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

16th JOINT MEETING
of the
BOARD OF SCIENTIFIC ADVISORS AND
NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
12 June 2024

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

BOARD OF SCIENTIFIC ADVISORS and
NATIONAL CANCER ADVISORY BOARD JOINT MEETING
BETHESDA, MARYLAND
Summary of Meeting
12 June 2024

The Board of Scientific Advisors (BSA) of the National Cancer Institute (NCI) and the National Cancer Advisory Board (NCAB) convened for the 16th Joint Meeting on 12 June 2024 in Conference Room TE406, East Wing, Shady Grove Campus, NCI, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public on Wednesday, 12 June 2024, from 8:30 a.m. to 3:52 p.m., and was closed to the public on Wednesday, 12 June 2024, from 4:00 p.m. to 4:53 p.m. The NCAB Chair, Dr. John D. Carpten, Director, Comprehensive Cancer Center, Director and Chief Science Officer, Beckman Research Institute of City of Hope, and the BSA Chair, Dr. Shelton Earp, Director, The University of North Carolina (UNC) Lineberger Comprehensive Cancer Center, and Director, UNC Cancer Care, UNC at Chapel Hill, presided during the open sessions. Dr. Carpten presided during the closed session. In the open sessions, the BSA considered new requests for applications (RFAs), cooperative agreements (Coop. Agr.), requests for proposals (RFPs), and program announcements with special receipt, referral, and/or review (PARs) of new and re-issue concepts presented by NCI program staff.

BSA Members

Dr. Shelton Earp (Chair)
Dr. Chandrakanth Are
Mr. Timothy Babich
Dr. Suzanne J. Baker
Dr. Karen M. Basen-Engquist
Dr. Andrew T. Chan
Dr. Nelson J. Chao
Dr. Gloria D. Coronado
Dr. Mark P. Doescher
Dr. Chyke A. Doubeni
Dr. Jennifer R. Grandis
Dr. Dorothy K. Hatsukami
Dr. Trey Ideker
Dr. Michelle M. Le Beau
Dr. Ana Maria Lopez
Dr. Karen M. Mustian
Dr. Lisa A. Newman
Dr. Raymond U. Osarogiagbon
Dr. Sylvia Katina Plevritis
Dr. Erle S. Robertson
Dr. Cornelia M. Ulrich
Dr. Samuel L. Volchenboum
Dr. Robert H. Vonderheide (absent)
Dr. Richard C. Zellars

NCAB Members

Dr. John D. Carpten (Chair)
Ms. Margaret Anne Anderson
Dr. Nilofer S. Azad
Dr. Anna D. Barker
Dr. Richard J. Boxer
Dr. Luis Alberto Diaz, Jr.
Dr. Andrea A. Hayes Dixon
Ms. Ysabel Duron
Dr. Howard J. Fingert
Dr. Christopher R. Friese
Ms. Julie Papanek Grant
Dr. Amy B. Heimberger
Dr. Nikan Khatibi
Dr. Ana Navas-Acien
Dr. Fred K. Tabung
Dr. Susan Thomas Vadaparampil
Dr. Ashani T. Weeraratna
Dr. Karen M. Winkfield

President's Cancer Panel

Dr. Elizabeth M. Jaffee (Chair) (absent)
Dr. Mitchel S. Berger (absent)
Dr. Carol L. Brown

Alternate *Ex Officio* NCAB Members

Dr. John Gordon, CPSC
Dr. Joseph R. Graber, DOE (absent)
Dr. Michelle Heacock, NIEHS (absent)
Dr. Michael Kelley, VA (absent)
Dr. Richard Pazdur, FDA (absent)
Dr. Craig D. Shriver, DoD (absent)
Dr. Kerry Souza, NIOSH (absent)
Dr. Lawrence A. Tabak, NIH (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. W. Kimryn Rathmell, Director, National Cancer Institute
Dr. Jill S. Barnholtz-Sloan, Acting Director, Center for Biomedical Informatics and Information Technology
Dr. Oliver Bogler, Director, Center for Cancer Training
Dr. Philip E. Castle, Director, Division of Cancer Prevention
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. James H. Doroshow, Director, Division of Cancer Treatment and Diagnosis
Dr. Dan Gallahan, Director, Division of Cancer Biology
Mr. Peter Garrett, Director, Office of Communications and Public Liaison
Dr. Katrina A.B. Goddard, Director, Division of Cancer Control and Population Sciences
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. James Gulley, Acting Co-Director and NCI Clinical Director, Center for Cancer Research
Dr. Ed Harlow, Special Advisor to the NCI Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Kristin Komschlies McConville, Acting Director, Office of Scientific Operations, NCI at Frederick
Ms. Amber Lowery, Acting Executive Officer and Acting Deputy Director for Management, Office of the Director
Dr. Douglas R. Lowy, Principal Deputy Director, National Cancer Institute
Dr. Glenn Merlino, Acting Co-Director and Scientific Director for Basic Research, Center for Cancer Research
Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program
Dr. Diane Palmieri, Director, Center for Research Strategy
Dr. Henry Rodriguez, Director, Office of Cancer Clinical Proteomics Research
Mr. Jeffrey Shilling, Chief Information Officer and Chief of Infrastructure and Information Technology Services Branch, Center for Biomedical Informatics and Information Technology
Dr. Dinah S. Singer, Deputy Director, Science Strategy and Development
Dr. Sanya A. Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology Transfer Programs
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

TABLE OF CONTENTS

WEDNESDAY, 12 JUNE 2024

WEDNESDAY, 12 JUNE 2024

I. CALL TO ORDER AND OPENING REMARKS—DRS. JOHN D. CARPTEN AND H. SHELTON EARP

Dr. John D. Carpten called to order the 16th Joint Board of Scientific Advisors (BSA) and National Cancer Advisory Board (NCAB) meeting. He welcomed members of the Boards, *ex officio* members, President's Cancer Panel members, 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. Carpten reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Dr. H. Shelton Earp and Dr. John D. Carpten called Board members' attention to the future meeting dates listed on the agenda, noting that the 2026 NCAB and BSA dates will need to be confirmed.

Motion. A motion to approve the 2026 NCAB meeting dates was approved unanimously.

Motion. A motion to approve the 2026 BSA meeting dates was approved unanimously.

Motion. A motion to accept the minutes of the 8 February 2024 NCAB meeting was approved unanimously.

Motion. A motion to accept the minutes of the 20 March 2024 BSA meeting was approved unanimously.

II. NCI DIRECTOR'S REPORT—DR. W. KIMRYN RATHMELL

Dr. W. Kimryn Rathmell, Director, NCI, welcomed members of both the BSA and NCAB to the 16th Joint Meeting of these Boards. Dr. Rathmell reported on recent news and updates, the budget outlook, and research and program highlights.

NCI Recent News and Updates. Dr. Rathmell noted that on 10 May 2024, President Joseph R. Biden announced the appointment of new NCAB members. Approvals are pending, and formal introductions will be made at a future meeting. Because the NCI Advisory Boards all have different roles and functions, a holistic orientation for all the Boards will be held later this year. Further details will be forthcoming.

Dr. Rathmell recognized recent accomplishments in professional societies and national cancer organizations. Three NCI Center for Cancer Research (CCR) investigators were elected to the National Academy of Sciences: Dr. Steven Rosenberg, Chief, Surgery Branch; Dr. Giorgio Trinchieri, Chief, Laboratory of Integrative Cancer Immunology; and Dr. Sandra Wolin, Chief, RNA Biology Laboratory. Dr. Rosenberg also received the American Association for Cancer Research (AACR) Award for Lifetime Achievement in Cancer Research. Dr. Jung-Min Lee, Senior Investigator, Women's Malignancies Branch, CCR, was elected to the American Society for Clinical Investigation; Dr. Elaine Jaffe, NIH Distinguished Investigator, Laboratory of Pathology, CCR, and Dr. Yves Pommier, Chief, Developmental Therapeutics Branch, CCR, were elected to the Association of American Physicians. In addition, Dr. Satish Gopal, Director, NCI Center for Global Health (CGH) received the American Society of Clinical Oncology (ASCO) Humanitarian Award for 2024.

Dr. Rathmell informed the Boards about several NCI leadership transitions. In the spring of 2024, Ms. Donna Siegle retired from her role as NCI Executive Officer, and Dr. Tony Kerlavage retired from his position of Director, Center for Biomedical Informatics and Information Technology (CBIIT). Dr. Henry Ciolino, Director, Office of Cancer Centers (OCC), will be retiring at the end of June.

Dr. Rathmell remarked that collectively, these leaders have more than 100 years of NCI experience and noted that NCI has named staff to acting and interim roles. Ms. Amber Lowery is Acting Executive Officer and Acting Deputy Director for Management, Office of the Director. Dr. Jill S. Barnholtz-Sloan is Acting Director, CBIIT. Dr. Krzysztof Ptak, Associate Director, will be Acting Director, OCC. In addition, Dr. Tom Misteli, Director, CCR, stepped down to focus on his research. Dr. James Gulley, NCI Clinical Director, and Dr. Glenn Merlino, Scientific Director for Basic Research, have been Acting Co-Directors of CCR since March 2024, and Dr. Carol Thiele, CCR Deputy Director, will assume this position the end of June 2024. Last, NCI is recruiting for several positions, including the Executive Officer; Director, Office of Scientific Operations at NCI Frederick; and Director, Center for External Affairs (CEA). The new CEA Director will coordinate and connect communications, legislative, and advocacy activities at NCI. Further updates will be provided at a future Board meeting. Regarding new additions to NCI leadership, Dr. Warren Kibbe, Chief Data Officer, Duke Cancer Institute, will be the new Deputy Director for Data Science and Strategy beginning 30 June 2024, and Dr. Shaalan Beg, former Vice President, Oncology Science 37, Fierce Biotech, has been named Senior Advisor for Clinical Research.

NCI is building leadership and leadership communication across the cancer research continuum and, in collaboration with the Frederick National Laboratory for Cancer Research (FNLCR), is hosting the inaugural U.S.-based Black in Cancer (BIC) Conference on 20–21 June 2024 on the NIH Bethesda campus. BIC is a grassroots effort launched in 2020, spearheaded by postdoctoral fellows who identified the need for the voices of Black researchers in cancer. Dr. Rathmell announced an upcoming name change for the Center to Reduce Cancer Health Disparities (CRCHD) to the Center for Cancer Health Equity (CCHE). Dr. Sanya A. Springfield, Director, CRCHD, spearheaded this change. In addition, Dr. Springfield and CRCHD have established a team of Cancer Equity Leaders who will work with the CCHE to promote health equity efforts.

