverty. Whatever the reason, she cannot shop, cook, or prepare meals for herself. In other words, she relies on Meals On Wheels programs to ensure she gets proper nutrition. And without that, she would probably be at risk of being forced to move out of her home prematurely into an institutional care facility. These folks reside in cities and suburbs and rural communities across America.

Thank you for the opportunity to bring these issues to your attention. Again, on behalf of MOWAA, local meal programs across America, and, most important, the at-risk and frail seniors that turn to them for meals and other nutrition services, we ask that you give serious consideration to renewing the commitment of your colleagues in previous Congresses and to increasing funding to a level that moves resolutely toward a level that is commensurate with that of a decade ago. A 10 percent increase for fiscal year 2005 is a good first step.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF NUTRITION AND AGING SERVICES PROGRAMS

Chairman Specter and Ranking Member Harkin: The National Association of Nutrition and Aging Services Programs (NANASP), a professional membership organization representing the interests of members at all levels of the aging network dedicated to providing quality nutrition and other direct services for older Americans, recommends an increase of 10 percent for the three Older Americans Act (OAA) nutrition programs as part of the fiscal year 2005 appropriations bill for the Department of Health and Human Services under your jurisdiction.

This position is taken in concert with the position of the 50-member Leadership Council of Aging Organizations (LCAO) of which NANASP is a member. LCAO supports a 10 percent across the board increase for all Older Americans Act programs.

NANASP's focus is the congregate and home delivered meals programs and the Nutrition Services Incentive Program, since our more than 800 members nationally work on the front lines every day providing seniors with nutrition and related services.

The President's budget called for a slight increase in funding of $4.35 million for the three OAA nutrition programs. However, the amount of the increase is only 0.6 percent of the total funding and does not even come close to inflation, estimated at 3 percent over the past fiscal year. In fact, the nutrition programs are entering a second decade of a funding deficit which is eroding the effectiveness of the programs for those being served. Whereas inflation has increased by 44.45 percent since 1990, funding for the OAA has only increased by 24.4 percent. Also since 1990, funding has only increased 9.8 percent for the congregate nutrition program.

Administration data for fiscal year 2002 indicates that while the OAA nutrition programs are serving more individuals, they are serving fewer meals to these individuals. This defeats a main benefit of the program which is to provide eligible seniors with a minimum of one-third of their required daily dietary allowance. The reduction in meals can present genuine hardships to the seniors who are served, especially those in the greatest economic need who are to be targeted for service under the Older Americans Act.

Furthermore, data provided by AARP forecasts that nearly 5 million meals will be cut from both the congregate and home delivered meals programs if no adjustments are made to the President's fiscal year 2005 budget. The question to ask is how do these meals get replaced?

A modest 10 percent increase in the nutrition programs constitutes about $71 million. This will help these programs to maintain services to their existing seniors thus avoiding the need for new or expanded waiting lists. Older adults waiting for basic services often wind up on nursing homes and are at risk for losing their homes and independence.

The Older Americans Act nutrition programs are a proven success story with more than 30 years of serving seniors in your state and throughout the country. Funds provided for these programs are investments in promoting and maintaining the independence of seniors. The Older Americans Act nutrition programs are more than just a meal. These are preventive programs: they help avert malnutrition and control chronic conditions such as diabetes, and through socialization and other individual contact help keep seniors from becoming isolated.

Programs with the longevity and proven track record of the elderly nutrition programs need to be supported with adequate, but fiscally reasonable funding levels. That is what we advocate today.

NANASP encourages you and all members of the Subcommittee to visit an elderly nutrition program in your state either during the upcoming spring recess or during May, which is Older Americans Month. NANASP is happy to provide you with the names and addresses of programs from your state. See firsthand how these programs are great value propositions. They provide value through their services to seniors and they provide value to the taxpayer dollar by delivering a core service and more in an efficient and localized manner in a home or community setting where older adults want to stay.

NATIONAL INSTITUTES OF HEALTH

PREPARED STATEMENT OF THE AMERICAN INSTITUTE FOR STUTTERING

Mr. Chairman and members of the Subcommittee, I am Catherine S. Montgomery, Executive Director of the American Institute for Stuttering (AIS). AIS was founded in 1997 in response to the need for a comprehensive treatment and training facility for stuttering in the United States. It is the only nonprofit facility in this country that offers both intensive and non-intensive treatment options for people of all ages while also providing clinical training to both new and established speech-language pathologists.

Stuttering is one of the few disorders that people still laugh at. The disorder wreaks havoc in one's life that few understand, and much of it is silent suffering, below the surface. Healthy intelligent children who stutter are placed in "special classes" and labeled eccentric, mentally ill and emotionally disturbed. In all honesty, many of these children have IQs 10 to 14 points higher than the general population. Public education is needed to rectify a long history of neglect and misunderstanding.

Developmental stuttering typically begins between the ages of 3 and 8 years of age. Some of the most important work now being done in stuttering is in early intervention treatment. It is very cost effective, yet many do not receive treatment due to a lack of clinicians trained specifically in speech-language pathology. There is also a dire lack of public awareness about the necessity for earlier diagnosis and treatment possibilities.

Despite the fact that stuttering affects approximately 3 million people in the United States, it remains almost imperceptible as a public health issue. It should be noted that suicide among teenagers who stutter is 3 to 4 times higher than the general population. AIS is launching "Let's Talk," a national public education and fundraising campaign to create a major cultural shift in public attitudes about stuttering.

"Let's Talk" targets six program objectives to better serve the stuttering community:

1. Public Education
2. Research
3. Clinical Treatment
4. Treatment Scholarships
5. Clinical Training
6. Advocacy

The American Institute for Stuttering has embarked upon a new professional relationship with New York Medical College and Ben Watson, Ph.D. Dr. Watson is among the few preeminent researchers in the United States whose focus is on learning more about the neurological roots of stuttering. He is now conducting two new exciting studies that will help move us along in our search for the cause of stuttering.

We know a great deal about the speech and language abilities and brain function of adults who stutter and we are learning a great deal about the speech and language abilities of young children at the onset of stuttering. Some people who stutter as children do not stutter as adults. The reason for that is not known but Dr. Watson is exploring this question through investigation of speech, language and brain function in young children who do and who do not stutter.

Previous studies show that brain activity in some people who stutter differs from that seen in nonstutterers. We now need to find out if, and how these differences in brain activity are related to stuttering. To answer these questions, scientists from New York Medical College and the Harlem Hospital Center are studying brain activity in persons who stutter during the production of both stuttered and fluent speech. This study may clarify the relationship between changes in brain activity and fluency breakdown.

The disorder of stuttering has been one of the most seriously misunderstood of human handicapping conditions. Approximately 1 percent of the population of the United States, some 3 million Americans, suffer this inability to speak freely and try to cope with the daily agonizing struggle and ridicule that accompanies it. The American Institute for Stuttering is dedicated to filling the serious void in the availability of quality treatment and training.

The American Institute for Stuttering asks that you support a 10 percent increase in the budget of the National Institutes of Health in order to maintain the momentum that has been built up over the past half-decade. Further, we would ask that additional funds be made available for the National Institute of Deafness and Other Communications Disorders (NIDCD) to support stuttering research. There is currently about $3 million of federal funding dedicated to stuttering research. This works out to about $1 per person afflicted with this disorder. Moreover, Mr. Chairman, we respectfully request that the committee provide NIDCD with resources to support a consensus conference on stuttering. Such a conference will bring together the leading scientists in the field to assess the current state of the science and will hopefully identify future research opportunities.

Thank you for this occasion to present this testimony.

PREPARED STATEMENT OF THE NATIONAL PRIMATE RESEARCH CENTERS

The Directors of the National Primate Research Centers (NPRCs) respectfully submit this written testimony for the record of the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education. The NPRCs appreciate the commitment that the members of this Subcommittee have made to biomedical research through strong support for the National Institutes of Health (NIH). Given your leadership on this issue, the NPRCs urge Congress to direct resources to vital biomedical research infrastructure in order to ensure that the suc-

cess of the federal investment in NIH will not be compromised as a result of deficient research resources.

The NPRCs are a national network of eight primate research centers supported by the NIH National Center for Research Resources (NCRR). The centers comprise the National Primate Research Program (NPRP), which was developed in 1960 in response to recommendations provided to Congress by the National Heart Institute Advisory Council. This program seeks to address human health problems through scientific research using the animal models that most closely resemble humans in their genetics, physiology, and disease processes—primates. The NPRCs were developed specifically as resources to advance primate research by providing specialized research facilities and technologies as well as unique living environments for primates. NPRCs support research that is sponsored by nearly every institute of NIH. For example, NPRCs conduct research to help understand and treat diseases such as heart disease, cancer, diabetes, Alzheimer's, Parkinson's, and AIDS. They also conduct research on emerging infectious disease and on many aspects of biodefense. Each NPRC makes its facilities available to investigators from around the country. In fact, the NPRCs support more than 1,500 NIH funded investigators each year. This collaborative research environment allows scientists to combine their individual expertises beyond the scope of established disciplinary research projects.

Research involving animals is a vital element in achieving this goal of continued medical progress for human health. The specific availability of information in the primate genome, which is quite similar to the human genome, makes primates essential in studies that require an integrated understanding of a whole biological system. Primate studies allow scientists to answer fundamental questions regarding both specific diseases and normal physiological processes that cannot be addressed directly in humans or effectively in more evolutionarily distant species such as rodents. Recent reports suggest that extensive analysis of genome structure and function in nonhuman primates could make immediate and significant contributions to the overall mission of NIH by accelerating progress in understanding many human diseases.

In the 1950's, primate research produced the first vaccine for one of the world's worst childhood killers, the Polio virus, reducing the number of cases in the United States from 58,000 to one or two per year. Primates have also served as the best model for various types of HIV research, and their availability for use has resulted in at least 14 licensed anti-viral drugs for treatment of HIV infection. Primate models will continue to be necessary to defend the world against future and assuredly occurring scourges of which we have already had hints, like SARS and West Nile Virus. In addition to these deadly viral epidemics, primate research has enabled the discovery of better treatments and therapies for diseases such as diabetes, heart disease, high blood pressure, kidney disease, depression, and other psychiatric illnesses. Treatments for stroke and cataracts, and the advancement of prenatal and postnatal care have also resulted from primate research. Furthermore, in addition to the potential to provide answers for long-standing research questions, primate research provides an unparalleled opportunity to address more recently defined research priorities such as those relating to the threat of bioterrorism.

Mr. Chairman, as you and your Subcommittee work to define your priorities for the year and set goals for the future, NPRCs ask that you continue the commitment of support for NIH and its mission by providing the highest funding level possible in the NIH appropriations bill. An increase would enable researchers to continue vital merit based studies on devastating diseases and disabilities, as well as address new and emerging national health priorities. The NPRCs believe this increase is justified by both the health needs and research capabilities of the nation. The President's budget asks for a 2.6 percent NIH increase; however, NPRCs, the Ad Hoc Group for Medical Research Funding, and other leaders of the research community hope for more. Funding for NIH has helped to expand our nation's capabilities in biomedical research, and develop new treatments and cures for many diseases, but many unsolved human health mysteries still remain. Medical research is a long-term process and in order to continue to meet the evolving challenges of improving human health we must not let our commitment wane. It is therefore essential to sustain the momentum of NIH-funded research so that it continues to meet the goal of improving the health of all Americans.

NIH relies on the NPRCs to provide centralized, professional care, management, and research conducted with primates. Consequently, the NPRCs, which are funded by annual NIH P51 base grants, have become an indispensable national scientific resource. Increased base grant funds from NIH/NCRR to meet the current and projected NPRC operational and modernization costs are critical to the success of NPRCs and their programs. NPRCs directors ask that you direct NIH to adopt and fund the NPRP Five Year Federal Advancement Initiative, developed by the NPRCs

directors, for the NPRP, which addresses necessary upgrades and program capacity expansions. The total anticipated cost of the NPRP Federal Advancement Initiative would be $100 million over the current funding level for the NPRP P51 base grant during the 5 year period of fiscal years 2005–2009. Over 5 years, the NPRP Federal Advancement Initiative aims to increase the following by 20 percent : (1) the nationwide availability of primates; (2) the quality and capacity of primate housing and breeding facilities, as well as the availability of related state-of-the-art diagnostic and clinical support equipment at NPRCs; and (3) the number of personnel trained in primate care and management at the NPRCs. The NPRCs urge Congress to direct NIH to adopt and fund the Federal Advancement Initiative, beginning with a $36 million increase in funding for the P51 base grant in fiscal year 2005. The NPRCs also ask that Congress directs NIH to engage in a meaningful planning process to invest in the long-term needs of the NPRCs.

For 2 consecutive years, language strongly in support of NPRCs has appeared in the report accompanying the Labor/HHS/Education Appropriations bills. The reports recognize the importance of the NPRCs as well as centers' demanding resource requirements. The fiscal year 2004 House report directs NCRR to periodically assess NPRCs needs, and to increase the P51 base grant funds for the centers. The report also directs NCRR to submit the first of the periodic assessments along with the fiscal year 2005 budget request. As you know, the Senate issued report language stating that NCRR is expected to fully commit to the Five Year Federal Advancement Initiative. Thus far, while NPRCs have seen modest increases in base grant funds, the initiative has yet to be applied and funded by NCRR.

Biomedical researchers across the nation are experiencing shortages in the availability of primates for essential research. NPRCs, the federally funded primate resource, have found it increasingly difficult to provide sufficient numbers of primates for ambitious and high priority federal research projects on cancer, AIDS, and biodefense. In many cases, NIH funded scientists must wait a year or more to begin their research due to the limited availability of primates and/or space. These critical shortages can only be addressed by expanding existing breeding colonies and developing bridging programs to effectively use under-utilized species of primates in research. Ultimately, this would reduce the wait period for the use of primates, expediting the start of critical research projects. Presently, the budget of each NPRC falls below the amount required to maintain crucial services at existing levels. By adopting and funding the Federal Advancement Initiative, not only will the centers be able to sustain existing programs, but they will have the ability to build much needed programs that will better serve the nation's federally funded primate researchers.

Accommodating and properly caring for increasing numbers of primates also requires additional funding to modernize and expand primate housing and research facilities. As primate populations grow and primate resources increase, proper infrastructure will be necessary to house and care for these additional animals. Under the Federal Advancement Initiative, additional P51 base grant funds will also be invested in repairs, renovation, and construction of research facilities, as well as the purchase of modern laboratory equipment. These are essential upgrades needed to ensure that the federally funded research community can translate new discoveries into treatments and cures. Increased funding under the P51 will give the NPRCs the ability to develop the state-of-the-art capabilities and facilities necessary to keep pace with the expanded NIH research agenda.

Since nonhuman primates represent the most sophisticated and relevant animal models for many areas of biomedical research, there is a heightened need to use primate models prior to human clinical trials, as well as a heightened responsibility to properly care for and manage these animals. Thus, the Federal Advancement Initiative proposes to use increased P51 base grant funding to ensure that adequate numbers of experts are trained in laboratory animal medicine and research. Each NPRC requires a highly trained and experienced primate management team comprised of behavioral specialists, veterinarians, and primate research experts. As the number of primates at the NPRCs grows, proportional expansion of the primate management teams is essential to maintain primate health and research success.

The NPRCs provide scientists across the nation with unmatched access to these crucial research models in the process of making significant medical discoveries and translating these discoveries into effective therapies and treatments. This is an essential and valuable centralized service for researchers who cannot afford to use and maintain scarce and expensive primates solely for individual research projects. For every dollar provided to the NPRCs, more than $10 in NIH research is leveraged, which is equivalent to approximately $600 million in NIH research that could not otherwise be carried out.

With this in mind, the NPRCs express their sincere hope that the nation will continue to sustain the healthy development of its biomedical research program and that this Subcommittee will continue its support and leadership on behalf of NIH and its research partners across the nation.

Mr. Chairman, as you and your Subcommittee work to define your priorities for the year and set goals for the future, the NPRCs directors ask that you direct NIH to adopt and fund the NPRP Five Year Federal Advancement Initiative. Investing in and enriching the NPRCs will help to expand our nation's capabilities in biomedical research, and enable the development of new treatments and cures for many diseases. NIH adoption of the NPRP Federal Advancement Initiative will allow NPRCs, as well as NIH, to continue to meet and advance the goal of improving the health of all Americans.

Thank you for the opportunity to submit this written testimony and for your attention to the recommendations of the NPRCs concerning funding for NIH in fiscal year 2005 and implementation of the NPRCs Five Year Federal Advancement Initiative.

PREPARED STATEMENT OF THE FACIOSCAPULOHUMERAL MUSCULAR DYSTROPHY SOCIETY

Mr. Chairman, it is a great pleasure to submit this testimony to you today.

My name is Carol Anne Perez, of Lexington, Massachusetts, and I am testifying as Executive Director of the FacioScapuloHumeral Muscular Dystrophy Society (FSH Society, Inc.) and as an individual who has lived with the devastating facioscapulohumeral muscular dystrophy (FSHD) disorder for nearly 70 years.

Facioscapulohumeral muscular dystrophy (FSHD) is the third most prevalent form of muscle disease. FSHD is a neuromuscular disorder that is transmitted genetically to 120,000 people. Conservatively, it affects 14,000 persons in the United States. For men, women, and children the major consequence of inheriting FSHD is progressive and severe loss of all skeletal muscles gradually bringing weakness and reduced mobility. The usual pattern is of initial noticeable weakness of facial, scapular and upper arm muscles and subsequent weaknesses of other skeletal muscles. Retinal and cochlear disease, as well as mental retardation, can be associated with FSHD. 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 are 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 and their children and grandchildren as well. As a human services professional, wife, mother, and grandmother I am now in wheelchair due to the effects of FSHD.

In accordance with its primary purpose of serving the FSHD community, both in the United States and abroad, the FSH Society, through outreach at home and international networking, has brought together more than 3,000 FSHD-affected families committed to working cooperatively. From the moment of their introduction into the FSH Society, these families, and, in many instances, their friends are bonded with their fellow members both by their common knowledge of what it is to live with FSHD and by the ardent desire they all feel to be part of a concerted effort to discover how to treat the disease and, ultimately, to cure it.

People who have FSHD must cope with continuing, unrelenting, unpredictable and never-ending losses. The most unlucky, those who are affected from birth, are deprived of virtually all the ordinary joys and pleasures of childhood and adolescence. But no matter at which stage of life the disease makes itself known, there is never after that any reprieve from continuing loss of physical ability, or ever for a moment relief from the physical and emotional pain that FSHD brings in its train. Every morning, FSHD sufferers wake up to face the reality that neither a cause for their disease nor any treatment for it has yet been found.

Insidiously and systematically, FSHD denies a person the full range of choices in life. FSHD affects the way you walk, the way you dress, the way you work, the way you wash, the way you sleep, the way you relate, the way you parent, the way you love, the way and where you live, and the way people perceive and treat you. You cannot smile, hold a baby in your arms, close your eyes to sleep, run, walk on the beach, or climb stairs. Each new day brings renewed awareness of the things you may not be able to do the next day. This is what life is for tens of thousands of people affected by FSHD worldwide.

Through the FSH Society, FSHD patients have found ways to be useful to medical and clinical researchers working on their disease. The FSH Society acts as a clearinghouse for information on the FSHD disorder and on potential drugs and devices

designed to alleviate its effects. It fosters communication among FSHD patients, their families and caregivers, charitable organizations, government agencies, industry, scientific researchers, and academic institutions. It solicits grants and contributions from members of the FSH Society, and from foundations, the pharmaceutical industry, and others to support scientific research and development. It makes grants and awards to qualified research applicants. In less than 5 years, the FSH Society has raised more than $1 million for research and has invested it in two dozen innovative research programs internationally. One of the FSH Society's key assets, its Scientific Advisory Board, is composed of international experts whose awareness of current FSHD research ensures both that new research is not duplicative but complementary and that it will fill gaps in existing knowledge. The FSH Society's work in education, advocacy, and training has led to increased funding in the United States and abroad. It was a key participant in drafting the Muscular Dystrophy Community Assistance Research and Education Act of 2001 (MD CARE Act) which in the United States mandates research and investigation into all forms of Muscular Dystrophy.

The Appropriations Committees in both the U.S. House and the U.S. Senate have repeatedly instructed the National Institutes of Health (NIH) to enhance and broaden the portfolio in FSHD and muscular dystrophy in general. The NIH accounting for the total overall NIH and the subset of muscular dystrophy appropriations in millions of dollars for the past 5 years follows:

NATIONAL INSTITUTES OF HEALTH (NIH) APPROPRIATIONS HISTORY SOURCE: NIH/OD BUDGET OFFICE & NIH CRISP DATABASE ON-LINE

[Dollars in millions]

Fiscal year	NIH overall dollars	MD research dollars	MD percent of NIH	FSH research dollars	FSHD percent of MD	FSHD percent of NIH
2000	$17,821	$12.6	0.071	$0.4	3.18	0.0022
2001	20,458	21.0	0.103	0.5	2.38	0.0024
2002	23,296	27.6	0.118	1.3	4.71	0.0056
2003	27,067	39.1	0.144	1.5	3.83	0.0055
2004E	27,887	40.2	0.144	2.7	6.71	0.0097

Due to major initiatives from the volunteer health agencies and the extramural community of researchers, FSHD research at the NIH and funding through the NIH is moving ahead at a steady pace though seemingly incredibly slow for those of us suffering from FSHD. Notwithstanding these positive changes at the NIH as well as major cooperative initiatives from the volunteer health agencies and the extramural community of researchers, we realize that major changes are slow but we are hopeful that this year the NIH will initiate new and increased funding for FSHD.

Funding increases for FSHD as related to the entire muscular dystrophy portfolio are not keeping pace with all muscular dystrophy. FSHD is the third most prevalent form of muscle disease and a common muscular dystrophy. Yet, in 2003 it received only 3.83 percent of the total NIH wide muscular dystrophy portfolio and that number has improved slightly to an estimated 6.71 percent for fiscal year 2004.

Mr. Chairman, as you know, the National Institute of Child Health and Human Development (NICHD), the National Institute of Arthritis and Musculoskeletal Disorders (NIAMS), and, the National Institute of Neurological Disorders and Stroke (NINDS) are three of the National Institutes of Health (NIH) institutes called upon by the Muscular Dystrophy Community Assistance Research and Education Act of 2001 (MD CARE Act) to develop a research plan for muscular dystrophy (MD) research and education conducted through the National Institutes of Health. Certainly, other NIH institutes will be called into action where appropriate such as NHLBI, NEI, NIA, NIMH, NHGRI, NCRR, FIC, and OD.

NATIONAL INSTITUTES OF HEALTH (NIH) MUSCULAR DYSTROPHY AND FSHD APPROPRIATIONS HISTORY SOURCE: NIH/OD BUDGET OFFICE & NIH CRISP DATABASE ON-LINE

[In millions of dollars]

Fiscal year	Total NIH dollars on MD	NIAMS dollars on MD	NINDS dollars on MD	NICHD dollars on MD	NIH wide dollars on FSHD
2000	12.6	4.8	4.9	1.2	0.4

NATIONAL INSTITUTES OF HEALTH (NIH) MUSCULAR DYSTROPHY AND FSHD APPROPRIATIONS HISTORY SOURCE: NIH/OD BUDGET OFFICE & NIH CRISP DATABASE ON-LINE—Continued

[In millions of dollars]

Fiscal year	Total NIH dollars on MD	NIAMS dollars on MD	NINDS dollars on MD	NICHD dollars on MD	NIH wide dollars on FSHD
2001	21.0	9.2	8.2	0.5	0.5
2002	27.6	11.1	9.8	0.6	1.3
2003	39.1	15.5	13.2	4.5	1.5
2004E	40.2	15.9	13.5	4.7	2.7
2005E	41.0	16.3	13.7	4.8	2.8

In fiscal year 2004 year-to-date, the National Institute of Child Health and Human Development (NICHD) does not have a single research grant or project directly focused or covering FSHD. NICHD is spending $0 out of an estimated $4.7M on directly titled FSHD projects. NICHD is spending 0 percent of its muscular dystrophy budget on FSHD.

In fiscal year 2004 year-to-date, the National Institute of Arthritis and Musculoskeletal Disorders (NIAMS) is funding two directly titled projects on FSHD and the NIH FSHD Research Patient Registry. The directly titled grants and contracts are 5–R21–AR–48318–03 at $198,000, 5–R21–AR–48327–03 at $125,000, and, 3–N01–AR–02250–004 $175,754. Directly focused and titled research grants on FSHD actually decreased in fiscal year 2004 due to the expiration of a third R21 and no new directly titled and relevant projects being funded. No new projects directly titled and focused on FSHD have been initiated in the past 3 years. Not a single one. The total direct expenditure from the lead institute on FSHD muscular dystrophy, the NIAMS, was $498,754. The NIAMS is spending 3.1 percent of its total muscular dystrophy budget on FSHD. Something is definitely and clearly wrong with this picture.

In fiscal year 2004 year-to-date, the National Institute of Neurological Disorders and Stroke (NINDS) is funding seven directly titled projects on FSHD and the NIH U54 Cooperative Research Center at the University of Rochester. The NINDS is currently funding four R21 style grants, two R01 style grants, the U54 MD CRC, and the NIH FSHD Research Patient Registry. NINDS has increased its portfolio by one R21 grant, two R01 grants and one U54 Cooperative Research Center in the last year. The NINDS is spending 16.3 percent of its total muscular dystrophy budget on FSHD. The NINDS has shown an uncanny ability to move the field of FSHD research ahead with many excellent research projects as well as sponsoring the unprecedented NIH Cooperative Research Center. The second request for applications for the next round of Wellstone Muscular Dystrophy Centers has just been announced. The late Senator Wellstone would have been proud of the achievements made to date in the area of muscular dystrophy and it is very befitting and appropriate that the muscular dystrophy research centers create a living memory for his substantial efforts.

While it is recognized that research grants, grant applications and interest of the researchers may ebb and flow, we are seriously concerned and perplexed with the total lack of presence by the NICHD in FSHD and weak showing of FSHD grants and the dip in direct FSHD support by the NIAMS, ostensibly the lead institute at the NIH, on muscular dystrophy. FSHD is the third most prevalent form of muscular dystrophy and the NIAMS has 3.1 percent of its dystrophy portfolio allocated to this disease. In the case made that the NIH is not receiving enough grants applications for FSHD, it can be said that the volunteer health agencies and extramural community of researchers have done everything in our power to grow the area of research and to promote new researchers and research projects. The NIH needs to recognize that there is a systemic problem as relates to FSHD and that the extramural research community needs to know that there are specific grant mechanisms and announcements with money associated.

The NINDS, NIAMS, NICHD and relevant NIH institutes understand that FSHD is a unique disease and that there are exciting breakthroughs around understanding the molecular basis of FSHD. Elucidation of the molecular pathogenic pathways of the FSHD disease is instrumental to improved patient diagnosis, counseling, management and treatment. It is now generally accepted that FSHD is caused by a deletion (contraction) of D4Z4 repeats on the chromosome 4q. New mutations are frequently encountered and approximately half of cases seem to be due to somatic rearrangements. An interesting gender difference in disease expression in mosaic patients—males are more susceptible to disease—suggest a hormonal modulation of

the phenotype. FSHD is associated with a genomic rearrangement and it is unlikely that the D4Z4 deletion structurally compromises a putative FSHD gene. Evidence strongly supports a model in which the D4Z4 contraction induces a change in the chromosomal environment, more specifically the chromatin structure, which in its turn modulates the gene expression of gene(s) in cis or in trans. This may occur by a spreading or looping mechanism, or more speculatively, by a mechanism similar to transvection as chromosome ends of 4q and 10q seem to exhibit a higher pairing frequency and other forms of cross talk. However, identification of the exact molecular mechanism and the crucial target gene(s) has still to be done. There is increasing evidence for FSHD-specific changes in the chromatin structure and the histone code. Most arguments suggest a unique (novel) pathogenic mechanism behind FSHD. Elucidation of this intricate molecular network is instrumental to the development of evidence-based treatment (and preventive) strategies.

The following is a non-exhaustive list of top priority research targets and areas for investigation that has been given by FSHD research experts to the NIH for consideration as the NIH research plan is developed. The order is not intended to indicate priority rating. (1.) Detailed characterization of individual candidate genes on chromosome 4q; (2.) Identification of the difference between 4qA and 4qB; only short 4qA is causing FSHD; (3.) The molecular causes and consequences of the exchange between 4q and 10q; (4.) Chromatin structure and nuclear organization—histone code; methylation, acetylation etc.; (5.) Establishment of the gene expression modulation on chromosome 4q and genome-wide; (6.) Development of functional models in vitro (cellular) and in vivo (transgenic); (7.) Implementation of systems biology (integrated –omics and bioinformatics) to reveal molecular and metabolic pathways involved; (8.) Harmonize and standardize molecular diagnostic procedures; (9.) Systematic ascertainment and characterization of (homogenous) patient populations for clinical trials; (10.) Generation of tools and reagents to monitor (pharmacological, training, or gene therapy) interventions; (11.) Identification of additional FSHD loci and genes.

Congress has been very generous with the NIH. Congress has repeatedly mandated more effort in muscular dystrophy research in general and FSHD research in particular. But this is not happening. We ask Congress to continue its support for the overall budget increases for the NIH as this will alleviate the serious budget constraints faced by this most remarkable federal agency. We also ask that Congress request an explanation from the program staff and Directors of the NIH NIAMS and NICHD for the inability to do better in the area of FSHD despite repeated Congressional requests. We implore Congress to request the NIH to specifically build the research portfolio on FSHD through all available means, including re-issuing specific calls for research on FSHD at an accelerated rate, to make up for historical and present neglect.

Mr. Chairman, we trust your judgment on the matter before us. We believe the Committee should explore why muscular dystrophy in general and FSHD in particular has been left behind in the great rise in research support at the NIH. Frankly, we are extremely frustrated that amid a huge increase in funding and strong unambiguous expressions of Congressional support, the NIH commitment in facioscapulohumeral muscular dystrophy (FSHD) is so feeble. Mr. Chairman thanks to your extraordinary efforts, consideration and work in this area I have hope that we will find solutions and that hope keeps me going.

Mr. Chairman, again, thank you for providing this opportunity to testify before your Subcommittee.

PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL SOCIETY

SUMMARY OF RECOMMENDATIONS

—As a member of the Ad Hoc Group for Medical Research Funding, APS recommends $30.78 billion for NIH in fiscal year 2005.

—APS requests Committee support for increased behavioral and social science research and training at NIH in order to: better meet the Nation's health needs, many of which are behavioral in nature; realize the exciting scientific opportunities in behavioral and social science research, and; accommodate the changing nature of science, in which new fields and new frontiers of inquiry are rapidly emerging.

—Committee support is requested for specific behavioral science activities at a number of individual institutes. This testimony provides examples to illustrate the exciting and important behavioral and social science work being supported at NIH.

Mr. Chairman, Members of the Committee: On behalf of our members, I want to thank the Committee for your leadership in the bipartisan effort to double NIH budget. As a member of the Ad Hoc Group for Medical Research Funding, the American Psychological Society recommends $30.78 billion for NIH in fiscal year 2005.

While the process of doubling the budget of NIH was completed on schedule, by no means is our work finished. We must think of that process not as a culmination, but as the beginning of something miraculous in the world of science and discovery. Within NIH budget, my testimony focuses on the behavioral and social science research activities of NIH.

OVERVIEW—BASIC AND APPLIED PSYCHOLOGICAL RESEARCH RELATED TO HEALTH

The effects of behavior on health are indisputable. Many serious health conditions—heart disease, lung disease, diabetes, schizophrenia, AIDS, and so many more—are behavioral in origin. Consider, for example, the devastating health consequences of smoking, drinking, taking drugs, engaging in risky sexual behaviors. None of these conditions can be fully understood without an awareness of the behavioral and psychological factors involved in causing, treating and preventing them.

APS members include thousands of scientists who, with NIH support, conduct basic, applied, and clinical research related to physical and mental health at our Nation's leading universities and colleges. Virtually every institute at NIH supports some amount of psychological science. 24 of the 27 institutes at NIH fund behavioral science research, and seven institutes commit over $100 million to this enterprise. Six institutes commit over 20 percent of their resources to behavioral science research. That places these pursuits squarely at the forefront of the most pressing health issues facing this nation. We ask that you continue to help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, and by encouraging NIH to advance a model of health that includes behavior in deciding its scientific priorities.

BEHAVIORAL SCIENCE RESEARCH TRAINING—A GUARANTEED INVESTMENT

The National Academy of Sciences is currently conducting its congressionally authorized study of research personnel needs with regard to the National Research Service Awards. In recent years, NIH has chosen to only implement the recommendations of NAS selectively, if at all. NAS produces unbiased, highly analytical reports, and they should receive more attention from all of the NIH institutes. This is a serious issue in behavioral science at NIH, where the demand for behavioral science investigators at NCI, NIMH, and other institutes outpaces the current supply of behavioral science researchers. In order to meet the future needs of research in health and behavior, NIH must have a comprehensive training strategy in place today, one that focuses on training young investigators in the core disciplines of behavioral and social science research as well as in multidisciplinary perspectives.

This Committee has expressed interest in this study in the past. Your colleagues in the House stated in their fiscal year 2004 appropriations report, "The Committee recognizes the continuing need for young investigators and clinical scientists, and encourages NIH to increase its support for research training and loan repayment programs. The Committee is aware that the National Academy of Sciences is currently conducting its congressionally authorized study of research personnel needs with regard to the National Research Training Awards. This Committee has expressed interest in this study in the past, and is looking forward to receiving NAS's recommendations with regard to health research training priorities."——(H. Rpt. 108–188 p. 97)

I would now like to turn my attention to the behavioral science research that is taking place at the individual institutes.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

Strengthening Clinical Science and Evidence Based Treatment.—In January, the National Institute of Mental Health hosted a conference in cooperation with the Academy of Psychological Clinical Sciences. Its goal was to begin a dialogue on the growing gap between psychological clinical science training and clinical treatment. Building a solid footing for the training and development of future clinical researchers was the broad aim of the gathering. The meeting between the Academy and NIMH brought leaders of the two groups together to outline the challenges to clinical science training and develop a strategy for strengthening that training. Also discussed was the need to encourage more students to pursue research careers, and support the use of evidence-based treatments by practitioners. We believe this is the perfect illustration of what Congress had in mind when it chose to double the NIH

budget; applying advances in science and research to the treatment of those in need, and watching the two fields progress as one to the benefit of all. We ask the Committee to support the efforts of NIMH as the institutes takes this very complex first step in the on-going fight against mental illness.

Basic Behavioral Research at NIMH.—The behavioral science research branch at NIMH plays a pivotal role at the institute, funding research in cognitive science, personality and social cognition, and biobehavioral regulation. Knowledge derived from the investigation of basic behavioral processes is critical to the specification of behavioral abnormalities in mental disorders, as well as to the identification of risk and protective factors and the development of effective interventions. NIMH is to be commended for promoting the transfer of knowledge into application. At the same time, basic behavioral research at NIMH must continue to receive the same strong support it traditionally receives there. This is crucial, as NIMH is a de facto source of basic behavioral knowledge that is tapped by many other institutes. Until other institutes begin to support larger amounts of basic behavioral science research connected to their respective missions, it is essential that NIMH's programs of research into behavioral phenomena such as cognition, emotion, psychopathology, perception, development, and others continues to flourish. The National Mental Health Advisory Council has formed a task force that is currently examining the basic science portfolio of NIMH, including basic behavioral science. Their charge is to recommend the best course of research for the future, based on past successes and the current direction that research is headed in. Basic behavioral research is critical not only to the mission of NIMH, but also to the health of the nation. We ask the Committee to encourage NIMH's continued efforts to strengthen the ties between basic and clinical behavioral research, and to monitor NIMH's basic behavioral science portfolio in order to ensure continued progress in our understanding of the causes, treatment, and prevention of mental illness and the promotion of mental health.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

NIGMS is the only National Institute specifically mandated to support research not targeted to specific diseases or disorders. That legislative mandate also extends to behavioral science research. The research mission of NIGMS encompasses "general or basic medical sciences *and related natural or behavioral sciences* [emphasis added] which have significance for two or more other national research institutes."——(TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 11, Sec. 285k) Unfortunately, NIGMS does not now support behavioral science research or training. This is an enormous oversight, given the wide range of fundamental behavioral topics with relevance to a variety of diseases and health conditions. Congress addressed this issue for the past 5 years in the reports on the fiscal year 2000, fiscal year 2001, fiscal year 2002, fiscal year 2003, and fiscal year 2004 appropriations for NIH. Specifically, you said: "The Committee believes that NIGMS has a scientific mandate to support basic behavioral research because of the clear relevance of fundamental behavioral factors to a variety of diseases and health conditions. The Committee encourages the NIGMS to incorporate basic behavioral research as part of its portfolio, especially in the areas of cognition, behavioral neuroscience, behavioral genetics, psychophysiology, methodology and evaluation, and experimental psychology."

Last September, Senators Specter, Harkin, and Inouye engaged in a colloquy on this subject, which appeared in the Congressional Record. All three of these Senators agreed on the important role that basic behavioral science plays in our national research agenda. Pressing national health issues such as post-traumatic stress disorder, unintentional injuries, and tobacco, alcohol and drug addiction can all benefit from basic behavioral research. We ask the committee to please continue its efforts to have NIGMS include basic behavioral research and research training in its portfolio.

In response to these repeated requests from Congress, a working group has been established with the charge of examining the basic behavioral science research portfolio for the whole of NIH. Consisting of experts in basic behavioral sciences from both inside and outside NIH, this group was established to offer recommendations on the future of this research, in terms of both what should be studied and at which institutes. It will report its findings to the NIH Director's Advisory Council. In their fiscal year 2005 Congressional Justification document, NIGMS cited this working group and committed to working with it. We ask that the committee monitor the progress of this working group and carefully evaluate its findings.

Basic behavioral research in addiction (significance for NIDA, NIAAA, NCI and NHLBI), obesity (significance for NIDDK, NHLBI, and NICHD), behavioral genetics (significance for NIDA, NIAAA, NINDS, and NHGRI) and neuroscience (significance

for NIMH, NINDS, and NHGRI) just to name a few, are all within the NIGMS mission. We ask the Committee to direct NIGMS to develop a plan for establishing a basic behavioral science research program at NIGMS.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NIDA is committed to bringing the Nation the best possible prevention and treatment interventions for drug abuse and addiction by harnessing the power of science. They accomplish this mission through a wide variety of research centers and projects, all of which are on the cutting edge of today's science and research methods.

National Drug Abuse Treatment Clinical Trials Network (CTN).—NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) is helping bring new medications and behavioral treatments for addiction to communities. Since its establishment in 1999, the CTN has expanded from 5 to 17 sites across the country. The mission of the CTN is to conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions of therapeutic effect in rigorous, multi-site clinical trials to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations; and then transfer the research results to physicians, providers, and their patients to improve the quality of drug abuse treatment throughout the country using science as the vehicle.

Brain, Behavior, and Health: An Integrative Approach.—Scientific understanding has reached a stage where all the elements of the human brain can be mapped out. NIDA will take a leadership role in working with other NIH Institutes and Centers and with external groups, to better understand the interactions among brain, behavior, and health. Understanding these connections will help us NIDA in the development of new prevention strategies. Science will find ways to make us better able to modify behavior in ways that encourage people to take advantage of existing preventive strategies. All the research initiatives being put forward by NIDA for fiscal year 2005 will be undertaken within this integrated approach to brain, behavior, and health.

Comorbidity.—The mentally ill are at very high risk for substance abuse and addiction. Comorbidity between drug abuse and mental illness needs to be addressed in order to provide treatments and services that are truly effective. NIDA would like to expand research to better understand the comorbid nature of these disorders and to translate this knowledge into improved prevention and treatment strategies. We ask this Committee to increase NIDA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from drug abuse and addiction in this Nation.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA has broadened its behavioral science portfolio in order to understand the underlying psychological and cognitive processes that lead people to drink, and the impact of chronic alcohol abuse on those processes.

Advancing Behavioral Therapies for Alcoholism.—Behavioral, non-pharmacological therapies currently are the most widely used method of treating alcohol dependence and alcohol abuse. To advance the effectiveness of behavioral therapies, NIAAA is examining approaches to improving clinicians' abilities to engage and retain adults and adolescents in treatment. NIAAA plans to expand research on the mechanisms of action of successful behavioral therapies, behavioral therapies for alcohol-abusing patients who have psychiatric disorders, which significantly complicates therapeutic interventions, and combinations of new medications with behavioral therapies to sustain recovery.

Underage Drinking.—After the successful launch of NIAAA's initiative to reduce college drinking through education and intervention (the web site has received over 12 million hits in just under 2 years), the attention of the institute has gone one step further and is now more committed than ever to the eradication of underage drinking. Risk factors for alcoholism manifest largely in adolescence, and possibly in childhood. Underage drinking leads to problems for young people that will have long term effects on their lives. This is a public health risk that requires the best research, including behavioral and psychological science research that Congress can support. The development of better prevention strategies and learning more about the mind/body interaction, as well as environmental influences, are some of the steps that NIAAA has taken in this fight against a formidable and destructive opponent. We ask this Committee to increase NIAAA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from alcohol abuse and addiction.

Having already established itself as a leader among NIH Institutes in many fields of research, NCI has made enormous advances in the behavioral sciences.

NCI's Behavioral Research Program.—Scientists estimate that as many as 50 percent to 75 percent of cancer deaths in the United States are caused by human behaviors such as smoking, physical inactivity, and poor dietary choices. NCI's comprehensive behavioral science research program ranges from basic behavioral science to research on the development, testing and dissemination of disease prevention and health promotion interventions in areas such as tobacco use, diet, and even sun protection. Focusing on transdisciplinary and collaborative research, NCI's Behavioral Program has expanded to five branches, including a basic biobehavioral research branch, a health communication and informatics research branch, and the tobacco control research branch.

Health Communications.—Recognizing the central role of effective communication in addressing issues of health and behavior, NCI has also undertaken a major effort to develop science-based communications strategies for disseminating information and persuasive messages about cancer prevention and treatment to the public. Researchers are exploring innovative strategies for communicating cancer information to diverse populations, looking at various communication approaches such as message tailoring and framing with application in multiple communication channels. These messages draw from a foundation of basic behavioral and social science research into such issues as how people learn and remember health information, how they perceive health risks, and how they are persuaded to adopt healthy behaviors.

We ask Congress to support NCI's behavioral science research and training initiatives and to encourage other institutes to use these programs as models.

I would now like to turn to some crosscutting initiatives in which behavioral research plays a critical role.

NIH Roadmap.—There has been much attention paid in recent months to the cross NIH initiative known as the "Roadmap." This project will take NIH into the 21st century by revolutionizing the way the institutes think about research and its application into and impact on health services. Transdisciplinary teams of researchers, including behavioral scientists, will conduct high risk/high reward research that will put us on a path towards a healthier population. An excellent example of this transdisciplinary research and the importance of behavioral science is an RFA for health research training issued under the Roadmap program entitled: INTERDISCIPLINARY HEALTH RESEARCH TRAINING: BEHAVIOR, ENVIRONMENT AND BIOLOGY. Among the goals of the RFA is the study of mental disorders by approaches that integrate neuroscience, genetics, behavioral science, computational science/modeling, and clinical sciences, in an attempt to understand the confluence of genetic, biological, behavioral and environmental factors involved in the etiology, treatment and prevention of these disorders.

Obesity.—Obesity is a health problem all too often overlooked; yet, recently it has begun to receive the attention it is warranted. It is no longer a condition that can be overlooked, as it is the leading cause of health problems in America, even more so than smoking. Motivation, counseling, marketing and communication are all important tools if we are to create a healthier nation led by healthier children. If we are to see results, the message that we communicate must be rooted in science and research. Evidence based research, translated into practice, will ensure safe and effective messages. The use of science in promoting behavioral changes should not and cannot be ignored. It has shown us that obesity leads to increased risk of diabetes, heart disease, and even cancer. The behavioral and physiological changes that occur during high-risk periods for weight gain must be clarified. This information can then be used to design individualized interventions, in order to prevent future weight gains and obesity. Research in this field benefits several institutes, such as NHLBI, NICHD, NIDDK, NIA, and NCI.

Sexual Behavior Research and Peer Review.—Recently, much publicity has been given to research conducted at NIH that involves human sexuality and sexually transmitted disease. This research is critical to the health of all Americans, and must continue unimpeded. Recent attacks on NIH for supporting research in health and behavior are motivated by objections to particular behaviors or to the populations being studied. These attacks are intended to stop funding of research relating to such things as reproductive functioning, sexually transmitted diseases, substance abuse, and other public health problems. This research has enormous implications for understanding and preventing a range of health problems, including HIV and AIDS; problems of physical, mental and social development in children; violence; addiction; teen pregnancy; and numerous other conditions that stem from behavioral threats to health. These problems are not limited to particular segments

of our society; the health and economic consequences of these behaviors affect individuals, families and communities of all ethnic backgrounds, professions, and income levels. Our best and only hope for combating these issues is a robust health research agenda based on scientific priorities and methods. The American Psychological Society strongly supports the scientific peer review system of the National Institutes of Health and we encourage Congress and the public to reject efforts to undermine that system by attacking selected grants. NIH's system for evaluating research proposals ensures that the best science is brought to bear on our nation's most pressing public health problems. On this subject, NIH director Zerhouni wrote to Congress: "I fully support NIH's continued investment in research on human sexuality, and I believe that the peer review process has worked properly and provided a level of valuable and independent view in this important area of research." In the interest of public health, our Nation's leaders must take whatever steps are necessary to protect the scientific peer review system from the chilling effects of ideological influences.

It is not possible to highlight all of the worthy behavioral science research programs at NIH. In addition to those I've discussed here, many other institutes play a key role in NIH behavioral science research enterprise. These include the National Institute on Aging, the National Heart Lung and Blood Institute, the National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, and within NIH Director's office, the Office of Behavioral and Social Sciences Research. Behavioral science is a central part of the mission of each of these, and each deserves the Committee's support.

This concludes my testimony. Again, thank you for the opportunity to discuss NIH appropriations for fiscal year 2004 and specifically, the importance of behavioral science research in addressing the Nation's public health concerns. I would be pleased to answer any questions or provide additional information.

PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

SUMMARY—FUNDING RECOMMENDATIONS

[In millions of dollars]

Agency	Amount
National Institutes of Health	30,000.0
National Heart, Lung and Blood Institute	3,165.8
National Institute of Allergy and Infectious Disease	4,733.3
National Institute of Environmental Health Sciences	694.1
Fogarty International Center	71.5
National Institute of Nursing Research	148.5
Centers for Disease Control and Prevention	7,500.0
National Institute for Occupational Safety and Health	306.9
Office on Smoking and Health	130.0
Environmental Health: Asthma Activities	70.0
Tuberculosis Control Programs	528.0

The American Thoracic Society (ATS) is are pleased to submit our recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview.

The American Thoracic Society, founded in 1905, is an independently incorporated, international education and scientific society that focuses on respiratory and critical care medicine. The Society's members help prevent and fight respiratory disease around the globe through research, education, patient care and advocacy. The Society's long-range goal is to decrease morbidity and mortality from disorders and life-threatening acute illnesses.

MAGNITUDE OF LUNG DISEASE

Lung disease in America is a serious problem. Each year, an estimated 342,000 Americans die of lung disease. Lung disease is responsible for 1 in every 7 deaths, making it America's number three cause of death. More than 35 million Americans suffer from a chronic lung disease. In 2002, lung diseases cost the U.S. economy an estimated $141.8 billion in direct and indirect costs.

Lung diseases represent a spectrum of chronic and acute conditions that interfere with the lung's ability to extract oxygen from the atmosphere, protect against environmental or biological challenges and regulate a number of metabolic processes.

Lung diseases include chronic obstructive pulmonary diseases, lung cancer, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, asthma and severe acute respiratory syndrome (SARS).

