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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Budget hearings testimony

TESTIMONY

of

DONNA E. SHALALA
U.S. SECRETARY OF HEALTH AND HUMAN SERVICES

before

THE HOUSE APPROPRIATIONS SUBCOMMITTEE
ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION
AND RELATED AGENCIES

Tuesday, March 3, 1998

Good morning, Chairman Porter, Congressman Obey, members of the Subcommittee:

Before I begin, I would like to pay tribute to a member of this subcommittee who has made great contributions to the health and well-being of our nation – Congressman Louis Stokes. I want him to know that his hard work, tenacity and dedication have changed the lives of countless Americans.

Mr. Stokes came to Congress in 1969, the last year we saw a balanced budget. His career has spanned 30 years and in that period his contributions to the American people have been enormous. During his tenure, he has earned the title of "TRIO Champion." He has fought for numerous education programs, like the Historically Black Colleges, magnet schools and also Title I, which provides children with assistance in reading and math. He has been a great ally of health care issues. His leadership on this committee has resulted in increased funding for health professions training, Healthy Start, Maternal and Child Health, Community Health Centers, Centers of Excellence, biomedical research and the list goes on and on. He shares our concern for programs that combat heart disease, diabetes, breast cancer and AIDS. In all of these endeavors, he has placed the nation's health at the top of his agenda.

The Congress and the nation will soon lose a great public advocate. But we wish him a happy, healthy, and much-deserved retirement. Congressman Stokes, on behalf of the residents of your Congressional district, and our home state, we are grateful for your leadership and your steadfast commitment to improving the health of all Americans. We will all miss you and we wish you all the best in the years to come.

Mr. Chairman, I am pleased to appear before you today to discuss the President's FY 1999 budget for the Department of Health and Human Services.

BALANCING THE BUDGET

Last year we spoke at great length about the need to balance the budget. I am pleased to inform you that the President's 1999 budget achieves that goal. But we were able to meet this challenge only because of the extensive cooperation between the Congress and the Administration last year. We proved that by working together, seeking innovative solutions, and squeezing every dollar from our budget, we can put our fiscal house in order. Emerson once said that "success is leaving the world a bit better than you found it." We have left the budget much better than we found it and in doing so we have provided our children with a path to a better fiscal future. This budget proves that we can take on new initiatives in the context of a balanced budget – if we are innovative and disciplined. I am very proud of our collective accomplishment, and I'm sure each of you shares my pride.

Because of our success in achieving a balanced budget, we can now turn renewed attention to the pressing problems of tomorrow:, strengthening the public health and human services, continuing strong fiscal management and preparing for the 21st Century.

PREPARING FOR THE 21ST CENTURY

This is the last budget we will prepare for this millennium, and it sets forth the priorities for the next century, ranging from major increases in health research to promising child care for a million additional children to ending the scourge of youth tobacco use.

The 21st Century Research Fund

The President announced the 21st Century Research Fund to launch a new era of path-breaking scientific inquiry. HHS will play the largest role, with new resources for our constellation of stellar research agencies – including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Agency for Health Care Policy and Research.

First, the 21st Century Research Fund provides the resources necessary to combat cancer, heart disease, diabetes, AIDS, Alzheimer's, cancer, Parkinson's, Hepatitis C and other diseases . The President's budget includes an additional $1.2 billion increase to put us on a path to double our investment in medical knowledge, bridge the gap between scientific knowledge and health care delivery and prevent the spread of disease. By increasing by nearly 50 percent over five years our nation's commitment to NIH at the same time that we increase our commitment to CDC and AHCPR, this fund provides the resources necessary to achieve a better integrated system of health research.

We believe that a coordinated system of health research is the best way to achieve significant results in battling complicated diseases. We must continue to coordinate the efforts of NIH, CDC and AHCPR to attack these serious health threats.

To make our investment worthwhile, we must move our research from the laboratories into the clinics and hospitals. To illustrate this point, consider diabetes. Untreated diabetes is the sixth leading cause of death from disease and the leading cause of adult blindness, kidney failure and non-traumatic amputations. It also is a risk factor for stroke and heart attack. It is estimated that thirty-three percent of people with diabetes – over 8 million people – have gone undiagnosed. The incidence of diabetes is growing in the American population. Medical research alone will not cure this problem. In order to attack diabetes, we need the coordinated efforts of NIH, CDC, and AHCPR.

NIH focuses basic research on the causes of diabetes, including the genetic ones, and researches possible new avenues for treatment. Yet, NIH cannot alleviate diabetes alone. We need CDC's efforts in identifying those with diabetes and persuading them to seek treatment and to educate physicians on how to better detect this disease. We also need AHCPR's research which focuses on finding the most economic and least intrusive methods to screen individuals for diabetes. Without the essential research of NIH and the

prevention services of CDC and AHCPR we will not likely reduce the serious threat that diabetes poses to our society.

The 21st Century Research Fund solidifies the foundation for a coordinated biomedical research system, providing $25 million for CDC's prevention research programs, increasing AHCPR's funding by $25 million in FY 1999 alone, and setting the course to increase NIH funding by nearly half by 2003.

Cancer Research and Clinical Trials

Cancer has been one of the cruelest killers of this generation. The President's budget moves dramatically on this front. The NIH budget, for example, pays special attention to cancer research, increasing funding across NIH by 10 percent in 1999 and 65 percent by 2003. The President also seeks $750 million for a three year demonstration to enable Medicare patients to participate in cancer clinical trials. Medicare patients represent 50 percent of all cancer patients and are ten times more likely to get cancer. It is therefore appropriate to undertake this demonstration for those eligible for Medicare. This demonstration is fully financed by revenues which would result from passage of tobacco legislation.

Vice President Gore has lead the Administration's effort to step up our fight against cancer, and I am personally grateful for his tireless efforts to achieve these historic increases for canceer research.

Child Care

We live in changing times. Families are not the same as they were 30 years ago, the last time we balanced the budget. In millions of American families, both parents must work to support their children, and in millions of other families, single parents work doubly hard to support their children. Building on the Earned Income Tax Credit, the Child Tax Credit, the Family and Medical Leave Act, minimum wage increases and the new child health insurance program, the President's Child Care Initiative is another critical step in this Administration's commitment to our nation's families.

Our FY 1999 budget proposes new child care investments that will support parents' choices, so that they will be able to find and afford quality child care for their children while they work. It will answer their most troubling questions about child care: Can I get it? Can I afford it? And can I trust it for my children's safety and development?

At the center of the President's Child Care Initiative is our proposal to expand the Child Care and Development Block Grant by $7.5 billion over five years (an increase of

$1.2 billion in FY 1999). This will provide funds to the states to serve over 2 million children by the 2003.

The budget also grants tax credits to 3 million working families for child care and tax incentives for businesses that provide child care for their workers. Moreover, this budget includes $3 billion over five years to improve the quality of child care by providing challenge grants distributed by states to communities to improve early childhood education and the quality and safety of child care for children under five years old. In addition, the budget includes $250 million for investing in the education of child care workers and $500 million to help states enforce child care standards, and $150 million for research and consumer education.

Head Start

One of the President's top priorities has been and continues to be investing in Head Start. The President's budget contains $3.8 billion over five years. Because early investment in children gives them the best chance of continued success, by the year 2002 we will serve one million children in Head Start, including doubling to 80,000 the number of children 0-3 served by the Early Head Start Program.

Medicare Buy-in

Our Medicare buy-in program provides solutions to one of the most troubling problems our aging population faces: what happens if I lose my health coverage before I'm 65? The President's budget allows individuals aged 55 and over without access to health insurance to breathe a little easier. The budget proposes a three-pronged solution. First, it enables Americans ages 62 to 65 to buy into Medicare, through a premium designed so that the policy is self-financing. It also provides displaced workers who are ages 55 to 61 with an option to purchase Medicare. Finally, the President's proposal gives individuals who retired early and whose companies have reneged on their health benefits the option to buy into their former employers' health care.

PUBLIC HEALTH CHALLENGES OF THE 21ST CENTURY

Public Health services affect every single American every day of their life. From AIDS prevention and treatment to tobacco control for our youth, our FY 1999 budget builds on and expands our commitment to programs that will make all Americans more health conscious and protect them from traditional and emerging threats to our public health.

Ryan White

We have seen significant progress in the fight against HIV and AIDS. In the first half of 1997, AIDS deaths decreased by 44 percent. Nonetheless, more progress must be achieved. In 1997, The Department of Health and Human Services and the Henry K. Kaiser Family Foundation issued new guidelines for standardizing and improving the quality of care for HIV-infected persons. The quest to ensure access to new methods of treatment must continue. The President's budget addresses this issue and provides $1.3 billion, an increase of $165 million, for Ryan White treatment activities. The AIDS Drug Assistance Program (ADAP) will receive $100 million of this increase for helping individuals gain access to combination drug therapies consistent with the new guidelines.

Food Safety and Emerging Infectious Diseases

The President's budget includes an additional $25 million for a combined effort by CDC to develop and expand national early warning systems for unsafe food and emerging infectious diseases. We must make certain that food-borne diseases don't affect our families. Similarly, we need to closely monitor infectious diseases. Our budget develops an effective national surveillance network and expands the geographic coverage of this early warning network to 30 states. The food safety initiative improves the quality and scope of food-borne disease surveillance in eight FoodNet sites, links the federal and state health laboratories with computer technology that will enhance data sharing, and provides training to detect food-borne diseases in exports from foreign countries, including Mexico and some Latin American countries. In addition, FDA is seeking $50 million to complement efforts in food safety.

Racial Disparities

We have already talked of the serious threat diabetes poses to Americans. Yet, there is another disturbing statistic associated with diabetes. Between 1980 and 1994, the number of African-Americans with diabetes rose 33 percent, 3 times the rate of increase for all other Americans. Native Americans also suffer from diabetes at extremely high rates. If we are to ensure a better future, we must find the answers to this disparity and correct this problem and the many other racial health disparities that exist. The President's budget includes $400 million over five years as part of a broader initiative to find new targeted means of reducing the health disparities that persist among minorities. This money is intended to target health outcomes in six areas where minorities experience serious inequalities in health services and health status. These include: infant mortality, breast and cervical cancer, heart disease and stroke, diabetes, HIV/AIDS, and child and adult immunization. This effort will be Department-wide and will be coordinated by the Centers for Disease Control and Prevention and will be supplemented by a host of non-budget

activities that involve the community and experts in this area to help solve this urgent problem.

Substance Abuse

We must continue our efforts at all levels of government and in the private sector to eliminate substance abuse. Consequently, the President's FY 1999 budget provides an additional $200 million in funds for the Substance Abuse Performance Partnership Block Grant. A total of $1.5 billion will enable states and local communities to enhance their treatment capacity and continue efforts to control and treat substance abuse. We also are concentrating our research efforts in the biological basis of addiction, enhancing prevention techniques, and assessing prevention intervention approaches. With a coordinated effort, we can end this destructive plague.

Tobacco

Our budget request reflects the strong commitment of this Administration and all Americans to ending the tragic and destructive use of tobacco products by children and teenagers. We also are committed to finding the most effective methods for adults who want to quit the addiction that tobacco use creates. For example, CDC and FDA tobacco education and control programs will receive $200 million from the President's budget proposal. CDC will direct a total of $51 million to fund state-based prevention and control activities, including: training and programmatic support for school-based smoking cessation programs; national surveillance activities; state prevention and control plans to protect nonsmokers from exposure to environmental smoke; and state programs to address oral cancer.

The President has made clear his strong desire to work with the Congress to protect our children from the disease and death caused by tobacco use. To do that, we must have comprehensive legislation. Five key elements must be included in such legislation: (1) a significant price increase to reduce teen smoking, including tough penalties if targets are not met; (2) full authority for FDA to regulate tobacco products; (3) changes in the way the tobacco industry does business; (4) progress toward other public health goals; and (5) protection for tobacco farmers and their communities. The President has called for tobacco legislation that will raise the price of cigarettes by up to $1.50 per pack over ten years and curtail tobacco use among youth. We estimate that the President's budget proposal, coupled with sales and advertising restrictions, would reduce underage tobacco use by 39 percent to 46 percent in 2003 and spare almost one million of today's young people from the premature deaths related to tobacco use.

INNOVATIVE PROGRAM AND FISCAL MANAGEMENT

In describing our budget, we must not forget that this committee played a major role in achieving balanced budget savings. It is important to note that our Department played a significant role, as well, in balancing the budget and will contribute $150 billion over the next five years in Medicare and Medicaid savings. After all, at HHS, we believe in responsible, innovative management. In this budget, we have developed innovative solutions to squeeze every ounce of productivity from our taxpayer dollars. We also intend to add additional non-federal resources to meet our program obligations in the years ahead. We need your support for new legislation on many of these proposals. We will work closely with the Congress and this subcommittee to enact this necessary legislation.

Fraud-busting

While I have just mentioned future management efforts, I would like to mention briefly one of our most recent success stories. It's no secret – it's called fraud-busting. In 1997 alone, thanks to the outstanding efforts of the Office of the Inspector General, we returned almost $1 billion to the Medicare Trust Fund in our aggressive pursuit of those organizations and individuals who steal from the Medicare system. When you steal from the Medicare system, you steal from our most vulnerable citizens and we will not tolerate it. New HCFA legislation that we are offering will return an additional $2.4 billion in savings to the Medicare system. We also are proposing a new audit user fee within the Medicare Integrity Program (MIP) that will allow us to double our audit and medical review spending.

The Administration on Aging (AoA), with its vast network of state and area agencies on aging and community-based services, is another partner in the long-term federal effort to fight and prevent fraud and abuse in the Medicare and Medicaid programs. AoA uses the funds allocated under the Health Insurance Portability and Accountability Act (HIPAA) to train and educate both paid and volunteer staff in the aging network. The results are in -- fraud-busting is a smart investment.

User Fees

With the passage of Balanced Budget Act (BBA) and HIPAA, the Health Care Financing Administration (HCFA) has acquired substantial new responsibilities. Without adequate resources these responsibilities simply cannot be accomplished. Given the tight limitations of the BBA, we have sought out alternative fiscal resources. We have proposed $264.5 million in new user fees for services that we furnish our nation's health care providers. I ask the Congress to enact these essential user fees. Our proposed user fees provide for more efficient administration of the Medicare program while allowing greater

control against fraud, waste and abuse. Without such fees, HCFA's ability to implement the BBA and HIPAA requirements would be hindered. Our total program level, including user fees, would allow us to implement the new legislative requirements and help ensure millennium compliance of internal and external computer systems.

Government Performance and Results Act (GPRA)

The budget we have presented highlights the incremental changes that HHS is proposing through its programs. Along with the FY 1999 budget, we also sent to you our first GPRA annual performance plans. These plans focus on the Department's stewardship of all of the resources entrusted to HHS. Our performance plans have been developed in partnership with the states, local and tribal governments, and non-governmental partners who use these resources efficiently.

For example, to help improve health outcomes for individuals in need, particularly children, we have set a performance goal for community health centers to serve an additional 150,000 uninsured and under-served persons in FY 1999.

Similarly, we plan in FY 1999 to increase to 59 percent the proportion of Medicare beneficiaries age 65 and older who will have received a screening mammogram in a 2-year period. As you know, a mammogram is a safe, effective means of detecting breast cancer at an early and treatable stage. This common-sense goal will lead to improved health outcomes for Medicare beneficiaries and avoid the financing of unnecessary, high-cost medical services.

These are brief illustrations of the results that HHS and its partners want to achieve through all of our programs, but they are representative of the goals presented throughout our performance plans for FY 1999. In the coming years, we believe that the focus on results that is fostered by GPRA will enable us to improve our ability to match the most effective forms of service delivery with populations that have the greatest need. GPRA will be an ongoing process. It is neither a quick management fix nor a vague management plan. It can and will work to improve our programs as long as there is a clear and continuing cooperation between the executive and legislative branches on the means to improve programs once the GPRA results are in.

We have proposed our blueprint for the next millennium and I believe it is an excellent drawing.

Conclusion

Mr. Chairman, we share many common goals in this budget. Most importantly, our

concern for a balanced budget continues. We share the common goal of the best health research program ever. We want to end the tragedy of underage tobacco use. We want to expand safe, affordable, high quality child care to another million children. We want to sustain our commitment to Head Start. We want to improve food safety and curb emerging infectious diseases. And, we most assuredly want to maintain a vigorous attack on health care fraud.

Chairman Porter, Congressman Obey and members of the subcommittee: I want to join you in meeting the health and human resource challenges before us in this budget. We have much to accomplish together. I would be happy to address any questions you may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Fiscal Year 1999 Budget Request

Witnesses appearing before the
House Subcommittee on Labor-HHS-Education Appropriations

Nancy-Ann Min DeParle
Administrator, HCFA

accompanied by

Ms. Elaine Raubach, Director, Budget & Analysis Group, Health Care Financing Administration (HCFA)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Nancy-Ann Min DeParle
Administrator, Health Care Financing Administration

on
Fiscal Year 1999 President's Budget Request
for the Health Care Financing Administration

No direct HIV/AIDS references

Mr. Chairman and Members of the Subcommittee:

I am honored to be here today to present the fiscal year 1999 budget request of the Health Care Financing Administration. This is my first opportunity to testify before this Subcommittee as Administrator and I look forward to working with the Members of this Committee on important issues for our Nation's Medicare and Medicaid beneficiaries. The next several years will surely be an exciting and challenging time for our agency.

As we look forward, nothing is clearer than the need to ensure that Medicare and Medicaid are strong, well-managed, and responsive to the beneficiaries. And that is my goal as Administrator. We have an obligation to ensure that our programs are administered efficiently and the services we are purchasing for our beneficiaries are of high quality.