NCI Budget. Dr. Rathmell reminded BSA and NCAB members that NCI submits a Professional Judgment Budget Proposal (also called the Bypass Budget) directly to Congress. The Bypass Budget estimates the cost of the work that NCI is expected to perform. The Annual Plan and Budget Proposal for Fiscal Year (FY) 2023, which the President considers before recommending a budget, was $7.7 billion (B), but the enacted budget was $7.3 B. For the 2024 Professional Judgment Budget, the NCI proposed a budget increase to $9.9 B but received $7.2 B enacted. This is the first decrease in funding that NCI has had in several fiscal years, and the effect is compounded with the ending of the 21st Century Cures Act funding. NCI was allotted an increase to enable its work, but the net decrease was $96 million (M). Inflation has been increasing more than the budget estimates for several years. Already behind, NCI has been asked to implement new initiatives and aims to improve cancer health care.

For the 2025 Professional Judgment Budget, the NCI is proposing a budget increase to $11 B, which reflects inflation and projected costs for such efforts as conducting clinical trials, gathering and analyzing cancer data, and using the data. The FY 2025 President's Budget Proposal, released on 11 March 2024, includes $7.8 B for NCI discretionary spending and proposes $1.4 B of mandatory funding for the Cancer Moonshot℠. With an increase in appropriations, NCI could bring more innovation to clinical trials, begin projects that address environmental health and cancer, and increase efforts in the cancer data space.

NCI has established final paylines for FY 2024: 10th percentile for R01 grants to established and new investigators, 17th percentile for R01 grants to early-stage investigators (ESIs), and 10th percentile for exploratory grants (R21). Noncompeting grants (e.g., Type 2 grants) will be funded at 95 percent of the committed level. Training awards, such as R00, R03, and R50 awards; Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) awards; and P30 NCI-Designated Cancer Centers (Cancer Centers) grants, are exempt from the 5-percent reduction. In addition, from FY 2016 to the present, NCI increased paylines for ESIs R01/R37 by 6 percent, resulting in an increase from the 12th

to 17th percentile. Additional information about NCI budget and appropriations can be found on the NCI website, including the updated Budget and Appropriations webpage and NCI's Bottom Line: A Blog about Grants and More.

The National Cancer Plan (NCP), which was implemented in 2023, is a roadmap for defining the cancer agenda for the nation, focusing on goals to make significant advancements for cancer. The NCP has four health-centered goals, preventing cancer, detecting cancers early, developing effective treatments, delivering optimal care, and four empowering goals, i.e., eliminating inequities, maximizing data utility, optimizing the workforce, and engaging every person. President Biden announced the reignited Cancer Moonshot 2 years ago, with the bold but achievable goals to reduce the U.S. cancer death rate by 50 percent by 2047 and to improve the experience of patients with cancer and their families. Dr. Rathmell highlighted values to guide achieving these overall goals, including talent development, creativity and innovation, empowerment, and fiscal responsibility.

Cancer Research and Program Highlights. Dr. Rathmell noted that NCI has achieved numerous accomplishments in basic science, artificial intelligence (AI) and data science, and translational and clinical research. A detailed list can be accessed online at Cancer Currents: An NCI Cancer Research Blog, but Dr. Rathmell focused on transforming research efforts, including clinical trials. NCI has implemented decentralized clinical trial designs, enabling clinical trials to reach the communities that need them the most. In January 2024, NCI launched the Virtual Clinical Trials Office (VCTO) Pilot Program, which provides an opportunity to incorporate the virtual experience of interaction into the clinical workspace and research environment. In February 2023, NCI launched the Clinical Trials Innovation Unit (CTIU) in collaboration with the U.S. Food and Drug Administration (FDA) and extramural clinical trials leaders, including NCI's National Clinical Trials Network (NCTN) group chairs. The CTIU aims to conduct better, faster, and more accessible cancer clinical trials. The Pragmatica–Lung Cancer Treatment Trial (Pragmatica) was designed to be such a model of accelerating results. The next step for the CTIU is to develop approaches for accelerating clinical trials so that they benefit patients sooner.

The NCI Molecular Analysis for Therapy Choice (NCI-MATCH) trial exemplifies how a decentralized trial can accrue rapidly and address multiple questions in a well-designed manner. Two NCI-MATCH successor trials, MyeloMATCH and ComboMATCH, are underway. Other efforts to collaborate and transform in the clinical research space include the Vanguard Study, which is evaluating a multicancer detection (MCD) blood test to better understand early detection based on blood biomarkers and how to interpret that information. NCI established the Self-Collection for HPV Testing to Improve Cervical Cancer Prevention (SHIP) Trial Network, which aligns with the NCP goal of early detection. The SHIP Trial Network was developed in collaboration with federal and private-sector partners and patient advocacy groups, all addressing disparities. Internationally, NCI is co-sponsoring several clinical trials and is one of seven leading organizations collaborating in the International Agency for Research on Cancer (IARC) G7 Cancer. The focus areas of IARC G7 Cancer are prevention and rare tumors.

On the theme of bringing cancer research to the community, NCI established the BSA *ad hoc* Working Group to Enhance Community Cancer Research and Quality Care to provide guidance on the development of efforts to increase community capacity to conduct cancer research and to enhance the ability to provide high-quality cancer care. The Working Group began its activities in May 2024 and will present a report of its findings at a future Board meeting. Dr. Rathmell acknowledged the BSA and NCAB members participating on this Working Group.

Dr. Rathmell has conducted open calls on social media platforms, requesting feedback on reimaging clinical research to accelerate progress for people with cancer. She also has visited with trainees and advocates during visits to NCI Community Oncology Research Program (NCORP) sites. In July 2024, NCI will host a new Annual Scientific Priorities Retreat to identify the gaps in research and

areas of greatest impact. NCI will be inviting the chairs of its seven Boards to attend, as well as members of the community.

In closing, Dr. Rathmell solicited the BSA and NCAB members to provide input on what areas they would like to hear more or less about, research areas that NCI should prioritize in its RFAs, and how to resource programs during this period of limited funding.

Questions and Answers

Dr. Gloria D. Coronado, Associate Director, Population Sciences, Maynard Endowed Prevention and Control Chair, University of Arizona Cancer Center, is inspired by the new focus on data, data harmonization, and data science and noted that efforts to share data have increased over the years. In this new area of data availability and data sharing, the opportunity exists to incorporate training on using data into both training grants and educational programs at academic centers. She also noted the need to focus on training the next generation of scientists to access and use the available data.

Dr. Andrea Hayes Dixon, Dean, Howard University College of Medicine, Vice President of Clinical Affairs, Chair of Surgery, Howard University Hospital, expressed appreciation to NCI for increasing funding to ESIs, which had been a long-term recommendation of these Boards. She asked what programs were reduced or eliminated because of the budget decrease. Dr. Rathmell explained that funding noncompeting grants at 95 percent allowed NCI to maintain the support of its existing programs.

Dr. Cornelia M. Ulrich, Chief Scientific Officer and Executive Director, Comprehensive Cancer Center, Huntsman Cancer Institute, The University of Utah, lauded NCI on appointing Dr. Kibbe as Deputy of Data Science and Strategy and on establishing the position. She noted the importance of understanding the role of data science and AI in cancer research and called attention to the Common Fund program Complement Animal Research in Experimentation (commonly called Complement-ARIE) as one to leverage.

Dr. Trey Ideker, Professor, Department of Medicine, University of California, San Diego, pointed out the need to educate people entering cancer research from the AI field. He also asked about the balance between the total funding for R01s that an ESI receives versus regular R01s to other investigators. Dr. Rathmell explained that the percentage difference between the two is minimal.

Dr. Samuel L. Volchenboum, Associate Professor of Pediatrics, Director, Pediatric Cancer Data Commons, Pritzker School of Medicine, University of Chicago, noted the ongoing issue of the lack of standardized data in protocols and the significant amount of manual curation required because protocols are written in Microsoft Word. He suggested automating the process of order sets and follow-up studies as well as inclusion-exclusion criteria for clinical trials matching. He encouraged NCI to take a leadership role in resolving these issues. Dr. Rathmell called attention to a 2-day summit on common data elements (Advancing the Use and Development of Common Data Elements [CDEs] in Research) that addressed some of these issues.

Dr. Luis Alberto Diaz, Jr., Head, Division of Solid Tumor Oncology, Grayer Family Chair in Medicine, Department of Medicine, Memorial Sloan Kettering Cancer Center, commented on the importance of decentralized clinical trials to accelerate clinical development in a way that has not before been possible. He observed that barriers with licensing procedures restrict clinicians' ability to discuss or even engage with patients across state lines and hinder data and material transfer agreements. He added that each academic research center has its own unique forms and that approaches to centralize forms and address the barriers he noted could have significant impact on NCI's vision for clinical trials.
Dr. Rathmell, who has advocated for licensure for telehealth, explained that licensing procedures are not ones that NCI can change but can be clear about where that has had an impact for patients.

Dr. Karen M. Mustian, Dean's Professor of Oncology and Surgery, Departments of Surgery, Radiation Oncology, and Public Health Sciences, University of Rochester School of Medicine and Dentistry, noted that discussions have not focused on digital therapeutics and that landscape as it relates to behavior, which is involved in primary prevention, cancer control, and survivorship research across the cancer research continuum. She emphasized NCI thinking about and supporting this growing research area. She pointed out the redundancy among NCORP sites and Cancer Centers in patient registries. She also pointed out the burden of registering patients in the Oncology Patient Enrollment Network (commonly called OPEN) for NCI treatment and NCORP trials, as well as in the OnCore® Clinical Trials Management System to meet the Cancer Center requirements and follow their local metrics. Decreasing the burden at these sites and centers will require addressing the redundancy in the system and making processes interoperable.

Ms. Ysabel Duron, Founder and Executive Director, The Latino Cancer Institute, commented on a common theme among the NIH *All of Us* Research Program consortia of problems enrolling low-literacy and Spanish-speaking participants due to the lengthy consent process. She asked about considering new approaches and better consenting models for different communities. She expressed concern that communities are still not receiving basic cancer screening and are falling even further behind in understanding science and AI and how they intersect their lives. She asked about plans to ensure that routine screenings remain at the forefront in NCI. Dr. Rathmell noted that the NCP is instrumental in keeping the main focus balanced between prevention, early detection, and developing advanced therapeutics. She noted that Pragmatica uses a shorter consent form, which also is available in Spanish. She agreed with the need to consider expanding into other communities.

