DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2009 Budget Request

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

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National Institute of Biomedical Imaging and Bioengineering

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Richard J. Turman, Deputy Assistant Secretary, Budget

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) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2009 budget of $300,254,000 includes an increase of $1,609,000 over the FY 2008 appropriated level of $298,645,000.

The NIBIB is leading the development of revolutionary technologies that will change the face of medicine in the U.S. and around the world. The Institute is partnering with industry, academia, and other Federal agencies to provide innovative and safe biomedical technologies to improve public health and reduce suffering due to injury and illness. The NIBIB has the 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 rapidly facilitate discoveries and translate them to clinical practice. NIBIB recently launched the Quantum Grants Program, which supports high impact, high risk, interdisciplinary and transformative research focused on major biomedical problems. This innovative program promises to harness the power of technological discovery and team science to translate new knowledge into practical healthcare benefits for the nation. The overall goal of the program is to make a profound advance in healthcare by supporting research on targeted projects that will develop new technologies and modalities for the diagnosis, treatment, or prevention of disease in a relatively short period of time.

Nanotechnology to Detect Single Cancer Cells and Prevent Metastases

Malignancies of the brain are among the most lethal forms of cancer, and are diagnosed in over 43,000 new patients each year. Typical treatment involves surgical removal of tumors; however, this process is impeded by the difficulties involved in identifying tumor margins. For these same reasons, conventional follow-up treatment using chemotherapy and radiation often has limited success. To address these problems, NIBIB-funded investigators are developing nanoparticles that will selectively bind to tumor cells in the brain. These particles will aid in the visualization of tumors to allow for maximum removal of the tumor mass and also facilitate nonsurgical destruction of the residual cancer cells that are remote or extend out from the tumor mass. This technological advance is expected to lead to significant improvement in the treatment of brain tumors and improved quality of life for patients.

Metastatic disease is ultimately responsible for the majority of cancer-related deaths. Consequently, this is one of the most important biological problems to address in the area of cancer research. NIBIB Quantum Grant recipients are developing a point-of-care disposable microchip device that can determine the type, severity, and aggressiveness of a wide range of cancers by detecting tumor cells that are circulating in the blood stream. This microchip will be capable of separating specific circulating tumor cells from whole human blood at concentrations as low as one in a billion. Detecting the presence of tumor cells at such low concentrations enables earlier intervention in the treatment of metastatic lung cancer, which remains the leading cause of cancer death in the U.S. This point-of-care test can potentially transform patient care through early molecular diagnosis of lung cancer and identification of new biomarkers with which to track disease progression.

Quantum Project to Develop a Curative Therapy for Diabetes: Insulin Producing Cells

Diabetes is a growing problem worldwide. According to the American Diabetes Association, it affects over 20 million people in the U.S. and results in annual health care costs exceeding $116 billion. Current means of diabetes management, including administration of insulin, do not always prevent serious long-term complications of the disease such as nerve damage, vascular disease, retinopathy, and renal failure. Transplantation of pancreatic islets to restore insulin production offers significant promise by removing the need for daily personal management of diabetes. However, the supply of donor pancreata falls far short of meeting medical needs. New sources of insulin-producing cells will be required to realize the full potential of replacement cell therapy for diabetes. NIBIB-funded investigators are working to generate insulin-producing pancreatic cells from stem cells that have been isolated from amniotic fluid. Successful development of an abundant source of transplantable insulin-producing cells would have a profound impact on the treatment of this major public health problem.

Point-of-Care Technologies to Revolutionize Healthcare in the 21st Century

A significant challenge for the future of healthcare is making predictive, preemptive, preventive and personalized care accessible to everyone. These goals require the ability to provide diagnostic testing and therapy at the point-of-care. The development of low-cost technologies that can easily and reliably be used by a variety of healthcare providers or by patients themselves is needed. The NIBIB is supporting a Point-of-Care Technologies Research Network to drive the development of appropriate diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical needs. The research network will address pressing needs in point-of-care testing, such as diagnosis of infectious disease for global health, detection of pathogens for disaster response and critical care, diagnosis of acute neurological emergencies, and diagnosis of sexually transmitted diseases. The network will also develop reliable diagnostic tests that can be used by untrained patients in a home care or other primary care setting.