The ATS is pleased that the Subcommittee provided increases in the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) budget last fiscal year. The ATS is pleased that the Administration and Congress modestly increased the National Institute of Health (NIH) budget in fiscal year 2004. However, we are extremely concerned with the President's fiscal year 2005 budget that proposes a mere 2 percent increase for NIH and signficiant cuts for CDC. We ask that this Subcommittee recommend a 10 percent increase for NIH. In order to stem the devastating effects of lung disease, research funding must continue to grow to sustain the medical breakthroughs made in recent years. While our statement will focus on selected parts of the Public Health Service, we are firmly committed to appropriate funding for all sectors of our nation's public health infrastructure.

COPD

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in the United States and the third leading cause of death worldwide. Yet, COPD remains relatively unknown to most Americans. COPD is the term used to describe the airflow obstruction associated mainly with emphysema and chronic bronchitis and is a growing health problem.

While the exact prevalence of COPD is not well defined, it affects tens of millions of Americans and can be an extremely debilitating condition. It has been estimated that 13.3 million patients have been diagnosed with some form of COPD and as many as 24 million more are undiagnosed.

In 2001, 13.3 million adults, aged 18 and older in the United States were estimated to have COPD. In addition, according to the new government data based on a 2001 prevalence survey, 3 million Americans have been diagnosed with emphysema and 11.2 million are diagnosed with chronic bronchitis. In 2001, 118,000 people in the United States died of COPD, with the death rate for women with COPD surpassing the death rate of men with COPD. COPD costs the U.S. economy an estimated $32.1 billion a year.

Medical treatments exist to address symptom relief and slow the progression of the disease. Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Research in the genetic susceptibility underlying COPD is making progress. Also, there are promising research leads on medications to repair damage to lung tissue caused by COPD. Additional research is needed to pursue these leads.

Despite these promising leads, the ATS feels that research resources committed to COPD are not commensurate with the impact COPD has on the United States and the world. Clearly more needs to be done to make Americans aware of COPD, its causes and symptoms. We understand that the National Heart Lung and Blood Institute (NHLBI) is developing a public education program on COPD. The ATS supports this effort and encourages the NHLBI to partner with the patient and physician community in developing the COPD public education campaign. Additionally, we recommend the Subcommittee encourage NHLBI to devote additional resources to finding improved treatments and a cure for COPD. It affects tens of millions of Americans and can be an extremely debilitating condition. It has been estimated that 13.3 million patients have been diagnosed with some form of COPD and as many as 24 million more are undiagnosed.

The ATS is pleased to announce the formation of a new congressional caucus that will focus on COPD. On March 30, 2004, the Congressional COPD Caucus officially began its work and the ATS encourages members of this Subcommittee to join.

ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes of the lungs become swollen and narrowed, preventing air from getting into or out of the lung. A broad range of environmental triggers that vary from one asthma-sufferer to another causes these obstructive spasms of the bronchi.

Last month, the CDC issued a new report indicating that asthma rates have risen for the past 10 years. It is estimated that close to 20.3 million people suffer from asthma, including an estimated 6.3 million children. While some children appear to out grow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition.

Asthma is expensive. The growth in the prevalence of asthma will have a significant impact on our nation's health expenditures, especially Medicaid. The direct medical costs and indirect costs for asthma are estimated to exceed $14 billion annually. Asthma also represents the most common cause of school absenteeism due to chronic disease. In 2001, there were 2 million emergency room visits due to asthma.

Asthma also kills. In 2001, 4,200 people in the United States died as a result of an asthma attack. Approximately 65 percent of these deaths occurred in women. A disproportionate share of these deaths occurred in African American families.

As the prevalence of asthma has grown, so has asthma research. Researchers are developing better ways to treat and manage chronic asthma. Research supported by the National Heart, Lung and Blood Institute (NHLBI) has discovered genetic components as well as how infectious disease contributes to asthma. NHLBI researchers have also developed better animal models to allow expression of selected asthmatic genetic traits. This will allow researchers to develop a greater understanding of how genes and environmental triggers influence asthma's onset, severity and long-term consequences.

Progress is being made to fight the growing asthma epidemic. We are pleased to report that the fourth American Lung Association Asthma Clinical Research Centers (ACRC) Network study began in September 2003. That study hopes to determine if patient education and the ways of presenting asthma drugs can improve treatment. The first ACRC study concluded that a considerable reduction in the number of hospitalizations, resulting in lower health care costs, could be achieved if all people with asthma were vaccinated for influenza. The 19 ACRC centers around the United States evaluate treatment, education and other intervention strategies for asthma in adults and children. This network is one of the largest clinical research networks in the United States and will continue to develop innovations that will directly benefit patients.

The ATS also feels that the Centers for Disease Control and Prevention (CDC) must play a leadership role in the ways to assist those with asthma. National statistical estimates show that asthma is a growing problem in the United States. However, we do not have accurate data that provide regional and local information on the prevalence of asthma. To develop a targeted public health strategy to respond intelligently to asthma, we need locality-specific data. CDC should take the lead in collecting and analyzing this data.

Last year, Congress provided approximately $37 million for the CDC to conduct asthma programs. CDC will use these funds to conduct asthma outreach, education and tracking activities. We recommend that CDC be provided $70 million in fiscal year 2005 to expand programs and establish grants to community organizations for screening, treatment, education and prevention of childhood asthma.

In the past, Congress enacted legislation that directs the National Asthma Education and Prevention Program at NHBLI to develop a plan for the federal government to respond to the growing asthma epidemic in the United States. This plan should bring together key public and private organizations to develop a national asthma plan to coordinate the many elements of an effective public health response to asthma. Components of a national plan should include research, surveillance, patient and provider education, community awareness, indoor and outdoor air quality, and access to health care providers and medication.

TUBERCULOSIS

The first lung disease research began with the treatment of those who had tuberculosis (TB) (TB) or "consumption", as it was called at the turn of the 20th century. Tuberculosis is an airborne infection caused by a bacterium, *Mycobacterium tuberculosis.* Tuberculosis primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine.

Tuberculosis is spread through coughs, sneezes and close proximity to someone with active tuberculosis. People with active tuberculosis are most likely to spread the disease to others they spend a lot of time with, such as family members or coworkers. It cannot be spread by touch or sharing utensils used by an infected person.

Tuberculosis takes a toll on the U.S. economy, with total direct and indirect costs of $1.1 billion. There are an estimated 10 million to 15 million Americans who carry latent tuberculosis infection. Each has the potential to develop active tuberculosis in the future. About 10 percent of these individuals will develop active disease at some point in their lives. In 2003, there were 14,871 cases of active tuberculosis reported in the United States. This is only a 1.4 percent decline in the number of cases reported in 2002 and is the smallest annual decrease reported since 1992, the

year the incidence of tuberculosis peaked during a period of resurgence from 1985–1992.

Upon review of this information, many have concluded that a cycle of neglect has begun, reminiscent of the previous resurgence. The ATS, in collaboration with the National Coalition for Elimination of Tuberculosis, recommends an increase of $105 million for TB control in fiscal year 2005 to allow the CDC undertake an unprecedented initiative, Intensified Support and Activities to Accelerate Control (ISAAC) to enhance, maximize and target resources to sustain the momentum of the past decade and accelerate the control and elimination of tuberculosis. ISAAC targets tuberculosis in African Americans, tuberculosis along the United States-Mexico border, allows for universal genotyping of all culture positive TB cases and expands clinical trials for new tools for the diagnosis and treatment of tuberculosis.

In the summer of 2000, the Institutes of Medicine (IOM) published a report, entitled: *Ending Neglect: The Elimination of Tuberculosis in the United States.* The report documents the cycles of attention and progress toward TB elimination, the periods of insufficient funding and the re-emergence of tuberculosis. The IOM report provides the United States with a road map of recommendations on how to eliminate tuberculosis in the United States. The IOM report identifies needed detection, treatment, prevention and research activities. The report concludes that with proper funding, organization of prevention and control activities and research for development of new tools, tuberculosis can be eliminated as a public health problem in the United States. We have endorsed the IOM report and its recommendations. The components of ISAAC begin to fully implement the recommendations of the IOM.

While declining overall TBB rates is good news, the slowing of the decline in rates and the emergence and spread of multi-drug resistant TtuberculosisB poses a significant threat to the public health of our nation. Increased support is needed if the United States is going to continue progress toward the elimination of tuberculosis.

The NIH also has a prominent role to play in the elimination of tuberculosis. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances has put the goal of an effective TB vaccine within reach. The National Institute of Allergy and Infectious Disease has developed a Blueprint for Tuberculosis Vaccine Development. We encourage the subcommittee to fully fund the TB vaccine blueprint.

Fogarty International Center TB Training Programs

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. The goal is to develop a cadre of health professionals in the developing world who can begin controlling the global AIDS epidemic.

Because of the link between AIDS and TB infection, the FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area of TB treatment and research. This supplemental program has been highly successful in beginning to create the human infrastructure to treat the nearly 2 billion people who have tuberculosis worldwide.

However, we believe TB training grants should not be offered exclusively to institutions that have received AIDS training grants. The TB grants program should be expanded and open to competition from all institutions. The ATS recommends that Congress provide an additional $3 million for the FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

NIOSH—RESEARCHING AND PREVENTING OCCUPATIONAL LUNG DISEASE

The ATS is extremely concerned that the president's budget proposes to cut the National Institute of Occupational Safety and Health (NIOSH) extramural research program. We strongly encourage this subcommittee to reject the Administration's proposed cut to the NIOSH research program. Occupational safety and health research are valuable and deserve additional funding.

Protecting the health of our nation's workforce will require research, training, tracking and new technologies. We recommend that the Subcommittee provide a $30 million increase for the NIOSH budget. The $30 million increase will be used for the NIOSH Emergency Preparedness agenda, including activities at the National Personal Protective Technology Laboratory, improve workers' safety, and invest in protective technology that will help our nation respond to the growing threat of bioterrorism. In addition, increased NIOSH funding is needed for NIOSH-sponsored prevention, intervention and information programs. These programs respond to existing workplace health programs, conduct prevention education programs, and work with labor and industry groups to lower the risk of workplace injury and illness.

Finally, the overall funding increase for NIOSH will increase training of occupational health professionals in the United States. A recent IOM Report, *Safe Work in the 21st Century: Education and Training Needs for the Next Decades Occupational Safety and Health Personnel,* identified a growing shortage of trained occupational health professionals in the United States. Unlike the majority of medical subspecialties, occupational health professionals do not receive Medicare training support. One such program is the Capacity Building for Worker safety and health that includes training opportunities for occupational health professionals at NIOSH—sponsored Centers of Excellence. We believe more funds are needed in order to track the incidence of serious work-related illnesses and injury.

PHYSICIAN WORKFORCE SUPPLY

As the number of people diagnosed with lung diseases rises, we need to ask, who will be treating lung disease patients in the future? The ATS is also concerned about the supply of physicians in the United States. The ATS is concerned about the supply of physicians in the United States. A recent study published in the Journal of the American Medical Association predicts that there will be an acute shortage of physicians trained to treat patients with critical care illness and lung disease starting in 2007.[1] While the study focuses on supply of pulmonary/critical care physicians, what is driving the shortage is the predicated increase in demand for physician services caused by the aging of the U.S. population.

Policy makers have given much thought and attention to how the aging population will affect Social Security and other programs for the elderly. Significant attention has been given to the acute shortage of nurses. However, such forward thinking does not seem to be applied to our physician workforce.

We are pleased that Bureau of Workforce Analysis at the Health Resources and Services Administration (HRSA) will be conducting a study on physician workforce supply in the United States. We are hopeful that the HRSA study will confirm the looming shortage of physicians in the United States and make policy recommendations on how best to add physicians to the workforce before it becomes a serious crisis.

LUNG-DISEASE OPPORTUNITIES AND ADVANCES

Pulmonary researchers have made significant advances in lung disease research. NHBLI has identified areas of lung disease research that it will be exploring in the next year. One area of focus will be acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). NHLBI created Specialized Centers of Clinically Oriented Research (SCCOR) in translational research in acute lung injury. Patients experiencing ALI and ARDS suddenly develop severe lung inflammation that results in hypoxemia, loss of lung compliance and possibly multi-organ system failure. The SCCOR program will foster multi-disciplinary basic and clinical research related to ALI and ARDS, which will eventually have a positive impact on their prevention, diagnosis and treatment.

Another area of focus is COPD and lung cancer research. Nearly a quarter of a million Americans die each year of either COPD or lung cancer. NHLBI hopes to address the gap in knowledge that a common pathogenetic mechanism may be involved as a risk factor for COPD and lung cancer. The research will focus on a search for the similarities of the cellular and molecular mechanisms that lead to COPD and lung cancer. This new research could have important implications for the prevention and management of both diseases.

One area of new and emerging research conducted by the NHBLI deals with Sleep-disordered breathing (SDB). SDB is a medical condition associated with upper airway obstruction and cessation of breathing that leads to repeated episodes of asphyxia during the night. SDB is very prevalent in the U.S. population with conservative estimates set at 2 percent to 3 percent of all children, 5 percent of middle age adults, and in excess of 15 percent of the aged population. The major health-related implications and morbid consequences of SDB include the neurocognitive and cardiovascular morbidities, depression, hypertension, increased frequency of myocardial infarction and stroke, and increased frequency of motor vehicle accidents due to the increased sleepiness induced by the disruption of sleep in SDB patients. Both the frequency of SDB and its consequences are anticipated to increase in the next decades due to the aging of the overall U.S. population and the ongoing epidemic of

[1] D. Angus, et al. Current and Project Workforce Requirements for Care of the Critically Ill and Patients with Pulmonary Disease: Can We Meet the Requirements of an Aging Population? JAMA 2000; 284:2762–2770.

obesity that afflicts our country. The ATS supports the need for more research into the causes, diagnosis and treatment of SDB.

In conclusion, lung disease is a growing problem in the United States. It is this country's third leading cause of death, responsible for 1 in 7 deaths. The lung disease death rate continues to climb. Overall, lung disease and breathing problems constitute the number one killer of babies under the age of 1 year. Worldwide, tuberculosis kills 3 million people each year, more people than any other single infectious agent. The level of support this Subcommittee approves for lung disease programs should reflect the urgency illustrated by these numbers.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

The American Society of Clinical Oncology (ASCO) is the world's leading professional society representing more than 20,000 physicians and health care providers engaged in cancer treatment and research. ASCO appreciates the opportunity to submit a statement for the Subcommittee record. This is a time when cancer clinical researchers faces tremendous challenges and also significant opportunities, and we recommend several actions that will ensure the efficient translation of basic research findings into new treatments.

ASCO members owe a tremendous debt to this Subcommittee and the Congress for your leadership over the past decade in boosting the funding for the National Institutes of Health (NIH). The doubling of the NIH budget between fiscal year 1999 and fiscal year 2003 is a particularly impressive accomplishment, but Congress acted as a steadfast friend to research for many years before the period by guaranteeing that NIH had the resources it needed to support basic, translational, and clinical research.

With the resources that have been provided to NIH and to biomedical researchers across the country, our knowledge of the genetic, molecular, and cellular basis of many diseases has increased dramatically. There has been a revolution in our understanding of cancer, and the traditional approach to cancer, which was based on the site of the cancer, is changing. Instead of seeking to develop treatments based on the location of the cancer, we are instead looking for treatments that correct the underlying genetic or molecular defect that causes the disease. The promise of cancer research has never been greater, although realizing that promise will be difficult and will require significant resources.

ASCO and others in the research community are aware of the current budget situation and the effect it will likely have on NIH appropriations. Nevertheless, we strongly urge that Congress make every effort to boost NIH funding, as continued funding increases will ensure that the basic research progress made in recent years will continue and that those basic research findings will be translated to new treatments. We endorse the recommendation of the Federation of American Societies for Experimental Biology and others in the research community that NIH funding be increased by 10 percent in fiscal year 2005, to a total of $30.6 billion.

THE NIH ROADMAP

The leaders of NIH have given serious consideration to reforms that will equip NIH to remain the world's leading biomedical research institute in the 21st century. ASCO believes that the three main areas of focus of the Roadmap—establishing new pathways to discovery, developing research teams of the future, and re-engineering the clinical research enterprise—are appropriate, and achieving these goals of the Roadmap would equip researchers for developing new treatments.

We are gratified that the NIH Roadmap emphasizes the need to re-engineer the clinical research enterprise. Although the cancer clinical trials system at the National Cancer Institute (NCI) is strong and has been a major factor in advances in cancer care, we welcome the NIH Roadmap's critical look at clinical trials systems as a means of improving those systems. Clinical researchers must be provided the tools, including informatics and tissue or specimen repositories, to conduct their work efficiently, and the Roadmap acknowledges the need for those investments.

In addition, the drafters of the NIH Roadmap properly identify a crisis in clinical research training and suggest steps to enhance training. ASCO has initiated programs to improve the training of cancer clinical researchers, and we welcome the special attention that NIH is directing to this issue.

Implementation of the NIH Roadmap initiatives cannot be accomplished at the expense of successful core programs at NCI and other institutes, but Congress should foster the important reforms outlined in the Roadmap.

THE CANCER CLINICAL TRIALS SYSTEM

NCI has supported the development of a sophisticated system for conducting clinical trials that depends heavily on the participation of community oncologists, along with oncologists at cancer centers around the nation. Patients who are treated in the community have the option of enrolling in clinical trials, as their oncologists are almost certainly part of the nation's clinical trials system. This system of treatment, where the majority of cancer patients receive their care in the community and have access to the full range of treatment options, including clinical trial enrollment, has evolved over the last 30 years.

The Medicare Modernization Act of 2003 (MMA) changes dramatically the method by which cancer chemotherapy services provided by oncologists in their offices are reimbursed by Medicare. The current system of payment for cancer chemotherapy drugs will be shifted from an average wholesale price methodology to an average sales price methodology, and accompanying reductions will be made in reimbursement for the services required to administer chemotherapy in the physician's office. The estimates are that, in the aggregate, reimbursement for cancer chemotherapy services will not decline from 2003 to 2004. However, ASCO's preliminary predictions suggest a dramatic reduction in payment for cancer care beginning in January 2005. One of the tasks facing ASCO is to monitor this situation carefully and report to Congress the effects of reimbursement changes.

We realize that this Subcommittee does not have jurisdiction over Medicare. We are raising this issue with the Subcommittee, however, because the potential effects of Medicare reimbursement changes include a serious threat to the clinical research enterprise. In surveys that ASCO has conducted among its members who are engaged in office-based practice, a significant number of those surveyed indicate that, in light of the potential Medicare reimbursement changes in 2005, they will be less inclined to participate in clinical research. Some members have already reported that they have stopped participating in clinical trials. ASCO members have for years reported that the per person payment they receive for NCI-funded clinical trials is inadequate to pay the costs associated with enrolling a patient on trial and collecting and reporting data from the trial. These physicians have subsidized NIH-funded trials with payments from industry-sponsored trials and from clinical income. According to reports from the field, oncologists will not be able to continue this cross-subsidization, because the funds simply will not be available to support this longstanding ad hoc practice.

The task ahead of us now is translating the significant advances in our fundamental knowledge of cancer into new treatments. In no area of research are the opportunities greater than in cancer, and those opportunities will be realized by the rapid completion of clinical trials testing new therapies. If the community physicians who enroll the majority of patients in clinical trials are no longer actively participating in clinical research, the clinical research enterprise will be slowed.

At the same time that ASCO monitors the effects of MMA cancer reimbursement changes and develops appropriate reform proposals, Congress should encourage NCI to undertake a review of the current system of paying for clinical trials. An immediate action that NCI can take is improving the payments to physicians for enrolling cancer patients in trials. Modest increases in payments have been approved by NCI in recent years, but they are inadequate. In addition, ASCO believes that more substantial changes—beyond a boost in the per-patient rate of payment—may be necessary to ensure that oncologists at cancer centers and in the community continue to participate in clinical research and that all other players in clinical research, including NCI and industry, remain committed to participation in cancer clinical research. This is an urgent matter, and we recommend action by NCI to address it.

MINORITY ENROLLMENT IN CLINICAL TRIALS

It is estimated that fewer than 5 percent of adults with cancer enroll in clinical trials. The rate of participation is even lower among minorities. ASCO commends NCI for its efforts to boost involvement of African American, Hispanic, Asian American, and American Indian patients in clinical trials, in part through the Minority-Based Community Clinical Oncology Program. This program includes 11 minority-based CCOPs and involves more than 40 hospitals and 100 minority investigators. We also support the Special Population Networks, which involve research institutions and community providers in investigations of the causes of cancer disparities. This knowledge is vital to our efforts to erase cancer disparities, and NCI is properly investing resources in this research initiative.

RESEARCH TO COMBAT BIOTERRORISM AND ENSURE HOMELAND SECURITY

ASCO is pleased that the biodefense request for fiscal year 2005 includes $47 million for the Public Health and Social Services Emergency Fund, which will support targeted research to develop medical countermeasures to treat nuclear or radiological injuries. Cancer researchers have expertise that will be critical to this effort, which includes: (1) developing drugs to prevent injury from radiological exposure; (2) improving methods for measuring radiological exposure, and (3) developing methods or drugs to restore injured tissues and eliminate materials from contaminated tissue. Cancer researchers are actively engaged in research to understand the late and long-term effects of cancer treatment, including chemotherapy and radiation therapy, and their expertise in these research areas equips them to be engaged in the targeted research that will likely be funded by the Public Health and Social Services Emergency Fund.

ASCO appreciates the opportunity to submit this statement. Congress, through its strong support of NIH, has facilitated an explosion of knowledge about cancer and other serious and life-threatening illnesses. Although we are poised to translate those basic research findings into new treatments, the clinical trials system for testing treatments is fragile. ASCO urges Congress to protect the clinical trials system, so that we can capitalize on the tremendous investment in basic research during the past decade.

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 was founded in 1946. Since its inception, the Society's highest priority has been to support research aimed at finding the cause of MS, better treatments, and a cure. In 2004, the National MS Society will spend over $31 million on MS research supporting over 300 MS investigations. By the end of 2004, the Society cumulatively will have expended some $420 million since awarding its first three grants in 1947. This represents the largest privately funded program of basic, clinical, and applied research and training related to MS in the world.

Multiple sclerosis is a chronic, unpredictable and often disabling disease of the central nervous system. Symptoms range from numbness in the limbs, to loss of vision, and in some instances partial or total paralysis. The progress, severity and specific symptoms of MS in any one person can vary and cannot yet be predicted, but advances in research and treatment are giving hope to those affected by the disease.

The federal investment in the National Institutes of Health (NIH) plays a major role in MS research. There are two institutes that conduct or fund the majority of MS research: the National Institute of Neurological Disorders and Stroke (NINDS) which funds 75 percent, and the National Institute of Allergy and Infectious Diseases (NIAID) which funds about 20 percent.

For fiscal year 2004 and fiscal year 2005, it is estimated that NIH expenditures on MS research will be $101.3 million and $102.8 million, respectively. While this demonstrates a good NIH investment in MS, the amount seems low considering that the annual direct and indirect disease cost is approximately $20 billion for all people with MS in the United States.[1]

To ensure an adequate federal investment in MS research, the Society has a three-pronged strategy: (1) request funding for specific research priorities relevant to MS; (2) encourage collaboration across NIH institutes and between NIH and outside organizations; and (3) advocate for a 10 percent funding increase for NIH overall in fiscal year 2005. The National MS Society has had a long and productive relationship with NIH, particularly with NINDS. Our founder Sylvia Lawry helped spearhead the legislation that established NINDS in 1950. Intramural scientists from NINDS serve on our scientific advisory committees and help the Society make research project decisions. These outstanding scientists/physicians volunteer their time to ensure that the research supported by the Society and NIH are in concert, and not in opposition.

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[1] Based on a 1994 Duke University study, indexed for 2002 by the National MS Society, the average annual cost of MS is estimated at $50,000 per person due to lost wages, increased medical care and other expenses. Nationwide, there are an estimated 400,000 people with MS.

FUNDING RESEARCH PRIORITIES RELEVANT TO MS

The National MS Society will continue to pursue research opportunities with NIH in priority areas that are key to furthering the understanding of MS. We also will closely monitor NIH's progress in expanding its commitment to MS research as suggested by Congress.

Last year, as part of our NIH advocacy efforts, the Society had the following congressional "report language" added by the House and Senate Appropriations Conference Committee as an instruction to NIH in the fiscal year 2004 omnibus appropriations package:

"The conferees urge NINDS to increase its overall investment in multiple sclerosis (MS) research. Special emphasis on imaging, biological markers and clinical trials for new therapeutics should be areas of high priority. The conferees are pleased to note the development of a joint symposium on MS genetics sponsored by NINDS and the National MS Society, and encourage the Institute to take a more active role at the NIH in furthering MS genetics research by developing collaborative strategies with the National Human Genome Research Institute and other relevant NIH institutes. The conferees request that NIH report back to Congress no later than September 30, 2004 with progress in its efforts to expand its commitment to multiple sclerosis. The conferees also are pleased to note a major success in past years in the creation of a joint collaborative research program in 'gender and immunity' between the National Institute on Allergy and Infectious Diseases (NIAID) and a major voluntary association for the disease, in which NINDS participates. The conferees encourage NINDS to seek similar collaborative activities related to MS."

The Society was pleased that late in 2003 NINDS funded a 5-year $30 million clinical trial that will test the effects of combining two of the MS injected therapies against the use of a single therapy. As part of this clinical trial, NINDS is including an additional $3–4 million to study the correlation between the clinical course of MS and data from biological markers (magnetic resonance imaging). The Society also was pleased that in 2003 NINDS and NMSS co-sponsored a scientific workshop on the role of genetics in MS. As an outcome of this workshop, the Society is looking to work closely with NINDS on genetics projects, such as the development of a collaborative and international MS genetics network. Such a network would facilitate the execution of small and large-scale studies utilizing both the latest technology to find genes that may confer susceptibility to MS.

We look forward to the year-end report from NINDS on its commitment to MS research.

In 2004, we will look to NINDS to establish a Working Group on MS (as has been done for Parkinson's Disease) to initiate planning to ensure that MS research is adequately supported throughout NIH and to collect information on research obstacles.

THE IMPORTANCE OF COLLABORATION

We cannot overemphasize the importance of collaboration. The National MS Society encourages NIH to increase collaboration across institutes and to pursue collaborative opportunities with other organizations.

—Collaboration fosters an interdisciplinary approach to the investigation of complex biomedical problems.

—Jointly funded research projects significantly leverage limited resources and advance the research agendas of all involved parties.

We are pleased to see that NIH Director Zerhouni made collaboration (both intramural and extramural) one of the pillars of his Roadmap Initiative—a 3-year plan addressing key research issues throughout NIH. As we see it, there is no other choice.

To date, the Society has been successful with NIH on jointly funding a major initiative on gender and immune function. In 2001, the Society entered into a $20 million collaborative project with NIAID and other NIH institutes to investigate gender effects on the immune function, including autoimmunity. This is important because most autoimmune diseases (including MS) are far more prevalent in women than men. The Society is co-funding six projects and will contribute up to $4 million to this project. We would like to engage in other collaborative projects, especially with NINDS.

The Society asks Congress to urge NIH to increase inter-institute collaboration as well as collaboration with external public, non-profit, educational and private sector organizations. Possible areas for collaborative research could include:

—*Neurological repair*.—How to effect recovery of tissue (and function) lost due to neurodegenerative diseases, including MS.

—*Neurological degeneration*.—Using MS as a model to study neurological degeneration in diseases such as Alzheimer's Disease, Parkinson's Disease and MS.
—*Genetics*.—The role of genetics in susceptibility to, and disease course of neurological and immunological disorders, including MS.
—*Imaging*.—Creation of Magnetic Resonance Imaging (MRI) centers to study repair, neuroprotection and other clinical issues that cut across a number of neurological disorders such as stroke, Alzheimer's Disease, Parkinson's Disease and MS. One possible eligibility requirement for these centers could be that a facility have expertise in at least two diseases.
—Pediatric research into diseases that rarely, but sometimes affect children.

We believe the NIH Director should establish inter-institute, cross-disease working groups in the above areas to examine and recommend worthy research topics that will set the stage for future collaborative projects.

Increased internal and external collaboration, which we hope will occur at NIH, points to the need for improved research tracking. The Society also asks that Congress recommend a standard project coding mechanism across all NIH institutes, so that the true research investment in various diseases is accurately represented to the public.

OVERALL NIH FUNDING INCREASE FOR FISCAL YEAR 2005

The Society is concerned that NIH may face a second year of overall low funding increases. Furthermore, in fiscal year 2003 and fiscal year 2004, only bioterrorism research received a healthy increase, with much smaller increases allocated for disease research. We fear the same may occur in fiscal year 2005. This is particularly disappointing after the fiscal years 1999–2003 funding campaign that doubled the NIH budget in the 5 year period.

—We urge Congress to appropriate a 10 percent fiscal year 2005 funding increase for NIH.
—While there is a need to increase our country's investment in bioterrorism research, we ask Congress to balance the fiscal year 2005 NIH appropriation to allow growth across all NIH institutes and all areas of disease research.

We thank the Subcommittee for this opportunity to comment and applaud your commitment to advancing the health and well-being of all Americans through investment in biomedical research.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN UNIVERSITIES

Mr. Chairman and members of the subcommittee: The Association of American Universities, representing 60 prominent research universities in the United States, appreciates this opportunity to submit testimony in support of the National Institutes of Health (NIH). Some 85 percent of the NIH budget is spent on research grants and contracts at higher education institutions across the United States. NIH research grants support nearly 40,000 graduate students and post-docs in universities and help develop a robust and diverse base of scientific talent critical to the future success of the nation's medical research efforts. AAU and its member research universities are very aware of the current restraints on domestic discretionary spending due to proposed funding increases for defense and homeland security programs, but have concerns about the long-term vitality of the biomedical research enterprise if the committee does not recognize that our nation's investment in NIH is also a top priority. AAU strongly urges the committee to provide a 10 percent increase in the fiscal year 2005 NIH budget because today's medical science translates into accelerated cures for tomorrow.

Past investment in NIH and our national biomedical research enterprise—the medical science performed by more than 217,000 scientists at more than 2,800 institutions around the country—has led to an exponential increase in the complexity of medical questions that can be asked and answered. NIH Director Elias Zerhouni has testified eloquently before your subcommittee about the health care revolution of a generation ago: medical research has transformed formerly lethal diseases into manageable afflictions and has given patients and their families more years of life. In the past 20 years, some of mankind's gravest scourges, such as childhood cancers, have been tamed. Deaths from heart attack and stroke have been cut by hundreds of thousands per year. HIV/AIDS, which was a death sentence 10 years ago, has become an onerous but survivable burden for those fortunate enough to live in the United States and receive triple-drug therapies. Today's biomedical research enterprise offers the hope of cures that add not just years to life, but quality of life to those years. AAU endorses the NIH "Roadmap for Research" developed by Dr. Zerhouni and his colleagues as an important framework for making the strategic in-

vestments that will fully capitalize on recent breakthroughs in genomics, bioinformatics, and molecular medicine. Cures—not just therapies—for juvenile diabetes, heart disease, osteoporosis, stroke and multiple cancers are within our grasp, if we can accelerate promising new research.

NIH-supported scientists have transformed the health and quality of life of all Americans. To take just one example, more than half of all cancers treated today will be cured. U.S. medical science is the envy of the world and the hope of mankind because science—not politics or ideology—has determined what research is supported. Recent investments in NIH funded research have:

—Yielded 100 new cancer drugs that are now in clinical trials. NIH-supported university research, for example, has produced therapies that target prostate cancer cells and the blood supply of other solid tumors, leaving healthy tissues untouched.

—Facilitated clinical trials to further develop at least 11 vaccines to address the HIV subtypes that together cause most of the HIV infections around the world. Since 1987, NIH's National Institute for Allergy and Infectious Diseases (NIAID) has enrolled more than 3,357 volunteers in 53 Phase I & Phase II preventive HIV vaccine trials of 28 candidate vaccines.

—Enabled scientists to identify the first drug to have an effect on both insulin production and insulin action as a potential therapeutic agent for type 2 diabetes. This example of an NIH investment in basic research could help the 17 million Americans who suffer from this disease.

—Revolutionized biomedical science through the sequencing of the human genome. Researchers now are able to locate, identify, and describe the function of many human genes. This new knowledge will lead to genetic tests to diagnose diseases and the development of drug therapies that are tailored to individual patients.

AAU urges the committee to provide appropriate funding for NIH or many promising opportunities will not be funded. If NIH receives inadequate funding in fiscal year 2005, we will lose significant opportunities to cure disease and comfort the afflicted. A 10 percent increase for NIH will:

—Enable faster and cheaper genomic sequencing. Currently it costs $2–3 billion to sequence an entire genome. An investment of $50 million today will enable the development of new technologies that will cut the cost of sequencing to $100,000 for a complex mammal within 5 years and drive the cost of an entire genome to $1,000 within 10 years.

—Support the new science of proteomics that has enabled physicians to distinguish among different types of ovarian or breast cancer tumors and reveal patterns that may have important clinical implications. Because of previous investments, doctors can now tailor therapies such as chemotherapy and radiation to patients based upon their tumor types, dramatically increasing cure rates and reducing the suffering of women who don't have to undergo painful therapies needlessly. Today's investment will drive the cost of diagnosis down to pennies per patient and further individualize cancer therapies.

—Fund the National Cancer Clinical Trial Database that allows patients to access information about NCI funded research by disease type; enables scientists to use recent technological innovations to produce vast amounts of information about the genes and proteins active within cancer cells; and allows cancer funding agencies to coordinate research efforts across agencies.

—Further reduce the time it takes to develop a vaccine, which has plummeted from 15 years to fewer than four. For example, two vaccine candidates for West Nile virus were in clinical trials within 3 years of West Nile's arrival in the continental United States. And biomedical researchers were able to take the knowledge and tools made possible by the NIH doubling to identify and sequence the SARS virus in a matter of weeks. As the nation braces for newly emerging infectious diseases such as bird flu or a bioterror attack, we must continue to develop new or improved vaccines.

CONCLUSION

As a nation, we enjoy the benefits of a system that recruits talented individuals and encourages them to compete for research funding. These individuals undergo a lengthy, rigorous and highly selective apprenticeship before they apply for their own research funds. The competition for research support is fierce, and at best only about 30 percent of the applicants for NIH funds are successful. When the success rate falls substantially below this level, important projects are disrupted and promising young people are dissuaded from research careers. Thus, in order to sustain

the high quality of the biomedical research system, we must continue to provide resources to encourage the research of our nation's best scientists.

It is imperative that this committee continue its legacy of bi-partisan support for NIH—the future health of the nation depends of it. In a year when defense and homeland security are top priorities, the committee must not allow investments for NIH to erode. The scientific community is tirelessly working to translate research into tangible benefits for all Americans. The health and quality of millions of lives depends on strong support from this committee for the fiscal year 2005 NIH budget.

Thank you for this opportunity to submit testimony and please let me know if you have questions.

PREPARED STATEMENT OF THE MARCH OF DIMES BIRTH DEFECTS FOUNDATION

The 3 million volunteers and 1,400 staff members of the March of Dimes appreciate the opportunity to submit the Foundation's federal funding recommendations for fiscal year 2005. The March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to prevent polio. Today, the Foundation works to improve the health of mothers, infants and children by preventing birth defects and infant mortality through research, community services, education, and advocacy. The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community, and other volunteers affiliated with 54 chapters in every state, the District of Columbia and Puerto Rico.

The volunteers and staff of the March of Dimes are deeply concerned that for the first time since 1958, the infant mortality rate increased in 2002. Increases in deaths due to premature birth, birth defects, and maternal complications during pregnancy are the top reasons for this increase. In our judgment, the modest funding increases recommended below would have an immediate and positive impact on this disturbing trend.

NATIONAL INSTITUTES OF HEALTH

The March of Dimes joins the larger research community in recommending a 10 percent increase in funding for the National Institutes of Health (NIH), bringing total federal support to just over $30 billion. A sustained investment in medical research is vital to discovering the interventions needed to prevent and treat diseases and conditions. Because of the profound impact on women and children of the work supported by the National Institute of Child Health and Human Development, funding for this Institute is of particular interest to the March of Dimes.

National Institute for Child Health and Human Development

The mission of the National Institute for Child Health and Human Development (NICHD) is closely aligned with that of the March of Dimes. The Foundation recommends an overall increase in funding of 10 percent for NICHD. With this increase in resources, NICHD could expand research in several areas that are crucial to improving the health of women and children. Additional funds would permit expansion of research into preterm labor and delivery and into the causes of birth defects, and would enable NICHD to begin implementing the National Children's Study of environmental and genetic influences on child health and development.

According to the National Center for Health Statistics, in 2002, more than 480,000 babies were born prematurely in the United States—1 in 8 births. Since 1981, the preterm birth rate has increased nearly 29 percent. Premature birth accounts for 23 percent of deaths in the first month of life. Those babies that survive are more likely than full-term infants to face serious multiple health problems including cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss. Preterm labor can happen to any pregnant woman and the causes of nearly half of all preterm births are unknown. An analysis of Agency for Healthcare Research and Quality data conducted by the March of Dimes Perinatal Data Center estimated that the total national hospital bill for premature babies was $13.6 billion in 2001. With overall hospital charges increasing rapidly—13 percent in 2001—the financial burden of prematurity is expected to worsen until we know how to prevent preterm births.

The March of Dimes recommends a 10 percent increase for NICHD in fiscal year 2005 and an increase of at least $50 million over the next 5 years to boost prematurity-related research. This increase should be devoted to a comprehensive biomedical research program to study preterm delivery etiology, prevention and treatment regimens.

Division of Reproductive Health

The National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health works to promote optimal reproductive and infant health, but does not have the resources it requires to study the growing problem of preterm birth. Therefore, the March of Dimes recommends a $20 million increase in fiscal year 2005 to expand research related to preterm birth. The growing problem of preterm birth requires an expanded, comprehensive prevention research agenda to identify the causes, risk factors and ways to prevent preterm birth. In particular, two specific programs should receive additional funding: (1) the Pregnancy Risk Assessment Monitoring System and (2) epidemiological research.

The Pregnancy Risk Assessment Monitoring System (PRAMS) is a state-specific, population based surveillance system designed to identify and monitor maternal behaviors and experiences before, during, and after pregnancy. Currently, CDC supports cooperative agreements with 31 states that allow PRAMS to cover about 60 percent of all U.S. births. Data collected through PRAMS is used by researchers and policy makers to increase understanding of adverse pregnancy outcomes, to develop and modify maternal and child health programs, and to incorporate the most up to date research findings into standards of practice. The March of Dimes recommends an increase of $5 million to expand PRAMS so that CDC can develop national estimates on behavioral as well as demographic risk factors for preterm birth.

Epidemiological research conducted at CDC is vital to reducing the incidence of preterm labor and delivery. The March of Dimes recommends an increase of $15 million to expand research on the prevention of preterm delivery for women at risk, focusing especially on factors contributing to higher rates of preterm delivery in African-American women. Increasing CDC's activities related to preterm birth will improve early detection of women at risk for preterm labor and lead to new interventions for those at greatest risk.

National Center on Birth Defects and Developmental Disabilities

According to CDC, birth defects are the leading cause of infant mortality accounting for more than 20 percent of all infant deaths and are responsible for about 30 percent of all pediatric hospital admissions. Of the 4 million babies born each year in the United States, approximately 150,000 are born with one or more serious birth defects. In addition, birth defects are the fifth-leading cause of years of potential life lost and contribute substantially to childhood morbidity and long-term disability. The causes of about 70 percent of all birth defects are still unknown.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) works to prevent birth defects for which causes have already been identified and conducts research on those defects for which causes have not yet been found. The March of Dimes urges members of the Subcommittee to increase funding for the Center to $160 million in fiscal year 2005 (includes the transfer of Hereditary Blood Disorders Division). This modest increase will provide the resources necessary to expand prevention activities where causes are known, and to accelerate the pace of research where causes have not as yet been identified. An increase of $15.9 million in funding for prevention, surveillance, and research activities is vital to making progress in the fight against birth defects.

Prevention: Folic Acid Education Campaign

The NCBDDD is conducting a national public and health professions education campaign designed to increase the number of women taking folic acid daily. According to CDC, each year, an estimated 2,500 babies are born with neural tube defects (NTDs), birth defects of the brain and spinal cord, including anencephaly and spina bifida. CDC estimates that up to 70 percent of NTDs could be prevented if all women of childbearing age consume 400 micrograms of folic acid daily, beginning before pregnancy. Fortification of the grain supply together with health provider and consumer education has resulted in a 32 percent decline in the rates of spina bifida. However, the growing popularity of low-carbohydrate diets has caused an increasing number of women to reduce or eliminate their daily intake of bread and other grains. A 2003 Gallup Organization survey conducted for the March of Dimes found that only 32 percent of women in the United States between the ages of 18 and 45 take a multivitamin containing folic acid on a daily basis, up only 4 percent since 1995. When asked what would make them more likely to take a multivitamin containing folic acid on a daily basis, 33 percent of women said they would be more likely to do so on the advice of their doctor or health care provider. Therefore, it is critical that CDC step up its campaign to educate every woman of childbearing age about the importance of taking a daily multivitamin containing folic acid.

To enable CDC to educate more women of child bearing age and their health providers about the importance of folic acid, the March of Dimes recommends an appropriation of at least $5 million in fiscal year 2005 for the Folic Acid Education Campaign.

Surveillance: State Cooperative Agreements to Improve Birth Defects Tracking

NCBDDD funds state initiatives to develop, implement, and/or expand community-based birth defects tracking systems, programs to prevent birth defects, and activities to improve access to health services for infants and children with birth defects. Surveillance forms the backbone of a vital public health network. CDC is currently supporting cooperative agreements with 28 states, each funded at an annual level of between $100,000 and $200,000 for each of 3 years. The March of Dimes encourages Subcommittee Members to add $3.4 million (a total of $7.5 million) to state-based birth defects surveillance activities. As you may know, resources have not been adequate to fund all states seeking assistance. Additional funding is needed to support creation of programs where none exist and improvement of programs already receiving support.

Research: Regional Centers for Birth Defects Research and Prevention

NCBDDD currently funds 10 regional Centers for Birth Defects Research and Prevention (each Center receives approximately $900,000 per year) to conduct epidemiological research on birth defects. The centers are located in Arkansas, California, Georgia, Iowa, Massachusetts, New Jersey, New York, North Carolina, Texas, and Utah. These centers obtain data and identify cases for inclusion in the National Birth Defects Prevention Study, the largest case-control study of birth defects ever conducted. The centers study the effectiveness of primary prevention of birth defects, the teratogenicity of various drugs, the environmental causes of birth defects and the genetic factors pertaining to susceptibility to environmental causes of birth defects. For example in response to a scientific study showing a possible association between the drug loratadine, also sold under the brand name Claritin®, and the occurrence of the birth defect hypospadias the National Birth Defects Prevention Study conducted a study that showed no association. This information will be useful to any woman who takes loratadine and becomes pregnant. The March of Dimes encourages the Subcommittee to add $10 million (for a total of $17.3 million in funding) to support the important and promising work of the regional centers.

ADDITIONAL CDC PROGRAMS

National Immunization Program

Immunizations are critical to the health and well-being of children. CDC's National Immunization Program provides grants to 64 state, local, and territorial public health agencies to reduce the incidence of disability and death resulting from vaccine preventable diseases. The March of Dimes urges the Subcommitttee to continue its longstanding policy of ensuring that federal vaccine programs are adequately funded to move the nation closer to the goal of vaccinating at least 90 percent of children and adults. To account for vaccine price increases, introduction of new vaccines, and to facilitate implementation of recent Institute of Medicine recommendations, the March of Dimes recommends an overall increase of $180 million in fiscal year 2005 for the National Immunization Program.

Polio Eradication

The March of Dimes was founded to find ways of preventing poliomyelitis. Although success in developing the Salk and Sabin vaccines enabled the Foundation to shift its focus to a new set of challenges, we continue to support completing the task of polio eradication worldwide. Global polio eradication will save lives and reduce unnecessary health-related costs. The March of Dimes supports a funding level of $106.4 million for CDC's fiscal year 2005 global polio eradication activities. With polio epidemics now confined to only 6 countries (Nigeria, India, Pakistan, Niger, Egypt and Afghanistan), it is important that the U.S. government maintain its commitment to completion of the worldwide eradication initiative.

National Center for Health Statistics

The Foundation also supports the vital work of the National Center for Health Statistics (NCHS) which provides information essential for research and programmatic initiatives. NCHS' surveys to assess the health status of American's care are critical to many programs and initiatives. For example, the National Vital Statistics System is a major source of information on utilization of health services, preterm births, low birthweight as well as outcomes including birth defects and infant mortality. Increased funding would allow CDC to modernize this system using

web-based technology that would facilitate rapid compilation of data and improvement in the accuracy and completeness of information obtained from health professionals and facilities. This information is needed to track trends in birth outcomes and to support birth defects registries. Additional resources would also enable CDC to continue the National Survey of Family Growth which provides essential information on factors affecting birth outcomes.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Newborn Screening

Newborn screening is a public health activity used to identify genetic, metabolic, hormonal and/or functional conditions in newborns. Many such disorders, if left untreated, can cause disability, mental retardation, and even death. Although nearly all babies born in the United States undergo newborn screening tests for some genetic birth defects, the number and quality of these tests varies from state to state. The March of Dimes recommends that every baby born in the United States receive, at a minimum, screening for a core set of nine metabolic disorders as well as hearing deficiencies.

In fiscal year 2004, the Congress provided first-time funding for implementation of Title XXVI of the Children's Health Act of 2000. This program is designed to strengthen state newborn screening programs; to improve states' ability to develop, evaluate, and acquire innovative testing technologies; and to establish and improve programs to provide screening, counseling, testing and special services for newborns and children at risk for heritable disorders. The March of Dimes proposes an appropriation of $25 million to support HRSA's work with states to expand the heritable disorders (newborn screening) program authorized through Title XXVI.

Maternal and Child Health Block Grant

Title V of the Social Security Act, the Maternal and Child Health (MCH) block grant, funds community-based services such as home visiting and respite care for children with special health care needs. MCH complements Medicaid and the State Children's Health Insurance Program by providing "wrap-around" services and other needed health services. The March of Dimes recommends fully funding the block grant at the authorized level of $850 million and notes that in order to hold states harmless an appropriation of $807 million is required. Additional funding would enable states to expand critical services such as prenatal and infancy home visitation programs, strategy that helps improve birth outcomes. According to the Maternal and Child Health Bureau, 900,000 children with special health care needs use MCH services. These children would also benefit as increased resources would enable states to raise spending limits for home visits respite care, physical and occupational therapy, durable medical equipment, and other support services.

Consolidated Health Centers

Consolidated (Community) Health Centers are an important source of obstetric and pediatric care for more than 13 million individuals, 40 percent of whom are uninsured. The Foundation recommends new funding sufficient to increase the number of centers and to improve the scope of perinatal services provided. Adding funds to this program would be consistent with the President's 5-year plan to create and expand health center sites in 1,200 communities and to increase the number of patients served annually to more than 16 million.

Thank you for the opportunity to testify on the federally supported programs of highest priority to the March of Dimes. The Foundation's staff and volunteers look forward to working with Members of the Subcommittee to improve the health of mothers, infants and children.

