

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL CANCER INSTITUTE  
7<sup>th</sup> VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting  
September 12, 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  
September 12, 2017**

The National Cancer Advisory Board (NCAB) convened for its 7<sup>th</sup> virtual regular meeting on 12 September 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 Tuesday, 12 September 2017, from 1:00 p.m. to 2:00 p.m., and closed to the public from 2:00 p.m. to 2:30 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 (—participated via teleconference)  
Dr. Yuan Chang  
Dr. David C. Christiani  
Dr. Judy E. Garber (absent)  
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 (absent)  
Dr. Mack Roach, III  
Dr. Charles L. Sawyers  
Dr. Margaret R. Spitz  
Dr. Max S. Wicha (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. 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, 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. Tony Kerlavage, Acting 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

### **Liaison Representatives**

Ms. Carolyn Aldige, Prevent Cancer Research Foundation  
Ms. Paula Bowen, Kidney Cancer Association  
Mr. William Bro, Kidney Cancer Association  
Dr. Carol Brown, Society of Gynecologic Oncologists  
Dr. Margaret Foti, American Association for Cancer Research  
Dr. Leo Giambarresi, American Urological Association  
Dr. Francis Giardiello, American Gastroenterological Association  
Dr. Mary Gullatte, Oncology Nursing Society  
Dr. Gerald F. Joseph, American College of Obstetricians and Gynecologists  
Dr. Steven L. 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. Shelly Fuld Nasso, National Cancer Institute, Council of Research Advocates  
Ms. Leah Ralph, Association of Community Cancer Centers  
Ms. Susan Shriver, National Coalition for Cancer Survivorship  
Ms. Kristy Smith, American Cancer Society  
Ms. Barbara Duffy Stewart, Association of American Cancer Institutes  
Dr. Johannes Vieweg, American Urological Association  
Dr. Pamela A. Wilcox, American College of Radiology  
COL (Ret.) James E. Williams, Jr., Intercultural Cancer Council

**TABLE OF CONTENTS**

**TUESDAY, 12 SEPTEMBER 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, and Dinah Singer .....	1
	Questions and Answers .....	4
IV.	Legislative Report—M. K. Holohan.....	4
	Questions and Answers .....	4
V.	Adjournment of Open Session—Dr. Elizabeth M. Jaffee .....	5
VI.	Closed Session—Dr. Elizabeth M. Jaffee .....	5
VII.	Adjournment—Dr. Elizabeth M. Jaffee .....	5

**TUESDAY, 12 SEPTEMBER 2017**

**I. CALL TO ORDER AND OPENING REMARKS—DR. ELIZABETH M. JAFFEE**

Dr. Elizabeth Jaffee called to order the 7<sup>th</sup> 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.

**Motion.** A motion to accept the minutes of the 20–21 June 2017 June Joint Meeting of the Board of Scientific Advisors (BSA) and the NCAB was approved unanimously.

Dr. Jaffee congratulated Dr. Douglas R. Lowy, Acting Director, NCI, and Dr. John T. Schiller, Center for Cancer Research (CCR), NCI, on receiving the 2017 Lasker-DeBaakey Clinical Medical Research Award.

**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—DRS. DOUGLAS R. LOWY, JAMES H. DOROSHOW, AND DINAH SINGER**

Dr. Lowy welcomed NCAB members and attendees to the 7<sup>th</sup> virtual meeting of NCAB and provided an update on NCI activities. He was joined by Drs. James H. Doroshow, Deputy Director, Clinical and Translational Research, NCI, who provided an update on the NCI-Molecular Analysis for Therapy Choice (NCI-MATCH) trial, and Dinah Singer, Acting Deputy Director, NCI, who updated the attendees on the Outstanding Investigator Award (R35), Research Specialist Award (R50), and Cancer Moonshot<sup>SM</sup> Initiative.

**NCI Activities.** Dr. Lowy informed members that the NCI is carefully monitoring the conditions of the NCI-designated Cancer Centers and NCI grantees in the aftermath of the recent hurricanes. Dr. Stephen T. White, Special Assistant to the Director, Division of Cancer Biology (DCB), NCI, is serving as a liaison for the NCI in this effort. The University of Houston has reported on potentially serious problems that may have resulted from flooding, but the extent of the damage is yet to be determined. Sources in Puerto Rico have not indicated any concerns, and it is too soon for any evaluations of the damage to Florida.

