DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH NATIONAL CANCER INSTITUTE 13th VIRTUAL NATIONAL CANCER ADVISORY BOARD

Summary of Meeting September 2, 2020

Virtual Meeting National Cancer Institute National Institutes of Health Bethesda, Maryland

NATIONAL CANCER ADVISORY BOARD BETHESDA, MARYLAND Summary of Meeting 2 September 2020

The National Cancer Advisory Board (NCAB) convened for its 13th virtual regular meeting on 2 September 2020. The meeting was open to the public on Wednesday, 2 September 2020, from 1:00 p.m. to 3:20 p.m., and closed to the public from 3:450 p.m. to 4:26 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) Dr. Peter C. Adamson Dr. Francis Ali-Osman Dr. Anna D. Barker Dr. Deborah Watkins Bruner Dr. Yuan Chang (absent) Dr. Howard J. Fingert Mr. Lawrence O. Gostin Dr. Andrea A. Hayes-Jordan Dr. Scott W. Hiebert Dr. Nikan Khatibi* Dr. Timothy J. Ley Dr. Electra D. Paskett Dr. Nancy J. Raab-Traub Dr. Margaret R. Spitz Dr. Susan Thomas Vadaparampil Dr. Max S. Wicha

* Pending appointment

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Norman E. Sharpless, Director, National Cancer Institute Dr. L. Michelle Bennett, Director, Center for Research Strategy 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. Robert Croyle, Director, Division of Cancer Control and Population Sciences Dr. William Dahut, Scientific Director for Clinical Research, Center for Cancer Research Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research Dr. Dan Gallahan, Acting Director, Division of Cancer Biology Mr. Peter Garrett, Director, Office of Communications and Public Liaison Dr. Satish Gopal, Director, Center for Global Health Dr. Paulette S. Gray, Director, Division of Extramural Activities Dr. Ed Harlow, Special Advisor to the NCI Director Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis Dr. Sara Hook, Director, Office of Scientific Operations, NCI at Frederick Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology Dr. Douglas R. Lowy, Principal 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. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program Dr. Henry Rodriguez, Acting Deputy 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, 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. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
- Dr. Maureen Johnson, Executive Secretary, Office of the Director

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WEDNESDAY, 2 SEPTEMBER 2020

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

Dr. Elizabeth M. Jaffee called to order the 13th 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 13 June 2020 Joint Meeting of the Board of Scientific Advisors (BSA) and the NCAB, with a correction in a wording change from whole "exome" sequencing to whole "genome" sequencing, 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 noted that the 2022 meeting dates will need to be approved.

Motion. A motion to approve the NCAB 2022 meeting dates was approved unanimously.

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

Dr. Norman E. Sharpless, Director, NCI, welcomed NCAB members and attendees to the 13th Virtual Meeting and provided updates on NCI's appropriations, coronavirus disease 2019 (COVID-19) activities, cancer research progress, and other activities.

Recognition of Retiring NCAB Member. On behalf of the NCI, Dr. Sharpless recognized the contributions made by 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, whose term has expired. He expressed appreciation for Dr. Jaffee's service and dedication over the course of her terms as NCAB member from 2013 to 2016 and then as NCAB Chair from 2016 to 2020.

NCAB Announcements. Dr. Sharpless announced that at the 30 November–2 December 2020 Joint BSA and NCAB meeting, Dr. Scott W. Hiebert, Hortense B. Ingram Chair in Cancer Research, Professor of Biochemistry, Department of Biochemistry, Vanderbilt University School of Medicine, will serve as Acting Chair, NCAB, and Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro-Oncology, Professor Emeritus of Neurosurgery, Duke University Medical Center, and Chair, of the NCAB ad hoc Subcommittee on Global Cancer Research, will now serve as the Chair of the NCAB Subcommittee on Special Actions. He noted that as the Chair of the Special Actions Subcommittee, Dr. Ali-Osman will preside over the closed session. Dr. Sharpless welcomed new NCAB member, Dr. Nikan Khatibi, Chief Executive Officer and Medical Director, Ahura Healthcare Corporation.

NCI Appropriations. Dr. Sharpless reminded the NCAB members that the fiscal year (FY) 2021 National Institutes of Health (NIH)/NCI budget appropriations process is in progress. The House Appropriations Subcommittee on Health and Human Services, Education, and Related Agencies (Labor– Department of Health and Human Services [HHS] released its FY 2021 markup bill, which includes increases to the NCI regular appropriations and \$414 million (M) in emergency funding related to COVID-19 restart costs. The proposed budget also continues the special appropriations for the Cancer Moonshot[™] and Childhood Cancer Data Initiative (CCDI). Congress has addressed legislation concerning the COVID-19 pandemic and is working on a fifth emergency appropriations bill. Dr. Sharpless noted that Ms. M.K. Holohan, Director, Office of Government and Congressional Relations (OGCR), will provide further details on the NCI FY 2021 budget later in the meeting.

NCI COVID-19 Activities. Dr. Sharpless updated the NCAB members on increased and steady media coverage on the future impact of the COVID-19 pandemic on cancer patients. In the June 2020 issue of *Science*, it was reported that the NCI-supported Cancer Intervention and Surveillance Modeling Network (CISNET) modelers estimated 10,000 (i.e., 1%) additional cancer deaths for two common cancers, i.e., breast and colon, over the next 10 years compared with a scenario without a disruption in care. Dr. Sharpless emphasized that this conservative CISNET analysis does not account for other cancers, which assuredly will be affected by the pandemic. Multiple analyses of different types of data (e.g., insurance coverage, electronic health records, and health services research) of these effects have been illustrated in the United States and the United Kingdom, all converging on a similar theme, which is massive decreases in cancer screenings, decreases in new cancer diagnoses, and delays in care. A recent account on how COVID-19 has changed cancer care, published in the 28 August 2020 issue of Time Magazine with graphical depictions from four separate reports, called attention to reduced screening, reduced pre-diagnoses, deferred care, and additional cancer deaths in the future. Dr. Sharpless remarked that a 50 percent decrease in some of the data sets reported in the literature is of great concern. particularly, in terms of new cancer diagnoses. Although many are optimistic that this decrease is not major and may reflect reduced diagnoses of indolent cancers of lesser clinical significance to patients, Dr. Sharpless indicated that he does not share this view because a reduction in diagnoses in lung and pancreatic cancers has been observed. In addition, increases in cancer morbidity, a lesser publicized topic, also have been significant for patients, who are not seeking care because of concerns related to potential exposure to COVID-19.