MARCH OF DIMES FISCAL YEAR 2005 FEDERAL FUNDING PRIORITIES

[In millions of dollars]

Program	Fiscal year	
	2004 funding	2005 March of Dimes recommendation
National Institutes of Health (Total)	27,878.0	30,666.0
National Institute of Child Health & Human Development	1,242.0	1,366.0
National Human Genome Research Institute	479.0	527.0
National Center on Minority Health and Disparities	192.0	211.0
Centers for Disease Control and Prevention (Total)	6,972.0	8,100.0

MARCH OF DIMES FISCAL YEAR 2005 FEDERAL FUNDING PRIORITIES—Continued

[In millions of dollars]

Program	Fiscal year	
	2004 funding	2005 March of Dimes recommendation
Center on Birth Defects and Developmental Disabilities	113.0	[1] 160.0
Regional Centers for Birth Defects Research & Prevention	7.3	17.3
State Cooperative Agreements to Improve Birth Defects Tracking	4.1	7.5
Folic Acid Education Campaign	2.5	5.0
Immunization	644.0	824.0
Polio Eradication	106.4	106.4
Safe Motherhood/Infant Health (NCCDPHP)	54.0	74.0
Pregnancy Risk Assessment Monitoring System	7.1	12.0
Prevention Research (Preterm Birth)	1.3	16.3
National Center for Health Statistics	128.0	181.0
Health Resources and Services Administration (Total)	6,600.0	8,000.0
Maternal and Child Health Block Grant	730.0	850.0
Newborn Screening	2.0	25.0
Newborn Hearing Screening	10.0	10.0
Consolidated (Community) Health Centers	1,617.0	1,867.0
Healthy Start	98.0	98.0
Agency for Healthcare Research and Quality	304.0	390.0

[1] Fiscal year 2005 funding recommendation includes $22 million transfer of the Hereditary Blood Disorders Division and $25 million in new funding.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2005

—A 10 percent increase for the National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

—Continue to expand the NIDDK Nephrotic Syndrome (NS)/Focal Segmental Glomerulosclerosis (FSGS) research portfolio by aggressively supporting grant proposals in this area and encouraging the National Center for Minority Health and Health Disparities (NCMHD) to initiate studies into the incidence/cause of NS/FSGS in the African-American population.

—The NephCure Foundation enthusiastically supports the Scientific Conference/Workshop being sponsored by the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK). The workshop will take place early in 2005 and will examine areas of promise surrounding glomerular disease and will develop a future agenda for Focal Segmental Glomerulosclerosis (FSGS) research.

—The NephCure Foundation encourages follow up to the 2005 scientific workshop in hopes that it will initiate grant proposals focused on achieving the goals and opportunities developed by the workshop.

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the NephCure Foundation (NCF), a non-profit organization driven by a blue-ribbon panel of respected medical experts and a dedicated band of patients and families working for a common goal—to save kidneys and lives.

I am Ed Hearn, former Major League Baseball Player for the Kansas City Royals. My career as a professional athlete came to an abrupt end in 1988, when I was diagnosed with Focal Segmental Glomerulosclerosis (FSGS), a debilitating and degenerative kidney disease. Today, after two life-changing kidney transplants, a successful bout against cancer, the aid of a breathing machine each night, a $3,000 IV once a month, and $40,000 of medication per year, I live to tell my story and to speak for those suffering from FSGS. My hope is that we can find the means to prevent this life-threatening disease from affecting our youth and from jeopardizing the normalcy of their lives as it has mine and many others. I remain hopeful that a cure for FSGS will be discovered, but until then, we must focus on prevention.

TREATMENT TRIALS BEGINNING, BUT NO CURE IN SIGHT

Mr. Chairman, FSGS is one of a cluster of glomerular diseases that attack the one million tiny filtering units contained in each human kidney. These filters are called nephrons and the diseases attack the portion of the nephron called the

glomerulus, scarring and often destroying the irreplaceable filters. Scientists do not know why glomerular injury occurs and they are not sure how to stop its inevitable destruction of the kidney.

When I was a teenager, doctors found protein in my urine and told me that some day I might have kidney trouble. I thought "Fine, maybe I'll have to deal with that when I'm an old man down the road." Some day happened much sooner than anyone expected. I believe that because I was a highly-conditioned athlete—and catchers are more conditioned than most—my body initially masked the symptoms of FSGS.

My first kidney transplant lasted more than 7 years until the FSGS returned. I received a second kidney from my aunt in 2000, but my body rejected it almost immediately, and I received a third transplant in May 2002. My story is not unique; there are thousands of other people in this country who have had their lives disrupted due to the sudden onset of FSGS.

We are extremely thankful that an NIDDK-funded clinical trial began this year to study the efficacy of the current treatments for FSGS, and that ancillary studies are underway to examine tissue samples of injured glomerulus. However, these clinical trials hold no particular hope for patients who suffer from FSGS.

As children are most often affected by this disease, there are thousands of young people who are in a race against time, hoping for a treatment that will save their lives. The NephCure Foundation today raises its voice to speak for them all, asking you to take specific actions that will aid our quest to find the cause and the cure of NS/FSGS.

First and foremost, we support a 10 percent increase for the National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

TOO LITTLE DATA ABOUT A GROWING PROBLEM

When glomerular disease strikes, the resulting Nephrotic Syndrome causes loss of protein in the urine and symptoms such as edema, a swelling that often appears first in the face. For example, many physicians mistake children's puffy eyelids as an allergy symptom. Stories of similar misdiagnoses are common at our Foundation. With experts projecting a substantial increase in Nephrotic Syndrome in the coming years, there is a clear need to educate pediatricians and family physicians about glomerular disease and its symptoms.

The NephCure Foundation has numerous education programs underway, including patient education seminars; the most recent of which took place in May 2003. News of our most recent activities can be found on our web site at www.nephcure.org. However, our efforts alone are not enough.

NIDDK launched a major federal outreach program early in 2002—the National Kidney Disease Education Program—we seek your support in urging NIDDK to assure that glomerular disease receives high visibility in this important program.

GLOMERULAR DISEASE STRIKES MINORITY POPULATIONS

Nephrologists tell us that glomerular diseases such as FSGS affect a disproportionate number of African-Americans and, according to NIDDK, "the worst prognosis is observed in African-American children." NephCure officials have described this situation in a meeting with Dr. John Ruffin, director of the National Center for Minority Health and Health Disparities (NCMHD).

As the NCMHD becomes fully operational and plans programs, our Foundation will continue to work with the Center to encourage the creation of programs to study the high incidence of glomerular disease within the African-American population.

We ask the Committee to join with us in expanding the NS/FSGS research portfolio by requesting that the National Center for Minority Health and Health Disparities seize the opportunity to establish research into the phenomenon of glomerular disease within the African American community.

MORE BASIC SCIENCE IS NEEDED

The current FSGS clinical trials which follow an estimated 400 patients over a 3-year period, are limited, according to the RFA, to examining the "impact of immunomodulatory therapy on proteinuria." While the trials may lead to safer or more efficient care for children with FSGS, no one is suggesting that they will bring us closer to finding the cause and cure. Science has yet to prove that FSGS is an immune-mediated disease.

Scientists tell us that much more needs to be done in the area of basic science, beginning with collection of tissue and fluid samples from a large number of pa-

tients on which years of important scientific research can be founded. NephCure is collaborating with the NIH in a major way to work for such progress.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has agreed to match, dollar-for-dollar, funds raised by NephCure that will allow researchers to obtain DNA samples from hundreds of FSGS patients in upcoming clinical trials. The NIDDK will match up to $300,000 raised by NephCure for a combined total of $600,000. These trials are an ancillary study in conjunction with the first-ever national medication trials of FSGS treatment that may possibly lead to better understanding of the more common Nephrotic Syndrome, which can be a precursor to FSGS.

We enthusiastically support NIDDK in sponsoring a scientific workshop/conference to take place early in 2005, with the intent to review the most promising existing science in glomerular disease, and focus on methods of translating this scientific information into improved patient care. This goal is consistent with the NIH Roadmap to Research initiative developed by NIH Director, Dr. Elias Zerhouni.

We sincerely believe that the workshop will expose opportunities and challenges in glomerular disease research, and evaluate the resources needed to carry out these opportunities and challenges. The workshop/conference will lend hope to the thousands of young people whose kidneys and lives are threatened by this terrible disease, and give meaning and honor to their heroic stories.

The NephCure Foundation encourages follow up to the scientific workshop/conference in hopes that it will generate grant proposals focused on achieving the research goals and opportunities developed by the workshop.

We anticipate the potential for a Program Announcement and the potential for a Special Emphasis Program Announcement resulting from the conference or some other traditional mechanism to generate grant proposals. These mechanisms to encourage investigator initiated grant proposals should help to continue to expand the NS/FSGS portfolio at NIH.

Mr. Chairman, as you know, patient support and advocacy groups such as the NephCure Foundation work closely with medical research organizations. They share a mutual understanding that unless major research efforts are undertaken, advances and improvements in the health of patients will not occur. Every year, the NephCure Foundation participates in advocating increased funding for the NIH and NIDDK. We want to reiterate how deeply grateful we are for your leadership and that of the subcommittee on medical research matters, which means so much for the health of the people in our nation.

I will be pleased to answer any questions you may have.

PREPARED STATEMENT OF THE DIGESTIVE DISEASE NATIONAL COALITION

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Provide increased funding for the National Institutes of Health (NIH) at 10 percent for fiscal year 2005. Increase funding for the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases by 10 percent for fiscal year 2005.

—Continue focus on digestive disease research and education at NIH, including the areas of Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Colorectal Cancer, Endoscopic Research, Pancreatic Cancer, Celiac Disease, and Hemochromatosis.

—$25 million for the Centers for Disease Control and Prevention's (CDC) Hepatitis Prevention and Control activities.

—$30 million for the Centers for Disease Control and Prevention's (CDC) National Viral Hepatitis Roundtable Program

Chairman Specter, thank you for the opportunity to again submit testimony to the Subcommittee. Founded in 1978, the Digestive Disease National Coalition (DDNC) is a voluntary health organization comprised of 25 professional societies and patient organizations concerned with the many diseases of the digestive tract. The Coalition has as its goal a desire to improve the health and the quality of life of the millions of Americans suffering from both acute and chronic digestive diseases.

The DDNC promotes a strong federal investment in digestive disease research, patient care, disease prevention, and public awareness. The DDNC is a broad coalition of groups representing disorders such as Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Pancreatic Cancer, Ulcers, Pediatric and Adult Gastroesophageal Reflux Disease, Colorectal Cancer, Celiac Disease, and Hemochromatosis.

Mr. Chairman, the social and economic impact of digestive disease is enormous and difficult to grasp. Digestive disorders afflict approximately 65 million Americans. This results in 50 million visits to physicians, over 10 million hospitalizations, collectively 230 million days of restricted activity. The total cost associated with digestive diseases has been conservatively estimated at $60 billion a year.

The DDNC would like to thank the subcommittee for its past support of digestive disease research and prevention programs at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). With respect to the coming fiscal year the DDNC is recommending an increase of 10 percent to $30 billion for the National Institutes of Health (NIH) and all of its Institutes. Specifically the DDNC recommends that the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), and the National Institute of Allergy and Infectious Diseases (NIAID be given $5.25 billion, $2.01 billion, and $4.77 billion respectively. We at the DDNC respectfully request that any increase for NIH does not come at the expense of other Public Health Service agencies.

With the historic doubling of the budget for NIH completed and the challenging budgetary constraints the Subcommittee currently operates under, the DDNC would like to highlight the research being accomplished by NIDDK which warrants the increase for NIH.

INFLAMMATORY BOWEL DISEASE

In the United States today about 1 million people suffer from Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD). These are serious diseases that affect the gastrointestinal tract causing bleeding, diarrhea, abdominal pain, and fever. Complications arising from IBD can include anemia, ulcers of the skin, eye disease, colon cancer, liver disease, arthritis, and osteoporosis. Crohn's disease and ulcerative colitis are not usually fatal but can be devastating. The cause of IBD is still unknown, but research has led to great breakthroughs in therapy.

In recent years researchers have made significant progress in the fight against IBD. In 1998, the FDA approved the first drug ever specifically to fight Crohn's disease, a remarkable milestone. The DDNC encourages the subcommittee to continue its support of IBD research at NIDDK and NIAID at a level commensurate with the overall increase for each institute. The DDNC would like to applaud the NIDDK for its strong commitment to IBD research through the Inflammatory Bowel Disease Genetics Research Consortium. The DDNC urges the Consortium will continue its work in IBD research. The DDNC would also commend NIDDK for organizing and hosting the upcoming meeting entitled: "Research on Inflammatory Bowel Disease", later this month.

Given the recent advancements in treatment for these diseases and the increased risk that IBD patients have for developing colorectal cancer, the DDNC strongly believes that generating improved epidemiological information on the IBD population is essential if we are to provide patients with the best possible care. Therefore the DDNC and its member organization the Crohn's and Colitis Foundation of America encourage the CDC to initiate a nationwide IBD surveillance and epidemiological program in fiscal year 2005.

HEPATITIS C: A LOOMING THREAT TO HEALTH

It is estimated that there are over 4 million Americans who have been infected with Hepatitis C of which over 2.7 million remain chronically infected. About 10,000 die each year and the Centers for Disease Control and Prevention (CDC) estimates that the death rate will more than triple by 2010 unless there is additional research, education, and more effective treatments and public health interventions. Hepatitis C infection is the largest single cause for liver transplantation and one of the principal causes of liver cancer and cirrhosis. There is currently no vaccine for hepatitis C, and treatment has limited success, making the infection among the most costly diseases in terms of health care costs, lost wages, and reduced productivity. Patients who are older at the time of infection, those who continually ingest alcohol, and those co-infected with HIV demonstrate accelerated progression to more advanced liver disease.

The DDNC applauds all the work NIH and CDC have accomplished over the past year in the areas of hepatitis and liver disease. An example of this commitment has been the convening of the second National Institutes of Health Management of Hepatitis C Consensus Development Conference, which occurred in June 2002. The Conference made 17 specific and high priority research recommendations that need to be pursued to develop better treatments and a cure for hepatitis. The DDNC urges

that these recommendations be funded in fiscal year 2005. The DDNC also commends NIDDK for the establishment of the Biliary Atresia Research Consortium and the Adult-to-Adult Living Donor Liver Transplant Cohort Study. The convening of conferences on Hepatitis C and Renal Disease and Hepatitis C in Prisons, plus the New Direction for Therapy of Primary Biliary Cirrhosis are just some more positive examples of the work NIDDK has undertaken to combat hepatitis and liver disease. The DDNC urges NIDDK to continue support research in this area.

The DDNC supports $30 million for the CDC's Hepatitis Prevention and Control activities. The hepatitis division at CDC supports the hepatitis C prevention strategy and other cooperative nationwide activities aimed at prevention and awareness of hepatitis A, B, and C. The DDNC also urges the CDC's leadership and support for the National Viral Hepatitis Roundtable to establish a comprehensive approach among all stakeholders for viral hepatitis prevention, education, strategic coordination, and advocacy.

COLORECTAL CANCER PREVENTION

Colorectal cancer is the third most commonly diagnosed cancer for both men and woman in the United States and the second leading cause of cancer-related deaths. Colorectal cancer affects men and women equally. Although colorectal cancer is preventable and curable when polyps are detected early, a General Accounting Office report issued in March 2000 documented that less than 10 percent of Medicare beneficiaries have been screened for colorectal cancer. This report revealed a tremendous need to inform the public about the availability of screening and educate health care providers about colorectal cancer screening guidelines. In 2003, the New York City Department of Health has recommended colonoscopy for everyone over age 50 to prevent colorectal cancer.

The DDNC recommends a funding level of $25 million for the CDC's Colorectal Cancer Screening and Prevention Program. This important program supports enhanced colorectal screening and public awareness activities throughout the United States. The DDNC also supports the continued development of the CDC-supported National Colorectal Cancer Roundtable, which provides a forum among organizations concerned with colorectal cancer to develop and implement consistent prevention, screening, and awareness strategies.

PANCREATIC CANCER

In 2002, an estimated 28,300 people in the United States were found to have pancreatic cancer and approximately 28,200 died from the disease. Pancreatic cancer is the fifth leading cause of cancer death in men and women. Only 2 out of 10 patients will live 1 year after the cancer is found and only a very few will survive after 5 years. Although we do not know exactly what causes pancreatic cancer, several risk factors linked to the disease have been identified:

(1) *Age*.—Most people are over 60 years old when the cancer is found;

(2) *Sex*.—Men have pancreatic cancer more often than women;

(3) *Race*.—African Americans are more likely to develop pancreatic cancer than are white or Asian Americans;

(4) *Smoking*

(5) *Diet*.—Increased red meats and fats; and

(6) *Diabetes*

The National Cancer Institute (NCI) has established a Pancreatic Cancer Progress Review Group charged with developing a detailed research agenda for the disease. The DDNC commends NIDDK for the establishment in 2002 on an initiative entitled: *Liver, Pancreas, and Gastrointestinal Cell Genome Anatomy Project.* The DDNC hopes this new initiative will call more attention and greater resources to the diseases of the Pancreas. The DDNC encourages the Subcommittee to provide an increase for pancreatic cancer research at a level commensurate with the overall percentage increase for NCI and NIDDK.

IRRITABLE BOWEL SYNDROME (IBS)

IBS is a disorder that affects an estimated 35 million Americans. The medical community has been slow in recognizing IBS as a legitimate disease and the burden of illness associated with it. Patients often see several doctors before they are given an accurate diagnosis. Once a diagnosis of IBS is made, medical treatment is limited because the medical community still does not understand the pathophysiology of the underlying conditions.

Living with IBS is a challenge, patients face a life of learning to manage a chronic illness that is accompanied by pain and unrelenting gastrointestinal symptoms. Trying to learn how to manage the symptoms is not easy. There is a loss of spontaneity

when symptoms may intrude at any time. IBS is an unpredictable and fickle disease. A patient can wake up in the morning feeling fine and within a short time encounter abdominal cramping to the point of being doubled over in pain and unable to function.

The unpredictable bowel symptoms may make it next to impossible to leave your home. It is difficult to ease the pain than may repeatedly occur periodically throughout the day. A patient can become reluctant to eat for fear that just eating a meal will trigger symptoms all over again. IBS has a broad and significant impact on a person's quality of life. It strikes individuals from all walks of life and results in a significant toll of human suffering and disability.

While there is much we don't understand about the causes and treatment of IBS, we do know that IBS is a chronic complex of systems affecting as many as one in five adults. In addition:

—It is reported more by women than men;
—It is the most common gastrointestinal diagnosis among gastroenterology practices in the United States;
—It is a leading cause of worker absenteeism in the United States; and
—It costs the U.S. Health Care System an estimated $8 billion annually.

Mr. Chairman, much more can still be done to address the needs of the nearly 35 million Americans suffering from irritable bowel syndrome and other functional gastrointestinal disorders.

CELIAC DISEASE

Celiac Disease is a life-long condition in which the body develops an allergy to gluten, a protein found in wheat, barley, and rye, which can result in damage to the small intestine. Celiac disease affects as many as 2 million Americans. Onset of the disease can occur at any age. The common symptoms of Celiac Disease include fatigue, anemia, chronic diarrhea or constipation, weight loss, and bone pain. The only treatment for celiac disease is strict adherence to a gluten-free diet. Undiagnosed and untreated celiac disease can lead to other disorders such as osteoporosis, infertility, neurological conditions, and in rare cases cancer. Persons with Celiac Disease often have other associated autoimmune disorders as well.

The DDNC along with our Celiac Disease applauds the NIDDK for organizing and hosting the upcoming meeting entitled "Consensus Development Conference on Celiac Disease." The DDNC urges the Subcommittee to recommend more research, medical education, and public awareness around Celiac Disease.

The DDNC understand the challenging budgetary constraints and times we live in that is subcommittee is operating under, yet we hope you will carefully consider the tremendous benefits to be gained by supporting a strong research and education program at NIH and CDC. Millions of Americans are pinning their hopes for a better life, or even life itself, on digestive disease research conducted through the National Institutes of Health.

Mr. Chairman, on behalf of the millions of digestive disease sufferers, we appreciate your consideration of the views of the Digestive Disease National Coalition. We look forward to working with you and your staff.

Digestive Disease National Coalition

The Digestive Disease National Coalition was founded 25 years ago. Since its inception, the goals of the coalition have remained the same: to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients with digestive diseases.

PREPARED STATEMENT OF THE FIRST CANDLE/SUDDEN INFANT DEATH SYNDROME ALLIANCE

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Provide a 10 percent increase for fiscal year 2005 to the National Institutes of Health (NIH) and a proportional increase of 10 percent to the individual institutes and centers, specifically, the National Institute of Child Health and Human Development (NICHD).
—Transition from NICHD's successful SIDS 5-year research plan to a more comprehensive plan focusing on SIDS, stillbirth, and miscarriage.
—Continue to fund the SIDS and Other Infant Death Program Support Center at the Maternal and Child Health Bureau, within the Health Resources and Services Administration (HRSA).

—Fund 3 SIDS death scene protocol demonstration projects through the Centers for Disease Control and Prevention (CDC) in rural, urban, and suburban settings to provide a nation-wide protocol for dealing with SIDS death scenes.

Mr. Chairman and members of the Subcommittee, thank you for again allowing First Candle/SIDS Alliance the opportunity to submit testimony to this Subcommittee. First Candle is a national voluntary health organization uniting parents, caregivers, and researchers nationwide with government, business, and community service groups. Our mission is to promote infant health and survival during the prenatal period through 2 years of age through advocacy, education, and research, while at the same time providing compassionate grief support to those affected by an infant death.

Mr. Chairman, we still need your help, commitment, and support to help solve the mysteries of Sudden Infant Death Syndrome (SIDS) and stillbirth and ensure healthy pregnancies for all women.

Despite the fact that SIDS cases have been documented for years, organized scientific research into SIDS only began in the mid 1970's. In the three decades since, scientists are now beginning to make significant progress in unraveling this enigma of SIDS, which robs families of their infant children. As an example of this progress, we now know that in many SIDS related deaths there is an abnormality or underdevelopment in a region of the infant's brain, which is thought to control the heart and lung functions. In these cases, the irregularity may hamper normal respiratory activity. While this may not be the sole cause of SIDS, it could contribute to a larger respiratory problem leading to death when combined with other circumstances.

As a direct result of SIDS research and the "Back to Sleep" educational and awareness campaign on infant sleep positioning, SIDS deaths have been reduced by 50 percent since 1992, leading to the greatest decline in infant mortality rates in over 20 years.

Despite this exceptional news, our research and educational campaign is far from finished. There are still more than 2,500 SIDS deaths in the United States each year and SIDS continues to be the number one cause of death for children between 1 month and 1 year of age. SIDS is a major component of the United States infant mortality rate. In spite of these facts, we still do not yet understand the causes of SIDS nor do we possess any guaranteed method for its prevention.

Stillbirth is the death of an infant in-utero past 20 completed gestational weeks. The majority of these deaths occur at or near full-term; therefore, otherwise healthy babies die shortly before or during birth. There are more than 26,000 parents in the United States alone that experience a stillbirth annually, and it is estimated that nearly two-thirds of all stillbirth deaths remain unexplained. This translates to more than 70 stillborn babies delivered in the United States each day. More than half of these deaths are at 28 weeks or more gestation, and one in five full term babies are stillborn.

In spite of these statistics and the impact stillbirth has on families, little attention has been paid to the problem. There is a dire need for increased public awareness and federal funding to support stillbirth research and education programs. In 2003, NICHD committed $3 million to conduct five projects, which focus on central data collection and research protocols for stillbirth deaths. First Candle urges the Subcommittee to support continued funding for stillbirth research at NICHD.

First Candle is grateful for the Subcommittee's past support of SIDS activities, especially the support of NICHD. We urge you to again provide the additional funding necessary for the third Five-Year SIDS Research Plan to ensure that NICHD can continue to address critical SIDS research initiatives and expand on their recent funding for stillbirth research. Specifically, First Candle is supporting a funding increase of 10 percent for NIH overall, and a 10 percent increase for NICHD. We respectfully ask that the increases for NIH do not come at the expense of other Public Health Service agencies. Further research is essential to find the reasons for and means of preventing the tragedies of SIDS and stillbirth.

First Candle urges the Subcommittee to support infant death educational, awareness, and counseling activities that take place at the MCHB, and the death scene investigation protocol demonstration projects at the CDC. These programs are a vital companion to the research conducted at NICHD. Without prevention, awareness, counseling, and standardized investigation procedures, competent scientific research does not translate into meaningful advances for parents and families.

HIGHLIGHTS OF FEDERALLY FUNDED ACTIVITIES

National Institute of Child Health and Human Development (NICHD)

The mechanism of SIDS is still unknown; there are no clinical or biologic tests to identify a newborn at high risk of succumbing to SIDS; and more work is needed

to increase the implementation of "Back to Sleep" among all caregivers and in communities with high rates of infant death. To address and focus its efforts on these challenges, NICHD has developed and implemented three SIDS Five-Year Research Plans. Now that NICHD is focusing more globally on infant health, First Candle is encouraging the institute to transition from their successful SIDS 5-year research plan to a more comprehensive plan focusing on SIDS, stillbirth, and miscarriage.

Maternal and Child Health Bureau (MCHB)

First Candle has entered into a collaborative effort with MCHB to kickoff the "Healthy Child Care America Back to Sleep Campaign". This initiative builds on the success of the "Healthy Child Care America" and "Back to Sleep" campaigns to unite child care, health, and SIDS prevention partners across the country to reduce the number of SIDS-related deaths in child care settings.

The MCHB continues to support a number of SIDS and Other Infant Death related services and programs, including the following activities:

—National SIDS Resource Center, a major source of current information about SIDS.

—Maternal and Child Health Service Block Grant (MCH), which grants funds to states providing a range of services to SIDS families. Block grant funds support activities like: contact families immediately after death, discussion of autopsy results with the family, and support and counseling through the first year of bereavement. Unfortunately, in many jurisdictions across the country, funds for these services have been decreased or eliminated due to budgetary difficulties.

—Field training and curriculum to health care providers for case management of families who have experienced an infant death, and the development of model programs, particularly for the underserved and minorities. Demonstration grants have been established and are continuing in four states to target services for specific populations: California, Massachusetts, Missouri, and New York.

—National SIDS & Infant Death Program Support Center to address SIDS service issues at the federal level on an ongoing basis. First Candle runs this center, which opened in 1999, and has experienced notable success. The support center is working to expand bereavement services to family members of those who experience stillbirth and miscarriage.

Centers for Disease Control and Prevention (CDC)

To develop a better statistical figure on SIDS cases, Congress recommended in 1993 the establishment of a standard death scene protocol to offset discrepancies on unexplained infant deaths between states. It was hoped that this protocol would be adopted by states not only for statistical measure, but to help avoid what can become awkward and emotionally charged misunderstandings at the death scene. In 1996, CDC published the protocol, and since that time several states have adopted the standard. It is First Candle's long term goal to ensure that all states fully adopt and implement the protocol. To help realize this goal, First Candle would like Congress to appropriate funds for CDC to heed Congress' recommendations for the past several years and implement the demonstration projects that follow these guidelines in several community settings nationwide. We recommend a demonstration project in each of the following, a rural community setting, an urban community setting, and a suburban community setting. We would also encourage CDC to implement a nationwide survey to measure how many locales have already implemented the protocol independently and to analyze the results thus far.

In conclusion, we are all too painfully aware that SIDS has historically been a mystery, leaving in its wake devastated families and bewildered physicians. Not only have there been no answers on the cause of SIDS, but there have been no answers on how to effectively prevent its occurrence. Today we are beginning to find some of the answers on cause and prevention, and therefore reduce the risk of SIDS. Because of the "unknown", however, babies are still vulnerable even when parents and caregivers take the cautionary steps to prevent SIDS deaths. This tragedy will continue if research efforts are stalled or halted, especially when we are at the point where so much progress has been made. Now is the time for a re-energized effort against this tragic syndrome. Staggering statistics and the critical need for public awareness and research into the scope and causes of stillbirth has led to the joining together of parents and professionals to formally advocate for research into the causes and prevention of pre-term infant death. Now is the time for research into the horrible tragedy of stillbirth that too frequently becomes the outcome of a seemingly normal pregnancy.

On behalf of the thousands of families who have been devastated by the loss of a baby to SIDS, stillbirth, or miscarriage and the millions of concerned and fright-

ened parents, I ask for your support, and thank you again for allowing First Candle to submit this testimony.

First Candle/Sudden Infant Death Syndrome Alliance

First Candle/SIDS Alliance is an organization of parents and friends of SIDS, Stillbirth and Other Infant Death victims along with medical, business, and civic groups who are concerned about the health our nation's children. The Alliance is engaged in ongoing efforts to expand its scientific program, strengthen services for families, and provide public education and advocacy opportunities. An important goal is to improve community understanding and elevate SIDS, Stillbirth and Other Infant Death to the level of societal concern appropriate to one of our nation's major causes of infant mortality.

PREPARED STATEMENT OF THE NATIONAL SLEEP FOUNDATION

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Provide a 10 percent increase for fiscal year 2005 to the National Institutes of Health (NIH) and a proportional increase of 10 percent to the individual institutes and centers, specifically, the National Heart, Lung, and Blood Institute (NHLBI).

—Urge the National Center on Sleep Disorders Research (NCSDR) to partner with other federal agencies, such as the Centers for Disease Control and Prevention (CDC), and voluntary health organizations, such as the National Sleep Foundation (NSF), to develop a collaborative sleep education and public awareness initiative.

Mr. Chairman and members of the Subcommittee, thank you for allowing me present testimony today on behalf of the National Sleep Foundation or NSF. I am Dr. James Walsh, Chairman of the Board of Directors of the National Sleep Foundation, Executive Director of the Sleep Medicine and Research Center affiliated with St. John's Mercy and St. Luke's Hospitals, and Clinical Professor of Psychiatry at St. Louis University. The National Sleep Foundation is an independent, non-profit organization whose mission is to enhance public awareness about the need for sufficient restorative sleep, to increase the detection and treatment of sleep disorders, to foster sleep-related programs and policy for the betterment of public health, and to promote sleep research. We work with thousands of sleep medicine and other health care professionals, researchers, patients, drowsy driving victims throughout the country, and collaborate with many government and private organizations with the goal of preventing health and safety problems related to sleep deprivation and untreated sleep disorders.

Sleep problems, whether in the form of medical disorders, or related to work schedules and a 24/7 lifestyle, are ubiquitous in our society. At least 40 million Americans suffer from sleep disorders; yet more than 60 percent of adults have never been asked about the quality of their sleep by a physician, and fewer than 20 percent have ever initiated such a discussion. Millions of individuals struggle to stay alert at school, on the job, and on the road. The latest estimates from the National Highway Transportation Safety Administration and the Federal Motor Carriers Safety Administration implicate fatigue and sleepiness in 1.1 million crashes annually. A recent study in Sweden showed that sleep disturbances are the second greatest risk factor for fatal accidents at work. Sleep apnea, a sleep-related breathing disorder which affects at least 5 percent of adult Americans, is closely related to some of America's most pressing health problems, such as obesity, hypertension, heart failure, and diabetes. Chronic insomnia, experienced by 10 percent of our population is a strong risk factor for depression and other widespread mental health conditions. Sleep disorders, sleep deprivation, and excessive daytime sleepiness add approximately $15 billion to our national health care bill each year. The National Center on Sleep Disorders Research estimates that by the year 2050, sleep problems will affect as many as 100 million Americans.

Sleep science has clearly demonstrated the importance of sleep to health and well being, yet research studies continue to show that millions of Americans are at risk for the serious health, safety consequences of sleep disorders and inadequate sleep. Moreover their quality of life suffers and the personal and national economic impact is staggering. NSF believes that every American needs to understand that good health includes healthy sleep, just as it includes regular exercise and balanced nutrition. We must elevate sleep to the top of the national health agenda. We need your help to make this happen.

Our biggest challenge is bridging the gap between the outstanding scientific advances we have seen in recent years and the level of knowledge about sleep held

by health care practitioners, educators, employers, and the general public. This gap in knowledge is being discussed as I present this testimony today, by hundreds of concerned professionals. Yesterday and today, the National Center on Sleep Disorders Research, the National Heart, Lung, and Blood Institute, and the Trans-NIH Sleep Research Coordinating Committee are sponsoring a translational conference entitled "Frontiers of Knowledge in Sleep and Sleep Disorders: Opportunities for Improving Health and Quality of Life." This two-day program has assembled health care providers, public health and education experts, policy makers, patient advocacy organizations, sleep medicine specialists, and other stakeholders. It is intended to address how information about sleep and sleep disorders can translate into improvements in public health and safety using cost-effective, comprehensive, and broadly-applied strategies for education, societal change, and improved sleep-related health care.

This conference is an important step in translating research into practice and into a broad-based public health message. The development of a sleep education and public awareness initiative would serve as a key legacy for the sleep translational conference and provide a forum for dissemination of the outcomes of the sleep translational conference. The National Sleep Foundation has been leading the way on public education regarding sleep and sleep disorders since it was founded in 1990. NSF and others have done a lot, but so much more needs to be done in order to educate the public and actually change behavior. Because resources are limited and the challenges great, we think creative and new partnerships need to be created to address the issues that are before us.

Therefore, we recommend that The National Center on Sleep Disorders Research be encouraged to partner with other federal agencies, such as the Centers for Disease Control and Prevention, and voluntary health organizations, such as NSF, to develop an ongoing, inclusive mechanism for public and professional awareness on sleep, sleep disorders, and the consequences of fatigue. Such a collaboration between federal agencies and voluntary health organizations would create an opportunity for dramatically improving public health and safety as well as the quality of life for millions, if not all, Americans.

Thank you again for the opportunity to present testimony before you today. I would be pleased to address any comments or questions.

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Provide a 10 percent increase, to $30.8 billion, for fiscal year 2005 to the National Institutes of Health (NIH) budget. Within NIH, provide proportional increases of 10 percent to the various institutes and centers, specifically, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). We request NIDDK's budget to be increased by 10 percent to $1.85 billion.
—Continue to accelerate funding for extramural clinical and basic functional gastrointestinal research at NIDDK.
—Continue to urge NIDDK to develop a strategic plan setting research goals on IBS and functional bowel diseases and disorders.
—Urge NIDDK to develop a standardization of scales to measure incontinence severity and quality of life and to develop strategies for primary prevention of fecal incontinence associated with childbirth.
—Provide funding to NIDDK and the National Cancer Institute (NCI) for more research on the causes of esophageal cancer.

Chairman Specter and members of the Subcommittee, thank you for the opportunity to present this written statement regarding the importance of functional gastrointestinal and motility research at the National Institutes of Health.

IFFGD, the International Foundation for Functional Gastrointestinal Disorders, has been serving the digestive disease community for 13 years. We work to broaden the understanding about functional gastrointestinal and motility disorders in adults and children.

Through publications, professional symposia, and other means IFFGD addresses issues and raises awareness about disorders and diseases that many people are uncomfortable and embarrassed to talk about. Bowel conditions are often hidden in our society. Not only are they misunderstood, but the burden of illness and human toll has not been fully recognized.

The majority of the diseases and disorders we address have no cure. We have yet to completely understand the pathophysiology of the underlying conditions. Many

patients face a life of learning to manage chronic illnesses that are often accompanied by pain and a variety of gastrointestinal symptoms. The costs associated with these diseases are great; conservative estimates range between $25–$30 billion annually. The human toll is not only on the individual but also on the family. Economic costs spill over into the workplace and every aspect of daily life. In essence these diseases reflect lost potential for the individual and society.

FECAL INCONTINENCE

At least 6.5 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly. Incontinence crosses all age groups from children to older adults, but is more common among women and in the elderly of both sexes. Often it is a symptom associated with various neurological diseases and cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with multiple sclerosis, diabetes, colon cancer, uterine cancer, and a host of other diseases.

Causes of fecal incontinence are many and may include damage to the anal sphincter muscles, nerve damage, loss of storage capacity in the rectum, chronic diarrhea, or pelvic floor dysfunction. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Society is not tolerant of loss of bowel control. Some individuals with incontinence don't want to leave the house out of fear they might have an episode of incontinence in public. Most try to hide the problem as long as possible and may not reveal it to their own doctor unless asked. Isolation adds to the burden of illness as these individuals withdraw from friends and family, and social support.

In November 2002, IFFGD sponsored, with NIH support, a multidisciplinary consensus conference—"Advancing the Treatment of Fecal and Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities." The proceedings were disseminated in the January 2004 Supplement of *Gastroenterology*, the journal of the American Gastroenterological Association. Among other outcomes, the conference resulted in six key research recommendations to address currently unmet needs:

1. More comprehensive identification of quality of life issues associated with fecal incontinence and improved assessment and communication of treatment outcomes related to quality of life.
2. Standardization of scales to measure incontinence severity and quality of life.
3. Assessment of the utility of diagnostic tests for affecting management strategies and treatment outcomes.
4. Development of new drug compounds offering new treatment approaches to fecal incontinence.
5. Development and testing of strategies for primary prevention of fecal incontinence associated with childbirth.
6. Further understanding of the process of stigmatization as it applies to the experience of individuals with fecal incontinence.

IRRITABLE BOWEL SYNDROME (IBS)

IBS affects between 25 and 45 million people of all ages in the United States (an estimated 10 to 15 percent of the population). The disorder affects people of all ages, even children. Approximately 60 to 65 percent of IBS sufferers in the United States are reportedly female and 35 to 40 percent are male. This chronic disease is characterized by a group of symptoms, which can include abdominal pain or discomfort associated with a change in bowel pattern, such as loose or frequent bowel movements, and/or hard or infrequent bowel movements. Although the cause of IBS is not understood, it is becoming clear that this disease needs a multidisciplinary approach in research.

Similar to other chronic illnesses and depending on severity, IBS can be emotionally and physically debilitating. Because of persistent, unpredictable, and often painful bowel symptoms, maintaining work or academic schedules becomes challenging. Individuals who suffer from this disorder may distance themselves from social activities and even may fear leaving their home.

In the House and Senate Fiscal Year 2004 Labor, Health and Human Services, and Education Appropriations bills, Congress recommended that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) develop an IBS strategic plan. The development of a strategic plan on IBS would greatly increase the institute's progress toward the needed research on this functional gastrointestinal disorder.

GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Gastroesophageal reflux disease, or GERD, is a very common disorder affecting both adults and children, which results from the back-flow of acidic stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and regurgitation of acid. But sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications. However, periodic heartburn is a symptom so common that many people overlook its potential to cause tissue damage and disease. This is unfortunate because, through awareness and a diagnosis, individuals can receive one of several treatment options available for GERD. Untreated, GERD may lead to severe complications such as inflammation, stricture, or Barrett's esophagus, a potentially pre-cancerous condition.

Gastroesophageal reflux, involving regurgitation of gastric contents into the esophagus, affects as many as one-third or more of all full term infants born in America each year, but generally resolves by 6 to 12 months of age. Gastroesophageal reflux disease (GERD) results when symptoms persist or tissue damage occurs. Medical therapy may then be required in order to control the disease, which in infants commonly manifests as symptoms such as regurgitation with poor weight gain, esophagitis, respiratory symptoms, or irritability. In children and adolescents, the natural history of GERD is similar to that of adult patients, in whom GERD tends to be persistent and may require long-term treatment.

ESOPHAGEAL CANCER

Approximately 13,000 new cases of esophageal cancer are diagnosed every year in this country. Although the causes of this cancer are unknown, it is thought that it may be more prevalent in individuals who develop Barrett's esophagus. Diagnosis usually occurs when the disease is in an advanced stage; early effective screening tools are needed.

GASTROINTESTINAL MOTILITY DISORDERS

Gastrointestinal motility disorders can affect any part or parts of the gastrointestinal tract. Gastroparesis, chronic intestinal pseudo-obstruction (CIP), and Hirschsprung's disease, are just a few examples of gastrointestinal motility disorders.

Gastroparesis is a painful disorder where the nerves to the stomach are damaged or stop working, which leads to the stomach taking too long to empty its contents. Symptoms of gastroparesis can include: nausea, vomiting, early satiety or an early feeling of fullness when eating, weight loss, abdominal bloating, and abdominal discomfort. This disorder is often a complication of diabetes. An estimated 20 percent of people with type 1 diabetes develop gastroparesis. Individuals with type 2 diabetes can also develop gastroparesis.

Approximately, 200 new cases of Chronic Intestinal Pseudo-Obstruction or CIP are diagnosed in American children each year. This rare and serious disorder occurs when coordinated contractions, or peristalsis, in the intestinal tract become altered and inefficient. When this happens, nutritional requirements cannot be adequately met. CIP is often life threatening and treatment challenging. Continued clinical and basic research is needed before the disease is fully understood, and improved treatment or ultimately a cure found.

Hirschsprung's disease (HD) is a serious and sometimes life-threatening congenital disorder that is caused by absence of nerve cells in the rectum and/or colon, which can cause obstruction, inflammation, and severe constipation. It occurs in about one out of every 5,000 American children born each year. The treatment is primarily surgical to remove the abnormal bowel. Approximately 10–20 percent of children with HD will continue to have complications following surgery. These complications include infection, fecal incontinence, and persistent constipation.

FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS AND THE NATIONAL INSTITUTES OF HEALTH

The International Foundation for Functional Gastrointestinal Disorders recommends an increase to $30.8 billion or 10 percent for NIH overall, and a 10 percent increase for NIDDK, or $1.85 billion. However, we request that this increase for NIH does not come at the expense of other Public Health Service agencies.

We urge the subcommittee to provide the necessary funding for the expansion of the NIDDK's research program on functional gastrointestinal (GI) and motility dis-

orders, this increased funding will allow for the growth of new research, a prevalence study and a strategic plan on IBS, and increased public and professional awareness of functional GI and motility disorders.

A primary goal of IFFGD's mission is to ensure that advancements concerning GI disorders result in improvements in care and the quality of life of those affected. As we all work together, it is hoped this goal will be realized and the suffering and pain millions of people face daily will end.

Mr. Chairman, on behalf of millions of patients and the families of those with functional GI or motility disorders thank you for your consideration.

The International Foundation for Functional Gastrointestinal Disorders

The International Foundation for Functional Gastrointestinal Disorders is a nonprofit education and research organization founded in 1991. IFFGD addresses the issues surrounding life with gastrointestinal (GI) functional and motility disorders and increases the awareness about these disorders among the general public, researchers, and the clinical care community.

PREPARED STATEMENT OF THE HEPATITIS FOUNDATION INTERNATIONAL

SUMMARY OF FISCAL YEAR 2005 RECOMMENDATIONS

—Continue the great strides in research and prevention at the National Institutes of Health (NIH) by providing a 10 percent budget increase for fiscal year 2005. Increase funding for the National Institute for Allergy and Infectious Diseases (NIAID) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) by 10 percent.

—$41 million in fiscal year 2005 for a hepatitis B vaccination program for high risk adults at CDC as recommended by the National Hepatitis C Prevention Strategy.

—$40 million in fiscal year 2005 for CDC's Prevention Research Centers.

—Continued support of the National Viral Hepatitis Roundtable.

Mr. Chairman and members of the subcommittee thank you for your continued leadership in promoting better research, prevention, and control of diseases affecting the health of our nation. I am Thelma King Thiel, Chairman and Chief Executive Officer of the Hepatitis Foundation International (HFI), representing members of 425 patient support groups across the nation, the majority of whom suffer from chronic viral hepatitis.

Currently, five types of viral hepatitis have been identified, ranging from type A to type E. All of these viruses cause acute, or short-term, viral hepatitis. Hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. While treatment options are available for all types of hepatitis, individuals with chronic viral hepatitis (types B, C, and D) represent the majority of liver failure and transplant patients. Treatment options and immunizations are available for most types of hepatitis (see below). However, all types of viral hepatitis are preventable.

HEPATITIS A

The hepatitis A virus (HAV) is contracted through fecal/oral contact (i.e. fecal contamination of food, or diaper changing tables if not cleaned properly), and sexual contact. In addition, eating raw or partially cooked shellfish contaminated with HAV can spread the virus. Children with HAV usually have no symptoms; however, adults may become quite ill suddenly experiencing jaundice, fatigue, nausea, vomiting, abdominal pain, dark urine/light stool, and fever. There is no treatment for HAV; however, recovery occurs over a 3 to 6 month period. About 1 in 1,000 with HAV suffer from a sudden and severe infection that may require a liver transplant. Luckily, a highly effective vaccine can prevent HAV. This vaccination is recommended for individuals who have chronic liver disease (i.e. HCV or HBV) or clotting factor disorders, in addition to those who travel or work in developing countries.

HEPATITIS B

Hepatitis B (HBV) claims an estimated 5,000 lives every year in the United States, even though we have therapies to both prevent and treat this disease. This disease is spread through contact with the blood and body fluids of an infected individual. Unfortunately, due to both a lack in funding to vaccinate adults at high risk of being infected and the absence of an integrated preventive education strategy, transmission of hepatitis B continues to be problematic. Additionally, there are sig-

nificant disparities in the occurrence of chronic HBV-infections. Asian Americans represent four percent of the population; however, they account for over half of the 1.3 million chronic hepatitis B cases in the United States. Current treatments have limited success in treating the chronically infected and there is no treatment available for those who are considered "HBV carriers." Preventive education and vaccination are the best defense against hepatitis B.

HEPATITIS C

Infection rates for hepatitis C (HCV) are at epidemic proportions. Unfortunately, as many are not aware of their infection until several years after infection, we are dealing with an "epidemic of discovery." This creates a vicious cycle, as individuals who are infected continue to spread the disease, unknowingly. Hepatitis C is also spread through contact with an infected individual's blood. The CDC estimates that there are over 4 million Americans who have been infected with hepatitis C, of which over 2.7 million remain chronically infected, with 8,000–10,000 deaths each year. Additionally, the death rate is expected to triple by 2010 unless additional steps are taken to improve outreach and education on the prevention of hepatitis C, new research is undertaken, and case-finding is enhanced and more effective treatments are developed. As there is no vaccine for HCV, prevention education and treatment of those who are infected serve as the most effective approach in halting the spread of this disease.

PREVENTION IS THE KEY

Only a major investment in immunization and preventive education will bring these diseases under control. All newborns, young children, young adults, and especially those who participate in high-risk behaviors must be a priority for immunization, outreach initiatives and preventive education. We recommend that the following activities be undertaken to prevent the further spread of all types of hepatitis:

—Provide effective preventive education in our elementary and secondary schools helping children avoid the ravages of health problems resulting from viral hepatitis infection.
—Training educators, health care professionals, and substance abuse counselors in effective communication and counseling techniques.
—Public awareness campaigns to alert individuals to assess their own risk behaviors, motivate them to seek medical advice, encourage immunization against hepatitis A and B, and to stop the consumption of any alcohol if they have participated in risky behaviors that may have exposed them to hepatitis C.
—Expansion of screening, referral services, medical management, counseling, and prevention education for individuals who have HIV/AIDS, many of whom may be co-infected with hepatitis.

HFI recommends an increase of $41 million in fiscal year 2005 for further implementation of CDC's Hepatitis C Prevention Strategy. This increase will support and expand the development of state-based prevention programs by increasing the number of state health departments with CDC funded hepatitis coordinators. The Strategy will use the most cost-effective way to implement demonstration projects evaluating how to integrate hepatitis C and hepatitis B prevention efforts into existing public health programs. Additionally, HFI recommends that $10 million be used to train and maintain hepatitis coordinators in every state.

CDC's Prevention Research Centers, an extramural research program, plays a critical role in reducing the human and economic costs of disease. Currently, CDC funds 26 prevention research centers at schools of public health and schools of medicine across the country. HFI encourages the Subcommittee to increase core funding for these prevention centers, as it has been decreasing since this program was first funded in 1986. We recommend the Subcommittee provide $40 million for the Prevention Research Centers program in fiscal year 2005.

INVESTMENTS IN RESEARCH

Investment in the National Institutes of Health (NIH) has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and development of strategies for disease prevention, diagnosis, treatment, and cures. Countless medical advances have directly benefited the lives of all Americans. NIH-supported scientists remain our best hope for sustaining momentum in pursuit of scientific opportunities and new health challenges. For example, research into why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for others currently infected. Other areas that need to be addressed are:

—Reasons why African Americans do not respond to antiviral agents in the treatment of chronic hepatitis C.
—Pediatric liver diseases, including viral hepatitis.
—The outcomes and treatment of renal dialysis patients who are infected with HCV.
—Co-infections of HIV/HCV and HIV/HBV positive patients.
—Hemophilia patients who are co-infected with HIV/HCV and HIV/HBV.
—The development of effective treatment programs to prevent recurrence of HCV infection following liver transplantation.
—The development of effective vaccines to prevent HCV infection.

