

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2005 Budget Request

Witness appearing before the  
Senate Subcommittee on Labor-HHS-Education Appropriations

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

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on  
FY 2005 President's Budget Request  
for the Office of the Director

Mr. Chairman, Members of the Committee:

I am pleased to present the President's budget request for the Office of the Director (OD) for FY 2005, a sum of \$359,645,000, which reflects an increase of \$32,556,000 over the comparable FY 2004 appropriation. The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD also is responsible for a number of special programs and for management of centralized support services to the operations of the entire NIH.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including environmental and public safety regulations of facilities. The principal OD offices providing these activities include the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy; Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and

Management. This request contains funds to support the functions of these offices.

In addition, the OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs; I will now discuss the budget request for the OD in greater detail.

## **NIH ROADMAP**

As part of the NIH Roadmap for Medical Research, the NIH has launched initiatives in FY 2004 critical to addressing the roadblocks to the acceleration of science conduct and transfer to the public. These initiatives promise to yield far-reaching dividends in medical knowledge and improved health for the public. Under the theme of New Pathways to Discovery, initiatives are aimed at quantifying and cataloging complex biological systems and in developing a better “tool box” for today’s researchers, for research teams of the future, and for re-engineering the clinical research enterprise. Examples of initiatives include the creation of an accessible public library database for chemically diverse small molecules, centers that will create new tools to describe the dynamics of protein interactions, development of novel technologies to study cellular metabolites, creation of national software engineering system that can facilitate the ability of scientists to tap into supercomputing networks and share and analyze complex data, and the early conceptual development of nanomedicine. The NIH Roadmap initiatives also have taken steps to prepare Research Teams of the Future, the second theme, by encouraging scientists and research institutions, including the NIH, to test alternative models for conducting research that take advantage of the scientific advances and complexities. A major focus has been placed on planning and research workforce training for the conduct of interdisciplinary research, that research that spawns new disciplines of science. In addition, a new award – the NIH Director’s Pioneer Award – will support a select group of investigators who have the potential for ground-breaking discoveries. Ultimately findings from the laboratory must reach the public, and the initiatives under the third theme – Re-engineering the Clinical Research Enterprise – are geared to address the roadblocks to the conduct of clinical research and its translation to

patients. These initiatives include the exploration of the ability to create and enhance interoperability among clinical trial networks, the testing the feasibility of establishing a National Clinical Research Associations program where community-based clinicians are trained to participate in studies and play a role in augmenting the transfer of research to their patients, and the assessment of patient-reported chronic disease outcomes. Critical work continues in the area of research policy analysis and coordination with an emphasis on harmonization and standardization of policies and requirements pertaining to clinical research. In addition, extension and expansions of clinical research training programs extramurally and intramurally have been initiated.

### **THE OFFICE OF AIDS RESEARCH**

The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. Each year, OAR oversees the development of the comprehensive NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual AIDS research budget for each Institute and Center; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. OAR identifies scientific areas that require focused attention and facilitates multi-institute activities to address those needs. OAR coordinates, monitors and fosters plans for NIH involvement in international AIDS research and training activities. OAR supports a number of initiatives to enhance

dissemination of research findings to researchers, physicians, patients and communities. The FY 2005 budget request for OAR is \$61,435,000.

## **THE OFFICE OF RESEARCH ON WOMEN'S HEALTH**

The Office of Research on Women's Health (ORWH), the focal point for women's health research for the Office of the Director, strengthens, enhances and supports research related to diseases, disorders, and conditions that affect women, and sex/gender studies on differences/similarities between men and women; ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH; and, develops opportunities for the advancement of women in biomedical careers and investigators in women's health research. The report, *An Agenda for Research on Women's Health for the 21<sup>st</sup> Century*, provides a framework for the ORWH to collaborate with the scientific and advocacy communities to address gaps in knowledge about women's health and sex and gender factors in health and disease. The FY 2005 budget request of \$41,577,000 includes an increase of \$626,000 over the FY 2004 appropriation.

