DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH NATIONAL CANCER INSTITUTE 4th VIRTUAL NATIONAL CANCER ADVISORY BOARD

Summary of Meeting September 16, 2015

Virtual
Conference Room TE406, East Wing, Shady Grove Campus
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

NATIONAL CANCER ADVISORY BOARD BETHESDA, MARYLAND Summary of Meeting September 16, 2015

The National Cancer Advisory Board (NCAB) convened for its 4th virtual regular meeting on 16 February 2015. NCAB members attended virtually, and NCI staff attended in Conference Room TE406, East Wing, Shady Grove Campus, National Institutes of Health (NIH), Bethesda, MD. The meeting was open to the public on Wednesday, 16 September 2015, from 1:00 p.m. to 1:35 p.m., and closed to the public from 1:35 p.m. to2:14 p.m. (is this the correct adjournment???). The NCAB Chair, Dr. Tyler E. Jacks, Director, Koch Institute for Integrative Cancer Research, David H. Koch Professor of Biology, Massachusetts Institute of Technology, presided during both the open and closed sessions.

NCAB Members

Dr. Tyler E. Jacks (Chair)

Dr. Peter C. Adamson

Dr. Deborah Watkins Bruner (absent)

Dr. Yuan Chang

Dr. David C. Christiani

Dr. Marcia R. Cruz-Correa

Dr. Kevin J. Cullen (attended in person)

Dr. Judy E. Garber

Dr. Elizabeth M. Jaffee

Dr. Beth Y. Karlan

Dr. Timothy J. Ley

Dr. Olufunmilayo F. Olopade

Dr. Mack Roach, III

Dr. Jonathan M. Samet

Dr. Charles L. Sawyers

Dr. William R. Sellers (absent)

Dr. Max S. Wicha

Alternate Ex Officio NCAB Members

Dr. Michael A. Babich, CPSC (absent)

Dr. Vincent J. Cogliano, EPA (absent)

Dr. Michael Kelley, VA (absent)

Dr. Aubrey Miller, NIEHS (absent)

Dr. Richard Pazdur, FDA (absent)

Dr. Craig D. Shriver, DoD (absent)

Dr. Michael Stebbins, OSTP (absent)

Dr. Marie Sweeney, NIOSH (absent)

Dr. Lawrence Tabak, NIH (absent)

Dr. Richard Thomas, DOL (absent)

Dr. Sharlene Weatherwax, DOE (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

- Dr. Douglas R. Lowy, Acting Director, National Cancer Institute
- Dr. Jeff Abrams, Acting Director for Clinical Research, Division of Cancer Treatment and Diagnosis
- Dr. Lynn Austin, Executive Officer, Deputy Director for Management
- Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
- Dr. Henry P. Ciolino, Acting Director, Office of Cancer Centers
- Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
- Dr. James Doroshow, Deputy Director for Clinical and Translational Research
- Dr. Paulette S. Gray, Director, Division of Extramural Activities
- Dr. Peter Greenwald, Associate Director for Prevention
- Dr. Ed Harlow, Special Assistant for Science Planning
- Dr. Toby Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
- Dr. Lee Helman, Acting Director, Center for Cancer Research
- Dr. Warren Kibbe, Director, Center for Bioinformatics and Information Technology
- Dr. Barry Kramer, Director, Division of Cancer Prevention
- Dr. Glenn Merlino, Acting Scientific Director for Basic Research, Center for Cancer Research
- Dr. Alan Rabson, Deputy Director, National Cancer Institute
- Dr. Dinah Singer, Director, Division of Cancer Biology
- Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
- Dr. Louis Staudt, Director, Center for Cancer Genomics
- Dr. Ted Trimble, Director, Center for Global Health
- Mr. Michael Weingarten, Director, Small Business Innovation Research
- Dr. Jonathan Wiest, Director, Center for Cancer Training
- Dr. Maureen Johnson, Executive Secretary, Office of the Director
- Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy

Liaison Representatives

- Ms. Carolyn Aldige, Cancer Research and Prevention Foundation
- Dr. Carolyn Best, American Urological Association
- Ms. Paula Bowen, Kidney Cancer Association
- Dr. Susan Braun, National Cancer Institute, Director's Consumer Liaison Group
- Mr. William Bro, Kidney Cancer Association
- Dr. Carol Brown, Society of Gynecologic Oncologists
- Mr. Matthew Farber, Association of Community Cancer Centers
- Dr. Margaret Foti, American Association for Cancer Research
- Dr. Francis Giardiello, American Gastroenterological Association
- Dr. Mary Gullatte, Oncology Nursing Society
- Ms. Shandi E. Hill, American Society of Therapeutic Radiology and Oncology
- Ms. Ruth Hoffman, Candlelighters Childhood Cancer Foundation
- Dr. Gerald F. Joseph, Jr., American College of Obstetricians and Gynecologists
- Ms. Rebecca A. Kirch, American Cancer Society
- Dr. Steven Klein, National Science Foundation
- Ms. Laura Levit, American Society of Clinical Oncology
- Dr. W. Marston Linehan, Society of Urologic Oncology