Dr. Sharpless indicated that the NCI also has worked to address racial disparities in cancer outcomes, the effects of which have been exacerbated during the COVID-19 pandemic, given its disproportionate impact on communities of color. The cancer community should collectively sound a warning about the effects of the pandemic and seek innovative ways to prioritize care for both patients and their caregivers that emphasize safe returns to work (e.g., practicing social distancing and wearing masks). Dr. Sharpless called attention to the fact that cancer kills nearly 600,000 Americans every year and is the leading cause of death from disease of Americans under the age of 65, regardless of a pandemic. The NCI is interested in hearing from NCAB members about other COVID-19-related practices and procedures established at their respective institutions and having a better understanding of what additionally can be done to address this issue.

Members were informed that the NCI is actively evaluating how COVID-19 is affecting people with cancer and is monitoring and responding to the impact on NCI clinical trials. On 21 May 2020, the NCI launched the NCI COVID-19 on Cancer Patients Study (NCCAPS), which is a natural history study focusing on longitudinal data and sample collection and extensive biomarker analyses. As of 24 August 2020, 742 sites had been activated across the Experimental Therapeutics Clinical Trials Network (ETCTN), NCI National Clinical Trials Network (NCTN), and NCI Community Oncology Research Program (NCORP) in 49 states and Puerto Rico. A total of 136 patients have been screened and 96 enrolled in NCCAPS. An amendment is in progress to begin enrolling pediatric cancer patients in NCCAPS. Dr. Sharpless explained that accrual across the NCTN from 3 February 2020 to 23 August 2020 decreased 50 percent during COVID-19, with the maximum decrease occurring the week of 14 April 2020. The accruals are now beginning to return to the pre-pandemic rate, but the NCI is concerned that large screening and prevention trials already experiencing low accruals have been significantly affected. As a steward of federal funding, the NCI is closely monitoring these types of trials, which tend to be resource intensive, including the Tomosynthesis Mammographic Imaging Screening Trial (TMIST). Dr. Sharpless directed attention to a detailed report on this topic, which will be provided later in the

meeting.

An emerging trend from the COVID-19 era is the rapid adoption and implementation of novel telehealth approaches to lessen the impact of the pandemic on patient care, in general, including cancer care. Dr. Sharpless remarked on how telehealth provides a convenient option for patients and presents opportunities for health services researchers to assess optimal approaches. He called attention to a recent report from one NCI-Designated Cancer Center (Cancer Center), Memorial Sloan Kettering Cancer Center (MSKCC), on the rapid pivoting of its Tobacco Treatment Program to telehealth to provide tobacco-cessation treatment for people with cancer. MSKCC also evaluated patient attendance rates by in-person counseling versus remote telehealth counseling visits and challenges on all levels (e.g., patient, clinician, and health care system) as a result of telehealth services. Dr. Sharpless pointed out that this effort was supported by the Cancer MoonshotSM-initiated Tobacco Cessation Program. The NCI recently issued a request for information on telehealth approaches and is now considering how best to support relevant research questions related to telehealth. He noted that Ms. Holohan will discuss policy changes and legislation addressing telehealth for cancer patients later in the meeting.

NCI Activities and Cancer Research Progress. Dr. Sharpless announced that on 27 August 2020, the NCI hosted a virtual launch of Cancer Grand Challenges (CGC), a partnership with Cancer Research UK (CRUK). Nearly 2,000 people attended the online launch. Dr. Sharpless, Dr. Dinah Singer, Deputy Director, Science Strategy and Development, and CRUK representatives presented on the potential of the CGC. This initiative leverages the NCI Provocative Questions (PQ) Initiative, with an added emphasis on both international multidisciplinary teams and patient involvement. The CGC will use the PQ funds every other year and is also supported by CRUK funds. The NCI and CRUK are finalizing the list of new challenges being framed as questions, which will be released in October 2020. The first stage of the competition involves expressions of interest from the teams, which will be accepted through April 2021. The CGC is one way to encourage and support high-risk, extremely innovative cancer research on a large scale, complements the NCI investigator-initiated research and Research Project Grant (RPG) research portfolio, and is expected to stimulate innovative ideas in overcoming barriers to research and make fundamental biological advances that will have direct impact on cancer patients.

Dr. Sharpless informed the NCAB members that the NCI is in the early stages of establishing a new equity inclusion program. He noted that this NCI-wide effort is designed to review aspects of equity and inclusion within the cancer research community and is a commitment towards improving conditions where possible. The program will consist of an NCI Equity Council directing three working groups that represent three broad aspect aspects of inclusion: (1) enhancing research to address cancer health disparities; (2) ensuring diversity of thought and background in the cancer research workforce; and (3) promoting an inclusive and equitable community at the NCI. The working groups will be composed of NCI leadership (senior and junior) and will represent a diversity of perspectives on this topic. As Chair of the NCI Equity Council, Dr. Sharpless intends to listen to the challenging issues that face the NCI, from NCI's leaders and staff across the working groups and across the entire NCI. The aim is to take meaningful action to affect positive change. Input from the broader cancer research community is encouraged. Concrete solutions being discussed within the equity and inclusion working groups include providing support for diversity of thought in the RPG Pool in FY 2020, making use of selective pay to award grants just outside of the payline, and using the analytic capabilities from the NCI Center for Research Strategy (CRS) to perform an in-depth analysis of the NCI cancer health disparities research portfolio, which is being facilitated by the NCAB ad hoc Subcommittee on Population Science, Epidemiology, and Disparities.