We call this management concept "beneficiary-centered purchasing" and it is at the core of our mission. Our internal reorganization, which was implemented last summer, and our activities implementing the Balanced Budget Act have helped to make that concept the driving principle in our day-to-day operations.

Our 1999 budget request reflects our commitment to aligning the agency's top priorities with the changes in the health care marketplace that will take Medicare and Medicaid into the 21st century. As the first chart shows, these priorities include implementation of the nearly 300

provisions of the Balanced Budget Act in a timely and efficient manner. This is an enormously complex and demanding undertaking. It includes implementing two brand new programs -- the Medicare+Choice program, which will provide beneficiaries with more health plan choices and the Children's Health Insurance Program, which will extend health insurance to millions of uninsured children. In addition, another top priority is strengthening HCFA's ability to fight waste, fraud, and abuse in Medicare and Medicaid. The new budget law includes a variety of provisions which will help us in this program integrity effort and the President asked for additional tools in his new budget proposal. And finally, we are hard at work making sure that the data systems that manage Medicare and Medicaid payments are millennium compliant.

The President's 1999 budget request includes three accounts that are of interest to this Subcommittee: Grants to States for Medicaid; Payments to the Health Care Trust Funds; and Program Management. I will highlight the first two accounts briefly and then discuss our Program Management request for the funds critical to accomplishing all of our priorities.

GRANTS TO STATES FOR MEDICAID

In fiscal year 1999, Medicaid will serve more than 34 million eligible persons--an increase of almost 2 percent over fiscal year 1998, not including beneficiaries covered by the Children's Health Insurance Program. Federal Medicaid obligations for fiscal year 1999 are estimated at nearly $108 billion, an increase of almost 6.9 percent, or almost $7 billion over fiscal year 1998. Total Federal and State Medicaid expenditures are projected to reach $189.3 billion in fiscal year 1999, of which the Federal share is about 57 percent. We are committed to continue working with the States to encourage efficiency in Medicaid and innovative expansions of health care coverage, particularly through the new Children's Health Insurance Program.

PAYMENTS TO HEALTH CARE TRUST FUNDS

Our request of nearly $63 billion includes a Federal general revenue subsidy to the Supplemental Medical Insurance (SMI) Trust Fund of $62.2 billion. This is an increase of $2.4 billion over the expected fiscal year 1998 Federal contribution. While growth in managed

care use and the Balanced Budget Act's partial transfer of home health benefits to SMI produce faster rising total outlay projections in SMI, the impact on the Federal contribution is moderated by the transfer of $10.4 billion from the Hospital Insurance Trust Fund to cover two-thirds of the new SMI benefit for FY 1999.

PROGRAM MANAGEMENT

Our Program Management request shows that it is possible for a government agency to handle massive national health benefit programs with increasing efficiency and productivity. Our request supports the President's commitment to a balanced federal budget, even in the midst of the most sweeping changes since Medicare and Medicaid were begun over 30 years ago. Indeed, for the past several years we have been making tough decisions in financing program administration from an essentially flat base, in constant dollars -- as shown in the second chart. However, I think that now more than ever all of us would agree to the importance of maintaining adequate resources to continue to ensure that the programs are strong, well-managed, and providing beneficiaries the best possible service.

We are actually requesting less than 1 percent of total program outlays for Program Management funding. This administrative cost compares favorable to the private sector. For example, the Blue Cross and Blue Shield Association's advertised administrative costs are 12.5 percent of benefit payments. We expect Medicare and Medicaid benefits, including the Children's Health Insurance Program, will total over $329 billion in fiscal year 1999. However, none of those mandatory benefits can be paid without the completion of activities funded from this discretionary account. Our Program Management request totals $2.1 billion, and consists of the Program Management appropriation request of $1.7 billion; proposed discretionary user fees of $264.5 million; and current law user fees of $195 million. In sum, the total request reflects an increase of $254.5 million from the fiscal year 1998 program level.

FUNDING THROUGH USER FEES

Before I briefly discuss the items or "accounts" that comprise Program Management, I

would like to describe HCFA's user fee proposals that are critical to the implementation of our priorities. Our budget request relies upon the enactment of $264.5 million in proposed discretionary user fees and $195 million in current law user fees that together will finance almost 22 percent of our budget request -- as shown in the third chart. Full funding of these fees are crucial to our ability to maintain our priority program operations as well as our new responsibilities such as implementing the new Medicare+Choice program that will give beneficiaries more health care options. We recognize the importance of controlling discretionary spending if we are to achieve a balanced federal budget. We also recognize the equally compelling need for adequate administrative spending to effectively manage the Medicare and Medicaid programs. We have attempted to reconcile these precepts through the proposal of alternative user fee funding mechanisms, to make needed funds available.

These user fees will support ongoing Medicare+Choice information campaign activities nationwide, as well as strengthen the effectiveness and efficiency of HCFA's Program Management operations. The new user fees cover provider and supplier enrollment registration, managed care application and renewal, initial provider certification, provider re-certification, paper claims submission, and duplicate or "unprocessable" claims submission. A significant portion of our budget depends on the enactment of these user fees. We need full funding of these user fees to avoid significant disruption of HCFA's operations that could delay the implementation of the Administration's priorities. We are eager to work with both this Committee and the authorizing committees to enact this critical source of funding.

I would now like to discuss briefly the items or "accounts" that comprise Program Management: Research and Demonstrations, Medicare Contractors, Medicare State Certification, and Federal Administration.

RESEARCH AND DEMONSTRATIONS

Our Research and Demonstrations request is $50.0 million, the same as the fiscal year 1998 appropriated level. The request includes $11.0 million to continue the Medicare Current

Beneficiary Survey, whose data supports HCFA researchers in many studies of health care financing delivery mechanisms. The remaining $39.0 million includes $18.4 million for the continuation of ongoing research activities and $20.6 million to implement new projects that support Congressional and Administration priorities, including activities to support the Balanced Budget Act. Of the total budget request for research, $11.0 million will support congressionally-mandated projects.

MEDICARE CONTRACTORS

Our request for Medicare contractors demonstrates that we continue to strive to do more with less while emphasizing customer service. In fiscal year 1999, Medicare contractors will process an estimated 935 million claims--almost a 5 percent increase over FY 1998. Despite this growth in volume, our Medicare contractors request includes an increase of less than 7 percent, or $54.2 million, above the fiscal year 1998 appropriated level for basic claims processing activities. Our fiscal year 1999 request for Medicare contractors is $1.3 billion and consists of the appropriation request of $1.1 billion plus $165.5 million in proposed discretionary user fees. This funding level accommodates the expected increase in claims workloads, provides resources sufficient to ensure integrity in claims processing operations, and allows for other critical operational support including millennium compliance.

Contractor functions are at the heart of the Medicare program. Over the past few years, we have made great strides in improving efficiency in the area of claims processing through productivity investments including the transition of contractors to selected standard claims processing systems, and customer service improvements. We will continue to improve efficiency in these areas.

MEDICARE STATE CERTIFICATION

The Medicare State certification program ensures that facilities participating in Medicare meet Federal health, safety, and program standards. The Medicaid Survey and Certification counterpart is funded through the Grants to States for Medicaid account. State Survey and

Certification activities seek to secure quality services for all Medicare and Medicaid beneficiaries. Our Medicare State Certification budget request is $167.0 million or $13.0 million over the fiscal year 1998 appropriated level. The fiscal year 1999 request consists of the $104.7 million appropriation request plus $62.3 million in proposed discretionary user fees.

This funding level will provide the necessary resources for us to keep pace with the continuous growth in this program. More specifically, the request will support inspections of all facilities seeking to participate in Medicare for the first time as well as re-inspections of all currently participating nursing homes and home health agencies that are statutorily mandated. Also, the request supports inspections of a minimum of 10 percent of non-statutorily mandated facilities. Moreover, we will continue to pursue increased program efficiencies and look at ways to improve our survey process.

FEDERAL ADMINISTRATION

The Federal Administration portion of the Program Management account supports the day-to-day operations of HCFA's headquarters as well as our 10 regional offices. The fiscal year 1999 request of $455.8 million consists of our appropriation request of $419.1 million plus $36.7 million in proposed discretionary user fees. This request includes $322.6 million to fund 4,217 FTEs, which includes 190 additional FTEs to support balanced budget implementation and 65 additional FTEs to support activities attributable to the Health Insurance Portability and Accountability Act. These additional resources are paramount to the successful implementation of this legislation, especially in the Medicare+Choice managed care provisions and activities to assist States as they implement insurance reform. Moreover, leveraging the talent of our staff will increase our ability to serve and meet the future health care needs and challenges for the 73 million Medicare and Medicaid beneficiaries. The request also includes funding to ensure millennium compliance of Medicare systems at the HCFA data center.

MEDICARE INTEGRITY PROGRAM

In fiscal year 1999 we will continue to implement the provisions of HIPAA, including

measures to both prevent fraud and penalize wrongdoers. The Medicare Integrity Program (MIP) will help us target fraud and abuse resources at the most vulnerable areas to maximize our return on investment, to protect scarce taxpayer funds, and to protect the fiscal integrity of the Trust Funds so that Medicare is available to those who need it today and in the next century. This budget requests $395 million in proposed mandatory user fees, together with the mandatory MIP funding level of $560 million, for a total investment of $955 million. The proposed user fees will bolster our flexibility to focus on areas expected to yield the greatest return on investment. Although this user fee is not subject to appropriations, we look forward to working with this Committee as well as the authorizing Committee to enact our entire user fee bill.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

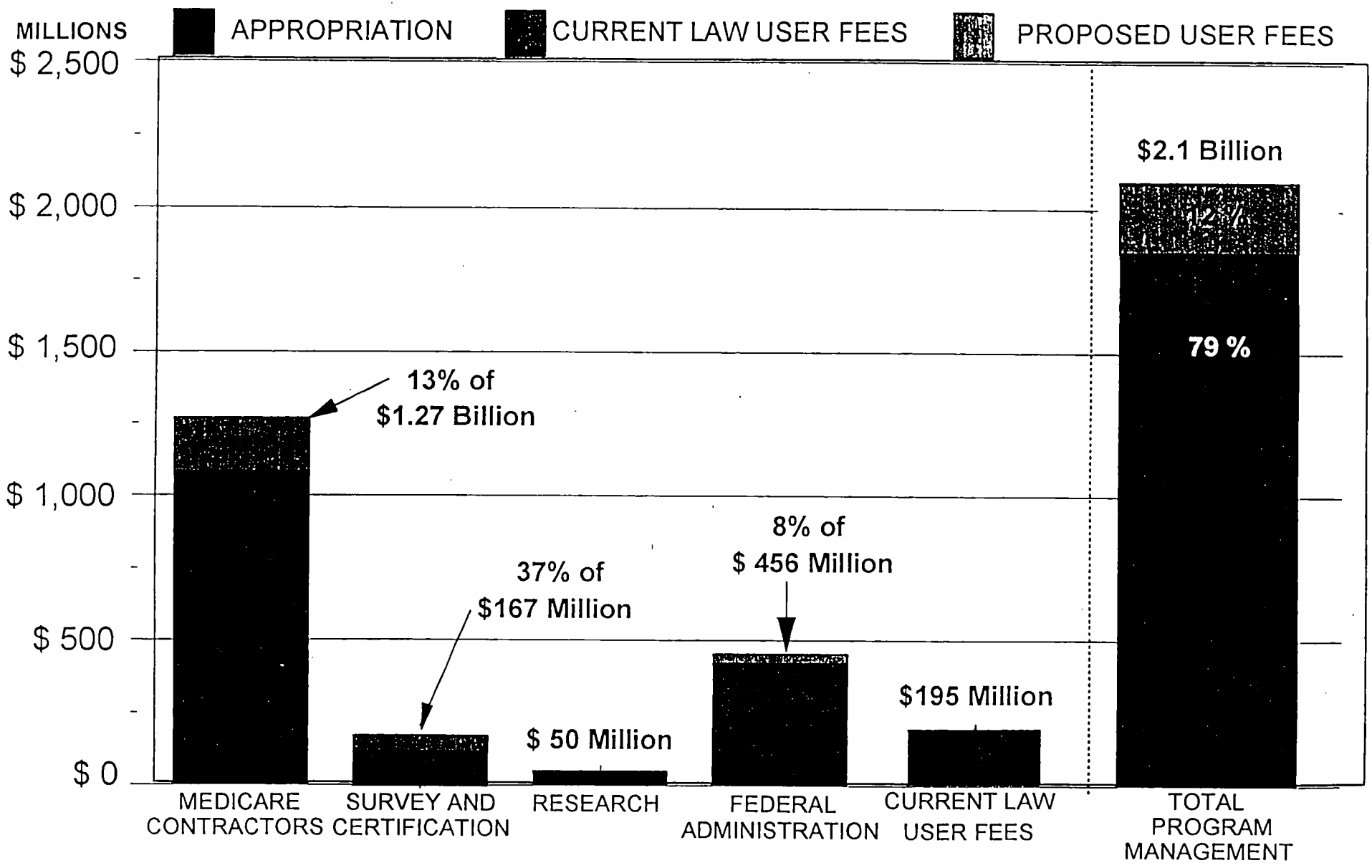
Our budget request also incorporates the first Annual Performance Plan required under GPRA. The fiscal year 1999 performance goals and measures are detailed in our performance plan, and are linked to both the budget and to HHS's GPRA Strategic Plan (transmitted to Congress on September 30, 1997). However, in fiscal year 1999 we have been granted a waiver by the Office of Management and Budget from the GPRA requirement that performance goals be established for Medicaid. The waiver grant will provide us the additional time needed to consult with States regarding goals and data sources. Performance targets in the Plan are partially a function of resource levels requested in the President's budget, and could change based upon final congressional appropriations action. We look forward to receiving feedback from Congress on the usefulness of our Performance Plan, as well as to working with Congress on achieving the goals specified in our plan.

Our fiscal year 1999 budget request comes at a very exciting time in American health care. Enactment of the Balanced Budget Act and other key legislative changes will improve the way in which Medicare and Medicaid are financed and managed. Our fiscal year 1999 budget request was formulated to be both flexible and responsive to these changes. I am confident that this budget request will enable us to respond quickly and effectively to the needs of the Nation's rapidly changing health care system, as we approach the 21st century. The years ahead promise

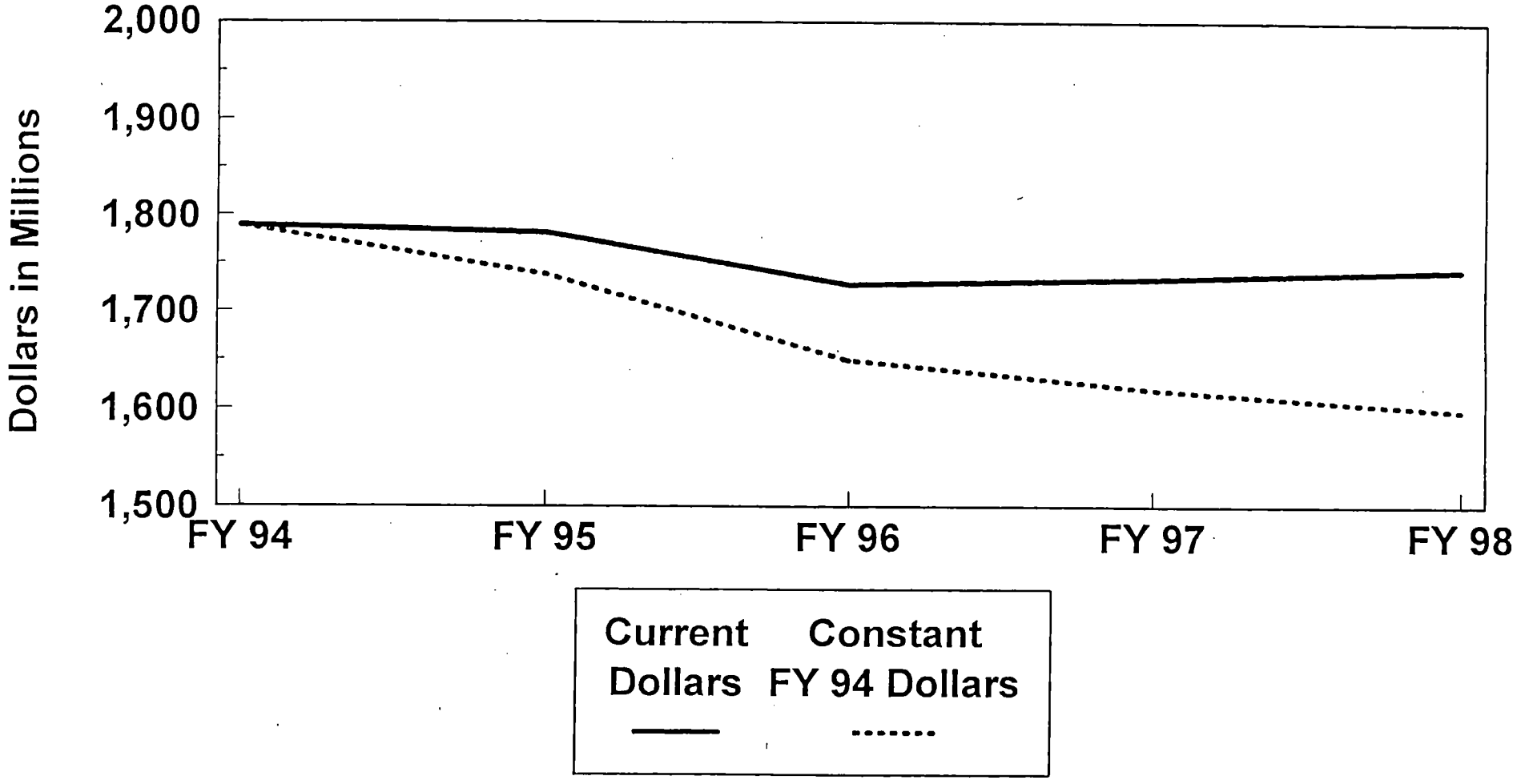
great opportunities to improve the effectiveness and efficiency in which the Government ensures the continuation of health care services and other vital safety net programs that so many millions of Americans increasingly rely upon.

