

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
5th VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 24, 2016**

**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
February 24, 2016**

The National Cancer Advisory Board (NCAB) convened for its 5th virtual regular meeting on 24 February 2016. NCAB members attended virtually, and National Cancer Institute (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, 24 February 2016, from 1:00 p.m. to 1:40 p.m., and closed to the public from 1:40 p.m. to 2:10 p.m. 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
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 I. Olopade (absent)
Dr. Mack Roach, III
Dr. Jonathan M. Samet
Dr. Charles L. Sawyers
Dr. William R. Sellers
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, Director, Division of Cancer Treatment and Diagnosis
Dr. Lynn Austin, Executive Officer, Deputy Director for Management
Dr. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Stephen J. Chanock, 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 Advisor to the Acting Director
Dr. Toby Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Lee Helman, Acting Director, Center for Cancer Research
Dr. Warren Kibbe, Acting Deputy Director and Director, Center for Bioinformatics and Information Technology
Dr. Barry Kramer, Director, Division of Cancer Prevention
Dr. Jerry Lee, Director, Center for Strategic Scientific Initiatives
Dr. Glenn Merlino, Acting Scientific Director for Basic Research, Center for Cancer Research
Dr. Craig Reynolds, Director, Office of Scientific Operations, NCI Campus at Frederick
Dr. Dinah Singer, Acting Deputy Director and 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. Robert Wiltrout, Special Advisor to the Acting Director
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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, FEBRUARY 24, 2016

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

Dr. Tyler E. Jacks called to order the 5th virtual NCAB meeting. Dr. Jacks welcomed 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), 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. He also thanked Dr. Gray and the DEA staff for setting up the infrastructure for the virtual meeting.

Motion. A motion to accept the minutes of the December 1, 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 ACTING DIRECTOR'S REPORT—DR. DOUGLAS R. LOWY

Dr. Douglas R. Lowy, Acting Director, welcomed members and provided an update on the NCI budget and the Vice President's Cancer Initiative (VPCI).

Outlook for Cancer Research Funding. Dr. Lowy noted the strong bipartisan support for the NCI and NIH, including the cancer research opportunities, key role of advocacy, and faster progress for patients. The current environment suggests potential for continuing increases in Federal cancer research funding, and the NCI will continue its role of coordination with private funding efforts.

The fiscal year (FY) 2016 appropriations include an overall increase of approximately \$265 million (M) for the NCI, of which the President's Precision Medicine Initiative in Oncology (PMI-Oncology) represents \$70 M. The remaining \$195 M includes \$10 M to increase the base for Cancer Center support grants, which will affect one-third of the NCI-designated Cancer Centers; \$55 M to start the VPCI; and \$80 M for research project grants (RPGs), of which \$50 M will support Type 2 awards and \$30 M for a new and competing RPG pool. An additional \$20 M also will be allocated from reprogrammed NCI funds, increasing the RPG pool of \$100 M from the FY 2016 base funding level. The NCI has maintained its purchasing power from 2012 through 2016, at a level similar to 1999, the first year after the doubling of the NIH budget. The FY 2017 President's Budget would provide a notable increase.

The Vice President's Cancer Initiative. Dr. Lowy stated that Vice President Joseph Biden's goal with this Initiative is to accelerate progress in cancer research, including prevention and screening, spanning cutting-edge basic research to wider uptake of standard of care. Mr. Biden will encourage greater cooperation in breaking down silos that exist within and between academia, government, and the private sector. Data sharing has important prominence in the initiative. Dr. Lowy noted Mr. Biden's long-term commitment to the Initiative and recognition that fundamentally changing the trajectory of cancer through prevention, early detection, and game-changing treatments will take time. The VPCI is also referred to as a "moonshot," but Dr. Lowy cautioned that the Initiative should be not be perceived as a one-time silver bullet to cure cancer.

The VPCI's focus on prevention, screening, and implementation will include preventive vaccines against infectious and noninfectious targets, screening tests with body-fluid samples, and increased uptake

of the standard of care for prevention, screening, and treatment. The Initiative's efforts to advance cancer treatment trials will emphasize increased immunotherapy and combination therapy trials, greater participation in clinical trials, and the development of a drug formulary from many companies to facilitate preclinical and trial access to investigational agents at the NCI. Other proposed research includes the development of drugs for pediatric cancer, increased genomic analysis of tumor and stromal cells, increased preclinical study of therapeutic cancer vaccines and cancer immunotherapy, increased basic research, and the development of a fund to support research in exceptional opportunities.

The Cancer Moonshot Federal Task Force met on February 1, 2016, led by Vice President Biden and attended by President Barack Obama, Dr. Francis Collins, Director, NIH, and other Federal leaders, to organize the different agencies and departments of the government to consider how to work more collaboratively and effectively on helping patients with cancer and advancing cancer research. As an example of collaboration, the NCI currently is working on three pilot data projects with the Department of Energy (DOE).

A VPCI Blue Ribbon Panel will be established as a Working Group of the NCAB, with members including cancer researchers, cancer advocates, the private sector, and those with significant knowledge and commitment to overcoming health disparities. The Panel will evaluate the proposed science; consider ways to incentivize or further develop collaboration, public-private partnerships, and data sharing; and consider other research opportunities. The Panel will report its findings to the NCAB at the Joint Board Meeting in June 2016. Dr. Lowy reflected on the effort and resources needed to advance the VPCI, and he announced the promotions of Drs. Dinah Singer, Director, Division of Cancer Biology, and Warren Kibbe, Director, Center for Biomedical Informatics and Information Technology (CBIIT) to NCI Acting Deputy Directors to support the Initiative. Dr. Lowy expressed appreciation to the NCAB and NCI staff for their advice, support, and dedication.

