DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2004 Budget Request

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

Roderic I. Pettigrew, Ph.D., M.D., Director
National Institute of Biomedical Imaging and Bioengineering

April 8, 2003

Kerry N. Weems, Acting Assistant Secretary for Budget, Technology and Finance, HHS
William R. Beldon, Acting Deputy Assistant Secretary for Budget, HHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

Dr. Roderic I. Pettigrew
Director, National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health
on
Fiscal Year 2004 President's Budget Request
for the National Institute of Biomedical Imaging and Bioengineering

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The fiscal year (FY) 2004 budget includes $282,109,000, an increase of $3,838,000 over the FY 2003 enacted level of $278,271,000 comparable for transfers proposed in the President's request.

The NIBIB's mission is to lead the development and application of breakthrough technologies in the physical and engineering sciences to facilitate an improved fundamental understanding of complex biological processes. This research agenda will dramatically advance the Nation's health care by improving the detection, management, understanding and, ultimately, the prevention of disease. Health care and technology have long been linked in the U.S. Today, cardiac pacemakers, mammograms, sustained release medications, and artificial hips are but a few examples of how biomedical imaging and bioengineering are transforming health care.

In September 2002, I began my tenure as the first Director of the NIBIB. I assumed my role during a time when the landscape of conducting biomedical research is changing. It is this altered landscape, wherein the most efficacious medical advances depend on multidisciplinary findings obtained from researchers working together at the

interface between the biological and quantitative sciences, that led to the creation of the NIBIB. This new environment, combined with recent budgetary increases, visionary predecessors, the rapid pace in technology development, and high-quality investigator-initiated research, has allowed the NIBIB–just in its second year of operation–to establish a strong research foundation on which to capitalize. To illustrate these points, my testimony will highlight recently achieved milestones, outline research plans and directions, and describe areas of progress and opportunity.

MILESTONES TO SUCCESS

The NIBIB, the newest Institute at the National Institutes of Health (NIH), was established by law December 29, 2000, and received its first appropriation and grant funding authority in FY 2002, just 15 months ago. Since its establishment, NIBIB staff have achieved significant milestones. In FY 2002 the NIBIB funded approximately 300 research applications, participated in approximately 170 extramural symposia, planned 16 NIH-based symposia and workshops, served as lead on 5 trans-NIH initiatives, and collaborated on 4 trans-NIH programs.

Additional milestones have been achieved in FY 2003. In January, the NIBIB held the first meeting of its National Advisory Council. The Institute has also built a solid research infrastructure through the release of numerous basic and applied research solicitations in promising areas of scientific investigation, including tissue engineering, advanced biomaterials, image-guided interventions, low-cost medical imaging modalities, biosensor technology, and cellular and molecular imaging.

The NIBIB has successfully fostered extensive linkages and collaborations with other NIH Institutes and Centers, Federal agencies, academic institutions, private industry, and scientific societies. As examples, the NIBIB administers and participates in the Bioengineering Consortium (BECON), an NIH-wide consortium dedicated to promoting and coordinating bioengineering research across the NIH. The NIBIB and the National Science Foundation are collaborating with the National Academy of Engineering–a private, independent, nonprofit institution–on a project entitled "Engineering and the Health Care System." This study focuses on ways to harness advances in engineering applications to improve health care delivery. The NIBIB will collaborate with the National Institute of Diabetes and Digestive and Kidney Diseases to develop a program for monitoring pancreatic insulin cell failure in diabetes. This would constitute a significant advance in diabetes research.

THE NIBIB RESEARCH PORTFOLIO

In December 2002, the NIBIB officially launched its strategic planning process with an interactive workshop entitled "Future Research Directions." This workshop helped identify high-priority research focus areas and associated high-impact projects and technologies that could contribute significantly to biomedical research and global healthcare needs. Areas identified as highly relevant to NIBIB's mission include image-guided interventions, cellular and molecular imaging, computational biology, biosensor technologies, optical imaging technologies, and regenerative medicine. The Institute is now poised to realize the promise within these areas of opportunity.

