

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
6th VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 15, 2017**

**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 15, 2017**

The National Cancer Advisory Board (NCAB) convened for its 6th virtual regular meeting on 15 February 2017. 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, 15 February 2017, from 1:00 p.m. to 2:05 p.m., and closed to the public from 2:05 p.m. to 3:30 p.m. The NCAB Chair, Dr. Elizabeth M. Jaffee, Deputy Director, The Sidney Kimmel Comprehensive Cancer Center, Co-Director, Skip Viragh Center for Pancreas Cancer, The Dana and Albert “Cubby” Broccoli Professor of Oncology, Johns Hopkins University, presided during both the open and closed sessions.

NCAB Members

Dr. Elizabeth M. Jaffee (Chair – attended in person)
Dr. Peter C. Adamson
Dr. Francis Ali-Osman
Dr. Deborah Watkins Bruner
Dr. Yuan Chang
Dr. David C. Christiani
Dr. Judy E. Garber
Mr. Lawrence O. Gostin
Dr. Scott W. Hiebert
Dr. Beth Y. Karlan
Dr. Timothy J. Ley
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub
Dr. Mack Roach, III
Dr. Charles L. Sawyers
Dr. Margaret R. Spitz
Dr. Max S. Wicha

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. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
Dr. William Dahut, Acting Scientific Director for Clinical Research, Center for Cancer Research
Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research
Dr. Dan Gallahan, Deputy Director, Division of Cancer Biology
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the Acting Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Warren Kibbe, Acting Deputy Director and Director, Center for Bioinformatics and Information Technology
Dr. Kristin Komschlies, Acting Director, Office of Scientific Operations, NCI Campus at Frederick
Dr. Barry Kramer, Director, Division of Cancer Prevention
Dr. Jerry Lee, Deputy Director, Center for Strategic Scientific Initiatives
Dr. Glenn Merlino, Scientific Director for Basic Research, Center for Cancer Research
Dr. Tom Misteli, Director, Center for Cancer Research
Ms. Donna Siegle, Acting Executive Officer, Acting Deputy Director for Management
Dr. Dinah Singer, Acting Deputy Director and Director, Division of Cancer Biology
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Dr. Ted Trimble, Director, Center for Global Health
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology Transfer Programs
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

TABLE OF CONTENTS**WEDNESDAY, 15 FEBRUARY 2017**

I.	Call to Order and Opening Remarks—Dr. Elizabeth M. Jaffee	1
II.	Future Board Meeting Dates— Dr. Elizabeth M. Jaffee.....	1
III.	NCI Acting Director’s Report—Drs. Douglas R. Lowy, James H. Doroshow, Warren Kibbe and Dinah Singer	1
	Questions and Answers	4
IV.	Annual Delegations of Authority—Dr. Paulette S. Gray.....	4
V.	Proposed Organizational Change: Center for Cancer Research— Dr. Tom Misteli	5
VI.	Adjournment of Open Session— Dr. Elizabeth M. Jaffee	6
VII.	Closed Session— Dr. Elizabeth M. Jaffee	6
VIII.	Adjournment— Dr. Elizabeth M. Jaffee	6

WEDNESDAY, FEBRUARY 15, 2017**I. CALL TO ORDER AND OPENING REMARKS— DR. ELIZABETH M. JAFFEE**

Dr. Elizabeth Jaffee called to order the 6th virtual NCAB meeting. She welcomed members of the Board, 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. Jaffee reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations. She 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 6, 2016, Joint Meeting of the Board of Scientific Advisors and the NCAB was approved unanimously.

II. FUTURE BOARD MEETING DATES—DR. ELIZABETH M. JAFFEE

Dr. Jaffee 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 NCAB members and attendees to the sixth virtual meeting and provided an update on the NCI budget and appropriations process. He was joined by Drs. James H. Doroshov, Deputy Director, Clinical and Translational Research, who provided an update on the NCI-Molecular Analysis for Therapy Choice (NCI-MATCH) trial and the NCI Virtual Drug Formulary; Warren Kibbe, Acting Deputy Director, NCI, who provided an update on the Genomic Data Commons (GDC); and Dinah Singer, Acting Deputy Director, NCI, who updated the attendees on the Blue-Ribbon Panel's (BRP's) Cancer MoonshotSM recommendations.