Dr. Lisa A. Newman, Professor of Surgery, Chief, Division of Breast Surgery, Weill Cornell Medicine, commented on the disproportionately growing incidence and mortality of the burden of cancer in low- and middle-income countries (LMICs). Understanding tumor biology, tumor genomics, and ancestral germline genetics is relevant to our diverse population in the United States, but the picture is mixed in terms of financially supporting global cancer control efforts in LMICs. U.S. dollars are very effective in these countries in providing basic supplies. Training and exchange programs and transporting tumor specimens from one point to another for research can be very expensive. She asked Dr. Rathmell how she sees these issues factoring into NCI's current financially constrained budget environment. Dr. Rathmell noted that these are real issues, but it will not serve NCI well to back itself into a corner. Each organization can enhance the other's knowledge. She added that environmental exposures and climate change will have impacts on cancer from which people will not be immune.

III. LEGISLATIVE REPORT—MS. M.K. HOLOHAN

Ms. M.K. Holohan, Director, Office of Government and Congressional Relations (OGCR), reported on the FY 2024 appropriations bill, the FY 2025 appropriations process, and legislative issues to watch over the next few months. She also described some cancer research-oriented engagement and advocacy by researchers representing AACR and AACI.

The Fiscal Responsibility Act (FRA), passed in June 2023 as part of a bipartisan agreement to raise the debt ceiling, allowed defense discretionary spending to increase by 3 percent (the amount proposed in the President's FY 2024 budget). The FRA stipulated a 1-percent increase in FY 2025 for both defense and nondefense discretionary spending.

The FY 2024 NIH enacted budget provided $7.22 B for NCI and included a $120 million increase to NCI's base budget. However, because the FY 2023 Moonshot allocation of $216 million was the last year of the Cures mandatory funding stream for the Cancer Moonshot , there was a net decrease of $96 million for the overall NCI budget (loss of $216 million offset by the increase to the base budget of $96 million).

Ms. Holohan noted that in April 2024, longtime appropriator Rep. Tom Cole (R-Oklahoma) became the Chair of the House Appropriations Committee. The former Chair, Rep. Kay Granger of Texas, stepped down from the role after the FY 2024 spending bills were completed and announced that she would retire from Congress at the end of her term.

The President's FY 2025 budget proposal was released on 11 March 2024 and allocates $50.1 billion for NIH, an increase of $2.4 billion over the FY 2023 enacted level. The NIH total includes $7.8 billion for NCI discretionary spending (an increase of approximately $500 million over the FY 2023 level) and proposes $1.5 billion in mandatory funds for the Cancer Moonshot.

Department of Health and Human Services (HHS) Secretary Xavier Becerra has testified in support of the FY2025 HHS budget request before multiple House and Senate committees. On May 23, 2024, the Senate Appropriations Labor-HHS Subcommittee held a hearing on the NIH FY 2025 budget request. NIH Director Dr. Monica Bertagnolli testified at the hearing and was joined by Dr. Rathmell and Drs. Jeanne Marrazzo, Director, NIAID, , Dr. Nora Volkow, Director, NIDA, Dr. Richard Hodes, Director, NIA, and Dr. Gary Gibbons, Director, NHBLI. The House Appropriations Committee did not hold an FY 2025 budget hearing for NIH.

Ms. Holohan noted that there is "must-pass" legislation that must be completed in the remainder of the 118th Congress, including the annual farm bill and the National Defense Authorization Act (NDA) There is limited time when both chambers of Congress are in session, with the August recess and just a brief session in September before Election Day on November 5. The outcome of the elections will have an impact on what work Congress completes during the lame duck session (post-Election through December). We anticipate a continuing resolution to begin FY 2025, likely to extend through much of December. It is more likely than not (but far from certain) that the 118th Congress will complete the FY 2025 spending bills, instead of leaving them to the next Congress, and the next Administration, to manage.

Ms. Holohan commented that there has been activity on a number of legislative issues relevant to the cancer community, including telehealth, drug shortages, and clinical trials. Policies extending telehealth put in place by federal agencies during the COVID-19 public health emergency have expired, and legislators are considering permanent solutions. Legislators are also focusing on drug shortages, clinical trials, and the potential use and misuse of AI.

Regarding cancer research, engagement, and advocacy, the Association of American Cancer Institutes(AACI)/AACR had a joint Hill Day in May 2024 which coincided with the release of the 2024 AACR Cancer Disparities Progress Report . NCI's Dr. Sanya Springfield participated in the development of the report, and she represented NCI at a congressional briefing marking the release of the report, along with VCU Massey Cancer Center Director, Dr. Robert Winn and AACR's Dr. Marge Foti.

Dr. Rathmell has been actively engaging the White House and has met with several members of Congress, including Rep. Rosa DeLauro (D-CT), Ranking Member, House Appropriations Full Committee and L-HHS Subcommittee, and Senator Shelley Moore Capito (R-WV, Ranking Member, L-HHS Subcommittee). She also recently met with Rep. Joe Morelle (D-New York), who lost his daughter to breast cancer.

Questions and Answers

Dr. Coronado asked about the Cancer Moonshot and the NCI budget. Ms. Holohan explained that the initial Cancer Moonshot 7-year funding ended with the FY 2023 appropriation.

IV. RECOGNITION OF RETIRING BSA MEMBERS—DR. W. KIMRYN RATHMELL

On behalf of NCI, Dr. Rathmell recognized the contributions made by BSA members whose terms have ended. She expressed appreciation for their service and dedication during the course of their terms. Those retiring BSA members are **Dr. Sylvia Katina Plevritis,** William M. Hume Professor of Biomedical Data Science and of Radiology, Chair, Department of Biomedical Data Science, Associate Director, Cancer AI for the Stanford Cancer Institute, Stanford University School of Medicine, and **Dr. Robert H. Vonderheide,** Director, Abramson Cancer Center, Vice Dean, Cancer Programs, Perelman School of Medicine, Vice President, Cancer Programs, University of Pennsylvania Health System, John H. Glick, MD Abramson Cancer Center Director's Professor, Perelman School of Medicine, University of Pennsylvania.

V. HIGHLIGHTS OF THE CENTER FOR CANCER GENOMICS—DRS. LOUIS STAUDT AND ALEX K. SHALEK

Dr. Louis Staudt, Director, Center for Cancer Genomics (CCG), CCR, NCI, presented on validated human cancer models needed to develop combination targeted therapies efforts for next-generation cancer models. This process involves identifying putative driver genes and essential cancer pathways. More work is needed to ensure the models incorporate comparisons to the primary tumor and clinical annotations, recurrent genetic lesions in human cancer, models for rare cancer subtypes, and recapitulation of phenotypic variation, as well as the subpopulation variation.

The Human Cancer Models Initiative (HCMI) was established in 2016 to create next-generation cancer models that would include full genomic and clinical characterization. HCMI models are annotated with whole-genome sequencing, exome sequencing, RNA sequencing, and methylation analysis. All data were collected with informed consent and include standardized case reports, patient demographics, disease diagnosis, treatment, and outcome information.

HCMI sites were established across the United States, with the goal of developing 1,000 human cancer models. Data from cell lines and biopsies are distributed widely to cancer researchers. The models are profiled across sites in a uniform manner. Data management is coordinated through the NCI Genomic Data Commons, with support from the Frederick National Laboratory for Cancer Research and Information Management Services, Inc. Thus far, HCMI has developed 743 models, of which 307 have been launched through the American Type Culture Collection (more commonly referred to as ATCC). Top tumor types include brain, pancreas, colon, esophagus, skin, rectum, stomach, connective tissue, biliary tract, and lung, Dr. Staudt presented data showing that HCMI models match the transcriptional state of HCMI and The Cancer Genome Atlas (TCGA) tumors.

Dr. Staudt explained that targeted cancer monotherapies have shown limited success, but resistance emerges frequently. Combination therapies have been largely empirical and not based on deep knowledge of regulatory networks. Current models of signaling and regulatory networks in cancer do not account for cancer type–specific epigenetic differences, influences of oncogenic alterations, and network redundancy and complexity. The models typically are descriptive, but they generally have not been predictive and are static, not dynamic, over time. Dr. Staudt underscored the importance of understanding networks to propose and test combinations effectively.

Dr. Staudt proposed a "functional TCGA initiative" that would include hubs of excellence for CRISPR, proteomics, single cells, chemical biology, and cell biology. One main activity of this effort would be a coordinated set of experiments in which an agreed-upon set of models would be perturbed with a set of perturbagens, and data would be collected in a multidimensional fashion and fed into computational hubs. The ultimate goal would be to develop next-generation models of cancer regulatory networks. Future deliverables would include reference perturbation data sets, detailed wiring diagrams of

intercellular networks, synthetic lethal relationships with clinically available drugs, new targets for therapeutic development, combination drug strategies, and Phase 1 trials.

Dr. Alex K. Shalek, J. W. Kieckhefer Professor, Institute for Medical Engineering and Science and the Department of Chemistry, Director, Health Innovation Hub, Massachusetts Institute of Technology, spoke on the relevance of cell state for cancer research. He emphasized the importance of moving beyond a paradigm focused on DNA to consider integrative RNA phenotypes in selecting therapies for cancers. Currently, DNA mutations serve as the cornerstone of precision medicine. A low rate of response, however, has been recorded with this approach; only 40 percent of patients have an actionable alteration, and less than 5 percent show a response. Dr. Shalek emphasized the importance of targeting cancer cells, not just cancer mutations. Components for consideration include epigenetics and the microenvironment, which lead to changes in gene expression.

Dr. Shalek's team has developed approaches to examine cells at high resolution to profile the cell state. These technologies can capture multiple molecular features, including cell surface proteins, intracellular proteins, mRNA, DNA methylation, genomic sequences, histone modifications, chromatin accessibility, and spatial positions. With this approach, the team has developed an integrated pipeline to define and model cell states; a proof of concept has been developed for pancreatic cancer. These findings provide key insights into drug responses.

