

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
9th VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
August 14, 2018**

**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
August 14, 2018**

The National Cancer Advisory Board (NCAB) convened for its 9th virtual regular meeting on August 14, 2018. NCAB members attended virtually, and National Cancer Institute (NCI) staff attended in Conference Room TE406, East Wing, Shady Grove Campus, National Institutes of Health (NIH), Bethesda, MD. The meeting was open to the public on Tuesday, August 14, 2018, from 1:00 p.m. to 2:37 p.m., and closed to the public from 2:50 p.m. to 3:35 p.m. The NCAB Chair, Dr. Elizabeth M. Jaffee, Deputy Director, The Sidney Kimmel Comprehensive Cancer Center, The Dana and Albert “Cubby” Broccoli Professor of Oncology, Co-Director, Skip Viragh Center for Pancreas Cancer, 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 W. Bruner
Dr. Yuan Chang
Dr. David C. Christiani
Dr. Judy E. Garber
Mr. Lawrence O. Gostin
Dr. Scott W. Hiebert
Dr. Beth Y. Karlan
Dr. Timothy J. Ley
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub
Dr. Mack Roach, III
Dr. Charles L. Sawyers
Dr. Margaret R. Spitz
Dr. Max S. Wicha (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Norman E. Sharpless, Director, National Cancer Institute
Dr. Jeffrey S. Abrams, Acting Director for Clinical Research, Division of Cancer Treatment and
Diagnosis
Dr. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences, 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, Deputy 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 Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Tony Kerlavage, Acting Director, Center for Biomedical Informatics and Information Technology
Dr. Kristin Komschlies, Deputy Director, Office of Scientific Operations, NCI Campus at Frederick
Dr. Barry Kramer, Director, Division of Cancer Prevention
Dr. Douglas R. Lowy, Deputy Director, National Cancer Institute
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, Acting Chief Information Officer and Chief of Infrastructure and Information
Technology Services Branch, Center for Bioinformatics and Information Technology
Ms. Donna Siegle, Acting Executive Officer, and Acting Deputy Director for Management
Dr. Dinah Singer, Acting Deputy Director and Director, Division of Cancer Biology
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology
Transfer Programs
Dr. Jonathan Wiest, Director, Center for Cancer Training
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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TUESDAY, AUGUST 14, 2018

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

Dr. Elizabeth M. Jaffee called to order the 9th 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), 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 June 26–27, 2018, 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 and in the Board book.

III. NCI DIRECTOR'S REPORT—DR. NORMAN E. SHARPLESS

Dr. Norman E. Sharpless, Director, NCI, welcomed NCAB members and attendees to the 9th virtual meeting and provided updates on the NCI budget, legislative activities, Cancer MoonshotSM, and Research Specialist Award (R50). Dr. Sharpless also highlighted two recent initiatives: the Rare Tumor Patient Engagement Network and the multi-institutional Research on Prostate Cancer in Men of African Ancestry— Defining the Roles of Genetics, Tumor Markers, and Social Stress study (formerly called RESPOND).

NCI Budget. Dr. Sharpless expressed appreciation to the NCI Office of Budget and Finance (OBF) which has been actively working to ensure that all contracts and grants are funded in a timely manner as fiscal year (FY) 2018 ends and FY 2019 approaches. Recognizing that the NCI regular appropriations have steadily increased since FY 2015, Dr. Sharpless reported that Congress is reconciling the House and Senate Appropriations on Labor, Health and Human Services, Education, and Related Agencies FY 2019 bills that, if approved, will continue the increase in regular appropriations and for the first time, will raise the total NCI budget to more than \$6 billion (B). The sustained increase in regular appropriations reflects the continued bipartisan congressional support for the NIH and NCI that remains strong.

Dr. Sharpless explained that in addition to the regular appropriations, the NCI is appropriated Cancer MoonshotSM funding annually as authorized by the 21st Century Cures Act of 2016. The FY 2019 Cancer MoonshotSM allotment will increase by \$100 million (M) over the FY 2018 appropriation and will raise the total funding to \$400 M. Beginning in FY 2020 until the end of the 7-year funding period, the annual allotments will decrease by \$200 M. Dr. Sharpless conveyed that the NCI will need to plan carefully for the Cancer MoonshotSM variable appropriation structure and will work expeditiously to issue funding opportunity announcements (FOAs) to accelerate preclinical drug development and translation of emerging therapies to the clinic.

