

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
16th VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 10, 2022**

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

**NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
10 February 2022**

The National Cancer Advisory Board (NCAB) convened for its 16th virtual regular meeting on 10 February 2022. The meeting was open to the public on Thursday, 10 February 2022, from 1:00 p.m. to 3:46 p.m., and closed to the public from 3:55 p.m. to 5:30 p.m. The NCAB Chair, Dr. John D. Carpten, Professor and Chair, Department of Translational Genomics, Royce and Mary Trotter Chair in Cancer Research, Keck School of Medicine, University of Southern California, presided during both the open and closed sessions.

NCAB Members

Dr. John D. Carpten (Chair)
Dr. Francis Ali-Osman
Dr. Nilofer S. Azad
Dr. Anna D. Barker
Dr. Luis Alberto Diaz, Jr.* (absent)
Dr. Howard J. Fingert
Dr. Christopher R. Friese
Mr. Lawrence O. Gostin
Dr. Andrea A. Hayes-Jordan
Dr. Amy B. Heimberger
Dr. Scott W. Hiebert
Dr. Nikan Khatibi (absent)
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub
Dr. Margaret R. Spitz
Dr. Susan Thomas Vadaparampil
Dr. Ashani T. Weeraratna
Dr. Karen M. Winkfield

President's Cancer Panel

Dr. John P. Williams (Chair) (absent)
Mr. Robert A. Ingram (absent)
Dr. Edith P. Mitchell

Alternate Ex Officio NCAB Members

Dr. Michael A. Babich, CPSC	Dr. Richard Pazdur, FDA (absent)
Dr. Gwen W. Collman, NIEHS	Dr. Tara A. Schwetz, NIH (absent)
Dr. Joseph R. Graber, DOE	Dr. Craig D. Shriver, DoD
Dr. Michael Kelley, VA	Dr. Kerry Souza, NIOSH (absent)

* Pending Appointment

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Norman E. Sharpless, Director, National Cancer Institute
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. 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. Katrina A.B. Goddard, Director, Division of Cancer Control and Population Sciences
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the NCI Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology
Dr. Kristin Komschlies McConville, Acting Director, Office of Scientific Operations, NCI at Frederick
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. Diane Palmieri, Acting Director, Center for Research Strategy
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 and Acting Director, Center for Strategic Scientific Initiatives
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. Brigitte C. Widemann, Special Advisor to the Director for Childhood Cancer
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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THURSDAY, 10 FEBRUARY 2022

I. CALL TO ORDER AND OPENING REMARKS—DR. JOHN D. CARPTEN

Dr. John D. Carpten called to order the 16th virtual National Cancer Advisory Board (NCAB) meeting. He welcomed members of the Board, *ex officio* members, President’s Cancer Panel (PCP) members, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Carpten reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to accept the minutes of the 7–9 December 2021 Joint Meeting of the Board of Scientific Advisors (BSA) and the NCAB was approved unanimously.

II. FUTURE BOARD MEETING DATES—DR. JOHN D. CARPTEN

Dr. Carpten called Board members’ attention to the future meeting dates listed on the agenda.

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

Dr. Norman E. Sharpless, Director, NCI, welcomed NCAB members and attendees to the 16th virtual meeting and provided an update on the National Cancer Act (NCA) of 1971, Cancer MoonshotSM, NCI appropriations and paylines, and cancer research highlights.

50th Anniversary of the National Cancer Act of 1971. Dr. Sharpless noted that the NCI commemorated the 50th anniversary of the NCA of 1971, which was signed on 23 December 1971. The NCI led a national media effort to communicate the importance of the past 50 years of cancer research as a result of the NCA among stakeholders across the cancer community. Other groups joined in this media campaign to highlight the opportunities for future progress in cancer research. In a recent NCA-50 video, the First Lady, Dr. Jill Biden, enunciated some of the progress made and challenges that still need to be addressed. The NCAB viewed this video.

NCI Budget Appropriations and Paylines. Dr. Sharpless reported on the NCI budget and interim paylines. He reminded the NCAB members that the NCI regular appropriations have increased steadily since fiscal year (FY) 2015. The FY 2021 budget continued the appropriations for the Cancer MoonshotSM and Childhood Cancer Data Initiative (CCDI). The NCI received a one-time, multiyear allotment beginning in FY 2020 to support COVID-19 serological research. The federal government is operating under a continuing resolution (CR) that funds the government through 18 February 2022, which potentially could be a full-year CR as congressional leaders have indicated. Dr. Sharpless noted that Ms. M.K. Holohan, Director, Office of Government and Congressional Relations (OGCR), NCI, will provide further details on the NCI FY 2022 budget and other legislative affairs later in the meeting.