Dr. Shalek proposed state-specific screening to capture critical features for drug response. He shared clinical data indicating an association between state and response to chemotherapy. His current efforts are focused on extending the framework to multiple cancer types. His team is working in collaboration with others at NCI to examine different transcriptional programs that can be identified across multiple cancers. Current data suggest that transcriptional state can be used to predict which particular perturbations will show sensitivity. Future efforts include benchmarking the cell state, vetting new biomarkers, and identifying pan-cancer and disease-specific targets.

Questions and Answers

Dr. Ideker commented that the true interrelation between transcriptomics and genomics is not fully understood. More work is needed to understand these dynamics. He suggested clearly defining the goals of this effort, as well as its connections to similar ongoing projects. Dr. Staudt responded that the projects would focus on a specific cancer, with an initial effort to redefine the regulatory networks in that cancer type. The ultimate goal of this effort is to develop new therapies; other outcomes include gaining basic scientific knowledge and better understanding networks.

Dr. Shalek added that his team is interested in understanding how multiple different cell intrinsic and extrinsic factors integrate to defined states. He underscored the importance of understanding the influence of genetics in this context and agreed to discuss this topic further. He emphasized that more experiments are needed to fully understand these dynamics.

NCAB Chair, Dr. Carpten, highlighted the importance of considering the characteristics of the patients from whom these models were derived, as well as the complexity of the models. Dr. Andrew T. Chan, Chief, Clinical and Translational Epidemiology Unit, Massachusetts General Hospital (MGH), Director of Epidemiology, MGH Cancer Center, Daniel K. Podolsky Professor of Medicine, Harvard Medical School, added that researchers could also profile precancerous or normal tissue from the same patient, with a goal of developing prevention models. Dr. Staudt agreed and underscored the importance of controls in model building.

Dr. Ashani T. Weeraratna, Bloomberg Distinguished Professor of Cancer Biology, E.V. McCollum Chair of Biochemistry and Molecular Biology, Johns Hopkins Bloomberg School of Public Health, Co-Program Leader, Cancer Invasion and Metastasis, Sidney Kimmel Cancer Center, Johns

Hopkins School of Medicine, remarked that the team's technologies and tools are tumor-centric; she inquired about other factors that are being considered. Dr. Staudt noted that other factors for consideration include cytokines and cell types through mixed cultures.

Dr. Karen M. Winkfield, Executive Director, Meharry–Vanderbilt Alliance, Ingram Professor of Cancer Research, Professor of Radiation Oncology, Vanderbilt University School of Medicine, inquired about the ancestry of the samples in this effort and asked whether this factor has been considered in analysis. She also wondered how methylation status could affect perturbation. Dr. Staudt noted that the program has deliberately sought extra funding from the NCI Equity Council to develop new models that include communities that are underrepresented in research. He agreed on the importance of profiling methylation status. Dr. Shalek agreed on the importance of these points and highlighted the need to engage scientists from multiple communities in such discussions.

Dr. Plevritis suggested considering how AI and other data science tools can be applied for model development efforts and underscored the value of leveraging existing data when building out the initiative at scale.

VI. NCI VIRTUAL CLINICAL TRIALS OFFICE PILOT PROGRAM—DRS. JAMES H. DOROSHOW AND AUGUSTO OCHOA

Dr. James H. Doroshow, Director, Division of Cancer Treatment and Diagnosis (DCTD), NCI, presented an overview of NCI's Virtual Clinical Trials Office (VCTO) Pilot Program. He began by sharing data depicting the effects of the COVID-19 pandemic on clinical trial capacity. Challenges in this context include research staff capacity, patient volume, willingness to participate, and adherence to clinical trial requirements. As a result, trial enrollment numbers have not returned to pre-pandemic levels, particularly for investigator-initiated trials.

Dr. Doroshow proposed that NCI could assist the Cancer Centers and other sites that play a critical role in accrual by hiring staff to undertake the portfolio of services that clinical trial offices provide (e.g., screening, entry, informed consent, data management, coordination of study visits, regulatory support, adverse event reporting). His team conducted a survey among Cancer Centers to assess their specific needs. Six sites were selected to initiate the program in fall 2023, reflecting their need for the services, as well as their potential to accrue underserved and rural populations. These sites included three Cancer Centers and three NCORP sites. To date, 4,221 patients have been screened, 88 eligible patients have been identified, and 24 accruals have been facilitated.

Lessons learned during the pilot include the importance of establishing sequential and concurrent processes (e.g., execution of memorandum of understanding, creation of site accounts for pilot staff), obtaining access (e.g., electronic health records [EHRs], third-party administrators), and recognizing that no two clinical sites are the same. Future efforts related to these lessons can be grouped within the areas of site engagement, preparation, execution, access, and support. Future activities in this effort include expanding services to the six original sites, adding at least three more lead sites, streamlining onboarding processes, and adding long-term follow-up services.

Dr. Augusto Ochoa, Deputy Director, Louisiana State University–LCMC Health Cancer Center, described his site's experience within the program. He first underscored NCORP's importance in enhancing clinical trial participation in underserved regions. The Gulf South Minority Clinical Trials Network, which is funded by NCORP, includes 49 clinical sites throughout the Gulf South region. This effort has helped increase the number of patients, in particular, patients from minority populations, participating in clinical trials. Dr. Ochoa noted that trial recruitment in rural communities is a significant challenge and reflects difficulties in hiring and retaining staff. Additionally, travel is a challenge for patients.

The team devised an approach to bring virtual research support to the sites. They obtained permission to access EHRs. Nurses who were located in New Orleans, Louisiana, screened clinics virtually, identified patients who were potentially eligible for clinical trials, and discussed those patients with the onsite physician. The physician then spoke with the patient about participating in a clinical trial. Patients who consented were connected with a virtual research nurse, who carried out the enrollment procedures. This approach was tested in two sites: a small rural hospital and a small academic practice at a suburban hospital not associated directly with a Cancer Center. The team learned that patient screening could be performed in advance. Dr. Ochoa also noted that capabilities for virtual consultations were expanded during the COVID-19 pandemic. He emphasized that overall, these efforts have attracted the attention of the physicians at the sites, who rapidly increased the number of clinical trials that they wanted to open.

Since its initiation, the program has screened more than 2,300 patients and enrolled about 140 patients. These efforts have been essential for establishing clinicians' interest and building trust with rural sites and community clinics. Dr. Ochoa emphasized the importance of working closely with each site to understand its unique needs. The virtual nurse meets weekly with the physicians, and quarterly meetings are held in person. The team also is collecting data to refine the process. Dr. Ochoa underscored the value of NCORP's support in these efforts. He emphasized that many cancer patients are seen and treated at community practices and that focused efforts are needed to address the challenges that they face.

Questions and Answers

Dr. Susan Thomas Vadaparampil, Associate Center Director, Community Outreach, Engagement, and Equity, Professor, Department of Health Outcomes and Behavior, Moffitt Cancer Center, asked how the team is selecting sites to participate. Dr. Doroshow explained that a survey was conducted among the NCORP sites, with a focus on data management, rural or underserved patient populations, protocols, and information technology systems. The team created a grid to analyze the responses and prioritize sites. Dr. Doroshow emphasized that rural and underserved populations were an area of focus.

Ms. Duron asked whether the team considered developing a community health care workforce that addresses cultural and language differences. Dr. Ochoa agreed on the importance of this point. He explained that the team has initiated conversations with community outreach programs that oversee screening and early detection programs for breast, cervical, and colorectal cancers; the goal is to help community educators serve as facilitators of this process.

In response to questions from Dr. Ulrich about incorporating patient education and considering AI models in this context, Dr. Doroshow noted that the program is developing educational materials for patients, nurses, and providers. He also highlighted the importance and complexity of AI models and emphasized the value of human support and knowledge in providing these services.

Dr. Howard J. Fingert, Vice President, Medical-Oncology, ONO PHARMA USA, Inc., inquired about efforts focused on adherence, retention, and completion. Dr. Doroshow confirmed that these metrics are being collected through data management efforts.

Dr. Raymond U. Osarogiagbon, Adjunct Research Professor, Department of Medicine, Vanderbilt University, Chief Scientist, Baptist Memorial Health Care Corporation, emphasized the importance of addressing institution- and provider-level barriers. Dr. Osarogiagbon asked whether the Extension for Community Healthcare Outcomes (ECHO®) model could be applied in this context. Dr. Ochoa affirmed that the ECHO model was considered at the beginning of the development process. He underscored the importance of working with sites to gain trust and identify priorities.

In response to a question from Dr. Hayes Dixon about the diversity of the virtual research nurses of the communities being served, Dr. Ochoa explained that the sites work closely with the communities served and understand their needs, and the nurses are selected by those sites. When asked about the nurses' flexibility in terms of interactions occurring at home with the patient or via cellphone, Dr. Ochoa emphasized that follow-up communication with the nurses is essential.

Dr. Ana Maria Lopez, Professor, Medical Oncology and Integrative Medicine and Nutritional Sciences, Director, Integrative Oncology, Associate Director, Diversity, Equity, and Inclusion, Sidney Kimmel Cancer Center, NCI Designated, Thomas Jefferson University, spoke on the importance of dissemination in this effort and inquired about resistance faced in the context of clinical trials. Dr. Ochoa remarked on the importance of educating physicians on these topics. He emphasized that clinical trials have become increasingly recognized as a part of treatment planning, but physician training is needed in this context.

VII. ONGOING AND NEW BUSINESS—DRS. JOHN D. CARPTEN AND SHELTON EARP

NCAB Subcommittee on Clinical Investigations. Dr. Nilofer S. Azad, Professor of Oncology, Co-Director, Developmental Therapeutics Program, Co-Leader, Cancer Genetics and Epigenetics, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, and Chair of the NCAB Subcommittee on Clinical Investigations, presented the report of 11 June 2024 meeting. Dr. Azad reported that the Subcommittee heard about Pragmatica in a presentation by Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program (CTEP), DCTD, NCI. Dr. Mooney provided an update on an interim analysis of the trial and presented the results of the survey administered in the NCTN in 2022. The Subcommittee reiterated its prior discussion on improvements of the NCTN and enrollment and funding challenges. During this meeting, the Subcommittee learned how Pragmatica (a collaboration with industry partners Eli Lilly & Co. and Merck) was designed to address these key barriers and to answer a question important to the research and clinical treatment communities, but it focuses on an area regarding patient treatment that is not being addressed by industry. The Subcommittee was updated on Pragmatica's overall design, randomization, and simplified design, including the simplified consenting process. The Subcommittee was impressed that Pragmatica is achieving its goal of accruing a more diverse patient population. Dr. Azad noted that the Subcommittee discussed focusing efforts on important scientific and clinical questions and, at the same time, building on the diversity of the existing studies. They also discussed the challenges of a pragmatic study, developing new testable treatment options, and involving a steering committee to assist in understanding key scientific and clinical questions.

