DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
11th VIRTUAL NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
September 4, 2019

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

NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
4 September 2019

The National Cancer Advisory Board (NCAB) convened for its 11th virtual regular meeting on 4 September 2019. NCAB members attended virtually, and National Cancer Institute (NCI) staff attended in Conference Room TE406, East Wing, Shady Grove Campus, National Institutes of Health, Bethesda, MD. The meeting was open to the public on Wednesday, 4 September 2019, from 1:00 p.m. to 2:15 p.m., and closed to the public from 2:30 p.m. to 3:15 p.m. The NCAB Chair, Dr. Elizabeth M. Jaffee, Deputy Director, The Sidney Kimmel Comprehensive Cancer Center, Co-Director, Skip Viragh Center for Pancreas Cancer, The Dana and Albert "Cubby" Broccoli Professor of Oncology, Johns Hopkins University, presided during both the open and closed sessions.

NCAB Members

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

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Douglas R. Lowy, Acting Director, National Cancer Institute
Dr. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences, and Interim Director, Center for Global Health
Dr. William Dahut, Scientific Director for Clinical Research, Center for Cancer Research
Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research
Dr. Dan Gallahan, Acting Director, Division of Cancer Biology
Mr. Peter Garrett, Director, Office of Communications and Public Liaison
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the NCI Acting Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Sara Hook, Director, Office of Scientific Operations, NCI Campus at Frederick
Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology
Dr. Glenn Merlino, Scientific Director for Basic Research, Center for Cancer Research
Dr. Tom Misteli, Director, Center for Cancer Research
Dr. Henry Rodriguez, Acting Associate Director, Center for Strategic Scientific Initiatives
Mr. Jeff Shilling, Chief Information Officer and Chief of Infrastructure and Information Technology Services Branch, Center for Bioinformatics and Information Technology
Ms. Donna Siegle, Executive Officer and Deputy Director for Management, Office of the Director
Dr. Dinah Singer, Deputy Director for Science Strategy and Development
Dr. Sanya 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. Jonathan Wiest, Director, Center for Cancer Training
Dr. Deborah M. Winn, Acting Director, Division of Cancer Prevention
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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WEDNESDAY, 4 SEPTEMBER 2019

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

Dr. Elizabeth M. Jaffee called to order the 11th virtual National Cancer Advisory Board (NCAB) meeting. She welcomed members of the Board, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Jaffee reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to accept the minutes of the 10 June 2019 Joint Meeting of the Board of Scientific Advisors (BSA) and the NCAB was approved unanimously.

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

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

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

Dr. Douglas R., Lowy, Acting Director, NCI, welcomed NCAB members and attendees to the 11th virtual meeting and provided an update on the NCI: Research Project Grant (RPG) Pool, budget, *Annual Plan & Budget Proposal for FY 2021*, and programs and staff changes.

RPG Pool. Dr. Lowy informed the NCAB members that data from the National Institutes of Health (NIH) Research Portfolio Online Reporting Tools (RePORT) showed a large difference between the competing (Type 2) NCI R01 applications received over the past 10 years compared with the NCI budget (i.e., regular appropriations). Although the number of applications continues to increase in fiscal year (FY) 2019, the rate of increase has slowed from the previous 5 years. Since FY 2001, the NCI RPG Pool applications success rates have been lower than other NIH Institutes and Centers (ICs). This difference in success rates further diverged starting in FY 2015. The success rates for all other NIH ICs increased, but decreased for the NCI; this is primarily attributable to the increase in NCI applications compared to the other ICs. Dr. Lowy detailed the most salient factors that have contributed to the significant increase in NCI RPG applications. The number of unique principal investigator applications has increased, including applications migrating from other NIH ICs and multi-principal investigator proposals. There was a 15 percent increase in the number of applications submitted per principal investigator over the past 5 years. The applications in response to a Program Announcement with Special Receipt, Referral, and/or Review (PAR) increased. Collectively, these factors have led to the decrease in paylines.