The Hepatitis Foundation International supports a 10 percent increase for NIH in fiscal year 2005. HFI also recommends a comparable increase of 10 percent in hepatitis research funding at the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Allergy and Infectious Diseases.

NATIONAL VIRAL HEPATITIS ROUNDTABLE

Victims of hepatitis suffer emotionally as well as physically. They experience discrimination in employment, strained personal relationships and severe depression when treatments fail to control their illness as well as during their treatment. Traditionally, however, there has not been an organized effort to periodically convene all stakeholder organizations that play a role in hepatitis prevention, education, treatment and patient advocacy. Successfully addressing viral hepatitis will require a comprehensive and strategic approach developed by all key stakeholders.

In order to fill this void, HFI and CDC co-founded the "National Viral Hepatitis Roundtable." HFI believes that a National Viral Hepatitis Roundtable will enhance and assist CDC's viral hepatitis mission for the prevention, control, and elimination of hepatitis virus infections in the United States, as well as the international public health community. It will provide an infrastructure for the sharing of information and education of all stakeholders.

The "National Viral Hepatitis Roundtable" is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States through research, strategic planning, coordination, advocacy, and leadership.

HFI is dedicated to the eradication of viral hepatitis, which affects over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle. Thank you for providing this opportunity to present our testimony.

The Hepatitis Foundation International

The Hepatitis Foundation International (HFI) is dedicated to the eradication of viral hepatitis, a disease affecting over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle.

Our mission has four distinct parts:
—Teach the public and hepatitis patients how to prevent, diagnose, and treat viral hepatitis.
—Prevent viral hepatitis by promoting liver wellness and healthful lifestyles.
—Serve as advocates for hepatitis patients and the related medical community worldwide.
—Support research into prevention, treatment, and cures for viral hepatitis.

PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2005

—A 10 percent increase for all institutes and centers at the National Institutes of Health (NIH), specifically the National Center for Research Resources (NCRR), the National Center for Minority Health and Health Disparities (NCMHD), and the National Cancer Institute (NCI).
—Urge NCI to continue to support the establishment of collaborative minority health comprehensive cancer centers at historically minority institutions in collaboration with existing NCI cancer centers. Continue to urge NCRR and NCMHD to collaborate on the establishment of a cancer center at a historically minority institution.

—Urge the Department of Health and Human Services, particularly the Office of Minority Health (OMH), to develop a focused effort on faculty support to address the residency training programs at minority medical institutions.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present you with testimony. Charles R. Drew University is one of four predominantly minority medical schools in the country, and the only one located west of the Mississippi River.

Charles R. Drew University of Medicine and Science is located in the Watts-section of South Central Los Angeles, and has a mission of rendering quality medical education to underrepresented minority students, and, through its affiliation with the University of California Los Angeles (UCLA) at the co-located King-Drew Medical Center, Drew provides valuable health care services to the medically underserved community. Through innovative basic science, clinical, and health services research programs, Drew University works to address the health and social issues that strike hardest and deepest among inner city and minority populations.

The population of this medically underserved community is predominately African American and Hispanic. Many of these people would be without health care if not for the services provided by the King-Drew Medical Center and Charles R. Drew University of Medicine and Science. This record of service has led Charles R. Drew University (in partnership with UCLA School of Medicine) to be designated as a Health Resources and Services Administration Minority Center of Excellence.

A RESPONSE TO HEALTH DISPARITIES

Racial and ethnic disparities in health outcomes for a multitude of major diseases in minority and underserved communities continue to plague this nation that was built on a premise of equality. As articulated in the Institute of Medicine report entitled "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care", this problem is not getting better on its own. For example, African American males develop cancer 15 percent more frequently than white males. Similarly, African American women are not as likely as white women to develop breast cancer, but are much more likely to die from the disease once it is detected. In fact, according to the American Cancer Society, those who are poor, lack health insurance, or otherwise have inadequate access to high-quality cancer care, typically experience high cancer incidence and mortality rates. Despite these devastating statistics, we are still not doing enough to try to combat cancer in our communities.

In response to these findings and the high cancer rate in our own community, Charles R. Drew University of Medicine and Science proposes that a Minority Health Comprehensive Cancer Center be built on its campus.

The Center would specialize in providing not only medical treatment services for the community, but would also serve as a research facility, focusing on prevention and the development of new strategies in the fight against cancer.

Mr. Chairman, the support that this subcommittee has given to the National Institutes of Health (NIH) and its various institutes and centers has and continues to be invaluable to our University and our community. The dream of a state of the art facility to aid in the fight against cancer in our underserved community would be impossible without the resources of NIH.

To help facilitate the establishment of a Minority Health Comprehensive Cancer Center at Charles R. Drew University of Medicine and Science, the University is seeking support from the National Institutes of Health's National Center for Research Resources (NCRR), the National Center for Minority Health and Health Disparities (NCMHD), and the National Cancer Institute (NCI).

ACADEMIC RENEWAL AND CLINICAL FACULTY RECRUITMENT

Some of the major challenges faced in sustaining high quality graduate medical education programs in "safety-net" medical centers with missions focused on the medically underserved, are directly related to the lack of sufficient numbers of clinical faculty highly trained in academic medicine. To address these challenges, a plan for academic enrichment is proposed.

The plan is a strategic initiative to position Charles R. Drew University in the first decade of the 21st Century, as a leader in Urban Academic Health Sciences with an emphasis on training physicians and other health professionals to meet the needs of the medically underserved. The Plan for Academic Enrichment is an opportunity to enhance the impact of Charles R. Drew University as a national center of excellence in meeting the national, state, and local challenge of preparing a diverse complement of excellent physicians and other health professionals to close the health disparity gap by affording culturally sensitive quality care to the medically underserved and economically disadvantaged. A central component of the plan is the

enrichment of academic excellence through the recruitment of new, highly qualified clinical teaching faculty, with solid research skills, to be members of the Charles R. Drew College of Medicine faculty to strengthen both the graduate and undergraduate medical education programs.

CONCLUSION

Despite our knowledge about racial/ethnic, socio-cultural and gender-based disparities in health outcomes, the "gap" continues to widen in most instances. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventive care and/or research is completely inaccessible either due to distance or lack of facilities and expertise. This is a critical loss of untapped potential in both physical and intellectual contributions to the entire society.

Even though institutions like Drew are ideally situated (by location, population, and institutional commitment) for the study of conditions in which health disparities have been well documented, research is limited by the paucity of appropriate research facilities. With your help, this cancer center will facilitate translation of insights gained through research into greater understanding of disparities in cancer incidence, morbidity and mortality and ultimately to improved outcomes.

We look forward to working with you to lessen the burden of cancer for all Americans through greater understanding of cancer, its causes, and its cures. We also look forward to working with the Department of Health and Human Services to address the residency training program issues at Charles R. Drew University.

Mr. Chairman, thank you for the opportunity to present on behalf of Charles R. Drew University of Medicine and Science.

PREPARED STATEMENT OF MENDED HEARTS, INC.

I am Robert H. Gelenter, the legal representative for the Mended Hearts, Inc, a national heart disease patient support group of more than 289 chapters across the country and in Canada. We visit patients in about 460 hospitals throughout the United States. I have been appointed by the group to assist in this lobbying effort—a volunteer position.

More than 28 years ago, I was diagnosed with a rare heart disease. After having severe chest pains and trouble breathing for more than 2 years, I was diagnosed with hypertrophic cardiomyopathy, a disease in which the heart enlarges. The heart muscle eventually thickens so much that it can't pump blood effectively and does not grow in the normal parallel patterns. An estimated 36 percent of young athletes who die suddenly die from this disease. But, it affects men and women of all ages. It is sudden and one of the things known about this disease is sudden cardiac death. There is no cure for this disease. Medication may work and there is surgery that may or may not alleviate the pain. If that doesn't work a patient may need a heart transplant, yet spare organs are scarce. The doctor who made my diagnosis was trained at the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Initially, I received several medications which allowed me to engage in most activities. But, some activities, such as walking up hills, gave me problems like shortness of breath and severe chest pains. But, generally I could function normally. However, after about 11 years, the discomfort was increasing, and it became apparent that I was in serious trouble. I could not walk 60 feet without having to stop to catch my breath. Sometimes the pain was so great that I would almost double over in the middle of the street. My wife told me that my face would become gray. The perspiration would pour off by body. If I was lucky I could find a chair to sit on. The quality of my life had deteriorated so drastically that I knew I needed some treatment.

Finally in 1988, I went to Georgetown University Medical Center for an angiogram—the gold standard for diagnosing heart problems. The cardiologist who performed the angiogram told me that he had bad news and worse news. The bad news was that I had a 95 percent blockage in my left anterior descending heart artery—the so-called "widow makers spot." The worse news was that I had a major chance of having a major heart attack with a less than a 5 percent chance of surviving that heart attack because of the hypertrophic cardiomyopathy. At this point, my wife was quietly crying and I was perspiring profusely. Since Georgetown University Medical Center did not have the expertise to operate on me, they called the NIH to see if they would accept me as a patient. I was sent home pending notice from the NIH.

My parents begged me to go to New York or San Francisco for second opinions. But, I knew that I had run out of alternatives. No matter what the result, I needed treatment and I needed it immediately.

I was accepted by the NIH. After entering the National Heart, Lung, and Blood Institute on February 6, I was operated on February 11, 1988. No matter how trite the expression—that was the first day of the rest of my life. The surgery, considered drastic and rare, is still considered the gold standard throughout the world for the treatment of hypertrophic cardiomyopathy. The Murrow Procedure, in honor of the creator, was developed and improved at the NIH.

Although this surgery is no longer performed at the National Heart, Lung, and Blood Institute, there is another experimental ongoing protocol in which the same effect is being attempted by using alcohol to deaden the excessive heart tissue.

Now, I am on medication for the rest of my life. My condition is progressive. Eight years ago, I was fitted with a pacemaker to insure that my heart beats at the correct rate. I am 100 percent dependent on this pacemaker. Without the pacemaker, there are times when my normal heart beat is so slow that I would die.

I am eternally grateful to the physicians funded by the National Heart, Lung, and Blood Institute, particularly to Dr. MacIntosh and his staff, for the gift of life. Because of this marvelous research supported by the NHLBI, I have lived 15 years pain free. I have seen two children graduate from college and three grandchildren born, I have shared these years with a wonderful wife. I have been able to work at my profession—an attorney at law.

I have had the gift of life restored to me. So to express my gratitude for that gift, I visit patients recovering from heart episodes at two hospitals, Washington Hospital Center and Washington Adventist Hospital.

I ask for an fiscal year 2005 appropriation of $3.5 billion for the NHLBI, including $2.1 billion for its heart disease and stroke-related budget.

My experience is the proof that the research supported by the National Heart, Lung, and Blood Institute benefits not just the patients at the NIH Clinical Center, but throughout the United States. The benefits go worldwide as well.

Heart attack, stroke and other cardiovascular diseases remain the No. 1 killer and major cause of disability of men and women in the United States. Nearly 40 percent of people who die in the United States die from cardiovascular diseases. This year, more than 930,000 Americans will die from cardiovascular diseases, including almost 150,000 under the age of 65.

Thank you for your support of National Heart, Lung, and Blood Institute's heart research.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

INTRODUCTION

The American College of Cardiology (ACC) is a 30,890 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiovascular specialists practicing in the United States. The ACC submits for the record this statement of support for increased funding for heart-related research through the National Heart, Lung, and Blood Institute (NHLBI) in fiscal year 2005, as well as support for increased funding for the Agency for Health Care Research and Quality (AHRQ), education and awareness programs through the Centers for Disease Control and Prevention (CDC) State Heart Disease and Stroke Prevention Program, and state and local programs designed to increase public access to automated external defibrillators (AEDs).

The ACC expresses its appreciation to Congress for successfully completing the doubling of the NIH budget by fiscal year 2003. Although the increase in funding has greatly benefited cardiovascular-related research, the National Institutes of Health (NIH) still invests only 8 percent of its budget on heart research and a mere 1 percent on stroke research—a funding level that fails to reflect that 40 percent of all deaths in this country are attributable to cardiovascular disease. The ACC appreciates current budget constraints, but hopes this subcommittee will continue its commitment toward medical research funding and the improvement of public health in the fiscal year 2005 budget. According to a recent study conducted by MEDTAP International and co-sponsored by the ACC, national health advancements since 1980 are due primarily to investments in health care, and for each additional dollar

spent in the United States for health care services $2.40 to $3.00 in tangible gains have been made.

The ACC, however, is concerned that President Bush's proposed fiscal year 2005 budget calls for only a 2.6 percent increase above fiscal year 2004 levels for the NIH and only a 0.3 percent increase for the CDC's Heart Disease and Stroke Prevention Program. Low-level funding increases for NIH, in addition to inadequate funding levels proposed in the President's budget for enhanced public access to AEDs, and the flat-funding proposed for the AHRQ, is of great concern to the ACC and its members.

Cardiovascular disease continues to claim more lives each year than the next seven leading causes of death combined. Recent data shows that in 2001 more than 64 million Americans were shown to have suffered from at least one form of cardiovascular disease, of which nearly 1 million died as a direct result. The overall (indirect and direct) cost of cardiovascular disease for 2004 is estimated to be at least $368.4 billion. Heart disease is not only tragically rampant in the United States, but it is also financially burdensome. The ACC believes that further investment in life-saving research, as well as in education and awareness programs, is essential to combat the leading cause of death of men and women in this country.

The ACC Supports the Following fiscal year 2005 Appropriations Funding Levels:

—NIH (overall funding)—$30.6 billion

—NHLBI—$3.5 billion (includes $2.1 billion for heart- and stroke-related activities)

—AHRQ—$443 million

—CDC State Heart Disease and Stroke Prevention Program—$80 million

—Community and Rural AED Access—$45 million

MEDICAL RESEARCH

The ACC believes that the federal government must expand its financial commitment to medical research, most specifically at the NHLBI, through support for the NIH and its new "NIH Roadmap" initiative which was initiated at NIH to help identify major opportunities and gaps in biomedical research and allow for greater collaboration between all NIH institutes. Increased NHLBI funding over the years has allowed investigators to develop better diagnostic tools and surgical techniques, as well as study new methods of treatment for cardiac patients. We must aim for better patient prevention, early cardiovascular disease diagnoses, and improved treatment of our patients. As such, the ACC is particularly supportive of initiatives related to clinical cardiology and issues of clinical relevance to the practice of cardiology. The ACC also firmly believes in the value of promoting clinical investigative careers and of large-scale clinical trials which aid the discovery and application of therapeutic and/or medical treatments to cardiovascular disease. In addition, the ACC would like to stress the importance of funding the AHRQ at a level that allows for their continued application of research to cardiovascular care. AHRQ activities play a large role in ensuring that our members can provide patients with the most up-to-date and effective treatments available.

Research Success Due to Past Legislative Investment in NHLBI

Another major advancement during the NIH doubling was with the implementation of a major clinical trial testing approaches to lowering the risk of cardiovascular disease in adults with Type 2 diabetes. Seventy percent of Americans diagnosed with Type 2 diabetes ultimately die of cardiovascular disease. The ACC is quite concerned about the cardiovascular health impact of diabetes and obesity in Americans, particularly in children. This trial, referred to as Action to Control Cardiovascular Risk in Diabetes (ACCORD) evaluates the effects of intense blood sugar control along with very aggressive control of blood pressure and lipids. The overall goal of ACCORD is to discover a better treatment for those suffering from Type 2 diabetes than is presently available. The ACC is pleased to see research attention being paid to the correlation of diabetes and metabolic syndromes with cardiovascular disease, because this devotion of resources helps to gain a better understanding of and treatment methods for these debilitating diseases.

Research Success Due to Investments in Women and Heart Disease

This year, more women than men will die from cardiovascular disease, making the inclusion of women in more heart-related research studies absolutely integral. Since 1984, men have experienced a decline in deaths due to cardiovascular disease, yet despite a growing number of female-specific research initiatives, women have not yet experienced this decline.

To this end, the ACC is proud to be participating in several national campaigns this year that help raise awareness about the incidence and morbidity of heart dis-

ease and stroke in women, including the NHLBI's The Heart Truth, and the American Heart Association's "Go Red for Women." In addition, on February 20, 2004, the ACC teamed with the Sister to Sister Foundation for its National Woman's Heart Day to help provide free screenings, educational seminars, cardiovascular health information, and fitness and cooking demonstrations to women around the country. The ACC is pleased that new clinical studies are underway at NIH that will hopefully help clarify the gender differences that directly affect diagnosis and treatment of women with heart disease.

Women's Health Initiative

Thanks to Congress' financial commitment during the doubling of the NIH budget, the NHLBI was able to proceed with the Women's Health Initiative (WHI) which yielded the first conclusive evidence of risks associated with long-term estrogen plus progestin hormone replacement therapy (HRT). This groundbreaking discovery changed the delivery of care for millions of American women and raised the public's awareness regarding heightened risks for heart attack, stroke and/or blood clots during long-term HRT use. The ACC was pleased by the findings yielded through the WHI and would like to see continued research focused on the unique causes and outcomes of heart disease in women. The ACC also believes that only through randomized clinical trials can we fully understand how medicines and devices affect human health.

Women's Ischemia Syndrome Evaluation

The Women's Ischemia Syndrome Evaluation (WISE) Study is a four-center, NHLBI study evaluating approximately 1,000 women referred for elective diagnostic coronary angiography because of suspected ischemia, a shortage of oxygen and blood to the heart muscle. It is the largest NIH-funded study dedicated solely to women, with the goal of examining the nature and scope of gender differences in both chronic and acute cardiac ischemia.

Prior reports suggested that, compared with men, clinical manifestations of ischemic heart disease in women appear approximately 10 or more years later. Women demonstrate more symptoms suggesting ischemic heart disease, yet the symptoms in women, such as chest discomfort and dyspnea, are more difficult to interpret.

There is now a better snapshot of the extent of cardiovascular disease in women, thanks to WISE Study findings revealed at the ACC Annual Scientific Session in March 2004 (ACC 2004) by Barry L. Sharaf, M.D., F.A.C.C. Based on the 4-year, risk-adjusted outcomes by extent of coronary disease, there was a 9.4 percent death or myocardial infarction (MI) rate (or about 2.7 percent annually) in women with minimal or no symptoms of disease detected by angiography. This is an unacceptable event rate. In another presentation by Leslee J. Shaw, Ph.D., at ACC 2004 regarding the WISE Study, the estimated lifetime cost of care for cardiovascular disease detected by angiography was detailed. Dr. Shaw found that women with no disease detectable by angiography have in excess of three-quarters of a million dollars lifetime costs for care. In an era of shrinking health care resources, such a high cost is unsustainable. This high rate of death or myocardial infarction, combined with escalating health care costs, clearly demonstrates the need for improved detection of cardiovascular disease in women.

The ACC believes it is imperative to increase awareness among women about their risk of heart disease. Thanks to findings yielded from the WISE Study, cardiovascular specialists are gaining a better understanding that there is a "female-pattern" of ischemia-related symptoms that is distinct from that seen in men. Cardiologists have also come to understand that a "clean" angiogram in symptomatic women does not mean a benign outcome. The ACC believes that the WISE Study discoveries are a good start in unraveling the mystery of women and heart disease, but more research looking at issues like concealed plaque and inflammation in the vessel wall, the prognostic ability of blood markers, and the role of the microvasculature, needs to be conducted.

NHLBI Research Opportunities Threatened by President's Fiscal Year 2005 2.5 Percent Funding Increase

Much progress has been made in cardiovascular research and clinical trials to this date, but the ACC believes that if the numbers proposed in the President's fiscal year 2005 budget are instituted new and exciting opportunities could be postponed if not cancelled, and the continuation and/or expansion of current NHLBI cardiovascular research programs could also be threatened. The ACC encourages Congress to take necessary steps to avoid such a predicament through funding the NHLBI at $3.5 billion in fiscal year 2005, so that the following fundamentally important programs among others have a chance of development.

Enhancing the Use of Longitudinal Data on Cardiovascular Disease and its Risk Factors in Older Adults: The Cardiovascular Health Study (CHS)

This initiative would allow for continued utilization of the data and specimens collected during the CHS study which began in 1987 and is set to terminate in 2005. Specifically, the initiative would ensure access to CHS data and specimens to the entire scientific community and allow for continued follow-up of study participants. Investigators are particularly interested in the research and treatment of cardiovascular disease in elderly patients (age 75 and older), a focus area which could be enhanced through the use of longitudinal data obtained by the CHS.

Randomized Trial of Heart Failure (HF) Management

ACC believes that the incorporation of clinical practice methods and provider education into NHLBI trials benefits not only cardiovascular patients but also the cardiologists who translate new therapies into regular cardiovascular care techniques. This trial is a perfect example of a mutually beneficial initiative. The multi-center/randomized trial would assess costs, quality of life, physician compliance, and patient adherence to prescribed treatments in order to identify and disseminate clinically useful and effective tools for translation of proven therapies for HF into clinical practice.

Community-Responsive Interventions to Reduce Cardiovascular Risk in American Indians and Alaska Natives

Despite the fact that American Indians and Alaska Natives are disproportionately affected by cardiovascular diseases, the President's 2.5 percent budget increase for NHLBI in fiscal year 2005 is inadequate for fostering the development of preventative intervention into community health care systems or through other health care means within American Indian and Alaska Native communities. If instituted within the fiscal year 2005 budget cycle, this NHLBI program would work to find solutions to obesity, diabetes, and cardiovascular diseases within these minority communities.

Priority Research Programs at NHLBI for Fiscal Year 2005

The NHLBI finds new and innovative methods for yielding research and clinical trial results year after year. These results, when translated into practice, ensure that cardiovascular specialists and other health care providers are able to provide patients with the highest quality care possible. Due largely to the medical research and education programs supported by the NHLBI, many Americans who suffer from or are at risk for cardiovascular disease now have access to a greater variety of diagnostic tests, medical treatments, and information about prevention. The research priorities set forth by the NHLBI are a direct result of input from health care community, including that of ACC members. The ACC believes it is imperative to appropriately fund the NHBLI in fiscal year 2005 so that the NHLBI can continue to create and implement ground-breaking cardiovascular research.

Last year, the ACC recommended the implementation of an NHLBI program titled "Overweight and Obesity Prevention and Control at the Worksite," which would support the design and testing of innovative worksite intervention to prevent and control overweight and obesity in adults. Almost two-thirds (61 percent) of American adults are overweight or obese, and each year an estimated 300,000 American adults die of causes related to obesity. The ACC is pleased that this program has officially gained NHLBI recognition and is being considered for implementation in fiscal year 2005. Some of the strategies within the program include implementing environmental and policy changes to increase employees' physical activity, offering healthful food choices in cafeterias and vending machines, and enhancing social support from fellow workers to encourage improved diet and physical activity. The ACC encourages Congress to concur with this NHLBI-recommended program and allow for full funding of the "Overweight and Obesity Prevention and Control at the Worksite" in fiscal year 2005.

Currently there is a growing need to address cardiovascular infections caused by the bacterium *Staphylococcus aureus,* commonly referred to as Staph infections, following cardiac surgery. The ACC believes that there is great value in fully funding the NHLBI-proposed "Clinical Trials for the Prevention and Treatment of Infections after Cardiac Surgery" parallel randomized clinical trials. These trials would provide conclusive evidence of the need for improved control of Staph infections by assessing the costs and benefits of new antibacterial strategies. Due to the serious risk of infection following cardiac surgery, the ACC hopes that increased funding for the NHLBI will allow these important trials to be conducted.

Collaboration among federal agencies has proven an effective and efficient means for enhancing research, facilitating appropriate regulation, and providing accurate clinical outcomes data. An "Interagency Registry of Mechanical Circulatory Support

for Heart Failure" would create a registry of mechanical circulatory support for heart failure, as well as an associated tissue repository for shared use by all related federal agencies. Such a registry would help standardize reporting of patient characteristics, indications, implantation procedures, and adverse events. With increased funding for NHLBI in fiscal year 2005, such collaboration will be possible.

AHRQ—Moving Research into Practice

The research and education developments that the federal government has facilitated are remarkable and promising. However, the best research is of no value if it never reaches the patient. The AHRQ is charged with ensuring that advances in medicine become the baseline for medical care. By fulfilling the mission of placing today's breakthroughs in the hands of physicians tomorrow, AHRQ injects up-to-the-minute research into day-to-day medical decisions and treatments. The research facilitated by the AHRQ provides reliable information on health care outcomes, quality, cost, use, medical errors, and access, enabling the public to make better-informed decisions about health care. The ACC regularly works with AHRQ to create and disseminate cardiovascular clinical practice guidelines. Having the AHRQ address some of the evidence to practice issues remains a critical step in evaluating the utility of practice guidelines.

For example, in fiscal year 2000, AHRQ released the "Translating Research into Practice II (TRIP II)" request for applications (RFA). The response to this RFA was overwhelming, so much so that currently 13 studies are underway due to this initiative. TRIP II specifically focuses on increasing the frequency of partnerships between researchers and health care systems and organizations to heighten the effect of practice-based, patient outcome research in applied settings.

Although the AHRQ remains a vital partner to both the clinical research community and other private sector organizations, it has not received a funding increase in the past two budget cycles. This continuous flat-funding does not allow the AHRQ to adjust to annual inflationary costs, nor does it provide the opportunity for new development or growth. The ACC is extremely concerned by this funding plateau particularly because of the AHRQ's central role in reviewing current scientific evidence and providing practical clinical information to the public, such as its recent work on blood pressure monitoring. The ACC urges Congress to support increased funding of the AHRQ at $443 million in fiscal year 2005.

CARDIOVASCULAR DISEASE AWARENESS AND EDUCATION

CDC State Heart Disease and Stroke Prevention Program

Education and awareness campaigns that focus on for heart disease and stroke prevention are in underway at the CDC's State Heart Disease and Stroke Prevention Program, but progress has been stalled due to insufficient funding. Only 11 of the 33 designated CDC State Heart Disease and Stroke Prevention Programs are funded adequately enough to progress from the planning stage to the implementation stage. This program's inventive heart disease and stroke reduction/control programs, particularly among underprivileged Americans, would help to reduce the incidence and impact of cardiovascular disease as well as to raise awareness of secondary preventative measures.

The State Heart Disease and Stroke Prevention Program aims to prevent and control heart disease and stroke risk factors including high cholesterol and blood pressure. Yet, the program can not reach its full potential for saving lives and reducing the costs associated with the disease unless it becomes a fully functioning national program. The ACC encourages Congress to approve an fiscal year 2005 funding level of $80 million for the Heart Disease and Stroke Prevention Program at the CDC. Approving this funding level would guarantee elevation of additional states from the planning to the implementation stage of their prevention programs, to continue comprehensively fund those 11 states whose programs are underway in the "implementation stage," and to supply the states that have yet to begin the planning stage with the financial means for implementation and establishment of their own State Heart Disease and Stroke Prevention Programs.

Public Access to AEDs

Since its formal introduction in 1960, cardiopulmonary resuscitation (CPR) has been the mainstay in close-chest resuscitation of unresponsive cardiac attack victims. While this method is still an effective and recommended treatment for helping oxygenated blood reach the brain and organs, defibrillation through proper use of an AED is the only sure way to restore the heart's normal rhythm. For people experiencing sudden cardiac arrest, every minute counts. Unfortunately, for every minute that passes without defibrillation, a victim's chance of survival decreases by 7–10 percent. In only 8 or 10 minutes, death is nearly certain. The price of an AED

varies by make and model, but typically costs around $3,000—a small price when compared with needless loss of life.

AEDs accurately analyze cardiac rhythms and, if appropriate, deliver an electric lifesaving countershock. AEDs are widely used by trained emergency personnel and first responders such as firefighters and police personnel. Thanks to the growing body of evidence that "public access defibrillation," or PAD, can decrease the amount of time between cardiac arrest and defibrillation, there has been a concerted effort to expand public access to AEDs and to improve training and education on these lifesaving devices. AEDs can now be found in most high-traffic public areas including schools, shopping malls, airports and convention centers.

The ACC appreciates Congress' continued attention to the importance of public access to AEDs with the passage of several legislative initiatives over the past few years including the "Automatic Defibrillation in Adam's Memory Act" (Public Law 108–41), the "Rural AED Act," the "Cardiac Arrest Survival Act," and the "Community Access to Emergency Defibrillation Act." While the ACC appreciates the Congress' commitment to this important issue, the financial commitment to Community and Rural AED programs dwindled in the fiscal year 2004 budget despite the urging of the ACC and the AHA. Community and rural AED programs were grouped together and funded at less than $12 million, collectively in fiscal year 2004. The ACC is quite concerned that the benefits brought to communities around the country through increased access to AEDs could go unrealized if AED programs are not funded at a higher level in the fiscal year 2005 budget. The ACC, therefore, urges Congress to fund community and rural AED public access programs at $45 million in fiscal year 2005.

CONCLUSION

The ACC is optimistic about what the future holds for the treatment and prevention of cardiovascular disease. The potential for work completed through the NHLBI, the CDC State Heart Disease and Stroke Prevention Programs, and the AHRQ, is enormous with a strong financial commitment from this subcommittee. The ACC encourages the subcommittee to continue its investment in cardiovascular research and educational programs within the fiscal year 2005 budget and appreciates the opportunity to share its views on this important topic.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR HEART AND STROKE RESEARCH

My name is Jack Owen Wood. I solicit your support for more aggressive federal funding for research into prevention and treatment of the sister diseases, stroke and heart disease. Strokes and heart attacks are occurring at an alarming rate.

I am representing the National Coalition for Heart and Stroke Research. The coalition consists of 18 national organizations representing more than 5 million volunteers and members united in support for increased funding for heart and stroke research. Members of the Coalition include: American Academy of Neurology; American Academy of Physical Medicine and Rehabilitation; American Association for Vascular Surgery; American Association of Neurological Surgeons; American College of Cardiology; American College of Chest Physicians; American Heart Association; American Neurological Association; American Stroke Association; Association of Black Cardiologists; Citizens for Public Action on Blood Pressure and Cholesterol, Inc.; Compliment; Congress of Neurological Surgeons; Mended Hearts, Inc.; National Stroke Association NASPE/Heart Rhythm Society; Society of Interventional Radiology; Society for Vascular Surgery; amd WomenHeart: the National Coalition for Women with Heart Disease.

I will deal primarily with one man's personal experience with stroke and its functional and financial costs—my own. I have only the use of my right arm.

I was born in 1937, raised in Vicksburg, Mississippi, earned an engineering degree at Mississippi State University and currently reside in Port Orchard, Washington.

I worked for the Boeing Company in Seattle, am a former Director of the Washington State Energy Office, served as Director of Cost and Revenue Analysis and as the Forcasting Manager for a major Northwest Area Natural Gas Utility until May 1, 1995.

On May 1, 1995, at the age of 57, I was stricken and severely disabled by my stroke. Two years later I experienced a triple bypass heart operation. You might say I've "been there and done that" for both major cardiovascular diseases. So you see, I am an expert.

Several years ago I was offered an exciting and rewarding volunteer opportunity. I was asked to lead the "JACK WOOD STROKE VICTOR TOUR" for the American Heart Association.

The JACK WOOD STROKE VICTOR TOUR was a 5-state lobbying tour. Through it I tried to meet personally with every Northwest Congressional representative on his or her home turf (in Alaska, Idaho, Montana, Oregon and Washington). In each meeting I was joined by local people, stroke survivors and their families and medical professionals. I told my story and asked them to join the Congressional Heart and Stroke Coalition and to support increased federal funding for heart and stroke research.

I am proud to say I traveled to 18 communities and met personally with 28 members of our delegation or their staff. Nearly half of our congressional delegation is now members of the Congressional Heart and Stroke Coalition.

One of the most powerful memories for me was the frequency in which Members of Congress or staff members related their personal experience with stroke. One member I spoke to lost both parents to stroke. I suspect many of you have stories too.

I realize your interest is greater than the physical impact of my stroke. Your concern must include the financial impact, not only to me, but also on our country from increased health care costs and lost productivity and its many implications.

I have confronted the difficult and painful task of calculating that cost to me. Besides being a man whose stroke took his ability to pick up and play with his grandchildren and his livelihood, I remain a statistician at heart. I couldn't resist calculating and telling that part of my story. But please remember my story is not dissimilar to that of many of the 4.8 million stroke survivors in the United States. Many of whom were stricken in their prime earning years. Who in a matter of moments, seemingly without warning, are transformed from a contributor and provider to a receiver and patient.

Allow me to highlight three figures that I feel sum up my data and should be important to you. I estimate that my stroke at age 57:

—Reduced my earnings before retirement age 65 by over $600,000.

—Subsequently, the cost to the federal government in lost income and other taxes, early Medicare payments and Social Security disability payments is over $320,000.

—My HMO spent approximately $150,000 to respond to and treat my stroke.

—One man, over $1 million.

About 700,000 Americans will suffer a stroke this year costing this nation an estimated $54 billion in medical expenses and lost productivity.

Earlier I described a stroke as occurring seemingly without warning. All too often as in my case, people either don't know or ignore the signs of a stroke, even one in progress. When my stroke hit I denied it. It took me two days after my stroke to acknowledge it and seek help. Because of research into new treatments, we now have tPA, a clot-busting drug, which if administered within 3 hours of the onset of stroke symptoms, can dramatically reduce the damage of clot-based strokes. Had I recognized and acknowledged my stroke, gone to a hospital with a neurologist on staff and had there been tPA, the impact of my stroke most certainly would have been lessened.

What is even more painful to me is that my impending stroke could have been detected. Unfortunately, we need to create easier and less expensive diagnostic techniques so that effective diagnostics can be given routinely as part of regular health exams. And they must be covered through insurance.

I am not asking for your sympathy. Instead, please think of me as two of the ghosts in the famous Dickens' story. Please don't misunderstand, I'm not casting you as Scrooge. See me as both the ghosts of things past and things yet to be. I too am here to tell you, the future, which I represent, needs not be. It is largely up to you.

I hope my story and estimate of the cost of my stroke convinces you that taking on stroke and heart disease through increased research, leading to better prevention, diagnosis and treatment is fiscally responsible. The human and financial costs are astronomical.

Thank you for your past support of research.

PREPARED STATEMENT OF THE COOLEY'S ANEMIA FOUNDATION

SUBJECT

Both Alicia and Michael are Cooley's anemia patients. In their testimony, they will point to the research successes and the need to continue the focus on the most

scientifically opportune fields of research. Alicia will describe the tragic impact of the inability of some patients to comply with the excruciating treatment regimen for the disease and Michael will request the subcommittee's help in supporting blood safety surveillance through the CDC and other important research at the NIH.

ALICIA SOMMA

Good morning, Mr. Chairman. My name is Alicia Somma. Michael Giammalvo and I both have Cooley's anemia, a fatal genetic blood disease for which there is currently no cure. Michael is going to describe to the subcommittee what treatment for Cooley's anemia, or thalassemia (which is the medical name) is like, and I am going to tell you the story of my friend Nick who simply could not stand to undergo the treatment.

MICHAEL GIAMMALVO

Good morning, Mr. Chairman. My name is Michael Giammalvo and I am 13 years old. I was born with Cooley's anemia, which is a fatal genetic blood disease. Because my body cannot produce red blood cells like most other people's do, I have to receive a blood transfusion every two weeks. Getting a blood transfusion that frequently is not fun, but I have to do it to stay alive.

The problem with this treatment is that it creates a very bad side effect. When people receive blood transfusions as much as Alicia and I do, the iron that is in the transfused blood goes into our bodies. The body does not know how to get rid of it, so it builds up in the heart and the liver.

To get rid of the iron, patients have to infuse a drug called Desferal. It is in a pump that we wear. The drug is pumped through a needle that we have to insert under our skin. Most Cooley's anemia patients have to infuse Desferal five days a week for 8–12 hours at a time. The needle hurts. I sometimes can't go to my friends' houses for sleepovers or do other things that other kids do.

There are times when I really don't want to take the Desferal and I make it hard on my parents. And, some patients, especially ones who are a little older than me—teenagers—just stop taking it. Alicia will tell you about somebody who did that.

ALICIA

Mr. Chairman, this is the first time I have spoken in public about what happened to my friend Nick Alessi—so please bear with me if this is a little hard for me.

As a child growing up with this fatal illness, it's difficult not to feel different. Being the only kid in your class making regular week-long trips to the hospital, you can't help but feel alone. Nick made that feeling go away for me. Going to get treated and seeing him there showed me that I wasn't the only person with Cooley's anemia. Sitting in that infusion room, he and I became friends, and he made my life normal.

Constantly updated on each other's health, when I heard Nick hadn't been compliant with our nightly treatment, I was crushed, almost as if it had happened to me. Over time, he grew very ill, the overloaded iron began attacking his heart, and we all knew he was in danger. I spoke with his father often, giving him advice on how to deal with this enormous obstacle.

We decided that I should talk to Nick myself, regardless of the awkwardness I'd feel, because his condition was getting worse everyday. We arranged to have dinner together and discuss his problems, but unfortunately, I never got that chance to have that dinner and I never got the chance to save my childhood friend. We had all tried our hardest to save Nicholas Alessi, and we all failed. It's just hard to convince someone that you have to do something so barbaric to yourself to save your own life. Dealing with this has been immensely difficult, knowing that it could all be prevented. As I said, Nick was my friend and now he is gone.

Mr. Chairman, NIH does research on using non-invasive methods of measuring iron in our livers and hearts and on addressing other related issues like osteoporosis (which I have even though I am only 18 years old), hepatitis C (which more than one third of our patients have), and more. CDC spends $2.2 million to monitor the safety of the blood we transfuse into our bodies. The FDA is currently reviewing a drug that might be taken orally to remove iron, rather than the long, painful infusion but it is still months or years away from being available to all patients.

Addressing these issues are all things that only the government can do. And, we would not ask this of our government if it were not so important. I know that you have a lot of people asking you for a lot of things today and that you can't do everything. But, Michael and I are here today to speak on behalf of Nick Alessi—because he can't be here to speak for himself. Thank you for all you have done and for all you will do in the future.

We would be pleased to answer any questions.

PREPARED STATEMENT OF THE DORIS DAY ANIMAL LEAGUE

Chairman Specter, Ranking Member Harkin and Members of the Subcommittee: The Doris Day Animal League represents 350,000 members and supporters nationwide who support a strong commitment by the federal government to research, development, standardization, validation and acceptance of non-animal and other alternative test methods. We are submitting our testimony on behalf of the Society for Animal Protective Legislation, too. Thank you for the opportunity to present testimony relevant to the fiscal year 2005 budget request for the National Institute of Environmental Health Sciences for the Center for the Evaluation of Alternative Toxicological Test Methods (NICEATM) for the Interagency Coordinating Committee for the Validation of Alternative Test Methods (ICCVAM) activities for fiscal year 2005.

In 2000, the passage of the ICCVAM Authorization Act into Public Law 106–545, created a new paradigm for the field of toxicology. It requires federal regulatory agencies to ensure that new and revised animal and alternative test methods be scientifically validated prior to recommending or requiring use by industry. An internationally agreed upon definition of validation is supported by the 15 federal regulatory and research agencies that compose the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), including the EPA. The definition is: "the process by which the reliability and relevance of a procedure are established for a specific use."

FUNCTION OF THE ICCVAM

The ICCVAM performs an invaluable function for regulatory agencies, industry, public health and animal protection organizations by assessing the validation of new, revised and alternative toxicological test methods that have interagency application. After appropriate independent peer review of the test method, the ICCVAM recommends the test to the federal regulatory agencies that regulated the particular endpoint the test measures. In turn, the federal agencies maintain their authority to incorporate the validated test methods as appropriate for the agencies' regulatory mandates. This streamlined approach to assessment of validation of new, revised and alternative test methods has reduced the regulator burden of individual agencies, provided a "one-stop shop" for industry, animal protection, public health and environmental advocates for consideration of methods and set uniform criteria for what constitutes a validated test methods. In addition, from the perspective of animal protection advocates, ICCVAM can served to appropriately assess test methods that can refine, reduce and replace the use of animals in toxicological testing. This function will provide credibility to the argument that scientifically validated alternative test methods, which refine, reduce of replace animals, should be expeditiously integrated into federal toxicological regulations, requirements and recommendations.

HISTORY OF ICCVAM

The ICCVAM is currently composed of representatives from the relevant federal regulatory and research agencies. It was created from an initial mandate in the NIH Revitalization Act of 1993 for NIEHS to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use." In 1994, NIEHS established the ad hoc ICCVAM to write a report that would recommend criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to federal agencies and the scientific community. Through a series of public meetings, interested stakeholders and agency representatives from all 14 regulatory and research agencies, developed the NIH Publication No. 97–3981, "Validation and Regulatory Acceptance of Toxicological Test Methods." This report, and subsequent revisions, has become the sound science guide for consideration of new, revised and alternative test methods by the federal agencies and interested stakeholders.

After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS' NICEATM. Representatives from federal regulatory and research agencies and their programs have continued to meet, with advice from the NICEATM's Advisory Committee and independent peer review committees, to assess the validation of new, revised and alternative toxicological methods. Since then, several methods have undergone rigorous assessment and are deemed scientifically valid and acceptable. In addition, the ICCVAM is working to streamline assessment

of methods from the European Union (EU) that have already been validated for use within the EU. The open public comment process, input by interested stakeholders and the continued commitment by the federal agencies has led to ICCVAM's success. It has resulted in a more coordinated review process for rigorous scientific assessment of the validation of new, revised and alternative test methods.

REQUEST FOR APPROPRIATIONS

On December 19, 2000, the "ICCVAM Authorization Act" which makes the entity a permanent standing committee, was signed into Public Law No. 106–545. For several years, the NIEHS has provided between $1 and $2.6 million per fiscal year to the NICEATM for ICCVAM's activities. In order to ensure that federal regulatory agencies and their stakeholders benefit from the work of the ICCVAM, it is important to fund it at an appropriate level. I respectfully urge the Subcommittee to support and appropriation for the NIEHS' NICEATM for ICCVAM's activities at $3.5 million for fiscal year 2005. This appropriation request includes all FTEs, funding for independent peer review assessment of test methods and meetings of the ICCVAM and other activities as deemed appropriate by the Director of the NIEHS.

REQUEST FOR COMMITTEE REPORT LANGUAGE

I also respectfully request the Subcommittee consider the following report language for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations bill:

"The Committee supports the assessment of scientific validation of new, revised and alternative toxicological test methods by the ICCVAM. The Committee urges the fifteen regulatory and research agencies composing the ICCVAM to use the expertise and credibility of the ICCVAM for assessments to obviate their individual consideration of new, revised and alternative test methods. The Committee also urges the regulatory and research agencies to incorporate scientifically validated new, revised and alternative test methods into their regulations, requirements and recommendations in an expeditious manner."

Thank you for the opportunity to submit this request on behalf of the Doris Day Animal League and the Society for Animal Protective Legislation.

PREPARED STATEMENT OF THE JEFFREY MODELL FOUNDATION

SUBJECT

Mrs. Modell will, first and foremost, thank the committee and its members for its past assistance and support. She will also testify in favor of increases in funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Concerning CDC, she will request an increase in the current program that provides funding for a national education and awareness program related to primary immunodeficiency diseases to allow the Foundation to expand the program to reach underserved African-American and Hispanic communities. Within NIH, her testimony will focus specifically on NICHD, NIAID and NHLBI.

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to testify before you today. I am Vicki Modell and, along with my husband Fred, we created the Jeffrey Modell Foundation in 1987 in memory of our son, who died at the age of 15 as a result of a life long battle against one of the 100-plus primary immunodeficiency diseases.

First and foremost, Mr. Chairman, I am here today to thank you and all the members of this committee on both a personal and a professional level. Personal because whenever Fred and I come to Washington, whether it is to testify here before the committee or to meet with the members of the subcommittee individually in their offices, every Member of Congress and every member of your staffs are unfailingly polite, courteous, interested and caring.

And, professional because over the last seven years that we have been coming to Washington, we have been given the opportunity to build a partnership with the Congress, the Centers for Disease Control and Prevention, the National Institutes of Health, as well as with our own supporters in the private sector, including industry and other concerned donors.

We believe that we have maximized the benefits for patients from the support that this subcommittee has afforded us. We are going to tell you a remarkable story of success, of hope, and of future challenges this morning.

This subcommittee is currently funding CDC with $2.2 million for physician education and public awareness of immune deficiencies. The Jeffrey Modell Foundation

operates the program under a contract with CDC. Although we only receive about $1.8 million of the money (CDC keeps the rest for its "administrative expenses"), we have leveraged that money into a $15 million national campaign.

The Foundation has raised more than $1.0 million, largely from our supporters in the pharmaceutical and blood-related industries. Working with the Ad Council and a major New York City ad firm, we put together a media campaign alerting families to the possibility that repetitive infections may indicate a deeper, underlying problem and explaining to parents how to get their children tested. That campaign has generated more than $12 million in donated media time on television and radio, as well as magazine ad space.

But, the campaign has been even more than the advertising.

—We have conducted physician symposia for CME credit all over the country.

—Working with NIH, we have produced educational materials for doctors and families. We have mailed 38,000 posters—one to every school nurse in the United States.

—NICHD has mailed information to every member of the American Academy of Pediatrics and the American Academy of Family Practice.

—We have developed and improved a terrific website.

All of these steps would not be possible without the support of this subcommittee, but there is so much more that we can do.

We fully recognize what a difficult appropriations year this is going to be. We know that, like every year, the demands on the subcommittee far exceed the allocation that you will likely have available. We also understand that our needs are small in the bigger picture of funding multi-billion programs like Pell Grants or the No Child Left Behind program. Yet, we have taken a small amount of money—for which we are eternally grateful—and generated $7 of private money for every $1 of government money.

Mr. Chairman, one of the great unmet needs in our education and awareness program is underserved African American and Hispanic populations. Any such program concerning an undiagnosed disease needs to make special provisions for reaching these groups. You need to seek time on different radio stations, different television networks, and space in different magazines.

Yet we know that this must be done. If you visit the Emergency Room at our home hospital in New York—Mount Sinai—then you visit the infusion room operated by the Department of Immunology, you see two very different populations. Yet the research tells us that there is not an ethnic component to this disease. That means that the visible differences relate to our medical system, not the incidence of disease.

We are prepared to take on this challenge, much as this Congress has been willing to address the problems of health disparities through the NIH and elsewhere. We believe that we can begin to make a dent in the problem by increasing the funding available for this program to $2.7 million from $2.2 million.

Mr. Chairman, as you know, we have other interests within the purview of this committee, as well. We have along history of collaboration with NICHD, which has been our strongest supporter under the able leadership of Dr. Duane Alexander. We have helped to fund research at NIAID. We have funded post-doctoral fellows at NHGRI. We are now jointly funding a conference with NHLBI.

Our interactions with these many NIH institutes has convinced us that further increases in their budget—to whatever level fits within your allocation—will be put to good use and will benefit chronically ill people like our patients.

Mr. Chairman, as I said in the beginning of my remarks, Fred and I are very grateful. We cannot begin to thank you and the subcommittee enough for all of the support and encouragement that we have received from you whenever we come to Washington. While we may never be able to repay all your kindnesses, you should know that the work that you do enables the work that we do. And, every young person who is diagnosed—early and properly—and then receives treatment is a young person who life is better for what you have done.

Thank you again. I would be pleased to answer any questions.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR DENTAL RESEARCH

SUMMARY

Dental research is concerned with the prevention, causes, diagnosis, and treatment of diseases and disorders that affect the teeth, mouth, jaws, and related systemic diseases. Dental health is an important, vital part of health throughout life.

INTRODUCTION

I am Dr. Michael Alfano, Dean of the New York University School of Dentistry. This testimony I am presenting is on behalf of the American Association of Dental Research (AADR). The AADR is a non-profit organization with over 5,000 individual members and 100 institutional members within the United States. AADR's mission is to enhance the quality and scope of oral health, advance research and increase knowledge for the improvement of oral health, and increase opportunities for scientific changes.

Mr. Chairman and members of the Committee, we want to thank you for this opportunity to testify about the exciting advances in oral health sciences. I would like to discuss our fiscal year 2005 budget recommendations for the National Institute of Dental and Craniofacial Research (NIDCR).