Questions and Answers

Dr. Christopher R. Friese, Elizabeth Tone Hosmer Professor of Nursing, Director, Center for Improving Patient and Population Sciences, Associate Director for Cancer Control and Population Sciences, University of Michigan Rogel Cancer Center, University of Michigan, suggested embedding an evaluation to determine the components that are accelerating accrual in Pragmatica, which could serve as a roadmap for future studies.

Dr. Osarogiagbon commented on embracing the innovation in trials being introduced in the field, such as in Pragmatica, moving away from long-standing practices, and fully understanding pragmatic trials. Dr. Rathmell noted that NCI hosted a CTIU retreat to better understand what has and has not worked and what needs to be improved. The FDA was well represented at this retreat.

Dr. Vadaparampil suggested exploring ways to partner with implementation scientists at NCI or externally to conduct a correlative or parallel study of what works as new clinical sites are activated in Pragmatica.

Dr. Chyke A. Doubeni, Professor, Department of Family and Community Medicine, Associate Director, Diversity, Equity, and Inclusion, The Ohio State University Comprehensive Cancer Center, Chief Health Equity Officer, Wexner Medical Center, Director, Center for Health Equity, The Ohio State University, noted the challenge of building on Pragmatica's platform as trial complexity increases, for example, regarding imaging data. He commented on having a plan to systematically address such challenges.

Dr. Chan highlighted the challenge of balancing the complexity of some trials with the pragmatic design, particularly regarding biospecimens and biorepositories. He commented on the need to consider the value of these biospecimens and how they inform future science rather than perceiving their collection as barriers.

Motion. A motion to accept the report of the 11 June 2024 NCAB Clinical Investigations Subcommittee meeting was approved unanimously.

NCAB *Ad Hoc* Subcommittee on Population Science, Epidemiology, and Disparities. Dr. Winkfield, Chair of the NCAB *ad hoc* Subcommittee on Population Science, Epidemiology, and Disparities, presented the report of the 11 June 2024 meeting. Dr. Winkfield noted that the Subcommittee briefly reviewed the charge and spent the bulk of its time discussing ongoing work at the NIH relevant to this group. During the meeting, Dr. Philip E. Castle, Director, Division of Cancer Prevention, and Executive Secretary, provided an update on NCI investments in blood-based MCD technologies, the Cancer Screening Research Network (CSRN), and the Vanguard Study. The Subcommittee discussed the challenges of using MCD tests and how NCI can serve as an honest broker. Dr. Castle, who has been doing this type of work for decades, shared how he would address some of the challenges associated with MCD technologies. Dr. Springfield discussed the reorganization, current programs, and initiatives of CRCHD. The Subcommittee was informed of CRCHD's upcoming name change to CCHE and was updated on the center's new initiative, the Cancer Equity Leaders. Dr. Springfield provided a detailed overview of CRCHD's programs and initiatives, including the Continuing Umbrella of Research Experiences (CURE) program, which offers unique training and career development opportunities to enhance and increase diversity in the cancer and cancer health disparities research workforce. The Subcommittee briefly discussed its priorities and agenda moving forward; a survey will be developed and circulated to the members for their input.

Questions and Answers

Dr. Doubeni noted the gap in the delivery of cancer prevention and detection and highlighted the opportunity for national screening of adults for social determinants of health (SDoH) in all hospitals and for improved, safer, and more effective cancer detection.

Dr. Anna D. Barker, Chief Strategy Officer, Ellison Institute for Transformative Medicine, University of Southern California, asked whether the MCD tests being evaluated were laboratory-developed tests and how the FDA is regulating these tests. Dr. Barker commented on financial toxicity to patients as an unintended consequences of MCD technologies. Dr. Richard Pazdur, Director, Oncology Center of Excellence (OCE), FDA, was not present at the meeting. A representative from the OCE attending on Dr. Pazdur's behalf noted the recent FDA rule on laboratory-developed tests.

Dr. Ideker noted the challenge in using MCD tests because of the tendency in the field to not release the feature sets and the molecular markers that are being combined.

Dr. Ulrich commented that an analysis of the financial impact of the MCD tests on the health care system would be helpful.

Ms. Duron suggested developing educational toolkits on MCD tests to be widely disseminated to help the community decide when to use these tests.

Motion. A motion to accept the report of the 11 June 2024 NCAB *ad hoc* Subcommittee on Population Science, Epidemiology, and Disparities meeting was approved unanimously.

NCAB *Ad Hoc* Subcommittee on Experimental Therapeutics. Dr. Richard J. Boxer, Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles, Chair of the NCAB *ad hoc* Subcommittee on Experimental Therapeutics, presented the report of the 11 June 2024 meeting. Dr. Boxer thanked NCI for reconvening this group and the Boards for their support. The Subcommittee worked over the past 6 months to develop a broader mission statement that would help NCI today and into the future and one that considers training and other ways that Subcommittee could serve the cancer community. Dr. Boxer noted that in addition to updating the mission statement, the Subcommittee decided that it would be valuable to mobilize and utilize the advice, expertise, knowledge of the NCAB members to address experimental therapeutics, which Dr. Rathmell endorsed. The Subcommittee is planning to host a workshop bringing together the relevant partners of the NCAB, NCI, academia, and the private sector to discuss and develop three to four actionable items for the future of therapeutics for the patient. The Subcommittee discussed focus areas of interest and future agenda items.

Questions and Answers

Dr. Boxer clarified that the Subcommittee is an *ad hoc* advisory subcommittee to the NCI Director, NCI, and NCAB and will generate a report of its recommendations but will not be the ones performing the experimental therapeutics work.

Dr. Friese suggested inviting patient advocates and representatives of the broader cancer advocacy community to this experimental therapeutics workshop.

Motion. A motion to accept the report of the 11 June 2024 NCAB *ad hoc* Subcommittee on Experimental Therapeutics meeting was approved unanimously.

Motion. A motion to accept the revised mission statement of the NCAB *ad hoc* Subcommittee on Experimental Therapeutics was approved unanimously.

Future Agenda Items. The BSA and NCAB members suggested several agenda items for future meetings, including the following: an update on how NCI communicates with the public, including the plan in place and projects that focus on bringing together community health workers; a report on NCI-Designated Cancer Centers' engagement with communities and the metrics of performance; an update on recent major investments in Cancer Moonshot–funded Cancer Immune Monitoring and Analysis Centers (CIMACs) and their efforts to validate biomarkers for optimizing immuno-oncology therapies; a review of cancer control efforts ongoing in NCI's NCTN and clinical trials groups and NCORP Research Bases; and a discussion of ways to systematically address the financial toxicity experienced by patients receiving cancer care. Members were asked to forward any additional suggestions for potential future agenda items to the respective Board chairs and Dr. Gray.

VIII. RFA/COOP. AGR., RFP, AND PAR CONCEPTS—NEW—NCI PROGRAM STAFF

Division of Cancer Control and Population Sciences

The Confluence of Cancer and HIV Stigma in HIV-Positive Individuals Diagnosed with Cancer (New RFA)—Dr. Robin Vanderpool

Dr. Robin Vanderpool, Chief, Health Communications and Informatics Research Branch,

DCCPS, NCI, presented a new RFA concept on The Confluence of Cancer and HIV Stigma in HIV-Positive Individuals Diagnosed with Cancer. HIV remains a burden worldwide. Globally, 39 million people are living with HIV, and approximately 1.3 million new cases are diagnosed annually. Among people with HIV, the elevated cancer risk is influenced by multiple factors, including coinfection with oncogenic viruses; a higher prevalence of behavioral risk factors, such as tobacco use; increased life expectancy and the development of more common cancers; and sociocultural factors and barriers to care that contribute to increased risk and poor outcomes for both diseases. Globally, people with HIV and cancer experience worse cancer survival and increased cancer mortality rates, which is attributed to both patient–provider and system-level factors. These include comorbidities and immunosuppression; treatment and survivorship disparities; provider and health system discrimination; poor care coordination; and the cumulative burden of coping with and managing both HIV and cancer.

Dr. Vanderpool explained that embedded within the distinct experience of a dual diagnosis of cancer and HIV is the social phenomenon of stigma. In the context of this concept, stigma is defined as a "well-documented social process characterized by negative beliefs, attitudes, and stereotypes associated with specific attributes or characteristics, such as being diagnosed with HIV or cancer that leads to blame, devaluation, discrimination, and social exclusion." People with HIV and cancer experience stigma associated with both HIV and cancer. Traditionally, HIV stigma and cancer stigma have been studied independently. Research on the confluence of the two stigmas for people with both HIV and cancer is limited.

The purpose of this RFA is to expand current understanding of the confluence of cancer stigma and HIV stigma among people living with both cancer and HIV. The aim is to assess the impact of these two converging stigmas; leverage stigma reduction interventions at multiple levels to intervene on modifiable mechanisms of stigma that contribute to negative cancer outcomes; and promote research in diverse domestic and international contexts, focusing on regions where the HIV-cancer burden is elevated.

Research topics responsive to this RFA include longitudinal studies to assess the impact of cancer stigma and HIV stigma on cancer outcomes; studies that investigate factors that exacerbate or mitigate the association of the dual stigmas with cancer outcomes; and studies that develop and evaluate stigma-reduction interventions implemented at individual, provider, community, and/or structural levels. NCI is proposing two dedicated RFAs to support a bolus of transdisciplinary research projects led by domestic and international investigative teams using the R01 and R21 funding mechanisms. NCI-appropriated AIDS funds, as established by the NIH Office of AIDS Research (OAR), will support this research. This concept has been reviewed by OAR and deemed AIDS-aligned.

Subcommittee Review. Dr. Doubeni expressed the Subcommittee's enthusiasm and strong support for the concept, which is addressing an underexplored area of cancer research. The Subcommittee appreciates NCI staff responses to their questions about the scope, consideration of other stigmatized identities, outcomes of interest, and RFA promotion.

The first-year cost, for this one-time issuance, is estimated at $6 M for five to six R01 awards and three R21 awards, with a total cost of $27 M for 5 years.

