DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

NATIONAL ADVISORY COUNCIL FOR BIOMEDICAL IMAGING AND BIOENGINEERING Summary of Meeting¹ January 25, 2013

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 31st meeting on January 25, 2013, via Adobe Connect, in Bethesda, Maryland. Dr. Roderic I. Pettigrew, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), presided as Council chairperson. In accordance with Public Law 92-463, the meeting was open to the public from 11:00 a.m. to 11:45 a.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 11:55 a.m. to 12:05 p.m. for the consideration of grant applications.

Council members present:

Dr. John C. Gore, Vanderbilt University, Nashville, TN

Dr. Nola M. Hylton, University of California, San Francisco, CA

Dr. Cato T. Laurencin, University of Connecticut, Farmington, CT

Dr. Mark Musen, Stanford University, Stanford, CA

Dr. Etta D. Pisano, Medical University of South Carolina, Charleston, SC

Dr. Buddy Ratner, University of Washington, Seattle, WA

Dr. Bruce Tromberg, University of California, Irvine, CA

Dr. Sheldon Weinbaum, The City College of New York, New York, NY

Dr. Michael Yaszemski, Mayo Clinic College of Medicine, Rochester, MN

Ex officio members present:

Dr. P. Hunter Peckham, U.S. Department of Veterans Affairs, Cleveland, OH Dr. Sohi Rastegar, National Science Foundation, Arlington, VA Dr. James G. Smirniotopoulos, Uniformed Services University of the Health Sciences, Bethesda, MD

Council members absent:

Dr. W. Eric L. Grimson, Massachusetts Institute of Technology, Cambridge, MA Dr. Hedvig Hricak, Memorial Sloan Kettering Cancer Center, New York, NY

Ex officio members absent:

Dr. Francis Collins, National Institutes of Health, Bethesda, MD Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD Ms. Kathleen Sebelius, U.S. Department of Health and Human Services, Washington, DC

Chairperson: Dr. Roderic I. Pettigrew

Executive Secretary: Dr. Anthony Demsey

¹ For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a conflict of interest may occur. This procedure only applies to applications that are discussed individually, not to "en bloc" actions.

Also present: NIBIB staff present for portions of the meeting: Mr. Angelos Bacas Dr. Richard A. Baird Ms. Sheila Barrett Ms. Barbara Cantilena Dr. Richard Conroy Ms. Zoe Ann Copeland Ms. Christine Cooper Ms. Nancy Curling Ms. Marilyn Daly Dr. Emilio Dimitriadis Mr. Jeff Domanski Ms. Kate Egan Ms. Angela Eldridge Dr. Zeynep Erim Ms. Carol Fitzpatrick Dr. Yan Fu Dr. David George Ms. Pam Glikman Dr. Ruth Grossman Dr. John Hayes Ms. Eunica Haynes Dr. William Heetderks Mr. James Huff Dr. Rosemarie Hunziker Mr. Tom Izzard Dr. Albert Jin Dr. Thomas Johnson Dr. Chris Kelley Ms. Margot Kern Dr. Brenda Korte Dr. Steven Krosnick

Ms. Kai Lakeman Dr. Richard Leapman Ms. Karin Lee Dr. Christina Liu Dr. Guoying Liu Dr. Hector Lopez Dr. Shadi Mamaghani Dr. Alan McLaughlin Ms. Jessica Meade Mr. Todd Merchak Mr. Joe Mosimann Dr. Peter Moy Dr. Vinay Pai Dr. Grace Peng Dr. Karen Peterson Mr. Jose Pinto Mr. Keith Pirnia Mr. Mohammed Rahamatullah Ms. Vicki Rein Ms. Stephanie Sabourin Dr. Antonio Sastre Dr. Belinda P. Seto Mr. Shaun Sims Dr. Manana Sukhareva Ms. Florence Turska Ms. Rachel Vizzi Mr. Kwesi Wright Ms. Li-Yin Xi Dr. Ruixia Zhou Dr. Steven Zullo

Non-NIBIB National Institutes of Health (NIH) employees: None

Non-NIH Federal employees:

None

Members of the public present for portions of the meeting:

Mr. Michael Kalutkiewicz, Academy of Radiology Research Ms. Naomi Webber, Lewis Burke Associates, LLC

I. Call to Order: Dr. Anthony Demsey

Dr. Anthony Demsey called to order the 31st meeting of the National Advisory Council for Biomedical Imaging and Bioengineering. He reminded attendees that the morning session of the meeting was open to the public, welcomed attendees, and introduced Dr. Roderic Pettigrew, who formally welcomed all participants.