NCI Budget. Dr. Lowy reported that the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (L-HHS) approved its FY 2020 spending bill markup, which includes a 5 percent increase above the FY 2019 enacted budget for the NCI and also includes a $50 million (M) annual appropriation for the new Childhood Cancer Data Initiative (CCDI). The NCI is hopeful that the Senate Appropriations L-HHS Subcommittee spending bill markup reflects similar increases for the NIH and the NCI. Dr. Lowy noted that Ms. M. K. Holohan, Director, Office of Government and Congressional Relations, will provide a detailed report on the NIH/NCI budget process later in the meeting. Dr. Lowy conveyed that the NCI anticipates being able to increase both paylines and success rates above those of FY 2019 if the enacted budget is close to the appropriators' markup bills.

Dr. Lowy announced NCI's new blog—"NCI Bottom Line: A Blog About Grants & More"—scheduled to be launched on 10 September 2019. The primary audience is NCI-supported grantees,

administrators, and applicants, and the main focus is on NCI grants, funding policy updates, and research activities/priorities.

NCI *Annual Plan & Budget Proposal for FY 2021*. Dr. Lowy told NCAB members that the NCI released its *Annual Plan & Budget Proposal for FY 2021* (also referred to as the Bypass or Professional Judgment Budget Proposal). The Bypass Budget, which is forwarded directly to Congress and the White House Office of Management and Budget, does not enter the NIH/NCI regular budget process and is generally released 1 fiscal year in advance. The release of the 2021 budget proposal marks the 50th anniversary of the 1971 National Cancer Act, and a copy of the abbreviated at-a-glance version is contained in the Board's book. The full version can be accessed from the NCI website, and hardcopies will be available in late September 2019. Dr. Lowy shared an inspiring story about one pediatric fibrosarcoma patient featured in the 2021 Annual Plan who benefited from targeted treatment and is now cancer free after being unresponsive to standard therapies. Under the NCI precision medicine protocol at the Memorial Sloan Kettering Cancer Center, genomic analysis of the patient's tumor revealed a neurotrophic receptor tyrosine kinase gene fusion, which was treated with a then-investigational new drug—larotrectinib (Vitrakvi®)—which was subsequently approved by the U.S. Food and Drug Administration (FDA).

Dr. Lowy remarked that the NCI is committed to saving one life from cancer and has lofty aspirations of saving the entire world, but not without a great deal of considerations to future funding opportunities. In its 2021 Annual Plan, the NCI is proposing a 15 percent budget increase to enable raising R01 paylines to the 15th percentile. The NCI is strongly supporting three research areas (not exhaustive of all research): the immune system and microbiome, implementation science, and artificial intelligence. In addition to patient stories, NCI-supported investigator stories also are featured, including research highlights from three principal investigators: Dr. Tomi Akinyemiju, Associate Professor, Department of Population Health Sciences, Duke University, who is focusing on health disparities in ovarian cancer; Dr. Ross Brownson, Steven H. and Susan U. Lipstein Distinguished Professor, Washington University in St. Louis, who is focusing on implementation research for cancer health disparities; and Dr. Mark Schiffman, Senior Investigator, NCI, who is focusing on artificial intelligence and cervical cancer screening.

New and Ongoing NCI Initiatives. Dr. Lowy remarked on the NCI's recent efforts to address pediatric cancer research and noted the July 2019 CCDI Symposium, which he noted will be described in detail later in the meeting. He expressed appreciation to the symposium organizers and acknowledged NCAB member, Dr. Peter C. Adamson, Chair, Children's Oncology Group (COG), Alan R. Cohen Endowed Chair in Pediatrics, Children's Hospital of Philadelphia, University of Pennsylvania, for his active participation in the symposium.

On 7 August 2019, the Centers for Medicare & Medicaid Services (CMS) announced its decision to provide nationwide coverage to Medicare beneficiaries for the FDA-approved chimeric antigen receptor (CAR) T-cell therapy. The clinical database of the NCI and National Heart, Lung, and Blood Institute (NHLBI)-supported Center for International Blood and Marrow Transplant Research (CIBMTR) contains outcomes data from 1,400 Medicare patients, which could provide evidence of therapeutic efficacy in this population. Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research, NCI, is working with the CMS and FDA to evaluate this data registry for potential Medicare CAR T-cell patients.

