DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2007 Budget Request

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

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Richard J. Turman, Deputy Assistant Secretary, Budget

Mr. Chairman and Members of the Committee:

I am pleased to present the Fiscal Year (FY) 2007 President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The FY 2007 budget includes $294,850,000***;*** a decrease of $1,960,000 over the FY 2006 enacted level of $296,810,000 comparable for transfers proposed in the President's request.

BRIDGING THE PHYSICAL AND LIFE SCIENCES

The mission of the NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care. To demonstrate our commitment, the NIBIB gives special consideration for funding to research grant applications that bridge and integrate the life and physical sciences.

TRANSLATING TECHNOLOGY INTO CLINICAL PRACTICE

Ultimately, the NIBIB seeks to translate research findings made in the laboratory into solutions that advance human health by reducing disease burden and improving quality of life. One highly successful example of a research and commercialization effort supported in part by the NIBIB is an automated, digital-imaging device called the "array microscope." The system utilizes an array of 100 miniaturized objectives to produce a single, seamless sweep of a microscope slide of a histopathology sample. The result is a microscopic-level resolution, multi-colored digitized image of the pathology sample. The most immediate impact of this technology is expected to be in medical pathology. These "virtual slides" can be easily stored in a patient's record and can also be viewed over the Internet, providing immediate on-line access to expert second opinions.

The recently released "Quantum Project" initiative is another example of how the NIBIB strives to support a more integrated and focused research agenda using multidisciplinary approaches to develop innovative and marketable technologies. The goal of this unique program is to make a "quantum" advance in healthcare by funding research on a specific project or projects that will translate into new technologies and modalities for the treatment, prevention and cure of disease or resolve a major health care problem within a reasonable time frame. In these "bench to bedside" partnerships, a team of interdisciplinary scientists will conduct collaborative research that will result in a prototype product that can be translated into clinical practice.

TECHNOLOGIES TO IMPROVE HEALTH CARE DELIVERY

With the advent of miniaturized devices and wireless communication, the way in which doctors care for patients has changed dramatically. Empowering clinicians to make decisions at the bedside, or the "point-of-care," has the potential to significantly impact health care delivery and help address the challenges of health disparities. The success of such a shift relies on the development of portable diagnostic and monitoring devices for near-patient testing. The NIBIB has contributed to advances in this area by funding the development of sensor and microsystem technologies for point-of-care testing. These instruments combine multiple analytical functions into self-contained, portable devices that can be used by non-specialists to detect and diagnose disease, and can enable the selection and monitoring of optimal therapies. These advances limit the reliance on submission of samples to centralized laboratories and will make results more readily available within minutes as opposed to several hours or days, enabling clinicians to make decisions regarding treatment when these decisions can have the greatest

impact. An example under development at the NIBIB is a handheld system for the rapid detection and identification of bacteria which cause urinary tract infections. The research team anticipates this test could become available in the next two to three years. To further capitalize on these advances, the NIBIB is planning an initiative to support research on critical areas for the development of other hand-held, diagnostic devices. These systems could reduce the cost of health care, much as integrated electronics have reduced the cost of computing, and greatly simplify and improve patient delivery of care.

NEXT GENERATION MINIMALLY-INVASIVE TECHNOLOGIES

Advances in imaging technologies have spurred new minimally-invasive procedures to accurately identify the site of disease and injury, provide tissue for a definitive diagnosis, administer treatment with minimal trauma, and monitor treatment responses. Image-guided interventions are not only more efficient in terms of time and cost, but their less invasive nature may result in fewer complications and less damage to tissue. For example, NIBIB investigators are developing new magnetic resonance imaging (MRI) techniques to detect and treat organ rejection non-invasively. The current standard for diagnosing and staging rejection is the biopsy, which is invasive, painful, and prone to sampling errors that can yield false negative results. The development of a non-invasive imaging-based method that can replace the biopsy is highly desirable.

Over the next year, the NIBIB intends to expand its image-guided interventions program by supporting research on the development of technologies that allow the surgeon to visualize the patient seamlessly, in three-dimensional preoperative images; track intraoperative changes with real-time imaging; and restore a normal sense of

touch through robotic tools with sensors for touch feedback, or haptics. This research may lead to new minimally-invasive surgical procedures with fewer complications, shorter hospital stays, and reduced costs. To plan for future initiatives in this area, the NIBIB recently organized an interagency retreat to identify high priority challenges that can serve as short- and long-term goals. Eight Federal agencies and nine NIH Institutes and Centers (ICs) participated in this retreat.

MEDICAL ROBOTICS

First generation surgical robots are already being installed in a number of operating rooms around the country. Although these robots can't perform surgery on their own, they are certainly lending a mechanical hand. Robots are being used in medicine because they allow for unprecedented control and precision of surgical instruments and reduce trauma to the patient, dramatically improving surgical outcomes and lowering health care costs. Robots are also being used in rehabilitation as they provide considerable opportunities to improve the quality of life for physically disabled people. For example, one of the most common stroke disabilities is a paralyzed arm. The NIBIB and the National Institute of Child Health and Human Development are jointly funding the development of two robotic devices that could accelerate rehabilitation of patients with paralyzed arms and reduce the cost of physical therapy. These devices can also treat people who have experienced catastrophic events, such as war injuries resulting in limb loss. Testing with stroke patients is expected to begin this year using one device.

Traumatic injury or neurological diseases can also significantly alter or impair the lifestyle of an individual. To help patients lead more productive lives, NIBIB scientists

are developing a non-invasive brain-computer interface to provide both communication and control functions. By recording brain waves from the scalp and then decoding them, this system allows people to move a cursor to spell words, and even to control a robotic arm. Initial efforts to test this new technology in the field are underway.