II. Director's Remarks: Dr. Roderic I. Pettigrew

Dr. Pettigrew began his remarks acknowledging that the NACBIB meeting was being held online for the first time.

A. Awards

Dr. Robert Langer, the David H. Koch Institute Professor at the Massachusetts Institute of Technology (MIT), was awarded a National Medal of Technology and Innovation, one of the nation's highest honors. In addition to numerous other awards, Dr. Langer has received research funding from NIBIB for over a decade, including a Merit Award.

Drs. Norbert Pelc and Gordana Vunjak-Novakovic were inducted into the National Academy of Engineering for their work in imaging algorithms and technologies and tissue engineering, respectively. Dr. Pelc was also one of the first members of NACBIB.

Four of the 300 high school semifinalists of the 2013 Intel Science Talent Search conducted research and were mentored within the NIBIB Intramural Research Program.

B. Departing Staff

Dr. Alan McLaughlin, currently the director of the NIBIB Division of Applied Science and Technology, will be retiring at the end of January, following 26 years of Federal service at NIH. Dr. McLaughlin's distinguished career in biophysics and biochemistry includes post-doctoral training at Oxford University and appointments at Ivy League institutions.

C. Budget and Legislation

NIH continues to operate under a continuing resolution (CR) through March 27, 2013.

On January 1, 2013, the American Taxpayer Relief Act was passed, which averted the immediate sequestration threat of an 8.2 percent cut in NIH spending for fiscal year (FY) 2013. Without further legislation, the President will order a new sequester on March 1, 2013, which would be implemented on March 27, 2013. Provisions in the Act would result in a potential reduction in FY 2013 NIH spending of less than 8.2 percent, but the final amount is still undetermined.

The Federal debt limit was reached on December 31, 2012. Legislation passed on January 23, 2013, suspended enforcement of the debt limit until May 18, 2013. Negotiations to address the consequences of the debt limit on NIH spending are ongoing.

At the current time, NIH will not further reduce spending in anticipation of sequestration. NIH will continue to fund non-competing grants in FY 2013 at 90 percent of the approved funding level, as has been done in prior years under a continuing resolution.

D. NIH Activities

New Senior Scientific Positions Established in NIH's Office of the Director

Following on recommendations from three reports from the Advisory Committee to the Director, NIH Director Dr. Francis Collins established two new positions to address issues in scientific workforce diversity and big data.

The Chief Officer for Scientific Workforce Diversity will take charge of NIH's efforts to enhance diversity among the biomedical research community, and the Associate Director for Data Science will lead a series of NIH-wide initiatives to capitalize on the rapid growth of biomedical research data. Dr. Roderic Pettigrew of NIBIB and Dr. Eric Green of the National Human Genome Research Institute (NHGRI) have accepted acting roles of these respective positions during recruitment efforts.

Examples of key initiatives for increasing diversity in the research workforce that will be undertaken include a program to support building infrastructure, particularly in under-resourced institutions; a network of established researchers who can serve as mentors for individuals taking part in the aforementioned program; and pilot studies conducted by the NIH Center for Scientific Review to identify potential bias within the peer review system. In the area of big data, initiatives are being pursued that will update and improve the

information technology infrastructure at NIH, as well as enhance the advancement of knowledge and impact on health afforded by the growth in research data.

NIBIB Training: Expanding Diversity in Engineering and Physical Sciences Contract

In FY 2013, the National Institute on Drug Abuse (NIDA) is co-funding NIBIB's training contract to increase diversity within the STEM pipeline. The additional support will double the size of the current cohort, now providing support of 40 of the70 Meyerhoff Scholars at the University of Maryland Baltimore County; another cohort at Savannah State University will also continue to receive funding. This contract aims to evaluate the success of the Meyerhoff Scholars program to develop a template that may be exported to other universities.