Dr. Lowy stated that Dr. Norman E. "Ned" Sharpless, Director, Lineberger Comprehensive Cancer Center, Wellcome Distinguished Professor in Cancer Research, University of North Carolina at Chapel Hill, is expected to be sworn in soon as NCI Director. NCI personnel are looking forward to working with Dr. Sharpless in what is likely to be a strategic period for the NCI and NIH regarding cancer research and community advocacy.

Dr. Lowy announced that the NCI fiscal year (FY) 2019 Bypass Budget was released on September 12, 2017. He expressed appreciation to Dr. L. Michelle Bennett, Director, Center for Research Strategy (CRS), NCI; Peter Garrett, Director, Office of Communications and Public Liaison (OCPL), NCI; and CRS and OCPL staff for their role in achieving this goal. He noted that the NCI is operating under a continuing resolution (CR) that funds the government through December 8, 2017, and that Ms. M. K. Holohan, Director, Office of Government and Congressional Relations (OGCR), NCI, would provide more details on the CR and budget later in the meeting.

**Next Generation Research Initiative (NGRI).** Dr. Lowy informed members that the Grant Support Index (GSI) has been renamed the Next Generation Researchers Initiative (NGRI) (<https://grants.nih.gov/ngri.htm>). Although the name has changed, the concept remains the same. Dr. Lowy discussed NCI's progress related to the GSI/NGRI to date. Although FY 2017 will soon close, Dr. Bennett and CRS staff have managed to complete an in-depth review of the productivity and funding trends for NCI investigators, including Early Stage Investigators (ESIs). Using the results of these detailed analyses, the NCI will increase the number of funded ESIs in FY 2017 above the FY 2016 funding levels. The NCI will continue to evaluate funding trends internally, discuss the options with the Scientific Program Leaders (SPL), and report any updates to the NCAB and BSA.

Dr. Lowy called attention to the data to support NCI's decision to increase funded ESIs. CRS' review of NCI funding trends from 1990 to 2015—broken down by the ages of NCI Research Project Grant (RPG) or R01 investigators in 5-year intervals—revealed that the number of funded investigators increased in all age groups except for ESIs younger than 40 years of age, while the total number of investigators has increased overall. NIH funding has not been stable or consistent from 1990 to 2015 and has been influenced by several activities, including lifting mandatory retirement in 1998; doubling the NIH budget during 1998–2003; issuing the 2010 ESI Policy; and imposing a federal budget sequester in FY 2014. A primary factor speculated to be attributing to the under-age-40 demographics trend could be the length of time spent in postdoctoral fellowships. In addition, the turnover of NCI R01s is greater than non-NCI R01s on average during the past 3 years for new (Type 1) and competing (Type 2) awards. Furthermore, the success rate of competing renewals among the NCI grantees was lower than that of non-NCI grantees in 2014. These data and more are under review for FY 2018.

**NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE).** Dr. Lowy reported that the NCI recently signed, after 1.5 years of negotiations, an interagency agreement (IAA) with the U.S. Department of Veterans Affairs (VA) to increase participation among VA patients in NCI clinical trials. He acknowledged Dr. Sheila Prindiville, Director, Coordinating Center for Clinical Trials (CCCT), NCI; Dr. Michael Kelley, National Program Director of Oncology, Department of Veterans Affairs, and Professor of Medicine, Duke University School of Medicine; CCCT staff; and the NAVIGATE team members for their efforts on the agreement.

A 2010 update of cancer incidence among patients in the VA, which was published in the July edition of *Military Medicine*, showed that although most of the cancers are diagnosed in men, women also are being diagnosed as the composition of the VA population shifts. The age-adjusted rates for cancer were higher in the VA population than in the general U.S. cancer population, 20 percent of newly diagnosed patients were African American, and a high percentage of patients were living in the southern region of the United States. Clinical trial activation challenges—such as regulatory and policy issues with the central Institutional Review Board (IRB) and patient access to care, including travel and financial challenges—are barriers to VA patients' participation in NCI clinical trials.