NANOTECHNOLOGY FOR DISEASE DETECTION AND DRUG DELIVERY

Detection of dormant metastatic tumor cells is a critical but elusive goal in cancer treatment. To find these cells, NIBIB researchers are developing non-invasive optical imaging techniques that are less costly and more accessible than MRI-based techniques and are free of the side effects associated with radioactive imaging agents. Microscopic or nanoscale "bubbles," called polymerosomes, containing embedded fluorescent materials are the key to this new approach. These labeled bubbles are injected directly into a tumor and then imaged. Also in development are polymersomes that would deliver chemotherapy agents directly to a tumor. The surface of the bubble can carry a molecule that would bind to tumor cells, and its membrane would also hold fluorescent molecules for detection by optical imaging, with the chemotherapy "payload' carried in the interior. One investigator has developed a special device which improves drug release by ultrasonic fragmentation of the bubble.

ENHANCED SUPPORT FOR NEW INVESTIGATORS

New investigators are the innovators of the future – they bring fresh ideas and technologies to existing biomedical research programs, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIBIB-funded research is essential to the health of the biomedical imaging and bioengineering research enterprise. The NIBIB is specifically targeting new investigators for special

funding consideration. This proved to be quite successful in the first year of this policy, and a continuation of this program is planned.

TRAINING FOR THE FUTURE

An important goal of the NIBIB is to train a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research. Researchers trained in biomedical imaging and bioengineering must be able to demonstrate technical competency in multiple fields as well as the ability to think independently, communicate ideas effectively, work in teams, and contribute to a strong vision that transcends a narrow discipline. To this end, the NIBIB will work with the community to develop new programs that cross-train research scientists in the biological and quantitative sciences. For example, the NIBIB's Research Supplements to Promote Clinical Resident Research Experiences program has been very successful. This novel training mechanism is designed to serve as a "first step" in attracting outstanding clinicians into research careers related to the mission of the NIBIB by providing a one to two-year research opportunity during residency training.

The NIBIB has also developed several public and private collaborations to catalyze research at this interface. For example, the NIBIB and the Howard Hughes Medical Institute partnered in a novel public-private partnership to stimulate the development of new interdisciplinary graduate training programs that integrate the physical, quantitative, and engineering sciences with the life sciences. This program will train a new generation of researchers, equipped to meet the challenges of the 21st Century.

NIH ROADMAP FOR BIOMEDICAL RESEARCH

An overarching goal of the NIH Roadmap is to facilitate the development of broad-

based innovative, novel and multidisciplinary science and technology that has the potential to further advances in health care. This goal is well aligned with the NIBIB mission and is actively supported on a number of fronts. For example, over the last year NIBIB has been the lead Institute in a Roadmap initiative entitled "Innovation in Molecular Imaging Probes." Molecular imaging approaches can be used to study cellular events and biochemical abnormalities. The major roadblocks to *in vivo* clinical applications of molecular imaging are the poor sensitivity and potential toxicity of the current probes. This initiative supports research programs that will circumvent these roadblocks.

NIH BLUEPRINT

The Neuroscience Blueprint is a framework designed to enhance cooperative activities among the NIH ICs that support research on the nervous system. During the last year, NIBIB contributed to the development of a number of initiatives, leading or participating in three project teams. These initiatives aim to support research and development of imaging technology for high resolution imaging of neural activity that is reflected in electrophysiological signals; and to develop a framework to address the critical need for neuroimaging data and software tools sharing and integration. The NIBIB also participated in the development of neuroscience training initiatives.

Department of Health and Human Services
National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering

Roderic I. Pettigrew, Ph.D., M.D.

Roderic I. Pettigrew, Ph.D., M.D. began his appointment as the first director of the NIBIB in September 2002. Prior to his appointment at NIBIB, he was a Professor of Radiology, Medicine (Cardiology) and Bioengineering 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 dynamic three-dimensional imaging of the heart using magnetic resonance (MRI). He also was co-developer of the first computer software package specifically designed for cardiac imaging using 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 medicine and engineering from Rensselaer Polytechnic Institute; and a Ph.D. in applied radiation physics from the Massachusetts Institute of Technology, where he was a Whitaker Harvard-MIT Health Science Scholar. After completing his Ph.D., he received an M.D. from the University of Miami School of Medicine in an accelerated two-year program. He did his 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 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, a member of Phi Beta Kappa, is the recipient of numerous awards, including the Bennie Award (Benjamin E. Mays) for Achievement in 1989. Also in 1989, when the Radiological Society of North America celebrated its 75th Diamond anniversary scientific meeting, the largest medical meeting in the world, it selected Dr. Pettigrew to give the keynote Eugene P. Pendergrass New Horizons Lecture. In 1990, he was named the Most Distinguished Alumnus of the University of Miami. He has served as chairman of the Diagnostic Radiology Study Section, Center for Scientific Review, NIH, and has received multiple grants from the NIH for his research on cardiac imaging. He is on numerous editorial boards, scientific societies' Boards of Directors, and is a frequent invited lecturer at international scientific meetings. Dr. Pettigrew has also been elected a Fellow of the American Heart Association, the American College of Cardiology, the International Society of Magnetic Resonance in Medicine, and the American Institute of Medical and Biomedical Engineering.

Office of Budget

Richard J. Turman

Mr. Turman is the Deputy Assistant Secretary for Budget, HHS. He joined federal service as a Presidential Management Intern in 1987 at the Office of Management and Budget, where he worked as a Budget Examiner and later as a Branch Chief. He has worked as a Legislative Assistant in the Senate, as the Director of Federal Relations for an association of research universities, and as the Associate Director for Budget of the National Institutes of Health. He received a Bachelor's Degree from the University of California, Santa Cruz, and a Masters in Public Policy from the University of California, Berkeley.