Highlighting evidence of progress in cancer, Dr. Sharpless remarked that lung cancer mortality rates have declined significantly in recent years and that NCI basic science research, combined with the tools and methodologies of the Division of Cancer Control and Population Sciences (DCCPS)

Surveillance Research Program (SRP), has played a major role. In fact, one SRP-led study published in the 13 August 2020 issue of the *New England Journal of Medicine* revealed striking improvements and survival for non-small cell lung cancer (NSCLC) but not for small cell lung cancer (SCLC). This current analysis applied novel methodologies to NCI Surveillance, Epidemiology, and End Results (SEER) data to demonstrate that the therapeutic benefits developed over decades of basic science investigations have affected and continue to affect significantly new national cancer survival statistics with measurable benefit for patients. This in-depth examination of lung cancer mortality declines by disease subtype extends the *Annual Report to the Nation on the Status of Cancer*. Dr. Sharpless wrote an editorial in *Stat News* conveying this message, and he noted that further details on this study will be provided later in the meeting.

Dr. Sharpless highlighted two efforts in data science: Cancer Research Data Commons (CRDC) and Integrated Canine Data Commons (ICDC). The NCI has been focused on the CRDC, which enables the research community to share diverse data types securely, including data from The Cancer Genome Atlas (TCGA), Therapeutically Applicable Research to Generate Effective Treatments (TARGET), Clinical Proteomics and Tumor Analysis Consortium (CPTAC), and most recently, the ICDC. Two components that will drive interoperability of the data include: (1) the CRDC standard data model, CRDC-H, which is harmonizing data across the CRDC and its repositories and (2) the search engine Cancer Data Aggregator, which will assist researchers in data queries across the various repositories. On 26 August 2020, the NCI launched the ICDC, a cloud-based, open access repository of canine cancer data developed by the Frederick National Laboratory for Cancer Research (FNLCR), representing another node of the CDRC. The ICDC will further research on human cancer by enabling comparative analyses with canine cancer. The infrastructure consists of a graphical user interface and an application programming interface to assist software developers in data queries.

Dr. Sharpless informed the NCAB members that the NCI released its Annual Plan and Budget Proposal for Fiscal Year 2022 (also called the Bypass Budget or Professional Judgement Budget) in August 2020. This year, the NCI has taken an all-digital approach, and the scientific content and stories of patients and cancer researchers are incorporated into the NCI main website content at Cancer.gov. The NCI anticipates that this approach will engage readers and stakeholders with these materials throughout the year ahead. An all-digital approach also intersects with plans to commemorate the 50th anniversary of the National Cancer Act of 1971. The Annual Plan highlights four scientific priorities and emerging opportunities: (1) cancer drug resistance; (2) molecular diagnostics for treatments; (3) obesity and cancer; and (4) cancer survivorship. The NCI Professional Judgment Budget for FY 2022 proposes a "5 in '25" plan to increase funding to the RPG Pool with the goal of reaching a 15th percentile payline for R01 grants by FY 2025. He noted that this plan and rate of increase (i.e., \$200 M) has enabled the NCI to reach the 10th percentile in FY 2020; however, it will take multiple years to reach the 15th percentile payline. To achieve this aspirational and resource-intensive goal by FY 2025 and without making cuts to major programs outside of the RPG pool, Dr. Sharpless noted that the NCI will need continued support from Congress. He expressed appreciation to Dr. L. Michelle Bennett, Director, CRS, and her team, the Office of Budget and Finance, and the Office of Communications and Public Liaison for their efforts in developing the Annual Plan.

Questions and Answers

The NCAB Chair, Dr. Jaffee, asked what approach would be needed to achieve the 15 percentile payline and whether the increases include additional applications from early stage investigators (ESIs). Dr. Sharpless explained that reaching this target goal will take more than one year and will require consecutive increases annually to the RPG pool to support non-competing and new awards in subsequent out-years. Even with the regular annual increases to the RPG pool, increases of \$200 M were necessary to move from the 8 percent to the 10 percent payline. He stated that the NCI has conveyed to Congress the importance of increasing the R01 paylines to support the next generation of cancer researchers and those

messages have been well received. Dr. Sharpless anticipates that the increases to the RPG pool will enable the NCI to fund additional ESIs through select pay.

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

Ms. Holohan reported on the FY 2021 appropriations process, telehealth advocacy and legislation, and COVID-19 supplemental funding. She noted that 29 days remain in FY 2020 and that the FY 2021 appropriations process is ongoing. On 6 July 2020, the House Appropriations Labor-HHS Subcommittee passed its FY 2021 bill out of committee; this includes a \$5.5 billion (B) increase to the NIH, \$5 B of which is allotted for emergency funding. The House considered this emergency funding and a hybrid approach that does not weigh against the budget caps established in the Budget Control Act of 2011 but provides the NIH and other agencies with room for addressing their priorities. The NCI total appropriation amounts to \$6.9 B and includes \$414 M allotted for emergency funding and \$190 M for the Cancer MoonshotSM. The Senate Appropriations Subcommittee on Labor–HHS hearing on the FY 2021 NIH budget request was postponed during the COVID-19 pandemic and has not been rescheduled. A continuing resolution (CR) is likely and could possibly be combined with the fifth supplemental COVID-19 spending package; the 3 November 2020 elections also will have an impact. Historically, election years have tended to cause a delay in appropriations bills, particularly when the leadership in one or both chambers changes. In addition, election years, midterms, and presidential election years affect the timing of CRs, which can present challenges for planning and executing the NCI budget. In the past eight election years, only one appropriation bill was completed in a timely manner not warranting a longstanding CR.

