

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH

Continuing America's Leadership: The Future of Medical Innovation for Patients

Witness appearing before the  
Senate Health, Education, Labor, and Pensions Committee

Roderic I. Pettigrew, Ph.D., M.D.  
Director, National Institute of Biomedical Imaging and Bioengineering

April 28, 2015

Mr. Chairman and Members of the Committee:

I am pleased to present this testimony to you for the hearing on Biomedical Innovation. I am Roderic I. Pettigrew, Ph.D., M.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB). We are one of 27 Institutes and Centers at the National Institutes of Health. NIBIB is a relatively new IC. It was created in December 2000 and we awarded our first grants in 2002. NIBIB supports more than 800 grants and the work of more than 5,000 researchers, and an Intramural Research Program at NIH. At NIBIB we focus on creating biomedical technologies to improve health.

Our mission is to lead the development and accelerate the application of biomedical technologies to improve health. We are advancing medical care through better understanding, prevention, detection, and treatment of disease. We conduct and support emerging technology research and development that lead 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, which are leading to practical innovations that advance 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. An estimated 276,000 people were living with a spinal cord injury in 2014. Each year approximately 12,500 new cases occur<sup>1</sup>.

---

<sup>1</sup> *Spinal Cord Injury Facts and Figures at a Glance*. February 2015. The National SCI Statistical Center, The University of Alabama at Birmingham.

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 7 patients treated to date. This is a first-of-its-kind experimental study funded by NIBIB. 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 and not yet at the clinical trial stage, 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 tested through a grant funded by NIBIB, 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 proof-of-concept study, this novel device was able to isolate breast cancer cells from the blood of 36 women. Physicians were then able to grow the tumor cells from 6 of the blood samples in the laboratory to characterize their genetic and molecular features and test sensitivities to drugs. A subset of these human cells were able to also grow tumors in mice where the effectiveness of the selected drugs in inhibiting tumor growth was demonstrated. In this initial study, treatments were not given to patients; however this approach successfully demonstrated the potential to identify a range of genetic changes, or mutations, in an individual's cancer cells to enable personalize therapy.

### **MOBILE TECHNOLOGY TO ADVANCE HEALTHCARE**

Depending on a variety of factors, such as environmental exposure and lifestyle, individuals with the same genetic makeup can have very different health outcomes. The use of mobile technology has the potential to 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, smartphones are natural points of engagement for the large percentage of U.S. adults who own them. Interfacing smartphones with a variety of biosensors may allow the linkage of an individual's electronic medical records and genomic data with information captured by the smartphone on environmental exposure and behavior if it were done with appropriate security and privacy protections. 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 link and 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, which has been a priority for the President, as outlined in his FY 2016 Budget proposal for an additional \$70 million, 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.

### **CONCLUSION**

NIBIB drives technological innovation to expand biomedical knowledge and create improved diagnostics and therapeutics for this and future generations. By integrating engineering with the physical and life sciences, NIBIB develops practical solutions to complex biomedical problems. These advances are improving human health across our Nation and worldwide.