Questions and Answers

Dr. Jacks congratulated Drs. Singer and Kibbe on their elevation to the positions of NCI Acting Deputy Directors.

Dr. Max S. Wicha, Deputy Director of the Taubman Institute, Distinguished Professor of Oncology, and Professor, Internal Medicine, Division of Hematology and Oncology, University of Michigan, wondered about the sustainability of the VPCI given the annual allocation process by Congress. Dr. Lowy remarked on a recent Congressional reception where both Democratic and Republican Representatives and Senators affirmed the need to provide additional appropriations to the NIH in the near future years. He added that the Vice President understands that to be most effective, the Initiative will need to be sustained and sustainable, but that a new administration and Congress would need to be committed to supporting the cancer mission.

Dr. Charles L. Sawyers, Chairman, Human Oncology and Pathogenesis Program, Memorial Sloan-Kettering Cancer Center, Investigator, Howard Hughes Medical Institute, and Professor of Medicine, Weill-Cornell Medical College, wondered about new NCI interactions with other stakeholder agencies, such as the Centers for Medicare and Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA). Dr. Lowy highlighted regular ongoing interactions with the FDA that have increased as a consequence of the VPCI, as well as preliminary discussions with CMS personnel and other agencies.

Dr. Kevin J. Cullen, Director, Marlene and Stewart Greenebaum Cancer Center, and Professor of Medicine, University of Maryland, asked about the recompetition for the contract at the Frederick National Laboratory for Cancer Research (FNLRCR) and what influence the VPCI might have on NCI's

direction for the FNLCR. Dr. Lowy replied that the Frederick National Laboratory Advisory Committee (FNLAC) will hold an open discussion about the recompetition at its May 2016 meeting, after which the request for proposals (RFP) will be issued. The effect that the VPCI might have on the FNLCR recompetition is unknown.

Dr. Jacks asked about the projected lifespan of the VPCI's Blue Ribbon Panel and its functioning as an NCAB Working Group. Dr. Lowy confirmed that, in addition to constituting the Panel, the NCAB could empower the Panel to exist and have activities for a designated period of time. He added that the Blue Ribbon Panel will be an important activity about which the NCAB and Board of Scientific Advisors (BSA) will advise the NCI.

IV. ANNUAL DELEGATIONS OF AUTHORITY—DR. PAULETTE S. GRAY

Dr. Gray requested concurrence by the NCAB on two Delegations of Authority to the Director of the NCI. She described the delegations and the provisions in the Statement of Understanding. Delegation A allows the Director to obtain the services of not more than 151 special experts or consultants who have scientific or professional qualifications. Dr. Gray also said that Delegation B specifies that the NCAB delegates to the NCI Director can appoint advisory committees composed of private citizens and officials of Federal, state, and local governments to advise the Director with respect to his functions.

The Statement of Understanding with NCI Staff on Operating Principles in Extramural Grants also falls within the Delegations of Authority to the Director, NCI. NCAB operations are conducted in accordance with management and review procedures described in the NIH Manual Issuance 4513. Concurrence of the NCAB with recommendations of initial review groups will be required, except for the following: (1) Training grants and fellowships and other non-research grant applications are not subject to NCAB review and approval, and without other concerns may be awarded without presentation to the NCAB for concurrence, with the exception of Ruth L. Kirschstein National Research Service Awards. (2) Applications over the 50th percentile will not have summary statements presented to the NCAB unless the Institute is considering an award of such an application or other special consideration is required, requested, or required by NCI or NIH policy or for special consideration by an appointed member of the Board. (3) For applications assigned raw scores that are not percentiled, the cutoff will be a priority impact score of 50 for all mechanisms except R41, R42, R43, and R44 awards; for the latter, all scored applications will be included. Expedited Concurrence: (1) for R01 and R21 applications with percentiled or raw scores that fall within the NCI paylines for that mechanism, a process of expedited concurrence will be used; and (2) the Executive Secretary will alert Board members with responsibility for expedited concurrence when review outcomes for eligible applications are available on the Electronic Expedited Concurrence portion of the Electronic Council Book. Administrative Adjustments: (1) Permission is delegated to the Director, NCI, to allow staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards. (2) Administrative requests for increases in direct costs that are the result of marked expansion or significant change in the scientific content of a program after formal peer review will be referred to the Board for advice and recommendation. (3) Actions not requiring Board review or advice, such as change of institution, change of principal investigator (PI), phase-out of interim support, or additional support, need not be reported to the Board. (4) NCI staff may restore requested time and support that were deleted by the initial review group when justified by the PI in an appeal letter or when restoration is in the best interest of the NCI and the project is of high NCI programmatic relevance.

In an effort to continue responsible stewardship of public funds, the NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators. Applications from PIs who have \$1 M or more in direct costs from active NIH RPGs must be given additional consideration.

Motion. A motion to approve the NCI Annual Delegations of Authority was approved unanimously.

V. 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.

En bloc: The NCAB **en bloc** vote for concurrence with IRG recommendations was unanimous. During the closed session, a total of 2,500 NCI applications requesting direct cost support of \$760,131,722. Five FDA SBIR applications requesting \$509,222 were also included in the **en bloc** vote for concurrence.

VI. ADJOURNMENT— DR. TYLER E. JACKS

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

There being no further business, the 5th virtual meeting of the NCAB was adjourned at 2:10 p.m. on Wednesday, 24 February 2016.

06/28/2016
Date

/s/ Tyler E. Jacks
Tyler E. Jacks, M.D., Chair

06/28/2016
Date

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