Research priorities for women's health emphasize the importance of interdisciplinary research with collaboration and integration of knowledge from multiple areas of scientific expertise; lifespan issues and the continuum from intrauterine life into elderly years; health disparities/differences and diversity among different populations or subpopulations of women; and, sex/gender differences in health and disease and therapeutic interventions at genetic, molecular, cellular, and functional levels. Areas of research interest for 2005 include: pathogenesis of diseases including prevalence/validation of sex differences in diagnosis/treatment of disorders/diseases; clinical trial methodology; mental health studies; new agents for management of menopausal symptoms; treatments/interventions for diseases that show enhanced clinical features in women; and other specific areas such as CFS, and benign gynecologic disorders including uterine fibroids. Special emphasis areas for women's health research include genetics/pharmacogenomics, and the genetic, molecular and cellular bases for

action of pharmacologic agents known to have differential effects in females; and, prevention and treatment, from basic biological factors to effects of risk behaviors or interventions. There is expansion of new research in the ORWH specialized centers of interdisciplinary research in women's health and sex and gender factors, and the unique ORWH interdisciplinary career development program in women's health research that fosters the mentored development of junior faculty and assists them in bridging advanced training towards a goal of research independence. In addition, the ORWH has now implemented a new Intramural Program on Research on Women's Health to focus on NIH intramural women's health and sex and gender comparison research. The ORWH continues to partner with Institutes and Centers to ensure compliance with NIH policies for the inclusion of women and minorities in clinical research, and that analyses by sex/gender are addressed by investigators funded by the NIH.

### **THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH**

The NIH has a long history of funding health-related behavioral and social sciences research, and the results of this work have contributed significantly to our understanding, treatment, and prevention of disease. The Office of Behavioral and Social Sciences Research (OBSSR) furthers NIH's ability to capitalize on the scientific opportunities that exist in behavioral and social sciences research by providing leadership in identifying and implementing research programs in behavioral and social sciences that are likely to improve our understanding of the processes underlying health and disease and provide directions for intervention. OBSSR works to integrate a behavioral and social science approach across the programs of the NIH. The FY 2005 OD budget includes \$26,321,000 for OBSSR, an increase of \$415,000 over the FY 2004 appropriation.

Many exciting scientific developments are occurring at the intersection of behavioral and social science research and biomedical research. It has become apparent that increasingly, scientific advances are being made at the interfaces of traditional disciplines, and that approaches to science are becoming more integrative. OBSSR has

begun development of a program to provide interdisciplinary training to postdoctoral fellows in NIH intramural laboratories. This program would provide a mechanism whereby an individual with a PhD in a behavioral or social science discipline might acquire interdisciplinary training that included biomedical research. Alternatively, someone trained in a more traditional biomedical field would receive postdoctoral training that included a behavioral or social science component. In addition to the benefits to be realized by the individual trainees, this program would also show NIH leading, by example, our Roadmap efforts to build interdisciplinary Research Teams of the Future.

OBSSR is also developing an initiative to advance discovery of scientific knowledge about eHealth technologies for health behavior change and chronic disease management. Consumers, patients, and providers are increasingly using eHealth applications, particularly the Internet, to seek health information for themselves or family and friends, communicate with others who have a similar disease or illness, and to communicate with their health care providers. These technologies offer people the ability to obtain health information at relatively low cost, including those with limited or no access to health care professionals or services, and historically underserved populations. While the use of eHealth interventions is becoming widespread, these techniques have yet to receive much rigorous evaluation. This initiative's goal is to bring together components of NIH, the Robert Wood Johnson Foundation and other public agencies and private foundations in a "meeting of the minds" about the state of eHealth evaluation research for health behavior change and chronic disease management, future directions in the field, and the role of NIH and others in developing a research agenda for this area.