OVERVIEW

Oral health is an important component of health. Good teeth and healthy gums for chewing and appearance, as well as taste buds and saliva to enjoy food and facilitate speech, all make major contributions to quality of life. Over the years, discoveries stemming from dental research have reduced the burden of oral disease for many Americans—although much remains to be done to reduce further the prevalence of oral diseases and their impact on overall health and well-being, as identified in Surgeon General (SG) David Satcher's Report of 2002: *Oral Health in America* and reinforced by current SG Richard Carmona in his 2003 *National Call to Action to Promote Oral Health.*

Of even broader interest, however, the oral cavity also offers intriguing potential as a diagnostic window to the rest of the body—potential being pursued by the National Institute of Dental & Craniofacial Research (NIDCR). In fact, the Director of the National Institutes of Health, Dr. Elias Zerhouni, believed the potential for salivary diagnostics was so promising that he allocated some of his discretionary funds toward this research. Dr. Zerhouni has also complimented the NIDCR for its salivary research as exemplifying the type of interdisciplinary research that will be necessary to improve overall health outcomes for patients.

SALIVA AS A DIAGNOSTIC AND MONITORING TOOL

Saliva is the protective fluid of the oral cavity. With its vast supply of microbe killers, saliva combats invading pathogens such as HIV and a host of bacteria associated with oral and systemic diseases. Antibodies directed against pathogens, such as polio and cold viruses, are found in saliva. Large salivary glycoproteins, called mucins, appear to have antiviral properties as well.

Oral fluid is also a mirror of the body, containing many compounds indicating a person's health and disease status and, like blood and urine, its composition may be altered in the presence of disease. Saliva, however, may be collected in a much less invasive fashion than either blood or urine.

Technologies are being developed at the NIDCR and by multidisciplinary teams in universities supported by grants from the NIDCR. These technologies offer huge clinical and commercial opportunity and may one day catalyze a shift in our current health system of disease detection to real-time health surveillance. For example:

—Studies have uncovered in saliva the presence of a cancer-related protein whose concentration increases in the presence of breast cancer—a potential diagnostic marker for the early detection of breast cancer in women.

—Saliva is gaining value as a diagnostic aid and potential monitor of disease progression in systemic disorders, including Alzheimer's disease, Sjören's syndrome (an important autoimmune disease), cystic fibrosis, and diabetes.

—Saliva is also proving to be an effective tool to monitor levels of hormones and therapeutic medications.

—Research opportunities abound to develop more sensitive and specific assays to measure and understand changes in saliva beyond oral and systemic diseases in areas such as genetic defects, nutritional status, and age-specific changes.

GENE THERAPY USING SALIVARY GLANDS

Gene therapy, substituting effective genes for those that are missing or nonfunctional and not producing needed proteins, offers hope for many patients, especially those who have conditions caused by a deficiency in a single protein, such as Type I diabetes, growth hormone deficiency, and hypoparathyroidism. Many of the difficulties involved in the delivery of such genes to internal organs can be avoided by incorporating functioning genes into salivary glands, which can in turn make the deficient protein and provide therapeutic benefit. If resources become available, the

NIDCR is proposing an evaluation of gene transfer techniques in three clinical trials, involving patients with:
—adult growth hormone deficiency,
—chronic renal failure, and
—Sjören's syndrome and salivary gland damage.

BIOMIMETICS/TISSUE ENGINEERING

Advances in the design of materials and an increasing understanding of mechanisms by which tissues of the craniofacial complex develop have positioned scientists to replace tissues lost as a result of developmental defects, pathology, or trauma. Interdisciplinary teams of scientists supported by the NIDCR:
—continued to improve dental restorative and implant materials;
—identified mechanisms to address osteoporosis and other conditions by making one cell type become another, e.g., inducing more bone marrow cells to become bone cells rather than fat cells;
—discovered that the "baby teeth," which children begin to lose normally around age six, contain a rich supply of stem cells that may have more potential for differentiation into other cell types than do adult stem cells, and are identifying these other cell types as funding permits; and
—created a distinct portion of the lower jaw from rat adult stem cells that is the precise three-dimensional shape of the human mandibular joint.

Researchers have long dreamed of engineering new teeth, knees, hips, and other body parts from a person's own tissues. Research to date has provided a solid base for making this dream a reality. Noting the ease of access to the oral cavity, Dr. Bruce Baum, a scientist at the NIDCR, has noted that "the mouth is one of the best laboratories' in the body to study issues in human biology that go beyond dental research."

RESEARCH IN PATIENT CARE SETTINGS

In November 2003, the NIDCR announced support for Dental Practice-Based Research Networks (PBRNs) to provide an infrastructure for answering important clinical questions routinely faced by dental practitioners (http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-05-006.html). Indeed, the 2002 American Dental Association Future of Dentistry report specifically recommends that national clinical research networks be established that link treatment approaches and outcomes in private practice settings.

By connecting community-based dental providers with experienced clinical investigators, PBRNs will enhance clinical research supported by the NIDCR and produce findings that are immediately relevant to practitioners and their patients. Because research is conducted in the real-world environment of dental practice, results may be more readily accepted by practitioners and rapidly integrated into dental practice. Importantly, PBRNs also provide a very cost-efficient mechanism for conducting clinical studies, because they use existing personnel and the infrastructure of established dental practices.

RECOMMENDATION

The National Institute of Dental and Craniofacial Research (NIDCR) is the leading agency supporting research in the oral and craniofacial area. NIDCR has already begun investing in all of the above areas, but the Institute needs additional funding if these initiatives are to become a reality. It is requested that an appropriation of $420,000,000 be provided for NIDCR in fiscal year 2005 to launch a major initiative to complete the development of the technology for using saliva as a low-cost, non-invasive, diagnostic instrument; to pursue gene therapy using the salivary glands; to accelerate efforts in biomaterials and tissue engineering (regeneration of teeth and other body parts); and to develop fully the recently announced Dental Practice-based Research Networks initiative.

In fiscal year 2005, the AADR also supports an appropriation of $30.6 billion for the NIH overall, $20,000,000 for CDC's Division of Oral Heath, $182,000,000 for the CDC's National Center for Health Statistics, and $443,000,000 for the Agency for Healthcare Research & Quality.

PREPARED STATEMENT OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

Mr. Chairman and Members of the Committee, I am James Ferguson, M.D., President of the Society for Maternal-Fetal Medicine. We appreciate the opportunity to testify before this Committee and are most appreciative of the support you have

provided over the years to the National Institutes of Health, in particular the National Institute of Child Health and Human Development.

The Society for Maternal-Fetal Medicine (SMFM), established in 1977, is a subspecialty organization, which was formed to promote research and education on issues that may confront a high-risk pregnant mother or unborn fetus. The SMFM has a very strong interest in improving pregnancy outcome through basic, translational and clinical research. Only through research can complications involving the mother or unborn fetus be understood, treated, prevented, and eventually solved.

Maternal-Fetal Medicine is a subspecialty within Obstetrics and Gynecology. Maternal-Fetal Medicine subspecialists pursue an additional 2 to 3 years of fellowship training following completion of their 4 year residency program in Obstetrics and Gynecology. Maternal-Fetal Medicine subspecialists provide consultative services to obstetricians, while in other cases they actually assume direct care responsibility for the special problems that high-risk mothers or high- risk fetuses face. The special problems faced by these mothers may lead to death, short-term or in some cases life-long problems for their babies. For example:

—*Preeclampsia*.—Preeclampsia is a dangerous condition characterized by high blood pressure and the presence of protein in the urine. It complicates 3 to 4 percent of pregnancies, strikes without warning and is a leading cause of maternal and fetal death. In some cases, the condition may progress to eclampsia, a series of potentially fatal seizures. Although the high blood pressure and seizures can be treated, the only cure for preeclampsia is delivery of the baby. Surviving infants are at increased risk for preterm birth, may be undergrown or have serious disorders requiring neonatal intensive care.

—*Preterm Birth*.—Preterm birth (Premature delivery) complicates approximately 10 percent of births and is a direct contributor to over 75 percent of the infant deaths and substantial newborn mortality and morbidity. Despite decades of committed research, the physiologic mechanisms underlying the onset of the process of giving birth, either preterm or term, have yet to be clearly identified.

—*Stillbirth*.—When fetal death occurs after 20 weeks or more gestation, it is referred to as stillbirth. For many parents who hear the heartbreaking news that their baby has died in the womb, the loss is completely unexpected. Half of all stillbirths occur in pregnancies that appear to be problem-free. While 14 percent of fetal deaths occur during labor and delivery, 86 percent of fetal deaths occur before labor begins. The only warning the pregnant woman may have that there is a problem is that the baby suddenly is no longer moving or kicking. The most common known causes of stillbirth include: placental problems, birth defects, growth restriction and infections. But for at least half of all stillbirths, the cause remains undetermined. Despite the significant and persistent burden of stillbirth, the phenomenon has remained largely unstudied.

—*Abnormal fetal growth*.—Abnormalities in the regulation of fetal growth may result in newborns that are significantly overgrown or undergrown and suffer complications related to the abnormal growth pattern. Inadequate fetal growth may occur in the absence of recognized causes e.g., maternal hypertension, smoking, or inadequate nutrition, and may be associated with intrauterine fetal demise or immediate neonatal and long-term consequences for the infant. Excess fetal growth may occur in pregnancies complicated by maternal obesity or diabetes, despite appropriate nutritional counseling and insulin therapy. Currently the management of under-and overgrown fetuses is empirical, aimed primarily at selection of safest time for delivery. There are no effective treatments to prevent or reverse either intrauterine growth restriction or fetal macrosomia.

—*Neonatal brain injury*.—The precise cause of the majority of cases of neonatal brain injury is unknown. In the past, much emphasis was placed on hypoxia and "asphyxia" as a cause. Recent studies suggest that maternal infection and subsequent fetal infection may play a major role in the causation of newborn brain abnormalities such as periventricular leukomalacia and white matter damage.

The National Institute of Child Health and Human Development (NIHCD) has been a leader in the field of maternal-fetal medicine research. Its commitment to basic, clinical and translational research has lead to new ways to treat and improve the health of pregnant women and infants. In the 1960's the birth weight at which infants had a 50-percent change for survival was approximately three (3) pounds; today it is 1½ pounds. Research conducted and supported by the NICHD, has given preterm infants and their families hope for the future.

RECENT ACCOMPLISHMENTS

NICHD supported research in maternal-fetal medicine has been dramatic. Great strides are being made in our understanding of pregnancy and its complications. Recent researching findings revealed that:

—abnormal levels of two molecules found in the blood appear to predict the development of preeclampsia. This observation is the most promising lead yet in the pursuit of this life-threatening disorder. If the development of preeclampsia can be reliably predicted, treatment strategies may be developed before more serious problems arise.

—women with heightened resistance to the hormone "insulin" in the early months of pregnancy are at risk to develop preeclampsia. This finding suggests that physicians may be able to initiate preventive measures early in a pregnancy for women with insulin resistance. The research also implicates insulin resistance as a causative factor in preeclampsia; thus, it may ultimately be possible to prevent preeclampsia by improving insulin sensitivity in at-risk women early in a pregnancy or even before conception.

—an anti-diabetes drug, metformin, lowered the risk of a miscarriage in the first trimester of pregnancy for women with polycystic ovary syndrome (PCOS). The investigators had already demonstrated that the drug increases blood flow in the uterus and brings about changes in the uterine lining.

MATERNAL FETAL MEDICINE UNITS NETWORK

The National Institute of Child Health and Human Development created the Maternal Fetal Medicine Units Network (MFMU) in 1986 to address major clinical questions in maternal fetal medicine and obstetrics, particularly with respect to the continuing problem of preterm birth. The Network supports 14 clinical academic institutions and one data center. Typically, the network has four to six studies and/or trials ongoing at any given time. This approach provides optimal efficiency and cost-effective research. Over the last year, two trials studying progesterone for the prevention of preterm birth in high-risk women and Factor V Leiden mutations have been completed. This research will benefit countless women at risk of preterm birth.Over the last year, a trial on the identification of a therapy, progesterone, that prevents recurrent preterm birth in high-risk women has been completed. This is one of the first advances in this area, despite extensive efforts over decades.

Areas of Need

NICHD is at the forefront of several novel and important research areas, but there are still many areas that we are not close to understanding about maternal health, pregnancy, fetal well-being, labor and delivery and the developing child.

—The next major advance in elucidating the etiology of preterm delivery involves understanding the mechanism through the evaluation of protein and gene expression. These techniques are widely used in other medical fields, and it is imperative that they are used to understand prematurity. Through these new technologies, wide scale, high output genomic and proteomic strategies should be used to identify mechanisms underlying premature birth.

—New tools are needed to assess fetal growth; and non-invasive methods to assess changes in the uterine cervix and muscle (myometrium), and placental changes over time.

—Research should focus on the pre-pregnancy and early pregnancy periods; the role of the cervix; the role of the placenta, including functional mechanisms related to pregnancy outcomes and fetal well-being, such as fetal growth and preterm delivery.

—Strategies for predicting preterm birth should include multivariate analysis, such as that used in neural network analysis, and should focus on identifying the potentially reversible changes that take place prior to and during the early phase of pregnancy.

—Research should focus on the cases with highest mortality and morbidity and should not be diluted by inclusion of less relevant cases of preterm birth that are close to term.

—Research is needed to:

  —develop clinical methods to identify pregnancies where delaying delivery is futile or in some cases detrimental.

  —determine the effects of intervention on outcome.

  —identify the risk factors for adverse outcomes arising as result of pre-eclampsia, (abruption, preterm birth) in hypertensive women.

  —Understand the pathophysiologic abnormalities that lead to adverse pregnancy outcome in hypertensive women.

—Research is needed to explain the exact mechanism of how infections lead to brain injury at various stages of pregnancy and brain development. In addition, delineation of the biochemical pathyway leading to injury may allow for interventions before irreversible injury occurs.

RECOMMENDATIONS

Without a sustained and continued investment in the areas of need, the health of pregnant women and their babies will continue to be at risk. The SMFM therefore recommends:

—An increase of 10 percent in fiscal year 2005 for the National Institutes of Health, bringing its total budget to $30.6 billion, as supported by the Ad Hoc Group for Medical Research Funding.

—An increase of 10 percent or $1.366 billion in fiscal year 2005 for the National Institute of Child Health and Human Development.

—NICHD fully support the MFMU Network so that it can continue to address important research questions, with an emphasis on issues pertaining to preterm births and low birth weight deliveries.

—That the NICHD have a major initiative to focus on genomics and proteomics to hasten a better understanding behind the pathophysiology of premature birth, discover novel diagnostic biomarkers, and ultimately aid in formulating more effective interventional strategies to prevent premature birth.

—That the NICHD fully fund the cooperative network of clinical centers and data center to study stillbirth.

Thank you Mr. Chairman and Members of the Committee for the opportunity to express our concerns and recommendations before this Committee.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR OSTEOPOROSIS AND RELATED BONE DISEASES

Mr. Chairman and Members of the Committee: I am Joan Goldberg, Executive Director of the American Society for Bone and Mineral Research. I am here today on behalf of the National Coalition for Osteoporosis and Related Bone Diseases (the Coalition). We want to thank you for your continued support of the National Institutes of Health. Without your support the scientific achievements that have translated into direct benefits for millions of Americans afflicted with bone diseases such as Osteoporosis, Osteogenesis Imperfecta and Paget's disease of bone could not have been possible.

The participants of the Coalition are the National Osteoporosis Foundation, the American Society for Bone and Mineral Research, the Paget Foundation for Paget's Disease of Bone and Related Disorders and the Osteogenesis Imperfecta Foundation. The Coalition is committed to reducing the impact of bone diseases through expanded basic, clinical, epidemiological, and behavioral research and through education leading to improvements in patient care.

What do we know about bone? One misconception is that bone is a static tissue. Bone is a living tissue that makes up the body's skeleton. It is a truly remarkable structural material, which makes it ideal for its function of structural support. Bone provides mobility, protection of vital organs, and housing of the bone marrow. It is also a reservoir for calcium. This dynamic and highly tuned organ simultaneously balances growth to achieve strength and resilience, and repair without overgrowth. This balance is achieved by bone remodeling. An imbalance in remodeling, however, leads to the debilitating bone diseases such as osteoporosis, paget's disease of bone and osteogenesis imperfecta. These diseases are responsible for a large portion of healthcare expenditures in the United States. For example:

—OSTEOPOROSIS, or porous bone, is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. It is a major public health threat for 44 million Americans. Of the 10 million who have osteoporosis, 80 percent are women. Today, 2 million men have osteoporosis and almost 12 million more are at risk for the disease. Men with low levels of testosterone are especially at risk. This includes men being treated with certain medications for prostate cancer. Osteoporosis is responsible for more than 1.5 million fractures annually, including over 300,000 hip fractures; 700,000 vertebral fractures; 250,000 wrist fractures; and 300,000 fractures at other sites. The estimated national direct expenditures (hospital and nursing homes) for osteoporotic and associated fractures were $17 billion in 2001 ($47 million each day) and the cost is rising.

—PAGET'S DISEASE OF BONE, the second most prevalent bone disease after osteoporosis, is a chronic skeletal disorder that may result in enlarged or deformed bones in one or more regions of the skeleton. Excessive bone breakdown and formation can result in bone that is dense, but fragile. Complications may include arthritis, fractures, bowing of limbs, and hearing loss if the disease affects the skull. Prevalence in the population ranges from 1.5 percent to 8 percent depending on the person's age and geographical location. Paget's disease primarily affects people over 50.

—OSTEOGENESIS IMPERFECTA (OI) causes brittle bones that break easily due to a problem with collagen production. For example, a cough or sneeze can break a rib, rolling over can break a leg. There are four recognized types of OI, representing extreme variations in severity and affecting 20,000 to 50,000 people in the United States. In severe cases fractures occur before and during birth. Undiagnosed OI may result in accusations of child abuse. Besides fragile bones, people with OI may have hearing loss, brittle teeth, short stature, skeletal deformities, and respiratory difficulties.

—FIBROUS DYSPLASIA is a chronic disorder of the skeleton, which causes expansion of one or more bones due to abnormal development of fibrous tissue within the bone. Any bone can be affected, and involvement can be in one or several bones. Though many bones can be affected at once, fibrous dysplasia does not spread from one bone to another. At present there are no approved medical therapies. Surgery is sometimes recommended for severe complications.

Another bone-related complication of bone that must be called to your attention is bone metastasis (cancer spreading to bone). Bone metastasis is a frequent complication of cancer and occurs in up to 70 percent of patients with breast cancer and prostate cancer, and in approximately 15 to 30 percent of patients with lung, colon, stomach, bladder, uterine, rectal, and renal cancer. Bone metastases cause severe pain and fracture and once tumors spread to bone, they are incurable.

Federal funding appropriated by the Congress has allowed the National Institutes of Health to conduct and support research that has reduced the adverse impact of bone disease on quality of life. Research has—

—taught us how many Americans have low bone mass and therefore are at risk for osteoporosis. These individuals can now address their risk with exercise, diet, other behavioral and lifestyle changes, and medication, as appropriate.

—demonstrated that a variety of drugs currently available can reduce bone loss and fractures, and even build bone.

—led to a better understanding of calcium metabolism and, as a result, manufacturers of a variety of food products have fortified their products with this vital nutrient.

—identified the necessity of vitamin D, protein, iron, etc., in addition to calcium in building and maintaining strong bones, while also spotlighting the major public health problem of vitamin D deficiency.

—helped us to understand the need for weight-bearing exercise to build and maintain bone density and strength training to increase balance and flexibility to reduce falls.

—identified a genetic component in many bone diseases, paving the way for the development of genetic approaches to diagnosis and treatment.

—decreased fracture risk and extended the lifespan for children with OI.

It is apparent that the quality of life related to bone disease is improving for many Americans, but much still remains to be achieved in areas such as:

DIAGNOSTICS/IMAGING

—DXA is an imaging test that measures bone mineral density (BMD). It is the gold standard for predicting fracture risk, yet it may both under-diagnose and over-diagnose patients at risk. Moreover, DXA uses databases that are largely based on BMD scores of white women. Relating BMD scores to fracture risk for women of other racial groups and ethnicities—and doing the same for men—is even more imprecise.

—New diagnostic measures are required to predict fragility and fracture risk better through assessing skeletal strength three dimensionally, focusing on internal bone micro-architecture or structure.

TREATMENT/PHARMACOTHERAPY

—Much attention has been focused on the Women's Health Initiative study results and the risks involved in estrogen treatment. However, more information is needed about low-dose estrogen and its bone-protective benefits and risks.

—Most current drug treatments for osteoporosis work by slowing down the natural process of bone breakdown. PTH, a hormone, actually builds bone. However, we need more studies to learn how best to use the drugs currently available, for what populations, with or after what drug regimens, for how long, and how best to assess response and interaction with exercise and diet.
—The discovery of new molecules with unexpected roles in modulating bone mass points the way to development of other new therapies. One example is leptin, a molecule made by fat cells.
—A 5-year observational study suggested that regular intravenous doses of pamidronate (a bisphosphonate) helped increase bone mineral density, reduce fractures, increase mobility, and decrease bone pain in children with osteogenesis imperfecta. Controlled clinical drug therapy trials will enable assessment of the potential use of bisphosphonate drugs to improve quality of life for children and adults.
—The discovery that tumor cells increase the number of natural-occuring cells that destroy bone has improved treatment and quality of life for patients with bone metastases through the use of drugs called bisphosphonates. However, further research is needed to study the path of bone disease in breast cancer, prostate cancer, multiple myeloma, and other cancers that spread to bone.
—Research is needed to improve survival and quality of life and to prevent metastatic osteosarcoma for the approximately 600 children and teenagers in the United States who develop this cancer. Specifically, research is needed to:
  —Identify new intervention targets for therapy;
  —Develop better predictors of response to osteosarcoma treatment;
  —Develop in vivo and in vitro preclinical assays to improve treatment;
  —Study metastatic osteosarcoma biology compared to biology of normal bone cells and that of other cancer cells.

NOVEL APPROACHES

—Investigations into genetic approaches for bone disease are critical and stem from recent findings that bone doesn't form when one protein—Cbfa-1—is missing. Understanding how this protein is activated or turned on may lead to new therapies for bone disease.
—The identification and study of families with very high bone mass who never fracture have led to the discovery of the involvement of the "wnt pathway" in regulating bone mass. This pathway has not only become a potential therapeutic target for controlling skeletal mass, but has recently been implicated in the bone loss experienced in multiple myeloma (a bone- and blood-related cancer).
—Understanding the role of genes and the underlying abnormal functioning of cells involved in bone breakdown in patients with Paget's disease is critical to developing new treatments. We need additional investigation to understand the role the bone microenvironment plays in the development of Paget's disease and to identify the molecular processes involved.
—Bone marrow transplantation is being tested in the laboratory for the treatment of osteogenesis imperfecta. One technique requiring further development focuses on genetically engineering bone precursor cells, which reside in the bone marrow, so that the faulty osteogenesis imperfecta gene which causes frequent fractures would be blocked or turned off. Then these engineered cells could be transplanted back into the bone marrow to form healthy bone.
—The use of specific exercise regimes—such as jumping—in the growing child, and of vibrating devices, for adults, represent exciting avenues for continued exploration into low-cost approaches to strengthen bone.
—The potential for genetic therapy to cure osteogenesis imperfecta has been demonstrated in the test tube. Suppressing the gene that causes the mutant collagen must now be demonstrated in animal models.

Bone research must be considered a trans-NIH issue given that bone diseases can lead to or be linked to other diseases such as cancer. Studies are currently being supported and conducted by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (the lead institute for bone research), the National Institute on Aging, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, the National Institute of Dental and Craniofacial Research and the National Cancer Institute.

Mr. Chairman and members of the committee we are most appreciative of your past support for the programs of the National Institutes of Health. The momentum in research cannot stop. The American people are expecting and holding fast to the hope that one day cures will be found for the debilitating diseases of bone.

RECOMMENDATIONS

The National Coalition for Osteoporosis and Related Bone Diseases believe that improved treatments and a cures are in sight, but greater federal funding will be necessary if these advances are to be achieved. The Coalition, therefore:

—Joins the Ad Hoc Group for Medical Research Funding in urging the Committee to provide an appropriation of $30.6 billion in fiscal year 2005 for the National Institutes of Health—an increase of 10 percent.

—Supports the NIAMS Coalition recommendation of a 10 percent increase for the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the lead bone research institute.

—Supports increased funding for NIA, NIDCR, NIDDK, NCI, and NICHD, other Institutes that also fund bone-related research, as well as seeks additional support for bone programs at NIBIB and NCAM.

—Requests more funding for training, transitional grants and debt repayment programs for young investigators and clinical scientists.

Mr. Chairman, thank you for the opportunity to testify before this Committee.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH

The American Association for Cancer Research (AACR) is the world's oldest, largest, and most prestigious professional society of cancer scientists and clinicians. The AACR embraces the mission of our 22,000 members to advance the prevention, detection, control and cures of cancer through research, education, and communication.

The AACR is the authoritative voice for those who constitute a continuum of cancer research. It is the work of those within this continuum that contributed to reduced death rates and stabilized incidence in lung, breast, prostate and colorectal cancers during the last decade. The effort to contain cancer is achievable, and the progress we have made is encouraging for the future.

Research by members of the AACR will lead to new ways of preventing, controlling and curing cancers in people of all ages. Scientists are mining information from the Human Genome Project to discover how cells use genetic information to become cancers. Researchers are identifying the genes that cause cancer and are designing targeted drugs that help regulate those genes. Other molecules target the proteins that are encoded by the cancer causing genes. Early detection technologies that use novel imaging methods to find the cancer causing genes and proteins in tumors are enabling clinicians to devise tailored treatment strategies with better odds of helping patients and with fewer side effects.

Discoveries within laboratories will aid in preventing, detecting, and controlling the disease of cancer, empowering cancer patients with a better quality lifestyle and a more productive, longer life. Some will be cured. Others, through novel means of early detection or powerful new therapeutics, will circumvent the arduous plight of cancer.

Opportunities in cancer research have never been so abundant. New challenges await us. Those challenges stem in part from the changing demographics within the United States and across the world. We are an aging population in the United States. As we age, our risk of cancer increases. Only 2.2 people in every 100,000 Americans under the age of 65 develop cancer. Once past that landmark age, 10 times that number of people develop cancer.

In the next 15 years, one-fifth of the American people will become 65 years or older. Already, 12 percent of the American population is 66 years or older. The risk of getting cancer is compounded by the large number of people entering this higher risk category. The number of people who develop cancer is expected to grow exponentially. As a society, we have the opportunity to avert this pending crisis.

Two recent actions have started us in the right direction to avoid a cancer crisis of epidemic proportions. The first was the recent completion of the 5-year doubling of the NIH budget. The second was the bold Challenge Goal pronounced in 2001 by the Director of the National Cancer Institute: To eliminate the suffering and death from cancer by 2015. The American Association for Cancer Research supports the Director's challenge goal and stands ready to assist and contribute in any way possible to meet this challenge.

The state of scientific knowledge and technology has never been greater. Continued strong investment now will allow us to accelerate the pace of discovery and optimize the use of existing and new knowledge for the development and delivery of effective new cancer treatments.

Many of these opportunities are cogently set forth in *A Plan and Budget Proposal for Fiscal Year 2005* prepared by the Director of the National Cancer Institute. In-

formally referred to as the "Bypass Budget," this document is mandated by Congress as part of the National Cancer Act of 1971. Its purpose is to set forth the National Cancer Institute's forward-looking strategic plan to build on its research successes, support the cancer research workforce with the technologies and resources it needs, and ensure that research discoveries are applied to improve human health. The Bypass Budget is provided directly to the President for formulating the budget request to Congress. It is developed in close consultation with all sectors of the cancer community, including scientists and cancer survivors, and represents the NCI Director's best professional judgment on the opportunities available and the resources needed to optimize progress in the fight against cancer in that fiscal year.

The American Association for Cancer Research strongly supports the concept of the Bypass Budget. It is a vital tool to generate further research advances. AACR has identified a series of priority areas for investment—within the scope of the National Cancer Institute's action plan—that will significantly contribute to the achievement of the Director's Challenge Goal.

In core scientific areas, AACR has identified the following priorities:

—*Enhancing Investigator-initiated Research*.—Individual investigators in their laboratories and clinics are the foundation stone for innovations and advances in biomedical science. Their discoveries lead to better science and its productive application to patient care. Yet fewer than one-quarter of peer reviewed and approved research grant requests from these scientists are funded by the NCI. Increased funding for competing research grants and resources for investigator-initiated research are vital to the success of the cancer research enterprise.

—*Molecular Targets of Prevention, Diagnosis, and Treatment*.—Some of the most promising recent advances in cancer research have come from our increased understanding of the molecular causes of cancer. Intensified research will increase the number of effective cancer interventions directed at validated targets.

—*Development of Cancer Imaging and Molecular Sensing Technologies*.—Imaging advances are increasingly important in cancer treatment and care to non-invasively assess cancer progression.

In the area of public health, AACR includes the following among its priorities:

—*Research on Tobacco and Tobacco-related Cancers*.—Tobacco use is the leading preventable cause of death in the United States and is linked to nearly one-third of all deaths from cancer. Significant research investments are essential to accelerate research to understand, prevent, and treat tobacco use and addiction and to develop effective public health strategies to combat it.

—*Research on Obesity, Physical Activity, Diet, and Nutrition*.—Obesity may soon exceed tobacco as the primary cause of cancer. Extensive further research is critical to develop effective preventive strategies and interventions to protect the majority of our population that is at risk.

—*Reducing Cancer-related Health Disparities*.—The burden of cancer falls unequally on our society, with the low-income, medically underserved, elderly, and minority populations affected disproportionately by the disease. Further research is urgently needed to discover the causes for these disparities and to develop and deliver effective interventions to eliminate them.

In addition to the recommendations above, AACR has identified five other priority areas that are of key importance to accelerating progress against cancer:

—*Cancer Prevention*.—Cancer prevention and behavioral modification must be fundamental components of any realistic attempt to meet the Director's 2015 Challenge Goal. Concentrated and accelerated research is essential to generate new knowledge and advances in this largely uncharted territory.

—*Aging and Cancer*.—Close to 60 percent of all new cancers are in persons older than 65. Further research is urgently needed to adequately prepare for the impact of our aging population on our nation's healthcare system.

—*Training Translational Researchers*.—The number of physician-scientists who take findings from the laboratory through the preclinical, clinical, and regulatory processes to the patient's bedside are dwindling. This kind of translational cancer research demands a high level of research skill. Managed care allows very little time for physicians to engage in such research, and there is minimal funding and no defined career path for translational and clinical cancer researchers. Increased federal funding for training is crucial to attract, educate, train, and retain these clinical personnel if we are to have the skilled workforce needed to defeat cancer in the near future.

—*Expanding Our National Clinical Trials Program*.—Patients in clinical trials receive the most advanced treatment and prevention approaches for their particular cancers. These trials are highly cost effective; however, fewer than 5 percent of adult cancer patients participate in clinical trials, as compared to nearly 80 percent of children with cancer. Augmented funding for the national clinical

trials program is necessary so that adult participation, especially by minority and underserved patients, is doubled to at least 10 percent.

—*Extending the Bioinformatics Infrastructure*.—The value of the vast expansion of biomedical knowledge generated by today's researchers will match its potential value and usefulness only when it is collected, organized, integrated, stored, and made readily and universally accessible to the entire research community. Funding is needed to develop the state-of-the-art bioinformatics infrastructure for data mining and integration that is vital to accelerate research progress.

To maintain this nation's leadership in advanced biomedical research, and to take advantage of the abundant opportunities for research progress, we ask that you provide the National Institutes of Health with a sufficient level of funding to sustain the research momentum generated by the completion of the 5-year doubling of the budget. NIH officials and outside experts have testified that annual increases of at least 10 percent are required to preserve the research energy that has been unleashed by the doubling.

The cancer community is grateful for the 3.1 percent increase in the budget that the NIH received in 2004, but is deeply concerned about its impact on future progress. This is particularly troubling in light of the President's fiscal year 2005 Budget Request that only seeks a 2.6 percent increase for the NIH for next year. AACR shares this concern and urges the Committee to move boldly to furnish the funding levels necessary to undertake promising new research initiatives and to extend ongoing cutting-edge research through 2005 and beyond.

Specifically we urge your support to increase the budget of the National Institutes of Health to at least $30.61 billion in 2005. This 10 percent increase will allow the NIH to sustain and build upon its research progress while avoiding the severe disruption caused by cuts or nearly flat funding that is less than the rate of inflation.

We also ask that you fully fund the fiscal year 2005 Bypass Budget of the National Cancer Institute. At that level of funding, the NCI will be able to realize many of the vitally important research priority areas identified above and make the boldest strides possible against this disease. Thus, the AACR requests that the Committee fund the fiscal year 2005 NCI Bypass Budget request of the Director in the amount of $6.2 billion.

We have made remarkable progress in cancer research since the passage of the National Cancer Act in 1971. Your unflagging support for biomedical research for more than three decades has saved millions of lives and nurtured the productive research careers of thousands of our brightest and most dedicated scientists. More than 9.6 million cancer survivors alive today attest to the successful achievement of many of the goals of the National Cancer Act. With your continued positive support and leadership, the cancer community will be able to capitalize on the research momentum to convert our discoveries and new knowledge into the strategies and therapies that will make the Director's 2015 Challenge Goal a reality for all Americans.

PREPARED STATEMENT OF THE LYMPHOMA RESEARCH FOUNDATION

I am Melanie Smith, Director of Public Policy and Advocacy for the Lymphoma Research Foundation (LRF). I would like to express our appreciation for the opportunity to submit this statement to the record of the Labor, Health and Human Services and Education Appropriations Subcommittee. The LRF is the nation's largest lymphoma voluntary health organization, devoted to funding lymphoma research and providing information about the diseases to individuals diagnosed with lymphoma and their families and friends.

Our ultimate goal is to find a cure for all forms of lymphoma. To that end, we fund some of the world's leading lymphoma researchers at outstanding academic institutions. These researchers are engaged in research aimed at understanding the basic mechanisms of lymphoma and improving the current treatments for the disease. LRF also aims to equip those who are diagnosed with lymphoma with up-to-date information about treatment options. The organization sponsors educational conferences at which the leaders in lymphoma research and treatment address patients and families regarding cutting-edge research and the most recent developments in therapies.

BACKGROUND ON LYMPHOMA

Lymphoma is a major health problem. This year, approximately 54,400 cases of non-Hodgkin's lymphoma (NHL) will be diagnosed in this country, and more than 19,400 Americans will die from NHL. Also this year, 7,880 cases of Hodgkin's lymphoma will be diagnosed, and more than 1,320 Americans will die from the dis-

ease. Lymphoma is the most common form of blood cancer and the third most common form of childhood cancer. Nearly 500,000 Americans are living with lymphoma.

In recent years, there have been exciting reports regarding the improvements in treatments for a number of forms of cancer, as well as reports that the incidence of cancer overall is declining. Regrettably, NHL stands in contrast to the general trends in cancer incidence, and the treatment options for NHL remain inadequate. Since the early 1970s, incidence rates for NHL have nearly doubled, although incidence rates have stabilized the last few years. And the 5-year survival rate for NHL stands at 57 percent. These are not satisfactory numbers, and they serve as measures of the work we still have to do.

RESEARCH ON LYMPHOMA

In recent years, we have learned a great deal about the genetic, molecular, and cellular basis of cancer. We do not know the cause of most lymphomas, but there is increasing information to suggest a link between environmental factors and infections and the development of many lymphomas. The environmental factors include chemicals, toxins, and ultraviolet light, and the infectious agents include simian virus-40, hepatitis C, and Epstein Barr virus. There is also evidence that in some individuals, immune dysfunction is a critical factor in the development of lymphoma.

Our knowledge of cancer has improved significantly in the last decade, in large part due to the strong commitment of Congress to the National Institutes of Health (NIH) and its willingness to boost NIH funding, year after year. These funds have supported strong basic and clinical researchers who are focused on unlocking the secrets to cancer. There is a need to sustain that commitment to NIH, in order to equip scientists engaged in basic research and facilitate the translation of basic research findings into new treatments. This is certainly true in the case of lymphoma. There is a need to clarify the interactions among the environmental, viral, and immunogenetic factors that contribute to development of lymphoma and to ensure the development of new treatments based on our enhanced understanding of lymphoma.

Over the last decade, several new lymphoma treatments have been developed, expanding the options for those who are diagnosed with the disease. Lymphoma patients and researchers have clearly benefited from the nation's significant investment in research, and Congress deserves the appreciation of the community of lymphoma patients and researchers. Among the lymphoma treatments approved in the last decade are a monoclonal antibody and two different radioimmunotherapies. While we applaud the new treatments of the last decade, they are not a magic bullet; for many, lymphoma continues to be a fatal disease.

New therapies that capitalize on different research approaches are currently under investigation. These include therapeutic vaccines, immunotherapies, and proteasome inhibitors. Other work is focused on refining the chemotherapy regimens and developing treatment regimens with lower toxicities. All of this work deserves the support of private and public research funders.

ROLE OF NIH IN LYMPHOMA RESEARCH

Although LRF plays a critical and creative role in funding lymphoma research, NIH is, and will remain, the key player in this field. NIH is the pivotal player not only because of the magnitude of its financial commitment to lymphoma research, but also because of the role it can play in bringing together all of the partners in the research community—NIH intramural researchers, academic researchers, private foundations, industry, and the Food and Drug Administration (FDA).

NIH is also in the best position to encourage, facilitate, and fund the translation of basic research findings into new treatments. It is absolutely critical that we not lose the research momentum that has been the result in significant part of the doubling of the NIH budget between 1999 and 2003. This will require much more attention to translational and clinical research.

LRF recommends that NIH strengthen its lymphoma research program by several actions:

—The National Cancer Institute (NCI) should boost its support for translational and clinical lymphoma research. NCI should evaluate its current investment in clinical research and expand or initiate programs to strengthen the clinical research effort.

—NCI should also enhance its support for correlative studies of tumor biology and treatment response, as well as its investment in research on the late and long-term effects of current lymphoma treatments.

—The rate of payment for enrolling patients in NCI-sponsored clinical trials must be increased, as the current rate is inadequate to meet the costs associated with enrolling a patient in a clinical trial and collecting and analyzing the data associated with trial participation.
—NCI should enhance its research effort focused on understanding the complex interaction among environmental, viral and immunogenetic factors that are involved in the initiation and promotion of lymphoma.
—Although NCI has historically been the lead institute in funding lymphoma research, other institutes—the National Heart, Lung and Blood Institute (NHLBI), the National Institute on Aging (NIA), and the National Institute of Environmental Health Sciences (NIEHS)—should also evaluate and improve their lymphoma research programs. NIEHS has recently launched a targeted program to investigate the environmental links to breast cancer, and a lymphoma-focused program would be a logical outgrowth of the breast cancer program.

A strong partnership among voluntary health agencies like LRF, academic researchers, industry, NIH, and FDA will be optimal for advancing lymphoma research and improving the outlook for those who are diagnosed with the disease. New strategies are necessary for the rapid translation of basic research findings into new treatments. These strategies may include systems for funding collaborative research projects that engage researchers in multiple institutions and multiple disciplines, including academic researchers and industry. Private foundations are looking at creative means to ensure that their research dollars are optimized, and we encourage NIH to employ the same creative and flexible approaches.

ROLE OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION IN BLOOD CANCER EDUCATION

LRF is actively engaged in providing patients and their families and caregivers complete and up-to-date information about lymphoma, lymphoma research, and lymphoma treatment options. Because of our strong history in this area, we were gratified when Congress authorized and funded a program at the Centers for Disease Control and Prevention (CDC) for public and patient education on blood cancers. According to the authorizing statute and appropriations report language, the appropriated funds are intended to support private sector organizations that are engaged in blood cancer education. We believe these funds can be used effectively by organizations that have extensive experience in these educational efforts, and we encourage Congress to fund the program in fiscal year 2005, for a second year, to ensure that there is no sudden discontinuation of a worthy educational initiative.

LRF believes that strong partnerships will be a key feature of efforts to improve lymphoma treatments and provide lymphoma patients current information about their disease and treatment options. We encourage NCI to fund collaborative research ventures, and we urge CDC to support those private organizations that have years of experience in patient education. Those who receive a diagnosis of lymphoma face difficult choices, and we must work together to improve their options.

PREPARED STATEMENT OF WOMENHEART, THE NATIONAL COALITION FOR WOMEN WITH HEART DISEASE

Heart disease is the leading cause of death for American women, killing nearly 500,000 each year. Yet, according to a recent American Heart Association poll, less than half (46 percent) of women know this basic fact and, even more troubling, only 13 percent think that heart disease is their own most important health risk.

Ignorance often has fatal consequence. Women are not educated about their risk factors for heart disease so often do not take the necessary steps, such as cholesterol and blood pressure checks, to prevent or intervene in the earliest stages of the disease. They also are unaware of the signs and symptoms of heart attacks in women, which may differ than those in men. As a result, they do not get to the emergency room quickly enough to receive life-saving treatment. Many often die at home.

We ask the Subcommittee to increase funding for public education programs to increase women's knowledge of their heart disease risks and symptoms. Specifically, we urge a $10 million appropriation for NIH's National Heart, Lung and Blood Institute's existing "Heart Truth" campaign, which has been only modestly funded to-date. Through its adoption of the Red Dress as the national symbol for women and heart disease awareness, and the First Lady's participation in its public event, the campaign has put this long-ignored crucial women's health issue on the national agenda and is reaching thousands of women through its media relations and community outreach initiatives. However, a more significant campaign is needed to

reach the millions of American women who are at-risk for or undiagnosed with heart disease.

Thank you for your consideration.

The National Coalition for Women with Heart Disease is the nation's only patient advocacy organization representing the 8,000,000 that aims to increase their quality of life and quality of healthcare through support, information and advocacy. It is a non-profit public charity headquartered in Washington, DC.

PREPARED STATEMENT OF THE UPPER COUNTY BRANCH, MONTGOMERY COUNTY, MARYLAND STROKE CLUB

A STROKE SURVIVOR: A PERSONAL STORY

Hello. My name is Susan Emery. I am the presiding officer of the Upper County Branch of the Montgomery County Stroke Club and I'm a stroke survivor.

Our club conducts education and support activities for stroke survivors, their family members, and caregivers. We serve people in the Maryland suburbs of Washington, D.C., and are fortunate to be in the same county as the National Institutes of Health. We have benefited on many occasions by the participation of NIH staff members in our membership meetings. They have been generous in sharing information about their research into stroke prevention and treatment with us.

On December 26, 1965 at the age of 9, I was playing a new game with my brother and a few friends at the kitchen table. That's the last thing that I remember. I was unconscious for the next 2 days. My mother first learned, incorrectly, that I had spinal meningitis. I was transferred to another hospital where my mother was told that I had little chance of survival. Yet I'm here, more than 37 years later, and I've survived a stroke.

People seldom associate strokes with children. These strokes are rare, but they do happen. There are about three cases of stroke per year in every 100,000 children under age 14. One of the difficulties in dealing with strokes in children is getting the right diagnosis quickly. There are often delays in diagnosis of childhood stroke.

I spent 2 weeks in the hospital and the following 4 months in intensive physical therapy. My tenth birthday was spent in the hospital, and I have a picture in my photo album of myself with my mother and a new friend. My right eye is turned down, my mouth is turned down, but I'm still smiling. During the 4 months in therapy at Holy Cross in Detroit, I learned the basics: how to walk, how to talk, and how to move the fingers on my right hand. My mother followed the doctor's instructions and sent me back to school very quickly, where classmates helped me button and unbutton my coat and carry my books, and teachers taped papers to the desk so I could learn to write again. I survived that 4 months, and would never wish to repeat it.

I've been in therapy six times in my life. I need to tell you about the one time that was the most important to my family. I was 26 years old and had just had my first child. I kept her safe, for I knew my limitations. I always used my left hand to support her. But when she was 6 months old, she got to be a little heavy, and twice, as I was putting her on the floor to change her diaper, my right hand slipped from under her buttocks. She fell only inches in both cases and didn't even notice. But I noticed. I went in for 2 or 3 months of therapy close to Denver, Colorado, where I was living at the time. Here for the first time, they helped my right hand and arm dexterity through occupational therapy. I also learned that I had aphasia—the inability to speak, write or understand spoken or written language because of brain injury—because I called things like cornucopias, unicorns instead of fruit baskets. Instead of the word being the same, I picked a word that sounded the same. These therapists in Colorado worked with my mind and my body and I will forever be in their debt.

Close to 15 years ago, I made a new life for myself in Maryland. Here, I've been an outpatient at the National Rehabilitation Hospital three times: once for my right foot, once for my Achilles tendon and once for my right knee. I've seen numerous physiatrists, all of whom are excellent in their field. I've also seen my fair share of therapists. Since I've had therapy off and on for most of my life, I can honestly say that the first few times you go in to see a therapist, you'll come out hurting more than when you went in. But in the long run, they help tremendously.

On a work related note, I received a Bachelor of Science in 1978 from Michigan State University in Computer Science and worked for 12 years in the field. I started working in the telecommunications industry in 1990, and got a Master of Science from the University of Maryland, University College in Telecommunications Management. I now work for ITT Industries as a senior engineer on a contract sup-

porting the Federal Aviation Administration's leased telecommunications activities, and have worked there for more than 6 years. I've done more than survive. I've become a productive member of society.

Stroke research has changed my life. Without the research carried out 40 to 50 years ago, I would not have benefited from electric shock therapy that made me understand the muscles that moved my fingers. Without research done 30 years ago, I may not have been able to understand how to exercise my hand for dexterity. Without research performed 10 years ago, the people around me would not understand that they need to get me to the hospital quickly if ever I have another stroke. Without current support, researchers may never understand how to stop strokes before they happen or how to make current stroke survivors live healthier lives.

Stroke remains America's No. 3 killer and a major cause of permanent disability. An estimated 4.8 million Americans live with the consequences of stroke and about 1 in 4 is permanently disabled. Yet, stroke research receives a mere 1 percent of the National Institutes of Health budget. I strongly urge you to significantly increase funding for the National Institutes of Health-supported stroke research, particularly for National Institute of Neurological Disorders and Stroke-supported stroke research. NIH stroke research is essential to prevent strokes from happening to children and adults in the first place, and to advance recovery and rehabilitation of those who survive this potentially devastating illness.

PREPARED STATEMENT OF THE ILLINOIS NEUROFIBROMATOSIS, INC.

Thank you for the opportunity to present testimony to the Subcommittee on the importance of continued funding for Neurofibromatosis (NF), a terrible genetic disorder closely linked to cancer, learning disabilities, heart disease, brain tumors, and other disorders affecting up to 150 million Americans in this generation alone. Thanks in large measure to this Subcommittee's support; scientists have made enormous progress since the discovery of the NF1 gene in 1990. Major advances in just the past year have ushered in an exciting era of clinical and translational research in NF with broad implications for the general population.

I am David Evans, representing Illinois Neurofibromatosis, Inc., which is a participant in a national coalition of NF advocacy groups. I have lived with NF my entire life. Although I have not suffered any of NF's severe symptoms; I have experienced the social problems caused by being afflicted with NF. I have endured rude comments and harassment my entire life. On July 4, 1996 I was threatened with arrest if I would not leave a water park in Crestwood, Illinois. After other patrons complained to the owner, he informed me that I looked "terrible" and should wear a shirt or leave. I explained NF to him and assumed the matter was settled. Later however, he brought in the police and I was forced to leave. As a result of this experience I became active in Illinois NF, Inc. and have been on the board of directors since 1997.

WHAT IS NF?