NCI Budget and Appropriations. Dr. Lowy informed members that the NCI is operating under a continuing resolution (CR) that funds the government through April 28, 2017. Two possibilities for the federal budget past the current CR would be for Congress to either implement a full-year CR or pass an Omnibus spending bill for the remainder of fiscal year (FY) 2017. Although a full-year CR affords the NCI the benefit of having the Cancer MoonshotSM appropriation, this appropriation is not a substitute for the regular increased and sustained appropriations necessary to maximize progress in cancer research. Furthermore, stated Dr. Lowy, a full-year CR does not provide as positive outlook as sustained appropriations would for the NIH, NCI, and cancer research community. In FY 2016, the House Appropriations Subcommittee passed a bill to increase funding to the NIH by \$1.25 billion (B) and \$124 million (M) to the NCI; and the Senate Subcommittee on Appropriations passed a bill to increase funding to the NIH by \$2 B and by \$216 M to the NCI.

The NCI is aware of the critical role of increased and sustained appropriations from Congress in maintaining the cancer research portfolio and meeting the obligations to the cancer research community—investigator-initiated research and the research project grant (RPG) pool's new (Type 1) and competing (Type 2) awards are key investments. In addition, increased and sustained appropriations from Congress will allow NCI to train new scientists; support the NCI-designated Cancer Centers (Cancer Centers); expand ongoing initiatives, such as the RAS Program at the Fredrick National Laboratory for Cancer Research; and develop new initiatives. The NCI would be challenged to meet its goals if the government continues to operate under a full-year CR, instead of passing an Omnibus spending bill. Dr. Lowy remarked that congressional bipartisan support for the NIH and the NCI remains strong.

NCI Virtual Drug Formulary. Dr. Doroshov informed members that the Virtual Drug Formulary (NCI Formulary), a system established within the NCI that leverages existing mechanisms to

provide NCI principal investigators with investigational new drugs (INDs) more rapidly, launched January 2017 with 16 targeted agents from six pharmaceutical companies. This public-private partnership between the NCI and pharmaceutical and biotechnology companies, organized through Clinical Cooperative Research and Development Agreements (CRADAs) negotiated by NCI's Cancer Therapy Evaluation Program (CTEP), will expedite clinical trials by reducing the lengthy negotiation process to an 8-week review cycle for clinical and preclinical study proposals. A clinical Material Transfer Agreement (MTA) between the NCI and the Cancer Centers formalized the expectations of each party. The available agents, participating companies, intellectual property details, applicable forms, and other pertinent information can be accessed on the NCI Formulary website: nciformulary.cancer.gov. Dr. Doroshow emphasized the year-long efforts to establish the formulary and encouraged members to engage their colleagues and Cancer Center investigators to take advantage of this new system.

NCI-MATCH Trial. Members were reminded that the NCI-MATCH trial, coordinated through the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG ACRIN) Cancer Research Group, opened August 2015 with 10 treatment arms or targeted drugs. In a 3-month period, 795 patient tumors were screened (e.g., DNA sequencing to detect gene abnormalities that may be driving tumor growth) for actionable mutations. One thousand approved sites, including 80 percent of Cancer Centers and 90 percent of the NCI Community Oncology Research Program (NCORP) sites, are participating. On average, 115 patients are screened each month, exceeding original estimates of 50 screens per month. As of January 29, 2017, accrual is two-thirds complete, with biopsies of 4,094 patient tumors completed; 20 percent of patients screened (642) were eligible for the trial and enrolled for treatment. The genomic analysis success rate is 94 percent and the median turnaround time for results is 16 days. Although distributions of breast and colorectal cancers of patients enrolled for screening are higher, enrollments of patients with underrepresented cancers in other disease sites has been reasonable over the duration of the trial. As of October 2016, enrollment demographics showed that 80 percent of patients enrolled were Caucasian, 8 percent African American, and 6 percent Hispanic. The distribution of accrual by State was not a direct correlation to a specific population.

Accrual closed temporarily on November 11, 2015, to conduct a built-in interim analysis, and the trial reopened May 31, 2016, with 24 treatment arms; six or seven additional arms will be added by the end of February 2017. Seven of the 24 arms have completed accruals and are undergoing initial efficacy evaluations; several others are nearing complete accruals. To address rare cancers that may not otherwise be identified in this phase of the trial, the NCI is working to complete agreements with four additional Clinical Laboratory Improvement Amendments (CLIA) -certified laboratories—including two commercial laboratories, Foundation Medicine Inc. (FMI) and Caris Life Sciences, and two clinical laboratories, MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center—to identify through routine cancer screening for clinical care patients who may have rare driver mutations. This rare-variant initiative, expected to start May 2017, will verify results from these patients with the MATCH assays retrospectively.