Questions and Answers

Dr. Winkfield emphasized the importance of addressing the intersectionality of stigma and asked about the prevalence of cancer in individuals with HIV, both in the United States and globally.
Dr. Vanderpool explained that in 2020, in the United States, an estimated 8,000 cases of HIV and cancer were reported. In 2010, the leading cancers were Kaposi sarcoma and non-Hodgkin's lymphoma; by 2030, the trend is projected to transition to prostate, lung, and liver, all attributable to aging and longer life expectancy. Assessing the prevalence globally is more challenging due to cancer surveillance

difficulties. It has been reported that cervical cancer and HIV co-occurrence, as well as Kaposi sarcoma and HIV prevalence, is primarily concentrated in eastern and southern Africa.

Dr. Fingert noted the opportunity to understand the sources independent of stigma that are relevant to the poor outcomes in this population. He commented that a diagnosis of HIV (past or present) often remains an exclusion criteria in industry clinical trials but to a lesser extent in NCI trials. He attributes this to a misunderstanding of the prognostic outcomes and how to best interpret them. He emphasized that understanding the co-factors that are relevant to and different from the stigma may be informative to allow more patients into industry trials.

Dr. Vadaparampil pointed out that NCI, by providing administrative supplements on this topic, has built a cadre of investigators who would be interested in applying. Dr. Vanderpool expressed appreciation to NCI's CGH for providing those supplements for two fiscal years. In 2022, the CGH hosted a global cancer stigma conference with more than 100 participants from around the world. NCI also has been in contact about this opportunity with Fogarty International Center and National Institute of Mental Health colleagues who work in the HIV space.

Motion. A motion to approve the DCCPS' new RFA entitled "The Confluence of Cancer and HIV Stigma in HIV-Positive Individuals Diagnosed with Cancer" was approved unanimously.

Scaling-Up and Maintaining Evidence-Based Interventions to Maximize Impact on Cancer (SUMMIT) (New RFA)—Dr. David A. Chambers

Dr. David A. Chambers, Deputy Director, Implementation Science, DCCPS, NCI, presented a new RFA concept for Scaling-Up and Maintaining Evidence-Based Interventions to Maximize Impact on Cancer (SUMMIT). Dr. Chambers informed members that the goals of SUMMIT are to: 1) advance the science of scale-up and sustainment to increase the widescale, long-term delivery of effective cancer-related interventions; 2) reduce cancer-related deaths by significantly increasing lung cancer screening among populations at high risk for lung cancer and tobacco use treatment services among cancer survivors; and, 3) develop generalizable knowledge on how to scale-up and sustain effective cancer-related interventions.

Dr. Chambers highlighted that through the Cancer Moonshot and other initiatives, the field has built capacity and knowledge in various cancer control intervention areas, which positions it for a concept such as SUMMIT. Opportunities to scale up will align with the NCP and Cancer Moonshot goals to reduce cancer mortality by 50 percent over 25 years. To that end, tobacco-related care continues to provide examples where scale-up and sustainment can translate into the desired reductions in mortality. The U.S. Preventive Services Task Force recommended expanding the eligibility for lung cancer screening, but the uptake ranges from 4 percent to 28 percent. Cancer Intervention and Surveillance Modeling Network (or CISNET) modeling has demonstrated that increased lung cancer screening can save thousands of lives. The Cancer Center Cessation Initiative (C3I), which was funded by the Cancer Moonshot, implemented evidence-based tobacco use treatment for cancer patients.

SUMMIT will consist of two RFAs, both of which will concentrate on system-level strategies to scale up and sustain the respective interventions within health care clinics, with the opportunity for collaboration across studies. This research will leverage existing programs, including the NIH Pragmatic Trials Collaboratory. SUMMIT trials will activate across a minimum of 60 sites per trial for population-level impact. An example study would be a cluster randomized controlled trial with 100 Federally Qualified Health Center clinics to test comparative effectiveness of two system-level strategies to scale up and sustain lung cancer screening. The outcome would be a system-level guideline concordant care of lung cancer screening measured at 12, 18, and 24 months. NCI proposes using the two-phased UG3/UH3 funding mechanism for this research.

Subcommittee Review. Dr. Coronado expressed the Subcommittee's support for the innovative concept and noted that it has the potential to advance implementation science. She also noted that, unlike other implementation science research that primarily focuses on the implementation aspect, this concept addresses more of the scale-up and sustainability components. Combining lung cancer screening with tobacco use treatment is anticipated to be of high impact, especially as it aligns with the national goals of reducing cancer mortality. Additionally, the Subcommittee noted that the UG3/UH3 mechanism is appropriate for this research because it gives NCI a chance to influence, as well as potentially discontinue, studies that may not be meeting milestones in the first few years. She also noted that the Subcommittee commends NCI for demonstrating the commonality between the two RFAs regarding the science and for leveraging the NIH Pragmatic Trials Collaboratory, which has been a well-run and successful center. Even so, the Subcommittee expressed concern that the 60-clinic rule might be challenging if randomizing to 30 sites in each arm of the trial, especially in less-resourced sites. They encouraged collecting specimens to examine germline genetic ancestry and associations with increases in the sensitivity to tobacco-related lung cancer.

The first-year cost, for the one-time issuance, is estimated at $4.8 M for six UG3/UH3 awards, with a total cost of $42.2 M for 4 years.

Questions and Answers

Dr. Friese observed that 60 sites would be twice the median number of sites of the current portfolio but that the direct-cost budget per project has not been doubled accordingly. He suggested assessing the diversity of the 60 clinical sites, the adequacy of their representation of populations, and their capacity to recruit in a specific geographical location, which could vary by site.

Dr. Dorothy K. Hatsukami, Forster Family Chair in Cancer Prevention, Masonic Cancer Center, Professor, Department of Psychiatry and Behavioral Sciences, University of Minnesota, suggested examining the unintended consequences of launching a lung cancer screening trial and culturally tailored smoking cessation interventions for cancer survivors who are highly dependent on cigarettes or tobacco products.

Dr. Osarogiagbon noted that the American Cancer Society's National Lung Cancer Roundtable has recognized the gap in lung cancer screening as an implementation science problem, which speaks to the vast opportunity that this SUMMIT RFA represents.

Dr. Karen M. Basen-Engquist, Professor, Department of Behavioral Science, Division of Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center, asked how SUMMIT would interact with the existing C3I centers. Dr. Chambers explained that the C3I centers have practice laboratories and networks of particular sites. The plan is to leverage those networks and explore proposing a clinical trial.

Motion. A motion to approve DCCPS's new RFA entitled "Scaling-Up and Maintaining Evidence-Based Interventions to Maximize Impact on Cancer (SUMMIT)" was approved with 21 ayes, 1 nay, and 0 abstentions.

Office of the Director

Social Determinants of Health (SDoH) and Quality of Care Contributors to Cancer Disparities in People with HIV (RFA/Coop. Agr.)—Dr. Rebecca Liddell Huppi

Dr. Rebecca Liddell Huppi, Program Director, Office of HIV and AIDS Malignancy (OHAM), NCI, presented a new RFA concept to support Social Determinants of Health (SDoH) and Quality of Care Contributors to Cancer Disparities in People with HIV, which was developed in collaboration with DCCPS, DCP, and DCTD. Dr. Huppi noted that 1.2 million people in the United States have HIV, with

32,000 new diagnoses in 2021. The majority of the new diagnoses were highly concentrated in 48 counties; Washington, D.C.; and San Juan, Puerto Rico. More than 52 percent of new diagnoses occur in the South. Cancer is the most common cause of morbidity and mortality in people with HIV in the United States.

Compared with people who do not have HIV, people with HIV have lower cancer screening rates, are less likely to receive cancer treatment, have a more advanced cancer at diagnosis, and have higher cancer mortality. Research has shown that contributions to these disparities can be patient-driven, provider-driven, and health systems–related. Most of the research on SDoH and HIV care outcomes shows associations between a single factor (e.g., poverty) and clinical outcomes. Given that SDoH are complex, intersecting, and reinforcing, NCI recognizes a need to develop multilevel approaches to improve cancer prevention in and coordinated care of people with HIV.

The main scope of this RFA is research to better understand how multiple SDoH interact and contribute to health disparities in cancer prevention, diagnosis, treatment, and outcomes in people with HIV. Health disparities are further amplified in people with HIV, who often are members of multiple intersecting, underserved, and marginalized groups, including low socioeconomic groups, underrepresented racial and ethnic populations, sexual and gender minorities, and those who live in geographically isolated areas.

CRCHD, OHAM, the Division of Cancer Biology (DCB), and OCC have been collaborating on efforts that have informed the development of initiatives addressing disparities and SDoH research in cancer in people with HIV, including developing administrative supplements to the P30 Cancer Center core grants and developing the RFA "Basic/Translational Research on Health Disparities in Underrepresented People Living with HIV and Cancer."

A portfolio analysis of FY 2023 revealed four grants evaluating SDoH in HIV and cancer, indicating limited research in this area. OAM and CRCHD will logistically manage this RFA, which will use the U01 mechanism. NCI-appropriated AIDS funds, as established by OAR, will support this research. This concept has been reviewed by OAR and deemed AIDS-aligned.

Subcommittee Review. Dr. Lopez expressed the Subcommittee's enthusiasm and support for the concept. The Subcommittee was impressed with the scope of the RFA to address SDoH across the cancer research continuum and the level of collaboration in this research effort.

The first-year cost, for the one-time issuance, is estimated at $3 M for four U01 awards over three receipt dates, with a total cost of $45 M for 5 years.

Questions and Answers

Dr. Doubeni noted that conceptual models on SDoH as proposed in this RFA could leverage other entities, such as the World Health Organization Conceptual SDoH framework.

Dr. Hayes Dixon emphasized that SDoH must be broadly defined in the RFA. Dr. Winkfield concurred and noted that explicit language must be used in the RFA to emphasize that the focus is on research to address health-related social needs.

Motion. A motion to approve the OD's new RFA/Coop. Agr. entitled "Social Determinants of Health (SDoH) and Quality of Care Contributors to Cancer Disparities in People with HIV (U01)" was approved unanimously.

The NCI Pathway to Independence Award (K99/R00) (New PAR) —Dr. Michael Schmidt

Dr. Michael Schmidt, Program Director, Cancer Training Branch, Center for Cancer Training (CCT), NCI, presented a new PAR concept to establish the NCI Pathway to Independence Award (K99/R00). The objective is to help outstanding postdoctoral researchers complete, in a timely manner, needed mentored career development and transition to independent tenure-track or equivalent faculty positions. Applicants for the K99 award must be in a mentored, non-independent position and must have no more than 4 years of postdoctoral research training experience.