NF is a genetic disorder involving the uncontrolled growth of tumors along the nervous system which can result in terrible disfigurement, deformity, deafness, blindness, brain tumors, cancer, and/or death. NF can also cause other abnormalities such as unsightly benign tumors across the entire body and bone deformities. In addition, approximately one-half of children with NF suffer from learning disabilities. It is the most common neurological disorder caused by a single gene. While not all NF patients suffer from the most severe symptoms, all NF patients and their families live their lives with the uncertainty of not knowing whether they will be seriously affected one day because NF is a highly variable and progressive disease.

Approximately 100,000 Americans have NF, and it appears in approximately 1 in every 3,500 births. It strikes worldwide, without regard to gender, race or ethnicity. Approximately 50 percent of new NF cases result from a spontaneous mutation in an individual's genes, and 50 percent are inherited. There are two types of NF: NF1, which is more common, and NF2, which primarily involves acoustic neuromas and other tumors, causing deafness and balance problems. Advances in NF research will benefit over 150 million Americans in this generation alone because NF is directly linked to many of the most common diseases affecting the general population.

LINK TO OTHER ILLNESSES

Researchers have determined that NF is closely linked to cancer, heart disease, learning disabilities, memory loss, brain tumors, and other disorders including deaf-

ness, blindness and orthopedic disorders. Research on NF therefore stands to benefit millions of Americans:

Cancer.—Research has demonstrated that NF's tumor suppressor protein, neurofibromin, inhibits RAS, one of the major malignancy causing growth proteins involved in 30 percent of all cancer. Accordingly, advances in NF research may well lead to treatments and cures not only for NF patients but for all those who suffer from cancer and tumor-related disorders. Similar studies have also linked epidermal growth factor receptor (EGF–R) to malignant peripheral nerve sheath tumors (MPNSTs), a form of cancer which disproportionately strikes NF patients.

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 involved in cancer also causes heart valves to close. Neurofibromin, the protein produced by a normal NF1 gene, suppresses ras, thus opening up the heart valve. Promising new research has also connected NF1 to cells lining the blood vessels of the heart, with implications for other vascular disorders including hypertension, which affects 45 million Americans. 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.

Learning disabilities.—Learning disabilities are the most common neurological complication in children with NF1. Research aimed at rescuing learning deficits in children with NF could open the door to treatments affecting 35 million Americans and 5 percent of the world's population. Indeed, leading researchers have already rescued learning deficits in both mice and fruit flies with NF1, which will benefit all people with learning disabilities, not just those with NF as well as save federal, state and local governments and school districts billions of dollars in special education costs.

Deafness.—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.

SCIENTIFIC ADVANCES

The progress that has been made in NF research has been nothing short of phenomenal. In just over a dozen years since the discovery of the NF1 gene, researchers are now on the threshold of developing a treatment and cure for this terrible disease. Scientists who previously had been pessimistic are now genuinely excited about engaging in therapeutic experimentation and the phase II clinical trials already being conducted by NIH. Because of NF's implication with so many other diseases, many NF researchers believe that NF should serve as a model to study all diseases. Indeed, one leading researcher has stated that more is known about NF genetically than any other disease.

In just the past few years, scientists have made major breakthroughs bringing NF fully into the translational era, with treatments close at hand. These recent advances have included:

—Phase II clinical trials on two drug therapies;
—Developing advanced mouse models showing human symptoms;
—Rescuing learning deficits in mice;
—Linking NF to hypertension, which affects 45 million Americans, as well as congenital heart disease; and
—Launching natural history studies to analyze the progression of the disease.

Other advances since 1990 include:

—*The discovery of the NF1 and NF2 genes and gene products*.—The NF1 gene was discovered in 1990 and the NF2 gene was discovered in 1993.
—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. Most strikingly, researchers have discovered that NF regulates both the c-AMP pathway affecting learning and memory as well as the ras pathway affecting cancer. This discovery, which brought together cancer and neurology through NF's controlling both of these related pathways, holds monumental implications for finding the treatments and cures for many diseases which affect a vast segment of the population.
—*Development of advanced animal models*.—Researchers have developed advanced mouse models which exhibit human symptoms, such as malignant tumors, leukemia, and learning disabilities. Such animal models provide a unique method for addressing the fundamental aspects of disease development and for testing therapeutic strategies. NF researchers have also developed the fruit fly as a model animal organism to study not only NF but many other diseases.

—*Commencement of clinical trials at NCI*.—As a result of the enormous progress made in NF research, NCI has already commenced two clinical trials with pediatric NF1 patients, including phase II trials using of farnesyl transferase inhibitors and phase I trials using pirfenidone, and is developing a third clinical trial.

—*Development of drug and gene therapies*.—Leading NF researchers have been actively engaged in developing both drug and gene therapeutic experimentation in mice and fruit flies. In the case of NF1, these experiments have been directly related to tumor suppression and learning deficits. Researchers also believe that a gene therapy for NF2 can be developed; unlike other genetic forms of deafness, in which a 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.

—*Rescuing learning deficits in animal models*.—A paper published in the January 30, 2002 edition of Nature demonstrated how researchers were able to rescue learning deficits in mice with the same mutation that causes NF1 in humans—disabilities once thought to be irreversible. This discovery has enormous implications for the 35 million Americans suffering from learning disabilities. Studies on fruit flies have also demonstrated that the neurofibromin protein regulates the c-AMP pathway which is known to control learning and memory.

—*Development of Infrastructure*.—Researchers, with the help of the government, have been building expanded national and international NF centers, consortia, and other infrastructure for clinical and translational research and treatment.

FUTURE DIRECTIONS

NF research has now advanced to the translational and clinical stages which hold incredible promise for NF patients, as well as for patients who suffer from many of the diseases linked to NF. This research is costly and will require an increased commitment on the federal level. Specifically, future investment in the following areas would continue to advance research on NF:

—Clinical trials;

—Development of a clinical trials network to connect patients with experimental therapies;

—Development of new drug and genetic therapies;

—Further development of advanced animal models;

—Expansion of biochemical research on the functions of the NF gene and discovery of new targets for drug therapy;

—Natural history studies and identification of modifier genes—studies are already underway to provide a baseline for testing potential therapies and differentiate among different phenotypes of NF; and

—Development of NF Centers, tissue banks, and patient registries.

CONGRESSIONAL SUPPORT FOR NF RESEARCH

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 seven Institutes at NIH are currently supporting NF research (NINDS, NCI, NICHD, NCRR, NEI, NIDCD, and NHLBI), and NIH's total research portfolio has increased from $3 million in 1990 to over $20 million in fiscal year 2004.

The enormous advances in NF research would not have been possible without Congress's continued support of the NIH, and I would like to personally thank the members of this Subcommittee for their leadership in doubling the budget of the NIH over 5 years.

At the same time, we are concerned that the NF research portfolio at both the National Cancer Institute and the National Institute of Neurological Disorders and Strokes has declined by several million dollars in recent years, despite appropriations report language recommending a greater investment. Given the potential offered by NF research for progress against a range of diseases, and the completion of the 5-year doubling of the NIH budget, we are hopeful that NCI and NINDS will substantially increase NF research funding. We appreciate the Subcommittee's strong support for NF research dating back to 1990, and will continue to work with you to ensure that opportunities for major advances in NF research are aggressively pursued.

This Subcommittee has long recognized that our goal should be to translate the promise of scientific discovery into an improved quality of life for all Americans. The example of the progress realized in NF research demonstrates the success of this vision and commitment.

Thank you again for the opportunity to tell you of the progress and potential of NF research.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2005 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of approximately 2,000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP would like to thank the Subcommittee for its continued strong support for increased funding for the National Institutes of Health (NIH) over the last several years, particularly the additional funding you have provided for the National Institute of Mental Health (NIMH), the National Institute on Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA). Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding for mental health research and treatment, AAGP brings a unique perspective to these issues because of the elderly patient population served by our members.

There are serious concerns, shared by AAGP and researchers, clinicians, and consumers that there exists a critical disparity between appropriations for research, training, and health services and the projected mental health needs of older Americans. This disparity is evident in the convergence of several key factors:

—demographic projections inform us that, with the aging of the U.S. population, there will be an unprecedented increase in the burden of mental illness among aging persons, especially among the baby boom generation;
—this growth in the proportion of older adults and the prevalence of mental illness is expected to have a major direct and indirect impact on general health service use and costs;
—despite the fact that effective treatment exists, the current mental health needs of many older adults remain unmet;
—the number of physicians being trained in geriatric mental health research and clinical care is insufficient to meet current needs, and this workforce shortfall is projected to become a crisis as the U.S. population ages over the next decade;
—a major gap exists between research, mental health care policy, and service delivery; and
—despite recent significant increases in appropriations for support of research in mental health, the allocation of NIMH and CMHS funds for research that focuses specifically on aging and mental health is disproportionately low, and woefully inadequate to deal with the impending crisis of mental health in older Americans.

DEMOGRAPHIC PROJECTIONS AND THE MENTAL DISORDERS OF AGING

With the baby boom generation nearing retirement, the number of older Americans with mental disorders is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental health problems. A national crisis in geriatric mental health care is emerging and has received recent attention in the medical literature. Action must be taken now to avert serious problems in the near future. While many different types of mental and behavioral disorders can occur late in life, they are not an inevitable part of the aging process, and continued research holds the promise of improving the mental health and quality of life for older Americans.

The current number of health care practitioners, including physicians, who have training in geriatrics is inadequate. As the population ages, the number of older Americans experiencing mental problems will almost certainly increase. Since geriatric specialists are already in short supply, these demographic trends portend an intensifying shortage in the future. There must be a substantial public and private sector investment in geriatric education and training, with attention given to the importance of geriatric mental health needs. We will never have, nor will we need, a geriatric specialist for every older adult. However, without mainstreaming geriatrics into every aspect of medical school education and residency training, broad-based competence in geriatrics will never be achieved. There must be adequate

funding to provide incentives to increase the number of academic geriatricians to train health professionals from a variety of disciplines, including geriatric medicine and geriatric psychiatry.

Current and projected economic costs of mental disorders alone are staggering. The direct medical expense to care for a patient with Alzheimer's disease ranges from $18,000 to $36,000 a year per patient, depending on the severity of the disease. In addition, there are substantial indirect costs associated with caring for an Alzheimer's disease patient including social support, care giving, and often nursing home care. It is estimated that total costs associated with the care of patients with Alzheimer's disease is over $100 billion per year in the United States. Psychiatric symptoms (including depression, agitation, and psychotic symptoms) affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, and family burden. These psychiatric symptoms, associated with Alzheimer's disease, can increase the cost of treating these patients by more than 20 percent. Although NIA has supported extensive research on the cause and treatment of Alzheimer's, treatment of these behavioral and psychiatric symptoms has been neglected and should be supported through NIMH.

Depression is another example of a common problem among older persons. Approximately 30 percent of older persons in primary care settings have significant symptoms of depression; and depression is associated with greater health care costs, poorer health outcomes, and increased mortality. Of the approximately 32 million Americans who have attained age 65, about 5 million suffer from depression, resulting in increased disability, general health care utilization, and increased risk of suicide. Older adults have the highest rate of suicide rate compared to any other age group. Comprising only 13 percent of the U.S. population, individuals age 65 and older account for 19 percent of all suicides. The suicide rate for those 85 and older is twice the national average. More than half of older persons who commit suicide visited their primary care physician in the prior month—a truly stunning statistic.

The enormous and widely underestimated costs of late-life mental disorders justify major new investments. The personal and societal costs of mental illness and addictive disorders are high, but advances in research and treatment will help save lives, strengthen families, and save taxpayer dollars.

THE BENEFITS OF RESEARCH ON PUBLIC HEALTH

The U.S. Surgeon General's Report on Mental Health (1999) and the Administration on Aging Report on Older Adults and Mental Health (2001) underscore the prevalence of mental disorders in older persons and provide evidence that research has lead to the development of effective treatments. These reports summarize research findings showing that treatments are effective in relieving symptoms, improving functioning, and enhancing quality of life. Preliminary findings suggest that these interventions reduce the need for expensive and intensive acute and long-term services. However, it is also well demonstrated that there is a pronounced gap between research findings on the most effective treatment interventions and implementation by health care providers. This gap can be as long as 15 to 20 years. These reports stress the need for translational and health services research focused on identifying the most cost-effective interventions, as well as creating effective methods for improving the quality of health care practice in usual care settings. A major priority (neglected to date) is the development of a health services research agenda that examines the effectiveness and costs of proven models of mental health service delivery for older persons.

Special attention also needs to be paid to inadequately or poorly studied, serious late-life mental disorders. Illnesses such as schizophrenia, anxiety disorders, alcohol dependence and personality disorders have been largely ignored by both the research community and the funding agencies, despite the fact that these conditions take a major toll on patients, their care givers, and society at large. Many of AAGP's members are at the forefront of groundbreaking research on Alzheimer's disease, depression, and psychosis among the elderly, and we strongly believe that more research funds must be focused in these areas. Improving the treatment of late-life mental health problems will benefit not only the elderly, but also their children, whose lives are often profoundly affected by their parents' illness.

While the funding increases supported by this Subcommittee in recent years have been essential first steps to a better future, a committed and sustained investment in research is necessary to allow continuous progress on the many research advances made to date.

NATIONAL INSTITUTE OF MENTAL HEALTH

In his fiscal year 2005 budget, the President proposed an increase of $729 million for the National Institutes of Health (NIH), which would bring the entire NIH budget to a level of $28.8 billion. However, this 2.6 percent increase over the fiscal year 2004 funding level pales in comparison with recent annual double-digit increases. A decline in adequate funding increases could have a devastating impact on the ability of NIH to sustain the ongoing, multi-year research grants that have been initiated in recent years.

For NIMH, the President is proposing $1.421 billion for scientific and clinical research, a 2.8 percent increase over the agency's fiscal year 2004 appropriation of $1.382 billion. It is important to note that from fiscal year 1999 through fiscal year 2004, NIMH received increases that lagged behind the increases received by many of the other NIH institutes. Furthermore, the increase proposed by the Administration for NIMH for fiscal year 2005 is lower than that proposed for most of the other institutes at NIH. As Congress moves forward with deliberations on the fiscal year 2005 budget, AAGP believes that NIMH should receive a percentage increase that, at the very minimum, is equal to the average percentage increase for the other NIH institutes.

Commendable as recent funding increases for NIH and NIMH have been, AAGP would like to call the Subcommittee's attention to the fact that these increases have not always translated into comparable increases in funding that specifically address problems of older adults. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the 5-year period from fiscal year 1995 through fiscal year 2000 (from $485,140,000 in fiscal year 1995 to $771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from $46,989,000 to $59,771,000).

AAGP is pleased that NIMH has recently renewed its emphasis on mental disorders among the elderly, and commends the recent creation of a new Aging Treatment and Prevention Intervention Research Branch at NIMH as well as the establishment of an intra-NIMH consortium of scientists concerned with mental disorders in the aging population. However, funding for aging mental health research is still not keeping pace with that of other adult mental health research, and is actually decreasing proportionally when considered in the context of anticipated projections in growth of mental disorders in older persons. For example, the proportion of total NIMH newly funded extramural research grant funding devoted to aging research declined from an average of 8 percent from fiscal years 1995 to 1999 to a low of 6 percent in fiscal year 2000. To reverse this trend, it will also be important to constitute grant review committees with specialized expertise in geriatrics to ensure a fair review of research proposals. Review committees must take into account knowledge of the unique biological factors associated with the aging brain, the high prevalence of co-occurring medical illnesses, and the specific systems for financing and health services delivery for older Americans. In addition, AAGP would like the scope of this branch increased into a comprehensive aging branch that is responsible for all facets of clinical research, including translational, interventions, and disease-based psychopathology. Further, the branch should be given adequate resources to fulfill its primary mission within NIMH.

In addition to supporting research activities at NIMH, AAGP supports increased funding for research related to geriatric mental health at the other institutes of NIH that address issues relevant to mental health and aging, including the National Institute of Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Neurological Disorders and Stroke.

CENTER FOR MENTAL HEALTH SERVICES

It is also critical that there be adequate funding increases for the mental health initiatives under the jurisdiction of the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA). While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. AAGP was pleased that the final budgets for fiscal years 2002, 2003 and 2004 included $5 million for evidence-based mental health outreach and treatment to the elderly. However, AAGP is extremely alarmed to see that this program was eliminated in President Bush's fiscal year 2005 budget proposal. Restoring and increasing this mental health outreach and treatment program must be

a top priority, as it is the only Federally funded services program dedicated specifically to the mental health care of older adults.

Originally funded in the Fiscal Year 2002 Labor-HHS-Education Appropriations (Public Law 107–116), AAGP worked with members of this Subcommittee and its House counterpart on this initiative, which was intended as a first step in the effort to curb the projected growth of older adults in America suffering from mental disorders. The House Appropriations Committee Report on Fiscal Year 2002 Labor-HHS-Education Appropriations states that $5 million should be appropriated for a senior mental health outreach and treatment program within CMHS and that the funds are "intended to begin to address" the predicted increase of older adults suffering from mental illness. Regarding the same program, the Senate Appropriations Committee Report states, "The Committee strongly encourages CMHS to devote additional resources in fiscal year 2002 and subsequent fiscal years to this issue." Unfortunately, this initiative has not seen the subsequent increases its creators intended when Congress created this program.

Funding for the dissemination and implementation of evidence-based practices in "real world" care settings must be a top priority for Congress. Despite significant advances in research on the causes and treatment of mental disorders in older persons, there is a major gap between these research advances and clinical practice in usual care settings. The greatest challenge for the future of mental health care for older Americans is to bridge this gap between scientific knowledge and clinical practice in the community, and to translate research into patient care. Adequate funding for this geriatric mental health services initiative is essential to disseminate and implement evidence-based practices in routine clinical settings across the states. Consequently, we would urge that the $5 million for mental health outreach and treatment for the elderly included in the CMHS budget for fiscal year 2004 not only be restored, but also be increased to $20 million for fiscal year 2005.

Of that $20 million appropriation, AAGP believes that $10 million should be allocated to a National Evidence-Based Practices Program, which will disseminate and implement evidence-based mental health practices for older persons in usual care settings in the community. This program will be a collaborative effort, actively involving family members, consumers, mental health practitioners, experts, professional organizations, academics, and mental health administrators. With $10 million dedicated to a program to disseminate and implement evidence-based practice in geriatric mental health, there will be an assured focus on facilitating accurate, broad-based sustainable implementation of proven effective treatments, with an emphasis on practice change and consumer outcomes. Such a program should include several development phases including identification of a core set of evidence-based practices, development of evidence-based implementation, and practice improvement toolkits and field-testing of evidence-based implementation. This program will provide the foundation for a longer-term national effort that will have a direct effect on the well-being and mental health of older Americans.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

One of the most valuable resources in our efforts to improve access to and the quality of geriatric mental health services is the Agency for Healthcare Research and Quality (AHRQ). In recent years the Agency has supported important research on mental health topics including studies on children's mental health issues, the impact of mental health parity on consumers' share of mental health costs, improving care for depression in primary care, and cultural issues in the treatment of mental illness in minority populations. This work has led to important contributions to the mental health literature, and the advancement of effective diagnosis and treatment of mental illness. We applaud these efforts and urge the Committee to increase support for the critical work of this Agency.

However, we are concerned that the research agenda of the Agency has not given more attention to geriatric mental health issues. The prevalence of undiagnosed and untreated mental illness among the elderly is alarming. Conditions such as depression, anxiety, dementia, and substance abuse in older adults are often misdiagnosed or not recognized at all by primary and specialty care physicians. There is accumulating evidence that depression can exacerbate the effects of cardiac disease, cancer, strokes, and diabetes. Research has also shown that treatment of mental illness can improve health outcomes for those with chronic diseases. Effective treatments for mental illnesses in the elderly are available, but without access to physicians and other health professionals with the training to identify and treat these conditions, far too many seniors fail to receive needed care.

AAGP believes there is an urgent need to translate findings from aging-related biomedical and behavioral research into geriatric mental health care. By utilizing

the resources of the evidence-based practice centers under contract to AHRQ, results from geriatric mental health research can be evaluated and translated into findings that will improve access, foster appropriate practices, and reduce unnecessary and wasteful health care expenditures. We urge the Committee to direct AHRQ to support additional research projects focused on the diagnosis and treatment of mental illnesses in the geriatric population. We also believe a high priority should be given to the dissemination of scientific findings about what works best, to encourage physicians and other health professionals to adopt "best practices" in geriatric mental health care.

CONCLUSION

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following fiscal year 2005 funding recommendations:

1. The current rate of funding for aging grants at NIMH and CMHS is inadequate. Funding for NIMH and CMHS aging-related health services grants should be increased to be commensurate with current need—at least three times their current funding levels. In addition, the substantial projected increase in mental disorders in our aging population should be reflected in the budget process in terms of dollar amount of grants and absolute number of new grants;
2. Previous years' funding of $5 million for evidence-based mental health outreach and treatment for the elderly within CMHS was eliminated in President Bush's fiscal year 2005 budget proposal. To help the country's elderly access necessary mental health care, this funding must be restored and increased to $20 million;
3. A fair grant review process will be enhanced by committees with specific expertise and dedication to mental health and aging;
4. Adequate infrastructure and funding within both NIMH and CMHS to support the development of initiatives in aging research, to monitor the number and quality of applicants for aging research grants, to promote funding of meritorious projects, and to manage those grant portfolios;
5. The scope of the recently formed Aging Treatment and Prevention Intervention Research Branch at NIMH should be increased to include all relevant clinical research, including translational, interventions, and disease-based psychopathology, and must receive NIMH's full support so it may fulfill its primary mission;
6. AHRQ should undertake additional research projects focused on the diagnosis and treatment of mental illnesses in the geriatric population, and dissemination of information on best practices; and
7. Funding for NIAAA must be increased by at least 20 percent to enable it to undertake more research and collect more data focused on issues such as the link between alcohol use and late-life suicide and the impact of alcohol use across the lifespan.

AAGP strongly believes that the present research infrastructure, professional workforce with appropriate geriatric training, health care financing mechanisms, and mental health delivery systems are grossly inadequate to meet the challenges posed by the expected increase in the number of older Americans with mental disorders. Congress must support funding for research that addresses the diagnosis and treatment of mental illnesses, as well as programs for delivery of geriatric mental health services that increase the quality of life for those with late-life mental illness.

AAGP looks forward to working with the members of this Subcommittee and others in Congress to establish geriatric mental health research and services as a priority at NIMH, CMHS, AHRQ and NIAAA.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM), the largest single life science society with 43,000 members, is pleased to provide testimony in support of the nation's investment in the extraordinary work of the National Institutes of Health (NIH). Advances in NIH research have markedly intensified over the past 5 years during which the NIH budget has grown thanks to the foresight of Congress and the Administration. Robust funding increases have resulted in rapid strides in cutting edge research and new research tools to facilitate the development of vaccines, therapies and interventions that save and improve the lives of millions of people.

To ensure that progress is sustained, the ASM recommends that Congress make research and public health a high national priority and provide an increase of 10 percent for the NIH for fiscal year 2005. Continued strong funding increases will enable NIH to accelerate and expand promising basic and clinical research that will

lead to new preventions and treatments for tragic and costly illnesses and disabilities that continue to afflict and claim the lives of many people. The ASM encourages Congress to provide higher funding levels for research and public health that will address the alarming burden of disease in the United States and abroad and help prepare the nation for novel health threats and the next disease emergency that will inevitably occur in the future.

The public health and security of the nation depend on the continuation of strong investments in research and public health. The severe acute respiratory syndrome (SARS) epidemic of 2003 highlights the continuing need for investment in a strong biomedical and public health system that is prepared to respond to emerging diseases, whether naturally occurring or intentionally introduced. Previous NIH investment in emerging diseases research has allowed expeditious studies of SARS to identify targets for antiviral drugs, diagnostics and vaccines. Not only are people at risk for chronic diseases such as cancer, heart disease, stroke, diabetes and Alzheimer's disease, but also from new and emerging infectious diseases, such as the HIV pandemic, highly virulent influenza viruses, West Nile Virus, hepatitis A and C, and the possibility of the deliberate release of disease by bioterrorists, which still remains a threat.

The accomplishments and investment in biodefense research, facilities and resources should also facilitate defenses against naturally occurring infectious diseases that pose a real and present danger to global public health. Infectious diseases account for 26 percent of total global mortality and are the third leading cause of death in the United States. Despite impressive advances in microbiology, old diseases remain entrenched and new ones can appear suddenly and spread quickly. Sufficient and sustained federal funding for research helps protect against these enemies to public health.

INVESTIGATOR INITIATED RESEARCH

Most of the budget appropriated to the NIH each year flows outside the agency to an estimated 212,000 research personnel affiliated with approximately 28,000 organizations across the United States and elsewhere. This extramural research community competes for NIH grants through a merit based peer-review process; of the growing number of applications each year, estimated to exceed 35,000, less than one-third are projected to receive NIH funding. The proposed fiscal year 2005 budget supports an increase in the number of new and competing grants from 10,135 to 10,393, an additional 258 grants. Investigator initiated research is the primary tool by which biomedical research is funded and conducted and requires increased funding to take advantage of scientific opportunities that lead to new knowledge and its applications to health care.

NIH ROADMAP FOR MEDICAL RESEARCH

Within the proposed fiscal year 2005 budget, the NIH Roadmap for Medical Research plan would receive $237 million, an increase of $109 million over fiscal year 2004. Announced in September 2003, this set of 27 initiatives actuates an agency wide commitment to maximize research investment through intensive, multi-disciplinary projects with high potential to solve serious health problems. The Roadmap realizes three 21st-century visions of a vigorous research enterprise: building new pathways to discovery through new technologies, databases, and other resources; creating multidisciplinary research teams better prepared to tackle the complexities of modern research; and re-engineering clinical research structures to expedite the rapid translation of discoveries from the lab to the clinic. This trans-NIH effort is an approach that promises to stimulate research advances and interventions for public benefit.

BIODEFENSE RESEARCH

After the anthrax mail attacks of 2001, biodefense research has emerged as a major feature of the NIAID's mission to understand the pathogenesis of disease-causing microorganisms and host responses to them. NIAID scientists now are pursuing numerous countermeasures as therapeutics, diagnostics, and vaccines. The agency mobilizes research capabilities and extramural partnerships to prepare against "deliberately emerging disease" outbreaks. The NIH and particularly the NIAID have become significant partners in the broad-based, multi-faceted U.S. homeland security program. The fiscal year 2005 budget highlights the significance of NIAID biodefense efforts, with nearly $1.7 billion for research and infrastructure, 4.5 percent above fiscal year 2004's $1.6 billion.

The biodefense agenda at the NIAID reflects a new focus on science based security. Basic research forms the backbone of the NIAID counterterrorism efforts and

includes microbial physiology and ecology, genomics, studies of pathogenesis and host defenses, and development of animal disease models. Strong funding appropriations by Congress and the Administration over the past 2 years have made possible significant progress, evidenced by the more than 50 major NIAID biodefense initiatives now in place. Most of these initiatives are new, with intramural, academic, and industrial partners investigating all aspects of bioagents and emerging diseases. Components include expansion of the nation's biodefense laboratory infrastructure, enhanced communication and data-collecting networks, interdisciplinary studies on potential bioweapons, and investigations into basic mechanisms of disease and disease pathogens.

In 2003 NIAID and its collaborators achieved significant successes in both basic and applied areas related to biodefense. A candidate vaccine against the Ebola virus was found to protect lab monkeys against the deadly disease. Other researchers discovered that the anthrax bacterium toxin affects host cells in a previously unknown manner, which will redirect some aspects of anthrax therapeutics. Genome sequencing projects are on going for at least one strain of every bacterium, virus or protozoan considered a of priority pathogen. This vast genomics effort includes mapping of agents for such diseases as anthrax, brucellosis, Q fever, plague, smallpox, and tuberculosis. Researchers recently developed a rapid test for measuring antibodies to vaccinia that is 5 to 10 times more sensitive than standard detection techniques. NIAID has screened more than 800 compounds for antiviral activity against poxviruses and two clinical trials of a new smallpox vaccine have been completed. The search continues for vaccines against a long list of pathogenic bacteria and viruses, including next generation vaccines against smallpox and new vaccines for plague, tularemia, and other viral hemorrhagic fevers.

Current NIAID biodefense programs build upon the NIH tradition of creating networks of institutions and scientists best qualified to solve complex problems. Last year the NIAID funded 8 of the 10 planned Regional Centers for Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs), at a cost of about $350 million to be expended over 5 years. The RCEs will be responsible for a broad range of basic and applied research on disease biology, vaccines, and antibiotics, as well as development of novel computational and genomic approaches. As regional centers of excellence, they also will train new generations of science professionals in biodefense research, provide facilities for area researchers, and supply facilities and support to first-line responders in the event of a biodefense emergency. The NIH also is adding new biodefense-research facilities at its own Bethesda campus and at other NIH locations. Last fall, NIAID construction grants were awarded to leading universities for nine high-level biosafety laboratories. These state-of-the-art labs will contain special engineering and design features to prevent release into the environment of the most deadly microorganisms. The facilities also will be available to assist national, state and local public health officials when needed. Similar cooperative programs were established by the NIAID to encourage biodefense research within the pharmaceutical industry, human immunology research institutes, and computational science centers. The proposed fiscal year 2005 budget includes continued support of these efforts, as well as funding for the final two Centers for Excellence and $150 million for an additional 20 high-level biosafety laboratories.

INFECTIOUS DISEASE RESEARCH AND PUBLIC HEALTH

Centuries of triumph and defeat mark the human struggle against infectious disease. Many infectious diseases persist and continue to plague us. Each year populations are beset by one or more previously unknown diseases or pathogens. The World Health Organization estimates that more than 1,600 die each hour from an infectious disease, half under 5 years of age. Others suffer with debilitating infections. For instance, an estimated 40 million people worldwide are living with HIV/AIDS. Tuberculosis, malaria, and other familiar intractable diseases kill or sicken millions annually. New outbreaks surprise and alarm nations. Being prepared to detect, treat, and prevent any infectious disease is the central, science based mission of the NIAID, with well-funded medical research.

Newly emerging and re-emerging or resurging infectious diseases constantly change the landscape of microbiological research, creating moving targets for medical intervention and prevention. West Nile virus, monkeypox, dengue, multi-drug resistant tuberculosis and malaria are current examples of what faces NIAID-supported investigators. Last year's SARS outbreak illustrates the breadth and depth of NIAID research and response capabilities. It is a cautionary tale of how a previously unknown disease can quickly become a global news story of significant economic and public health importance. Within months the new respiratory illness had caused more than 8,000 cases and nearly 900 deaths in 30 countries, severely dis-

rupting international trade and travel—and yet it became a triumph for science and public health efforts, in large part due to effective, well-funded NIAID research. NIAID-supported scientists in Hong Kong were the first to show that SARS was caused by a virus; within days, they and CDC investigators identified the virus as a previously unknown type of coronavirus. An ongoing NIAID-funded program of influenza surveillance then found animal carriers of the virus in food markets in China. Related NIAID-supported work quickly followed, including several genetic analyses of the virus underway, an NIAID-developed mouse model of SARS, screening of up to 100,000 antiviral compounds for anti-SARS activity, several parallel approaches to vaccine development, as well as joint projects with private industry, researchers abroad, and China's Center for Disease Control. NIAID funding led to quick development of a rapid diagnostic test now being improved, and NIAID provides researchers with free SARS "gene chips" embedded with a reference strain of the virus for genetic screening of isolates. NIAID's extensive and multi-layered quick response to SARS was possible largely because of previous investments in virus and respiratory disease research.

Each year NIAID responsibilities for novel diseases grow greater, not less. Today a new threat of global potential, the so-called bird flu or H5N1 influenza, is emerging to join diseases like West Nile virus infection and bovine spongiform encephalopathy (BSE) as targets of NIAID initiatives. NIH supported laboratories are world leaders in research on transmissible spongiform encephalopathies that include BSE, Creutzfeldt-Jakob disease in humans, and chronic wasting disease in deer and elk. Last year there were more than 9,000 human cases of mosquito-borne West Nile virus infection in the United States. Since first detected in 1999, WNV has spread throughout North America and beyond. NIAID-supported scientists have developed an immunoassay to identify WNV and a new treatment already in early clinical trials.

A myriad of infectious diseases continue to take a toll on people worldwide. Infections of the respiratory tract continue to be the leading cause of acute illness worldwide. In the United States, diarrhea is the second most common infectious illness and diarrheal diseases account for 15 to 34 percent of deaths in some countries. NIAID funding supports a broad variety of basic and applied research to better understand food- and waterborne-illnesses. Sexually transmitted infections (STIs) affect over 15 million people in the United States each year. NIAID-supported researchers recently discovered an unusual bacterium that may be the cause of many reproductive tract infections in women. More than 25 STIs have now been identified, and NIAID is supporting multiple projects aimed at preventing and treating STIs. Currently a new vaccine for genital herpes is in advanced clinical trials.

Together, HIV/AIDS, malaria and tuberculosis account for more than 5 million deaths each year. One of the principal goals of 21st-century medical science is the development of safe and effective vaccines against these three global killers. In the United States, more than 500,000 have died from AIDS-related illness; the CDC estimates that 850,000 to 950,000 Americans are living with HIV infection. HIV/AIDS research continues to be a significant component of NIH research: The Administration's fiscal year 2005 budget requests $2.9 billion for HIV/AIDS research at NIH, a 2.8 percent increase over fiscal year 2004. NIAID investigators continue to develop new treatments, and the number of AIDS vaccines in development and testing increases steadily.

Malaria threatens more than one-third of the world's population and kills more than 1 million each year. Although United States cases of malaria are unusual, the NIAID has become a leader in the accelerated development of malaria vaccines. The agency has initiated its first trial of a candidate malaria vaccine in Africa. One-third of the world's population also fights tuberculosis, another major global focus of the NIAID. A new recombinant vaccine made with several proteins from the bacterium that cause TB will soon enter human trials. Scientists recently discovered genetic mutations in the tuberculosis bacterium that contribute to worrisome antibiotic resistance.

The increasing use of antimicrobials in humans, animals and agriculture has contributed to pathogen resistance to antibiotics and some diseases are becoming more difficult to treat because of the emergence of drug resistance. NIAID supports antimicrobial research and the goals of the Interagency Task Force for Antimicrobial Resistance.

In recognition of impressive NIAID contributions to public health and homeland security, the ASM emphasizes that only sustained financial investment will guarantee continued success against today's infectious diseases, tomorrow's unpredictable pathogens, and the growing threat of antimicrobial resistance.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (HSUS) and our more than 8 million supporters nationwide, we appreciate the opportunity to provide testimony on our top funding priority for the Labor, Health and Human Services, and Education Subcommittee in fiscal year 2005.

PAIN AND DISTRESS RESEARCH

An estimated 40 percent of the National Institutes of Health (NIH) budget—or currently more than $11 billion—is devoted to some aspect of animal research. At this time, no funding is set aside specifically for research into alternatives that replace or reduce the use of vertebrate animals in research or that reduce the amount of pain and distress to which research animals are subjected. NIH may receive $28.8 billion in fiscal year 2005 if Congress fulfills the President's budget request. Out of this funding, we seek $2.5 million (0.009 percent) for research and development focused on identifying and alleviating animal pain and distress. We recommend that this R&D be conducted under the National Center for Research Resources (NCRR, responsible for NIH extramural funding). We also urge the Committee to specify in report language that NCRR should conduct this research in conjunction with, or "piggy-backed" onto, ongoing research that already causes pain and distress. No pain and distress should be inflicted solely for the purpose of this research, given the volume of existing research (we estimate a minimum of 20–25 percent of all animal research) that is believed to involve moderate to significant pain and/or distress.

In 1987, NIH announced a program to award grants for "research into methods of research that do not use vertebrate animals, use fewer vertebrate animals, or produce less pain and distress in vertebrate animals used in research." Many of the 17 program awards made from 1987 to 1989, totaling approximately $2.4 million, involved research on non-mammalian models, including projects on frogs, mollusks, and insects. Other awards included mathematical modeling and computer studies. This program, which was managed out of the Division for Research Resources (the precursor to NCRR), no longer exists at NIH, and it has not been replaced by any similar program.

A 2001 survey conducted by an independent polling firm indicates that concern about animal pain and distress strongly influences public opinion about animal research in general. Public support for animal research declines dramatically when pain and distress are involved: 62 percent support animal research when pain and distress are minimal, only 34 percent when moderate, and an even smaller 21 percent when animal suffering is severe. Despite this public concern, NIH has not continued to sponsor R&D exploring how to minimize animal suffering and distress in the laboratory.

During the past several years, our organization has been reviewing institutional policies and practices with respect to pain and distress in animal research. We have found that research institutions have inconsistent policies due to the lack of information on this subject, and that standards vary greatly from one institution to another. Painful techniques, such as the use of carbon dioxide to euthanize rats and mice, are widely practiced and approved even though studies indicate that carbon dioxide exposure for only a few seconds causes acute distress to humans. The federal standard for determining laboratory animal pain specifies that, if a procedure causes pain or distress to humans, it should be assumed to cause pain and distress to animals. Furthermore, while human experience can and should provide a useful guide in some cases, there are others in which humans are never subjected to the conditions facing laboratory animals. Information on pain and distress that animals themselves actually experience is important. For many accepted laboratory practices there is no scientific data regarding the painful or distressing effects on either people or animals.

A lack of data on the recognition, assessment, alleviation, and prevention of pain and distress in laboratory animals is commonly cited by scientists as a rationale for either not reporting pain and distress or not acting to mitigate it. This lack of data is obviously detrimental to the welfare of animals used in research, but it is also detrimental to the quality of science produced. Uncontrolled, undetected, and unalleviated pain, physical distress, or psychological distress result in alterations in physiologic and behavioral states, and confound the outcome of scientific research. Ultimately, the lack of information on pain and distress leads to misinterpretation of research results that could result in harmful effects in human beings when preclinical animal research results are applied to humans in clinical trials. It is worth noting that researchers themselves often comment publicly at scientific meetings

about the urgent need for funding in order to properly understand and mitigate pain and distress in research animals.

Our nation takes pride in leading the world in biomedical research, yet we lag behind many other countries in our efforts to minimize pain and distress in animal subjects. For example, the United Kingdom, Sweden, Switzerland, Germany, the Netherlands and the European Union all have committed funds specifically for the "three R's" (replacing the use of animals, reducing their use, and refining research techniques to minimize animal suffering).

We urge the Committee to make this small investment of $2.5 million to promote animal welfare and enhance the integrity of scientific research. We also respectfully request this accompanying committee report language:

"The Committee provides $2.5 million for the National Center for Research Resources to support research and development focused on improving methods for recognizing, assessing, and alleviating pain and distress in research animals. No pain and distress should be inflicted solely for the purpose of this initiative, since the investigations can and should be conducted in conjunction with ongoing research that is believed to involve pain and distress under Government Principle IV of Public Health Service Policy, which assumes that procedures that cause pain and distress in humans may cause pain and distress in animals."

Again, we appreciate the opportunity to share our views and top priority for the Labor, Health and Human Services, and Education Appropriation Act of fiscal year 2005. We hope the Committee will be able to accommodate this modest request that will benefit animals in research and the quality of the research. Thank you for your consideration.

PREPARED STATEMENT OF THE SOCIETY OF NUCLEAR MEDICINE

The Society of Nuclear Medicine (SNM) appreciates the opportunity to submit written comments for the record regarding funding for workforce education and training and biomedical research related programs in fiscal year 2005. SNM is an international scientific and professional organization founded in 1954 to promote the science, technology and practical application of nuclear medicine. Its 14,000+ members are physicians, technologists and scientists specializing in the research and practice of nuclear medicine.

To that end, SNM advocates ongoing and significant federal funding for programs to help ensure an adequate nuclear medicine workforce to care for the nation's citizens as well as increasing the our investment in biomedical research. The Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from disease.

WHAT IS NUCLEAR MEDICINE?

Nuclear medicine is a medical specialty that involves the use of small amounts of radioactive pharmaceuticals, called "Radiotracers" or "Tracers," to help diagnose and treat a variety of diseases. These tracers are detected by special types of cameras that work with computers to provide nuclear medicine physicians and the patient's doctor precise pictures of the area of the body being imaged. It is a way to gather medical information that may otherwise be unavailable, require exploratory surgery, or necessitate more expensive diagnostic tests.

Nuclear medicine procedures, such as PET (positron emission tomography) and SPECT (single-photon emission tomography), often identify abnormalities very early in the progression of a disease—long before some medical problems are apparent with other diagnostic tests. This early detection allows a disease to be treated early in its course when there may be a more successful prognosis.

An estimated 16 million nuclear medicine imaging and therapeutic procedures are performed each year in the United States. Nuclear medicine procedures are among the safest diagnostic imaging tests available. The amount of radiation from a nuclear medicine procedure is comparable to that received during a diagnostic x-ray.

Some of the more frequently performed nuclear medicine procedures include:

—Bone scans to examine orthopedic injuries, fractures, tumors or unexplained bone pain.

—Cardiac scans to identify normal or abnormal blood flow to the heart muscle, measure heart function or determine the existence or extent of damage to the heart muscle after a heart attack.

—Breast scans which are used in conjunction with mammograms to more accurately detect and locate cancerous tissue in the breasts.

—Liver and gallbladder scans to evaluate liver and gallbladder function.

—Cancer imaging to detect tumors and determine the severity (staging) of various types of cancer.
—Treatment of thyroid diseases and certain types of cancer.
—Brain imaging to investigate problems within the brain itself or in blood circulation to the brain.
—Renal imaging in children to examine kidney function.

SECURING AND MAINTAINING AN ADEQUATE NUCLEAR MEDICINE WORKFORCE

The field of nuclear medicine is not attracting enough incoming students to fill the current demand for nuclear medicine technologists (NMTs). Currently, there is approximately an 18 percent vacancy of NMTs as determined by the American Hospital Association (AHA). By 2010, the Bureau of Labor Statistics (BLS) projects that the United States will need an additional 8,000 NMTs to fill the projected demand created by the aging workforce and expanding senior population. Over the next 20 years, the BLS expects that there will be a 140 percent increase in the demand for imaging services. The use of diagnostic imaging services has been increasing by approximately 4 percent a year, even as the number of certified NMTs and registered radiologic technologists has remained stable. As a result, imaging technologists often work longer shifts and patients can face weeks of delay for routine exams.

A similar situation to the shortage of NMTs is developing for nuclear medicine physicians. According to the American Board of Medical Specialties (ABMS), there currently are 4,087 certified nuclear medicine physicians in the United States. At the same time, the number of physician training programs is also declining, exacerbating the future shortage.

Over the next 20 years, the number of people over the age of 65 with cancer is expected to double at the exact same time the nation will face shortages of medical personnel—including NMTs, physicians, nurses, laboratory personnel, and other specialists. New technology and an aging population have increased demand for NMTs, but personnel capacity is not keeping pace with the need. With an increasing number of people needing specialized care—such as nuclear medicine—coupled with an inadequate workforce, our nation faces a health care crisis of serious proportion with limited access to quality health care, particularly in traditionally underserved areas.

The workforce education and training programs at the Health Resources and Services Administration (HRSA) have created a network of initiatives across the country that supports the training of many disciplines of health providers. These are the only federal programs designed to create infrastructures at schools and in communities that facilitate customized training designed to bring the latest emerging national priorities to the populations at large and meet the health care needs of special, underserved populations.

These important workforce education and training programs are designed to increase access to health care in underserved areas by improving the quality, geographic distribution, and diversity of the health care workforce. To that end, SNM recommends funding of at least $550 million to fulfill this mission in the fiscal year 2005.

Additionally, the number of residency slots for training physicians in nuclear medicine is declining. The Society urges Congress to establish a nuclear medicine residency-training fund of $2 million per year for 5 years. This fund would provide 50 residency training positions each year to be used for an additional year of nuclear medicine training of radiology residents and additional 2-year nuclear medicine residencies. This addition of trained physicians will help ease the work force shortage and add to the number of available radiation protection experts in the event of a dirty bomb or other radiation incident.

SUSTAIN AND SEIZE RESEARCH OPPORTUNITIES

Our nation has profited immensely from our past federal investment in biomedical research at the National Institutes of Health (NIH). SNM is proud to join with the rest of the public health community in advocating $30.19 billion for the NIH in fiscal year 2005. This increase of 8.5 percent over fiscal year 2004 funding will allow NIH to sustain and build on its research progress resulting from the recent NIH budget doubling effort while avoiding the severe disruption to that progress that would result from a minimal increase.

The first successful nuclear magnetic resonance (NMR) experiments were performed in 1946 leading to the first nuclear magnetic resonance imaging (MRI) exam was performed on a human being in 1977. Critical advances in technology development now allow physicians to image in seconds what used to take hours. Research in biomedical imaging and bioengineering is progressing rapidly and recent techno-

logical advances have revolutionized the diagnosis and treatment of disease. Therefore, SNM requests $325 million for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to further the Institute's research in the development and application of emerging and breakthrough biomedical technologies that will facilitate improved disease detection, management, and prevention.

Cancer research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. We have seen extraordinary advances in cancer research resulting from our national investment that have produced effective prevention, early detection and treatment methods for many cancers. To that end, SNM asks the Committee to allocate $6.2 billion for the National Cancer Institute (NCI) in fiscal year 2005 as recommended by the NCI Director in the Bypass Budget submitted to Congress annually under the requirements of the National Cancer Act of 1971. The Bypass Budget represents the best estimation of the scientific community regarding the resources needed to continue our battle against cancer.

CONCLUSION

The Society of Nuclear Medicine once again stands ready to work with policymakers to advance policies that will reduce and prevent suffering from disease for all Americans, while ensuring an adequate nuclear medicine workforce. Again, we thank you for the opportunity to present our views on funding for nuclear medicine workforce and research related programs and stand ready to answer any questions you may have.

PREPARED STATEMENT OF THE NATIONAL PROSTATE CANCER COALITION

Mr. Chairman and members of the Committee, thank you for the opportunity to share my remarks. The National Prostate Cancer Coalition (NPCC) was founded in 1996 to combat a long overlooked killer of men. I came to NPCC in 2001, having just recently been impacted by the disease myself. In 2000, my grandfather was diagnosed with prostate cancer. Having served his country so valiantly in World War II, he was now facing a new battle. Luckily, because of early detection through the prostate specific antigen (PSA) test and the digital rectal exam (DRE), the disease was caught early and, following a radical prostatectomy, he is now cancer free. But there are many men who are not so lucky. That's why you must adequately fund prostate cancer research for veterans like my grandfather, families like mine, and men all over America.

Under the leadership of this committee we have seen prostate cancer research funding increase by nearly $300 million since in the last 6 years. While we have come a long way, there is still much work to be done. For the first year since the founding of NPCC, prostate cancer deaths will increase in 2004. Nearly 30,000 lives will be lost to the disease. Occurrences of prostate cancer are increasing as well, to over 230,000 men this year. While cases continue to grow, more men are catching the disease in its early stages, when the disease is most treatable, by early detection through screening.

NPCC would like to offer its gratitude on behalf of the 2 million American men with prostate cancer for the support this committee has offered in the past. The recent doubling of the National Institutes of Health's (NIH) budget has helped prostate cancer research funding to expand to record levels, but we must ensure this funding is used appropriately. To that end, your committee was instrumental in requiring NIH and the National Cancer Institute (NCI) to submit a professional judgment budget for fiscal year 2003-fiscal year 2008 to outline the agencies' plans for prostate cancer research. You have also been influential in requesting a fiscal budget for that document, which is expected to be submitted to the Committee by April 2004 (Senate Rpt. 108–081). While no one disputes the historic importance of doubling, we ask you to use your oversight capacity to ensure this funding is producing results for prostate cancer. Huge sums of taxpayers' money have been allocated to NIH over the years and it is now time to examine what this windfall has produced. Therefore, we request that you ask NIH to submit a yearly update on its prostate cancer research portfolio that reflects its progress according to the fiscal year 2003–fiscal year 2008 professional judgment budget.

We are entering an exciting time in biomedical research. The recent Food and Drug Administration's approval of Avastin has opened a new door for cancer research. Avastin targets cancerous cells by blocking their blood supply, an idea that had been previously dismissed by the medical community as "absurd." The drug not only signals a turning point in changing cancer into a manageable, chronic disease but also demonstrates the value of seeking out novel and innovative research. We

must encourage this kind of research at NIH, including assessing the value of stem cell research which has shown promise in research for neurological diseases, diabetes, and cancer.