Legislative Report. Dr. Sharpless provided an update on the FY 2019 appropriations, congressional hearings, and other legislation of interest. On June 28, 2018, the Senate Appropriations Subcommittee advanced its bill out of committee to increase funding for the NIH by \$2 B and to the NCI by \$82 M. The House Appropriations Subcommittee advanced its bill out of committee on July 11, 2018, to increase funding to the NIH by \$1.25 B and to the NCI by \$71 M. The House and Senate FY 2019

allowances also included full funding for the Cancer MoonshotSM. Dr. Sharpless joined Dr. Francis S. Collins, Director, NIH; Dr. Stephanie Devaney, Deputy Director, All of Us Research Program; and Dr. Scott Gottlieb, Commissioner, U.S. Food and Drug Administration (FDA), to testify at the House Energy and Commerce (E&C) Subcommittee on Health hearing on July 25, 2018. Implementation of the 21st Century Cures Act at the NIH and the FDA was discussed and similar testimony at the Senate E&C Subcommittee on Health hearing is planned.

Dr. Sharpless noted other legislation of interest to the NCI. The Childhood Cancer Survivorship, Treatment, Access and Research (STAR) Act, which directs the NCI to further research efforts in pediatric cancer survivorship, biospecimen collection, and pediatric oncology expertise on the NCAB, was signed into law in June 2018. The NCI is working to address compliance with the new law. The Research to Accelerate Cures and Equality (RACE) for Children Act was signed into law in August 2017. The FDA—after convening public meeting forums, consulting with the NCI, and soliciting input from the community—recently released the list of molecular targets relevant to pediatric cancer. This 7-page document consisting of molecular targets will assist pharmaceutical companies in fulfilling the RACE requirements of having a pediatric study plan for drugs relevant to the pediatric population that are under FDA review.

Cancer MoonshotSM. Dr. Sharpless reported that the NCI established Cancer MoonshotSM Implementation Teams (CMITs); has issued FOAs that support each of the 10 NCAB Blue Ribbon Panel (BRP) recommendations; has received grants; reviewed proposals; and is planning to announce award recipients soon. A select number of the FOAs may be reissued based on the start of their initial funding cycle, and progress updates will be forthcoming. Embedded within each of the 10 recommendation implementation plans are the many FOAs, grants, significant financial investments, and programs developed within the broader CMIT process extending from FY 2017 to FY 2019. Dr. Sharpless emphasized that the Cancer MoonshotSM provides the NCI a tremendous scientific opportunity to work in new areas but requires coordination internally and externally. He acknowledged Dr. Dinah Singer, Acting Deputy Director and Director, Division of Cancer Biology, NCI staff, and partners at the FDA for their role in managing this effort.

Dr. Sharpless highlighted five of the Cancer MoonshotSM BRP recommendations and focus areas, as well as implementation plans for their supporting initiatives, which are expected to be awarded soon. The Immuno-Oncology Translational Network (IOTN) will leverage the expertise and resources of immunotherapy investigators to accelerate translation of immunotherapy basic discoveries to clinical applications to improve treatment for hot (responsive) and cold (nonresponsive) cancers. The IOTN also will collaborate with existing NCI programs, including the PREVENT Cancer Preclinical Drug Development Program and Cancer Immunotherapy Trials Network. The Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium will implement the recommendation to improve understanding of fusion oncoproteins in pediatric cancer. The FusOnC2 Consortium will consist of multidisciplinary research teams that will focus on developing effective targeted agents for high-risk fusion-driven cancers. The Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes Initiative involves the development of sustainable approaches applicable in multiple care settings and to diverse populations. The Human Tumor Atlas Network will establish human tumor atlas and precancer research centers focusing on generating three- and four-dimensional atlases of tumor development. The Accelerating Colorectal Cancer Screening and Follow-up Through Implementation Science (ACCSIS) addresses the BRP recommendation to generate effective implementation strategies that substantially improve early cancer detection. A key feature is the ACCSIS Signature Trial, which will focus on the feasibility and pilot testing of multilevel interventions in affected populations in Phase 1 and comparative effectiveness trials of implementation strategies to improve screening in Phase 2.