Genomic Data Commons. Dr. Kibbe reminded members that the GDC, an existing effort to standardize and simplify genomic data submissions to the NCI, launched June 6, 2016, with 4.1 petabytes of data. There were more than 16,000 visits to the GDC data portal website (e.g., gdc.cancer.gov) in December 2016, and information on invasive breast carcinoma and kidney carcinoma has been downloaded most often since the GDC launched. At the June 2016 Cancer MoonshotSM Summit, FMI announced the release of 18,000 genomic profiles to the GDC, and the Multiple Myeloma Research Foundation (MMRF) announced in September 2016 the release of more than 1,000 cases of multiple myeloma (MM) from the Relating Clinical Outcomes in MM to Personal Assessment of Genetic Profile study, commonly known as CoMMpass. To date, all data from the FMI have been transferred to the GDC and data harmonization is complete. The final phase of quality control of data is in progress, and these data will soon be available to the cancer community. The GDC and MMRF currently are working to complete clinical data elements mapping and harmonization of the CoMMpass data. Biospecimen

metadata conversion from the Excel format to extensible markup language (XML) format and genomic data migration and testing are in progress. A midsummer 2017 release is anticipated.

Aligning with the BRP Cancer MoonshotSM recommendation to establish a National Cancer Data Ecosystem for Sharing and Analysis, the NCI Data Commons framework and the GDC are poised to support this effort. The key components of a Cancer Research Data Ecosystem can be viewed in three parts: discovery, patient-engaged research, and population-based research (e.g., surveillance big data implementation research).

Cancer MoonshotSM Recommendations Implementation Plan. Dr. Singer told members that following the approval of the September 2016 Report of the NCAB BRP on recommendations to accelerate the progress of cancer research across the continuum (i.e., basic science, clinical, and population science), the NCI began designing the implementation process to develop funding opportunities announcements (FOAs) for the Cancer MoonshotSM. In December 2016, Congress passed the 21st Century Cures Act authorizing \$1.8 B in funding for the Cancer MoonshotSM, to broadly support cancer research, and changed the name to the Beau Biden Cancer MoonshotSM; \$300 M are allocated for FY 2017. The FOAs have been developed to align the recommendations with the overall goals of the Beau Biden Cancer MoonshotSM and overarching cross-cutting themes of health disparities, prevention, technology development, data sharing, and partnerships. Given the timing of the funding approval, NCI was limited in time to engage the cancer research community and solicit its input on implementation of the recommendations. The goals for FY 2017 are to establish the foundation to lay the groundwork for implementing in FY 2018 and FY 2019 the broader initiatives that were outlined in the recommendations. The NCI currently is positioned to accelerate the progress of 5 of the 10 research areas for FY 2017 and support several new initiatives. The full list can be accessed on NCI's Cancer MoonshotSM website: www.cancer.gov/brp.

For FY 2018 and FY 2019, the NCI has designed a more structured implementation process that would allow for input from both the NCI community and broader cancer research community to accommodate the different and disparate recommendations. Twelve Cancer MoonshotSM Implementation Teams (CMITs) will be aligned with the 10 BRP recommendations; cancer immunology will have both adult and pediatric CMITs, and prevention and early detection will have both cancer screening and prevention CMITs. These 12 CMITs, comprising more than 250 representatives from NCI's intramural and extramural communities and other Institutes, will be charged to discuss approaches and develop initiatives for FY 2018 and FY 2019 that will achieve the goal of the recommendation. The CMITs will identify gaps and opportunities in the existing initiatives; seek input from others, including the NCAB, advocacy groups, and associations; and leverage existing partnerships. In addition, the CMITs are charged to provide oversight and coordination of the funded initiatives. To address communications across CMITs, which will be critical to the success of the implementation plan, NCI is proposing to establish an Implementation Coordinating Committee that would convene bimonthly meetings with coordinators who are assigned to each CMIT to share ideas and cross-cutting information and to discuss concepts. In parallel, an Implementation Partnership Committee would engage the appropriate partners for the research initiatives as they are being developed. Information on high-priority concepts would be forwarded to an Implementation Steering Committee for review and, from there, would be forwarded to NCI's Scientific Program Leaders (SPLs) for budgetary considerations and approval. Dr. Singer conveyed NCI's enthusiasm for implementation of the Beau Biden Cancer MoonshotSM recommendations as shared by all of NIH and noted that the CMITs launched in early February 2017, with 9 of the 12 teams having met at least once to begin the process.

Questions and Answers

Dr. Jaffee asked whether progress on the Beau Biden Cancer MoonshotSM recommendations would

be posted to the NCI website. Dr. Singer replied that the active Cancer MoonshotSM funding opportunities are posted to the NCI Cancer MoonshotSM website; this list will be updated as new initiatives are developed.