NCI supports all areas of cancer research and typically receives 200 applications per year. NCI investments over the past 5 years have been consistent, at around $6.5 M per year. The success rate for the K99 award is 15 percent. A recent evaluation of the outcomes for the NCI parent K99/R00 program, suggests that this award is working as intended. The evaluation also revealed that the program facilitates the successful transition of postdoctoral scholars to independence and is enhancing the likelihood of K99 awardees to secure R01 or R01-like grant support. Approximately 90 percent of K99 awardees transition to independence, and 65 percent are able to secure R01-equivalent grant support. Neither sex/gender nor race/ethnicity have significant impact on the transition rates or on the R01 award rates.

NCI CCT conducted a survey interview of K99 applicants and K99 awardees, as well as NCI R01 ESIs who never applied for a K99, to better understand what is working well with this mechanism and to identify any areas of concern. The majority of responders indicated that the K99/R00 was instrumental in their transition to independence and helped them to establish a productive independent research program.

A common theme among K99 awardees was that the limit of no more than 4 years of postdoctoral experience was discouraging high-impact research projects and biased the K99/R00 program to candidates applying from well-resourced laboratories. They also expressed concern that the 4-year cutoff would penalize researchers who are working on high-impact publications, which require more time to complete.

NCI is proposing a minor change to the K99 program to expand the eligibility from 4 years to 6 years of postdoctoral experience. This change will require that NCI issue its own K99/R00 PAR, and it is expected to lead to an increase in the number of applications from 200 to 300 per year. In addition, the K99 budget also will increase. With the implementation of this change, NCI plans to sunset the CCT Career Development Award (K22), which allowed up to 8 years of postdoctoral experience and is equivalent to the R00 phase of the K99/R00.

Subcommittee Review. Dr. Jennifer R. Grandis, Robert K. Werbe Distinguished Professor in Head and Neck Cancer, University of California, San Francisco, expressed the Subcommittee's strong support for the concept. Dr. Grandis noted that this K99/R00 award is one of a few NIH mechanisms that support individuals who are not U.S. citizens and commended the proposed change from 4 years to 6 years of postdoctoral experience. The Subcommittee appreciated the NCI staff responses to their concerns about bias, defining allowable applicants, and eligibility beyond 6 years. The Subcommittee emphasized continuing to engage the career transition (e.g., industry to academia) pool of talent in the advent of sunsetting the K22 award.

Questions and Answers

Members suggested balancing the Pathway to Independence Award (K99/R00) duration with the time to produce research output and the time to a first R01 grant application that meets the expectations of NCI and NIH.

Dr. Schmidt clarified that transitions in the first year of the K99 phase are allowed and require approval from the Division Director of CCT. He noted that early transitions are supported by a strong

offer for a tenure track position.

Motion. A motion to approve the OD's new PAR entitled "The NCI Pathway to Independence Award (K99/R00)" was approved unanimously.

Division of Cancer Control and Population Sciences

Tobacco, Alcohol, and Cannabis Control Policy Research for Health Equity (New PAR)— Dr. Annette Kaufman

Dr. Annette Kaufman, Program Director, Tobacco Control Research Branch, DCCPS, presented a PAR concept on Tobacco, Alcohol, and Cannabis Control Policy Research for Health Equity. Dr. Kaufman informed members that the goal is to support R01 and R21 research projects that focus on reducing disparities in tobacco, alcohol, and/or cannabis exposure or use by evaluating new or adapted policies pertaining to these substances in the United States. The main hypothesis being addressed is whether tobacco, alcohol, and/or cannabis policies differentially impact the exposure/use of all three substances among disparate populations. Tobacco, alcohol, and cannabis are the most frequently used drugs in the United States.

In a review of the statistics, Dr. Kaufman informed members that the 2022 National Survey on Drug Use and Health (NSDUH) data showed that among people aged 12 and older, 48.7 percent used alcohol, 26.4 percent used tobacco or nicotine products, and 15 percent used cannabis in the last month. Disparities in use exist for all three substances. The 12-month and lifetime prevalence of alcohol use disorder is highest among those with lower incomes. Current cigarette smoking is associated with living in rural areas, lower education, lower income, and identifying as a sexual minority. Weekly or monthly cannabis use and cannabis dependence are greater among Black adults, Native American adults, and mixed race adults than among white adults. Research suggests that among those who use one of these products, co-use is common.

DCCPS unpublished National Survey on Drug Use and Health (NSDUH) data collected from 2015 to 2019 on adult past-month alcohol, cigarette, and cannabis use revealed that cannabis use is increasing, as is co-use. Co-use likely has synergistic effects on health outcomes, as well as other negative outcomes, such as lower smoking quit rates and higher rates of smoking relapse. Understanding both use and co-use is important for cancer prevention and control. Although data on the combined health effects of co-use are limited, it is well known that tobacco and alcohol are individually harmful. In the United States, combined tobacco and alcohol use is associated with one-third of cancer deaths. Data on the health effects of cannabis are limited, but smoking is the most common mode of cannabis administration, with 78.4 percent of past-year cannabis users 12 and older reporting that they had smoked cannabis in the past year.

The policy environment for these three substances is changing rapidly. Since 2012, the use of recreational cannabis has been legalized in 24 states, two territories, and Washington, D.C. Policies may not have the intended reach or affect all populations equally. In Oklahoma, for example, where medical cannabis use is legal, cannabis dispensaries are disproportionately located in areas with greater disadvantage, specifically in areas with a higher percentage of uninsured residents and no pharmacies. This suggest that cannabis retailers may take advantage of communities with limited health care access.

Science-based policy approaches are a key public health tool that can be wide reaching and cost-effective. They have the potential to promote health equity by reducing health disparities. Lower-income populations often respond more to tobacco tax and price increases than higher-income populations. A policy may have unanticipated or unintended consequences or be negligent in implementation, thereby worsening health disparities. Even when smoke-free air policies are in effect, secondhand tobacco smoke exposure continues to be higher among certain groups, including children, non-Hispanic Black people,

people with lower incomes, and people with less education. The patterns of use for these three substances can be complex, and the policies that pertain to one substance will affect the use of other substances on a population level, suggesting the need to evaluate the health equity impact of these rapidly changing policies on the use of all three substances.

These PARs will be responsive to research questions that address one or more policies pertaining to tobacco, alcohol, or cannabis. The research must assess exposure or use for all three substances. NCI is not limiting the number or types of studies that can be proposed. Researchers may propose randomized trials, naturalistic studies, or modeling studies. Studies on biological mechanisms or disease processes are excluded. The research must evaluate how the policy influences health disparities in one or more populations experiencing disparities. These groups are defined by NIH and include racial and ethnic minority groups, people with lower socioeconomic status, underserved rural populations, sexual and gender minority groups, and people with disabilities. Last, the research must be conducted in partnership with a community organization. These funding opportunities could support a wide range of policy research questions with important implications for cancer prevention and control.

Subcommittee Review. Dr. Hatsukami expressed the Subcommittee's strong enthusiasm and support for the concept. She commented that policies often are examined in isolation, without consideration of the impact a specific substance has on the use of other substances. This concept addresses co-use and health outcomes. The Subcommittee emphasized the importance of including cannabis in this research, given the fast-rising use and rapid evolution of policy across the United States.

Questions and Answers

Dr. Ideker requested clarity on the desired outcome as it relates to cancer. Dr. Kaufman noted that tobacco use is the leading cause of cancer death in the United States and worldwide and that alcohol use is the third-leading modifiable lifestyle factor. In addition, co-use with cannabis is increasing. The goal is to inform policies that affect those behaviors. Changing these behaviors is anticipated to lead to a reduction in cancer. She called attention to a study suggesting a causative link between cannabis smoking and testicular cancer, but the evidence is emerging.

Dr. Mark P. Doescher, Professor, Department of Family and Preventive Medicine, College of Medicine, University of Oklahoma Health Sciences Center, commented on having a hierarchy of the specific substances and the risk of cancer and evaluating how the dependent (i.e., tobacco, alcohol, cannabis) versus independent variables are structured in the PAR and how they affect outcomes and reduce health disparities.

Dr. Diaz noted that one study showed an association between head and neck cancer and cannabis use and also human papillomavirus (HPV) infection. He highlighted the steep decline in new visits in thoracic oncology that appear to be attributed to strict tobacco enforcement.

Motion. A motion to approve the OD's new PAR entitled "Tobacco, Alcohol, and Cannabis Control Policy Research for Health Equity" was unanimous.

Office of the Director

FY 2025 NCI SBIR Contract Topics (New RFP)—Dr. Monique Pond

Dr. Monique Pond, Program Director, SBIR Development Center, presented 13 Small Business Innovation Research (SBIR) research and development (R&D) contract topics for funding in FY 2025. The NCI SBIR budget is a congressionally mandated set-aside allotment of the overall NCI appropriations. The SBIR program supports promising startup companies with SBIR/STTR grants that are investigator initiated and SBIR contracts. In FY 2023, the NCI allocated $24 M of the budget to R&D

contracts; this amount can vary from year to year. NCI does not prescribe any fixed dollar amount for grants versus contracts but focuses on funding the best translational science that will help patients with cancer. With the contract mechanism, NCI is able to define narrowly focused topics that have specific product development goals and milestones, which is in contrast to the grant mechanism.

R&D contracts are used to stimulate commercialization in emerging areas; streamline stepwise product development; and support technology transfer from NIH laboratories to industry. The contract topics are diverse and serve needs beyond just NCI. All products developed must fulfill a commercial need. Contract proposals undergo a rigorous peer-review process, and the reviews are conducted by NCI DEA as opposed to the NIH Center for Scientific Review. In addition, contract proposals must align with the specific topic and the deliverables that are detailed in the solicitation.

Identifying the contract topics is an NCI-wide process. Each October, the SBIR Development Center solicits ideas for new contract proposals from across the NCI. Topics are submitted from program directors from the NCI Divisions, Offices, and Centers and also from the FDA Center for Devices and Radiological Health. Submitted topics then are evaluated by two NCI technology advisory group (TAG) panels: TAG 1 focuses on therapeutic diagnostics and molecular analysis technologies, and TAG 2 reviews radiation therapies, medical devices, and health IT and bioinformatics. The TAG panels are composed of subject-matter experts from across the NCI, who evaluate the submitted topics for innovation and concept, commercialization potential, and the ability to have a significant benefit for cancer patients, providers, and caregivers. The reviewers ensure that no duplication exists in the NCI SBIR portfolio and that re-issued topics are justified appropriately.