Rare Tumor Patient Engagement Network. Dr. Sharpless reported that the Center for Cancer Research's (CCR) Rare Tumor Patient Engagement Network project, which is funded by the Cancer

MoonshotSM, is an intra- and extramural effort that leverages the expertise and resources of the NIH Clinical Center and partners with patient advocacy groups and extramural Centers of Excellence. The Network will be composed of two parts—the NCI Comprehensive Oncology Network Evaluating Rare Central Nervous System Tumors (NCI-CONNECT) and the Moonshot Pediatric, Adolescent, and Adult Rare Tumors Network (MyPART)—with similar capabilities. Drs. Mark Gilbert and Terri Armstrong, Neuro-Oncology Branch investigators, co-lead the NCI-CONNECT and Drs. Karlyne Reilly and Bridgette Widemann, Pediatric Oncology Branch (POB) investigators, co-lead the MyPART. The aims are to identify specific populations with rare tumors; establish networks enabling patients to receive some level of care not currently available (e.g., molecular analysis or genomic phenotyping); and potentially standardize care where possible.

Research Specialist Award (RSA) (R50). Dr. Sharpless reminded NCAB members that the NCI established the Research Specialist Award in 2015 to encourage career development for exceptional non-tenure track scientists wanting to continue to pursue research in an existing NCI-funded research program but not as independent investigators. The RSA, within the R50 funding mechanism, provides salary support for core-based and laboratory-based scientists. Two FOAs have recently been issued. The RSA is a program for which the NCI would like to receive more applications.

RESPOND Study. Dr. Sharpless announced the launch of the RESPOND (Research on Prostate Cancer in Men of African Ancestry: Defining the Roles of Genetics, Tumor Markers, and Social Stress) study, which aims to address one of NCI's important health disparity research questions on prostate cancer health disparity in African American men. The study, which is being led by the University of Southern California (USC), leverages the African Ancestry Prostate Cancer Consortium; involves a network of prostate cancer investigators from across the United States; and will recruit 10,000 men from cancer registries within the network. The NCI RESPOND Program Director, Dr. Damali Martin, Division of Cancer Control and Population Sciences (DCCPS), will interact with the study principal investigator, Dr. Christopher Haimen, USC, and project lead investigators. The Prostate Cancer Foundation and the NIH Institute for Minority Health and Health Disparities are supporting this effort.

IV. INTER- AND INTRA-TUMORAL HETEROGENEITY IN PEDIATRIC SARCOMA— DR. JACK F. SHERN

Dr. Jack F. Shern, Assistant Clinical Investigator, CCR, presented his research on investigations of inter- and intra-tumoral heterogeneity in pediatric sarcoma, which began in 2010. Rhabdomyosarcoma (RMS) is considered the most common childhood soft tissue sarcoma (STS) being studied in many STS-related grants, but it is, in fact, a rare disease that occurs only in an estimated 350 children annually. Dr. Shern observed that pediatric patients often present to the clinic with lesions and extremity swelling that could be masked by signs of normal development (e.g., loss of teeth). Using all available technological advances, a diagnosis in 2010 consisted primarily of tissue biopsy and a pathology report resulting in minimal disease classification. Treatment options for pediatric patients include the well-established chemotherapy backbone regimen of vincristine, dactinomycin, and cyclophosphamide; radiation; and/or surgery. Although effective in some cases, the side effects from treatment can linger for the child's lifetime and are irreversible. Recognizing that improved subclassification of the disease beyond the two major subtypes—alveolar RMS and embryonal RMS—was needed, Dr. Shern and the POB's Oncogenomics Section collaborated with the Children's Oncology Group (COG) to interrogate the intertumor heterogeneity of RMS. In their 2014 study, a series of 147 tumors were evaluated using whole-genome, RNA, and exome sequencing. Results revealed two distinct RMS genotypes: fusion oncoprotein (e.g., *PAX3-FOXO*)-driven tumors and tumors harboring mutations in key signaling pathways in which the *RAS* isoform mutations (e.g., *KRAS* or *NRAS*) were more frequent.

Dr. Shern emphasized that although the fusion oncoprotein data are informative, they can be used as a prognostic marker for only a small subset of tumors; clinical classifications—low risk, medium risk,

and high risk—remain the norm. The NCI next collaborated with COG on an RMS project (ARST 14B1) to robustly investigate a fully clinical annotated cohort to determine whether genetic information could be used to further refine risk stratification for patients. In the COG ARST 14B1 project, samples from clinically annotated RMS cases were genetically analyzed and assayed for the detection of 39 specific Catalogue of Somatic Mutations in Cancer (COSMIC) Tier 1 driver genes known to be mutated in RMS. To date, 347 COG cases have been sequenced; of the 347 cases, 66 were fusion oncoprotein positive (fusion positive); and 281 were fusion oncoprotein negative (fusion negative). To increase the statistical power of the 281 fusion negative cases, the NCI POB collaborated with the Institute for Cancer Research, United Kingdom (UK), to receive an additional 316 sequenced UK RMS cases, which will increase the sequenced fusion negative cohort to 597.