Ms. Holohan explained that legislators have been discussing policy and advocacy related to telehealth, a topic about which the Centers for Medicare & Medicaid Services (CMS) Administrator, Ms. Seema Verma, has been out front and vocal in the media. The White House issued an Executive Order expanding telehealth during the COVID-19 pandemic, and the HHS issued Executive Actions to expand rural health care. The Medicare reimbursement policies encouraging telehealth have been very positive, and several bills and legislative proposals have been introduced. A broad advocacy coalition, including cancer medical research groups, has emphasized the urgency for temporary and permanent changes regarding reimbursement and billing, health care provider services, geographic research, and malpractice insurance at state borders.

Ms. Holohan reminded the NCAB members that, within a 50-day period, Congress developed and passed four emergency spending packages totaling \$2.6 trillion, but is currently deliberating on the breadth, scope, and cost of a fifth emergency supplemental spending package. On 15 May 2020, the House passed a \$3 trillion Health and Economic Recovery Omnibus Economic Solution (HEROES) Act; which includes a \$4 B appropriation to the NIH to prevent, prepare for, and respond to coronavirus, \$3 B of which is allocated for costs related to the reduction in laboratory productivity. On 27 July 2020, the Senate announced the Health, Economic Assistance, Liability Protection, and Schools (HEALS) Act encompassing eight bills totaling \$1 trillion, which includes \$15.5 B for the NIH, with \$10 B reserved for costs related to the reductivity. Ms. Holohan does not anticipate any additional action on the HEROES and HEALS Acts until mid to late September when both chambers of Congress are in session. Congress also will work to address a CR to fund the government if the FY 2021 budget has not been approved.

V. THE IMPACT OF ADVANCES IN LUNG CANCER TREATMENT ON POPULATION MORTALITY BY SUBTYPE—DR. NADIA HOWLADER

Dr. Nadia Howlader, Mathematical Statistician, Data Analytics Branch, SRP, DCCPS, presented a study on the effects of the advances of lung cancer treatment on population mortality by subtype (SCLC and NSCLC). Dr. Howlader expressed appreciation to her collaborators on the study, including colleagues

in the SRP and NCI SCLC Consortium, and she acknowledged Dr. Douglas R. Lowy, Principal Deputy Director, NCI, for his contributions and guidance. From 1975 to 2017, lung and bronchus mortality rates have steadily declined in men and women. The American Cancer Society (ACS) reported in its *Cancer Facts & Figures 2020* (generated using the SEER data) the largest 1-year decrease (2.2 percent) in cancer mortality from 2016 to 2017. The ACS concluded that lung cancer showed one of the most rapid declines, but the proportion of a specific disease subtype contributing to this overall trend of mortality is not well understood.

Dr. Howlader's study aimed to determine how the two major lung cancer subtypes, SCLC and NSCLC, contributed to the overall decline in mortality and whether this decline was additionally related to incidence or survival. Three scenarios of mortality decline were evaluated: Scenario 1, the incidence remains flat and survival improves; Scenario 2, incidence declines and survival remain flat; and Scenario 3, incidence declines and survival improve. The analysis cohort consisted of lung and bronchus cancer cases in SEER-18 data (i.e., collected in 18 SEER areas) from 2001 to 2016, which covers 28 percent of the U.S. SCLC and NSCLC population previously defined by Lewis *et al.* (2014). The study design methods made use of the incidence-based mortality (IBM) technique to partition subtype-specific mortality trends and the Joinpoint trend analysis software to assess the IBM trend changes over time. In addition, incidence and survival trends to understand IBM trends were assessed, and 2-year lung cancer–specific survival by subtypes was estimated. Because information on lung cancer subtypes is not available in the death certificate mortality records. The IBM, which is a rate of death among incident cases/general population in SEER areas for any given year, likely represents lung cancer mortality more accurately than death certificate mortality data.

The study results showed that in male NSCLC patients, the IBM rate decreased 3.2 percent annually from 2006 to 2013, and the decline nearly doubled to 6.2 percent from 2013 to 2016. The concurrent incidents also declined, but at a much slower rate, decreasing from 1.9 percent annually from 2001 to 2008 and 3 percent from 2008 and beyond. The 2-year lung cancer survival rate increased from 26 percent if diagnosed in 2001 to 35 percent if diagnosed in 2014. Similar trends in IBM rates were observed in female patients during this time span: The 2-year survival was 35 percent in 2001 and 44 percent in 2014. The declines in IBM rates and improvements in survival were observed across racial and ethnic groups, but the 2-year survival was worse among non-Hispanic Blacks/African Americans than among other minority groups. For SCLC, the improvements were minimal, and the 2-year survival was relatively unchanged in both men and women, with some decrease in mortality correlating to reduced use of tobacco products.

Dr. Howlader detailed the interpretation of the trends. The question being addressed is whether other factors (e.g., screening, smoking cessation, or therapies) could explain the steep decline in NSCLC mortality. Lung cancer screening rates remained low and were stable throughout the study period. Although the decreased smoking rates contributed to the declining incidence and mortality rates for lung cancer over time, this decrease alone cannot explain the magnitude of the mortality decline, especially given the timing. The U.S. Food and Drug Administration (FDA) approved several targeted therapies for lung cancer, which strongly correlate to the mortality declines.