Thank you for the opportunity to present HCFA's budget request. I look forward to working with this Committee and I would be happy to respond to any questions or suggestions that you may have.

FY 1999 PROGRAM MANAGEMENT FUNDING : APPROPRIATION AND USER FEES



Program Management Purchasing Power
FY 1994 - FY 1998



FY 1999 BUDGET PRIORITIES

- Reform and Strengthen Medicare by Implementing the Balanced Budget Act
- Launch Children's Health Insurance Program
- Sharpen Focus on Fraud, Waste and Abuse
- Ensure Data Systems are Millennium Compliant

Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
U.S. Department of Health and Human Services

President Clinton nominated Nancy-Ann Min DeParle to serve as the Administrator of the Health Care Financing Administration (HCFA) on June 27, 1997. Ms. DeParle served as Deputy Administrator until November 8, when the Senate approved her nomination as HCFA's eighth Administrator. From 1993-1997, she served as Associate Director for Health and personnel of the White House Office of Management and Budget (OMB) where she had responsibility for budgetary and policy maters relating to all Federal health programs, including Medicare and Medicaid. From 1987 - 1989, she served in the Cabinet of Tennessee Governor Ned McWherter as Commissioner of Human Services. Ms. DeParle administered a 6000-employee agency with a $500 million budget that provided Food Stamps, AFDC, rehabilitation, and child welfare services. Ms. DeParle has also worked as a lawyer representing states in litigation involving Federal health and welfare programs and as an adjunct professor at the Vanderbilt School of Law.

A native of Rockwood, Tennessee, Ms. DeParle received a B.A. with highest honors from the University of Tennessee, Knoxville, where she served as president of the student body. She holds B.A. and M.A. degrees from Balliol College, Oxford University, which she attended as a Rhodes Scholar, and a law degree from Harvard Law School.

In 1994, Ms. DeParle was named by Time magazine to its roster of "America's 50 most promising leaders age 40 and under."

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. resume	[Personally Identifiable Information] [partial] (7 pages)	00/00/1998	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Todd Summers
OA/Box Number: 21083

FOLDER TITLE:
Budget-FY [Fiscal Year] 98-HHS [Health and Human Services]-Shalala Testimony
(House Appropriations)

2018-0758-F
rs3229

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Biographical Sketch

NAME	Elaine M. Raubach
POSITION	Director, Budget & Analysis Group Office of Financial Management Health Care Financing Administration
BIRTHPLACE AND DATE	(b)(6)
EDUCATION	M.B.A. Loyola College, 1987 M.A. University of Virginia, 1971 A.B. Rutgers - The State University, 1970

EXPERIENCE

1997-Present	Director, Budget & Analysis Group Office of Financial Management Health Care Financing Administration
1996-1997	Director, Reorganization Implementation Team Office of the Administrator Health Care Financing Administration
1992-1996	Director, Office of Information Resources Management Bureau of Data Management & Strategy Health Care Financing Administration
1991-1992	Director, Division of ADP Planning and Resources Management Office of Information Resources Management Bureau of Data Management & Strategy Health Care Financing Administration
1987-1991	Deputy Director, Division of Budget Office of Financial Mangement Office of Budget and Administration Health Care Financing Administration

Dennis P. Williams
Deputy Assistant Secretary
For Budget
U.S. Department of Health and Human Services

Dennis Williams has served as Deputy Assistant Secretary for Budget since 1984.

Dennis provides advice and assistance to the Assistant Secretary for Management and budget, and the Secretary, on program policy and management issues dealing with the Department's budget. He is responsible for the formulation of the budget for HHS and its presentation to the Office of Management and Budget and to Congress.

From 1982 until 1984 he served as the Director, Division of Welfare Budget Analysis in HHS. Before that, starting in 1980 until 1982 he served as Chief, Health Care Financing Branch, Division of Health Budget Analysis.

From 1977 until 1980 Dennis was a Program Analyst in the Division of Health Budget Analysis.

Prior to his appointment at HHS, Dennis served from 1968 until 1971 as a Program specialist with the Office of Economic Opportunity and from 1965 to 1967 with the Peace corps in Turkey. He was awarded a doctorate in International Relations at the Johns Hopkins School of Advanced International Studies in 1976.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Fiscal Year 1999 Budget Request

Witnesses appearing before the
House Subcommittee on Labor-HHS-Education Appropriations

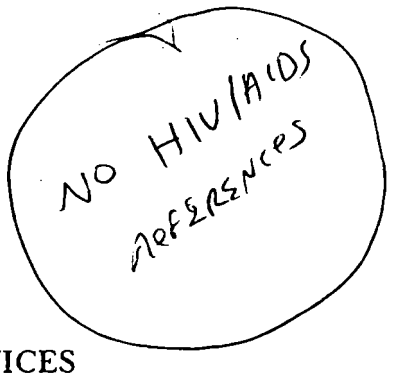
Dr. John M. Eisenberg
Administrator, AHCPR

accompanied by

Dr. Lisa Simpson, Deputy Administrator, Agency for Health Care Policy and Research

Ms. Rita Koch, Chief, Office of Management, Financial Management Staff

Mr. Dennis P. Williams, Deputy Assistant Secretary, Budget, Department of Health and Human Services



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Dr. John M. Eisenberg
Administrator, Agency for Health Care Policy and Research

on
Fiscal Year 1999 President's Budget Request
for the Agency for Health Care Policy and Research

Mr. Chairman and Members of the Committee, I am pleased to be here today for the first time as Administrator to present the President's budget request for the Agency for Health Care Policy and Research (AHCPR). AHCPR's mission is to provide science-based information that will improve decision making at all levels -- from patients, to clinicians, to health care system leaders, to public and private policymakers. AHCPR also has been designated by Secretary Shalala as lead agency on quality of care, and health care quality research will be the Agency's highest priority during the next year as our budget request reflects.

CHALLENGES FACING AHCPR'S CUSTOMERS

Our FY 1999 budget request recognizes the need to address the challenges faced by AHCPR's customers. Some of these challenges are long standing. However, new challenges have arisen because of rapid changes in the organization and financing of health care services.

The changing nature of health care delivery forces the health care industry to adapt at every level, and seek out information -- based on evidence -- that will guide decisionmaking by patients and clinicians, health care system leaders, and public and private policymakers. I cannot overstate the importance of an evidence base for clinical medicine. It gives health care professionals the information they need to make effective, timely diagnoses, and to provide appropriate treatment. Health professionals need to know what works to provide quality health care, and their patients deserve no less. However, while it is good to have a large body of information, we need to provide this information in a useful format.

We need an infrastructure in place that will provide patients with information on health care quality. This information should include outcomes of treatments, patient assessments, and other quality indicators. In addition, we also need to track our progress over time to provide policymakers with the ability to assess the quality, cost, and access to care in America.

The changes to the health care system have created new structures, processes, and settings in which care is delivered. Health care system leaders need answers to questions such as: what is the impact on quality? and What happens to patients' access to services, the cost of those services, how they are used, and what are the outcomes of patients who use the services?

BUILDING THE EVIDENCE BASE

I see AHCPR's clinical research as a continuum. First, we build the science base by conducting health services research that serves as the foundation for improved care. Second, we translate and disseminate the research in a format that can be used in clinical practice. Third, we evaluate the translation and dissemination of that research to make sure that it has reached the relevant audiences and is used appropriately.

I'd like to tell you about some of AHCPR's current work that promotes the development and use of science-based information, and then talk about what we hope to initiate in 1999 with your help.

AHCPR's sponsored research attempts to determine what works and doesn't work for a wide variety of common, costly medical conditions and treatments, and for which there is substantial variation in practice. For example, an AHCPR-supported study found that treating common ear infections in children with antibiotics, such as amoxicillin instead of more costly choices, could save millions of dollars a year without changing recovery rates. Middle ear infection is the most frequent reason for giving antibiotics to children in the United States, and no single antibiotic has been found to be superior in treating this condition. However, costs of antibiotics vary widely, from under $3 dollars to over $60 for a course of treatment.

Last fall, AHCPR named 12 Evidence-based Practice Centers, or EPCs, each of which will develop a scientific analysis, in the form of a report, of the evidence of the effectiveness of a various treatments, technologies, or procedures. This analysis will then be used by health care organizations, medical societies, physician practices, and others to develop their own quality improvement tools, including guidelines, quality improvement programs, and performance measures.

For example, an EPC at the Blue Cross and Blue Shield Association Technology Evaluation Center is studying testosterone suppression treatment for prostatic cancer. At present, prostate cancer is the second leading cause of cancer deaths in U.S. males with estimated costs of $1.5 billion per year in direct medical expenses and substantial costs expended in the Medicare Program. Clearly, we need to know what works and what doesn't work for this condition. Other EPC topics include rehabilitation of persons with traumatic brain injury, depression treatment with new drugs, and treatment of attention deficit-hyperactivity disorder.

In addition to EPCs, AHCPR, in partnership with the American Medical Association and the American Association of Health Plans, is establishing a National Guideline Clearinghouse (NGC) to provide one-stop-shopping for best practices in clinical care. The NGC will make existing clinical practice guidelines available to every clinician, patient, health system leader, and policymaker who can use a computer.

MEASURING AND IMPROVING HEALTH CARE QUALITY

Recent public debate has focused on the concern of many Americans that ongoing changes to the health care systems are having an adverse impact on the quality of health care, particularly for people with chronic conditions.

AHCPR's activities are helping to build the knowledge needed to measure and improve health care quality accurately and reliably. We are working to refine existing measures and develop new measures that accurately reflect the changing health care system. An important component in this effort to develop and test valid measures is to anticipate future measurement needs. The goal of our efforts is to begin to identify and develop the "next generation" of quality measures for certain conditions, population subgroups, particularly vulnerable populations such as the chronically ill, and in the full spectrum of treatment settings, such as rehabilitation and home care.

An important component of improving the quality of health care services is giving patients the information they need to make informed choices about their health care coverage, physicians, and treatment options. The White House recently announced the release of AHCPR's Consumer Assessments of Health Plans Survey (CAHPS), a series of questionnaires designed to be used by public- and private-sector health plans, employers, and other organizations to survey their members and employees. The information from CAHPS questionnaires can lead to informed choices based on quality.

We know that consumers select health plans based on the recommendations of their families, friends, and colleagues at work. While this is a good start, CAHPS provides information on the experiences of hundreds of people who already are in a particular plan. This provides a view of a health plan that is more representative and more reliable than what can be captured by the opinions of a few individuals. Since CAHPS allows for comparisons among similar and across different types of plans (managed care vs. fee for service), consumers will be able to get a complete picture of the what each option provides and how it stacks up to what else is available.

CAHPS already is being used by a wide range of private sector organizations, including Ford Motor Company's Department of Health Care Quality, which is testing it in two markets. The surveys have been used by more than 20 states, including California, Maryland, New Jersey, Washington, Texas, and Florida. The White House also announced last Friday that HCFA will begin fielding a CAHPS survey, developed in partnership by AHCPR and HCFA, to assess the quality of care in Medicare managed care plans.

FY 1999 BUDGET REQUEST

In fiscal year 1999, AHCPR requests a total of $171.4 million, an increase of $25 million over the FY 1998 Appropriation. This level of support will provide for new extramural research in areas such as outcomes and effectiveness research; measuring quality; research on health care markets, organization and delivery; evidence-based

practice research; pharmaceutical research; minority health; women's health; cost effectiveness analysis; and health services research training.

The increase of $25 million over the FY 1998 Appropriation will support the Secretarial Initiative to Improve Health Care Quality, outcomes research for the elderly, chronically ill and children, development of two Centers for Education and Research Therapeutics as directed by Congress in the FDA Reform Bill, and support for two Clinical Prevention Centers. Support will also continue, at a total of $27.8 million, for the Medical Expenditure Panel Survey (MEPS).

INITIATIVE TO IMPROVE HEALTH CARE QUALITY

In addition to the fundamental health services research on health care quality that will be carried out through investigator-initiated projects, in the FY 1999 Request, AHCPR will provide $15 million to support the Secretary's Initiative to Improve Health Care Quality. Through this initiative, the entire Department will collaborate to pursue five goals: making information on quality easier for consumers to use; strengthening value-based purchasing by the Department; improving the quality of health care services delivered directly by Department programs; expanding research that improves quality; and measuring national health care quality as reflected in our budget submission.

OUTCOMES FOR THE ELDERLY, CHRONICALLY ILL

In FY 1999, AHCPR will focus its research on the elderly and chronically ill population. The increasing growth of the elderly population in this nation will have a dramatic impact on the cost and organization of health care, particularly in the area of chronic illness and disability. New health services research totaling $5 million for this important population will be focused on the cost, quality and outcomes of care for chronic illness and disability.

CHILDREN'S HEALTH

AHCPR is also focusing its research on health care for children. The passage of CHIP provides a landmark opportunity to assist states and communities through the development and dissemination of tools to measure and improve the quality of care for children in this country. The $2 million included in the FY 1999 Request will provide support for applied research and demonstrations on the most important challenges in children's health. In addition, AHCPR will support research and evaluations of various state and local approaches to implementing the CHIP legislation. AHCPR will disseminate research findings and provide technical assistance to states, providers, and communities about what works in improving children's health.

CLINICAL PREVENTIVE SERVICES

Providers and patients have great interest in the full range of appropriate preventive care. These interventions have the potential to improve the health of the American

people, but we need to know what is effective. In FY 1999, we will support major new assessments of preventive services to provide information that will help decision making about preventive services. AHCPR also will sponsor the Put Prevention into Practice initiative, which creates and disseminates tools for providers, health systems, and patients to improve delivery and receipt of these preventive care recommendations.

CENTERS FOR EDUCATION AND RESEARCH THERAPEUTICS

The recently enacted Food and Drug Administration Modernization and Accountability Act of 1997 includes new responsibilities for AHCPR. A level of $1 million will allow AHCPR to support the establishment and operation of two Centers for Education and Research Therapeutics (CERTs). The CERTs will increase the awareness of new uses and risks of medical products, and help prevent adverse effects of medical products and the consequences of these effects.

THE MEDICAL EXPENDITURE PANEL SURVEY (MEPS)

Funding for MEPS continues to be one of our highest priorities in FY 1999 with a total of $27.8 million being allocated. I am pleased to announce that the first MEPS data became available in April, 1997 with subsequent releases thereafter. This data fulfilled one of our performance plan objectives, as required by Government Performance and Results Act (GPRA) of 1993, to release and disseminate MEPS data and information products in timely manner.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The timely release of MEPS data is only one objective in AHCPR's overall FY 1999 Performance Plan as required by GPRA. The FY 1999 President's Budget request for AHCPR incorporates the first Annual Performance Plan required under GPRA. The FY 1999 performance goals and measures are detailed in our performance plan, and are linked to both the budget and to the HHS GPRA Strategic Plan (transmitted to Congress on September 30, 1997). Performance targets in the Plan are partially a function of resource levels requested in the President's Budget, and could change based upon final Congressional Appropriation action. We look forward to Congress' feedback on the usefulness of our Performance Plan, as well as to working with Congress on achieving the goals laid out in our plan.

CONCLUSION

Mr. Chairman, the health care marketplace continues to change at a rapid rate, and timely and accurate information from AHCPR-supported research is critical to maintaining high quality health care for all Americans. Approval of AHCPR's budget request for FY 1999 will ensure that unbiased, reliable information on the cost-effectiveness of treatments for specific conditions, as well as strategies to translate the best science into routine practice, are implemented and result in high-quality care at an affordable cost. My colleagues and I will be happy to respond to any questions that you may have.

John M. Eisenberg, M.D., M.B.A.
Administrator
Agency for Health Care Policy and Research

John M. Eisenberg, M.D., M.B.A. was appointed Administrator of the Agency for Health Care Policy and Research (AHCPR) in April 1997. As Administrator, Dr. Eisenberg oversees the lead federal agency charged with conducting and sponsoring research to enhance the quality, appropriateness, and effectiveness of health care services, and access to care.

Dr. Eisenberg also serves as the Senior Advisor to the Secretary on Quality, with AHCPR designated as the Department of Health and Human Service's (HHS) lead agency for health care quality improvement issues. He coordinates HHS's work on behalf of the Secretary regarding the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry and chairs an interagency committee on quality. He also co-chairs the Department's Data Council. Since May, 1997, Dr. Eisenberg has also been Principal Deputy Assistant Secretary for Health and has served as Acting Assistant Secretary for Health.

A clinician and researcher, Dr. Eisenberg has held key positions in academic and clinical medicine. Prior to his appointment at AHCPR, Dr. Eisenberg was Chairman of the Department of Medicine, Physician-in-Chief, and Anton and Margaret Fuisz Professor of Medicine at Georgetown University. Previously, he was Chief of the Division of General Internal Medicine and Sol Katz Professor of General Internal Medicine at the University of Pennsylvania .

From 1986 through 1995, Dr. Eisenberg was a founding Commissioner of the Congressional Physician Payment Review Commission, serving as its Chairman from 1993-1995. He was the first physician to be elected President of the Association for Health Services Research in 1991-1992, and also served as President of the Foundation for Health Services Research. He has been President of the Society for General Internal Medicine, and Vice President of the Society for Medical Decision Making. Dr. Eisenberg is a member of the Institute of Medicine of the National Academy of Sciences. He served on the Board of Regents of the American College of Physicians and is a Master of the College, and was on the American Board of Internal Medicine.