Dr. Shern detailed the clinical characteristics, mutation frequency, and further characterizations of the COG cohort. Histology determinations were based on the consensus of three independent pathology reports. Cases are biased toward the male population due to the high prevalence of paratesticular tumors generally seen in RMS. One COSMIC Tier 1 mutation is identified in 221 of the 281 cases and the *BCOR*, *NF1*, *KRAS*, *NRAS*, and *TP53* genes are the most frequently mutated. Summarized by the clinical characteristics (e.g., anatomy), the *TP53* pathway mutations are common in extremity lesions; female genitourinary cases account for all the *DICER1* lesions; *HRAS* and *KRAS* mutations do not occur in orbital tumors; and *MYOD1* mutations are restricted to the head and neck region, primarily parameningeal. Although Tier 1 mutations exist in a large percentage of cases, the tumor-to-genetic lesion ratio is not a 1:1 relationship. These observations suggest that fusion negative RMS is a polyclonal or subclonal disease.

Dr. Shern remarked that the COG ARST 14B1 project can begin to address whether the increased number of mutations correlates to a worse outcome in RMS. Stratifying cases by mutation reveals distinct co-existing lesion patterns or mapping. In fact, data show that the *MYOD1* mutation always has a co-existing lesion, which is less likely for the RAS isoforms. In RMS cases of infants younger than 1 year of age, the frequency of the *KRAS* and *HRAS* mutations is high and the variant allele frequency of *HRAS* is more predominant. The next step was to identify predictive markers that could be used to better stratify the cohort. Their observations reveal that the *MYOD1* mutations are associated with worse outcomes in adolescent and young adult cases. The *TP53* mutations, which were similar to frequency of The Cancer Genome Atlas (TCGA) cohort, correlate to a decrease in event-free survival in medium-risk patients. The *MYCN* and *CDK4* amplifications are poor prognostic modifiers in *PAX* fusion positive tumors. Overall, these data provide a basis for genetically classifying RMS and can help improve risk stratification for patients.

Regarding pediatric RMS and recurrent tumors and relapse following various treatment modalities, Dr. Shern speculated on the role of intratumoral heterogeneity. Previous studies on recurrent embryonal RMS have shown a subclonal element to the disease. At diagnosis, two clones, one contributing 97 percent and a second contributing three percent, of the tumor were identified using diagnostic biopsy. After treatment, the 97 percent clone was eliminated, but the three percent clone remained and repopulated the tumor. Additional tools are needed to begin to dissect the heterogeneity of RMS tumors; profile tumors based on their mechanisms; and develop new therapies. Next-generation sequencing is one such tool. Dr. Shern summarized his work at the Clinical Center using single-cell RNA sequencing and single-cell gene profiling to assess metastatic disease prior to and after treatment that would be of value to immunology researchers, tumor microenvironment investigators, and the cancer research community in general.

In closing, Dr. Shern highlighted key aspects of the NIH Lasker Clinical Research Scholars Program, of which he is a recipient and highly recommends.

V. AD HOC DATA SCIENCE WORKING GROUP INTERIM REPORT—DRS. CHARLES L. SAWYERS AND MIA A. LEVY

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, presented the Data Science Working Group interim report. The Working Group—composed of two co-chairs and 14 members representing academia and industry—began preparations in April 2018 with introductory meetings held virtually; met in May 2018 for a face-to-face meeting at the NCI and received the charge from NCI Director, Dr. Sharpless; and continued discussions in followup teleconferences and emails. In their deliberations, the Working Group discussed data science priority areas; converged on a consensus on short- and long-term prioritizations; and established subgroups to address each of the priority areas. In its interim report, the Working Group described data science opportunities for the NCI and introduced four initial priority recommendations that the NCI could rapidly address. Broader discussions on data science efforts will continue, and a final report will be presented to the NCAB at a future meeting.

Drs. Sawyers and Mia L. Levy, Director, Cancer Health Informatics and Strategy, Ingram Associate Professor of Cancer Research, Associate Professor, Biomedical Informatics and Medicine, Vanderbilt-Ingram Cancer Center, Vanderbilt University, summarized the Working Group's four initial recommendation areas. Dr. Sawyers explained that Recommendation Area 1, Investments to Leapfrog Data Sharing for High-Value Data Sets, will leverage two types of data: Type 1, fully collected and annotated data sets that lack the necessary resources to support harmonization and data sharing in a public repository, such as the NCI Cancer Research Data Commons (CRDC); and Type 2, data sets that would be enhanced by additional data generation and/or data collections. The recommendation is to develop funding opportunities to support identification, enrichment, curation, harmonization, annotation, and publication of existing high-value data sets through the CRDC.