The overall goal of the NAVIGATE IAA is to enable more VA patients to enroll in NCI national clinical trials by initially focusing on activities to facilitate participation of Veteran Affairs Medical Centers (VAMC) in NCI trials. The long-term goals include seeking ways to sustain VAMC participation beyond the IAA. The primary activities are to provide infrastructure funding support for enrolling VA patients into NCI's National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) clinical trials and to establish an executive committee composed of NCI and VA personnel to oversee activities and address barriers as they arise. The anticipated benefits of NAVIGATE are increasing trial access for veterans, accelerating accruals, engaging minority populations, and increasing participation by VA clinical investigators. In addition, the program will provide opportunities for VA investigators to participate in NCI scientific steering committees and enhance the overall leadership role of the VA in cancer care and clinical research.

The next steps will be to form the executive committee, finalize the VA request for proposals, release solicitation for NAVIGATE sites in 2017, and host a kickoff meeting with selected sites and the executive committee in early to mid-2018. The total NCI investment in this early phase will be \$5 million for 3 years.

**NCI-MATCH Trial.** Dr. Doroshow informed members that the NCI Children's Oncology Group (NCI-COG) Pediatric MATCH trial opened and began accruals in July 2017. He acknowledged Dr. Peter C. Adamson, Chair, COG, Alan R. Cohen Endowed Chair in Pediatrics, The Children's Hospital in Philadelphia, and the COG for their efforts in organizing the pediatric trial.

Dr. Doroshow reported that the initial NCI-MATCH trial reached its goal of sequencing 6,000 adult patient tumors in June 2017 and seamlessly transitioned into the second phase, the Rare Cancer Variant trial, during July–August 2017. A new trial entry process is being implemented in which patients who are identified at two academic sites or two commercial sites already performing next-generation sequencing are referred to study treatment arms. Several additional academic and commercial groups have shown interest in participating as NCI-MATCH laboratories and will have until January 31, 2018, to submit letters of interest to the NCI. Further details can be found in the August 2, 2017, *Federal Register* Notice.

**Outstanding Investigator Award (R35), Research Specialist Award (R50), and Cancer Moonshot<sup>SM</sup> Initiative.** Dr. Singer reported that the Outstanding Investigator Award (OIA) (R35), which is designed to provide long-term support (i.e., \$600,000/year for 7 years) to experienced investigators with outstanding records of cancer research accomplishments, has been well received in the community. The applicant success rate averages 14 percent and, by the end of FY 2017, the NCI would have awarded a total of 107 awards to the first, second, and upcoming third group of OIA investigators.

Dr. Singer noted that the newer Research Specialist Award (RSA) (R50) program began in 2015 and supports development of a new career track for accomplished scientists who are strong contributors to biomedical research to serve as core leaders or laboratory-based research specialists. The NCI awarded 17 core-based and 17 laboratory-based RSAs to the first group of research specialists and is proposing to support an additional eight awards in each of the categories for the second group of applicants, which would total 50 RSA awards. Dr. Singer explained that the NCI will evaluate the OIA and RSA programs in 4 to 5 years to determine their success in achieving the programs' goals.

Dr. Singer reported that the NCI issued 10 Cancer Moonshot Requests for Applications (RFAs) in FY 2017 to support the following: Patient-Derived Xenograft (PDX) Development and Trial Centers; PDX Commons Center; Cancer Immune Monitoring and Analysis Centers; Cancer Immunologic Data Commons; Canine Immunotherapy Trials; Coordinating Center for Canine Immunotherapy; Consortium for Pancreatic Ductal Adenocarcinoma (PDAC) Translational Studies; PDAC Resource Center; Drug Resistance and Sensitivity; and New Enabling Technologies.

In addition, Dr. Singer continued, initiatives that were previously presented to the NCI advisory boards that are not RFAs but represent partnerships, contracts, and supplements, including the Partnership for Accelerating Cancer Therapies (PACT), are being supported. The NCI, through the work of the Cancer Moonshot Implementation Teams, has developed FY 2018 RFAs for each of the 10 NCAB Blue Ribbon Panel (BRP) recommendations that are detailed in the September 2016 BRP report. A few of the FY 2018 RFAs have been published; several are in the final stages and will be published soon, along with contracts.