Dr. Eisenberg has published over 200 articles and book chapters on topics such as physicians' practices, test use and efficacy, medical education, and clinical economics. His book, *Doctors' Decisions and the Cost of Medical Care*, was published in 1986. He was co-author of *Paying Physicians*, published in 1992, and co-editor of *The Physician's Practice*, published in 1980.

He is a magna cum laude graduate of Princeton University (1968) and the Washington University School of Medicine in St. Louis (1972). After his residency in Internal Medicine at the University of Pennsylvania, he was a Robert Wood Johnson Foundation Clinical Scholar and earned a Master of Business Administration degree at the Wharton School with distinction.

LISA SIMPSON, M.B., B.Ch., M.P.H.
Deputy Administrator
Agency for Health Care Policy and Research
Department of Health and Human Services

Dr. Simpson, a pediatrician and public health administrator, was appointed acting deputy administrator of the Agency for Health Care Policy and Research (AHCPR) in August 1995. She has served as senior advisor to the administration since 1994.

During her tenure at AHCPR, Dr. Simpson has promoted research that: enables physicians to improve clinical effectiveness; fosters partnerships between patients and clinicians in medical decision making; and, focuses on issues related to children.

Dr. Simpson is AHCPR's liaison for the National Committee for Quality Assurance. She participates in the American Medical Association's initiative on physician performance assessment and is an adjunct professor at Johns Hopkins University School of Public Health.

Prior to her services at AHCPR, Dr. Simpson was a senior policy analyst in the Office of the Assistant Secretary for Health. She was a mid-career fellow at the Institute for Health Policy Studies, School of Medicine, University of California, San Francisco from 1991 to 1993; and was the director of Maternal and Child Health for the State of Hawaii from 1988 to 1990.

Dr. Simpson holds a masters of public health (M.P.H.) from the University of Hawaii and a doctorate of medicine (M.B., B.Ch.) from Trinity College, Dublin, Ireland (1981).

RITA M. KOCH
Chief, Financial Management Staff
Agency for Health Care Policy and Research
U.S. Department of Health and Human Services

Ms. Koch is the Chief of Financial Management, in the Office of Management, for the Agency for Health Care Policy and Research. Prior to this position, she served as the Budget Policy Chief for the National Institutes of Health. Ms. Koch was a senior budget analyst for the National Archives and Records Administration from 1985 to 1987. Prior to this, Ms. Koch was a budget analyst at the Agricultural Marketing Service and the Food Safety and Inspection Service, both within the Department of Agriculture. Ms. Koch holds a master's degree in business administration in management of science, innovation, and technology from George Washington University and an undergraduate degree in political science (B.A.) from the University of Houston.

Ms. Koch has received several awards and recognition for her work including the NIH Director's Award in 1992 and has twice received the AHCPR Administrator's Award for Excellence, in 1994 and 1996.

DENNIS P. WILLIAMS
DEPUTY ASSISTANT SECRETARY
FOR BUDGET
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dennis Williams has served as Deputy Assistant Secretary for Budget since 1984.

Dennis provides advice and assistance to the Assistant Secretary for Management and Budget, and the Secretary, on program policy and management issues dealing with the Department's budget. He is responsible for the formulation of the budget for HHS and its presentation to the Office of Management and Budget and to Congress.

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From 1977 until 1980 Dennis was a Program Analyst in the Division of Health Budget Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Fiscal Year 1999 Budget Request

Witnesses appearing before the
House Subcommittee on Labor-HHS-Education Appropriations

Dr. Kenneth Olden
Director, NIEHS

accompanied by

Dr. Samuel H. Wilson, Deputy Director

Mr. Charles E. Leasure, Jr., Associate Director for Management

Ms. Laurie Johnson, Budget Officer

Dr. Harold Varmus, Director, National Institutes of Health

Mr. Dennis P. Williams, Deputy Assistant Secretary, Budget, Department Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

No HIV/AIDS References

Statement by

Dr. Kenneth Olden
Director, National Institute of Environmental Health Sciences

on
Fiscal Year 1999 President's Budget Request
for the National Institute of Environmental Health Sciences

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Environmental Health Sciences (NIEHS) for FiscalYear 1999, a sum of $348.1 million, an increase of $24.5 million over the comparable FY 1998 appropriation. Including the estimated allocation for AIDS in both years, total support proposed for NIEHS is $354.8 million, an increase of $24.7 million over the FY 1998 appropriation. Funds for NIEHS efforts in AIDS research are included within the Office of AIDS Research budget request. The activities of the NIEHS are covered within the NIH-wide Annual Performance Plan required under the Government Performance and Results Act (GPRA). The FY 1999 performance goals and measures for NIH are detailed in this performance plan and are linked to both the budget and the HHS GPRA Strategic Plan which was transmitted to Congress on September 30, 1997. NIH's performance targets in the Plan are partially a function of resource levels requested in the President's Budget and could change based upon final Congressional Appropriations action. NIH looks forward to Congress' feedback on the usefulness of its Performance Plan, as well as to working with Congress on achieving the NIH goals laid out in this Plan.

ENVIRONMENTAL HEALTH SCIENCE AND PUBLIC POLICY

As shown in Exhibit #1, the focus of my presentation is "Bridging the Gap Between Environmental Health Science and Public Policy". This topic logically leads to the question, "How many times during your tenure in the U.S. Congress have you faced the

quandary of being asked to intervene in environmental health policy issues in the face of significant uncertainties?"

Just last summer I imagine that many of you were queried about the health effects of *Pfiesteria* following fish kills along our eastern shores. This is an important issue where the concerns of agribusiness, industry, tourism, and environmentalism are all potentially involved. As another example, many of your constituents have perhaps expressed concern about health effects of low level electric and magnetic fields. Your concern has certainly been voiced to me in the form of a directive in the 1992 National Energy Policy Act; as Director of the NIEHS, I am required to give to you this year a report on the possible risks of these exposures. Perhaps some of you have been involved in the recent discussions surrounding federal reference doses for mercury. This issue is particularly important because developing fetuses are unusually sensitive to this neurotoxicant. Also I suspect that many of you were involved in discussions surrounding new ambient standards for ozone and particulate matter, which were reassessed by the EPA as part of its requirements under the Clean Air Act Amendments of 1990. Finally, you will soon be asked to consider the Environmental Protection Agency (EPA) proposal to require detailed reporting about chemicals and potential health hazards in drinking water. While expansion of federal environmental "right to know" regulation for drinking water is in principle a good thing, can Americans make informed decisions given the magnitude of the data gaps in the toxicological profiles on the mixture of over 700 chemicals in the drinking water of the U.S.?

What these few examples have in common is that, all too often, important public health decisions have to be made in the face of significant uncertainties. It is this inadequate information base, coupled with the undeniable economic costs of remediation, that continually forces those of you in Congress to determine where the balance should be between suspected public health effects of environmental exposures and the economic costs of reducing these exposures.

The frequency of such quandaries indicate how important it is to make strategic investments to generate not only more information, but better information for use in decision making. Some of the strategic investments required for optimal data generation and decision making are shown in Exhibit #2. I am convinced that the new cutting-edge technologies in genetics and cell biology position us to make significant progress in these areas. I will discuss some of the areas and the promises they hold.

INDIVIDUAL SUSCEPTIBILITY

Last year I discussed how a person's risk differs according to their genetic makeup and the need for this information to improve risk assessment decisions. An Environmental Genome Project was proposed that could address this knowledge gap. I am pleased to report that a trans-NIH effort, involving numerous Institutes, is underway to investigate the genetic basis of environmental disease susceptibility. The discovery of susceptibility genes is critical to a better understanding of numerous diseases, and the development of prevention and treatment strategies. Such studies will shed some light on the often asked question, "Why me, Doc?", and will help change the current one-size-fits-all approach to health care and environmental health and safety regulations.

EXPOSURE ASSESSMENT

Little is known about which compounds in our environment people are actually exposed to or how much of these exposures they absorb or store in their bodies. Recent advances in analytical techniques should permit detection of environmental and occupational chemicals in small samples of blood and urine. This past year the NIEHS has been developing an exposure assessment program, Body Burden 2000, that is evolving into a multiagency initiative involving the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), EPA, Department of Defense (DOD), and others. Already we have experienced success in a pilot project with CDC

designed to improve the exposure assessment of environmental endocrine disruptors. This information will be useful as regulatory agencies grapple with the issue of endocrine disruptors, particularly as they affect the health of children.

HIGH THROUGHPUT TECHNOLOGY

In 1992, I alerted you to the need for high throughput technologies for toxicologic testing. The last 50 years has witnessed the development of over 75,000 chemicals. Yet, according to a recently published Environmental Defense Fund report, "even the most basic toxicity testing cannot be found in the public record for nearly 75% of the top-volume chemicals in commercial use," (EDF, 1997). In a similar study, the National Academy of Sciences' National Research Council concluded that 78% of the highest-volume chemicals in commercial use "had not had even minimal toxicity testing" (NAS/NRC, 1984). We are clearly in a state of toxic ignorance and it is not likely to be resolved by our current reliance on 2-year rodent bioassays. The NIEHS has made considerable progress in developing technologies that can eliminate, or at least reduce, the testing backlog that leads to this state of toxic ignorance. As I have reported to you previously, the NIEHS, under the auspices of the National Toxicology Program (NTP), is evaluating the predictiveness of novel genetically engineered mouse models called transgenics. To date we have screened 32 chemicals in the new test systems and Exhibit #3 shows typical results. In most cases the same result was obtained in both the conventional and transgenic models and in all cases at least one of the three transgenic models repeated the result of the conventional bioassay. Thus a screen of three transgenics could potentially substitute for conventional rodent bioassays. Exhibit #4 shows the savings--in time, money, and animals--that this technology could offer. While I am not yet prepared to recommend the use of transgenics in lieu of the conventional rodent bioassays, the results are very exciting.

One of the most exciting aspects of this program is that it is being done in partnership with the pharmaceutical and chemical manufacturing industries. Also, since 1997, all 2-year studies reported by the NTP are accompanied by results from parallel studies in transgenic animals. This program will greatly increase our ability to evaluate the best uses for transgenic models in regulatory decision making. Based on progress with these alternative systems, the FDA is now allowing some test data to be submitted using transgenic animals.

Relying on whole animal bioassays, even transgenic animals, will not completely solve our information deficit. The NIEHS is developing a new methodology, called computational biology, that allows regulators to use a variety of information -- chemical structure relationships, tests in single cell systems, limited whole animal studies -- to assess how environmental agents alter critical biological systems and cause disease. The regulatory community has already used several examples of this approach as a basis for improving risk assessments. The NIEHS plans to provide even more tools for rapid assessments and is hoping to exploit advances in recombinant DNA technology, combinatorial chemistry, and microarray technology.

COMPLEX MIXTURES

Another strategic investment I discussed last year was the need to define health effects from exposures to complex mixtures, rather than the current system which only assesses effects of single compounds. The NIEHS will be funding university-based researchers throughout the country to address this critical research gap. I am confident that in the future I will have significant successes to share with you on the research outcomes of these studies.

CHILDREN'S HEALTH

Children are another critical strategic investment. As you know the developing child represents a particularly vulnerable target for adverse environmental effects. This Nation has been particularly vigilant in protecting its children at those times when solid, scientific information has been provided. The story of lead and its subsequent dramatic decline in children illustrates our determination to protect the child. This resolve, however, was only possible because of the firm scientific foundation provided by the research community, much of which was supported by the NIEHS. The NIEHS continues to support research in the critical area of children's susceptibility to environmental agents.

According to a recent report of the National Resources Defense Council (NRDC, 1997), the worst environmental threats to children's health include: lead, air pollution, pesticides, environmental tobacco smoke, and drinking water contamination. Other important health concerns include children's greater vulnerability to radiation-induced thyroid cancer, their susceptibility to the neurotoxicity of polychlorinated biphenyls and their potential interaction with environmental endocrine disruptors released into our environment that have the ability to alter hormone functions.

To address these problems the NIEHS is establishing Centers for Children's Environmental Health and Disease Prevention. Working jointly with the EPA and CDC, we are recruiting the research community to establish Children's Environmental Health and Disease Prevention Centers to define the environmental influences on asthma and other respiratory diseases, childhood learning, and growth development.

The incidence of childhood asthma is rising at an alarming rate, particularly among the urban poor. Common household allergens in the air may be contributing to this devastating disease. It remains to be proven if removing the allergens from a household

will provide an effective remedy in reducing asthma attacks or incidence. These propositions are under examination in multicenter, multiyear studies sponsored collaboratively by the NIEHS and the National Institute of Allergy and Infectious Diseases (NIAID). This Inner-City Asthma Study is a prevention trial to develop a comprehensive and cost-effective intervention strategy to reduce asthma morbidity in inner-city children and adolescents.

Given the NIEHS' interest in exposure assessment that I mentioned earlier, it is logical that we have added an exposure assessment study to complement this effort. A National Allergen Survey is being done in collaboration with the Department of Housing and Urban Development (HUD). It is a population-based, national survey of dust hazards in U.S. homes and will monitor for both allergens and lead. Our objective is to examine the relationship between allergen exposure and diseases such as asthma and allergies. This study will give us an estimate of allergen exposures in the general population, will estimate the magnitude of the allergen problem in the U.S., and will reveal how allergen exposures differ as a function of geographic region, socioeconomic status, housing type, and ethnicity.

SUMMARY

In summary, I have articulated a series of strategic investments worthy of public support. Improved methods for carcinogenicity testing and exposure assessment and expanded epidemiological and mechanistic studies are needed to gain a better understanding of gene-environment interaction. With these programs, the NIEHS is leading the way to modernize risk assessment and bridge the gap between environmental health science and the public policy it serves. I would be happy to respond to any questions you may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Biographical Sketch

NAME	Kenneth Olden, Ph.D.
POSITION	Director, National Institute of Environmental Health Sciences (NIEHS) and Director, National Toxicology Program (NTP)
BIRTHPLACE	(b)(6)
DATE	
EDUCATION	B.S., Knoxville College, 1960; M.S., University of Michigan, 1964; Ph.D., Temple University, 1970 (research done in absentia at the University of Rochester).
EXPERIENCE	
1991-present	Director, NIEHS and NTP
1985-1991	Director of the Howard University Cancer Center and Professor and Chairman of the Department of Oncology, Howard University Medical School
1984-1985	Associate Director for Basic Research and Deputy Director, Howard University Cancer Center, and Professor of Oncology, Howard University Medical School
1982-1984	Associate Director for Research and Deputy Director, Howard University Cancer Center, and Associate Professor of Oncology, Howard University Medical School
1979-1982	Associate Director for Research, Howard University Cancer Center, and Associate Professor of Oncology, Howard University Medical School
1978-1979	Research Biologist, Division of Cancer Biology and Diagnosis, National Cancer Institute

1977-1978	Expert (Biochemistry) Division of Cancer Biology and Diagnosis, National Cancer Institute
1974-1977	Senior Staff Fellow, Division of Cancer Biology and Diagnosis, National Cancer Institute
1970-1974	Research Fellow and Instructor of Physiology, Harvard University Medical School
1964-1965	Research Assistant, Department of Biological Chemistry, Columbia University

PROFESSIONAL ORGANIZATIONS

American Society for Cell Biology; American Society of Biological Chemistry; American Association of Cancer Research; Society for Biological Response Modifiers; Metastasis Research Society.

HONORS AND AWARDS

Porter Development Postdoctoral Fellow, 1970. NIH Postdoctoral Fellow, 1970-73. Macy Faculty Fellow, 1973-74. Citation Classic, Current Contents, Life Sciences, 1980. Member, Division of Cancer Biology and Diagnosis Board of Scientific Counselors, National Cancer Institute, 1981-85. Member, Public Policy Committee of the American Society for Cell Biology, 1984. Co-Chairman, Mid-Atlantic Region of National Black Leadership Initiative on Cancer, 1987-89. Member, Board of Directors, Association of American Cancer Institutes, 1987-90. Member, Division of Cancer Treatment Board of Scientific Counselors, National Cancer Institute, NIH, since 1988. Selected as "One of sixteen historical and contemporary role models" for the Museum of Science and Industry exhibit on Black Achievers in Science, Museum of Science and Industry, Chicago, IL, 1988. Member, Board of Directors of Association of Minority Health Professions Schools, 1988-present. Member and Co-Chairman of National Advisory Committee on Socio-Economically Disadvantaged of The American Cancer Society, 1988. Member, Advisory Panel Council for Cell Biology, National Science Foundation, 1989-90. Presidential appointment to membership on the National Cancer Advisory Board, 1991. Associate Editor of Cancer Research, The Journal of the National Cancer Institute, Cell Regulation, and Environmental Health Perspectives. Elected to membership in the Institute of Medicine in 1994. HHS Secretary's Distinguished Service Award, 1995. Presidential Meritorious Executive Rank Award and City of Medicine Award, 1996. Presidential Distinguished Executive Rank Award, 1997.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Biographical Sketch

NAME	Samuel H. Wilson, M.D.
POSITION	Deputy Director, National Institute of Environmental Health Sciences (NIEHS) and Deputy Director, National Toxicology Program (NTP)
BIRTHPLACE	(b)(6)
DATE	
EDUCATION	A.B., University of Denver, 1961 M.D., Harvard Medical School, 1968 Postdoctoral, Dartmouth Medical School, 1968 Postdoctoral, NIH, 1970.

