DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Budget Request for FY 2010

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

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Mr. Chairman and Members of the Committee:

I am pleased to present the President's Fiscal Year 2010 Budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The FY 2010 budget includes $312,687,000, which is $4,479,000 more than the FY 2009 appropriation of $308,208,000.

The NIBIB is leading the development of revolutionary technologies that will help transform medicine in the U.S. and around the world. It has primary responsibility for uniting the engineering and physical sciences with the life sciences to bring about new ways of thinking that will accelerate discovery and technology development. With a global vision and a public health mission, the Institute is working to develop technologies that enable personalized health care, early detection of disease, and treatments that are minimally-invasive, cost-effective and widely accessible.

TRANSLATING TECHNOLOGY INTO PRACTICE

Ultimately, NIBIB seeks to expand the translation of technological advances into solutions that improve human health by reducing disease and enhancing quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate discovery to clinical practice. NIBIB-supported scientists in the innovative Quantum Grants Program are making extraordinary progress to develop new technologies and modalities for the diagnosis, treatment, or prevention of disease that will result in practical healthcare benefits for the nation.

Changing Health Care Delivery through Point-of-Care Technologies

Testing at the point of initial contact, or "point-of-care," rather than at specialized centers or hospitals utilizes state-of-the-art diagnostics and information systems that can be used in the doctor's office or even at home. Consequently, the use of POC devices can also help patients monitor their wellness in preventive medicine. The POC approach to health care delivery can significantly improve the quality and reduce the

cost of health care by: providing earlier diagnosis of disease when treatment is more effective and less costly; making modern medicine available to those who lack access to regular care, such as people in rural settings or developing countries; combining cutting-edge diagnostic and communication technologies to bring patients into more frequent and regular contact with health care providers; and enabling a patient-centered process with home-based monitoring.

The NIBIB currently funds a network of four Point-of-Care Technologies Research Centers that target the development of new POC technologies for early and rapid detection of strokes, detection of sexually-transmitted diseases, rapid multi-pathogen detection for national disaster readiness, and diagnosis of infections that can be used in low-resource settings among under-served populations. Additionally, The NIBIB and the Department of Biotechnology (DBT) of the Ministry of Science and Technology of the Republic of India held a joint workshop on Low-Cost Diagnostic and Therapeutic Medical Technologies in November 2008 in Hyderabad, India. The workshop was a result of a bilateral agreement between the NIBIB and DBT to develop low-cost technologies to improve the quality of health care for underserved populations. Point-of-care testing is becoming a vital part of the world's health care delivery system, and is a key to reducing health care costs while maximizing accessibility for everyone.

Health Information Technology

Health information technology research that enables the integration of clinical data, medical image diagnostic and treatment data with the patient's medical history in a comprehensive electronic medical record will improve clinical decision-making. The ability to connect and exchange diagnostic information and medical images between health care providers, clinics, and hospitals will help provide the timely information that is needed for effective health care and will help reduce unnecessary, excessive, and duplicative procedures. A patient-centered approach to comprehensive electronic health records will allow patients access to their health information. This will enable patients to play an active role in their own wellness by enabling them to ask knowledgeable questions about treatment options. Additionally, patients are also empowered to provide

this information to any and all health care providers as needed, independent of their location or where the medical data was created or stored. The NIBIB supports research in new technologies to address issues such as: interoperability of data systems, compatibility of computer software across medical institutions; security of data during transmission; HIPPA compliance; and availability of affordable data systems for patient care providers.

Microchip Captures Early Circulating Cancer Cells

NBIB's budget request and its research projects are consistent with the President's multi-year commitment for Cancer. Malignant cancers shed cells that enter the circulation, travel to other areas of the body, and often grow into secondary tumors, or metastases. Indeed, metastases are responsible for the great majority of cancer deaths. It is estimated that 70,000 men per year are diagnosed with recurrent prostate cancer after prostatectomy, as shown by rising prostate surface antigens. For these men, the ability to detect and characterize the malignant cells in the blood may enable personalized therapy. Researchers are developing a technology to facilitate quantitative detection of circulating tumor cells (CTCs). They have engineered a microchip with a large surface area of an adhesion molecule that binds CTCs from whole blood, making detection of CTCs more reliable than previous approaches. They are analyzing molecular and genomic information in the CTC's to identify new biomarkers to customize treatments that are personalized for the patients and to predict treatment outcomes. The NIBIB-supported research has the potential to eliminate or greatly reduce cancer deaths due to metastases.