The NCI has tentatively established interim paylines for FY 2022: 9th percentile for R01 grants to established and new investigators, 14th percentile for R01 grants to early-stage investigators (ESIs), and 9th percentile for exploratory grants (R21). Non-competing grants (e.g., Type 2 grants) will be funded at the 90 percent level. Dr. Sharpless conveyed that the NCI anticipates increasing paylines with the approval of the FY 2022 budget. He called attention to an opinion column in the 28 December 2021 issue of *Scientific American* in which Senators Chris Coons (D-Delaware) and Jerry Moran (R-Kansas) proposed that a robust sustained investment of \$1 billion (B) to the NCI will further advance the fight against cancer. These senators and others have been strong supporters of American biomedical research, including cancer research.

Cancer MoonshotSM Update. Dr. Sharpless remarked that the White House has expressed strong interest in ending cancer and in making progress for patients. Congress, in a bipartisan manner, has shown consistent willingness over the past several years to provide support for cancer research. A community of researchers, scientists, and patient advocates exists that desires this outcome as well. This collaborative support positions the NCI favorably to make progress for patients with cancer. NCAB members were informed that on 2 February 2022, President Joseph R. Biden announced his plans to reignite the Cancer Moonshot (i.e., Cancer Moonshot) and to launch the “Ending cancer as we know it” campaign. Dr. Sharpless explained that the NCI has awaited this moment eagerly. In his Cancer Moonshot presentation, President Biden said that fighting cancer was a top Biden-Harris Administration priority, and he expressed strong enthusiasm for the progress of this initiative.

Dr. Sharpless noted the importance of highlighting the 5 years of success of the initial Cancer Moonshot launched in FY 2016, which has been led by Dr. Dinah Singer, Deputy Director, Scientific Strategy and Development, NCI. President Biden detailed his Administration’s enabling a broader and more ambitious set of goals and priorities that encompasses all the government, extending beyond any single Agency or Office. In his announcement, President Biden described an all-government approach (i.e., mobilizing the government) that includes convening a Cancer Cabinet. This cabinet will bring together 19 Agencies, Departments, and Offices, including the NCI and NIH; the Departments of Veterans Affairs (VA), Defense (DoD), Energy (DOE), and Agriculture (USDA) within the U.S. Department of Health and Human Services (HHS); the U.S. Environmental Protection Agency (EPA); U.S. Food and Drug Administration (FDA); Centers for Medicare & Medicaid Services (CMS); Centers for Disease Control and Prevention (CDC); and Office of Science and Technology Policy (OSTP). The aim is to help establish and make progress on the goals of ending cancer. The NCI will primarily be responsible for the research aspects, including developing new treatments and better prevention; the other Agencies, Departments, and Offices will ensure access, improve how care is delivered within communities, and promote health equity.

Members were reminded of the progress of the Cancer Moonshot to establish 70 new consortia and fund more than 240 new research projects across a wide variety of areas to accelerate cancer progress in the translational space. Because this funding sunsets in FY 2023, Dr. Sharpless noted that this is an opportune time to reignite this initiative.

Ending Cancer As We Know It Campaign. Dr. Sharpless conveyed that the NCI has discussed internally, and with colleagues at the White House, efforts aimed at “Ending cancer as we know it” and has put forth broad goals. These can be summarized as (1) diagnose cancer sooner; (2) prevent cancer; (3) address inequities; (4) target treatments to the right patients; (5) speed progress against the most deadly and rare cancers, including childhood cancers; (6) support patients, caregivers, and survivors; and (7) learn from all patients. The Cancer Moonshot aligns with these goals that reflect the scale and scope of how this effort is envisioned, as well as the directions understood to be important and promising. The goals of “Ending cancer as we know it” are framed differently from the traditional approach (e.g., targeting cancer-related genes or elucidating the immune response). The aim is to intentionally observe what cancer is today, how patients experience it, and how this tragic diagnosis that affects the daily lives of many patients can be improved.