Dr. Levy pointed out that the goal of Recommendation Area 2, Harmonize Terminologies Between Cancer Research and Clinical Care Data, is to achieve near clinical grade data within traditional clinical care settings, including NCI-designated Cancer Centers. The recommendation is to work with standards development organizations, private and federal, (e.g., the FDA and National Coordinator of Health Information Technology) to augment electronic health records (EHRs) data standards. Existing standards to leverage include the National Library of Medicine (NLM) standardized nomenclature for clinical drugs (RxNorm); Systematized Nomenclature of Human Medicine (SNOMED) International global language for health care; and the Regenstrief Institute Logical Observation Identifiers Names and Codes (LOINC). The benefits of harmonized terminologies are threefold. First, the utility and ease of incorporation/integration of clinical care data from EHRs in cancer research would be increased. Second, more efficient research, improved patient care, and real-world evidence generation would be enhanced. Third, the integration of the cancer and non-cancer research communities would be enhanced.

Dr. Levy emphasized that Recommendation Area 3, Support of Data Science Training at the Graduate Level, if implemented, will address workforce diversity challenges. The recommendation is to increase the number of graduate-level training programs and trainees in cancer data science using multilevel approaches that entail establishing a Cancer Data Science Training Program (T32); collaborating with current NIH training programs (e.g., the NLM Biomedical Training (T15) Program and the National Institute of General Medical Sciences Medical Scientist Training Program); and developing a short-term training program for clinicians and biological scientists. The Recommendation Area 3 Subgroup is proposing to broaden the scope to include postdoctoral-level training in the final recommendations.

Dr. Levy elaborated on Recommendation Area 4, Opportunities for Funding Challenges and Prizes, and the benefits. The recommendation is to sponsor a series of data science challenges (i.e.,

scientific competitions) that highlight four to eight topics per year and to begin with an idea challenge to identify the appropriate challenge topic, task, or question. The benefits of sponsoring data science challenges would be to spur computational cancer biology research, attract new talent to cancer research, and validate and broadly disseminate state-of-the-art tools and technologies. Importantly, scientific challenges in data science leverage openly shared data sets, foster the ability to work across harmonized data sets, and utilize participants with appropriate skills and expertise and would, therefore, demonstrate the interrelationship among all the Working Group recommendations. Drs. Levy and Sawyer expressed appreciation to the NCI for the opportunity to co-chair the Working Group and the NCI Center for Biomedical Informatics and Information Technology (CBIIT), NCI staff, and Working Group members for supporting this effort.

Questions and Answers

Dr. Electra D. Paskett, Marion N. Rowley Professor of Cancer Research, Director, Division of Cancer Prevention and Control, Department of Internal Medicine, College of Medicine, The Ohio State University, suggested including other data sources (e.g., patient-reported outcomes [PRO] and demographic epidemiological data) and leveraging existing big data from the NCI National Clinical Trials Network in the final Data Science Working Group recommendations on high-value data sets. Dr. Sawyer conveyed that the Working Group recognizes the value of including PRO data and explained that due to the time, all data sets the Subgroup discussed were not presented at today's meeting. The expectation is that applicants would, in a Letter of Intent, submit the types of data they have collected and anticipate providing support with the appropriate resources. The Working Group also is planning to conduct an analysis of the current data landscape to assist in decision-making and prioritization of existing high-value data sets, beyond those identified through NCI funding opportunities.

Dr. Jaffee asked about the timeline for completing the final report. Dr. Sawyers noted that the next full Working Group meeting is planned for September 2018 and activities will focus on completing the broader discussions on final priorities and recommendations and reviewing the progress on the landscape survey analysis. The Working Group welcomes comments on final recommendations and other ideas on what to include in its final report. Dr. Sharpless added that having an initial set of recommendations that can be approved and that the NCI could act upon within the next 3 to 6 months would be helpful. He expressed appreciation to the Working Group for their support.

Motion. A motion to accept the interim report of the NCAB *ad hoc* Data Science Working Group was approved unanimously.