Computed Tomography (CT) Imaging for Earlier Breast Cancer Detection

Breast cancer screening primarily consists of mammography for early detection. NIBIB-funded investigators have teamed with scientists from around the country to design, build, and test a working CT scanner to image the human breast. Initial clinical experience with the scanner prototype shows that overall breast CT performance is similar to that of screen-film mammography with comparable radiation doses. Women also found breast CT to be significantly more comfortable than screen-film mammography, primarily because breast CT does not require compression. Breast CT offers the advantage of 3D anatomic detail. As a result, fewer women would be recalled for evaluation of potential abnormalities that are artifacts imposed by the imaging. Breast CT may also offer an alternative to MR imaging for screening high-risk women for breast cancer and for determining the local extent of disease in newly diagnosed breast cancers. Further refinements in this technology are expected to improve detection and treatment of breast cancer. In the future, the breast CT scanner may provide an ideal imaging platform for the development of robotic breast biopsies and tumor ablation devices. Automated positioning techniques may make the biopsy procedure potentially more accurate, as well as faster and easier to perform, than it is with stereotactic or ultrasound guidance.

Magnetic Resonance Imaging Elastography Delineates Benign and Cancerous Lesions

Research has shown that malignant tumors are often characterized by substantially different mechanical properties than surrounding normal tissue. This accounts for the usefulness of palpitation to detect cancer in accessible regions of the body. In fact, most tumors of the thyroid, breast, and prostate are first detected by this diagnostic technique. However, small or inaccessible lesions cannot be detected by touch, and conventional diagnostic imaging methods such as ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI) do not provide information about the nature of a mass. NIBIB-funded investigators have extended MRI to quantitatively measure the stiffness of small masses deep within the body using acoustic waves. This technology, MRI elastography, will enable radiologists to distinguish between benign and cancerous lesions based on differences in the degree of stiffness. This has been proven to be especially useful to detect both benign and cancerous lesions in the liver.

Image-Guided Minimally-Invasive Robotic Assisted Therapies

Image-guided interventions (IGI) have the potential to replace more invasive treatments that are commonly used today. IGI techniques are faster, safer and less invasive than traditional surgical procedures, and recovery time is significantly shorter. An IGI is often more precisely targeted. For example, image-guided neurosurgery may decrease the risk of damage to normal nearby brain tissue. For biopsies, IGI can enable better targeting of smaller masses. IGI may also involve robotic manipulators that can operate in small and difficult-to-reach spaces, such as the inner ear, within the cambers of the heart or on a fetus *in utero*. In addition, IGI can be done remotely, bringing clinical expertise to underserved communities and remote locales. These improved capabilities are particularly important in light of the shifting trend in medicine towards early, pre-symptomatic detection of disease. NIBIB-funded investigators are developing MRI-guided, robotic-assisted therapeutic and diagnostic procedures for the treatment of prostate cancer. Also, better visualization techniques are being developed to minimize the time required for catheter-based treatment of abnormal heart rhythms.

Help for Aging Joints

Millions of people suffer from joint pain caused by damaged cartilage due to sports injuries or arthritis. In arthritis, joint cartilage is permanently destroyed, making even simple movements very painful. Total joint replacement is a major advancement in treatment of degenerative arthritis that has restored function to millions of individuals. A potentially less invasive alternative to total joint replacement is cartilage repair. Attempts to regenerate cartilage have had good success in the laboratory but this engineered cartilage does not integrate well with the host cartilage when implanted into a damaged joint. Researchers have developed a chondroitin sulfate (CS)-based biomaterial that can be applied to and integrate with a hydrogel layer containing cartilage cells. Using sophisticated imaging technologies, investigators have verified that the CS adhesive attached to and integrated with the native cartilage. The cells in the hydrogel grew and secreted cartilage components, forming new tissue that bound the hydrogel with the old cartilage remaining in the damaged joint. This technology is expected to improve the outcome of orthopedic and other surgical interventions, including repairing disks in the back.

Biographical Sketch

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.

Department of Health and Human Services
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