Dr. Howlader concluded that the steady decline in SCLC mortality could be explained entirely by the lower incidence of disease, potentially attributable to reduced tobacco use. The steady decline in NSCLC initially, followed by rapid decline in 2013 to 2016, is attributed primarily to the dissemination of FDA-approved targeted therapies for stage 4 epidermal growth factor receptor (EGFR)-positive NSCLC as first-line treatments. These estimates suggest possible population-level impacts of targeted therapies. Dr. Howlader pointed out that data on individual-level uptake of therapies are limited in SEER. The SRP is collaborating with the U.S. Department of Energy (DOE) (i.e., Joint Design of Advanced Computing Solutions for Cancer [JDACS4C]), which is enabling collection of cancer surveillance data from multiple

sources to populate detailed treatment and biomarkers along with a decrease in the interval for reporting. The aim is to create comprehensive longitudinal patient trajectories.

Questions and Answers

Dr. Sharpless commented that immunotherapy was approved by the FDA beginning in the 2015–2016 timeframe and asked whether the improvements in survival could be attributed to this action, given that this study evaluated data from 2016. Dr. Howlader explained that efforts are continuing to track the mortality trends by subtype, and she anticipates data demonstrating whether immunotherapy affects survival in the coming year.

VI. UPDATE ON TMIST: TOMOSYNTHESIS MAMMOGRAPHIC IMAGING SCREENING TRIAL—DR. PHILIP E. CASTLE

Dr. Jaffee, the NCAB Chair, noted that following this presentation, the Board will vote to concur with establishing an NCI Clinical Trials and Translational Research Advisory Committee (CTAC) *ad hoc* Working Group on Cancer Screening Trials. The mission statement and details on the Working Group activities were provided in the Board materials. Dr. Sharpless explained that, in general, the NCI has been evaluating the accrual to large NCTN trials that are resource extensive, which also have been sources of care disruption during the COVID-19 pandemic. Historically, the accrual in large screening trials at the NCI tends to be slow initially, but an in-depth investigation revealed considerably lower than expected enrollments. The NCI is soliciting input from the extramural community on this issue (and is the reason for today's presentation on this topic).

Dr. Phillip E. Castle, Director, Division of Cancer Prevention (DCP), provided an update on the impact of the SARS-CoV-2 (coronavirus causing COVID-19) pandemic on the DCP trials, particularly TMIST. He acknowledged the work of the prior DCP leadership and expressed appreciation to Dr. Deborah M. Winn, Deputy Director, DCCPS, who severed as Acting Director, DCP, for the past year, for her mentorship during his transition to the NCI. Dr. Castle echoed Dr. Sharpless that the COVID-19 pandemic has decreased accrual to the NCTN trials. Because some of these large-scale trials take time to complete, he noted the importance of asking whether they still are poised to answer the critical research questions they were intended to address, and whether they will do so in a timely manner. The NCI considers ongoing reviews of the active DCP prevention trials as its stewardship responsibility. Dr. Castle focused his presentation on TMIST, DCP's largest trial, which is being led by the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG–ACRIN).

The purpose of TMIST, a large randomized controlled trial (RCT), is to determine whether the cumulative rate of advanced breast cancer in women undergoing screening with tomosynthesis plus digital mammography (i.e., three-dimensional [3-D]) is reduced compared with digital mammography (i.e., 2-D) alone. For this study, advanced cancer is defined as any cancer diagnosed in the 4.5 years after study entry that is metastatic or is a large tumor (based on subtype), but mortality is not the endpoint. TMIST is conducted across both NCORP and non-NCORP sites. The trial was originally projected to complete enrollment by 2020 (2.5 years of accrual averaging 5,500 monthly) and finish in 2025, with a proposed sample size of 165,000 participants. The current enrollment is less than 30,000, and the 2021 to 2024 costs are estimated at \$94 M.

Dr. Castle reviewed the TMIST study schema, including the 4-year follow-up and acknowledged the volunteers for their willingness to participate in the study. He expressed appreciation to the TMIST team, DCP staff, and clinical site teams for their efforts. A total of 112 sites are currently open to accrual in the NCI Cancer Trials Support Unit (CTSU), 99 of which have enrolled at least one participant. Currently, 13 sites are open in the CTSU but have no enrollments as of 1 September 2020, and 23 U.S. sites and 3 international sites are in the process of submitting qualifications to activate TMIST. To date,

the actual accrual rate of 1,500 per month is well below the target rate of 5,500, with a maximum of 1,700 enrolled between January 2020 and February 2020.

Regarding the accruals and the impact of COVID-19, a 50-percent reduction in enrollments was observed for a 6-month period from March 2020 to August 2020. Dr. Castle highlighted two informative analyses comparing 2-D and 3-D mammography since the start of TMIST. A 2018 meta-analysis (Marinovich *et al.*) evaluating 17 studies showed that in single- and two-arm studies, 3-D detected more cancers, but the study reported slightly different recall rates when compared to 2-D. A 2020 observational study assessing 1.6 million screening examinations across 46 U.S. facilities (Lowry *et al.*) revealed that 3-D mammography reduces recall rates and detects more total and invasive breast cancer than 2-D mammography. A landscape analysis of ongoing trials in clinicaltrials.gov identified three large RCTs of 3-D and 2-D mammography being conducted in Europe. All three trials, which started after TMIST, have been projected to be completed in 4 years, and all have been delayed because of COVID-19. Dr. Castle emphasized that, regardless of the screening method, many of the same clinical questions about breast cancer screening remain, such as how to best screen women with dense breasts and how to address the fact that most women screening positive do not have clinical signs.