Ms. Margo Michaels, Education Network to Advance Cancer Clinical Trials

Dr. Patricia Mullan, American Association for Cancer Education

Ms. Christy Schmidt, American Cancer Society

Ms. Susan Silver, National Coalition for Cancer Survivorship

Ms. Barbara Duffy Stewart, Association of American Cancer Institutes

Dr. Johannes Vieweg, American Urological Association

Ms. Pamela Wilcox, American College of Radiology

COL (Ret.) James E. Williams, Jr., Intercultural Cancer Council

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WEDNESDAY, SEPTEMBER 16, 2015

I. CALL TO ORDER AND OPENING REMARKS—DR. TYLER E. JACKS

Dr. Tyler E. Jacks called to order the 4th virtual NCAB meeting. Dr. Jacks welcomed members of the Board, *ex officio* members of the Board, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Jacks reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Dr. Jacks extended a special welcome to new member, Dr. Yuan Chang, American Cancer Society Research Professor, Distinguished Professor of Pathology, and UPCI Chair of Cancer Virology, University of Pittsburgh Cancer Institute. He also thanked the NCI Center for Biomedical Informatics Information Technology (CBIIT) and Office of Facility Management (OFM) for setting up the infrastructure for the virtual meeting.

Motion. A motion to approve the NCAB meeting dates through 2017 was approved unanimously.

Motion. A motion to accept the minutes of the June 24, 2015, Joint Boards meeting was approved unanimously.

II. FUTURE BOARD MEETING DATES—DR. TYLER E. JACKS

Dr. Jacks called Board members' attention to the future meeting dates listed on the agenda.

III. NCI DIRECTOR'S REPORT—DR. DOUGLAS R. LOWY

Dr. Douglas R. Lowy, Acting Director, welcomed members and provided an update on several areas of scientific and clinical relevance to the NCI. Dr. Lowy referred members to the FY 2017 NCI Bypass Budget, which will be released to the public on September 17, 2015, and will be accessible online.

Aspirin for Cancer Prevention. Dr. Lowy stated that the United States Prevention Services Task Force (USPSTF) has produced a draft report that recommends low-dose aspirin for men and women between the ages of 50 and 59, with the goal of reducing the risk of colorectal cancer. The recommendation potentially provides an important change in the standard of care, and the report has been released for public comment. He reminded members that the NCI had presented on the topic to the Board and highlighted several outstanding questions concerning: the benefits of aspirin to those older than age 59; the mechanism of action by which aspirin can reduce cancer activity; and the identification of biomarkers that are predictive of benefit as an approach to increase the benefit-to-harm ratio.

New NCI Awards Update. Dr. Lowy told members that in the first round of the Outstanding Investigator Award (OIA) Program, the NCI has made 40 awards in Fiscal Year (FY) 2015 and plans to make 24 additional awards in FY 2016. The award solicitation will be reissued with minor changes, including the reduction of the research strategy from 12 to 6 pages. Other potential awards being discussed within the NCI and NIH to help the extramural community in the development and sustainability of conducting cutting-edge research include the support of research specialists and the transition from graduate student to postdoctoral researcher.

NCI-Designated Cancer Centers. Members were informed that the NCI intends to increase funding for Core grants for NCI-designated Cancer Centers. Approaches to increasing the award size will

be discussed at a meeting of a working group of Cancer Center Directors, chaired by Drs. Stanton Gerson and Chi Dang, in October 2015. Dr. Lowy stated that increases in funding commitments to the Cancer Centers will be held in abeyance until the NCI receives an increase in its appropriations.

Cancers and High-Risk Populations. Dr. Lowy announced a workshop on cancer health disparities to be held November 11–13, 2015, to consider biology, lifestyle, and access/utilization factors to develop a more cohesive, comprehensive research approach and increase the impact on cancers affecting high-risk populations. The conference co-Chairs are Drs. Edith Mitchell, Thomas Jefferson University; Lisa Richardson, Centers for Disease Control and Prevention (CDC); and Sandy Markowitz, Case-Western Reserve University. Dr. Michelle Bennett, NCI, is helping to coordinate the cancer health workshop. She also will head the newly established NCI Center for Research Strategy, which will focus on trans-NCI activities that span scientific disciplines to improve research cohesiveness at the Institute.