EXPERIENCE

1996-present	Deputy Director, NIEHS, NIH and NTP
1995-1996	Director, Centennial Center for Environmental Toxicology UTMB
1991-1996	Director, Sealy Center for Molecular Science, UTMB
1968-1992	Medical Officer, U.S. Public Health Service
1986-1991	Chief, Nucleic Acid Enzymology Section, Laboratory of Biochemistry, National Cancer Institute, NIH
1970-1985	Research Scientist, Laboratory of Biochemistry, National Cancer Institute, NIH
1961-1962	Graduate Fellow, Department of Chemistry, Denver Research Institute, University of Denver
1968-1970	Postdoctoral Fellow, Laboratory of Biochemical Genetics, National Heart Institute, NIH

1967-1968	Postdoctoral Fellow, Department of Biochemistry, Dartmouth Medical School
1964-1966	Student Research Associate, Department of Bacteriology and Immunology, Harvard Medical School

HONORS AND AWARDS

NIH Merit Award, 1997
Lecturer, Becton Dickinson/University of Maryland, B.C., Symposium, 1997
H.M. Parker Lecturer, Pacific Northwest Laboratory, DOE, 1997
Plenary Lecturer, Steiner Symposium, University of Maryland (BC), 1995
Keynote Lecturer, Seno Memorial Symposium, Yokohama, Japan, 1996
Plenary Lecturer, Beckman Symposium, City of Hope Medical Center, Duarte, CA, 1996
Corpus Ortigoza Lecturer, Baylor College of Medicine, Houston, Texas, 1996
The Mary Gibbs Jones Distinguished Chair in Environmental Toxicology, UTMB, 1995-96
Biochemistry Study Section, DRG, National Institutes of Health, 1992-96
PHS Meritorious Service Medal, NIH, 1988

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Biographical Sketch

NAME	Laurie Johnson
POSITION	Budget Officer, National Institute of Environmental Health Sciences
BIRTHPLACE	(b)(6)
DATE	
EDUCATION	Business Administration, Eastern Washington University, 1975
EXPERIENCE	
1995 - Present	Budget Officer, National Institute of Environmental Health Sciences
1994-1995	Acting Budget Officer, National Institute of Environmental Health Sciences
1986-1994	Budget Analyst, National Institute of Environmental Health Sciences
1984-1985	Supervisory Budget Analyst, Bonneville Power Administration, Portland, OR.
1980-1984	Budget Analyst, Bonneville Power Administration, Portland, OR.
1978-1980	Administrative Assistant, Bonneville Power Administration, Portland, OR.
1976-1978	Public Utilities Assistant, Bonneville Power Administration, Portland, OR.
HONORS AND AWARDS	National Institutes of Health Award of Merit, 1996

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF MANAGEMENT AND BUDGET

BIOGRAPHICAL SKETCH

NAME	Dennis P. Williams
POSITION	Deputy Assistant Secretary for Budget
BIRTHPLACE	
DATE OF BIRTH	(b)(6)
EDUCATION	B.A. Boston College, 1965 Ph.D., M.A., International Relations at the Johns Hopkins School of Advanced International Studies, 1976

EXPERIENCE

1984-present	Deputy Assistant Secretary for Budget
1982-1984	Director, Division of Welfare Budget Analysis
1980-1982	Chief, Health Care Financing Branch Division of Health Budget Analysis
1977-1980	Program Analyst in the Division of Health Budget Analysis
1968-1971	Program Specialist with the Office of Economic Opportunity
1965-1967	Volunteer with the Peace Corps in Turkey

HONORS AND AWARDS

1997	Secretary's Distinguished Service Award for Kennedy-Kassebaum Team
1995	Secretary's Distinguished Service Award for HHS Independent SSA Planning Team
1993	Secretary's Certificate of Appreciation for HHS Budget Development
1991	Presidential Meritorious Rank Award and Secretary's Distinguished Service Award

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NAME: Harold E. Varmus

POSITION: Director, National Institutes of Health

BIRTHPLACE: New York

DATE: December 18, 1939

EDUCATION: B.A., Amherst College, 1961
MA., Harvard University, 1962
MD., Columbia University , 1966

EXPERIENCE:

The first Nobel Laureate to serve as Director of the NIH. Previously a professor of microbiology, biochemistry, and biophysics and the American Cancer Society Professor of Molecular Virology at the University of California, San Francisco. Internationally recognized authority on retroviruses and the genetic basis of cancer.

In 1989, shared with UCSF colleague, J. Michael Bishop, M.D., a Nobel prize in Physiology or Medicine for demonstrating that cancer genes (oncogenes) can arise from normal cellular genes, called proto-oncogenes. Research activities have been supported by grants from the NIH, , the American Cancer Society, and the Melanie Bronfman Award for Breast Cancer. The research is continued through his laboratory at the National Cancer Institute, National Institutes of Health.

Prior to becoming Director of NIH, served as chairman of the Board of Biology for the National Research Council, advisor to the Congressional Caucus for Biomedical Research, member of the Joint Steering committee for Public Policy of Biomedical Societies, and co-chairman of the New Delegation for Biomedical Research, a coalition of leaders in the biomedical community. In 1986, chaired the subcommittee of the International Committee on the Taxonomy of Viruses that gave the AIDS virus its name, HIV.

The author or editor of four books and over 300 scientific papers. Elected to the Institute of Medicine, the National Academy of Sciences, and the American Academy of Arts and Sciences. Authored the book, "Genes and the Biology of Cancer," intended for a general audience, was co-authored with Robert Weinberg for the Scientific American Library.

After an internship and residency in internal medicine at Columbia-Presbyterian Hospital in New York, served as clinical associate for two year at the National Institute of Arthritis and Metabolic Diseases at the National Institutes of Health. Served as a post-doctoral fellow in Dr. Bishop's laboratory in 1970, initiating a longstanding collaboration to study tumor viruses, and was appointed to the faculty later that year. In 1979, became a full professor and an American Cancer Society Research Professor in 1984.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Biographical Sketch

NAME	Charles E. Leasure, Jr.
POSITION	Associate Director for Management, National Human Genome Research Institute (NHGRI)
BIRTHPLACE	
	(b)(6)
DATE	
EDUCATION	Business Administration, Georgetown University, 1960; Georgetown University Law Center, 1961
EXPERIENCE	
1998-present	Associate Director for Management, National Human Genome Research Institute
1988-1998	Associate Director for Management, National Institute of Environmental Health Sciences
1984-1988	Executive Officer, National Institute of Environmental Health Sciences
1974-1984	Associate Director for Administration, National Institute of Allergy and Infectious Diseases
1970-1974	Administrative Officer, National Cancer Institute
1969-1970	Contract Specialist, National Cancer Institute
1966-1969	Administrative Assistant, National Cancer Institute.
1965-1966	Employee Management Relations Specialist, Office of the Director, National Institutes of Health
1961-1965	U.S. Navy
AWARDS	Presidential Executive Rank Award, 1995

BRIDGING THE GAP BETWEEN ENVIRONMENTAL HEALTH SCIENCE AND PUBLIC POLICY

National Institute of
Environmental Health Sciences

EXHIBIT #1

Prescription Toward Relieving Toxic Ignorance

Step 1 -- Develop high throughput approaches for carcinogenicity and toxicity testing.

Step 2 -- Determine the basis for the wide variation in individual responsiveness to exposure to environmental toxicants.

Step 3 -- Define health effects from exposures to complex mixtures.

Step 4 -- Develop analytical techniques for direct assessment of human exposure.

Step 5 -- Elucidate environmental health and safety threats to children.

Step 6 -- Establish a mechanistic basis for toxicity.

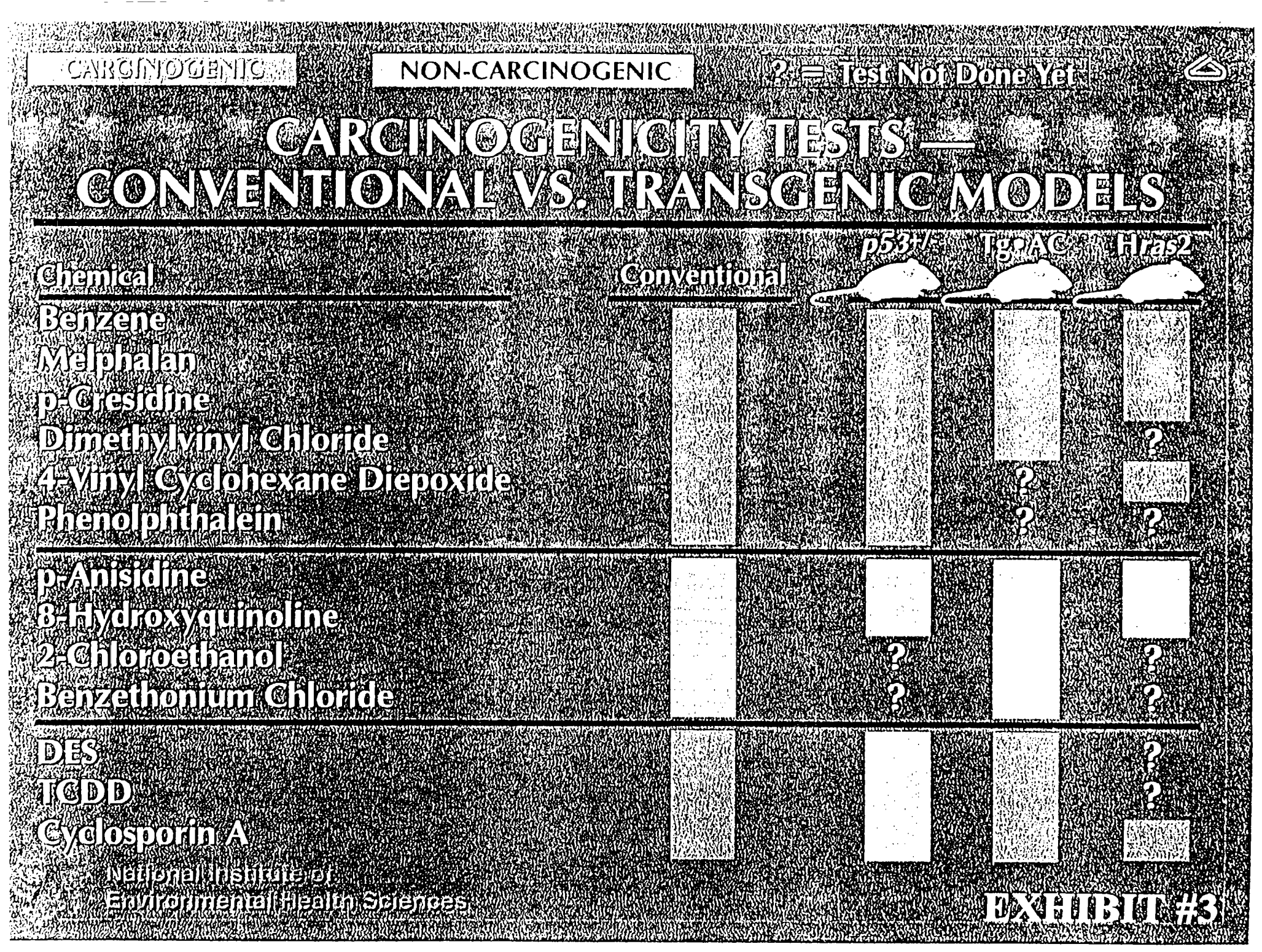
Step 7 -- Investigate possible complex interaction between poverty, environmental pollution, and health status.

National Institute of
Environmental Health Sciences

EXHIBIT #2

CARCINOGENIC | NON-CARCINOGENIC | ? = Test Not Done Yet

CARCINOGENICITY TESTS — CONVENTIONAL VS. TRANSGENIC MODELS



National Institute of Environmental Health Sciences

EXHIBIT #3

Advantages of Transgenic Rodent Bioassays

Transgenics	Conventional
6 months	2 years
$110,000	$2M - $6 Million
150 animals	800 animals

EXHIBIT #4

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 1999 Budget Request

Witnesses Appearing Before the House Subcommittee on Labor-HHS-Education Appropriations

Dr. Richard D. Klausner,
Director, National Cancer Institute

accompanied by

Dr. Alan Rabson,
Deputy Director, National Cancer Institute

and

Dr. Harold Varmus,
Director, National Institutes of Health

Mr. Dennis P. Williams,
Deputy Assistant Secretary, Budget, DHHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Dr. Richard D. Klausner
Director, National Cancer Institute

on
Fiscal Year 1999 President's Budget Request
for the National Cancer Institute

Mr. Chairman and Members of the Committee:

I am pleased to appear before you for the third time as Director of the NCI. The President in his FY 1999 budget has proposed that the NCI receive $2.536 billion, an increase of $215 million (or 9.27 percent) over the non-AIDS portion of the comparable FY 1998 appropriation. Including the estimated allocation for AIDS, total support proposed for NCI is $2.776 billion an increase of $229 million (or 8.99 percent) over the FY 1998 appropriation. Funds for NCI efforts in AIDS research are included within the Office of AIDS research budget request. This will allow us to both continue and accelerate the progress I believe that we are making.

Last year, we reported what we believed to be a historic observation--the first sustained, significant decrease in cancer mortality rates since such statistics were collected in the 1930s. We agreed then, in collaboration with the American Cancer Society and the National Center for Health Statistics of the Centers for Disease Control and Prevention, to issue an annual report card on cancer statistics. This year's report card, using numbers updated through 1995, will be presented at a press conference on Thursday, March 12, but I can tell you that the encouraging trends continue. This year, we have added incidence trends as well. From 1973 to 1990, overall cancer incidence rates increased by 1.2 percent per year. Since 1990, they have decreased by 0.7 percent per year. This drop includes three of the most common cancers: lung, colorectal, and prostate. Breast cancer rates, after increasing by 1.8 percent per year, are now flat.

Non-Hodgkin's lymphoma had been rising at the extraordinary rate of 3.5 percent per year. While it is still rising at 0.8 percent per year, the slowdown in the rate of increase is significant.

Likewise, overall death rates continue to decrease by 0.5 percent per year, after rising 0.4 percent per year. For white males, this drop is 0.9 percent per year, while for black males, the mortality rate drop is 1.3 percent per year. Quite significant changes in incidence, mortality and pattern of disease rates for prostate cancer, the most common cancer in men, are currently being carefully analyzed. Overwhelmingly, due to the continuing increase in tobacco-related cancer deaths for women, the drop in their mortality rates is less than for men, 0.1 percent per year in whites and by 0.2 percent per year in blacks. Not captured by the above statistics are prolonged survival and improved quality of life for many of the millions of cancer survivors in this country.

CONTROL AND PREVENTION

This year, I received reports from two outstanding blue ribbon panels advising the Institute on critical opportunities and needed approaches in cancer control and cancer prevention. We are now engaged in implementing the many recommendations of these groups, expanding our activities in these areas. Our response has included the formation of two newly configured divisions of the National Cancer Institute, the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences. These new divisions will strengthen our efforts in both cancer prevention and cancer control. This past year, in cancer prevention, we completed the accrual of 13,000 women at increased risk of developing breast cancer to a critical clinical trial to determine whether the anti-estrogen, tamoxifen, can actually prevent this disease. The development of new so-called "designer estrogens" is creating new possibilities for very selective hormone manipulation for cancer prevention and we are actively evaluating clinical trials to examine this. The NCI is currently sponsoring 85 chemoprevention

trials for breast, colorectal, lung, prostate and other cancers, a growing number of these based upon a real understanding of the mode of action of the interventions. Twenty-five new prevention trials are to be implemented over the next year.

Identifying populations and individuals at high risk for cancer is a growing focus of the NCI. The Cancer Genetics Network, will involve eight different centers throughout the U.S. The goal is not only to identify new genes that predispose to cancer but also to learn better ways to counsel people, help them cope with the sequelae of genetic testing, and apply cancer prevention and early detection strategies in high risk individuals. Evaluating the efficacy of surveillance and prevention in high risk groups is the subject of several initiatives. One such population is the 8-9 million cancer survivors in the U.S. who are at an increased risk for the development of second cancers. In FY 1998, we have invested five million new dollars to put in place a growing research portfolio under the coordination of our Office of Cancer Survivorship to address the many issues facing this population. Our goals include not only decreasing the risk of second cancers but also improving quality of life among our survivors.

INCREMENTAL ADVANCES

Advances in treatment often are incremental and they take time to have an effect on cancer mortality. It is this incremental progress that, in part, explains the mortality trends for numerous cancer sites. We have had few dramatic therapeutic breakthroughs in cancer research. We have, however, developed a clinical trials system to test and optimize often complex therapies. Over the past 12-24 months, we have completed clinical trials that have established new standards of optimal therapy for women with node-negative and locally advanced breast cancer, for women with advanced ovarian cancer, for patients with nasopharyngeal cancer, for melanoma, and for childhood renal cancer.

A major explanation for the incremental nature of progress in treatment is that, with the exception of hormonal manipulation, our therapies have not been designed to target the machinery of cancer. This brings me to focus on dramatic changes in the National Cancer Program.

THE FRUITS OF RESEARCH

Thirty years ago, Peyton Rous in his Nobel Lecture said, "Tumors destroy man in a unique and appalling way, as flesh of his own flesh which has somehow been rendered proliferative, rampant, predatory and ungovernable...yet despite more than 70 years of experimental study, they remain the least understood...What can be the why for these happenings?" Three decades later, Dr. Rous would be amazed. With dizzying speed and growing precision, we are mapping the inner workings of the tumor cell, explaining how it behaves and how it assures an accepting and nurturing host. The black box cell of Dr. Rous seen in Figure 1 is being replaced by the intricate circuitries of Figure 2. The cancer genes so frequently reported in the news are altered relays in this circuitry. Viruses, carcinogens and radiation all act by altering one or more of these specific pathways. Each circuit suggests a rational target for prevention or therapy of cancer as shown in Figure 3. Dozens are being developed. Ten years ago, 60 drugs were entering clinical trials for cancer. Today, that number is about 320.