Developing a new approach to research is a priority for NPCC. The Prostate Cancer Research Funders Conference, first convened in 2001 and then revitalized last fall, seeks to formulate a collaborative, public-private approach to seek out new ways of attacking the problem of prostate cancer. Originally co-convened by NPCC and NCI, participants now also include the Department of Defense, the Veterans Health Administration, the Centers for Disease Control and Prevention, the Food and Drug Administration, Canadian and British government agencies, private foundations/organizations and representatives from industry. Members of the Conference have come together to form a partnership that allows them to focus on key objectives and to address commonly recognized barriers in research. This could propel research forward significantly. As the Conference continues, we ask that the Committee make its functionality part of its oversight commitments to prostate cancer research. Currently, federal agencies participate voluntarily, but they can opt in or out based on the tenure of executive leadership and its time-limited decisions. For the conference to be successful federal agencies engaged in the prostate cancer research should, in our opinion, be required to participate, and we ask for your leadership to make that happen.

Recognizing the importance of cutting edge research initiatives and collaborative research efforts, NIH director Elias Zerhouni, M.D. recently unveiled the NIH Roadmap. The Roadmap's strategy mirrors that of the Funders Conference, specifically by seeking out new approaches and ideas and stimulating cross-institutional and cross-center research for all NIH driven biomedical research. Believing, we think correctly, that the synergies in the Roadmap can achieve outcomes that are greater than those any one Institute or Center can achieve, we support its efforts to advance key biomedical research initiatives at an exponential rate. NPCC applauds the Roadmap and pledges its support to take biomedical research in new directions.

As NIH and NCI look to redefine and increase the efficiencies of their research programs, Congress must equip them with the resources they need to implement new initiatives. Unprecedented increases in NIH and NCI's funding over the last 6 years have created opportunities never before available. We must take advantage of these achievements, to not do so will not only harm cancer patients everywhere but is, quite simply, poor business sense.

In his fiscal year 2005 budget, President Bush has requested a 2.6 percent increase ($28.8 billion) in NIH funding over the fiscal year 2004 level. Over the past 30 years, the agency has averaged an annual growth rate of 8 percent. Leading biomedical research groups like the Federation of American Societies for Experimental Biology (FASEB) have stated if increases are held to 2 percent-3 percent the grant funding rate at NIH will drop below 30 percent and approximately 500 fewer grants would be funded. To allow NIH and NCI to adequately continue to fund promising grants and research first realized during the budget doubling, Congress must appropriate at least an 8.5 percent increase ($30.25 billion) in funding for these agencies in fiscal year 2005. That may seem like a large number, but in reality, it is only a small fraction of the estimated $189 billion that cancer alone costs this nation yearly.

Increasing NIH's budget by 8.5 percent would also allow NCI to dedicate more than $400 million to prostate cancer research in fiscal year 2005. Last year, NCI received only a 3.3 percent increase in funding over the previous year's level. Yet, with previously committed grant awards and outlays to the NIH Roadmap, NCI is "effectively operating with a budget that is $2.7 million less than last year's operating budget (NCI Cancer Bulletin 2/3/04)." The President's fiscal year 2005 budget allocates $4.87 billion to NCI, slightly less than the fiscal year 2004 increase. This level will mean even tougher choices in awarding grants at NCI. We believe that Congress should fully fund the NCI Director's Bypass Budget at $6.2 billion, which would rapidly accelerate the nations' fight against all cancers.

As you know, education and early detection through screening are the catalyst to beating prostate cancer. Right now, the PSA blood test and DRE physical exam are the best measures for detecting prostate cancer early. We ask the Committee to allocate at least $20 million to the Center for Disease Control and Prevention's (CDC) prostate cancer awareness program. We also encourage the Committee to work with CDC to address our concern that the agency places insufficient value on these screening tools.

Thank you again for the leadership you have shown in advancing biomedical and, more specifically, prostate cancer research. Under your leadership, the nation's war on cancer has reached heights never before realized. We look forward to continuing to work with you and the members of the Committee until a cure is found.

PREPARED STATEMENT OF THE SOUTHERN METHODIST UNIVERSITY SCHOOL OF ENGINEERING

Mr. Chairman and Members of the Subcommittee, I am very grateful to be able to offer testimony on the importance of maintaining our global economic leadership position through a wise and sustained investment in engineering education. And, I want to share with you the early success of a program called the Texas Engineering and Technical Consortium that has emerged as a national model for increasing the technical capabilities of our workforce.

As you know, engineering and technology is an important engine of our national economy. The innovations created by our working engineers have fueled the information revolution, increased our national security, brought more efficient health care, and created a larger food supply to the world.

Our remarkable engineering successes have been the product of our talented and highly skilled technical workforce. Unfortunately, recent national trends don't bode well for increasing the number of homegrown high-tech workers. A 2003 national survey [1] showed that the level of interest in engineering majors by college bound high school seniors has declined by 37 percent over the last 12 years. Sadly, this is a uniquely American phenomenon; much of the rest of world understands how important an engineering and technical workforce will be to their long-term economic health. Within the decade, some predict that India and China together could graduate nearly 1 million engineers per year, a number 20 times greater than the production of engineers here in the United States.

The recently released Hart-Rudman report for the U.S. Commission on the National Security/21st Century says:

"The harsh fact is that the United States need for the highest quality human capital in science, mathematics, and engineering is not being met." [2]

Why is This Important to Both Texas and the Nation?

Engineering and technology have been drivers of the Texas and national economy for nearly 100 years. With the discovery of oil at Spindletop by Austrian born engineer Francis Lucas to the kick-start of the high tech industry by Jack Kilby's invention of the integrated circuit in Dallas, Texas engineers have had a profound and historic impact for both our state's and nation's economy. And today, Texas is a major hub for engineering innovation—employing nearly half a million high tech and engineering workers, with annual wages of $36 billion, while exporting $29 billion in goods and services.

Yet today, this important and large industry is being replenished by only 4,500 new college graduates in engineering and computer scientists each year. This reality will impact all of us. For example, over the next decade, the Joint Strike Fighter program based at Lockheed Martin in Ft. Worth, expects to hire twice as many engineers each year than the entire state produces. This workforce imbalance is bad for Texas and bad for our nation. Our only hope for maintaining global leadership in engineering innovation is to invest today in the education of the best, most diverse, population of engineers in the world.

A CALL TO ACTION: CONTINUE INVESTING IN SUCCESSFUL PROGRAMS LIKE THE TEXAS ENGINEERING AND TECHNICAL CONSORTIUM

Fortunately, I am happy to report that the Texas Engineering and Technical Consortium, which you supported in last year's budget at $3 million, is beginning to pay real dividends. Texas Senators Kay Bailey Hutchison and John Cornyn led the way in supporting our request for federal resources to match state and corporate contributions.

This innovative effort, aimed at doubling the number of engineers and computer scientists graduating from our universities, is already having a significant impact. In fact, The Infinity Project, one program funded by TETC that I direct, is having a profound effect on national engineering education at the high school level—a key barrier to college success. This award winning engineering curricula has increased high school students' interest in engineering by 40-fold in schools that offer the program. And there are other great examples as well.

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[1] "Maintaining a Strong Engineering Workforce," ACT Policy Report, authors R. Noeth, T. Cruce, and M. Harmston, 2003.

[2] Road Map for National Security: Imperative for Change, The Phase III Report of the U.S. Commission on the National Security/21st Century, pp. 30, February 15, 2001.

The wise investments of the state and federal government, along with high-technology companies of Advanced Micro Devices (AMD), Applied Materials, Hewlett-Packard, Intel, International SEMATECH, Lockheed Martin, Motorola, National Instruments, National Semiconductor, Sabre, and Texas Instruments is changing how Texas universities identify, recruit, educate, and mentor tomorrow's engineers. Through these efforts, TETC is establishing a national model for other states to follow as they address their own workforce needs.

But I am here to tell you that our work has really just begun. As a nation, we have struggled for decades to attract a diverse set of well-prepared students to the exciting world of engineering, math, and science. Permanent solutions to this problem have been elusive—and further still, programs that have shown promise often don't get the sustained funding necessary to have a real impact.

Therefore, on behalf of the 34 Texas universities and industry leaders participating in TETC, I ask that you continue investing in the Texas Engineering and Technical Consortium.

The program is sound and successful. I ask you to help make our progress sustainable.

CONCLUSION

I want to thank Chairman Arlen Specter, Ranking Member Tom Harkin, Members of the Subcommittee and, of course, Senators Hutchison and Cornyn once again for supporting TETC. On behalf of all of us across this nation who care deeply about the economic health of our country, I appreciate your interest in improving the quantity, quality, and diversity of America's technical workforce.

PREPARED STATEMENT OF THE K–12 SCIENCE, TECHNOLOGY, ENGINEERING & MATHEMATICS EDUCATION COALITION

We encourage you to continue the federal commitment to math and science education by maintaining the peer-reviewed Math and Science Partnerships (MSPs) at the National Science Foundation (NSF) and supporting robust funding for both the U.S. Department of Education (ED) and the NSF Math and Science Partnership programs.

We urge you to oppose the Administration's budget proposal that would phase-out the NSF MSP program and establish a new federal grant administered by the Secretary of Education that would, in effect, limit individual states' discretion to target much-needed funds for local science and mathematics education reforms.

We believe that the MSPs at both the Department of Education and at NSF are necessary and complementary. Without one, the other is significantly weakened.

The competitive, peer-reviewed, NSF MSPs seek to develop scientifically sound, model, reform initiatives that will improve teacher quality, develop challenging curricula, and increase student achievement in mathematics and science. The funds appropriated under NCLB for the ED MSPs go directly to the states as formula grants, providing funds to all states to replicate and implement these initiatives throughout the country.

While we support the Administration's proposal to increase funding for the ED MSPs, we oppose the creation of a new $120 million ED grant program that runs counter to congressional intent by focusing only on math and reducing state flexibility to target funds to areas of greatest need. We encourage you to oppose new restrictions on the additional funding slotted for the state-based ED MSPs.

In summary, we strongly urge Congress to:

—reject the Administration's proposed phase-out of the NSF MSP program;

—oppose additional restrictions to the ED MSP program; and,

—provide robust funding for both MSP programs.

If you have any questions, please contact Patti Curtis at 202–785–7385.

PREPARED STATEMENT OF AMERICANS FOR THE ARTS

REQUEST

Americans for the Arts is pleased to submit testimony supporting fiscal year 2005 appropriations of $53 million for the Arts in Education program of the U.S. Department of Education (USDE).

Americans for the Arts is one of the leading national nonprofit organizations for advancing the arts and arts education in America. With a 40-plus year record of objective arts industry research, we are dedicated to representing and serving local

communities and creating opportunities for every American to participate in and appreciate all forms of the arts. Our belief in the importance of practical research causes us to take special pleasure in supporting USDE's Arts in Education program, which is generating impressive evidence on the best ways to improve overall academic achievement by integrating the arts into the school curriculum. The evidence of improved academic achievement is itself impressive. For example:

—Mississippi's Whole School Initiative found that schools with a high degree of implementation far surpassed other schools in their ability to meet No Child Left Behind (NCLB) reading targets.

—In Houston, analysis showed that students in participating elementary schools out-performed their demographic peers on the Iowa Test of Basic Skills, and that the benefits lasted beyond graduation and on into middle school.

We have provided more detailed information on the Mississippi example below.

As members of the Subcommittee know, the Elementary and Secondary Education Act provides that funding up to $15 million be directed to the John F. Kennedy Center for the Performing Arts and VSA arts. Prior to fiscal year 2001, funding never exceeded that level. Since fiscal year 2001, however, Congress has appropriated funding sufficient to support a broader array of arts education programs. For fiscal year 2004, Congress appropriated $35.1 million. In addition to the Kennedy Center and VSA arts, USDE now supports grants competitions to:

—further develop established arts education models;

—support professional development for arts educators in four arts disciplines; and

—establish partnerships between schools and community cultural organizations to serve at-risk children and youth.

We ask the Subcommittee to appropriate $53 million for fiscal year 2005, with the bulk of the increase to be allocated to the Arts in Education Model Development and Dissemination Program, Professional Development training in music, theater, dance and the visual arts, as well as Cultural Partnerships for At-risk Children and Youth.

FOUR REASONS TO INCREASE ARTS EDUCATION FUNDING

The most important reason to support arts education is simply stated: arts education works for children. Research increasingly confirms its beneficial effects in several areas, including but not limited to academic achievement. We refer the Subcommittee to a research compendium *Critical Links: Learning in the Arts and Student Academic and Social Development*,[1] released by the Arts Education Partnership in 2002, which includes 62 separate studies pointing to "critical links" between arts education and reading, writing, mathematics, cognitive skills, motivation, social behavior, and the school environment. The studies suggest that arts education may be especially useful for students who are economically disadvantaged and/or in need of remedial instruction.

The second reason to increase funding is that schools desperately want it. Even now, when the accountability and testing regimens of NCLB have focused schools' attention on what some call "the basics," many schools understand that the arts are a core academic subject, as NCLB indeed stipulates, that they are essential, and that they work. The Department of Education's first model grant competition generated a flood of applications despite the tiny number of awards. A larger amount of funding, coupled with a smaller grant size, will at least begin to address the demand. Unfortunately, without an increase in funding, USDE will be unable to hold a new grant competition for 2 years.

The third reason is that while there is tremendous interest in arts education, substantial improvements need to be made to delivery systems. USDE's model grants program aims to further develop established programs that improve arts education, to evaluate these programs, and to disseminate the results. Thus, it is in accord with a central principle of the federal role in education: to find out what works and to disseminate this information to states and local school districts so that they may select and tailor programs to fit their own needs and circumstances. This is the reason that we urge the Subcommittee to recommend that funding include at least $1 million for evaluation and dissemination. We note that each of the projects funded under this program include a substantial research component. It is particularly important to add this modest amount of funding because the USDE's existing and planned research efforts, including the What Works Clearinghouse, do not include substantial work on arts education.

Finally, despite increases in overall federal spending for K–12 education, and despite the substantial flexibility given to states, evidence is beginning to accumulate

[1] http://www.aep-arts.org/CLTemphome.html

that schools are neglecting those areas of the curriculum that are not subject to the mandatory testing requirements of NCLB. The National Association of State Boards of Education (NASBE) identified the threat in its 2003 report *The Lost Curriculum*;[2] in response, NASBE's current quarterly policy journal, the *State Education Standard*,[3] is devoted entirely to "ensuring a place for the arts in America's schools." Earlier this month, the Council for Basic Education released a survey[4] of school principals in four states: fully one quarter of them report that they have decreased instructional time in the arts. Unfortunately—and perhaps even tragically—the shift away from the arts appears most concentrated in elementary schools and schools with large minority populations. We have supported NCLB, especially its inclusion of the arts as a core academic subject, and we believe that the problems facing arts education are a consequence that is very much unintended. Nevertheless, the problems are real and must be addressed. USDE's model development program—if there is sufficient funding for national dissemination—provides principals with desperately needed information on how to integrate the arts into the curriculum in a way that improves academic achievement.

CASE EXAMPLE: MISSISSIPPI'S WHOLE SCHOOLS INITIATIVE

In our testimony for fiscal year 2004 funding, we provided extensive information on structure and philosophy of the Whole School Initiative in Mississippi. This year, we can provide a preliminary analysis for the project's final evaluation report, which is due in June.

Recap of the Whole Schools Initiative

In 2001, the Whole Schools Initiative was 1 of 11 successful applicants for a grant from USDE's Arts in Education Model Development and Dissemination Program. The program's roots go back to 1991, when as a response to "back to basics" school reform and the lack of arts instruction in Mississippi, the Mississippi Arts Commission (MAC) commissioned a study of the Mississippi environment, appropriate national arts education models and relevant research. A pilot program began in 1992.

The Whole Schools Initiative was launched in 1998 with a core belief that art is essential to every child's education. It is the first comprehensive statewide arts education program in Mississippi. Its goals are to improve student academic achievement by infusing arts into the basic curriculum, to assist the professional and personal growth of teachers and administrators through arts experiences, to use the arts to increase parental and community involvement in schools and to assist schools in building a sustainable system for supporting arts infusion. Partnerships include local arts councils, Institutions of Higher Learning, the Mississippi Alliance for Arts Education, professional artists, local school districts and art museums.

Not only does the program improve the quality of arts education being offered in participating schools, it is often the only chance that Mississippi children, in poorly funded schools and from families living below the poverty level, will ever have to receive any formalized arts instruction. Nineteen of the initiative's 26 schools serve student populations where 35 percent or more of the students qualify to receive free/reduced lunches, fourteen schools have at least 70 percent and seven have at least 90 percent. Eleven schools involved in the initiative are located in rural communities and others serve them. Six of these schools have the lowest per pupil expenditure in the state.

This $1 million grant has allowed MAC to expand its role with universities, encouraging the development of pre-service courses that to strengthen arts infused instruction and aid arts majors in becoming effective instructional leaders. The grant has also enabled MAC to expand and refine its evaluation model. A final component of the USDE funding is allowing MAC to develop training materials and procedures that can be used to replicate the program in other settings. At the end of the 3-year grant period, the project will "blueprint" a model built on a research base, field-tested in a diverse set of schools, evaluated internally and externally, and which has already produced substantive results.

This funding has made possible extensive professional development opportunities for teachers and administrators. More than 15,000 students and 800 educators benefit annually from activities at a weeklong summer institute, two retreats, and field advisor visits. Other ways in which it is strengthening the program include a course for education majors that is being developed at the Delta State University, a "teacher friendly" and "teacher useful" interactive web site, and the designation of model

[2] http://www.nasbe.org/Research__Projects/Lost__Curriculum.html
[3] http://www.nasbe.org/Standard/index.html
[4] http://www.c-b-e.org/PDF/cbe__principal__Report.pdf

schools in the north, central, and southern regions of Mississippi where the initiative's work may be observed.

Other states will benefit from the documentation and dissemination of the initiative. Many states have a strong interest in implementing this model but lack the resources, knowledge, and experience to do so. States that have approached MAC and participated in the institute include New Mexico, Illinois, Kentucky, Florida, and Louisiana.

Preliminary Results of the Whole Schools Initiative

The preliminary analysis looks closely at WSI participating schools' NCLB performance in literacy, which was reported for the first time in the fall of 2003. Literacy was chosen as the analytic focus because most of the examined schools were elementary school buildings and learning to read was the foremost concern at that level. The first part of the analysis examines the performance of the 25 participating schools in the spring of 2003 and compares their results to the state average and to a matched set of comparison schools. The second examines a subset of 18 sites that: (1) completed a teacher survey concerning the implementation and impact of the initiative and (2) had grade levels that were included in the reporting requirements of NCLB.

The analysis suggests that two conclusions are warranted. First, schools attempting to create an arts-rich environment for their students performed as well as—if not slightly better than—both the state average for all Mississippi schools and a comparison group of schools demographically and geographically similar to themselves. Second, schools whose teachers reported higher implementation of WSI objectives far surpassed lower implementation schools in enabling their students to meet the all-important growth targets of NCLB. The implication of the analysis is that rather than stripping the curriculum of all but basic direct instruction in literacy and math under the spotlight of making adequate yearly progress, schools might consider enriching the learning environment with multiple opportunities to learn in the arts.

CONCLUSION

As the example of the Whole Schools Initiative demonstrates, federal funds boost the quality and quantity of support for arts education as well as the knowledge that can be gained and disseminated across the education establishment. Increased funding means more help for state departments of education, educators in schools, and local education agencies and cultural organizations. Most important, it means a better education for our children. We urge the Senate Subcommittee on Labor, Health and Human Services, and Education to recommend $53 million in funding for the USDE's Arts in Education programs in order to allow more programs like Mississippi's Whole Schools Initiative to flourish.

PREPARED STATEMENT OF THE CLOSE UP FOUNDATION

Mr. Chairman and distinguished members of the Subcommittee, my name is Stephen A. Janger, and I am president and founder of the Close Up Foundation. I am grateful for the opportunity to submit testimony in support of the Close Up Fellowships, previously known as the Allen J. Ellender Fellowships, which help low-income students and their participating teachers take part in our Close Up Washington civic education programs. On behalf of my colleagues at the Foundation and hundreds of thousands of young people and educators who have participated in Close Up through the years from school systems across the country, I want to express my appreciation for this Subcommittee's longstanding encouragement and support.

As you may recall, in my testimony last year, I described the impact of world events on Close Up's work—specifically, September 11 and the more recent hostilities in Iraq. We saw a decline in our program enrollments because of fear of travel to Washington, D.C., and subsequent travel bans. I am pleased to let you know that program enrollments appear to be improving and we are seeing a modest increase in participation over last year. I want to let you know also that we are doing all we can to broaden efforts to encourage participation in our civic education programs, knowing that our mission is more important and vital than it has been since our inception in 1971. We have reason to believe, based on our conversations with teachers and school districts, that next year will see an even more significant enrollment expansion because of the continued easing of travel anxieties and the relaxation of school travel bans.

The heart of our mission is the conduct of Close Up's weeklong program in Washington, D.C. During this program, students receive 12 to 14 hours of civic instruc-

tion and educational activities each day. Led by our trained Program Instructors, young people learn in a "living classroom" environment through study visits to Capitol Hill, embassies, and many of the country's most historic and symbolic sites. Policy specialists, journalists, lobbyists, and other insiders help show students how government works. Close Up's instructors add to these seminars by teaching the basics of government and citizenship through highly engaging role-playing, workshops, discussion groups, and simulations.

The centerpiece of the program is typically a face-to-face meeting with Members of Congress or your staffs. They are able to engage in a dialogue with an elected official or staff member "close up." In addition, students often see floor debates and committee hearings. They come to understand the process of government, may feel a bit less intimidated about how it works, and can begin to see that they have a role in the future of our democracy.

The difficult reality is that it has become more expensive to make this unique opportunity available for students from every background because the costs from even the most competitive vendors continue to increase. To pay for these experiences, our young participants, who come from very varied backgrounds and represent a wide range of academic performance, often start fundraising during their freshman and sophomore years to attend the program in their senior year. They generate funds from community contributions, fundraising activities, and old fashioned work to support the costs of travel and program tuition.

Not every Close Up participant is fortunate to come from an affluent background. Our work with Native Americans, Alaska Natives, Hispanics, African Americans, migrant students, the physically challenged, and students who are long-term cancer survivors takes us each year into populations with need for special help to make possible their participation. During my 34 years at Close Up, I have seen tens of thousands of these student-participants who have been able to participate in our Close Up Washington program only because of the Close Up Fellowships. The support of this Subcommittee not only covers up to half of a needy student's program, it serves as a meaningful "jump start" for the student who seeks additional support from local businesses, parents, schools and community organizations. In this way, the Fellowships have a significant multiplier effect at the community level.

The Carnegie Foundation published last year a highly collaborative report called "The Civic Mission of Schools." It may be the most significant statement in the civic education field in the last decade. It makes a strong case for making civic education much more of a priority in our elementary and secondary system of education. It also singles out practices, such as the experiential methodology of Close Up, as having the most effect. It also suggests that schools themselves cannot do it all by themselves. Partnerships, collaborations, use of external resources all can help schools better achieve their civic mission.

Beyond the funding support we work to generate each year from the corporate and philanthropic sectors, we could not be more proud of the partnerships we have been able to forge with states, districts, and individual schools. These partnerships not only provide a number of individual students and teachers with the opportunity to take part in Close Up's Washington program, but also to use this experience as a means of strengthening the entire curriculum and extracurricular activities as well in the area of civic education. This is another strong example of the multiplier effect.

I believe strongly that schools are still the best tool for instilling civic virtue and that community service, service learning, and participation in the development of public policy are essential training tools for good citizenship. With that in mind, I want to take this opportunity to briefly describe one of our programs that holds tremendous potential for growth.

Several years ago, we decided that our work with inner city schools needed greater focus and intensity. To that end we developed strong working relationships and raised significant extra financial support to dramatically increase the amount of fellowship resources for the major urban public school districts in Washington, D.C., Houston, and Tulsa. Within this current year, we have added Atlanta and Miami to this new series of program activities we call the Great American Cities Program.

Students receive a great deal of financial assistance from community support, and much is expected of them both before and after their Washington program experience. Students develop and implement community projects that contain in some form a public policy dimension. Teachers receive in-service training, led by our own staff and other experts, on how to foster and develop these programs. This is another example of the multiplier effect where Close Up Fellowships have provided through the years a partnership with school districts that enabled the launch of an innovative and effective program.

As you will read in a few testimonials following this statement—selected from the thousands we receive each year—Close Up's work with young people and educators provides inspiration, reduces cynicism and enhances understanding about the democratic process. Students see firsthand how individuals make a difference and that they themselves can leave things a little better than they found them.

Close Up was started more than three decades ago in another era of conflict to help address the disillusionment expressed by many young Americans during the Vietnam War. Our work has remained both relevant and effective, and is needed now more than ever. America today is faced with many policy choices, both international and domestic, that threaten to divide us. A greater dialogue among a thoughtful and patriotic citizenry is needed to help pull our country together. This has been our goal since our inception: to create a public of engaged, informed, and responsible citizens that Jefferson believed was the most important outcome of our nation's schools.

In closing, Mr. Chairman, I want to thank this Subcommittee for its strong support through the years. The nation's civic education efforts cannot afford to take a back seat to other curricula objectives. These efforts should underlie our important focus on literacy and science testing. It should be second nature to our young people that the blessings of this great country, and the responsibilities to sustain those blessings through active involvement in the democratic process, are the bedrock values and principles from which the liberties of personal and academic freedom are derived. These values and these principles are what set us apart as a nation.

The Close Up Foundation takes great pride in its national leadership in these values and principles from which we have never deviated since we began in 1971. The vital funding that we have received from this Subcommittee through the years, combined with our own efforts in the private sector to multiply that funding, has made it possible for hundreds of thousands of young people and their teachers representing every kind of background to understand and appreciate these core values and principles. Your continued support at an increased level for the Close Up Fellowships will help us do more—where it is most needed.

We respectfully request that this Subcommittee increase the Close Up Fellowships to a level of $4 million. This will enable us to multiply our efforts even further, so that those who are most often neglected or turned away from the civic involvement mainstream are brought into the democratic process. This is fundamental to our mission.

Thank you, Mr. Chairman, for your consideration of this request.

TESTIMONIALS OF CLOSE UP PARTICIPANTS

"I truly believe that your program is the most educational governmental program available to students in the United States. With the additions of teacher fellowships as well as student fellowships we are able to encourage and in fact provide for opportunities to all our students regardless of economic status or academic levels."——Todd Lee, Teacher, 2004 Tioga High School, Tioga, North Dakota.

"Many members of my staff have had an opportunity to met with a number of these students and their participating teachers directly. The feedback has been overwhelmingly positive. We are all pleased with the excitement for learning expressed about the program. We have also met regular with the leaders of the Close Up Foundation and their gifted young educators who are charged with conducting the program. To a person we are impressed by the integrity, commitment, and the passion they bring to their work."——Dr. David E. Sawyer, Superintendent, 2003 Tulsa Public Schools, Tulsa, Oklahoma.

"Close Up gave me the insider's view of Washington and our government. I now have a greater understanding of the political process. I learned that I can make a difference, and I now have a greater desire to participate in the political system. . . . Close Up gave me a passion and interest in the United States government."——Katherine McDermott, Student, 2004 Doniphan-Trumbull High School, Doniphan, Nebraska.

"Close Up is a huge part of my life. I met amazing people from all over the country and each one of those people helped me to fully establish and solidify my political views. Because of my involvement in Close Up I have been able to help educate my peers about how our government works as well as work for educating people about voting."——Andrea Nowak, Student 2004 Bishop Foley High School, Madison Heights, Michigan.

"I always had strong political views, but being surrounded by kids who 'didn't care' about current events, I never had to prove my ideas to anyone. Going on Close

Up, I realized that not everyone shared my views, in fact, some even said I was wrong! . . . While I didn't back down, I at least began to understand the other side's argument, something I would never have been able to do before. . . . Close Up opened me up to a whole new world of ideas, thought, and way of life. And while I may not agree, at least I can agree to disagree."——Emily Wolfe, Student, 2004 Newton South High School, Newton Centre, Massachusetts.

"The Close Up Program, in particular our time on Capital Hill, affords students the opportunity to experience democracy in a hands-on fashion, thus making it real to them. In addition, it validates the necessity of their role in a democratic society."——Lori Merkel, Teacher, 2003 East Valley High School, Spokane, Washington.

"This organization provides a unique experience for both students and teachers. I am a history teacher at Senn High School in Chicago. Like many Chicago Public Schools, we battle the effects of poverty every day in our classrooms. The opportunity the Close Up Foundation gives to these students is tremendous. This may be the only time in the lives of my students where they will have this type of access to Washington, DC and the officials who make decisions affecting their lives."——Johanna Klinsky, Teacher, 2004 Nicholas Senn High School, Chicago, Illinois.

". . . You . . . may not hear about the lives that are changed through your work each day, but please know that your support and leadership make dreams come true for students and create life-changing experiences. It may sound cliché, but it is so very true: Only in America can children who are born in the most humble of circumstances have real opportunities to make all of their dreams come true. Truly, the broad scope of American education positively impacts every student and extends to each student a special invitation to excellence."——Dr. Beverly Boone, Principal, 2003 The Anchor School, Biscoe, North Carolina.

PREPARED STATEMENT OF ZERO TO THREE

Chairman and Members of the Subcommittee: I am pleased to submit the following testimony on the Labor/Health and Human Services/Education and Related Agencies fiscal year 2005 Appropriations on behalf of ZERO TO THREE. My name is Matthew Melmed. For the last 9 years I have been the Executive Director of ZERO TO THREE. ZERO TO THREE is a national non-profit organization that has worked to advance the healthy development of America's babies and toddlers for over 25 years. I would like to start by thanking the Subcommittee for all of their work to ensure that our nation's at-risk infants and toddlers have access to early intervention and positive early learning experiences.

We know from the science of early childhood development that infancy and toddlerhood are times of intense intellectual engagement.[1] During this time—a remarkable 36 months—the brain undergoes its most dramatic development, and children acquire the ability to think, speak, learn, and reason. All babies and toddlers need positive early learning experiences to foster their intellectual, social, and emotional development and to lay the foundation for later school success. Babies and toddlers living in high-risk environments need additional supports to promote their healthy growth and development. Disparities in children's cognitive and social abilities become evident well before they enter Head Start or Pre-Kindergarten programs at age 4. I am here to talk to you today about why it is important to increase funding for three programs focused on the unique needs of low-income infants and toddlers—Early Head Start, the Child Care and Development Fund (CCDF) and Part C of the Individuals with Disabilities Education Act (IDEA).

EARLY HEAD START

What is Early Head Start?

Congress created Early Head Start in 1995 with strong bipartisan support. It is the only federal program specifically designed to improve the early education experiences of low-income babies and toddlers. The mission of Early Head Start is clear: to support healthy prenatal outcomes and enhance intellectual, social and emotional development of infants and toddlers to promote later success in school and life. Research demonstrates that Early Head Start is effective. The Congressionally mandated National Evaluation of Early Head Start—a rigorous, large-scale, random-assignment evaluation—concluded that Early Head Start is making a positive dif-

[1] Shonkoff J., and Phillips, D. (Eds.) (2000). National Research Council and Institute of Medicine. *From Neurons to Neighborhoods: The Science of Early Childhood Development.* Washington, DC: National Academy Press.

ference in areas associated with children's success in school, family self-sufficiency, and parental support of child development. Early Head Start serves over 63,000 low-income families with infants and toddlers through 708 community-based programs.[2] Unfortunately, only 3 percent of all eligible children and families are served.[3]

Is Early Head Start Effective?

Key to Early Head Start's success is its emphasis on the implementation of the Head Start Program Performance Standards, which ensure the highest quality care for babies and families and its comprehensive approach to serving children and families. What is most compelling about the Early Head Start data is that they reflect a broad set of indicators, all of which show positive impact—patterns of impacts varied in meaningful ways for different subgroups of families. For example, the National Evaluation found that Early Head Start produced statistically significant, positive impacts on standardized measures of children's cognitive and language development;[4] The Evaluation also found that Early Head Start parents were more involved and provided more support for learning; and that the program helped parents move toward self-sufficiency.

Funding

Currently, 10 percent of the overall Head Start budget is used to serve 63,000 low-income families with infants and toddlers through Early Head Start—only 3 percent of all eligible children. An increase in the overall Head Start appropriation is needed and will enable more eligible infants and toddlers to be served through the 10 percent Early Head Start set-aside. Congressional authorizers are currently considering an increase in the Early Head Start funding allocation—potentially doubling the allocation of funds for infants and toddlers enrolled in the program. Given the uncertainty of action on that legislation, we encourage the Subcommittee to increase the Early Head Start portion of the program to 12 percent of the total appropriation for Head Start in fiscal year 2005. Additional funds will enable us to protect and continue to build on the firm foundation that currently exists and to ensure that more eligible babies and families are able to benefit from the services of Early Head Start.

THE CHILD CARE AND DEVELOPMENT FUND (CCDF)

What is CCDF?

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 revamped the structure of federal funding for child care and created the Child Care and Development Fund (CCDF). This streamlined block grant attempts to maximize states' flexibility in administering child care programs and establishes a single set of rules and regulations that apply to all components of the fund. CCDF funding is divided into three streams of federal funds: federal mandatory funds that do not require a state match; federal mandatory funds that do require a state match; and federal discretionary funds that do not require a state match. States are required to spend a minimum of 4 percent of CCDF funds on activities designed to improve the quality of child care. Today Congress earmarks $100 million of the CCDF funds for strategies to increase the supply and improve the quality of child care for infants and toddlers.

Is CCDF Effective?

CCDF provides funds to help improve the quality and supply of child care for low-income children and families. For example, the infant-toddler set-aside of CCDF, currently earmarked through the appropriations process, has helped states focus on the unique needs of infants and toddlers by investing in specialized infant-toddler provider training, providing technical assistance to programs and practitioners, and linking compensation with training and demonstrated competence. Another example is the quality set-aside of CCDF. The quality set-aside, currently 4 percent, provides funds to states in order to support and develop innovative strategies for improving the quality of child care. Strategies may include: training grants and loans to pro-

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[2] U.S. Department of Health and Human Services, Administration for Children and Families (2002). *Early Head Start Information Folder,* www.headstartinfo.org/infocenter/ehs__tkit3.htm. 2002 EHS Fact Sheet www.acf.hhs.gov/programs/hsb/research/factsheets/02/hsfs.htm.

[3] 2002 EHS Fact Sheet www.acf.hhs.gov/programs/hsb/research/factsheets/02/hsfs.htm. CPS Annual Demographic Survey, March Supplement 2001 Table 23 "Single Years of Age—Poverty Status of People in 2001" http://ferret.bls.census.gov/macro/032002/pov/new23__004.html.

[4] U.S. Department of Health and Human Services, Administration for Children and Families (2002). *Making a Difference in the Lives of Infants and Toddlers and Their Families: The Impacts of Early Head Start.* Washington, DC.

viders; improved monitoring; resource and referral counseling for parents to find child care; and other services related to improving the quality of child care.

Funding

Despite modest increases in federal child care funding, CCDF funds are insufficient to serve all eligible children. In fact, the Center for Law and Social Policy (CLASP) estimates that states served only about 14 percent of federally-eligible children (approximately 1 out of 7) in fiscal year 2000. Connecticut has an estimated 17,000 children on its waiting list for child care assistance and has not served any new low-income working families not receiving welfare since August 2002. A substantial increase is needed to ensure that all states are able to serve more eligible children and families. Although states have made great progress in improving the quality of child care for low-income children, additional resources are necessary to ensure that more low-income children have access to quality child care. We must significantly increase the percentage of the quality set-aside (from 4 to 10 percent) to improve the quality of child care. Finally, because the infant-toddler set-aside is earmarked through the appropriations process, we must ensure that the set-aside continues to grow as the overall funding for CCDF continues to grow.

PART C OF IDEA

What is Part C of IDEA?

Part C of the Individuals with Disabilities Education Act (IDEA) authorizes the federal support for early intervention programs for babies and toddlers with disabilities, and provides federal assistance for states to maintain and implement statewide systems of services for eligible children, age birth through 2 years, and their families. Under Part C, all participating states and jurisdictions must provide early intervention services to any child below age 3 who is experiencing developmental delays or has a diagnosed physical or mental condition that has a high probability of resulting in a developmental delay. In addition, states may choose to provide services for babies and toddlers who are "at-risk" for serious developmental problems, defined as circumstances (including biological or environmental conditions or both) that will seriously affect the child's development unless interventions are provided. The Part C system offers the opportunity to maximize the impact of Part B dollars (which provides for the education of children with disabilities ages 3–21). Early intervention services under Part C may prevent or minimize the need for more costly services under Part B later in a child's life. Research shows that intervention is more effective if begun before age 3.

Is Part C Effective?

The Office of Special Education Programs (OSEP) has commissioned the National Early Intervention Longitudinal Study (NEILS) to examine what happens to infants and toddlers with special needs and their families during and after Part C early intervention. NEILS is following a nationally representative sample of 3,338 infants and toddlers who received early intervention services. The sample consists of children from four age groups—the oldest children in the study exited early intervention in 1998, the youngest children in the study exited early intervention in 2001. For all age groups, the children were found to be advancing developmentally and showing greater mastery of milestones than they had when they entered early intervention.[5] For the children who entered early intervention between 6 and 12 months and between 12 and 18 months of age, a significant percentage had mastered many of the motor and self-help milestones by 1 year.[6] Children in these two age groups also showed progress with communication and cognition milestones.[7]

Funding

In spite of reports from states that referrals to Part C continue to increase, Part C has received only very small increases over the past few years. The fiscal year 2003 Part C appropriation was $434,159,000 while the current fiscal year 2004 appropriation for Part C is $444,363,000.[8] Although estimates of children with disabilities under age 3 range from 3 percent to 5.2 percent,[9] as of December 1, 2002, only

[5] U.S. Department of Education. (2002). Twenty-Fourth Annual Report to Congress on the Implementation of the Individuals with Disabilities Education Act, Washington, DC: U.S. Department of Education.

[6] Ibid.

[7] Ibid.

[8] Council for Exceptional Children, "Full Funding for IDEA: It's a Guarantee, Not Just a Promise." February, 2004. Arlington, VA: Council for Exceptional Children.

[9] Oser, C., & Cohen, J. (2003). America's babies: *The ZERO TO THREE Policy Center data book.* Washington, DC. ZERO TO THREE Press.

2.24 percent of all infants and toddlers (267,923) were served under Part C. Because the federal government is not paying its fair share to support the provisions of IDEA, the burden is placed on states and on families. And there is wide variation in the percentage of infants and toddlers enrolled in Part C across states. For example, Massachusetts serves 5.8 percent of infants and toddlers while Nevada serves less than 1 percent.[10] Substantial increases in the Part C appropriation are needed to ensure that all eligible infants and toddlers are served without having the burden placed on states and families.

CONCLUSION

During the first 3 years of life, children rapidly develop foundational capabilities—cognitive, social and emotional—on which subsequent development builds. These years are even more important for at-risk infants and toddlers. Early Head Start, the Child Care and Development Fund, and Part C of IDEA can serve as protective buffers against the multiple adverse influences that may hinder their development in all domains.

With the Subcommittee's help, we have made some gains over the past few years in increasing funding for early intervention and positive early learning experiences for at-risk infants and toddlers. The fact remains, however, that our overall policy and funding emphasis is still to wait until children are already behind developmentally before significant investments are made to address their needs. I urge the Subcommittee to change this pattern and invest in infants and toddlers early on, when that investment can have the biggest payoff—preventing problems or delays that become more costly to address as the children grow older. We do not need to accept that vulnerable children will inevitably have already fallen behind at age four and then provide special education and intensive prekindergarten services to help them play catch up. We know how to provide early intervention and positive early learning experiences to infants and toddlers that works. I hope the Subcommittee will make that initial investment to prevent very young children from falling behind.

Thank you for your time and for your commitment to our nation's infants, toddlers and families.

PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

SUMMARY OF REQUEST

For 35 years United Tribes Technical College (UTTC) has been providing postsecondary vocational education, job training and family services to Indian students from throughout the nation. Our request for fiscal year 2005 funding for tribally controlled postsecondary vocational institutions as authorized under Section 117 of the Carl Perkins Vocational and Applied Technology Act is:

—$8 million under Section 117 of the Perkins Act, which is $800,000 over the fiscal year 2004 enacted level. This funding is essential to our survival, as we receive no state-appropriated vocational education monies.

—Ensure that the provision that has been included since fiscal year 2002 in the Labor-HHS Education Appropriations Acts that waived the regulatory requirement that we utilize a restricted indirect cost rate is continued.

—Funding for renovation of our facilities, many of which are original to the Fort Abraham Lincoln army installation. A recent study commissioned by the Department of Education shows a facility need for UTTC of $49 million.

Restricted Indirect Cost Issue.—Beginning in fiscal year 2002 the Labor-HHS-Education Appropriations Act provided that notwithstanding any law or regulation, that Section 117 Perkins grantees are not required to utilize a restricted indirect cost rate. We thank you for taking this action, and ask that it be continued in the fiscal year 2005 Act.

In 2001, the Department of Education, for the first time, directed Indian grantees (both Section 116 and 117 grantees) to apply a "restricted indirect cost rate" to their grants. This means each tribal grantee must obtain another indirect cost rate—exclusively for its Perkins Act grant—from its cognizant federal agency (which in most cases is the Inspector General for the Department of the Interior.)

The Department gave two reasons for applying a restricted rate to these Perkins Act Indian programs: (1) The 1998 Amendments to the Perkins Act (Sec. 311(a))

[10] IDEAdata.com (2004). "Number and Percentage (Based on 2002 population estimates) of Infants and Toddlers Receiving Early Intervention Services." Retrieved April 22, 2004, from www.IDEAdata.org

prohibits the use of Perkins Act grant funds to supplant non-federal funds expended for vocational/technical programs. This "supplement, not supplant" limitation previously applied to State grants, only; and (2) A long-standing Department of Education regulation (promulgated years before the 1998 Perkins Amendments) automatically applies the restricted indirect cost rate requirement to any Department of Education grant program with a "supplement, not supplant" provision.

UTTC has no quarrel with the bases and objectives of the "supplement, not supplant" rule and seeks no change to this statutory provision. The primary targets of this rule are States and possibly local government entities that run vocational education programs with State or local funds.

By contrast, however, UTTC has little or no ability to violate this rule, as we have no source of non-federal funds to operate vocational education programs. Unlike States, we have no tax base and no source of non-federal funds to maintain a vocational education program. We depend on federal funding for our vocational/technical education program operations. Despite our inability to violate the supplanting prohibition, we are, nonetheless, being disadvantaged by a Department of Education regulation intended to enforce the prohibition against States who do have the ability to supplant.

—*Impact of new requirement on grantees*.—Under DoEd regulations, a "restricted indirect cost rate" makes unallowable certain indirect costs that are considered allowable by other federal programs. Primarily, these are costs that DoEd believes the grantee would otherwise incur if it did not receive a Perkins grant, such as the cost of the grantee's chief officer and heads of departments who report to the CEO, as well as the costs of maintaining offices for these personnel.

Prohibiting the Perkins grant from contributing its appropriate share to the grantee's indirect cost pool will most likely mean that other federal programs operated by the grantee would be expected to pick up a great share of the indirect cost pool. This outcome may well result in objections from the other program agencies that do not want to bear costs properly attributable to the Perkins grant.

We are caught between conflicting federal agency requirements and will find ourselves unable to recover the necessary share of indirect costs attributable to each of the federal programs we operate.

UTTC Excels.—We bring to your attention the following facts about UTTC, an institution with:

—An 89 percent retention rate

—A placement rate of 90 percent (job placement and going on to 4-year intuitions)

—A projected return on federal investment of 11 to 1 (2003 study comparing the projected earnings generated over a 29-year period of UTTC Associate of Applied Science graduates with the cost of educating them.)

—The highest level of accreditation. The North Central Association of Colleges and Schools has accredited UTTC again in 2001 for the longest period of time allowable—10 years or until 2011—and with no stipulations. We are also the only tribal college accredited to offer on-line associate degrees.

The demand for our services is growing and we are serving more students.—For the Spring Semester 2004, we enrolled 661 students from more than 45 tribes and 17 states. The majority of our students are from the Great Plains states, an area that, according to the 2001 BIA Labor Force Report, has an Indian reservation jobless rate of 75 percent. UTTC is proud that we have an annual placement rate of 90 percent. We hope to enroll 2000 adult students by 2008.

In addition, as of the Spring Semester 2004, we serve 185 children in our Theodore Jamerson Elementary school, and 133 children in our infant-toddler and preschool programs, bringing the population for whom we provide direct services to 979.

UTTC course offerings and partnerships with other educational institutions.—UTTC offers 14 vocational/technical programs and awards a total of 24 2-year degree and 1-year certificates. We are accredited by the North Central Association of Colleges and Schools.

We are very excited about the recent additions to our course offerings, and the particular relevance they hold for Indian communities. These programs are: (1) Injury Prevention, (2) On-Line Education, (3) Nutrition and Food Services, (4) Tribal Government Management, and (5) Tourism.

—*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 We received assistance through Indian Health Service to establish the only degree granting Injury Prevention program in the nation. Injuries are the number one cause of mortality among Native people for ages 1–44 and the third for overall death rates. IHS spends more than $150 million annually for the

treatment of non-fatal injuries, and treatment of injuries is the largest expenditure of IHS contract health funds. (IHS fiscal year 2004 Budget Book).

—*On-Line Education*.—We are working to bridge the "digital divide" by providing web-based education and Interactive Video Network courses from our North Dakota campus to American Indians residing at other remote sites and as well as to students on our campus. We currently have 47 students (15.5 FTE) taking on-line courses. We are accredited by the North Central Association of Colleges and Schools to provide on-line associate degrees. We were invited by North Central to share our experiences in gaining on-line accreditation at their March, 2004 meeting in Chicago and did make that presentation. We have also been invited by New Mexico State University to do the same.

At this point, nearly half of the students taking on-line courses are campus-based students. On-line courses provide the scheduling flexibility students need, especially those students with young children. Our on-line education is currently provided in the areas of Early Childhood Education and Injury Prevention We will be asking approval this year from the North Central Association to offer full degree on-line programs in the following areas: Health Information Technology, Nutrition and Food Science, Elementary Education, and also possibly Criminal Justice. This approval is required in order for us to offer federal financial aid to the students enrolled in these on-line courses.

—*High Demand exists for computer technicians*.—In the first year of implementation, the Computer Support Technician program is at maximum student capacity. In order to keep up with student demand, we will need more classrooms, equipment and instructors. Our program includes all of the Microsoft Systems certifications that translate into higher income earning potential for graduates.

—*Nutrition and Food Services*.—UTTC will meet the challenge of fighting diabetes in Indian Country through education. As this Subcommittee knows, the rate of diabetes is very high in Indian Country, with some tribal areas experiencing the highest incidence of diabetes in the world. About half of Indian adults have diabetes (Diabetes in American Indians and Alaska Natives, NIH Publication 99–4567, October 1999)

We offer a Nutrition and Food Services Associate of Applied Science degree in an effort to increase the number of Indians with expertise in nutrition and dietetics. Currently, there are only a handful of Indian professionals in the country with training in these areas. Future improvement plans include offering a Nutrition and Food Services degree with a strong emphasis on diabetes education and traditional food preparation.

We also established the United Tribes Diabetes Education Center to assist local tribal communities and our students and staff in decreasing the prevalence of diabetes by providing diabetes educational programs, materials and training. We published and made available tribal food guides to our on-campus community and to tribes.

—*Tribal Government Management/Tourism*.—Another of our new programs is tribal government management designed to help tribal leaders be more effective administrators. We continue to refine our curricula for this program.