VI. *AD HOC* GLOBAL HEALTH WORKING GROUP FINAL REPORT—DRS. DEBORAH W. BRUNER AND SATISH GOPAL

Dr. Deborah W. Bruner, Robert W. Woodruff Chair of Nursing, Nell Hodgson Woodruff School of Nursing, Associate Director for Outcomes Research, Winship Cancer Institute, Emory University, presented the Global Health Working Group Final Report and acknowledged the Working Group members, including *ex officio* members. On April 30, 2018, the Working Group met for a face-to-face meeting at the NCI; was given the charge by the NCI Director, Dr. Sharpless; and began its activities. To address the charges to (1) advise the NCAB and the NCI Director on the vision, accomplishments, and operations of the NCI Center for Global Health (CGH) and (2) focus on the mission, prioritization process, goals, and scientific activities of the CGH, the Working Group reviewed copious amounts of written materials and received updates on the current status and achievements from the CGH leadership. In addition, findings of an internal review report of the CGH were presented by NCI leadership.

After deliberations on the current framework of the integration of the CGH five programmatic areas in which global oncology research is at the center, the Working Group found that the amount of

time and resources dedicated to global oncology research activities were not well focused. The Working Group next turned its efforts to addressing the challenges and opportunities to clarify the overall CGH mission, including the operation and integration of existing global research activities across the NCI and the NIH, which they parlayed into a final report.

Dr. Bruner summarized the Working Group recommendations. Recommendation 1—Clarify the CGH Mission Statement and Goals—aims to incorporate into the mission a clear primary focus on global oncology research; address vulnerable populations and health disparities; and focus on unique scientific opportunities in low-to-middle income countries. Recommendation 2—Enhance the Coordination and Communication Within the CGH, NCI, and NIH—will involve clarifying the mission and aligning resources with the goals; developing clear internal communication regarding the mission; and integrating the activities of the CGH with those of other NIH Institutes and Centers, including the Fogarty International Center. Recommendation 3—Develop a Clear, Consistent, and Transparent Process for Setting Goals—entails aligning the CGH priorities with the NCI mission and defining metrics of success. In addition, priority setting should be consistent with the key issues (e.g., cancer burden, infrastructure, and sustainability). Recommendation 4—Establish an External Advisory Group to the CGH—will provide the necessary review and oversight for the CGH to assist in prioritizing new research, assessing diplomacy, and evaluating metrics of success. Recommendation 5—Establish Better Linkage with NCI-designated Cancer Centers—aims to identify and advance global health activities through new funding opportunities, such as Specialized Programs of Research Excellence (SPORE) focused on global oncology.

Dr. Satish Gopal, Assistant Professor of Medicine, Divisions of Hematology/Oncology and Infectious Diseases, Lineberger Comprehensive Cancer Center, the University of North Carolina at Chapel Hill, remarked that the final report reflects the high degree of consensus among the Working Group members, which was maintained during the deliberations.

Discussion

Dr. Sharpless expressed appreciation to the Working Group for addressing one of NCI's ongoing and complex set of activities.

No questions were asked during this session. Dr. Sharpless updated NCAB members on personnel changes and the status of the CGH.

The NCAB members were reminded of a major new development since convening the Global Health Working Group, which also was discussed at the June 26–27, 2018, Joint BSA and NCAB meeting. Dr. Edward Trimble, former Director, CGH, has taken a position as liaison to the World Health Organization on the cervical cancer initiative. The NCI has begun a nationwide search for a new CGH Director. Dr. Sharpless invited Dr. Robert T. Croyle, Director, DCCPS, and Interim Director, CGH, to provide a brief update of the CGH activities. Dr. Croyle commented that efforts have been focusing on short-term action items necessary for closing out FY 2018, including reviewing existing contracts, grants, interagency agreements, and partnerships. The CGH also is preparing to address the Working Group findings and recommendations. Dr. Douglas R. Lowy, Deputy Director, NCI, and Advisor to the CGH, expressed appreciation to the Working Group for its evaluation and providing recommendations that the NCI anticipates will strengthen the CGH.

Motion. A motion to accept the final report of the NCAB *ad hoc* Global Health Working Group was approved unanimously

VII. 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.

VIII. 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 2,435 NCI applications were reviewed requesting direct cost support of \$1,056,902,632 and three FDA applications requesting direct cost support of \$436,406.

IX. 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 9th virtual meeting of the NCAB was adjourned at 3:35 p.m. on Tuesday, August 14, 2018.

Date

Elizabeth M. Jaffee, M.D., Chair

Date

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