The NCI Community Oncology Research Program (NCORP) has successfully met its goals and objectives. Approximately 50 percent of patients accrued for the Adult NCI-Molecular Analysis for Therapy Choice (MATCH) were recruited through the 34 NCORP Community Sites and 12 Minority/Underserved Sites. On 22–23 August 2019, the NCI convened the NCORP site leaders for the 2019 NCORP Annual Meeting on the NIH main campus. With the recent program re-issuance

approved by the BSA, the NCI increased funding to the NCORP by $30 M annually and $20 M for the cooperative groups. Dr. Lowy acknowledged NCORP Director, Dr. Worta McCaskill-Stevens, for her leadership of the Program.

Dr. Lowy explained that the NCI has been implementing the Cancer Moonshot℠ Initiative's Open Access and Data Sharing Policy to ensure that data generated are shared with the cancer research community worldwide. He called attention to a recent report—"Open Access Takes Root at the NCI"—published in the August 2019 issue of *Science* with input from Dr. Dinah Singer, NCI Deputy Director, who has been on the forefront of the Cancer Moonshot℠ open access activities, all of which have been endorsed by the NIH Director, Dr. Francis S. Collins.

Dr. Lowy announced that the Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine became the 71st NCI-Designated Cancer Center and that the Indiana University Simon Cancer Center became the 51st Comprehensive Cancer Center. He noted a new topic of interest that will be discussed at the 2–3 December 2019 Joint Boards meeting by Dr. Michael Lauer, Deputy Director, Office of Extramural Research, NCI, on intellectual property issues in academia and threats from foreign entities. The NCAB members were encouraged to review the article published in the August 2019 issue of *The Hill* co-authored by two university presidents—Drs. Michael A. McRobbie, President of Indiana University, and Morton Schapiro, President of Northwestern University—on this topic.

Leadership Appointments and Vacancies. Dr. Lowy announced that Dr. Dinah Singer is now NCI Deputy Director for Scientific Strategy and Development; Ms. Joy Wiszneauckas has been named Director, Committee Management Office; Ms. Anne Lubenow is Chief of Staff, Office of the Director (OD); and Mr. Eric L. Cole is the Deputy Executive Officer, NCI. He noted NCI's ongoing recruitment efforts for directors for the Center for Global Health (CGH), Division of Cancer Prevention (DCP), and recently the Division of Cancer Biology (DCB); and associate director for the Cancer Therapy Evaluation Program (CTEP). Dr. Lowy expressed appreciation to Dr. Robert Croyle, Acting Director, CGH; Dr. Deborah M. Winn, Acting Director, DCP; Dr. Margaret Mooney, Acting Associate Director, CTEP; and Dr. Daniel Gallahan, Acting Director, DCB, for stepping in to fill these roles.

Questions and Answers

Dr. Charles L. Sawyers, Chairman, Human Oncology and Pathogenesis Program, Memorial Sloan Kettering Cancer Center, Investigator, Howard Hughes Medical Institute, Professor of Medicine, Weill Cornell Medical College, asked about the impact of the applications migrating from principal investigators from other NIH ICs compared to the other factors and whether those applications reflect a change in funding for cancer-related projects. Dr. Lowy attributed the increase in multi-principal investigator applications to an increased interest in cancer research in general. For example, immunology experts are partnering with cancer biologists on proposals. He explained that Dr. L. Michelle Bennett, Director, Center for Research Strategy (CRS), NCI, and CRS staff have been working on compiling this type of information, which will be reported at the December Joint Boards meeting.

Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro-Oncology Research, Professor of Surgery, Professor of Pathology, Department of Surgery and Pathology, Duke University Medical Center, suggested that the high number of applications from other NIH ICs provides rationale for establishing joint funding mechanisms. Dr. Lowy commented that those discussions have been growing across the NIH and noted that cancer research co-funding with other ICs is possible for short-term efforts, but the NCI remains the primary source of funding.

