DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2012 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

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Mr. Chairman and Members of the Committee:

I am pleased to present the President's Fiscal Year 2012 Budget Request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The FY 2012 budget is $322,106,000 which is $8,573,000 more than the FY 2011 appropriation of $313,533,000. This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences and reallocate the remaining portions of the National Center for Research Resources to other parts of NIH, including NIBIB.

The mission of NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. NIBIB invests resources in scientific and technological research opportunities at the convergence of the quantitative and life sciences, and in training the next generation of researchers. The Institute is at the forefront of translating scientific advances into engineered medical solutions. Ultimately, NIBIB seeks to realize innovations that address healthcare challenges, reduce disease mortality and morbidity, and enhance quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate basic science into new and better healthcare.

TRANSLATIONAL SCIENCE AND THERAPEUTICS DEVELOPMENT

Biodegradable Home-Based Vaccination System: Influenza is a major cause of morbidity and mortality worldwide. Despite vaccination campaigns, the CDC attributes 36,000 deaths and 226,000 hospitalizations per year in the U.S. to influenza, with an associated cost of approximately $100 billion per year. The number of cases could be greatly reduced if more people were vaccinated and if the vaccine was more effective. Researchers at the Georgia Institute of Technology are addressing both issues by developing a bio-dissolvable micro-patch that will allow people to vaccinate themselves. The patch is painless, has an application time of just seconds, has no biohazardous waste, does not require refrigeration for storage, and develops an enhanced immune response to flu. The patch combines cutting edge technology and

user-friendly simplicity to address this significant public health problem.

Noninvasive Image-Guided Therapy: Focused Ultrasound: NIBIB supports research to develop and promote innovative image-guided therapies. One of these technologies is High-Intensity Focused Ultrasound (HIFU). HIFU is a non-invasive, image-guided and controlled new therapy delivery system which consists of a highly focused beam of high-intensity ultrasound that is capable of ablating tissue in a targeted region of the body, without harming surrounding tissues. Researchers are combining magnetic resonance imaging and HIFU to form an image-guided therapy delivery system for non-invasive tumor ablation, which can either replace or complement surgery or radiation therapy. In addition, transcranial transmission of HIFU can also induce the opening of the blood-brain barrier, which allows delivery of drugs directly to specific locations in the brain. HIFU for treatment of uterine fibroids is now an FDA-approved clinical procedure. These developments could revolutionize surgery, cancer therapy and the delivery of therapeutic agents in new targeted approaches.

Regenerative Medicine for Wounded Warriors: The NIBIB is the lead NIH institute for participation in the U.S. Military's signature Armed Forces Institute for Regenerative Medicine (AFIRM), now in its third year. AFIRM is a multi-institutional, interdisciplinary network to develop advanced treatment options for our wounded servicemen and women. Researchers are addressing many severe medical conditions including burns, compartment syndrome, complex craniofacial injuries, limb/digit salvage, and wound healing.

TECHNOLOGIES TO ACCELERATE DISCOVERIES

Monitoring Tumor Cells and Cancer Biology: NIBIB Quantum Grant investigators have successfully developed a test capable of detecting a single cancer cell among the billions of normal cells in a blood sample. The microchip device, known as the HB-Chip (after the micro **h**erring**b**one pattern on the chip surface), enables the isolation of rare circulating tumor cells that may be the source of cancer metastasis. Subsequent

molecular characterizations of these cells have led to the discovery of several subtypes of prostate, breast, and lung cancer. These subtypes serve as the basis for customized cancer treatments that are tailored to specific patients. The isolation and characterization of circulating tumor cells has the potential to revolutionize the management of care in cancer patients. Recently, Johnson & Johnson announced a partnership with the researchers at Massachusetts General Hospital to further develop and market this blood test. 'Stand Up to Cancer,' an organization focused on translational cancer research, is supporting four leading cancer centers to launch clinical trials using the HB-Chip to determine the sensitivity and specificity of the device for various cancers.

Global Technologies for Disease at the Point of Care: NIBIB has partnered with the Department of Biotechnology and the Ministry of Science and Technology in India to support the development of low-cost diagnostic and therapeutic technologies that will be used in underserved communities worldwide. As the prevalence of chronic diseases in low-resource settings increases, PATH (Program for Appropriate Technology in Health, a nonprofit organization that improves the health of people around the world) is working on new initiatives to tackle diabetes. NIBIB-supported researchers are evaluating cost-effective technologies to monitor and screen for gestational and type 2 diabetes in India. These technologies are also applicable to rural and low resource settings in the U.S. and can lead to more effective interventions and therapies.