Progress in Cancer Mortality in the United States. Dr. Sharpless explained that one important way to understand the experience for cancer patients lies in examining cancer mortality, particularly age-adjusted cancer mortality, across the United States. The NCI, along with the CDC and other agencies, collect this information annually as an unbiased metric of the progress in treating cancer. From 2015 to 2019, the age-adjusted cancer mortality declined significantly, from 215 to 146 deaths per population of 100,000. Heterogeneity across the states, however, was pronounced and persists today. In fact, some states have high rates relative to other states that have quite low rates. Dr. Sharpless expressed

appreciation to Dr. Zaria Tatalovich, Geospatial Scientist, Division of Cancer Control and Population Sciences (DCCPS), for organizing these data. On 2 February 2022, President Biden announced a new White House goal to reduce the death rate from cancer by 50 percent over the next 25 years—a reduction of age-adjusted mortality from 146 to 73 deaths per 100,000. Because cancer mortality has declined steadily since the 1990s at the national level, Dr. Sharpless remarked that this new goal, although bold, is achievable.

Promoting Health Equity. Dr. Sharpless emphasized that a large component of ending cancer and achieving the Administration’s goals for cancer mortality involves addressing health equity. President Biden emphasized that progress in cancer benefits all Americans. Health inequities in the United States are reflected in the mortality rates and are influenced poverty. CDC 4-year reports from 2000 to 2019 show that the age-adjusted mortality rates were higher in non-Hispanic Black/African American patients with cancer than in other minority patients, and this disparity is observed geographically. Although improvements have been made over the years, striking differences and heterogeneity among non-Hispanic American Indians/Alaska Natives persist. Geographic differences also have been observed; higher mortality rates have been observed in Kansas and Oklahoma for a variety of complex reasons, including tobacco use. On 5 February 2022, the Navajo Nation enacted the first commercial tobacco ban on American Indian Tribal lands. The Air is Life Act of 2021 initiative is an important development in cancer control.

Prevention, Screening, and Early Detection. A major focus of the Cancer Moonshot is on prevention, screening, and early detection, all of which are tools to control cancer at the population health level. The [President’s Cancer Panel](#) (Panel or PCP) has been working over the past year to identify gaps and barriers to cancer screening and released its report titled [Closing Gaps in Cancer Screening: Connecting People, Communities, and Systems to Improve Equity and Access](#). Barriers identified were lack of knowledge of guidelines and provider recommendations, fears or concerns about medical procedures, and difficulty navigating the health system. Logistical challenges include lack of transportation and parking and lack of access to medical services. The PCP outlined key recommendations to increase equitable access to care and to help all Americans better understand when and how they should be screened; development of strategies to improve access to cancer screening through community-oriented outreach; and expansion of self-sampling to screen for specific cancers (e.g., cervical and colon). In its report, the Panel also recommended that health care systems and medical offices establish methods and processes to allow all members of the medical team to work together to support cancer screening and make it a priority.

Screening rates across cancers declined significantly during the COVID-19 pandemic and have not recovered fully. The President announced a call to action on cancer screening to stimulate progress on missed screenings (9 million in the past 2 years) and help ensure that everyone in the United States benefits equitably from the NCI’s tools to prevent, detect, and diagnose cancer. The NCI will work with the NCI-Designated Cancer Centers (Cancer Centers) and other networks to prioritize cancer screening nationally; collect qualitative and quantitative data to understand the need; and disseminate these data and best practices in partnership with CMS, CDC, and the Health Resources and Services Administration (HRSA).

Multi-Cancer Detection (MCD) Assessments. Dr. Sharpless indicated that blood-based MCD tests continue to be a topic of interest across the federal government. MCDs have the potential to detect many cancers simultaneously in a single blood-based assay and potentially could reduce cancer mortality. The White House announced that federal agencies will develop a focus program to expeditiously study and evaluate MCD tests; the NCI will lead these efforts. The MCDs will require rigorous testing and cannot be assumed to work. Screening and early detection has the potential for overdiagnosis and overtreatment of indolent cancers and, therefore, can cause harm. To address these concerns, the NCI

published a request for information (RFI) seeking input from the community on this topic, and responses will be accepted through 21 March 2022.