Dr. Electra Paskett, Marion N. Rowley Professor of Cancer Research, Director, Division of Cancer Prevention and Control, Department of Internal Medicine, College of Medicine, The Ohio State University, expressed concern that the FY 2017 FOAs for Symptom Management may not align closely with the recommendation—in particular, FOAs PA-17-060 and -061, Oral Anticancer Agent; PA-17-109 and -110, Reduce Over-screening; and PAR-16-201 and -202, Tobacco Cessation. Dr. Deborah Watkins Bruner, Robert W. Woodruff Chair of Nursing, Nell Hodgson Woodruff School of Nursing, Associate Director for Outcomes Research, Winship Cancer Institute, Emory University, echoed Dr. Paskett's concern. Dr. Singer noted that those FOAs were listed incorrectly in the presentation and should be listed under Screening and Prevention. Dr. Lowy added that additional details will be provided as the implementation process progresses past this initial 2 months of funding; it is very early in the process.

In response to a query on the details of the human papilloma virus (HPV) trial that is funded with the Bill and Melinda Gates Foundation, Dr. Lowy stated that details on this HPV trial were presented at the December 2015 Joint Boards meeting. The study is a randomized control trial being conducted in Costa Rica to determine whether a single dose of the prophylactic HPV vaccines would provide durable protection against cervical cancer.

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 authority to the NCI Director to appoint one or more advisory committees composed of private citizens and officials of Federal, state, and local governments to advise the Director with respect to his or her 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 20th 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.

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. PROPOSED ORGANIZATIONAL CHANGE: CENTER FOR CANCER RESEARCH—DR. TOM MISTELI

Dr. Tom Misteli, Director, Center for Cancer Research (CCR), NCI, informed members of a proposed organizational change to transfer most the Dermatology Branch from CCR to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH. This change has been prompted by the June 2017 retirement of the current Branch Chief. The Dermatology Branch was established more than 50 years ago with an initial focus on cutaneous thymus cell (T cell) lymphoma and was led for many years by the current Director of NIAMS, Dr. Stephen I. Katz. The Branch has expanded into an international center of excellence for skin immune physiology with some research on cancer. In addition to the Branch Chief, the Branch consists of a tenured investigator, three tenure-track investigators, a senior clinician, and a senior research physician.

Additional factors prompting this organizational change include the major focus of activities on skin physiology, which more closely align with NIAMS' mission regarding skin diseases—building a new Dermatology Branch within the CCR to focus primarily on skin cancer would be challenging due to the necessary resources. Consolidating the skin cancer-related research into other Laboratories and Branches would be a major disruption and is therefore not feasible. The three tenure-track investigators would like to maintain their close collaborations and it would be challenging to find a space accommodative of all three. The CCR therefore proposes to transfer much of the Dermatology Branch to NIAMS, retaining one senior investigator and the senior research physician. Tenure-track investigators will retain adjunct appointments with the NCI, and clinical trials will not be affected because the senior clinician will continue to provide dermatology-related services to the CCR. The Dermatology Branch investigators and staff considered this organizational change appropriate and accommodating; an NCI-NIAMS Memorandum of Understanding has been established to address all pertinent issues.

Motion. A motion to concur on the proposed organizational change for the Center for Cancer Research was approved unanimously.

VI. ADJOURNMENT OF OPEN SESSION— DR. ELIZABETH M. JAFFEE

Dr. Jaffee informed members that the NCI and Department of Energy (DOE) have agreed to collaborate on a Joint Design of Advance Computing Solutions for Cancer. To enable this collaboration, the NCI and DOE are proposing to establish an Exascale Initiative Working Group.

Motion. A motion to approve establishment of a Department of Energy (DOE) NCI Exascale Initiative Working Group to support the NCI-DOE Collaboration on a Joint Design of Advance Computing Solutions for Cancer was approved unanimously.

In response to a query on legislative issues, Dr. Jaffee requested members to submit to Drs. Gray and Lowy comments on issues regarding legislation that might place burdens on the scientific research of NCI investigators, for review by the Office of Government and Congressional Relations.

Dr. Jaffee informed members of NCI’s plan to establish an NCAB Subcommittee focused on addressing issues related to population science, epidemiology, and diversity. Members should send notice of their interest in serving on the Subcommittee to Drs. Jaffee and Gray.

Dr. Jaffee adjourned the open session. Only Board members and designated NCI staff remained for the closed session.

VII. CLOSED SESSION— DR. ELIZABETH M. JAFFEE

“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.

The NCAB **en bloc** vote for concurrence with Initial Review Group (IRG) recommendations was unanimous. During the closed session, a total of 2,545 NCI applications were reviewed requesting direct cost support of \$875,623,343.

VIII. ADJOURNMENT— DR. DR. ELIZABETH M. JAFFEE

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

There being no further business, the 6th virtual meeting of the NCAB was adjourned at 3:30 p.m. on Wednesday, 15 February 2017.

Date

Elizabeth M. Jaffee, Ph.D., Chair

Date

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