Health Disparities and Youth. Members heard about a pilot program for middle school students in Baltimore, MD, spearheaded jointly by Drs. Sanya Springfield, Director, NCI Center to Reduce Cancer Health Disparities (CRCHD) and Kevin Cullen, Director, Marlene and Stewart Greenebaum Cancer Center, University of Maryland. Approximately 30 students from three schools will be selected to learn about the biology of cancer and research, with activities held at the middle school and at the University of Maryland Cancer Center. Dr. Lowy noted that this activity represents the NCI's first foray into promoting science at the middle school level, lauded Dr. Springfield for promoting the notion of long-term training for these students, and invited comment from Dr. Cullen, who expressed the Cancer Center's enthusiasm for the Program. The Program is sited in the Freddie Gray neighborhood, provides educational opportunities for children in the community, and includes an intensive mentoring and tutoring program for two afternoons a week and one day on the weekend, with the goal of helping students become more competitive for advanced training in science well before they attend college.

Precision Medicine Initiative in Oncology (PMI-Oncology). Dr. Lowy reminded members that the Joint Boards Meeting in June discussed the topic, and the NCI has continued to refine its approach. An NCI workshop in July 2015 on organoids and reprogrammed cell lines involving international investigators also provided input. In addition, the Frederick National Laboratory Advisory Committee (FNLAC) will hear about PMI-Oncology, including preclinical models and bioinformatics aspects, at its meeting in September. The NCI Molecular Analysis for Therapy Choice (NCI-MATCH) Program has opened, and Dr. James H. Doroshow, Deputy Director, attended a recent meeting organized for White House officials on these topics.

Dr. Doroshow provided an update on the NCI-MATCH Program, which accrued 60 patients at approximately 400 sites within 2 weeks of opening in August 2015, and includes 10 therapeutic arms. Accrual will be expanded to more than 2,000 sites with a total of at least 22 clinical trials conducted under the NCI-MATCH umbrella by the end of October. Dr. Doroshow noted a remarkable collaboration between NCI and ECOG-ACRIN staff who have made the processing of materials possible in as little as 5 to 10 days from the time of biopsy. He also described his briefing to White House staff about the NCI-MATCH Program and oncologic aspects of the PMI, including the focus on new models that are relevant to drug resistance and to a variety of tumors that are not well-represented in current collections of PDX and other models such as cell lines and xenografts.

Questions and Answers

In response to a query by Dr. Jacks, Dr. Lowy stated that the NCI would like to increase the budgets of NCI-designated Cancer Centers by 15 to 20 percent.

Dr. Marcia R. Cruz-Correa, Associate Professor of Medicine and Biochemistry, University of Puerto Rico, and Basic and Translational Science Director, University of Puerto Rico Comprehensive Cancer Center, expressed enthusiasm for the cancer health disparities pilot program for middle school students, and wondered about the schedule for the Research Specialist Award. Dr. Lowy responded that a launch date for the award program has not been set.

Dr. Olufunmilayo F. Olopade, Walter L. Palmer Distinguished Service Professor of Medicine and Human Genetics, Associate Dean for Global Health, and Director, Center for Clinical Cancer Genetics, The University of Chicago, Pritzker School of Medicine, asked about plans to expand the NCI-MATCH trials to encompass greater geographic areas and potentially increase the diverse populations to participate in NCI clinical trials. Dr. Doroshow referred to a pilot program with several universities that are located in areas with minority populations and have specific infrastructures in place to which the NCI could add resources specifically to assist in accrual to NCI-MATCH. Dr. Lowy added that the NCI will pay close attention that underrepresented minorities also are well-represented in preclinical models.

IV. CLOSED SESSION—DR. TYLER E. JACKS

This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 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 Board was informed that a comprehensive listing of all grant applications to be included in the en bloc vote was in the Special Actions package. Those grant applications as well as those announced during the closed session could be considered for funding by the Institute.

<u>En bloc</u>: The NCAB **en bloc** vote for concurrence with IRG recommendations was unanimous. During the closed session, a total of 2,597 NCI applications requesting direct cost support of \$880,206,540 were reviewed.

V. ADJOURNMENT— DR. TYLER E. JACKS

Date

Dr. Jacks thanked all of the Board members, as well as all of the visitors and observers, for attending.

ther business, the 4 th virtual meeting of the NCAB was adjourned at 3:00 p.m. per 2015.
Tyler E. Jacks, M.D., Chair

Paulette S. Gray, Ph.D., Executive Secretary