Cancer Research Advances. Dr. Sharpless highlighted publications that feature recent cancer research progress related to prevention and therapeutics with links to the NCI Intramural Research Program (IRP). DCCPS and Division of Cancer Epidemiology and Genetics (DCEG) investigators collaborated with the CDC on a study addressing the potential public health benefits of changing daily physical activity routines. The National Health and Nutrition Examination Survey (NHANES) data were used in this study. The results reported in the 24 January 2022 issue of the *Journal of the American Medical Association Internal Medicine* demonstrated that a small increase in physical activity could avert 7 to 17 percent of deaths per year. This NHANES study, which examined 4,800 U.S. adults, is the first to estimate preventable deaths through physical activity using accelerometer-based measurements in this population. Although the study design limitations of 1 week of monitoring will not infer causality, these data present actionable results that the NCI can evaluate further with additional research. Lack of physical activity partly affects obesity, a growing problem in the United States, and has become one of the leading modifiable behaviors regarding cancer risk. Increased physical activity may play a role in reducing the mortality of obesity-associated cancers at the population level.

The NCI continues strong support for investigator-initiated basic cancer biology; these efforts have enabled the identification of substrates for new discoveries, including therapies. Dr. Steven A. Rosenberg, Chief, Surgery Branch, Center for Cancer Research (CCR), recently published two reports of such therapeutic discoveries, specifically on immunotherapies. The Rosenberg laboratory used personalized tumor-infiltrating lymphocytes (TILs) to treat patients with refractory metastatic breast cancer in a Phase II clinical trial conducted at the NIH Clinical Center. The results, reported in the 1 February 2022 issue of the *Journal of Clinical Oncology*, showed that 28 of the 42 women with metastatic breast cancer enrolled in the trial had TILs that recognized at least one new mutated antigen and generated evidence of an immune reaction. To date, six women treated with neoantigen-specific TILs, combined with a checkpoint inhibitor, had rapid tumor shrinkages. In addition, Dr. Rosenberg and his team reported in the 3 February 2022 issue of *Science* molecular signatures of antitumor neoantigen-reactive T cells from metastatic human cancers. This research helps to identify, in the cancer, mini-TILs capable of inducing an anti-tumor response, thus simplifying production of these specialized cells. The NCI anticipates that these immunotherapy efforts would extend beyond the IRP and would be scalable to the wider cancer research community.

Personnel Changes. Dr. Sharpless noted that the NCI has long been committed to unraveling the intricacies of childhood cancer, recognizing that treatment is different for children than adults. The CCDI has demonstrated unique opportunities in this area and also highlighted challenges that remain. As NCI Director, Dr. Sharpless recognized the need for additional assistance in assessing pediatric cancer issues. Members were informed that Dr. Brigitte C. Widemann, Chief, Pediatric Oncology Branch, CCR, has been appointed as Special Advisor to the Director for Childhood Cancer.

NCI Workplace Civility and Anti-Harassment Initiative. Dr. Sharpless emphasized that the NCI is unequivocally committed to ensuring civility, kindness, and mutual respect in the workplace, which are core values at the NCI and at the NIH. The NCI is not a place where bullying or harassment of any kind is tolerated, which the NIH Anti-Harassment Policy indicates clearly. Dr. Lawrence A. Tabak, Acting Director, NIH, in his 10 February 2022 statement on the “Commitment to a Safe and Respectful Workplace at NIH,” remarked that inappropriate conduct of any kind will not be tolerated; timely and appropriate action will be taken against any individual found to be in violation of this policy.

The NCI established a Workplace Civility and Anti-Harassment initiative that is coordinated by an NCI Workplace Civility Committee made up of representatives from across NCI’s Divisions and

Centers. The NCI continues to communicate clear policies in this area, provides toolkits and training, and has incorporated anti-harassment training and guidance into employee onboarding and performance evaluations. The NCI has accessible channels for anyone who experiences harassment to report it safely and discreetly, without fear of retaliation. Timely and appropriate actions are taken to respond to all reports, a commitment the NCI takes seriously. The NCI believes that doing so is essential to fulfilling its goal to enable all staff at the NCI to bring their best selves to the research endeavor, reach their full potential, and contribute to the NCI mission to help reduce cancer burden.

Future of Cancer Research. Summarizing the 2 February 2022 White House event, Dr. Sharpless explained the First Lady's perception of cancer research reflected in her speech, in which she noted this time as being a golden age of cancer research and emphasized the need to make progress against cancer. This Administration believes now is the time to make that progress and succeed. In her remarks, Vice President Kamala Harris spoke about her mother's work as a cancer researcher and her succumbing to colon cancer. She explained how these experiences reflected in her passion and commitment to making progress against cancer. She remarked that the Cancer MoonshotSM demonstrates who Americans are as a Nation. Dr. Sharpless noted that these reflections are reminders of the point of the Cancer MoonshotSM and that the President and the White House like this metaphor, "Ending cancer as we know it," because it calls for galvanizing the entire federal government for the shared mission to end cancer.