Regenerating Brain Tissue to Promote Stroke Recovery

Brain cells can be irreversibly damaged in a matter of minutes when the blood supply carrying oxygen and glucose is interrupted in a stroke. Individuals who have had a stroke may experience partial paralysis or problems with awareness, attention, learning, judgment, memory, or speech. An international team of researchers from Baylor College of Medicine, Rice University, London's National Institute of Medical Research, King's College of London, and Edinburgh University is integrating cutting-

edge imaging, biological, and engineering techniques to map and understand normal brain regions that are responsible for generation of new neurons in the adult. The ultimate goal is to bioengineer a cellular system mimicking these brain regions that can eventually be used to replace and/or drive repair of stroke-damaged tissue.

Miniature Artificial Kidney Replaces Traditional Dialysis

Nearly half a million people in the U.S. suffer from end-stage renal disease (ESRD), and the incidence rate of this disease has been steadily increasing for over 25 years. Kidney transplantation provides the best option for ESRD patients, but a shortage of donors means that most patients never make it to the top of a waiting list. The alternative is dialysis, which is expensive, inconvenient, far less effective, and significantly lowers the patient's quality of life. An interdisciplinary group of researchers has envisioned a way to improve management of ESRD by developing an implantable, self-regulating, bioartificial kidney capable of filtering toxins from the blood as well as replacing some of the metabolic functions of a healthy kidney. Such an implantable bioartificial kidney could substitute for transplantation and will truly be a quantum leap in healthcare, giving hope, independence, and mobility to the 350,000 patients presently tethered to thrice-weekly in-center dialysis.

Insulin-Producing Cells from Amniotic Fluid Stem Cells Treat Diabetes

More than one million people in the U.S. suffer from type 1 diabetes, which is caused by the destruction of insulin-producing pancreatic islet cells. Currently available insulin therapy by itself does not cure the disease or prevent many of its long-term complications. Transplantation of islet cells has shown promise, but there is a shortage of donors, and the process is expensive, inefficient, and requires life-long immunosuppression. Researchers from Wake Forest University and the University of Miami have combined their expertise in stem cell differentiation and *in vivo* islet cell transplant studies to explore a new approach using amniotic fluid stem cells. The team has successfully isolated amniotic fluid stem cells and generated insulin-producing, islet-like cells *in vitro.* Future work will determine whether these cells are able to function and survive in animal models of diabetes. If successful, this approach could

potentially provide a curative treatment for type 1 diabetes through transplantation using cells produced from amniotic stem cells.

Molecular Theranostics: New Technologies for the Diagnosis and Treatment of Diseases

The concept of combining a therapeutic with a diagnostic agent is rapidly evolving and goes beyond traditional diagnostic tests that screen or confirm the presence of a disease. With specialized molecular imaging techniques and biomarkers, theranostics might predict risks of disease, diagnose disease, and monitor therapeutic response leading to real-time, cost-effective treatment. NIBIB supports a number of teams that are developing novel theranostics and approaches that can be applied in clinical studies of human patients. A team of chemists and neurosurgeons at the University of Michigan is developing highly specific, dye-loaded nanoparticles capable of delivering targeted photosensitizers to improve the survival of brain tumor patients. This technique will allow neurosurgeons to visualize the brain tumors for surgical resection of the main tumor mass while eradicating remaining tumor cells through a process known as photodynamic therapy. These particles also contain imaging contrasting agents to visualize response to therapy.

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 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. He has been elected to membership in the Institute of Medicine and 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 the Biomedical Engineering Society.