Dr. Timothy J. Ley, Professor of Medicine and Genetics, Division of Oncology, Department of Medicine, Washington University School of Medicine in St. Louis, asked whether redistributions, cuts to

existing NCI programs, and/or new streams of revenue would be the source of funding to support increasing paylines to the 15th percentile in FY 2021. Dr. Lowy remarked that phasing out existing programs has not been considered as an option. The NCI envisions ever-increasing regular appropriations as the means to support raising paylines in the future.

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

Ms. Holohan reported on the budget and appropriations, other legislation of interest, and Congressional visits and briefings. She reminded NCAB members that the NIH/NCI budget process for the regular appropriations begins with the release of the President's proposed budget, which appropriation committees consider as they prepare their legislation. Congress reconciles and finalizes the appropriations, the President signs the appropriations bill into law, and funds are made available to the NIH and the NCI. For FY 2019, the process for the regular appropriations was optimal, and there was an early decision on the budget, which allowed the NCI a full year to plan and appropriate funds for new and ongoing initiatives. The on-time appropriation for the L-HHS spending bill, packaged with the FY 2019 Defense spending bill (i.e., minibus), included a $2 billion (B) increase for the NIH above the FY 2018 enacted budget, a $74 M increase for the NCI, and $400 M for the Cancer Moonshot℠.

Regarding the status of the FY 2020 regular appropriations, Ms. Holohan explained that the President's budget request, released in March 2019, was based on the Budget Control Act (BCA) of 2011 levels and includes a 12 percent decrease in funding for the NIH, a 14.6 percent decrease for the NCI, and a $50 M appropriation for the CCDI. The Constitution entrusts Congress with the authority to set Federal budgets, which involves holding budget hearings and considering priorities from Federal agency representatives. Congressional appropriators may consider a FY 2020 Defense and L-HHS appropriations minibus, which facilitated the FY 2019 bill's being passed by Congress and signed into law. On 2 August 2019, the Bipartisan Budget Act (BBA) of 2019 was signed into law, raising the 2011 BCA budget caps for FYs 2020 and 2021 and averting mandatory cuts to the non-defense discretionary budget, which funds the NIH. The 2019 BBA did not appropriate funding for FY 2020. To date, the House Appropriations Committee has passed 10 of the 12 spending bills, including the L-HHS bill, which was approved on 19 June 2019. The FY 2020 House L-HHS bill includes a $300 M increase for the NCI, $195 M for the Cancer Moonshot℠, and $50 M for the CCDI. The Senate Appropriations Committee has not passed any FY 2020 spending bills out of committee. The Senate Appropriations L-HHS Subcommittee spending markup bill is scheduled for 10 September 2019. Congress will have only 13 days in September when both the House and Senate are in session to finalize the appropriations, which the President must sign by 30 September 2019. A short-term continuing resolution (CR) to fund the Government beyond the end of FY 2019 is being discussed.

Ms. Holohan noted that, in addition to finalizing the appropriations, Congressional leaders are increasing oversight on the impact of electronic cigarettes (e-cigarettes) on adolescents and young adults. The House Committee on Oversight and Reform held a hearing (Examining Juul's Role in the Youth Nicotine Epidemic) on 24–25 July 2019, to listen to testimony from the public and discuss with Juul Labs, Inc. (Juul) representatives about their company's role in the youth vaping epidemic. In August 2019, the Centers for Disease Control and Prevention released an official health advisory on severe pulmonary disease associated with using or inhaling vapor (i.e., vaping) from e-cigarettes. This level of Congressional oversight on the effects of vaping is expected to continue.

Ms. Holohan provided an update on other legislation of interest and NCI activities. The Childhood Cancer Survivorship, Treatment, Access and Research (STAR) Act—signed into law in June 2018—encouraged action from the NIH/NCI to focus on childhood, adolescent, and young adult (AYA) cancer survivorship research and on AYA biospecimen collection and biobanking resources. In FY 2019, the NCI began implementing activities in support of the STAR legislation. A Request for Applications (RFA) focusing on improving outcomes for pediatric/AYA cancer survivors was released in January

2019. The first awards will be announced soon, and the second application receipt date is scheduled for January 2020. To assess the state of childhood cancer biobanking resources, the NCI convened childhood cancer researchers and other stakeholders on 13 May 2019 for the "Enhancing Biobanking for Childhood Cancers" meeting to discuss opportunities and challenges in the field. A detailed report of this meeting can be accessed from the NCI website. In addition, the NCI issued funding supplements in August 2019 to support expanding and improving the COG Biospecimen Bank.