Questions and Answers

NCAB Chair Dr. Carpten inquired how the resignation of Dr. Eric Lander, Director, White House OSTP, would affect the Cancer Moonshot in terms of his role as science advisor and his commitment to the initiative. Dr. Sharpless commented that the White House has indicated clearly that the mission of the Cancer Moonshot extends beyond any one agency. Although Dr. Lander's departure will cause some interruption, a tremendous number of talented scientists across, and outside of the federal government, are available to help with this reignited initiative, which still is in the early phases of development.

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 expanding the pillars (i.e., goals) of the "Ending cancer as we know it" effort to include support for the community and conveying this recommendation to the soon-to-be-established White House Cancer Cabinet.

Dr. Andrea A. Hayes-Jordan, Chair, Department of Surgery, Howard University, expressed appreciation for the inclusion of access in the ending cancer pillars to address the disparities in health care. She highlighted a need for RFIs and requests for applications (RFAs) to solicit ideas and proposals, respectively, on how to improve access to treatments and decrease the disparities by involving the community, with the goal of reducing cancer deaths. Dr. Sharpless commented on the role of implementation science to these efforts and pointed out that RFIs and RFAs are planned on this topic.

Dr. Amy B. Heimberger, Jean Malnati Miller Professor of Brain Tumor Research, Vice Chair for Research, Department of Neurosurgery, Northwestern University Feinberg School of Medicine, asked about specific recommendations the Cancer Center Directors could convey to assist the NCI in advocating legislation expansion in endeavors, including the NCI portfolio. As a federal official, Dr. Sharpless would not be in a position to make such recommendations, but he noted ongoing discussions with the Cancer Center Directors about policy changes (e.g., health care across state lines, CMS coverage for cancer screening) and laws that would be helpful to patients.

NCAB Chair Dr. Carpten asked Dr. Sharpless for his perspective on areas of research highlighted from the President's speech on reigniting the Cancer MoonshotSM. Dr. Sharpless remarked on the three

announcements he thought were the most compelling and new: the goal to reduce all-cause cancer mortality by 50 percent in 25 years; the efforts related to prevention, screening, and early detection, including the MCD tests; and the commitment to addressing missed cancer screening as a priority.

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

Ms. Holohan reported on legislation of interest and issues to note, FY 2022 appropriations, congressional retirements, and midterm elections. She noted two areas receiving increased attention in Congress: telehealth and the FDA Accelerated Approval Program. More than 50 bills focusing on telehealth have been introduced during this 117th Congress. The main issues and concerns facing telehealth provisions are retaining the flexibility favored by patients and providers while balancing payments and problems with fraud and fitting this health care area into the existing system. The NCI is monitoring these concerns and new legislation closely. Recently appointed FDA Commissioner, Dr. Robert M. Califf, has been asked to take action to ensure that pharmaceutical companies provide the required data after receiving an accelerated approval for their drugs. The recent issues with accelerated approval of the Alzheimer's drug aducanumab (or Aduhelm) and the subsequent CMS coverage decisions have fueled these concerns.

On 4 February 2022, the House passed the America Creating Opportunities for Manufacturing, Pre-Eminence in Technology, and Economic Strength (COMPETES) Act of 2022. In July 2021, the Senate passed a similar version, the U.S. Innovation and Competition Act. A new Made It in America Act potentially could merge these similar pieces of legislations. Main provisions include support for U.S. manufacturing of semiconductors, automobiles, consumer electronics, and defense systems.

Ms. Holohan reviewed the President's FY 2022 budget request and proposed bills of the House and Senate Appropriations Subcommittees on Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS), the statuses of which have not changed since her last report. The House passed a CR to fund the government through 11 March 2022. The Senate is expected to vote on this CR in the coming week; however, concerns on a Substance Abuse and Mental Health Services Administration Harm Reduction grant program, as well as policy riders introduced, will need to be addressed. NCAB members were reminded that negotiations on the bipartisan infrastructure bill, FY 2022 budget resolution, and Build Back Better (BBB) package have diverted legislators' attention from the regular appropriations work. The Senate and the House recently agreed on parity regarding defense and non-defense spending. Senate Appropriations Committee Chair, Senator Patrick Leahy (D-Vermont), and Ranking Member, Senator Richard Shelby (R-Alabama), expressed optimism that the spending bills will be approved during this congressional session. Ms. Holohan noted an added incentive to resolving the issues and agreeing on the FY 2022 budget: After 10 years, congressional earmarks on House appropriation bills have returned.