## Questions and Answers

NCAB Chair Dr. Jaffee asked about the distribution of Outstanding Investigator Awards (OIAs) relative to the area of cancer research regarding laboratory science, clinical research, and population-based studies. Dr. Singer explained that approximately two-thirds of OIAs are distributed between DCB and the Division of Cancer Treatment and Diagnosis (DCTD) and one-third between the Division of Cancer Prevention (DCP) and the Division of Cancer Control and Population Sciences (DCCPS). Fewer applications were received through DCP and DCCPS, but all applications are reviewed as they are received.

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, sought clarity on the low success rate of competing renewals for Type 2 awards. Dr. Lowy clarified that the success rate for Type 2 awards was twice as high as that of Type 1 awards, but the NCI funds a higher percentage of Type 1 awards in comparison to the broader NIH.

## IV. LEGISLATIVE REPORT—M. K. HOLOHAN

Ms. Holohan reported on the status of the budget and appropriations process, congressional appropriations, and legislation of interest. She stated that the NCI/NIH budget process for the regular appropriations is currently between steps two and three of the four-step process. The 12 separate appropriation bills rarely are passed before the FY begins, resulting in CRs, stopgaps, or a 12-bill omnibus being normal; FY 2018 is looking to continue this trend. On September 8, 2017, the President signed the House of Representatives 601 bill into law, providing a CR to fund the government through December 8, 2017, as well as \$15.25 billion (B) for Hurricane Harvey relief and a temporary extension of the debt limit. Ms. Holohan reminded members that the White House Office of Management and Budget released the full FY 2018 budget on May 23, 2017, which includes a 20 percent decrease for the NIH budget compared to FY 2017. House and Senate Appropriations Subcommittees on Labor, Health and Human Services, Education, and Related Agencies considered the President's budget proposal, prepared legislation over the spending bills, and conducted hearings in May and June 2017; Dr. Lowy attended both hearings.

The House passed a bill to increase funding to the NIH by \$1.1 B and to the NCI by \$82 million (M); the Senate passed a bill to increase funding to the NIH by \$2 B and to the NCI by \$169 M. Also, \$300 M was appropriated for the 21st Century Cures Cancer Moonshot<sup>SM</sup> funding. The committees declined to consider the issues of direct costs or elimination of NIH's Fogarty International Center at this iteration, but these topics are likely to resurface in broader congressional discussions. This marks the third consecutive year that Congress voted to increase NIH regular appropriations, which includes increases for the NCI. Based on the trends being monitored by the NCI Office of Budget and Finance, the President's proposed budget and the House and Senate allowances differ greatly according to priorities, regardless of the Administration. Ms. Holohan remarked on the strong congressional bipartisan and bicameral support for the NIH and NCI. In 2017, more than 20 members and 50 staffers visited the NCI, including House Budget Committee staff. Members were told that the time to complete the FY 2018 budget is short, with only 36 legislative days remaining before the CR and debt limit suspension expire on December 8, 2017. All budget proposals exceed the current spending caps, and decisions will be contingent on absenting new legislation to lift the budget caps to delay sequestration in FY 2018 and disaster relief appropriations in the wake of the recent hurricanes.

## Questions and Answers

Dr. Sawyers wondered about the legal authority of the Executive Branch to enforce the 10 percent cap on NIH indirect costs affecting academic institutions that are conducting U.S. government-sponsored

research. Ms. Holohan acknowledged the interest in the extramural community on this issue, but was not aware of an analysis of the legal authorities. She will share with members the links to the language included in the appropriations report.

**V. ADJOURNMENT OF OPEN SESSION—DR. ELIZABETH M. JAFFEE**

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

**VI. 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 2,457 NCI applications were reviewed requesting direct cost support of \$868,546,718.

**VII. ADJOURNMENT—DR. DR. ELIZABETH M. JAFFEE**

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

There being no further business, the 7<sup>th</sup> virtual meeting of the NCAB was adjourned at 2:30 p.m. on Tuesday, 12 September 2017.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Elizabeth M. Jaffee, Ph.D., Chair

\_\_\_\_\_  
Date

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