Ms. Holohan noted recent and upcoming Congressional events. Dr. Lowy was invited to speak at the Glioblastoma Awareness Day reception held on 17 July 2019 at the Capitol, hosted by the congressional resolution co-sponsors, including Senators Lindsey Graham (R-SC) and Martha McSally (R-AZ). On 18 July 2019, members of the Congressional Cancer Survivors Caucus visited the NCI, met with Clinical Cancer Center investigators, and participated in discussions on survivorship care and patient-provider communication. Rep. David Trone (D-MD), a new member of Congress, visited the Advanced Technology Research Facility at NCI-Frederick, which is within his district, on 29 August 2019, and he is planning to visit the NIH in September with other freshman members of Congress to meet with the NIH OD staff. The Senate Cancer Coalition, a bipartisan group of 18 staffers, is scheduled to visit the NCI on 5 September 2019.

Questions and Answers

Dr. Sawyers asked how a CR would resonate in the NCI given the likelihood that the Senate will also propose some increase to the NIH and NCI budgets for FY 2020. Ms. Holohan explained that operating under a CR would not affect the ultimate FY 2020 funding levels and that a long-term CR is not what either Congress or the executive branch agencies want to happen. Dr. Lowy added that the NCI can continue to manage its activities if the full budget is approved by the end of the 2019 calendar year.

V. CHILDHOOD CANCER DATA INITIATIVE (CCDI) SCIENTIFIC SESSION REPORT—DRS. TONY KERLAVAGE AND JAIME GUIDRY AUVIL

Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology (CBIIT), provided an overview of the CCDI. He was joined by Dr. Jaime Guidry Auvil, Director, Office of Data Sharing, CBIIT, who reported on NCI pediatric cancer research efforts and data sources and summarized the activities of the CCDI scientific symposium.

CCDI: Background and Goals. Dr. Kerlavage reminded NCAB members that at the 12 February 2019, State of the Union Address, the President announced a $500 M investment for childhood cancer, which would be allocated over 10 years starting in FY 2020. Notably, childhood cancer survivors attended the State of the Union Address and these survivors serve as a striking reminder that there is hope for children diagnosed with cancer. The White House subsequently convened several stakeholder events with childhood cancer patients, their families, and patient advocates, which were organized by the Vice President. Dr. Norman Sharpless, then-NCI Director, and Dr. Lowy attended one of the events to discuss ways that funding dedicated to childhood cancers could accelerate the research.

Dr. Kerlavage emphasized that data sharing and data aggregation are important in cancer research, especially for childhood cancers, which represent 1 percent of all new cancer cases diagnosed in the United States annually. Collaboration among children's cancer centers is critical in this effort because of the large data sets necessary for answering complex scientific questions. Currently, the most effective treatments are not working for all childhood cancer patients, short- and long-term adverse effects of cancer and treatments exist, and for some cancer types virtually no progress is being observed. Aggregating and sharing data among childhood cancer researchers will improve understanding of cancer drug resistance and differential response to treatment, identify less toxic treatments and strategies for

disease management, and generate new ideas for interventions. Aside from data aggregation, the aim is to improve processes to transform data into knowledge that advances childhood cancer research.

Dr. Kerlavage described the technological, financial, and organizational challenges in data sharing that would need to be addressed. Unprecedented amounts of data are produced from basic and clinical research and clinical care, but different data types, data sets, tools, infrastructure/repositories and collections are isolated (i.e., in silos). Data collection practices, nomenclature, platforms, and policies vary among researchers, and existing information technology-related data systems are incompatible. Privacy protections and informed consent are not well understood in all instances. Dr. Kerlavage emphasized that despite these data challenges—when connected, data drives scientific discovery. One fundamental intent of the CCDI is to connect data from basic research, biospecimen repositories, clinical trials, preclinical models, and population studies, as well as real-world patient data.