Let me illustrate one. Thirty-five percent of breast cancers overexpress a protein called HER-2, a crucial link in one of these growth-controlling circuits. These cancers tend to be more aggressive, and clinical trials have shown that women with such cancers require more intensive therapy to achieve the same outcome as women with tumors that do not overexpress HER-2. Last December, Genentech announced the results of the first clinical trial using an agent targeted specifically to HER-2. That agent, when added to taxol, showed a clinical response rate three times greater than with taxol alone in women with advanced metastatic breast cancer. New clinical trials

will rapidly build on this result for breast and other cancers that overexpress this cancer gene, such as a proportion of ovarian and lung cancers.

In one of the more exciting tests of our new knowledge of cancer biology, we now know that altered circuits in cancer cells result in the production of molecules that stimulate the growth of blood vessels that nourish the growing tumor. Without these, the tumor will die or never grow beyond a microscopic size. Over the next year, we plan to have the first potent anti-angiogenesis agents into clinical trials for cancer. Knowledge about these cancer circuits will profoundly affect our approach to therapy although I believe they will also have a major impact on prevention.

THE CHALLENGE

To maintain this remarkable momentum of discovery, with the President's budget proposal, we can continue to increase the success rate for the funding of individual investigator-initiated research. We will continue to build on the infrastructure of the Cancer Genome Anatomy Project, which I introduced to you last year, to speed the discovery of the pieces of the machinery of cancer and especially to give us new molecular tools for early detection. This year, we will add to that project by beginning to catalog the natural variations in genes which will likely explain why different individuals respond to environmental, genetic and other causes of cancer so differently. This proposed budget will allow us to support a number of new initiatives which are aimed at bridging the gap between the explosion of discoveries in basic science and the need to translate these advances to our ultimate goal of reducing the burden of cancer for people.

Among these are:

- Develop chemistry-biology centers to capture revolutionary new approaches to the generation of millions of small molecules and to

couple this with so-called "smart assays" in order to target these newly defined cancer circuits.

- Build a new program for Rapid Access to Interventional Development, or RAID, which will allow the best new preclinical ideas in cancer intervention from investigators throughout the country to become available for clinical testing in an accelerated way.

- Build a re-designed, informatics-based clinical trials system to expand access to prevention, detection and treatment trials, to improve the speed and value of the trials and to allow the growing number of compelling ideas to be rapidly tested.

- Build a new imaging research network to rapidly evaluate emerging technologies in tumor imaging, both for early detection and staging and for image-guided therapy.

- Fund new clinical training pathways and fund mid-level and senior clinical investigators to protect their time to engage in both clinical research and mentoring.

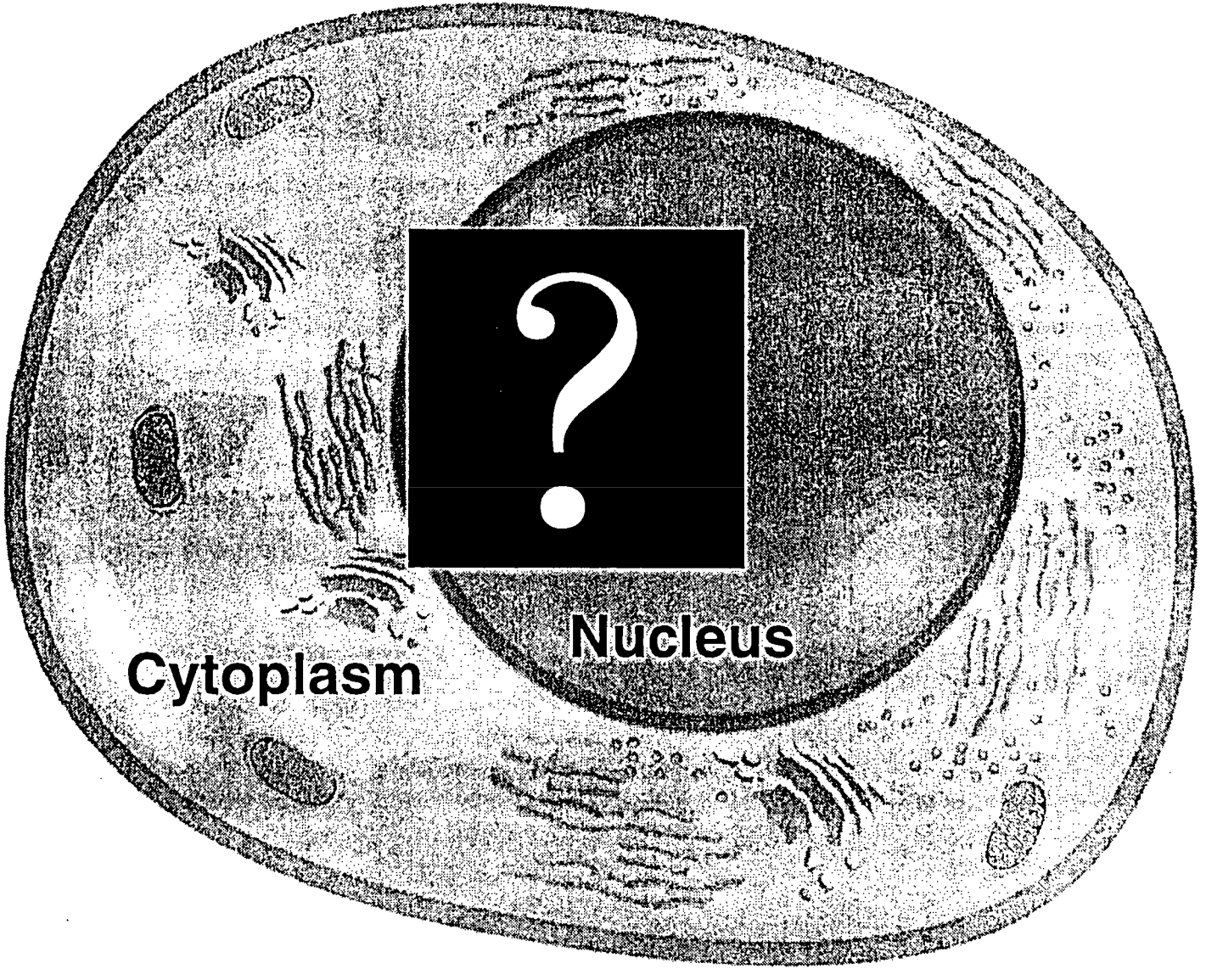
- Improve our cancer surveillance system so we have a better understanding of the burden of cancer and where we need special efforts to control cancer.

The activities of the NCI are covered within the NIH-wide Annual Performance Plan required under the Government Performance and Results Act (GPRA). The FY 1999 performance goals and measures for NIH are detailed in this performance plan and are linked to both the budget and the HHS GPRA Strategic Plan which was

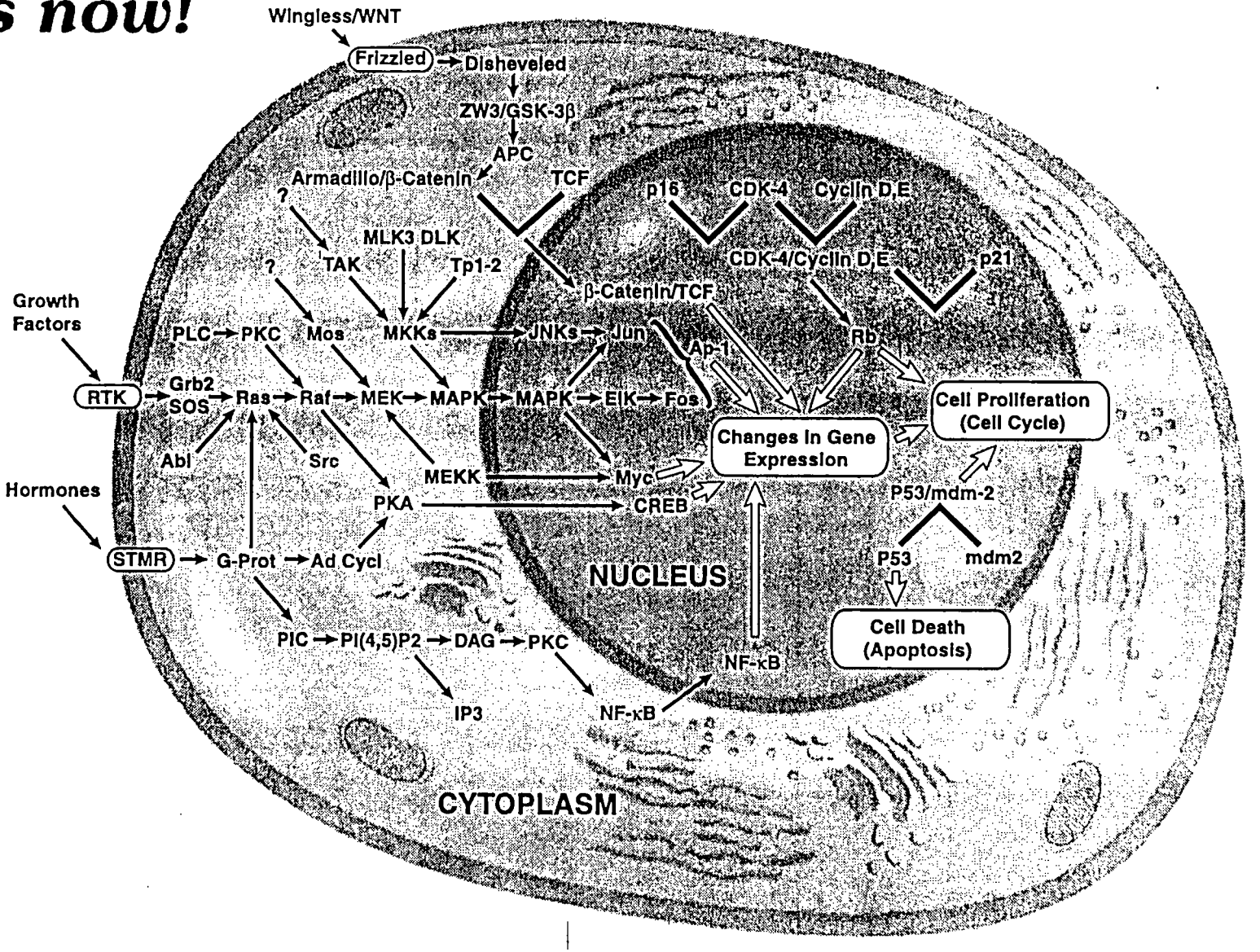
transmitted to Congress on September 30, 1997. NIH's performance targets in the Plan are partially a function of resource levels requested in the President's Budget and could change based upon final Congressional Appropriations action. NIH looks forward to Congress' feedback on the usefulness of its Performance Plan, as well as to working with Congress on achieving the NIH goals laid out in this Plan.

I will be happy to respond to any questions you may have.

This was then!

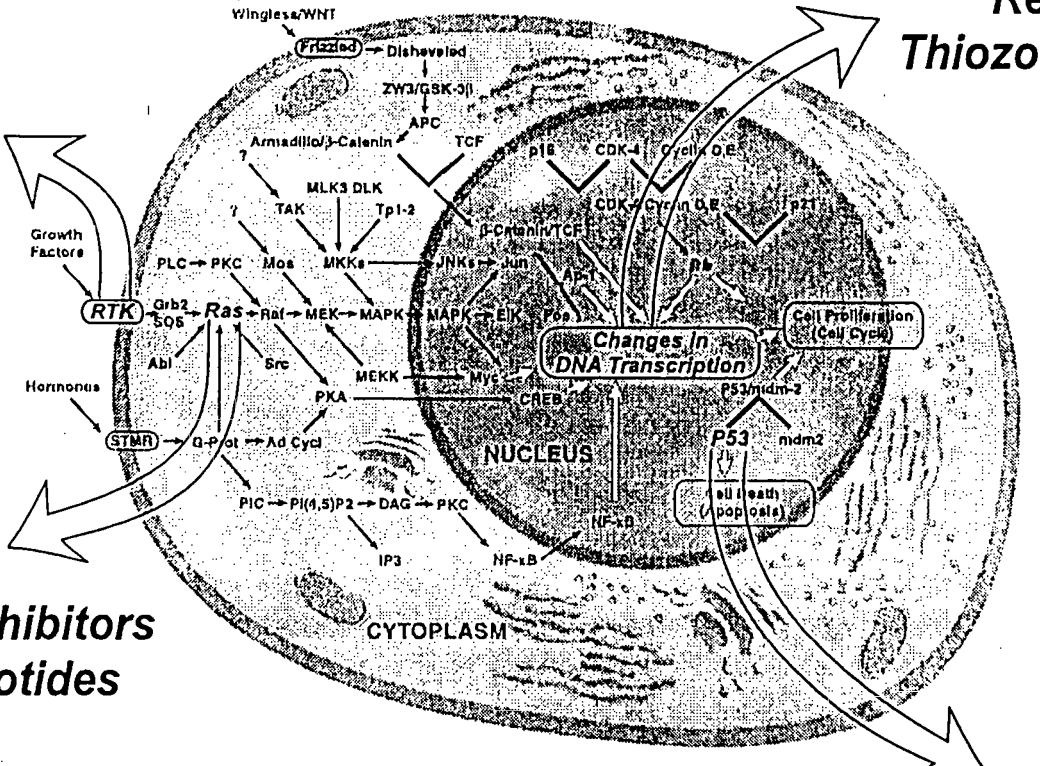


This is now!


Wingless/WNT
Frizzled
Disheveled
ZW3/GSK-3β
APC
Armadillo/β-Catenin
TCF
?
MLK3 DLK
TAK
Tp1-2
β-Catenin/TCF
p16
CDK-4
Cyclin D,E
CDK-4/Cyclin D,E
p21
Growth Factors
PLC
PKC
Mos
MKKs
JNKs
Jun
Ap-1
Rb
RTK
Grb2
SOS
Ras
Raf
MEK
MAPK
MAPK
Elk
Fos
Cell Proliferation (Cell Cycle)
Changes In Gene Expression
Abl
Src
MEKK
Myc
Hormones
PKA
CREB
P53/mdm-2
STMR
G-Prot
Ad Cycl
NUCLEUS
P53
mdm2
Cell Death (Apoptosis)
PIC
PI(4,5)P2
DAG
PKC
NF-κB
IP3
NF-κB
CYTOPLASM

EXAMPLES:
Anti-receptor antibodies
Tyrosine kinase inhibitors

EXAMPLES:
Retinoids
Rexinoids
Thiozolidinediones



EXAMPLES:
Farnesyl transferase inhibitors
Antisense oligonucleotides

EXAMPLES:
Oncolytic virus
Gene replacement

CURRICULUM VITAE
RICHARD D. KLAUSNER, M.D.

Personal: Born - (b)(6)

Education:

1973	B.S., Yale University - Summa Cum Laude Phi Beta Kappa Honors in Molecular Biophysics and Biochemistry
1976	M.D., Duke Medical School - Alpha Omega Alpha

Employment:

1976--1977	Fellow in Internal Medicine, Duke Medical Center, Durham, NC
1977--1978	House Officer, Internal Medicine, Massachusetts General Hospital,Boston, MA
1978--1979	Clinical Fellow in Internal Medicine, Massachusetts General Hospital Boston, MA Research Associate, Harvard Medical School, Boston, MA
1979--1981	Research Associate, National Cancer Institute, NIH, Bethesda, MD
1981--1983	Medical Officer, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, NIH, Bethesda, MD
1981--1985	Attending Physician, Acute Medicine Clinic, National Naval Medical Center
1982--1983	Instructor, Department of Medicine, USUHS
1983--1985	Assistant Clinical Professor of Medicine, USUHS
1983--1984	Senior Research Investigator, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, NIH, Bethesda, MD
1984--1997	Chief, Cell Biology and Metabolism Branch, National Institute of Child Health and Human Development, NIH, Bethesda, MD
1995--pres.	Director, National Cancer Institute, NIH

Panels and Advisory Boards:

1981--1985	Scientific Advisory Board, Sarnoff Fdn for Cardiovascular Research
1983--1985	Cell Biology Study Panel, National Science Foundation
1984--1987	Howard Hughes Education Committee, National Institutes of Health
1988--1994	Advisor to President, W.B. Saunders Company
1988--1990	Consultant to Vice-President, Genentech
1989--1993	Advisory Board, Searle Foundation
1989--1993	Scientific Advisory Board, Cytel
1990--1992	Chairman, Director's Task Force--Intramural Research Program, NIH
1991--1995	Chairman, Scientific Advisory Board, Ariad Pharmaceuticals
1991--1995	Advisory Board, Pharmacology Research Associate (PRAT) Program
1993--1994	Chair, Committee on Immunohematology, Am. Society for Hematology
1993--1995	Advisory Board, Albert Einstein College of Medicine
1993--1995	Chair, National Committee on Science Education Standards and Assessment, National Academy of Sciences
1993--1995	Member, National Delegation for Biomedical Research
1993--1995	Member, Coordinating Council for Education, Natl.Academy of Sciences
1994--1995	Fisher Biotechnology Council, Fisher Scientific International, Inc.
1994--1995	Scientific Advisory Board, Agennix, Inc.
1994--1995	Public Policy Committee, American Society of Cell Biology
1994--1996	Chair, Executive Editorial Committee of the National Committee on Science Education Standards and Assessment, National Academy of Sciences

1994--1995	Scientific Advisory Board, St. Jude Children's Research Hospital
1994--1995	Scientific Advisory Board, Howard Hughes Medical Institute
1994--1995	Elected to Council of the American Society for Cell Biology
1994--1996	Member, NIH Senior Biomedical Research Service Policy Board
1995--pres.	Scientific Advisory Board, Jane Coffin Child's Memorial Fund for Medical Research

Honors and Awards:

1986	Meritorious Service Award, Public Health Service
1988	Young Investigator Award, American Federation of Clinical Research
1988	Outstanding Scientist, 1988, Yale Alumni Association Award
1989	New York University Honors Award
1989	American Society of Endocrinology
1990	Charles Smith Professorship - Memorial Sloan Kettering
1992	Damashek Prize, American Society for Hematology
1992	Lederle Award
1993	Distinguished Service Medal, US Public Health Service
1993	Member, National Academy of Sciences, USA
1993	President-Elect, American Society for Clinical Investigation
1994	Alexander Wiener Award, New York Blood Center
1994	Distinguished Scientist Award, University of Oklahoma Medical Center
1994	Distinguished Medical Alumnus Award, Duke Univ. Medical Center
1994	Annual Research Symposium Honoree, Mayo Clinic Foundation
1994	President, American Society for Clinical Investigation
1995	Elected Fellow, American Academy of Arts and Sciences
1996	Cartwright Visiting Professor, University of Utah
1996	Centennial Award for Biomedical Research, Mem.Sloan-Kettering Cancer Ctr.
1996	National Public Leadership Award, National Coalition of Cancer Survivorship
1997	Rabbi Shai Shaknai Memorial Prize, Hebrew University, Jerusalem
1998	The Raymond Bourgine Award, Paris
1998	Gold Medal of Paris
1998	Dickson Prize, University of Pittsburgh School of Medicine

Societies:

1986	American Society for Clinical Investigation
1986	American Federation for Clinical Research
1989	American Society for Cell Biology
1989	American Society for Hematology
1993	National Academy of Sciences
1993	Sigma Xi
1995	American Association of Physicians
1995	American Association for Cancer Research
1996	American Society of Clinical Oncology
1996	Elected Member, Institute of Medicine

Research Interests:

- The molecular basis of normal & pathological states of iron metabolism in humans.
- Mechanisms of post-transcriptional gene regulation.
- Receptor biology with a particular emphasis on structure function relationships of signaling receptors in the immune system.
- Organelle cell biology
- Tumor suppressor genes

CURRICULUM VITAE

NAME: Alan Saul Rabson, M.D.