The 13 SBIR R&D contract topics were selected from 15 that were submitted and reflect NCI priority areas, commercial potential, and portfolio gaps. The topics are within the areas of therapeutics, medical devices, diagnostics, information technology (IT) and digital health, and research tools. All of the topics align with the NCP goals. Dr. Pond summarized the 13 topics and overall goals.

Therapeutics

Novel Delivery Systems for RNA-based Cancer Vaccines. Support the development of new delivery systems with enhanced properties to accelerate the development of RNA-based cancer vaccines.

Development of Cancer Immunoprevention Agents. Advance the development of novel, safe, and efficacious immunopreventive vaccines or immunomodulatory drugs (small molecules or biologics) for cancer prevention and interception in well-identified high-risk cohorts.

Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies. Support the development of safe and effective immune-modulating synthetic microbes for immuno-oncology therapeutic use in the clinic.

Development of Novel Therapeutics for Human Papillomavirus–Related Precancer. Develop effective HPV therapeutics that can treat chronic HPV infections and/or cause regression of precancers by preventing HPV-related cancers from developing at relevant organ sites (e.g., cervical, anogenital, oropharyngeal).

Precision Nutrition Interventions to Reduce Cancer-Related Symptoms. Support the development of new targeted nutritional products for patients experiencing nutrition impact symptoms to help clinical care teams maintain the patient's nutritional status and quality of life and bolster the patient's tolerance for cancer treatment.

Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention. Develop oral preventative agents for high-risk patients with inflammatory bowel disease (IBD) to prevent colon cancer.

Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer. Develop oral preventative agents for high-risk patients with IBD to prevent colon cancer.

Medical Devices Topics

Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment. Facilitate the commercial development of wearable sensors that can provide remote patient monitoring and assist clinical care teams in identifying cancer treatment–related toxicities early on.

Clinical Diagnostics and Molecular Analysis Topics

Point-of-Care Detection of Antibodies Against HPV 16/18 E6 and E7 Oncoproteins. Support the development and validation of a rapid, point-of-care (POC) test for HPV-related oropharyngeal cancers that includes the separate detection of antibodies against HPV16 and 18 E6 and E7 proteins.

Point-of-Care Technologies for Gastrointestinal Cancer Prevention and Early Detection. Advance the development of an affordable and scalable POC test that can effectively screen for precancerous conditions and early cancers in the gastrointestinal tract.

Information Technology and Digital Health

Development of Digital Biomarkers and Endpoints for Clinical Cancer Care. Facilitate the commercial development of digital biomarkers and/or endpoints that can help clinical care teams improve patient care (e.g., remote monitoring of a patient's response to treatment).

Digital Twin Software for Optimization of Cancer Radiation Therapy. Develop digital twin software that can inform radiation therapy in patient care by utilizing multiscale data for treatment optimization purposes.

Research Tools

Advanced Biomaterials to Improve Cancer Modeling for Research. Advance the development of versatile and accessible biomaterial-based tools (kits and reagents) for cancer researchers.

SBIR R&D Contracts: Impact and Success Stories

Dr. Pond emphasized that the SBIR R&D contracts have supported the successful commercialization of many products used for diagnosing, monitoring, or treating patients with cancer, such as Civasheet®, a brachytherapy device that is customizable to a specific patient's condition and offers a unidirectional option to shield healthy tissue. CivaTech developed two follow-on products that are commercially available and used in several clinics throughout the country. An analysis of the SBIR R&D contracts portfolio from 2013 to 2018 revealed that approximately 20 percent of funded projects have resulted in commercialized products. NCI considers contracts an important mechanism for NCI funding and one way to enable innovative products to reach the clinic for patients with cancer.

Subcommittee Review. Dr. Richard C. Zellars, William A. Mitchell Professor and Chair, Department of Radiation Oncology, Simon Comprehensive Cancer Center, Indiana University, expressed the Subcommittee's enthusiasm and strong support for the concept. The Subcommittee commended NCI for the focus on prevention.

Questions and Answers

Dr. Chandrakanth Are, Jerald L. and Carolyn J. Varner Professor in Surgical Oncology and Global Health, Associate Dean for Graduate Medical Education, University of Nebraska Medical Center,

suggested expanding the NCI SBIR contract topics to include research in developing surgical tools.

Dr. Fingert recommended reviewing and reporting on the impact of SBIR funding in terms of the number of patients treated with the products developed, as well as the benefits to communities throughout the United States.

Motion. A motion to concur on the OD's RFP entitled "FY 2025 NCI Small Business Innovation Research (SBIR) Contract Topics (R43)" was approved unanimously.

Division of Extramural Activities

PAR Re-Issue Concepts—Dr. Shamala Srinivas

Dr. Shamala Srinivas, Associate Director, Office of Referral, Review and Program Coordination, NCI, presented 17 re-issue PARs. Dr. Shrinivas informed members that the list and a link to each PAR were made available on the secure BSA-only website prior to the meeting. She also reminded the BSA of the NIH policy established in 2019 that requires an open forum discussion and acceptance by an Advisory Council/Board for new and re-issue RFAs, RFPs, and PARs. As such, due to the large volume of PAR re-issues that the NCI proposes annually, the Board will review the re-issues as a group, not individually, and will vote to concur/non-concur with the re-issuances.

- NCI Mentored Clinical Scientist Research Career Development Award to Promote Diversity
  - (K08 Clinical Trial Required) (PAR-21-299)
  - (K08 Independent Clinical Trial Not Allowed) (PAR-21-300)
- NCI Mentored Research Scientist Development Award to Promote Diversity
  - (K01 Independent Clinical Trial Not Allowed) (PAR-21-295)
  - (K01 Clinical Trial Required) (PAR-21-296)
- NCI Transition Career Development Award to Promote Diversity
  - (K22 Independent Clinical Trial Not Allowed) (PAR-21-300)
  - (K22 Clinical Trial Required) (PAR-21-301)
- Basic Research in Cancer Health Disparities
  - (R01 Clinical Trial Not Allowed) (PAR-21-322)
  - (R21 Clinical Trial Not Allowed) (PAR-21-323)
  - (R03 Clinical Trial Not Allowed) (PAR-21-324)
- The Metastasis Research Network (MetNet): MetNet Research Projects
  (U01 Clinical Trial Not Allowed) (PAR-22-234)
- Dissemination and Implementation Research in Health
  - (R01 Clinical Trial Optional) (PAR-22-105)
  - (R21 Clinical Trial Optional) (PAR-22-106)
  - (R03 Clinical Trial Not Allowed) (PAR-22-107)
- Cancer Epidemiology Cohorts: Building the Next Generation of Research Cohorts
  (U01 Clinical Trial Not Allowed) (PAR-22-161)
  Research Opportunities in Established Cancer Epidemiology Cohort Studies
  (U01 Clinical Trial Not Allowed (PAR-22-162)
- Clinical Characterization of Cancer Therapy-Induced Adverse Sequelae and Mechanism-Based Interventional Strategies
  (R01 Clinical Trial Optional) (PAR-21-329)
- Mechanisms That Impact Cancer Risk After Bariatric Surgery

- (R01 Clinical Trial Optional) (PAR-21-331);
- (R21 Clinical Trial Optional) (PAR-21-332)

- Cancer Prevention and Control Clinical Trials Planning Grant Program
  - (R34 Clinical Trials Optional) (PAR-22-173)
  - (U34 Clinical Trials Optional) (PAR-22-174)
- Utilizing the [Prostate, Lung, Colorectal, and Ovarian] PLCO Biospecimens Resource to Bridge Gaps in Cancer Etiology and Early Detection Research
  (U01 Clinical Trial Not Allowed) (PAR-21-330)
- Toward Translation of Nanotechnology Cancer Interventions (TTNCI)
  (R01 Clinical Trial Not Allowed) (PAR-22-071)
- Molecular Imaging of Inflammation in Cancer
  (R01 Clinical Trial Not Allowed) (PAR-21-294)
- Integration of Imaging and Fluid-Based Tumor Monitoring in Cancer Therapy
  (R01 Clinical Trial Optional) (PAR-21-290)
- Exploratory/Developmental Bioengineering Research Grants (EBRG)
  - (R21 Clinical Trial Not Allowed) (PAR-22-90)
  - (R21 Clinical Trial Optional) (PAR-22-91)
- Integrating Biospecimen Science Approaches into Clinical Assay Development
  (U01 Clinical Trial Not Allowed) (PAR-22-049)
- Cancer Center Support Grant (CCSG)
  (P30 Clinical Trial Optional) (PAR-21-321)

Questions and Answers

Dr. Katrina Goddard, Director, DCCPS, indicated that, in collaboration with the Center for Cancer Training (CCT) and DCP, in Dec. 2023, her division had published a Notice of Special Interest entitled 'National Cancer Institute Supports Applications for the Mentored Research Scientist Development Awards (K01) Within the Mission of the Division of Cancer Control and Population Sciences'. She noted that the first receipt date was in February 2024, and awards are expected to fill the gap that resulted from discontinuing the NCI Academic Career Development Award, i.e., the K07.

Motion. A motion to concur on the 17 re-issue of PARs was approved unanimously.

IX. ADJOURNMENT OF OPEN SESSION—DRS. JOHN D. CARPTEN AND SHELTON EARP

Dr. Carpten adjourned the open session. Only NCAB members and designated NCI staff remained for the closed session.

X. NCAB CLOSED SESSION—DR. JOHN D. CARPTEN

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., and section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. 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** motion to concur with IRG recommendations was unanimously approved. During the closed session, a total of 2,815 NCI applications were reviewed requesting direct cost support of $1,204,650,514.

XI. ADJOURNMENT OF NCAB CLOSED SESSION—DR. JOHN D. CARPTEN

Dr. Carpten thanked all the Board members, as well as the visitors and observers, for attending. There being no further business the 16th joint meeting of the BSA and NCAB was adjourned at 4:53 p.m. on Wednesday, 12 June 2024.

Date	H. Shelton Earp, M.D., Chair, BSA
Date	John D. Carpten, Ph.D., Chair, NCAB
Date	Paulette S. Gray, Ph.D., Executive Secretary