The NCI CCDI goals are fourfold: (1) Maximize every opportunity to improve treatments and outcomes for children with cancer. (2) Build a connected data infrastructure to enable childhood cancer data sharing from multiple sources. (3) Identify opportunities to improve the effect of data for patients, clinicians, and researchers. (4) Develop and enhance tools and methods to extract knowledge from data.

Pediatric Cancer Research: Progress and Current Activities. Dr. Guidry Auvil reported that NCI's support of pediatric cancer research has steadily increased since FY 2014 and reflects a critical component of the Institute's research portfolio. Because pediatric/AYA cancers are rare and present unique challenges and considerations for this population, the timing of the CCDI is essential.

Dr. Guidry Auvil highlighted examples of existing data sharing and data use opportunities in AYA cancer research that the CCDI could maximize. Acute lymphocytic leukemia (ALL) is the most common cancer in the pediatric/AYA population, and significant progress has been made over the past decades, primarily in the area of developing effective treatments. From 2009 to 2015, the 5-year relative survival rate for ALL was 90 percent, a significant improvement over the 54 percent observed in the 1970s. Despite these improvements in mortality rates, the fact remains that 10 percent of children diagnosed with ALL do not survive. Complicating matters is that available treatments for childhood cancers, some of which are promising, are based on adult therapies, even though the two cancers are distinct notwithstanding the similar histology. Echoing Dr. Kerlavage, Dr. Guidry Auvil noted that data aggregation across studies will improve understanding of childhood cancer treatment responses. Conversely, many cancers that arise in the pediatric/AYA population have seen little progress. Although the 5-year relative survival rate reported from 2000 to 2016 was 75 percent for childhood brain and central nervous system cancers, for others—such as diffuse intrinsic pontine glioma—the survival rate was as low as 5 percent. Fundamental biological reasons make treating these types of cancers difficult, and it is therapeutically challenging to identify a viable target. Improving data collection and connection will inform new ideas for innovative therapies.

The CCDI also could have an impact in addressing cancer treatment side effects. Thanks to selected promising treatments, the cure rates for children with cancer is high and the number of childhood cancer survivors is growing, but not without serious long-term side effects from these treatments. Sixty to 90 percent of childhood cancer survivors develop one or more chronic health conditions, and—depending on the cancer type—20 to 80 percent experience severe or life-threatening complications throughout their lives. Seventy-five percent also may develop secondary cancers, which are an equally serious concern for these survivors. The CCDI is aiming to identify less toxic treatments and strategies for managing cancer therapy side effects.

Dr. Guidry Auvil called attention to the many existing NCI programs, new and ongoing, focusing on childhood cancer research and addressing multiple cancer types and survivorship. These programs are generating high volumes of research and collecting large amounts of clinical data, all designed to answer

key questions. She highlighted some of the NCI programs and data repositories stored in various NIH- and NCI-supported databases. The National Center for Biotechnology Information (NCBI) databases (e.g., Sequence Read Archive, database of Genotypes and Phenotypes), Genomic Data Commons, and Cancer Research Data Commons (CRDC) contain data from the Childhood Cancer Survivor Study, COG, Pediatric MATCH, Therapeutically Applicable Research to Generate Effective Treatments (TARGET), and Gabriella Miller Kids First Research programs. These data also are housed in other databases managed by NCI grantees across the pediatric cancer research community, such as the St. Jude Children's Research Hospital, Children's Hospital of Philadelphia Data Research Center, and the University of Chicago Pediatric Data Commons. In addition, clinical and demographic data are stored in cancer registries and hospital systems supported by the NIH and the NCI (e.g., Surveillance, Epidemiology, and End Results [SEER]). Connecting these various data sets is the overarching goal of the CCDI and will enable new scientific questions on the prevention and treatment of childhood cancers to be answered.