Dr. Castle introduced key considerations for TMIST and detailed the rationale for the advice being sought from the Board. The under accrual, compounded by the effects of the SARS-CoV-2 pandemic, will likely result in delayed outcomes and escalate costs for the study. The ECOG–ACRIN is adding clinical sites, but it is unclear whether a 3,000 monthly accrual rate will be achieved. The relevance these data will have by completion of the trial is uncertain because of: (1) the projected 3-D mammography market and uptake; (2) existing evidence suggesting that 3-D is superior to 2-D mammography; and (3) other trials and observational cohorts that, although not optimal, will contribute additional and informative data. As initially conceived, TMIST will not complete accrual until FY 2023 or FY 2026, depending on the monthly accrual rate. Further delays can be expected if the effects of the pandemic are long term. The 5-year follow-up and 1-year primary data analysis will add approximately 6 years from the time of enrollment, meaning the completing and reporting of the data will occur between FY 2029 and FY 2032, rather than in FY 2025. By this time, ongoing breast cancer screening trials would have reported their results and radiological practice likely would have changed substantially. Given these unanticipated challenges because of the pandemic, the NCI proposes establishing a Cancer Screening Trial Working Group, reporting to the CTAC, to examine the utility of TMIST.

Dr. Castle clarified that TMIST is continuing as these considerations are being reviewed. The ECOG–ACRIN remains committed to the study and enrollment is ongoing, which the NCI central institutional review board (CIRB) has approved. The DCP recognizes that now is the time to evaluate the feasibility and relevance of TMIST and is looking forward to collaborating with the Working Group and key stakeholders to chart the best path forward.

Questions and Answers

Dr. Peter C. Adamson, Global Head, Oncology Development and Pediatric Innovation, Sanofi, expressed concern in the approach for establishing a Working Group to the CTAC at an NCAB meeting and emphasized that COVID-19's impact across NCTN trials would mirror the effects to TMIST if the presentation had included those data. Dr. Adamson also expressed concern with this course of a public announcement to suspend a large-scale trial without having discussions with the multiple investigators and then providing them the opportunity to develop an action plan to address accrual. Dr. Castle clarified that the NCI is requesting advice from a Cancer Screening Trials Working Group and is not advocating that TMIST be shut down. He reiterated the stewardship responsibility of bringing this information forward to the public, given that the trial costs over \$100 M. Dr. Sharpless thanked Dr. Adamson for his comments and indicated that the same accrual problem on the level of TMIST is not mirrored in other NCI clinical trials. Thus, establishing a working group is the most effective approach to addressing the

issues in TMIST, and the Federal Advisory Committee Act (FACA) process requires that it be conducted in a public forum. NCAB Executive Secretary, Dr. Gray, explained that the NCAB is the primary Board of the NCI and has the authority to establish a working group that will report to another Committee/Board, which would at some point report back to the NCAB. Dr. Gray further elaborated that a Cancer Screening Trials Working Group, not a TMIST Working Group, is being established and noted that this group may or will discuss other NCI screening trials. Dr. Sharpless added that this is the process in place to receive recommendations from the outside community on the disbursement of funds. Although internal discussions on TMIST accruals have been ongoing in the NCI, the perspective from the extramural community on continuing, modifying, or closing the trial is needed.

In response to a query by Dr. Adamson about CTAC establishing its own working group, Dr. Gray clarified that the NCI cannot initiate any recommendations from any working group without having a Board/Committee approve that working group's final report, after which the NCI can review and respond to the ideas presented.

Dr. Andrea A. Hayes-Jordan, Byah Thompson Doxey Distinguished Professor of Surgery, Division Chief, Pediatric Surgery, Surgeon-in-Chief, University of North Carolina Children's Hospital, asked whether the Cancer Screening Trials Working Group would have a continued purpose to evaluate other poorly accruing NCI trials of a specific dollar amount in the indefinite future. Dr. Sharpless replied that it is likely that other prevention and screening trials would be reviewed; TMIST is the most pressing because of its size and other shortcomings regarding accrual. Dr. Castle added that screening trials are complicated and challenging to conduct, even under the best circumstances. The aim is to be transparent about what is known concerning any given trial to inform whatever advice the NCI receives. Dr. Gray explained that the Working Group is expected to complete its evaluations within an appropriate period of time, but it should be less than 2 years.

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, sought clarity on who would be eligible to join the Working Group if the intent is only to evaluate screening and not prevention trials and whether minority population accrual targets had been established and were being met in TMIST. She also remarked that issues with the TMIST accruals had been identified prior to the COVID-19 pandemic and noted that determinations on when a trial closes is under the purview of the Data and Safety Monitoring Board (DSMB), not the CIRB, which evaluates human protections. Dr. Castle will consult with the TMIST team about the DSMB and minority accrual targets and provide that information to the Board. Dr. Gray commented that the composition of the Working Group has not been decided and would be discussed among the NCI senior leadership and CTAC. Thus, NCAB members interested in joining the Working Group should contact her.

Dr. Margaret R. Spitz, Professor, Department of Medicine, Dan L. Duncan Cancer Center, Baylor College of Medicine, commented that the adoption of 3-D mammography technology is widespread and expressed concern that the process of establishing a Working Group to make decisions about TMIST would take significant time. Dr. Sharpless acknowledged the pending timeframe, which was a major reason for this discussion with the Board today. He explained that the Working Group likely will need time to gather any additional data and information to inform its recommendations, while TMIST will be continuing its operations.

Dr. Max S. Wicha, Madeline and Sidney Forbes Professor of Oncology, Director, Forbes Institute for Cancer Discovery, Founding Director Emeritus, University of Michigan Rogel Cancer Center, Professor of Internal Medicine, Division of Hematology and Oncology, University of Michigan, asked whether a dialogue between TMIST leaders regarding the underaccruals had been constant and whether opportunities had been given to develop an alternative plan or change the trial goals. Dr. Sharpless pointed out that discussions on the TMIST accruals have been ongoing for 2 years and noted that the study investigators are well aware of NCI's concerns and have made efforts to make improvements. One question that remains is whether the accruals can increase at the pace necessary to complete the trial on time.