A newly established education program is tribal tourism management. UTTC has researched and developed core curricula for the tourism program and are partnering with three other tribal colleges (Sitting Bull, Fort Berthold, and Turtle Mountain) in this offering. The development of the tribal tourism program was well timed to coincide with the planned activities of the national Lewis and Clark Bicentennial last year. As you may know, Lewis and Clark and their party spent one quarter of their journey in North Dakota. UTTC art students were commissioned by the Thomas Jefferson Foundation to create historically accurate reproductions of Lewis and Clark-era Indian objects using traditional methods and natural materials. Our students had partners in this project including the National Park Services and the Peabody Museum at Harvard University. The objects made by our students are now part of a major exhibition in the Great Hall at Monticello about the Lewis and Clark expedition.

—*Job Training and Economic Development*.—UTTC is a designated Minority Business Center serving Montana, South Dakota and North Dakota. We also administer a Workforce Investment Act program and an internship program with private employers.

Economic Development Administration funding was made available to open a "University Center." The Center is used to help create economic development opportunities in tribal communities. While most states have such centers, this center is the first-ever tribal center.

Department of Education Study Documents our Facility/Housing Needs.—The 1998 Vocational Education and Applied Technology Act required the Department of

Education to study the facilities, housing and training needs of our institution. That report was published in November 2000 ("Assessment of Training and Housing Needs within Tribally Controlled Postsecondary Vocational Institutions, November 2000, American Institute of Research"). The report identified the need for $17 million for the renovation of existing housing and instructional buildings and $30 million for the construction of housing and instructional facilities.

We continue to identify housing as our greatest need. We have a waiting list of students some who wait from 1 to 3 years for admittance. For the first time in its history, in the 2002–2003 year, we were forced to find housing off campus for our students. Enrollment for the 2002–2003 year increased by 31 percent; and in 2003–2004 our enrollment increased another 20 percent. In order to accommodate the enrollment increase, UTTC partnered with local renters and the Burleigh County Housing Authority. Approximately 40 students and their dependents were housed off campus. The demand for additional housing also presents challenges for transportation, cafeteria, maintenance, and other services.

UTTC has now completed a new 86-bed single-student dormitory on campus. This dormitory is already completely full as are all of our other dormitories and student housing. To build the dormitory, we formed an alliance with the U.S. Department of Education, the U.S. Department of Agriculture, the American Indian College Fund, the Shakopee-Mdewakanton Sioux Tribe and other sources for funding. Our new dormitory has at the same time created new challenges such as shortages in classroom, office and other support facility space. However, more housing must be built to accommodate those on the waiting list and to meet expected increased enrollment.

Some of our housing must be renovated to meet local, state, and federal safety codes. In addition some homes may be condemned which will mean lower enrollments and fewer opportunities for those seeking a quality education.

Thank you for your consideration of our request. We cannot survive without the basic vocational education funds that come through the Department of Education's Perkins funds. They are essential to the operation of our campus and essential to the welfare of Indian people throughout the Great Plains region and beyond.

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

Mr. Chairman and Members of the Subcommittee, on behalf of this nation's 34 Tribal Colleges and Universities (TCUs), which compose the American Indian Higher Education Consortium (AIHEC), thank you for the opportunity to share our fiscal year 2005 funding requests for programs within the U.S. Department of Education, and the U.S. Department of Health and Human Services—Head Start program.

This statement will cover two areas: (a) background on the tribal colleges, and (b) justifications for our funding requests.

BACKGROUND ON TRIBAL COLLEGES

The Tribal College Movement began in 1968 with the establishment of Navajo Community College, now Diné College, in Tsaile, Arizona. Rapid growth of tribal colleges soon followed, primarily in the Northern Plains region. In 1972, the first six tribally controlled colleges established AIHEC to provide a support network for member institutions. Today, AIHEC represents 34 Tribal Colleges and Universities located in 12 states, which were begun specifically to serve the higher education needs of American Indian. Annually, these institutions serve approximately 30,000 full-and part-time students from over 250 federally recognized tribes.

The vast majority of TCUs is accredited by independent, regional accreditation agencies and like all institutions of higher education, must undergo stringent performance reviews on a periodic basis to retain their accreditation status. In addition to college level programming, TCUs provide much needed high school completion (GED), basic remediation, job training, college preparatory courses, and adult education. Tribal colleges fulfill additional roles within their respective reservation communities functioning as community centers, libraries, tribal archives, career and business centers, economic development centers, public-meeting places, and child care centers. Each TCU is committed to improving the lives of its students through higher education and to moving American Indians toward self-sufficiency.

Tribal colleges provide access to higher education for American Indians and others living in some of this nation's most rural and economically depressed areas. These institutions, chartered by their respective tribal governments, were established in response to the recognition by tribal leaders that local, culturally based institutions are best suited to help American Indians succeed in higher education. TCUs combine traditional teachings with conventional postsecondary courses and curricula.

They have developed innovative means to address the needs of tribal populations and are successful in overcoming longstanding barriers to higher education for American Indians. Since the first tribal college was established on the Navajo reservation, these vital institutions have come to represent the most significant development in the history of American Indian higher education, providing access to and promoting achievement among students who may otherwise never have known postsecondary education success.

Despite their remarkable accomplishments, tribal colleges remain the most poorly funded institutions of higher education in the country. Persistently inadequate funding remains the most significant barrier to their success. Funding for basic institutional operations of 26 reservation based colleges is provided through Title I of the Tribally Controlled College or University Assistance Act (Public Law 95–471). Funding under the Act was first appropriated in 1981. Over 20 years later, the funding level has reached just 70 percent of the authorized level of $6,000 per full-time Indian student. In fiscal year 2004, these colleges are receiving $4,230 per full-time equivalent Indian student toward their institutions operating budgets. While mainstream institutions have had a foundation of stable state tax-based support, TCUs must rely on year-to-year federal appropriations for their basic institutional operating funds. Because TCUs are located on Federal trust territories, states have no obligation to fund them even for the non-Indian state-resident students who account for approximately 20 percent of TCU enrollments. Yet, if these same students attended any other public institution in the state, the state would provide basic operating funds to the institution.

Inadequate funding has left many of our colleges with no choice but to operate under severely distressed conditions. Although facilities initiatives of the last few years have resulted in widespread construction at TCUs, many colleges began in surplus trailers; cast-off buildings; and facilities with crumbling foundations, faulty wiring, and leaking roofs and have a long way to go. Sustaining quality academic programs is a challenge without a reliable source of facilities maintenance and construction funding.

As a result of more than 200 years of Federal Indian policy—including policies of termination, assimilation and relocation—many reservation residents live in abject poverty comparable to that found in Third World nations. Through the efforts of tribal colleges, American Indian communities receive services they need to reestablish themselves as responsible, productive, and self reliant.

JUSTIFICATIONS

Higher Education Act

The Higher Education Act Amendments of 1998 created a separate section within Title III, Part A, specifically for the nation's Tribal Colleges and Universities (Section 316). Titles III and V programs support institutions that enroll large proportions of financially disadvantaged students and have low per-student expenditures. TCUs clearly fit this definition as they are among the most poorly funded institutions in America, yet they serve some of the most impoverished areas of the country. TCUs are victims of their own success. This year two new tribal colleges are eligible to compete for funding under Title III. Despite the increase in the size of the pool of eligible institutions, the President's fiscal year 2005 Budget recommends an increase of $500,000 to this vital program. We urge the Subcommittee fund section 316 at $26 million, an increase of $2.7 million over fiscal year 2004 and $2.2 over the President's request, and we ask that report language included in since fiscal year 2003 be restated clarifying that funds not needed to support continuation grants or new planning or implementation grants be available for facilities renovation and construction grants.

The importance of Pell grants to our students cannot be overstated. Department of Education figures show that at the majority of all tribal college students receive Pell grants, primarily because student income levels are so low and our students have far less access to other sources of aid than students at mainstream institutions. Within the Tribal College system, Pell grants are doing exactly what they were intended to do—they are serving the needs of the lowest income students by helping people gain access to higher education and become active, productive members of the workforce. We urge Congress to fund this critical program at the highest possible level.

Carl D. Perkins Vocational & Applied Technology Education Act

Tribally-Controlled Postsecondary Vocational Institutions.—Section 117 of the Perkins Act provides basic operating funds for two of our member institutions: United Tribes Technical College in Bismarck, North Dakota, and Crownpoint Institute of

Technology in Crownpoint, New Mexico. We urge Congress fund this program at $8 million and reiterate language included since fiscal year 2002 stating that Section 117 Perkins grantees need not utilize restricted indirect cost rate.

The President's fiscal year 2005 budget proposes the elimination of the Native American Program Section 116, which reserves 1.25 percent of appropriated funding to support Indian vocational programs. We strongly urge Congress to continue this program, which is vital to the survival of vocational education programs being offered at TCUs.

Greater Support of Indian Education Programs Under ESEA

American Indian Adult and Basic Education.—This section supports adult education programs for American Indians offered by TCUs, state and local education agencies, Indian tribes, institutions, and agencies. Despite a lack of funding, TCUs must find a way to continue to provide basic adult education classes for those Indians that the present K–12 Indian education system has failed. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a GED or, in some cases, learn to read. According to a 1995 survey conducted by the Carnegie Foundation for the Advancement of Teaching, 20 percent of the participating students had completed a tribal college GED program before beginning higher education classes at the tribal college. At some schools, the percentage is even higher. Clearly, the need for basic educational programs is tremendous, and TCUs need funding to support these crucial activities. Tribal colleges respectfully request that Congress appropriate $5 million to meet the ever-increasing demand for basic adult education services.

American Indian Teacher Corps.—American Indians are severely under-represented in the teaching and school administrator ranks nationally. These competitive programs, aimed at producing new American Indian teachers and school administrators for schools serving American Indian students, support the recruitment, training, and in-service professional development programs for Indians to become effective teachers and school administrators, and in doing so excellent role models for Indian children. We believe that the TCUs are the ideal catalysts for these initiatives because of our current work in this area and the existing articulation agreements TCUs hold with 4-year degree awarding institutions. We request Congress support these programs at $10 million and $5 million, respectively, to increase the number of qualified American Indian teachers and school administrators in Indian Country.

Department of Health and Human Services/Administration for Child, Youth and Families/Head Start

Tribal Colleges and Universities (TCU) Head Start Partnership Program.—The TCU/Head Start partnership has made a lasting investment in our Indian communities by creating and enhancing associate degree programs in Early Childhood Development and related fields. New graduates of these programs can help meet the mandate that 50 percent of all program teachers earn an associate degree in Early Childhood Development or a related discipline by 2003. One clear impediment to the ongoing success of this partnership program is the erratic availability of discretionary funding made available for the TCU/Head Start partnership. In fiscal year 1999, the first year of the program, six TCUs received 3-year awards; in fiscal year 2000, seven additional colleges received 3-year grant awards; in fiscal year 2001, duration of grants was extended from 3-years to 5-years but only three additional TCUs received grants; in fiscal year 2002 no new grants were awarded; and in fiscal year 2003, eight new grants were awarded. The President's fiscal year 2005 budget includes a request of $6.9 billion for Head Start Programs. We request Congress direct the Head Start Bureau to designate a minimum of $5 million for the TCU/Head Start Partnership program, to allow current grantees ensure that this critical program can be continued and be expanded so that all TCUs might participate in the TCU/Head Start Partnership program.

CONCLUSION

Tribal colleges are bringing education to thousands of American Indians. The modest Federal investment in the tribal colleges has paid great dividends in terms of employment, education, and economic development, and continuation of this investment makes sound moral and fiscal sense. We very much need help to sustain and grow our programs and achieve our missions.

Thank you again for this opportunity to present our funding requests. We respectfully ask the Members of this Subcommittee for their continued support of TCUs and full consideration of our fiscal year 2005 appropriations request.

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.

Located in Tallahassee, Florida's capitol, FSU is a comprehensive Research I university with a rapidly growing research base. The University serves as a center for advanced graduate and professional studies, exemplary research, and top quality undergraduate programs. Faculty members at FSU maintain a strong commitment to quality in teaching, to performance of research and creative activities and have a strong commitment to public service. Among the current or former faculty are numerous recipients of national and international honors including Nobel laureates, Pulitzer Prize winners, and several members of the National Academy of Sciences. Our scientists and engineers do excellent research, have strong interdisciplinary interests, and often work closely with industrial partners in the commercialization of the results of their research. Florida State University had over $162 million this past year in research awards.

FSU recently initiated a new medical school, the first in the United States in over two decades. Our emphasis is on training students to become primary care physicians, with a particular focus on geriatric medicine—consistent with the demographics of our state.

Florida State University 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 345 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 to our campus.

At Florida State University, we are very proud of our successes as well as our emerging reputation as one of the nation's top public research universities.

Mr. Chairman, let me tell you about a project we are pursuing this year through the U.S. Department of Education.

Florida State University (FSU), with support from the State of Florida and Governor Jeb Bush, initiated a state-wide partnership among the state's universities, local schools, teachers, principals, and other educational leaders to address the highest priority issues in K–12 education. The partnership, entitled the Multi-University Reading, Mathematics and Science Initiative (MURMSI), is designed to measurably improve teaching and learning in Reading, Mathematics and Science in Florida's K–20 schools with a special emphasis on students considered "at risk" due to economic or other conditions. It seeks to develop a deeper understanding of ways to improve Reading, Mathematics, and Science education through a strategically planned research agenda and action plans for change.

Randomized experiments that are highly valued in other fields, such as health, medicine, economics, psychology, political science—and more recently Pre-K education—are rare in K–12 education. As a result, existing research provides little knowledge about the cause and the effect of interventions and programs. The Education Sciences Reform Act of 2002 (H.R. 3801) passed by Congress includes language aimed to strengthen research design and methodology in education, including use of random assignment, when feasible, particularly in cases where researchers expect to make claims about causal relationships.

The connection between research and practice is also a weak link in K–12 education. A number of recent publications have substantiated a lack of connection between the results of systematic study and application in the field. Given the current budget outlook for Florida and the nation as a whole, it is critical that the dollars spent on education produce improved learning outcomes for students.

Well-designed research and development on priority educational issues can produce measurable gains in student performance. Critical knowledge related to improved learning must be produced and, in turn, applied throughout the state. To be effective, these R&D efforts must directly connect research, teacher preparation, professional development, practice and evaluation. To avoid duplication of effort, they must also be carefully coordinated across various stakeholder groups, including other universities, policy makers, K–12 leaders and teachers. By coordinating priorities, each entity can focus on its areas of expertise to accomplish the research, development, evaluation and dissemination functions essential to support Florida's K–20 system.

The work of this R&D collaboration—over a period of 5 years—involves the following:

—Assist Florida leaders and decision makers in developing a strategically planned research agenda targeting high priority statewide problems in K–20 Reading, Mathematics and Science education.
—Initiate, conduct and complete priority research projects (within each university) clearly responsive to critical statewide and national education needs using a data based, systems oriented model.
—Provide decision-makers timely technical advisories and summaries of findings on issues related to education policy and practice.
—Evaluate the impact of state K–20 initiatives designed to improve K–12 student performance in Reading, Mathematics and Science and disseminate the results.
—Design and recommend specific applications of the research findings and support implementation programs in school districts.
—Provide teacher professional development, especially in Reading, Mathematics and Science content areas, as teachers need to broaden and deepen their knowledge in response to changing educational and/or technological needs.

The first year of this initiative (fiscal year 2003) has been funded through a $1.5 million grant awarded to the FSU Learning Systems Institute by the U.S. Department of Education. Those resources were used to develop the research agenda described above and to initiate pilot research projects at universities across the state. During 2004, those pilot projects will continue and others will be added. In 2005, MURMSI will focus primarily on full implementation of the high priority research agenda in K–12 Reading, Mathematics and Science education. All aspects of this work will be done through the collaborative partnership and consensus-building process with other universities and stakeholders. Results of the research projects will be systematically shared with policy makers and educators throughout the state.

We are seeking $3 million in fiscal year 2005 to continue the work on this important state-wide project.

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 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 NCB DEVELOPMENT CORPORATION

On behalf of NCB Development Corporation, I am pleased to once again submit written testimony to the U.S. Senate's Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education on the subject of charter school facility finance. I am Terry D. Simonette, president and chief executive officer of NCB Development Corporation located in the District of Columbia and I would like to thank Chairman Specter and Ranking Member Harkin for the opportunity to submit this written testimony today on fiscal year 2005 funding for charter school facility finance which addresses the needs of the underserved and displaced communities under the jurisdiction of the Subcommittee. At the outset, let me share with you some background information on the NCB Development Corporation and our approach to address the charter school facility finance problem. Then I would like to share our thoughts on why charter schools should be looked at in a community development strategy.

NCB Development Corporation (NCBDC), an affiliate of National Cooperative Bank pursuant to the National Consumer Cooperative Bank Act (Public Law 95–351) is a national nonprofit organization that for 25 years has provided innovative financial and development services to improve the lives of low-income individuals, families, and communities. By creatively investing in our neighborhoods, advocating elected officials around public policy, and collaborating with other national and local community-based organizations, NCBDC helps charter schools finance and develop facilities; creates a policy environment that supports strong, self-sustaining communities; enables community health centers to expand to serve more patients; preserves and creates affordable housing; and helps socially responsible businesses thrive.

As you may already know, according to the Center for Education Reform, there are currently nearly 3,000 charter schools in 42 states and the District of Columbia giving nearly 750,000 students an opportunity to receive a quality education. Unlike traditional public schools, charter schools are not given a public building in which to operate. Instead, it is up to the charter school to find and fund an appropriate location. Operators, who are often concerned parents, teachers, or nonprofit organizations, typically have little experience with planning, zoning, and building code

regulations, let alone finding affordable space and adequate financing. And very few financing organizations are willing to lend to charter schools.

Since the mid-1990's, NCBDC has been considered an expert in the small community of organizations in the forefront of designing and implementing innovative financing strategies to meet a charter school's demand for capital. To date, between our lending and technical assistance programs, NCBDC has assisted 210 charter schools in 19 states obtain the facilities they require to accomplish their missions impacting 38,106 students, provided more than $66 million in facilities financing sustaining no monetary defaults and 0 percent loss rates on charter school lending, and helped leverage more than $100 million in additional funds. Major partners in these initiatives have included the U.S. Department of Education, Charter Friends National Network, the Florida Consortium of Charter Schools and the Midwest Charter Facilities Coalition.

As a 2001 recipient of a U.S. Department of Education National Activities Grant in and in partnership with the Charter Friends National Network established the Technical Assistance Project for Charter School Facilities to help charter schools develop and finance suitable buildings by providing on-the-ground technical assistance and workshops in facility development and financing. In the initial round of the highly competitive U.S. Department of Education's Charter School Facilities Financing Demonstration Grant Program, NCBDC partnered with The Reinvestment Fund, a leading community development financial institution based in Philadelphia, and Foundations, Inc., a leading technical assistance provider. In 2002, we were successful in receiving a $6.4 million grant to create the Charter School Capital Access Program (CCAP). CCAP successfully met the goal of raising $45 million from investors including PNC Bank of Pennsylvania to create a capital pool to help charter schools in the Mid-Atlantic States of New York, New Jersey, Pennsylvania, Delaware, and Virginia, and in the District of Columbia acquire, renovate, or construct facilities. This is a leverage ratio of nearly seven private dollars for every one public dollar.

In 2003, the U.S. Department of Education again recognized NCBDC's innovative work in charter school facility finance and awarded NCBDC a $6 million grant under the Credit Enhancement Program for Charter School Facilities, which is a valuable tool for motivating the private sector to get involved in charter school capital development. This grant will enable NCBDC to enhance facilities loans and educational opportunities for children in Florida, Georgia, Minnesota, and Wisconsin. NCBDC was one of four and the only repeat grantee having been awarded $6.4 million through the Department's initial Charter Schools Facilities Financing Demonstration Program as previously referenced.

Because we have seen firsthand the dire need for charter school facility finance, NCBDC supports the continuation and expansion of the Credit Enhancement for Charter School Facilities Program by increasing appropriations levels as authorized by the United States Congress in No Child Left Behind (NCLB or Public Law 107–110) signed into law on January 8, 2002.

According to a U.S. General Accounting Office (GAO) report commissioned by Congressional Requesters (GAO–03–899, September 2003) states: "The three greatest challenges facing new charter schools were securing a facility, obtaining start-up funding and acquiring the expertise necessary to run a charter school." The 2000 National Study of Charter Schools funded by the Office of Educational Research and Improvement within the U.S. Department of Education identified two of the same obstacles as lack of management expertise and inadequate facilities financing, which pose a formidable obstacle for the vast majority of start-up and established charter schools. Each of the three major financing approaches—municipal bonds, per pupil allocations, and conventional financing—offer only limited opportunities for charter schools that seek funds to lease, acquire, construct, or renovate a facility. There is a no more serious challenge facing charter schools nationally than obtaining upfront and ongoing financing for facilities. Despite the difficulty in securing credit, charter schools are remarkably resourceful in addressing their facilities needs, yet are generally unable to take advantage of the financing that is available to school districts and typically pay for facilities out of their regular operating funds. As a result, finding and funding a building impacts limited operating funds which in turn impacts teachers, administrative personnel and the purchase of everyday supplies.

Not finding a suitable home has delayed school openings, and forced schools to scale back their programs or shut down altogether, due to the inability to find adequate facilities. Charter schools are usually distinguished by their relatively small size; perceived instability of revenue streams, short operating track records, and political uncertainty. These characteristics pose formidable obstacles for the private sector, which has a low-risk tolerance and is often reluctant to lend in an "emerg-

ing" market. Consequently, charter schools also require new, creative financial models to address their growing demand for capital.

NCBDC applauds the President and the United States Congress in their commitment to charter school facility finance including the more than $37 million proved in the omnibus appropriations bill signed into law on January 23, 2004 (Public Law 108–199) for the continuation of the Credit Enhancement for Charter School Facilities Program and the President's $100 million request in his fiscal year 2005 budget released in February 2004. The Program will continue to assist charter schools in acquiring, leasing, and renovating school facilities. This is done through a competitive grant process to public and non-profit entities for loan guarantees, debt insurance, and other activities that facilitate private lending. While the demand for charter school facility finance is estimated nationally at more than $2 billion, $37 million falls far short of the $200 million in grants authorized yearly until 2007 in the NCLB, as outlined in the bipartisan Carper-Gregg Amendment in the act.

With our long history of a strong commitment to community development, particularly as it relates to underserved urban populations, NCBDC believes that strong schools are a cornerstone of any thriving community. Good schools keep families involved in neighborhoods, and this involvement is essential to community revitalization. Public charter schools encourage stability by offering parents a tuition-free choice outside the traditional public school; charter schools can keep families in communities with under-performing public schools. In addition, NCBDC has found that in the process of developing a facility, charter schools can be an effective tool for urban renewal and neighborhood revitalization. Finally, NCBDC believes that strong school-community partnerships, which are encouraged by charter schools, help build neighborhoods.

During this time of rising budget deficits and the rise in the cost of the war on terrorism, fiscal constraints make efforts to fulfill Congress' commitment to education, especially charter school facility finance, far more difficult then it has been in years past. Charter advocates, including NCBDC, have long been supportive of the efforts by the Administration and Congress to provide adequate appropriations for the charter school facilities initiatives set forth in the landmark bipartisan NCLB. We are hopeful that this Subcommittee, and ultimately this Congress, will provide appropriate charter school funding at the authorized levels, as charter schools are continuously faced with the lack of funding or expertise to purchase, build, or renovate a building and other physical plant requirements.

NCBDC appreciates this opportunity to reinforce the critical need served by supporting expanded funding for charter school facility finance. With your assistance, the charter school community can continue to make a difference in the lives of this nation's most vulnerable children, families, and communities. In summary, NCBDC requests a NCLB authorized fiscal year 2005 appropriation level of $200 million to help charters leverage private financing for facilities and start-up costs—an increase of $100 million over the President's fiscal year 2005 budget request and $163 million over the fiscal year 2004 appropriated level. In addition, NCBDC supports the continued expansion of the Public Charter Schools Program by supporting the President's fiscal year 2005 request of $219 million to provide grants to states to support 1,200 new and existing charter schools including $19 million for the new Charter Schools Per-Pupil Facilities Aid program.

Thank you again for allowing NCBDC to present its concerns regarding fiscal year 2005 appropriations provision of charter school facilities financing in written testimony before the Subcommittee.

RELATED AGENCIES

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for 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 nearly 250 community radio stations and related organizations across the country. Nearly half our members are rural stations and half are minority controlled stations. In addition, our members include many of the new Low Power FM stations that are putting new local voice on the airwaves. 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.

In summary, the points we wish to make to this Subcommittee are that NFCB:

—Requests $410 million CPB for fiscal year 2007, a $10 million increase over the fiscal year 2006 advance appropriation;

—Requests $60 million in fiscal year 2005 for conversion of public radio and television to digital broadcasting. Also supports funding for the Public TV interconnection system;
—Requests that advance funding for CPB is maintained to preserve journalistic integrity and facilitate planning and local fund raising by public broadcasters;
—Requests report language 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 $410 million for the Corporation for Public Broadcasting in fiscal year 2007.—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 community is unable to financially support the station 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.

For the past 28 years, CPB appropriations have been enacted 2 years in advance. This insulation has allowed pubic broadcasting to grow into a respected, independent, national resource that leverages its federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service and to explore additional non-governmental support to augment the federal funds. Most importantly, the insulation that forward-funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting."——House Report 94–245.

For the last few years, CPB has increased support to rural stations and committed resources to help public radio take advantage of new technologies such as the Internet, satellite radio and digital broadcasting. We commend these activities which we feel provide better service to the American people, 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 commends 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 Spanish. At the same time, American Indian Radio on Satellite (AIROS) is distributing programming for the Native American stations, arguably the fastest growing group of stations. There are now over 30 stations controlled by and serving Native Americans, primarily on Indian reservations.

This last year CPB undertook a comprehensive assessment of the Native American Radio system. It recognized the importance of these stations in serving local isolated communities (all but one are on Indian Reservations) and in preserving cultures that are in danger of being lost. The report recognized that ". . . very difficult environments." CPB funding is critical to these rural, minority stations. CPB's funding of the Intertribal Native Radio Summit in 2001 helped to pull these isolated stations together into a system of stations that can support each other. The report goes on to say "Nevertheless, the Native Radio system is relatively new, fragile and still needs help building its capacity at this time in its development."

CPB also funded a Summit for Latino Public Radio which took place this in September 2002 in Rohnert Park, California, home of the first Latino Public Radio station. These Summits have expanded the circle of support for Native and Latino Public Radio and identified projects that will improve efficiency among the stations through collaborations, and explore new ways of reaching the target audiences.

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 listeners. 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. An example of this support is the grant that NFCB received to update and publish our Public Radio Legal Handbook online. This provides easy to read information to stations about complying with governmental regulations so that stations can function legally and use their precious resources for programming instead of legal fees.

Finally, community radio supports $50 million in fiscal year 2005 for conversion to digital broadcasting by public radio and television.—It is critical that this digital funding be in addition to the on-going operational support that CPB provides. The Administration's proposal that digital money should be taken from the fiscal year 2005 CPB appropriation would effectively cut stations' grants by more than 25 percent. This would have a devastating impact during these hard economic times when stations are facing major cuts from state and institutional funds. And it would come at a time when the local voices of community and public radio are especially important to notify and support people during emergency situations and to help communities deal with the loss of loved ones—things that commercial radio is no longer able to do because of media consolidation.

While public television's digital conversion needs are mandated by the FCC, public radio is converting to digital to provide more public service and to keep up with what commercial radio is doing. The Federal Communications Commission has approved a standard for digital radio transmission. The initial conversion of radio stations is being concentrated in 13 seed markets. CPB has provided funding for 42 stations in these markets to convert to digital, is supporting additional research on AM radio conversion, and is working with radio transmitter and receiver manufacturers to build in the capacity to provide a second channel of programming. Most exciting to public radio is the encouraging results of tests that National Public Radio has conducted that indicate that stations can broadcast two high quality signals, even while they continue to provide the analog signal. The development of 2nd audio channels will potentially double the public service that public radio can provide, particularly in service to unserved and underserved communities. This initial funding will only help a small number of the stations that will ultimately need to convert to digital or be left behind.

Community Radio also supports funding for the public television interconnection system.

Federal funds distributed by the CPB should be available to all public radio stations eligible for Federal equipment support through the Public Telecommunications Facilities Program (PTFP) of the National Telecommunications and Information Agency of the Department of Commerce. In previous years, Federal support for public radio has been distributed through the PTFP grant program. The PTFP criteria for funding are exacting, but allow for wider participation among public stations. Stations eligible for PTFP funding and not for CPB funding include small-budget, rural and minority controlled stations and the new Low Power FM service.

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 2000 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 in general and community radio in particular, more important as a local voice than we have ever been. New Low Power FM stations are providing new local voices in their communities. Community radio is providing essential local emergency information, programming about the local impact of the major global events taking place, culturally appropriate information and entertainment in the language of the native culture, as well as helping to preserve cultures that are dying out.

During this time, the role of CPB as a convener of the system becomes even more important. The funding that it provides will allow the smaller stations to participate

along with the larger stations which have more resources, as we move into a new era of communications.

Thank you for your consideration of our testimony.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF MUSEUMS

Chairman Specter, Senator Harkin and distinguished members of the Subcommittee, the American Association of Museums (AAM) appreciates the opportunity to testify on the fiscal year 2005 budget for the museum program at the Institute of Museum and Library Services (IMLS). The museum program at IMLS is the primary federal entity devoted to assisting museums in fulfilling their role as centers for lifelong learning for all Americans. We respectfully request your approval of the Administration's budget request of $41.4 million for the Office of Museum Services, which reflects a strong endorsement of the vital public service role museums play in their communities.

The American Association of Museums, headquartered in Washington D.C., is the national service organization that represents and addresses the needs of museums and to enhance their ability to serve the public. AAM disseminates information on current standards and best practices and provides professional development for museum professionals to ensure that museums have the capacity to contribute to lifelong education in its broadest sense and to protect and preserve our shared cultural heritage. Since its founding in 1906, AAM has grown to more than 16,000 members across the United States—nearly 10,500 individual museum professionals and volunteers, more than 3,000 museums, and 2,500 corporate members.

In its reauthorization of IMLS last year, Congress reaffirmed its commitment to the public to ensure that museums will continue to be centers of lifelong learning and to protect and preserve our nation's heritage. By appropriating federal dollars for these purposes, you ensure that society will have museums that are relevant, inspiring and accessible.

Through its grant awards, IMLS has supported museums that are responding to the needs of their communities. We are especially excited about the new Museums for America program, which provides a critical source of funding that supports museums and their roles in public service, education and stewardship. With a focus on strategic planning and institutional mission, it addresses the specific needs of the museum and its community while helping accomplish IMLS's broader national goal of creating and sustaining a nation of learners.

We have already seen the results of IMLS investments in our field. Through the 2003 Learning Opportunities Grants, more than $15 million was awarded to 169 museums. This included a grant to the State Museum of Pennsylvania to create a distance learning program that provides professional development to science teachers in Central Pennsylvania. As school districts meet the challenges put forward in the No Child Left Behind Act, museums are stepping forward with their vast collections, research, and staff expertise to strengthen teachers' current knowledge and classroom instruction in the method of scientific inquiry as well as the other disciplines of arts and humanities.

A project in Iowa is another example of museum-school collaborations. With support from IMLS, the Grout Museum District provided a weeklong Museum School to 1,000 third grade students from the Waterloo and Cedar Falls public schools district. Children, their families and teachers experienced local history. Students applied their lessons in math, science, and language to real-world situations while gaining a greater understanding and appreciation for how their community fits into the larger world.

With grants from IMLS, these museums developed programs that addressed the specific needs of their communities. These examples, however, also represent a much larger commitment museums are making to public education. A recent IMLS survey also shows that museum expenditures in support of K–12 education now exceed $1 billion annually. In fact, the percentage of museums' median annual operating budgets spent on educational programming has increased four-fold just since 1996. With more than 18 million instructional hours in 2000–01, museums are offering a broad range of services to schools. They are key partners in developing curriculum, providing professional development for teachers, and offering direct services to students through visits to museums, classroom visits by museum educators, and Web based educational materials and programs. In some communities, students attend schools that are actually housed in museums and run by museum staff.

The commitment of museums to education does not end with their ties to formal education. Museums are also places of lifelong learning. They provide an environment rich with opportunity for intergenerational learning and sharing where chil-

dren, their parents, and their grandparents can work together to connect ideas and experiences in direct, vivid and meaningful ways. Museum visitors can come to know the struggles and accomplishments of different cultures and unfamiliar people and achieve a deeper understanding of their own families, neighborhoods, the country in which they live, and the world.

Museums do not undertake this educational responsibility without an equal commitment to the care, protection and preservation of our nation's heritage found in their collections. There are more than 750 million objects and living specimens being held in the public trust by American museums. This number grows as museums continue to acquire the material patrimony of our civilization to assure that they remain publicly available for generations to come. A rough estimate places the annual expenditure for the care of those public collections at $1.1 billion. The need for conservation is ongoing and these costs will continue to grow with time as collections expand and age.

IMLS makes significant investments in both direct support for conservation and assistance to museums with identifying and prioritizing their conservation needs. In 2003, Conservation Support grants were awarded to 86 institutions. This program requires a 1:1 match and allows institutions such as the Wentworth-Coolidge Mansion in Portsmouth, New Hampshire to make much needed repairs to its gutters, improve drainage on the site, and make other improvements that will prevent further moisture damage to this national historic landmark and its unique contents.

Through the Conservation Assessment Program, Idaho's Twin Falls County Historical Museum, Texas' Sam Houston Memorial Museum, and Alabama's Magnolia Grove-Hobson Memorial Shrine were able to have a general conservation survey of their collections, environmental conditions and sites. Conservation priorities are identified by professional conservators who spend 2 days on-site and provide a written report to help museums develop strategies for improved collections care. Many institutions use the report for long-term planning and for attracting financial support to meet the conservation needs identified in the report.

America's museums, by their missions and tax exempt status, exist for the benefit of the public. The museums in your states and across the country are responsible for preserving the past, defining the present and educating for our future. The leadership and support of the federal government is critical to each of our nation's museums. The United States has a strong tradition of financial support for the public service mission of museums through public-private partnerships. Museums have three major income sources—private charity and foundation grants, earned and investment income, and government funding. Private charity represents 36 percent of museums' budgets, earned and investment income represents 33 percent and 11 percent respectively, and government funding—local, state, and federal—is 25 percent of museums' budgets. The largest portion of government funding is from the local and state level, with only 2.5 percent coming from the federal government. But it is a critical 2.5 percent.

This diversity of funding sources for museums is critical to their long term financial stability, but the recent economic uncertainty has strained all sources of funding for museums. The good news is that museums are remarkably resilient institutions and are determined to continue with their full array of public programs. This commitment is due in part to IMLS awards made through the Museum Assessment Program.

More commonly known as MAP, participating museums can select from a menu of four assessments and receive a professional review of their operations in that area. Following the review, museums are given recommendations and technical assistance which help them identify how they measure up to best practices in the field and where they might need improvement. This independent report informs an institution as it sets priorities and plans to become a better museum. In 2003, 170 grants were awarded to institutions in 42 states, including the East Ely Railroad Depot Museum in Nevada, Kent Plantation House in Alexandria, LA, and the Fort Worth Botanic Garden in Texas.

Museums must remain responsive to the needs of their communities. The public is concerned about education and our economy. Our institutions are seeking additional new ways to collaborate with the schools and teachers to instill in every child a passion for learning. We are working with local officials to make our communities vibrant and attractive to businesses and tourists. Our nation's museum directors and staff are deeply committed to their work and to serving the public. Every day in our nation's museums, thousands of museum educators greet school buses of children, historians and scientists research our past, and registrars catalog and track millions of objects. And museum directors across the country are always seeking the resources to sustain their institutions so they can fulfill their educational and stewardship responsibilities.

I particularly applaud IMLS and the Administration for recognizing that the needs of our museums are not just for the collections or the public programs, but also for the ongoing professional development of the leaders and staff within our museums—directors, curators, registrars, educators, conservators, and many others. In the fiscal year 2005 budget, the Administration has requested $1 million for the professional development of museum personnel. We will need to invest more, but I believe this to be a good start.

A commitment from the federal government is needed to help museums and their staff fulfill their public obligations. In partnership with IMLS we believe we can do just that, and I stress the word partnership. We fully support the strong U.S. tradition of public-private partnerships supporting museums' public service mission. We believe that IMLS is in a unique position with its expertise and flexibility to help us address these current challenges and to help our museums plan for the future. What the agency lacks is the financial resources.

IMLS needs sufficient funding to help our museums ensure that current and future generations have the fullest access to, and understanding of, our national heritage through the highest quality exhibitions, education programs and digitized materials for the Web. Innovation in museums allows them to better serve the public. As I noted before, we believe the administration's fiscal year 2005 request for the museum programs at IMLS is an important step towards further realizing the potential of museum education and community involvement.

We recognize, Mr. Chairman, that you and your colleagues are under intense pressure to balance the funding needs of the many worthy programs under your jurisdiction. As you consider that balance, I am sure you will recall that last fall you and your colleagues strongly endorsed the mission of IMLS by reauthorizing the agency for another 5 years. That is why we believe $41.4 million for fiscal year 2005 is a reasonable and fiscally responsible budget that will serve the public's demand for museums that are relevant, inspiring and accessible.

We appreciate the opportunity to testify before the committee today and thank you all for your support of our nation's museums and the museum program at IMLS.

PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and Members of the Committee: We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2005 budget request.

The RRB administers comprehensive retirement/survivor and unemployment/sickness insurance benefit programs for railroad workers and their families under the Railroad Retirement and Railroad Unemployment Insurance Acts. The RRB also has administrative responsibilities under the Social Security Act for certain benefit payments and Medicare coverage for railroad workers. During fiscal year 2003, the RRB paid $8.9 billion in retirement/survivor benefits to about 666,000 beneficiaries, and $94.1 million in unemployment/sickness insurance benefits to about 37,000 claimants.

As we explain in greater detail below, the RRB's budget request for fiscal year 2005 is comprised of two parts, $110.66 million for day-to-day administrative expenses, plus $4,947,800 for information technology infrastructure improvements. This request is intended to meet immediate and significant needs of the agency in two principal areas: (1) additional staffing, not only to manage current workloads, but even more importantly, to begin the process of recruiting and training to meet the RRB's staffing needs going forward; and, (2) modernization and improvement of our information technology infrastructure to ensure that the RRB's automated systems will continue to function effectively and efficiently in the future. These are pressing needs that must be addressed. However, at the President's proposed budget level of $102.6 million, not only would these critical, longer-term needs not be funded, but the RRB's ability to continue to deliver quality and timely service in the short term would also be severely jeopardized.

REQUEST FOR ADMINISTRATIVE FUNDING IN FISCAL YEAR 2005

The RRB has demonstrated fiscal responsibility over the years by requesting only what was needed to administer the programs under the Railroad Retirement and Railroad Unemployment Insurance Acts for which we are responsible. Even though our request is $13 million over the President's proposed budget, it represents our considered opinion which will enable us to continue our successful stewardship of the entitlement programs for our constituents. In considering this additional funding, we believe it is appropriate to look at the financial position of the benefit pro-

grams we administer in their entirety. Specifically, we would like to point to the successful implementation of the Railroad Retirement and Survivors' Improvement Act of 2001. Under that Act, we transferred a net $20.39 billion to the National Railroad Retirement Investment Trust (NRRIT) from its inception in February 2002 through September 30, 2003. The funds held by the NRRIT grew to $23 billion during that period, reflecting a 19.9 percent return on investments in fiscal year 2003, a market value gain of $2.7 billion. By comparison, our requested increase in administrative funding represents less than one-half of 1 percent of that increase.

A funding level of $110.66 million for ongoing operations would allow the RRB to maintain our current high levels of timeliness and accuracy in claims processing operations and to provide the quality service our customers expect. Our requested appropriation would provide sufficient funding for 1,046 FTE's—the same number we plan to use in fiscal year 2004. The additional funding would prevent a costly and disruptive reduction-in-force and allow us to hire some new employees for essential positions.

The efficient and timely administration of our Acts requires well-trained and experienced staff. Although the RRB has already suffered significant workforce reductions over the last few years, we have been able to maintain and even improve customer service. This has been accomplished using a core of experienced staff and productivity gains through technology. Our immediate concern today is the aging of our workforce. The bulk of the additional funding in fiscal year 2005, is to mitigate the expected loss of experienced staff by hiring and training new employees and to increase available resources for advances in information technology.

This funding level would also allow us to provide resources for important administrative needs, including travel, training and overtime to support our service to the public. We would also be able to reinstate employee benefit programs, including transit benefit subsidies, which have been suspended due to insufficient funding. At our request level, an additional $300,000 would also be available for information technology. We would use this money to replace aging desktop computing equipment and software.

ENTERPRISE ARCHITECTURE CAPITAL ASSET PLAN

Our budget request includes funding the first year of our Enterprise Architecture Capital Asset Plan for fiscal years 2005–2007, which addresses the major initiatives needed to implement our target enterprise architecture. This request is highlighted separately because of its significance to the long-term continued viability of agency programs, and the realization that movement toward the desired target architecture will be a multi-year effort. We are requesting an additional $4,947,800 to begin these initiatives in fiscal year 2005.

Gartner Consulting has recommended that we investigate alternatives for our Computer Associates' Integrated Database Management System (IDMS) and be prepared to actively retire the platform beyond 2006. The Enterprise Architecture Capital Asset Plan includes funding for contractual assistance, tools and training to begin this transition as well as related initiatives. Funding has been requested in four key areas:

—*Infrastructure modernization initiative ($1,445,000)*.—A variety of improvements to the agency's infrastructure are required to support our target enterprise architecture. This initiative provides agency-wide support at the desktop, systems and network levels. Components include improvements to our data center infrastructure, client/server software and information security.

—*Modernization blueprint initiative ($1,992,800)*.—The primary feature of this initiative is the conversion of the RRB's database from IDMS to a relational database management system. The agency's day-to-day operations are heavily dependent on application systems that are based on IDMS technology. Delaying this transition in fiscal year 2005 would create a high risk that the loss of these systems could compromise the RRB's ability to pay benefits and fulfill its mission in the future.

—*Metadata repository initiative ($555,000)*.—This project funds the development of a preliminary metadata repository, which is a critical success factor for implementation of inter-governmental and internal data sharing services. The metadata repository will enable us to integrate data from various sources and mediums, including railroad employers and employees, annuitants and beneficiaries, State agencies, and other Federal government agencies.

—*E-Government service delivery initiative ($955,000)*.—This project funds our initiative to expand electronic services to the public via the RRB Internet website. In addition, this initiative funds the continued expansion of a system being developed to meet the requirements of the Government Paperwork Elimination

Act, which will permit private employers to store and file electronically, with executive agencies, forms containing information pertaining to employees. We will expand services to railroad employers by providing for on-line completion or transmission of all employer paper forms.

PRESIDENT'S PROPOSED FISCAL YEAR 2005 BUDGET

The President's proposed budget includes $102.6 million for RRB administrative expenses in fiscal year 2005. This total includes $100.5 million for the ongoing costs of current agency operations. In addition, the President's proposed budget includes $2.1 million to contract with a non-governmental disbursement agent for payment of railroad retirement and survivor benefits in accordance with provisions of the Railroad Retirement and Survivors' Improvement Act of 2001 (Public Law 107–90).

We believe that an appropriation at this level would seriously undermine the quality and timeliness of services to our customers in fiscal year 2005. The negative impact would also carry forward to subsequent years due to staff reductions, administrative cutbacks, and further postponement of important automation initiatives.

The reductions at the President's proposed level of funding for fiscal year 2005, would undermine the RRB's ability to process claims in a timely manner, including those for retirement, survivor and disability annuities. Delays would also occur in processing subsequent annuity adjustments, requests for reconsideration and employer reports. Customer outreach services would be reduced, creating delays in responding to inquiries and taking applications for benefits.

Customer service would also be affected if we are required to contract for the use of a non-governmental disbursement agent in fiscal year 2005. Not only would this action increase the RRB's operating costs, but our Inspector General and others have questioned whether certain services provided by the Department of the Treasury, such as reclamations, would be provided as effectively by a non-governmental disbursement agent. On March 20, 2003, we submitted a legislative proposal to permit the Department of the Treasury to continue to make payments of railroad retirement benefits.

We would need to make extremely deep cuts in funding for administrative needs throughout the RRB to operate at the President's proposed level in fiscal year 2005. Because 80 percent of our budget is used for employees' salaries and benefits, a major staff reduction would be unavoidable. We estimate that the President's proposed funding would support only 969 full-time equivalent staff years (FTE's), which is 77 FTE's less than we now plan to use in fiscal year 2004. To reduce agency staffing, we would need to impose a year-long hiring freeze, leaving positions unfilled as vacancies occur through attrition. We would also need to conduct a reduction-in-force of 39 employees at the beginning of fiscal year 2005. The RIF would cost an estimated $473,000.

Information technology (IT) funding would also be severely limited. At the President's proposed level of funding, the RRB would have only $1,325,000 for investments under our ongoing IT Capital Plan. Although e-Government initiatives are essential to maintaining a high level of public service and improving productivity in coming years, we would need to severely curtail purchases of desktop computing equipment and software needed by the agency's staff. In addition, we would have no funding available for the major projects in our Enterprise Architecture Capital Asset Plan. This plan includes funding to begin migration of agency systems from the Integrated Database Management System, which is nearing obsolescence. Not funding this initiative creates a high risk that the loss of these systems could compromise the RRB's ability to pay claims and fulfill our mission in the future.

The proposed budget would also provide insufficient funding for other administrative needs, many of which have been sharply reduced in recent years. We have already suspended several of our employee benefit programs, including transit benefit subsidies and certain award programs, which had contributed considerably to employee morale in the past. These programs would continue to be suspended in fiscal year 2005. We would also continue to severely limit funds allocated for variable expenses, such as overtime, travel, training, supplies and equipment.

In addition to the requests for administrative expenses, the Administration's budget includes $108 million to fund the continuing phase-out of vested dual benefits, and $150,000 for interest related to uncashed railroad retirement checks.

FINANCIAL STATUS OF THE TRUST FUNDS

Railroad Retirement Accounts.—As a result of $18.9 billion in net transfers to the National Railroad Retirement Investment Trust, the net position of the railroad retirement accounts decreased by $18.1 billion in fiscal year 2003, to $551.1 million.

In June 2003, we released the 22nd Actuarial Valuation, including the annual report on the railroad retirement system required by Section 22 of the Railroad Retirement Act of 1974, and Section 502 of the Railroad Retirement Solvency Act of 1983. The actuarial valuation contains generally favorable information concerning railroad retirement financing. However, the long-term stability of the system, under its current financing structure, is still dependent on future employment levels and investment returns. The valuation included projections of the status of the retirement trust funds under three employment assumptions. These indicated cash flow problems only under a pessimistic employment assumption, and then not until calendar year 2022.

Railroad Unemployment Insurance Accounts.—The equity balance of the railroad unemployment insurance accounts at the end of fiscal year 2003 was $51.5 million, an increase of $35.8 million from the previous year. The RRB's latest annual report on the financial status of the railroad unemployment insurance system, issued in June 2003, was generally favorable. The report indicated that even as maximum daily benefit rates rise 44 percent (from $52 to $75) from 2002 to 2013, experience-based contribution rates are expected to keep the unemployment insurance system solvent. The small loan made in fiscal year 2002 was repaid in May 2003, and no new loans are anticipated even under our most pessimistic assumption. The average employer contribution rate remains well below the maximum throughout the projection period, but a 1.5 percent surcharge is now in effect and is expected for calendar year 2005 and probably 2006. We did not recommend any financing changes based on this report.

In conclusion, we want to stress the RRB's continuing commitment to improving our operations and providing quality service to our beneficiaries. Thank you for your consideration of our administrative budget request. We will be happy to provide further information in response to any questions you may have.

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

SUBJECT INDEX

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

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