DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2016 Budget Request

Statement for the Record

Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

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

Director, National Institute of Biomedical Imaging and Bioengineering

Mr. Chairman and Members of the Committee:

I am pleased to present the President's Fiscal Year (FY) 2016 budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The FY 2016 NIBIB budget of $337,314,000 includes an increase of s $10,071,000 over the comparable FY 2015 level of $327,243,000.

NIBIB is dedicated to improving health through better understanding, prevention, detection, and treatment of disease. We conduct and support emerging technology research and development that leads to innovative biomedical solutions. Integrating engineering and physical sciences with life sciences by building partnerships with industry, academia, and other federal agencies is a high priority for the institute. In this testimony I share a few examples from the many exciting NIBIB-funded research efforts that are leading to better, faster, and less costly ways to improve the public health.

REVERSING PARALYSIS THROUGH SPINAL STIMULATION TECHNOLOGIES

Spinal cord injury can be devastating and affect almost anyone, from victims of auto accidents, to athletes, to soldiers on the battlefield. According to the Spinal Cord Injury Statistical Center, an estimated 276,000 people were living with a spinal cord injury in 2014. Each year approximately 12,500 new cases occur.

Once thought of as an injury with no hope of recovery, a novel therapy that involves electrical stimulation of the spinal cord has restored function to an unprecedented degree in the 6 patients treated to date. Following treatment, severely paralyzed patients recovered everyday bodily functions, including bowel, bladder and

sexual function. The return of these important basic functions has dramatically improved the quality of life of all who were treated. These patients also regained the ability to voluntarily stand and achieve limited limb movement, providing hope that further recovery may be possible with improvements to this treatment approach.

Although this research is still in its infancy, it has given real hope to people living with paralysis around the world. They have seen the positive impact in the small group of study participants and are eager to have such technologic advances transform their lives as well.

NEXT GENERATION CELL ENGINEERING

Our immune systems are highly proficient at attacking and destroying anything viewed as foreign when it enters the body. Yet cancer cells are largely ignored by the immune system because they are derived from our own cells and retain some of the same characteristics. A relatively new approach uses cell engineering to reprogram the immune system to identify cancer cells and destroy them. In a recent advance, researchers have developed a vaccine made of nanoscale biomaterials that is injected under the skin. Once injected, the nanomaterials form a 3D scaffold, creating a relatively large surface area for the immune system to assemble "killer" cells specifically programmed to attack tumors. The power of this approach was demonstrated in a mouse model, in which the 3D vaccine generated a potent immune response to lymphoma cells and inhibited tumor growth. While this study tested the feasibility of a single cancer vaccine, the same scaffold could also hold different antigens or drugs to treat a range of cancers or infectious diseases. This research promises a new class of therapeutic agents which harness and enhance the power of our natural defense mechanisms against disease.

ADVANCING PRECISION MEDICINE: EARLY DETECTION OF CANCER CELLS AT THE POINT-OF-CARE

Many therapies today work well for some people, but not for others. Matching a treatment to the unique features of an individual's disease is the goal of the President's Precision Medicine Initiative. NIBIB is supporting research in technology development to realize the vision of customized treatment. For example, researchers have developed a miniature palm-sized device to isolate rare circulating tumor cells from a small routine blood sample. Tested in a clinical study, this novel device was able to isolate breast cancer cells from the blood of 36 women. Physicians were then able to characterize the genetic and molecular features of the tumor cells in each case and select the most effective treatment for each person. This small, initial study successfully demonstrated the potential to identify a range of genetic changes, or mutations, in an individual's cancer cells, enabling a personalized therapy for each patient.

MOBILE TECHNOLOGY TO ADVANCE HEALTHCARE

Depending on a variety of factors, such as environmental exposure and lifestyle practices, individuals with the same genetic makeup can have very different health outcomes. The use of mobile technology can greatly assist researchers in gaining a better understanding of the environmental and behavioral factors that cause disease with the goal of preventing or intervening in the process. Today, a smartphone is a natural point of engagement for the large percentage of U.S. adults who own one. Interfacing smartphones with a variety of biosensors allows the linkage of an individual's electronic medical records and genomic data with information captured by the smartphone on environmental exposure and behavior. From measuring secondary smoke exposure to

counting steps, or testing vision, smartphones can record, track, and transmit a significant amount of health information. Smartphones can also be used as a tool for healthier living. They can be programmed to send automatic reminders to take a medication or an alert when a dose is missed. The overarching potential application relevant to the Precision Medicine initiative is to enrich the genomics and electronic health record data with a broad range of medical exposure and lifestyle information. This set of "big data" can then be evaluated or "mined" to identify new ways to improve human health.

BRAIN INITIATIVE

Approximately 100 billion neurons and 100 trillion connections make up the human brain and there is an enormous amount to explore and discover in this, the most complex of all human organs. As an institute that is very active in the BRAIN Initiative, NIBIB supports research that leads to the next generation of neuroscience discovery tools and technologies. These technologies are being developed to advance our understanding of the function of neural circuits and systems in health and disease. In one example, researchers are developing a completely new noninvasive method for portable 3D human brain visualization called Magnetic Particle Imaging. Based on intrinsic bioelectric properties and the use of injectable magnetic nanoparticles, this project could provide higher imaging clarity and a completely new way to characterize and understand changes in brain circuit function in mental and neurological disease.

These select highlights demonstrate how NIBIB is advancing technology to transform health care for all Americans.

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

Director, National Institute of Biomedical Imaging and Bioengineering

Roderic I. Pettigrew, Ph.D., M.D., is the first Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the NIH. In early 2013, Dr. Pettigrew was also appointed to initiate a new NIH position as the Acting Chief Officer for Scientific Workforce Diversity. This position, which he held until a permanent Chief Officer was recruited, was established by the NIH Director for the coordination and oversight of all NIH programs and activities designed to address the unique diversity and inclusion challenges of the biomedical research workforce.

Prior to his appointment at the NIH, Dr. Pettigrew 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. He is known internationally for his pioneering work at Emory University involving four-dimensional imaging of the cardiovascular system using magnetic resonance (MRI). His current research focuses on integrated imaging and predictive biomechanical modeling of coronary atherosclerotic disease.

Early on at the NIBIB he jointly led a national effort with Howard Hughes Medical Institute to create new interdisciplinary graduate training programs, and also established the Quantum Projects program to achieve “medical moon shots” by pursuing high-risk, high-impact projects designed to solve major healthcare problems. Under Dr. Pettigrew’s leadership, national collaborative and international initiatives have been issued to develop low cost and point-of-care medical technologies and at present, he

leads an effort to reduce CT radiation dose to background levels. He has also recently called for a US-India collaboration to develop unobtrusive technologies for frequent recording of blood pressure to address the world wide problem of hypertension.

Dr. Pettigrew has been elected to membership in two components of the US National Academies: the Institute of Medicine and the National Academy of Engineering. His awards include Phi Beta Kappa, the Bennie Award, Most Distinguished Alumnus of the University of Miami (1990), Herbert Nickens Award of the ABC, Pritzker Distinguished Achievement Award of the Biomedical Engineering Society, Distinguished Service Award of the National Medical Association, the Pierre Galletti Award of the American Institute of Medical and Biological Engineering, and the Inaugural Gold Medal Award of the Academy of Radiology Research.