Dr. Anna D. Barker, Chief Strategy Officer, Ellison Institute for Transformative Medicine, University of Southern California, commented that this process presented at this meeting is somewhat different than previous processes and sought clarification on whether this would be an NCAB Working Group. Dr. Gray clarified that this will not be an NCAB Working Group and reiterated that the NCAB can establish such a group and then ask another Board or Committee to oversee the activities; although not common, the NCI has used this process on other occasions.

Motion. A motion to concur with establishing an NCI Clinical Trials and Translational Research Advisory Committee *ad hoc* Working Group on Cancer Screening Trials was approved with 14 ayes, 0 nays, and 1 abstention.

VII. ONGOING AND NEW BUSINESS—DR. ELIZABETH M. JAFFEE

Dr. Jaffee invited the Subcommittee Chairs to present their respective reports.

NCAB ad hoc Subcommittee on Population Science, Epidemiology, and Disparities.

Dr. Paskett, Chair of the NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee, presented the report of the 1 September 2020 meeting. The NCI Director, Dr. Sharpless, and Principal Deputy Director, Dr. Lowy, attended the meeting. Dr. Paskett noted that the Subcommittee reviewed the charge, which initially focused on population science, epidemiology, and diversity, and, in discussion with NCI leadership at that time, made the decision to include health disparities. She remarked that health disparities are a timely topic for the Subcommittee and align with the three areas of NCI's new initiative on equity and inclusion introduced earlier by Dr. Sharpless. Dr. Paskett explained that the Subcommittee's initial activities will be to conduct an in-depth portfolio analysis of the existing NCI cancer disparities research by the different disparity populations. The analysis would span the cancer continuum (e.g., prevention, treatment, early detection, risk assessment, access to treatment, survivorship, and palliative care) by cancer type and identify any gaps in the continuum and/or populations. This analysis also will provide metrics on how the NCI is addressing disparities over time.

The Subcommittee heard a presentation from Dr. Emanuel Taylor from the Center to Reduce Cancer Health Disparities (CRCHD) on cancer health disparities described in the annual Minority Health and Health Disparities (MHHD) Report to Congress, with details on the budgetary aspects. Dr. Paskett highlighted that the MHHD Report focuses on minority health and disparities. The Subcommittee also discussed what the NCI senior leadership envisioned being completed by the 30 November–2 December 2020 Joint BSA and NCAB meeting. It was agreed that the NCI would perform a "deep dive" into the current research being conducted in one or two minority and underserved groups and report back to the Subcommittee at a future meeting. The first report will be in-depth analysis across the minority populations. Dr. Paskett pointed out that Drs. Bennett and Christine Burgess from the CRS described to the Subcommittee that approaches, such as artificial intelligence, would be used for performing the indepth portfolio analysis. After discussion, the Subcommittee decided to focus the first portfolio analysis on two minority populations, i.e., one heavily researched in the NCI, such as the Black/African American population, and the second of a limited researched group, such as the Hispanic/Latino, Asian American, American Indian, or Pacific Islander American populations.

Dr. Paskett explained that, following the CRS report, the next steps will be to draft a charge for the Subcommittee's *ad hoc* Cancer Disparities Working Group and discuss the types of expertise needed. The Working Group would then be charged to work closely with the NCI subject-matter experts to

facilitate the full portfolio analysis. For a future meeting topic, the Subcommittee requested an update on research training from the Center for Cancer Training.

Questions and Answers

In response to a query from Dr. Hayes-Jordan on whether access to care as it is related to treatment and outcome disparities is being included in the evaluation, Dr. Paskett replied that the Subcommittee will identify specific language to search the cancer continuum concerning disparities, which include access to care as a critical pillar.

Motion. A motion to accept the report of the 1 September 2020 NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee meeting was approved unanimously.

NCAB Planning and Budget Subcommittee. Dr. Barker, Chair of the NCAB Planning and Budget Subcommittee presented the report of the 1 September 2020 meeting. The NCI Director, Dr. Sharpless, and Principal Deputy Director, Dr. Lowy, attended the meeting. Dr. Barker explained that the Subcommittee, which was established in 1976, is charged to ensure that the NCI Bypass Budget reaches the President. She opened the Subcommittee discussion with three key questions focusing on how the NCAB: (1) might best assist the NCI in this current budget process, especially regarding the *Annual Plan and Budget Proposal for Fiscal Year 2022*; (2) can assist and support all of the analytics regarding the impact of COVID-19, such that cancer advocacy groups are engaged to increase awareness beyond the NCI; and (3) assist in finding new ways to supplement the NCI budget similar to the NCI–Cancer Research UK partnership. Dr. Sharpless specifically charged the Subcommittee to address ways to improve the RPG paylines, particularly for R01 grants.

The Subcommittee was provided with an overview of the current NCI budget and a look toward the future by Mr. Patrick McGarey, Associate Director for Finance and Legislation. The overview included details about an NCI budgetary challenge. Mr. McGarey stated that since FY 2013, the NCI budget (i.e., regular appropriations) has increased 20 percent, but the number of grant applications has increased by 50 percent or more. This challenges the NCI to keep its investments focused and prioritized. The Subcommittee discussed the FY 2020 budget and the effects from COVID-19, as well as the NCI supplemental funding from Congress to support COVID-19 serological research, which is a onetime (not a sustained) appropriation. The Subcommittee heard a presentation by Dr. Bennett from the CRS on the NCI Bypass Budget for FY 2022 and NCI's proposal to increase paylines to the 15th percentile. Discussions also focused on the pandemic's effect on the financial stability of the Cancer Centers and supporting strategies that increase the RPG paylines.