ADVANCED TECHNOLOGIES

Biomedical imaging and bioengineering are interdisciplinary fields that require collaborations not only among imagers and engineers, but also with biologists, chemists, mathematicians, computer scientists, and clinicians of all specialties. Today, the imaging and engineering sciences are essential for improved understanding of biological systems, detecting and controlling disease, and enhancing human health. Recent advances in these fields have enabled the diagnosis and treatment of various diseases using increasingly less invasive procedures. Benefits associated with minimally invasive imaging applications include quicker and more accurate diagnoses leading to improved patient outcomes at reduced costs. Minimally invasive image-guided interventions now serve as powerful tools in the operating room and can be applied to surgical procedures in urology, oncology, neurosurgery, ophthalmology, cardiology, and orthopedics. However, these techniques are in relatively early stages of development. A goal of the NIBIB is to further establish and validate minimally invasive image-guided therapies as standards for patient care and to support additional research in therapeutic areas where minimally invasive technologies do not yet exist. The NIBIB also has initiatives underway to encourage investigator-initiated research for tracking anatomical targets and instruments and for developing steerable devices, including catheters, endoscopes, and needles. A goal is to develop theses techniques so that they may be used to routinely identify disease at its earliest stages, even before symptoms arise. At that point, treatments can be instituted to cure the disease or preempt any serious consequences.

The combination of image-guided therapies with genomics and proteomics, has given researchers the capacity to develop new molecular probes and targets for disease detection, and to immediately direct treatment to the diseased site. By studying how a person's genetic blueprint is expressed through proteins, and how these proteins differ in healthy and diseased cells, researchers will be able to develop therapies tailor-made for an individual. As a first step towards "personalized medicine," NIBIB researchers are investigating tiny "barcoded" metal particles as a method for analyzing proteomes–the complete set of an organism's proteins. Advances in miniaturized devices not only have the potential to identify and characterize new proteins, but to advance the rapid screening of multiple compounds in the drug development process.

Molecular imaging provides a way to monitor cellular activities in normal and diseased states. The development of novel imaging technologies, combined with new or enhanced probes that bind to defined cellular targets, will allow this technique to be more broadly applied to biomolecules that are known indicators of a diseased state, such as an enzyme that may be overexpressed in a specific tumor. For example, NIBIB researchers have developed artificial fluorescent agents, called quantum dots, that glow and act as cell markers when bound to certain cancer cells. Further testing of these agents in animal models of cancer will determine their utility as effective imaging agents for the early detection of cancer in humans.

BIOINFORMATICS AND COMPUTATIONAL BIOLOGY

Advances in bioinformatics and computational biology have been identified as

one of the areas of greatest need, and one of the areas having the greatest potential for positive impact on the universe of medical science and health care. In recognition of the critical role these disciplines play in biomedical imaging and bioengineering, NIBIB supports fundamental research in computing technology, the targeted development and application of new biocomputing tools, and technologies that provide structural and functional data at the cellular level. Areas of NIBIB interest include the development of high performance computing and visualization methods applicable to the modeling of biological systems, the utilization of medical imaging data in computational modeling of biological systems and human physiology, the development of algorithms and software for the manipulation and analysis of imaging data, and computer modeling of tissue mechanics. Our goal is to advance an understanding of the integrated function of biological systems through the development and application of computational models, and to apply these models to the design of novel treatments and therapeutics. In support of this goal, a NIBIB researcher is developing a brain-computer interface (BCI) system that acquires and analyzes brain signals to create a communications channel directly between a person's brain and a computer. BCI technologies can allow people who are completely paralyzed to express wishes to caregivers and to use computer programs.

NANOTECHNOLOGY: SENSORS FOR MEDICINE

The term nanotechnology is used to describe many types of research at the atomic, molecular, or macromolecular level–research where the characteristic dimensions are less than one-thousandth of the diameter of a human hair. Biosensors are

nanoscale devices that detect, monitor, and transmit information about a physiological change, or about the presence of various chemicals, gases, or biological materials (bacteria and viruses). Laboratory diagnostics used in hematology, clinical chemistry, pathology, and microbiology already employ sensor technologies to perform simultaneous measurements for hundreds, maybe thousands, of substances in urine, blood, saliva, sweat, and interstitial fluids. The NIBIB has an active research program in sensor technologies and is expanding this area of research.

Knowledge gained through NIBIB-supported advances in nanotechnology, particularly in the areas of biosensors and molecular imaging, will be further leveraged for the development of sensors that can be applied to other critical research areas. For example, NIBIB researchers are adapting highly sensitive and selective biosensor arrays to provide a fingerprint for the identification of harmful bacteria and environmental health hazards. Future NIBIB efforts being planned in nanotechnology and sensors focus on the development of low-cost, miniaturized, integrated sampling detector systems for field use, including the development of systems that provide "detect-to-warn" capabilities, and that enable the rapid and accurate verification of exposure to harmful environmental agents.