CCDI Symposium Summary. Recognizing that operationalizing a CCDI extends beyond the NCI and its many pediatric cancer programs, Dr. Guidry Auvil explained that the NCI convened the broader pediatric cancer research community to discuss approaches and implementation. The 3-day scientific symposium, during which the NCI confirmed its CCDI goals, was held in Washington, D.C., on 29–31 July 2019, and was open to the public. Approximately 270 stakeholders in academia, Government, industry, and advocacy attended in person, and 700 attended remotely. The agenda included presentations on key perspectives from leading stakeholders (e.g., NCI, FDA), panel discussions with pediatric oncologists and data scientists, focused group breakout sessions, and a moderated poster session.

Dr. Guidry Auvil elaborated on the symposium's four areas of focus, which aligned with the CCDI goals and also framed the breakout group discussions. She highlighted the following key topics and recommendations that emerged from the symposium sessions:

Connect pediatric data sets. Identify and connect existing key pediatric research and clinical data repositories. Aggregate the COG study data that can be queried efficiently. Appoint a universal identifier and use an honest broker mechanism for implementation.

Collect pediatric data sets. Initiate a national pediatric cancer patient cohort that leverages data from basic science/discovery to clinical studies/care to surveillance. Implement a prototype master protocol with structured data extending from the clinical to molecular to outcomes. Harmonize preclinical data and develop a query portal for all investigators and clinicians.

Annotate pediatric data sets. Create a central resource catalog of available pediatric/AYA data, biospecimens, tools, analysis workflows, and other resources. Establish standards to generate structured phenotypic and genomic data from electronic medical records and clinical trials. Develop standards and best practices for sharing or transferring data between repositories.

Extract knowledge from data. Develop tools to automate the extraction of structured and unstructured data, standardize front-end data capture, and capture real-world data and patient-reported outcomes. Establish a limited set of standard analysis workflows that can be used to harmonize data across resources.

CCDI next steps. Dr. Kerlavage explained that the NCI invited the research community to submit ideas on ways to advance data sharing for childhood cancer, and a summary report is available on the NCI website. A post-symposium webinar is scheduled for 8 October 2019, and an NCI position paper on the CCDI approach is expected to be completed this fall. The NCI leadership has begun initial steps to implement the CCDI, which include establishing a resource catalog, connecting the highest value pediatric NCI-funded repositories and registries, and defining the criteria for an ideal data set.

Dr. Kerlavage closed by emphasizing that data sharing culture changes are necessary for the CCDI to succeed, and he noted some principles for success about data access and interoperability.

Dr. Jaffee explained that the NCAB will need to approve establishing a BSA CCDI Working Group to advance the recommendations from the scientific report.

Questions and Answers

Dr. Ali-Osman asked about the process for depositing data into a CCDI database. Dr. Kerlavage pointed out that the initial efforts will focus on leveraging existing NCBI resources from large NCI programs and the CRDC. The CBIIT is working on systems to make contributing data easier for investigators.

Dr. Adamson, Chair, Children's Oncology Group, Alan R. Cohen Endowed Chair in Pediatrics, Children's Hospital of Philadelphia, University of Pennsylvania, expressed appreciation to Drs. Kerlavage and Guidry Auvil for summarizing the CCDI and the symposium. He conveyed the childhood cancer community's excitement and enthusiasm for this Initiative and lauded the NCI for taking the lead on this effort.

Motion. A motion to concur with establishing an BSA *ad hoc* Working Group on the Childhood Cancer Data Initiative was approved unanimously.

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

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

VII. CLOSED SESSION—DR. ELIZABETH M. JAFFEE

This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 552b(c)(6), Title 5 U.S. code, and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

There was a review of grants and a discussion of personnel and proprietary issues. Members absented themselves from the meeting during discussions for which there was 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 2,571 NCI applications were reviewed requesting direct cost support of $924,265,014 and 1 FDA application requesting direct cost support of $110,600.

VIII. ADJOURNMENT—DR. ELIZABETH M. JAFFEE

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

There being no further business, the 11th virtual meeting of the NCAB was adjourned at 3:15 p.m. on Wednesday, 4 September 2019.

Date	Elizabeth M. Jaffee, M.D., Chair
Date	Paulette S. Gray, Ph.D., Executive Secretary