Behavioral and social factors contribute significantly to racial and ethnic health disparities. Consequently, OBSSR is committed to developing better knowledge of specific pathways to health disparities and to finding solutions. In February 2003, OBSSR published in the *American Journal of Public Health* a set of papers presenting scientific evidence of the effects of racial/ethnic bias on health and identifying areas for

future research to further explicate the relationship. The papers were the product of an OBSSR meeting of approximately 100 leading scientists held in April 2002. Currently, OBSSR is convening discussions among ICs regarding the role of social and behavioral science in their health disparities research activities and avenues for coordinated initiatives.

An effective way to ensure that results of behavioral and social science improve our society's health involves incorporating these in clinical practice. In order to start this process at an early stage in the training of the next generation of physicians, OBSSR funded the IOM to determine how to improve medical education. The results of this study [April 2004] will inform a training initiative that OBSSR with several ICs will launch this year.

### **THE OFFICE OF DISEASE PREVENTION**

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. There are several other offices within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) has as its mission to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health services to the public. The Office of Disease Prevention (ODP) has several specific programs/offices that strive to place new emphasis on the prevention and treatment of disease.

In FY 2005, the Office of Dietary Supplements (ODS) within ODP requests a budget of \$26,218,000, an increase of \$414,000 over the FY 2004 appropriation. In FY 2004, ODS published its 5-year Strategic Plan for 2004-2009, a major component of which is to significantly expand efforts to address the role of dietary supplements in

reducing the risk for chronic diseases. It will continue to promote the scientific study of the use of dietary supplements by supporting investigator-initiated research in conjunction with other ICs at NIH and stimulating research through conduct of conferences and through presentations at national and international meetings.

ODS, in collaboration with the National Heart, Lung, and Blood Institute and other NIH ICs, has sponsored a systematic review of the relationship between omega-3 fatty acids and a series of clinical indications, particularly coronary heart disease. Several reports will be published in FY 2004 based upon this review, which will serve as the basis for planning further NIH research on omega-3 fatty acids. Congressional language in recent appropriation reports directed ODS to enhance an ongoing collaboration for the development, validation, and dissemination of analytical methods and reference materials for botanical dietary supplements. ODS works with other partners in the public and private sectors to meet this objective. ODS supports the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics at the Centers for Disease Control and Prevention, in order to provide more information about dietary supplement use in the US population.

This will inform future research about potentially important target populations, such as children, women, and the elderly. Funding is used to create and populate a database of dietary supplements, as well as to support the measurement of blood levels of key metabolites associated with dietary supplement use. ODS collaborates with USDA to develop an analytically-based database of dietary supplement ingredients. ODS collaborates with other federal agencies to develop an approach to assessment of the health effects of bioactive factors in foods and dietary supplements. In its continuing efforts to inform the public about the benefits and risks of dietary supplements, ODS collaborates with USDA on the International Bibliographic Information on Dietary Supplements (IBIDS) database, which now includes a consumer-oriented search strategy. It has also disseminated a database devoted to federal funding of dietary supplement research, called CARDS, which is currently populated with data about the NIH investment from FY 1999-2002. ODS publishes Fact Sheets about vitamin and mineral

dietary supplements in collaboration with the NIH Clinical Center, as well as Fact Sheets about botanical supplements.

Another component of ODP, the Office of Rare Diseases (ORD) was formally established through the Rare Diseases Act of 2002, Public Law 107-280. The purpose of this Act is to increase the national investment in the development of diagnostics and treatments for approximately 25 million patients with more than 6,000 rare diseases. A rare disease is defined as one where fewer than 200,000 persons are affected in the United States. The Fiscal Year 2005 budget request for ORD is \$15,787,600, an increase of \$253,000 above the FY 2004 appropriation.