Dr. Barker highlighted that the Subcommittee made several recommendations regarding the NCI budget and next steps. The group agreed to reconvene at the beginning of FY 2021 to assess the financial unknowns and to consider strategies for assisting the advocacy/survivorship communities and professional organizations in communicating the current financial status of the 2020 and future NCI budgets. The Subcommittee will encourage the NCAB to formally express its support of the *Annual Plan and Budget Proposal for Fiscal Year 2022*, which focuses on increasing the payline to the 15th percentile. The Subcommittee also will consider strategies for establishing relationships with other cancer research organizations that could serve as partners to fund additional programs of joint interest.

Questions and Answers

Dr. Hiebert remarked on conveying to Congress NCAB's appreciation of its support that allowed the NCI to increase paylines from the 8th to 10th percentile. He recommended endorsing the concept and taking a motion to draft a letter to the NCI Director, which members could share with their respective legislators. Dr. Barker supported the recommendation and noted that the NCAB has taken similar actions

and has written letters relaying its support of various initiatives to congressional leaders. Dr. Gray clarified that the NCAB could make a motion regarding paylines that does not specifically ask the NCI to reach a certain percentile in FY 2021. After the motion is accepted, the NCI will consider how best to move forward, which can involve discussions with the Subcommittee Chair, Dr. Barker, and the NCAB Acting Chair, Dr. Hiebert at that time. Dr. Sharpless commented that a statement of endorsement from the NCAB concerning the NCI Annual Budget would speak volumes about the enthusiasm and importance of this topic and would serve as a record, regardless of who is appointed NCI Director. Dr. Barker added that such a statement would influence other cancer organizations, such as the American Association for Cancer Research and American Society for Clinical Oncology, which have a strong presence on Capitol Hill.

Motion. A motion to support the NCI strategy to increase R01 paylines to the 15th percentile over 5 years was approved unanimously.

Motion. A motion to accept the report of the 1 September 2020 NCAB Planning and Budget Subcommittee meeting was approved unanimously.

NCAB *ad hoc* **Subcommittee on Global Cancer Research.** Dr. Ali-Osman, Chair of the NCAB *ad hoc* Subcommittee on Global Cancer Research, presented the report of the 1 September 2020 meeting. The NCI Director, Dr. Sharpless, and Principal Deputy Director, Dr. Lowy, attended the meeting. Dr. Ali-Osman noted that the Subcommittee is charged with advising the NCAB and the NCI Director on strategic approaches and opportunities in global cancer research and prioritizing prospects and partnerships essential for the NCI to contribute globally to cancer research. A major activity for the Subcommittee over the past 2 years was to convene an *ad hoc* Working Group on Global Health to provide a strategic assessment of the Center for Global Health (CGH). The Working Group presented its final report and recommendations to the NCAB, which the NCI and CGH are actively implementing. Aligning with a key recommendation of the Working Group, the Subcommittee joined the NCI in welcoming Dr. Satish Gopal as new CGH Director in February 2020.

The Subcommittee heard presentations from CGH leadership. Dr. Gopal provided an update on the current status of the Center, described plans for improvements, and outlined his strategies for refreshed CGH goals, vision, and mission. Dr. Kalina Duncan described CGH's activities regarding cancer and COVID-19 in low- and middle-income countries, including new partnerships and future opportunities. Dr. Sudha Sivaram detailed the unique aspects of the CGH D43 global cancer research training program, which was developed in partnership with the NCI Center for Cancer Training. Dr. Ali-Osman conveyed the pleasure of the Subcommittee with the progress of the CGH in the short time Dr. Gopal took over as Director, and, especially under the constraints of working in the Covid-19 pandemic. The Subcommittee looks forward to the consolidation of CGH's plans and priorities under its new leadership. He informed the members that the subcommittee supports Center's plans, including, holding a GCH retreat, as well as, Dr. Gopal's initiation of the development of a strategic plan that will clarify the key priorities and strategic approaches for the CGH.

Motion. A motion to accept the report of the 1 September 2020 NCAB *ad hoc* Global Cancer Research Subcommittee meeting was approved unanimously.

NCAB *ad hoc* **Subcommittee on Experimental Therapeutics**. Dr. Timothy J. Ley, Professor of Medicine and Genetics, Division of Oncology, Department of Medicine, Washington University School of Medicine in St. Louis, Chair of the NCAB *ad hoc* Subcommittee on Experimental Therapeutics, presented the report of the 1 September 2020 meeting. The NCI Director, Dr. Sharpless, and Principal Deputy Director, Dr. Lowy, attended the meeting. Dr. Ley explained that, after more than a decade of inactivity, the Subcommittee has reconvened to review the existing portfolio. Dr. Sharpless charged the Subcommittee to assist the NCI in identifying high-priority research opportunities in experimental

therapeutics. The Subcommittee members reviewed their expertise and special interests relative to the charge/mission and heard a presentation by Dr. Rosemarie (Rose) Aurigemma of the Division of Cancer Treatment and Diagnosis regarding the NCI Experimental Therapeutics (NExT) Program. The Subcommittee was updated on the intramural and extramural contributions to the NCI experimental therapeutics portfolio and discussed setting priorities and defining areas to investigate in detail. Dr. Ley presented a list of 10 potential topics for the Subcommittee to consider, comment on, update, and prioritize. The group will reconvene and further discuss these prior to the 30 November–2 December 2020 Joint BSA and NCAB meeting.

Motion. A motion to accept the report of the 1 September 2020 NCAB *ad hoc* Experimental Therapeutics Subcommittee meeting was approved unanimously.

Future Agenda Items. The NCAB members were asked to forward any suggestions for potential future agenda items to Dr. Gray.

VIII. 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.

IX. 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 1,830 NCI applications were reviewed requesting direct cost support of \$656,718,761 and two FDA applications requesting direct cost support of \$375,686.

X. 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 13th Virtual Meeting of the NCAB was adjourned at 4:26 p.m. on Wednesday, 2 September 2020.

Date

Scott Hiebert, Ph.D., Acting Chair

Date

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