MULTIDISCIPLINARY RESEARCH TEAMS OF THE FUTURE

The era of the solo independent investigator is passing. Our research culture must be redirected to the formation of teams that span academic departments and scientific disciplines. Their formation is critical to the development and validation of

new technologies to aid in disease detection, treatment, and prevention. Therefore, a major goal of the NIBIB is to catalyze team science through initiatives that encourage multi-organizational and multidisciplinary teams. Programs differ from traditional NIH opportunities as they require collaborative efforts between quantitative and biomedical researchers. These will support institutional needs, infrastructure development, and the costs associated with making team science viable and attractive to academic institutions. Within a given area, specific clinical problems–such as our current effort to image pancreatic beta cell function in diabetes–will be identified to serve as a catalyst to drive the formation of the research team. The value in catalyzing team science lies not only in strengthening research capacity, but in fostering the formation of research teams among disciplines where they previously have not naturally formed.

In conclusion, the NIBIB is dedicated to promoting the development of emerging technologies and establishing opportunities that will encourage the necessary interdisciplinary collaborations to advance biomedical and global health care priorities. I would be pleased to respond to any questions that the Committee may have.

BIOGRAPHICAL INFORMATION ON RODERIC I. PETTIGREW, Ph.D., M.D.

Roderic I. Pettigrew, Ph.D., M.D., is the first permanent Director of the National Institute of Biomedical Imaging and Bioengineering at the NIH. Prior to his appointment at the NIH, he was Professor of Radiology, Medicine (Cardiology) at Emory University and Bioengineering at the Georgia Institute of Technology, and Director of the Emory Center for MR Research, Emory University School of Medicine, Atlanta, Georgia.

Dr. Pettigrew is known for his pioneering work at Emory University involving four-dimensional imaging of the heart using magnetic resonance (MRI). Dr. Pettigrew graduated cum laude from Morehouse College with a B.S. in physics, where he was a Merrill Scholar; has an M.S. in nuclear science and engineering from Rennselear Polytechnic Institute; and a Ph.D. in applied radiation physics from the Massachusetts Institute of Technology, where he was a Whitaker Harvard-MIT Health Sciences Scholar. Subsequently, he received an M.D. from the University of Miami School of Medicine in an accelerated two-year program, did an internship and residency in internal medicine at Emory University and completed a residency in nuclear medicine at the University of California, San Diego. Dr. Pettigrew then spent a year as a clinical research scientist with Picker International, the first manufacturer of MRI equipment. In 1985, he joined Emory as a Robert Wood Johnson Foundation Fellow with an interest in non-invasive cardiac imaging.

Dr. Pettigrew's awards include membership in Phi Beta Kappa, the Bennie Award (Benjamin E. Mays) for Achievement, and being named the Most Distinguished Alumnus of the University of Miami. In 1989, when the Radiological Society of North America celebrated its 75th Diamond anniversary scientific meeting, it selected Dr. Pettigrew to give the keynote Eugene P. Pendergrass New Horizons Lecture. He has also served as chairman of the Diagnostic Radiology Study Section, Center for Scientific Review, NIH.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF MANAGEMENT AND BUDGET
BIOGRAPHICAL SKETCH

NAME: Kerry N. Weems

POSITION: Deputy Assistant Secretary for Budget
BIRTHPLACE: Portales, New Mexico

EDUCATION:
B.A., Philosophy, New Mexico State University, 1978
BBA, Management, New Mexico State University, 1978
MBA, University of New Mexico, 1981

EXPERIENCE:

January 24-Present	Acting Assistant Secretary for Budget, Technology and Fiance
June 2002- Present	Deputy Assistant Secretary for Budget, HHS
2001 - 2002	Acting Deputy Assistant Secretary for Budget, HHS
1996 - 2002	Director, Division of Budget Policy, Execution and Management, HHS
1991 - 1996	Chief, Budget Planning Branch, HHS
1988 - 1991	Program Analyst, Office of Budget, HHS
1983 - 1988	Program and Budget Analyst, HHS (Social Security Administration)
1981 - 1983	Staff Member, United States Senate

HONORS AND AWARDS:

2001	Presidential Rank Award
1995	Secretary's Distinguished Service Award
1993	HHS Senior Management Citation

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF BUDGET

William R. Beldon

Mr. Beldon is currently serving as Acting Deputy Assistant Secretary for Budget, HHS. He has been a Division Director in the Budget Office for 16 years, most recently as Director of the Division of Discretionary Programs. Mr. Beldon started in federal service as an auditor in the Health, Education and Welfare Financial Management Intern program. Over the course of 30 years in the Budget Office, Mr. Beldon has held Program Analyst, Branch Chief and Division Director positions. Mr. Beldon received a Bachelor's Degree in History and Political Science from Marshall University and attended the University of Pittsburgh where he studied Public Administration. He resides in Fort Washington, Maryland.