Through its *Extramural Research Program*, the ORD supports a Rare Diseases Clinical Research Network with NIH Institutes and Centers (ICs). The major goals for the network include the systematic collection of clinical information to develop biomarkers and new approaches to diagnosis, treatment, and prevention of rare diseases, and to promote training of new clinical research investigators in rare diseases. ORD funded seven Rare Diseases Clinical Research Consortia and one Data and Technology Resources Coordinating Center. The consortia focus on urea cycle disorders, inborn errors of metabolism, rare neurological channelopathies, idiopathic bone marrow failure states and cytopenias, vasculitides, and defects in steroidogenesis. The patient support organizations are closely integrated into the consortia and the network.

The ORD *Intramural Research Program* promotes training in the areas of clinical and basic research into rare diseases and in biochemical genetics, fosters protocol-based initiatives into rare diseases not currently investigated in the intramural program, assists in the investigation of select, unique disorders of unknown etiology, provides overall research support for diagnostics and therapeutics of rare disorders, and supports five Bench-to-Bedside grants.

In its *Scientific Conferences Program*, in FY 2004, the ORD will cosponsor more than 70 scientific conferences on rare diseases. The 460 conferences sponsored to date

since 1995 have been shown to be excellent venues to establish a research agenda for specific rare diseases, take advantage of scientific opportunities, or eliminate barriers to advancing research.

To provide more comprehensive information, ORD, together with the National Human Genome Research Institute (NHGRI), established *the Genetic and Rare Diseases Information Center* to respond to requests for information about genetic and/or rare disorders. In its third year of operation, the information center broadened its language base to include Spanish in addition to English.

In FY 2004, ORD plans to establish a *Trans-NIH Rare Diseases Working Group* to encourage collaborative research activities, provide opportunities for input as new rare diseases research programs unfold, and gather information about the rare disease research programs supported by the ICs and Offices for mandated annual and biennial reports.

## **THE OFFICE OF SCIENCE EDUCATION**

The Office of Science Education (OSE) plans, develops, and coordinates science education programs to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The office's mission is to help people *understand* and *use* new knowledge uncovered by the NIH in pursuit of better health for everyone. The OSE works toward this mission by: creating programs to improve science education in schools (the *NIH Curriculum Supplement Series*); creating programs that stimulate interest in health and medical science careers (*the new LifeWorks Web site*); creating programs to advance public understanding of medical science, research, and careers; promoting NIH educational resources and programs; and advising NIH leadership about science education issues. All office programs target diverse populations including under-served communities, women, and minorities, with a special emphasis on the teachers of students from Kindergarten through grade 12. The OSE works closely with NIH institutes, centers, and offices on science education issues, and maintains the OSE Web site as a

source of information about available resources and programs.

<http://science.education.nih.gov>.

The NIH Curriculum Supplements series are *National Science Education Standards*-based lesson plans that are distributed free to K-12 teachers across the country. They incorporate the best of both science and education communities, and are intended to update science content and allow the teacher to incorporate the latest NIH research into classroom instructions. *Life Works* is a new OSE Web site created as a source of career information for students, teachers, counselors, and parents. The site will allow exploration of the educational requirements, knowledge, skills, and abilities required for over 100 health and medical science careers. The FY 2005 Budget request for OSE is \$3,899,000.

### **LOAN REPAYMENT AND SCHOLARSHIP PROGRAM**

The NIH, through the Office of Loan Repayment and Scholarship (OLRS), administers the Loan Repayment and Undergraduate Scholarship Programs. The NIH Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees to biomedical and behavioral research careers by countering the growing economic disincentives to embark on such careers, using as an incentive the repayment of educational loans. There are loan repayment programs designed to attract individuals to clinical research, pediatric research, health disparities research, and contraception and infertility research, and to attract individuals from disadvantaged backgrounds into clinical research. The AIDS, Clinical, and General Research Loan Repayment Programs are designed to attract investigators and physicians to the NIH's intramural research and research training programs. The NIH Undergraduate Scholarship Program (UGSP) is a scholarship program designed to support the training of undergraduate students from disadvantaged backgrounds in biomedical research careers and employment at the NIH. The FY 2005 Budget request for OLRS is \$7,250,000.

Thank you for giving me the opportunity to present this statement; I will be

pleased to answer questions.