DATE & PLACE OF BIRTH: July 1, 1926; Brooklyn, New York

CURRENT POSITION AND ADDRESS:

Deputy Director, National Cancer Institute, NIH

EDUCATION:

1948	-	B.A., University of Rochester, New York
1950	-	M.D., State University of New York, Downstate Medical Center, New York

EXPERIENCE:

1955-1956	-	Resident in Pathologic Anatomy, Pathologic Anatomy Department, Clinical Center, National Institutes of Health, Bethesda, Maryland
1970-1975	-	Deputy Chief, Laboratory of Pathology, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1974-date	-	Clinical Professor in Pathology, Georgetown University Medical Center, Washington, D.C.
1975-1996	-	Director, Division of Cancer Biology, Diagnosis, and Centers, NCI, NIH, Bethesda, MD
1977-date	-	Clinical Professor of Pathology, Uniformed Services University of the Health Sciences, Bethesda, MD
1977-date	-	Clinical Professor of Pathology, George Washington University, Washington, D.C.
1996-Date	-	Deputy Director, NCI, NIH, Bethesda, MD

HONORS AND OTHER SPECIAL RECOGNITION:

1948	-	Phi Beta Kappa, University of Rochester, New York
1949	-	Alpha Omega Alpha, State University of New York, Downstate Medical Center
1976	-	Sigma Xi, George Washington University, Washington, D.C.
1978	-	Distinguished Service Medal, U.S. Public Health Service
1987	-	Member, Institute of Medicine, National Academy of Sciences
1992	-	Fellow of The American Association for the Advancement of Science

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NAME:	Harold E. Varmus
POSITION:	Director, National Institutes of Health
BIRTHPLACE:	New York
DATE:	December 18, 1939
EDUCATION:	B.A., Amherst College, 1961 MA., Harvard University, 1962 MD., Columbia University , 1966

EXPERIENCE:

The first Nobel Laureate to serve as Director of the NIH. Previously a professor of microbiology, biochemistry, and biophysics and the American Cancer Society Professor of Molecular Virology at the University of California, San Francisco. Internationally recognized authority on retroviruses and the genetic basis of cancer.

In 1989, shared with UCSF colleague, J. Michael Bishop, M.D., a Nobel prize in Physiology or Medicine for demonstrating that cancer genes (oncogenes) can arise from normal cellular genes, called proto-oncogenes. Research activities have been supported by grants from the NIH, , the American Cancer Society, and the Melanie Bronfman Award for Breast Cancer. The research is continued through his laboratory at the National Cancer Institute, National Institutes of Health.

Prior to becoming Director of NIH, served as chairman of the Board of Biology for the National Research Council, advisor to the Congressional Caucus for Biomedical Research, member of the Joint Steering committee for Public Policy of Biomedical Societies, and co-chairman of the New Delegation for Biomedical Research, a coalition of leaders in the biomedical community. In 1986, chaired the subcommittee of the International Committee on the Taxonomy of Viruses that gave the AIDS virus its name, HIV.

The author or editor of four books and over 300 scientific papers. Elected to the Institute of Medicine, the National Academy of Sciences, and the American Academy of Arts and Sciences. Authored the book, "Genes and the Biology of Cancer," intended for a general audience, was co-authored with Robert Weinberg for the Scientific American Library.

After an internship and residency in internal medicine at Columbia-Presbyterian Hospital in New York, served as clinical associate for two year at the National Institute of Arthritis and Metabolic Diseases at the National Institutes of Health. Served as a post-doctoral fellow in Dr. Bishop's laboratory in 1970, initiating a longstanding collaboration to study tumor viruses, and was appointed to the faculty later that year. In 1979, became a full professor and an American Cancer Society Research Professor in 1984.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Dr. Harold E. Varmus

Director, National Institutes of Health

on

Fiscal Year 1999 President's Budget Request

for the National Institutes of Health

Mr. Chairman and Members of the Committee:

I am very pleased to present the President's FY 1999 budget request for the National Institutes of Health (NIH). As part of his initiative to invest in a Research Fund for the 21st Century, the President--with the strong endorsement of Vice-President Gore and Secretary Shalala-- is asking for $14.797 billion dollars for the NIH for the coming year, an increase of $1.15 billion (or 8.4%) over our FY 1998 appropriations of $13.647 billion. In addition, the Administration's five-year budget projection anticipates requests for increases for the following four years in an effort to develop stable growth to a level of $20.188 billion, approximately 50% above our current appropriations, by FY 2003.

My colleagues and I--and virtually all who support, or are supported by, the NIH--are enthusiastic about the prospects for building vigorously on the handsome increases the NIH has received over the past few years, when budgetary prospects were more problematic. We are heartened by this year's request, in part, because it embodies optimistic views about the nation's future: that our economic status has markedly improved with the balancing of the Federal budget; that the government now has the means as well as the responsibility to invest in projects that will benefit its people; and that our science is viewed as important for achieving many of those benefits, including improved health for people here and around the world.

We believe that the President's request for larger investments in the health sciences has come at an especially opportune time. First, discoveries are occurring at an unprecedented pace in biology and medicine, presaging revolutionary changes in medical practice during the next decade. Second, improved methods of care, based on laboratory and clinical science, can help the nation confront new and growing public health needs: the aging of the human population, here and abroad; the disproportionate growth of groups in the US that have historically experienced poorer health and shorter lives; and the persistence of many serious diseases in all parts of the world, despite remarkable scientific advances.

The promise of biomedical science: recent accomplishments

We present the President's request with the strong conviction that substantially increased resources can help us to achieve the promise of biomedical sciences more swiftly and address public health needs more forcefully. This conviction is inspired, in part, by the continued productivity of the scientists we support. The testimony my colleagues will present over the next three weeks will illustrate this productivity with many recent advances; here I will offer only a preview of the rich harvest they will describe.

As in each of the past few years, the isolation and analysis of genes have been prominent events for both the NIH and the world. This year, for example, we have reported the identity of genes responsible for a

familial form of Parkinson's disease and the previously mysterious Familial Mediterranean Fever; for the lethal childhood illnesses Niemann-Pick, type C, and the major form of Fanconi's Anemia; for some cases of age-related macular degeneration, a common cause of blindness; for the long QT syndrome, which causes abnormal cardiac rhythms and sudden death; and for several other diseases. In addition, notable progress has been made in constructing a detailed diagram of human chromosomes, with over 30,000 genes now mapped and with new genes being identified daily through the Human Genome Project and the Cancer Genome Anatomy Project. The systematic sequencing of the human genome is now underway, the elucidation of the genomes of several important model organisms is far advanced, and the complete blueprints of many single-cell organisms--most importantly this year, the geneticist's bacterial warhorse, E. coli--have been completed by laboratories in both the public and private sectors. Through improved computer services and innovations in bioinformatics, the NIH has made this new genetic information readily accessible to the entire scientific community.

We are at the dawn of the golden age of neuroscience thanks to a combination of factors, including genetic information about the causes of neurological diseases, refined imaging methods to watch the brain in action, and biochemical strategies to study signaling between cells, the growth of neurons and their axons, and the receptors for both licit and illicit drugs. For example, in the past year, we have watched changes in brain activity when patients use, or simply crave, cocaine; we have identified more of the proteins that cause nerve cells to grow towards or away from a site during development; and we have learned more about the molecules that mediate the sensation of pain after exposure to certain stimuli, such as chili peppers.

Our understanding of fundamental properties of normal and diseased cells has been enriched this year in many ways. For example, the gene encoding telomerase, the enzyme that normally maintains the ends of our chromosomes, has been isolated from several species, including man, and addition of the enzyme was shown to extend the lifespan of human cells grown in the laboratory. A regulator of gene activity was found essential for the production of bone-forming cells that could benefit patients with osteoporosis. New targets for drugs for human neurodegenerative disorders were identified when the abnormal proteins produced in those diseases were shown to kill nerve cells if expressed in mice.

We have also approached the goal of NIH-supported research--the prevention and treatment of disease--in many clinical spheres. Implanted cardiac defibrillators were shown to increase survival and to outperform standard drug treatment, and control of high blood pressure was found to reduce the likelihood of heart failure in the elderly. The age-adjusted mortality rate for cancer overall has continued to fall, and the overall cancer incidence rate has also started to decline. Newly discovered methods for disarming the immune system in primate models holds promise for safer organ transplants in man. Vaccine development has flourished, with an improved influenza vaccine, a new vaccine against rotaviruses (a major cause of infantile diarrhea worldwide), and experimental vaccines in progress against E.coli O157 and hepatitis E. Although we are far from a highly effective treatment for Alzheimer's disease, we now have better means for accurate, early diagnosis, and there is evidence that some compounds--anti-inflammatory drugs, vitamin E, and estrogens--may slow the disease process. The age of onset of alcohol use was shown to predict the likelihood of chronic alcoholism, encouraging efforts to intervene in early adolescence. Using new information about the factors that either promote or interfere with the growth of blood vessels, clinical trials have been initiated to promote vessel growth around narrowed arteries in the heart and peripheral muscles and to arrest the growth of vessels required for the spread of cancer. Therapeutic use of many kinds of drugs may be improved in the near future by the recent development of methods for slow delivery of active ingredients from drug-filled beads and means to target drugs to specific cells and tissues.

The promise of medical science: projections

In proposing a very substantial increase in the NIH budget, it is appropriate to describe at the outset some of the grand objectives that we believe to be within sight during the next decade or two. In general, we expect to see many new ways to prevent and treat diseases, with methods based largely on the knowledge and technologies our scientists are currently delivering. These new medical practices will have many beneficial effects-- most obviously, the direct effect of better health, but also the secondary

effects of improved productivity and reduced cost of illness. We expect to diminish the disabilities associated with aging, reduce the discrepancies in health status between different segments of our society, achieve improved control of diseases both common and rare, and contribute to the health of other (and often poorer) nations around the world. More specifically, we expect to predict, diagnose, and treat many inherited diseases that are currently unapproachable; to control cancers and cardiovascular, metabolic, and neurological diseases more effectively through better preventive strategies, earlier detection, and rational therapies; to develop vaccines against infectious diseases, both persistent and new, including malaria, tuberculosis, and AIDS; and to find behavioral strategies that will encourage healthy lifestyles and adherence to proven therapies.

The advent of molecular medicine

Our confidence that many of these things will come true is based largely on the idea that revolutionary discoveries in many fields--especially genetics, neuroscience, cell biology, bioengineering, and computer sciences--have the power to transform the practice of medicine. This notion is especially well-illustrated by the passage our scientists are now making from molecular biology to molecular medicine. In this transition, the scientific methods that have allowed investigators to study life's macromolecules--DNA, RNA, and protein--are being applied to the prevention and treatment of disease, in accord with the molecular mechanisms responsible for each disease.

The marked improvement in the treatment of AIDS that we reported here last year is a marvelous example of this approach. The new therapies are built entirely on an understanding of the disease at the most fundamental level: AIDS is caused by a retrovirus, HIV, whose growth depends on three enzymes encoded by its own collection of genes (its genome). Many of the facts about these enzymes were determined by analyzing the relatively small genome of HIV and then by characterizing their biochemical properties. Now we know that drugs that inhibit HIV enzymes will block key steps in virus multiplication, and inhibitors of two enzymes, used in combination, have impressively reduced AIDS mortality rates in this country.

We will consider the public health significance of these developments more fully later in the hearings. I tell this story briefly here because it serves as a harbinger of the rational, mechanism-based approach to medicine that will be the major legacy of molecular and genetic science.

Although there are other important examples of mechanism-based medicine--such as the use of cholesterol-lowering drugs to prevent coronary artery disease or the use of hormones to treat endocrine dysfunction--the next dramatic transformation of medicine through genetics and molecular biology is likely to occur in the study of cancer. This is true, in part, because cancer is intrinsically a disease based on mutations, both inherited and acquired during life; because the genes implicated in many kinds of cancer were among those first isolated from the genomes of vertebrate animals; and because the functions of many of the implicated genes and their encoded proteins have been relatively well characterized during the past two decades. As a result, it is already possible to predict an individual's genetic predisposition to several forms of cancer (including melanoma, breast and colon cancers, skin tumors, and a number of rare cancer syndromes); to assess the genetic damage in certain types of cancers in order to gauge the likely course of the illness and select optimal therapies; to design novel means for destroying cancer cells--with drugs, toxic antibodies, immune cells, or gene therapies that address specific abnormalities in a patient's cancer; and to take advantage of new knowledge about blood vessel growth or the mechanisms of cell death to test entirely novel approaches to cancer therapy.

Cancer has been one of the cruelest killers of this generation. The President's budget moves dramatically on this front to take advantage of the scientific opportunities I have outlined. The NIH budget, for example, pays special attention to cancer research, increasing funding across NIH by 10 percent in 1999 and 65 percent by 2003.

In the near future, our ability to conceive new ways to prevent and treat cancer--and many other diseases--will be based on a much more detailed and profound view of the biology of disease. I want to illustrate this important point with a single new technique among the many recently devised. This method--sometimes called the expression array--takes advantage of the extensive and still growing collections of gene pieces made available by genome technologies. If hundreds or thousands of such

pieces are attached to solid supports (glass chips or nylon filters) in an orderly array, it is possible to ask whether each gene is active or inactive in a single type of cell or to ask whether the activity of each gene is increased or decreased by a disease process or environmental change.

An example of the application of this method and its potential utility in human disease is provided by the attached photograph. In this still unpublished experiment, the activities of about ten thousand human genes were compared after an indolent form of lymphoma changed into an aggressive form. The presence of a color signal shows that a gene is active; if the color is red, it is more active in the aggressive disease; if it is green, it is more active in the indolent form; if it is yellow, there is no difference. This is more than an academic exercise. Some of the results could have a direct bearing on the choice of treatment. For example, one gene that is very active in the aggressive disease makes an enzyme (bleomycin hydrolase) that destroys a drug (bleomycin) commonly used in chemotherapy of other cancers. Interestingly, some of the genes showing changes have been implicated in the cause of other cancers.

In considering this example, it is important to remember four additional points. First, the molecular and genetic technology illustrated here is applicable not only to the treatment of disease. As in so many things supported by NIH research, we envision equally profound applications to the prevention of disease. For example, we will be able to assess individuals early in life for their genetic susceptibility to environmental carcinogens, drugs, and toxic substances. Second, the new methods will strongly influence our approaches to many diseases, not just cancer. For example, we already use related molecular methods commonly in the control and treatment of infectious diseases, such as AIDS. In addition, the prevention, diagnosis and treatment of neurological, metabolic, and degenerative disorders are also likely to be advanced enormously by such techniques. Third, molecular methods are only one among many types of innovation now visible on the horizon. Among the others are new chemical strategies for generating novel compounds to be tested as candidate drugs; new methods to visualize diseased tissue at the very earliest and most treatable stages; bioengineering techniques to fabricate replacement tissues and tissue mimetics; and devices to measure brain function and behavior that will improve approaches to mental illness and to disease prevention and management. Finally, the illustrated experiment is the result of active collaboration among university, government, and industry scientists; such interactions are vital to our efforts to control disease and will be actively encouraged in coming years.