E. Science Highlights

Bioengineering Breakthrough Selectively Suppresses Autoimmune Multiple Sclerosis

As reported in Nature Biotechnology in November 2012, Drs. Stephen Miller and Lonnie Shea at Northwestern University, Evanston, Illinois, teamed up with researchers at the University of Sydney, and the Myelin Repair Foundation in Saratoga, California, and have engineered microscopic, biodegradable particles capable of delivering a specific antigen to shut down the body's natural immune response, which goes awry in autoimmune disorders such as multiple sclerosis.

Dr. Rosemarie Hunziker of NIBIB's Division of Discovery Science and Technology elaborated on the pathways by which microparticles "re-tolerize" activated immune cells, thereby shutting down maladaptive immune reactions, and the increased feasibility and exportability of microparticle preparations, as compared to traditional cell preparations. This work represents the first demonstration of selective control of the immune response using a synthetically prepared antigen and may be widely applicable to other autoimmune phenomena.

Non-invasive Coronary & Microvascular Thrombolysis Using Ultrasound

Drs. Feng Xie and Thomas Porter, and colleagues at the University of Nebraska Medical Center, recently described the use of conventional 3D ultrasound with microbubbles and a thrombolytic agent as a safe, non-invasive alternative to clot-busting medications alone, which have been associated with serious risks, particularly in children.

This work builds on previous studies suggesting that ultrasound can enhance the permeation of thrombolytic agents. The addition of microbubbles takes advantage of the mechanical index that ultrasound imaging devices are required to display, allowing the use of ultrasound to deliver a strong mechanical force to selectively destroy tissue. Using a pig model, the researchers showed that the combination therapy not only restored blood flow in blocked arteries around the heart but also achieved improved flow among the surrounding microvasculature, which often requires additional surgery following traditional angioplasty. Dr. Porter was also involved with a related clinical trial of 10 patients in the Netherlands, which further demonstrated that the combination therapy can be safely and easily delivered to adults within an acute cardiac care setting.

While further pilot testing is needed, this advance provides the promise of a completely non-invasive method of treating a serious and prevalent disease that is currently preferentially treated with the minimally invasive approach of coronary angioplasty.

III. Review of Council Procedures and Regulations: Dr. Anthony Demsey

Dr. Demsey noted for the record that a quorum was present for this Council meeting. Council members Drs. Grimson and Hricak and Ex Officio Dr. Plant were unable to attend. Dr. Demsey welcomed visitors and members of the science press and scientific society constituencies. He thanked Ms. Carol Fitzpatrick and Ms. Pam Glikman, as well as IT staff, for their work in organizing the meeting.

F. Council Regulations, Policies, and Procedures

Dr. Demsey summarized elements of the Government in the Sunshine Act and the Federal Advisory Committee Act that govern all Advisory Council meetings. These Acts require the U.S. Department of Health and Human Services to open Advisory Council meetings to the public except when proprietary or personal information is discussed. To comply with these regulations, NACBIB meetings are announced in the Federal Register, and are open to the public for all except the review of grant applications. Dr. Demsey reviewed conflict-of-interest, confidentiality, and lobbying guidelines.

G. Future NACBIB Meeting Dates

The next NACBIB meeting is scheduled for Friday, May 17, 2013. Dr. Demsey asked Council members to inform him about conflicts with any of the upcoming meeting dates listed at the bottom of the agenda.

H. Approval of the September 14, 2012, NACBIB Meeting Minutes

A motion to approve minutes of the September 14, 2012, NACBIB meeting was forwarded, seconded, and approved unanimously.

I. Reaffirmation of Council Procedures

A motion was forwarded and seconded to reaffirm Council operating procedures, with no modifications. The Council operating procedures were reaffirmed unanimously.

J. Draft Biennial Report on Compliance with Human Subjects Inclusion Policies

Dr. Demsey noted that with Council's concurrence, the biennial report on compliance with human subject inclusion policies will be forwarded to the Office of the Director, NIH.

IV. Adjournment

The open session of the NACBIB meeting was adjourned at 11:45 a.m.

V. Closed Session

The grant application review portion of the meeting was closed to the public in accordance with provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). The closed session was adjourned at 12:05 p.m.

Certification:

We certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.²

Anthony Demsey, Ph.D. Executive Secretary, National Advisory Council for Biomedical Imaging and Bioengineering Director, Office of Research Administration National Institute of Biomedical Imaging and Bioengineering

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

² These minutes will be approved formally by the Council at the next meeting on January 25, 2013, and corrections or notations will be stated in the minutes of that meeting.