In the U.S., about 500 mothers die every year during childbirth, and in Africa, childbirth-related deaths are nearly 300,000 annually. Many of these deaths could be prevented if these populations had ready access to ultrasound exams, which identify mothers at high risk for birth complications. In addition, cardiovascular disease and abdominal illnesses could be broadly monitored and managed with wide access to ultrasound exams. NIBIB has supported the successful development by GE of a hand-held battery powered portable ultrasound system (VSCAN^{tm}) that costs approximately $8,000 but has the features of a conventional hospital or office based system costing approximately $200,000. The broad goal is to make ultrasound imaging as available as stethoscopes, to facilitate earlier detection and monitoring response to therapies.

TECHNOLOGIES TO IMPROVE EVIDENCE-BASED CLINICAL DECISIONS

Patients routinely receive their healthcare at multiple locations ranging from physician's offices to major medical centers. For optimal care, medical records and medical imaging studies must be readily available at different sites. To address the need for sharing of images and to enhance the adoption of evidence and comparative effectiveness in clinical decisions, NIBIB has funded several coordinated projects.

Patient Controlled Web-Based Access and Sharing of Medical Images: A contract with the Radiological Society of North America (RSNA) includes five academic institutions: UCSF, University of Maryland, Mayo Clinic, University of Chicago, and Mount Sinai. Two additional grants provide support to Wake Forest University and the University of Alabama at Birmingham. Each of these projects is developing an approach to patient-controlled medical image sharing systems for secured image sharing among radiologists and clinicians across organizational boundaries. The project at Wake Forest University has a special focus on image sharing in rural and under - served areas. Validation testing of patient health records that can accept images with the appropriate controls and privacy safeguards has begun and will start enrolling patients in the near future.

On Line Decision Support Systems: NIBIB is providing resources to the Brigham and Women's Hospital and the Massachusetts General Hospital to implement information technology systems that include clinical decision support capability. These systems enable the care providers to make clinical decisions that are based on the best available evidence and the patient's comprehensive medical data set, including clinical images.

NEW INVESTIGATORS, NEW IDEAS

Nanoparticles for Improved Drug Delivery: Overcoming the Mucus Barrier: The delivery of bioactive molecules to target tissues can significantly improve drug effectiveness while reducing side effects by concentrating medicine at selected sites in

the body. While the barrier properties of mucus provide protection against infection and other potentially toxic particles, they also have thwarted efforts to achieve uniform and sustained drug delivery to mucosal surfaces, and have likely prevented successful delivery of genes that could potentially treat fatal diseases, such as cystic fibrosis. The work of NIBIB grantee Dr. Justin Hanes at Johns Hopkins University seeks to understand the properties of mucosal barriers and use this knowledge to guide the development of polymeric nanoparticulate carriers capable of more efficient drug and gene delivery to the respiratory tract, female reproductive tract, gastrointestinal tract, surface of the eye, and other mucosal tissues for improved therapies. The delivery of bioactive molecules to target tissues can significantly improve drug effectiveness while reducing side effects by concentrating medicine at selected sites in the body.

Robotic Prostheses for Amputees: Despite significant technological advances over the past decade, state-of-the-art transfemoral prostheses are unable to provide power for joint motion. The absence of joint power significantly impairs the ability of these prostheses to restore many locomotive functions, including walking upstairs and up slopes, running, and jumping, all of which require significant net positive power at the knee joint, ankle joint, or both. Dr. Michael Goldfarb, an NIBIB Edward C. Nagy Young Investigator, recently reported the development of the first robotic transfemoral prosthesis with fully powered knee and ankle joints. The device allows above-the-knee amputees to walk 25% faster with less energy than is expended with conventional prosthetics and provides increased balance, agility, and recovery reflexes to prevent falls. In April, Freedom Innovations announced a worldwide licensing agreement for exclusive rights to commercialize this device.

The Institute's emphasis on interdisciplinary approaches to biomedical research has provided unprecedented opportunities for collaborations among the life and physical scientists leading to advances in biology and medicine through the quantitative, physical sciences, and engineering perspective, as well as the development of technologies that reflect the translation of biological mechanisms. These advances will produce remarkable improvements in the health of individuals around the world.

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

Roderic I. Pettigrew, Ph.D., M.D., is the first Director of the National Institute of Biomedical Imaging and Bioengineering. 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 cardiovascular system 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. He has been elected to membership in, both the Institute of Medicine, and the National Academy of Engineering of the National Academies, fellowship in the American Heart Association, American College of Cardiology,

American Institute for Medical and Biological Engineering, International Society for Magnetic Resonance in Medicine, and Honorary Fellow of the Biomedical Engineering Society.