Realizing the potential of the FY 1999 budget request

The budget request I bring here today offers remarkable prospects for making fundamental discoveries and harnessing new knowledge to control disease. But increased administrative responsibility accompanies increased financial support. We at the NIH must insure that our funds will be well spent, that our goals are pursued efficiently, and that the identifiable barriers to progress are removed. I will describe five areas in which we are planning to address this responsibility with FY 1999 funds.

1) Research grants

The most important instrument used by the NIH to achieve its goals is the research project grant. In FY 1999, we plan to increase the number of grants substantially to an all time record of just over 30,000 awards. We will also set a record for the number of new and competing awards--nearly 8300--achieving a success rate for applicants that is very close to one-third. We foresee sustaining, or even improving, that success rate over the next four years, thereby creating a healthier and more stable environment for the pursuit of imaginative science than we have experienced in several years. In addition, the size of the average new and competing award will increase by about ten percent. In part, this will allow us to fulfill our pledge to support at least as many new investigators as in past years while shifting support for all of them into the more flexible basic grant mechanism (R01). The larger award size will also permit Institutes to fund a greater number of grants at the levels recommended by review groups and to better support expensive forms of research, such as patient-oriented research or research that requires vertebrate animals to provide models for human disease.

In the best tradition of NIH-supported science, the topics of many of these grants will not be known until investigators have written proposals and our expert reviewers have judged them. But the Institute

Directors and I have also developed a list of many important research topics to which we expect to devote enhanced resources within the President's request. As in recent years, these topics have been grouped within six broad areas of research emphasis-- disorders of the nervous system, genetic medicine, pathogenesis, computers and instrumentation, new approaches to disease prevention, and new avenues to therapeutics. Initiatives within each of these domains address a wide spectrum of diseases--diabetes, cancer, heart disease, and many others--with various kinds of fundamental and clinical science; you will hear about some of them from the Institute Directors at subsequent hearings. We expect an expanded grant portfolio to accelerate the process of discovery across a large frontier of medical science.

2) Instruments

As medical science has become more complex, it has also become more dependent on innovative instrumentation. Genome sequencing, the visualization of molecules, cells, and intact organs, the storage and retrieval of scientific information--all are possible because of the advances made by engineers, physicists, computer scientists, and many others who have contributed to the development of new instruments. With the resources requested in the President's budget proposal, we will expand our efforts to develop new and more powerful instruments; to attract trainees and scientists in many other fields to the problems posed by biology and medicine; to allow more groups of investigators to purchase shared instruments; and to expand the use of computers for analysis, exchange, and storage of data.

3) Talent

With increased resources, we will be able enhance our efforts to recruit and train the most talented individuals for careers in biomedical research. It currently requires at least a decade of study and supervised research before today's college graduates become independent investigators, and they may not make their most important discoveries until the year 2020 or thereafter. Thus the decisions we make today have long-term effects.

We will use several strategies to encourage young people with a variety of intellectual and cultural backgrounds to embark on research careers. We will fund innovative research training programs that emphasize trans-disciplinary work; we propose to increase by 25 percent the stipends that we provide to graduate students and post-doctoral fellows; and we will create a research environment that offers improved stability and likelihood of research funding than was true in the early years of this decade.

4) Clinical research

We recognize that the promises of biomedical research to better human health can be achieved only if we strengthen the nation's capacity to perform clinical research, especially the research carried out through direct interactions with patient populations. To do this, we have been putting into practice the many recommendations of my distinguished Panel on Clinical Research. With the funds requested for FY 1999, we will take several important steps, in addition to those that I described last year. Most importantly, we will initiate several new categories of awards to enhance the training and support of clinical investigators: a program that will finance a supervised five year apprenticeship for over 400 young investigators; a program that will provide salary support for the clinical research activities of 250 to 400 mid-career scientists who can serve as mentors; and a training program that will bring organized didactic programs in clinical research to over twenty institutions.

In addition to these training programs, we will significantly increase support for our outstanding centers for clinical research, including the General Clinical Research Centers (GCRCs); expand our new and very popular program on the NIH campus that introduces medical and dental students to clinical research; continue loan repayment programs to clinical trainees from disadvantaged backgrounds in our intramural program; and support the continued construction of the Mark O. Hatfield Clinical Research Center on our campus.

We also plan to augment our clinical trials by developing comprehensive and accessible data bases; by enhancing patient recruitment, especially into clinical trials networks; by initiating definitive trials of alternative and complementary medications; and by continuing recently-initiated discussions with

industry, academia, and other agencies about improved design of clinical trials.

5) Administration

We continue to believe that a healthy organization requires frequent review and close oversight of its scientific and administrative practices. Thus, despite our traditionally strong reputation for expert review of grant applications, the Center for Scientific Review has recently undertaken a thorough re-examination and restructuring of our peer review panels. We have also continued to strengthen evaluations of our intramural scientific programs and recently initiated five-year reviews of Institute Directors.

Last year, in response to a directive from this Subcommittee, we commissioned from the Arthur Andersen organization a large-scale review of administration at the NIH. While the review was generally complimentary of our practices, it did include over 80 recommendations for improvement. We are giving these recommendations very serious consideration, and many will be implemented in the coming year.

We were also asked to initiate a formal study of the processes by which we identify priorities for research funding; a contract to do this has been signed with the Institute of Medicine. In the meantime, we have sought more advice than usual from many of our professional and advocacy constituencies to plan the use of the enhanced resources requested for FY 1999.

Finally, as mandated by the Government Performance and Results Act (GPRA), we have incorporated our first Annual Performance Plan, with appropriate goals and measures, into this budget request. The NIH Plan is also linked to the Department of Health and Human Service's GPRA Strategic Plan, which was transmitted to the Congress on September 30, 1997. We expect to work closely with this Subcommittee and the rest of the Congress during the appropriations process to insure compatibility between our goals as outlined in our GPRA Plan and the expectations created by final Congressional action on our budget request.

Conclusion

Mr. Chairman and Committee Members, we are in the midst of a remarkable phase in the history of biomedical science, and we have an opportunity to create a stable environment for continued discovery that will benefit our nation and the world for many decades to come. I hope we can work together to seize this opportunity and realize its benefits. I will be pleased to answer any questions you may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Dr. Claire V. Broome

Acting Director, Centers for Disease Control and Prevention

on

Fiscal Year 1999 President's Budget Request

for the Centers for Disease Control and Prevention

Mr. Chairman and Members of the Committee:

I am pleased to speak with you today in support of the President's budget request for the Centers for Disease Control and Prevention (CDC) for Fiscal Year 1999 in the amount of $2.45 billion, an increase of $78.6 million, 3 percent, over the FY 1998 appropriation. Thank you for your ongoing support of the Nation's prevention agency. Before I begin to summarize our scientific successes of the past year and to tell you of exciting avenues for CDC's research and programs in fiscal year 1999 (FY 1999), I want to assure you of CDC's continued commitment to attaining the highest level of public health for everyone in our country.

I am confident that each of you here today would agree that prevention is vitally important to the health of this Nation. Although it is crucial to be able to diagnose, treat, and cure people who become sick or injured, we would all prefer to remain healthy in the first place. Prevention works! For example, by vaccinating every child against measles, 1.6 million cases are averted each year. For every dollar spent, $13.5 are saved--approximately $2.6 billion per year.

As history tells us, public health expenditures make the most substantial contributions to longer, healthier lives. The greatest strides in this century in the health of our citizens have been achieved through broad public health measures such as protecting the food and water supplies, immunizing our children against life-threatening diseases, and making working conditions safer and healthier. An infant born in the U.S. today has 30 more years of life expected than an infant born in 1900. As you see on the first chart, 25 of these years are due to the success the public health system has had in protecting the public and providing information to help people to stay well. Today, we know what works to prevent many diseases and injuries, and yet there is a disconnect between knowing and doing.

Prevention is a wise investment. Chart 2 shows that currently only about 1 percent of the $1 trillion U.S. health care budget is spent on prevention. The fact is that as we approach the turn of the century we could be doing more for the quality of the Nation's health. Millions of people are still dying prematurely or suffering unnecessarily from preventable disease, injury, and disability. The challenge before us is not only finding cures to known diseases, but also implementing the prevention strategies we know to be effective in keeping our Nation healthy. We know prevention strategies that work, and we should act now to conduct the research and implement the programs in communities that improve the quality of life for all Americans. Mr. Chairman, the President's request for CDC moves us toward that urgent need.

Let me take a moment to mention some of CDC's prevention strategies that we know work. We know how to prevent your children and grandchildren from the unnecessary deaths and head injuries caused by bicycle crashes. Bicycle helmets work! In 1995, 905 people in the United States died as a result of bicycle crashes, and there were 587,000 visits to emergency departments for treatment of bicycle-related injuries. About one-third of the emergency department visits and 60% of the deaths involved a head injury. Yet approximately 80% of the bicycle-related head injuries could be prevented through the simple and effective use of helmets. Bicycle helmet laws are not enough to ensure that everyone using a bicycle consistently uses a helmet. Of particular concern are children, who sustain most of the

bicycle-related injuries. One study showed that only 50% of children own a bicycle helmet, and only 25% reportedly always wore their helmet when riding. Studies have also shown that the use of bicycle helmets increased with parental income and education level. We should find ways to reach the children of all communities, so that bicycle helmets become an automatic part of riding a bicycle.

We know how to help protect our senior citizens from the suffering and untimely deaths associated with influenza. Influenza vaccine works! It works not only to prevent deaths but to help seniors maintain healthy function and quality of life. Yet 45% of person 65 and older, the fastest-growing age group in this country, did not receive influenza vaccine in the past year. More than 18,000 of them died unnecessarily of flu-related causes. Each year, an estimated 45,000 adults die of infections related to influenza, pneumococcal infections, and hepatitis B, even though we have safe, effective vaccines to prevent these diseases. And minority groups are disproportionately affected by these diseases. We are working to discover ways to encourage adults, particularly the elderly to get these life-saving vaccines.

We know how to help protect the nation's greatest potential resource, our children and grandchildren, from certain birth defects. Folic acid works! Each year 4,000 babies are born with the life-threatening birth defects spina bifida and anencephaly. We have known since 1991 that at least half of these cases can be prevented if women of childbearing age consume adequate amounts of the vitamin folic acid. However, this scientific breakthrough has not yet been translated into a reduction in these birth defects because 75% of women of childbearing age still do not get enough folic acid in their diet. We now need to discover through prevention research conducted in communities how to help women consume appropriate amounts of this essential vitamin.

We know how to help prevent today's healthy young people from becoming tomorrow's victims of heart disease and stroke. Approximately 70% of Americans die as a result of chronic diseases. Cardiovascular disease (CVD) is the leading killer for men and women and across all racial and ethnic groups. CVD is responsible for over 960,000 deaths each year, and as Chart 3 shows, minorities are disproportionately affected by coronary heart disease, one form of CVD. Research has shown that moderate physical activity and a healthy diet can help protect Americans of all ages from the ravages of heart attack and stroke, diabetes, and even some cancers. Physical activity and proper nutrition work! The second leading preventable cause of death in the nation is poor diet coupled with lack of physical activity. Prevention research conducted in communities can be used to help us transform what is known into action.

We have scientific know-how that must be acted upon if the health of the American people is to improve in the next millennium. It took 200 years after the discovery of the smallpox vaccine to eradicate the disease. It has taken over 50 years to reach a point where we can see the end of the threat of polio worldwide. How long will it take to prevent unnecessary cases of spina bifida and anencephaly due to inadequate consumption of folic acid, flu deaths in our senior citizens, chronic diseases due to lack of exercise and poor diet, or brain damage in children who don't use bike helmets? By enacting the funding for CDC in the President's Budget, we can go a long way towards addressing these public health problems.

CDC, the nation's prevention agency, is in a unique position to carry out prevention programs from discovery to action. We have access to the superb health information resources of both the National Center for Health Statistics, a national treasure of health data and vital statistics, and the essential monitoring and reporting networks at the state and local levels. These health information systems keep us abreast of the state of the Nation's health and enable us to monitor disease trends and detect outbreaks. Because of our scientific expertise and our close ties with state and local health departments and other community-based organizations, we have the tools in place to identify a community's health problems, conduct research to find solutions, develop and evaluate interventions to solve the problems, and work in communities across the country to see that scientific discoveries are actually transformed into programs and practices that help people remain healthy.

The President's FY 1999 budget includes funding increases to CDC in five critical areas. These increases will help us move from knowing what works to putting that knowledge to work.

Food Safety: This President's budget includes a $5 million increase to support activities under the Food Safety Initiative. Each year an estimated 6.5 to 33 million Americans develop a foodborne illness, and

9,000 persons die as a result. The annual cost attributed to foodborne illness is $5-$6 billion. Ensuring the safety of the nation's food supply is one of government's most enduring and important functions. This increase will enable CDC to expand the National Early Warning System for detecting foodborne diseases, make improvements to the quality and scope of foodborne disease surveillance, and enhance links between federal and State public health laboratories with sophisticated computer technology that will enhance communications and data sharing. We know how to increase the safety of America's food supply. With your help, we can act.

Adolescent Smoking and Health: The President's FY 1999 budget includes a $46 million increase for our continuing struggle to keep the next generation of young people from starting to smoke. Smoking is the number one cause of death in this country, resulting in 420,000 deaths each year. In addition to this preventable loss of life, medical costs were estimated to total $50 billion in 1993. Studies show that over 80% of adult smokers became regular smokers before the age of 18. Each day, to our national shame, over 3,000 young people begin smoking. The budget increase will allow CDC to increase grants to States for their smoking control programs by 50%. This will include both the States that participated in the NIH American Stop Smoking Intervention Study (ASSIST) program and the States supported through CDC's Initiative to Mobilize for the Prevention and Control of Tobacco use (IMPACT) program. CDC will build on the foundation laid by the IMPACT program and the research findings of the ASSIST program to prevent young people from smoking and to help older smokers stop. We know ways to help protect young people from addiction to nicotine. With your help, we can do it.

Eliminating Disparities: The President's budget includes a total of $80 million for the Department to support a major goal in his Initiative on Race. Of this amount, CDC would receive $55 million to address the President's ambitious goal to eliminate disparities in health status suffered by racial and ethnic minority populations by the year 2010. For example, the rate of AIDS is more than seven times higher for African-Americans than for white Americans, and more than three times higher for Hispanics than for whites. Because of its experience in conducting prevention research and programs, CDC will play a major role in the President's Race Initiative. CDC will help conduct a series of community-based research/demonstration projects to address six areas of identified health disparities: HIV infections, infant mortality, cancer, cardiovascular disease, diabetes, and child and adult immunizations. Racial disparities in health can be reduced or eliminated with an investment in innovative strategies at the community level, as evidenced most recently in the significant gains in childhood immunization rates of minority children. We know that we can reduce the extra burden of disease borne by our minority populations. With your help, we can act.

Emerging Infectious Diseases: The President's budget contains $79 million, an increase of $25 million, to help combat emerging infectious disease. You have only to listen to the nightly news to know that the nation remains vulnerable to deadly infectious diseases. Terms such as hepatitis C, Ebola virus, and avian flu have become household words. Hepatitis C, only recently identified, accounts for 8,000-10,000 deaths per year, and yet most of the 3.9 million chronically infected Americans are unaware of their infections. Emerging infections contribute substantially to the ongoing burden of infectious diseases on the American people. For example, annual direct medical costs of influenza in the U.S. have been estimated at $5 billion, plus another $12 million in lost productivity. Developing systematic tracking and surveillance efforts to detect those threats before they reach epidemic proportions is a high priority for CDC. The requested budget increase will be used to expand the Nation's emerging infectious disease early warning system in as many as three additional states, for a total of 33 states. These efforts will strengthen the surveillance network and capacity of State and local health departments to respond to infectious diseases by increasing the speed at which outbreaks and drug-resistant diseases can be identified, investigated, and controlled. History has show us how to control infectious diseases--and what happens when we don't.. With your help, we can do it.

Prevention Research. While we have many proven prevention strategies, such as the ones mentioned, and are implementing successful programs based on these, there is much that we don't know. For instance, we often know what needs to be done but don't always know the best way to do it. To put prevention know-how into action in communities requires more than just the initial discovery. It requires research that can help transform findings from bench-level research into prevention programs that reach people--and research that can tell us about the effectiveness and cost-effectiveness of those programs. The President's FY 1999 budget contains $25 million for a new prevention research program at CDC as

part of the Research Fund for America. These next few charts illustrate what CDC means by prevention research. With this funding CDC will support extramural research in academic health centers, such as schools of public health and medical schools, and other community organizations. As illustrated by Charts 4 and 5, this research will answer a variety of critical public health questions that will help us learn more about putting prevention strategies into practice. It will also help us support critical studies identified in existing research agendas, such as the collaborative National Occupational Research Agenda. Using the deadly hantavirus outbreak as an example, Chart 6 shows the broad continuum of prevention research as practiced by CDC. To illustrate how we cooperate with our sister agencies in prevention research, Chart 7 depicts a collaborative effort between CDC and NIH to study Type II diabetes. We know that prevention research is needed to address real health problems. With your help, we will do it.

The FY 1999 President's Budget request for CDC incorporates the first Annual Performance Plan required under the Government Performance and Results Act (GPRA). The FY 1999 performance goals and measures for CDC are detailed in our performance plan and are linked to both the Budget and to HHS's GPRA Strategic Plan. Performance targets in the Plan are partially a function of resource levels requested in Appropriations action. We look forward to feedback from Congress on the usefulness of our Performance Plan, as well as to working with Congress on achieving the goals laid out in the plan.

Mr. Chairman, with your support for the President's budget request of $2,457,197,000 for CDC, the agency will be able to move more prevention know-how into practice in communities across the nation. Thank you for this opportunity to appear before the Committee. I will be happy to answer any questions you may have.