Regarding legislation of interest to the NCI, Representatives Diana DeGette (D-Colorado) and Frederick Stephen Upton (R-Michigan) introduced a draft version of the 21st Century Cures 2.0 Act (Cures 2.0, H.R. 6000) to the House in November 2021. Cures 2.0 would establish Advanced Research Projects Agency for Health (ARPA-H) within the NIH and authorize research funding in several areas, including telehealth. Representative Anna Eshoo (D-California), Chair, Health Subcommittee of the House Committee on Energy and Commerce, introduced a bill to establish ARPA-H within HHS. Although the President's budget proposes establishing ARPA-H within the NIH, opinions in Congress are split, and sponsoring legislators, during a recent hearing of the Health Subcommittee, suggested drafting a complementary bill addressing maximum effectiveness of this initiative. FY 2022 is a must-pass legislation year, and the FDA user fee legislation must be reauthorized. Specifically, the Prescription Drug User Fee Act (commonly called PDUFA) is authorized every 5 years and provides an opportunity to link other smaller authorizing legislation. In January 2022, the Senate Committee on Health Education, Labor and Pensions, chaired by Senator Patty Murray (D-Washington), released the draft version of the

Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics) Act. PREVENT will require Senate confirmation for the CDC Director, strategic planning for the CDC, and collaborations between the NIH and CDC. Public comments have been solicited, and responses will be reviewed for updating the final version.

As of 25 January 2022, six Senators will be retiring (1 Democrat and 5 Republicans), including Patrick Leahy and Richard Shelby; 42 Representatives (29 Democrats and 13 Republicans) also will be retiring. Ms. Holohan noted that some of the retiring Representatives have been engaged with or had leadership roles affecting the NCI and NIH during their tenures, including Jackie Speier (D-California), G.K. Butterfield (D-North Carolina), David Price (D-North Carolina), Lucille Roybal-Allard (D-California), Kevin Brady (R-Texas), and Adam Kinzinger (R-Illinois). Regarding the midterm elections, Ms. Holohan reminded the members that since 1946, with two exceptions, the President's party has lost seats.

Questions and Answers

In response to a question from NCAB Chair Dr. Carpten about the impact of decreases to the NIH budget to NCI's proposed FY 2022 initiatives, Ms. Holohan explained that the initiatives being proposed are not large-scale efforts and have no specific budgets attached. She noted that the President's budget and the House and Senate bills include increases for the NIH, but the levels of increases vary.

Dr. Christopher R. Friese, Elizabeth Tone Hosmer Professor of Nursing, Director, Center for Improving Patient and Population Sciences, Associate Director for Cancer Control and Population Sciences, University of Michigan Rogel Cancer Center, University of Michigan, asked whether discussions on where ARPA-H would reside (i.e., the NIH or HHS) were occurring in the Senate. Ms. Holohan responded that the Senate had not introduced any legislation, but she expects that questions about ARPA-H will arise during the FY 2023 appropriations hearings.

V. ANNUAL DELEGATIONS OF AUTHORITY—DR. PAULETTE S. GRAY

Dr. Paulette S. Gray, Director, DEA, requested concurrence by the NCAB on two Delegations of Authority to the Director of the NCI. Dr. Gray described the delegations and provisions in the Statement of Understanding. She informed members that Delegation A allows the Director to obtain the services of not more than 151 special experts or consultants who have scientific or professional qualifications. Dr. Gray also explained that Delegation B specifies that the NCAB delegates authority to the NCI Director to appoint one or more advisory committees composed of private citizens and officials of federal, state, and local governments to advise the Director with respect to his or her functions.

The Statement of Understanding with NCI Staff on Operating Principles in Extramural Grants also falls within the Delegations of Authority to the Director, NCI. NCAB operations are conducted in accordance with management and review procedures described in the NIH Manual Issuance 4513. Concurrence of the NCAB with recommendations of initial review groups will be required, except for the following: (1) Training grants and fellowships and other non-research grant applications are not subject to NCAB review and approval and, without other concerns, may be awarded without presentation to the NCAB for concurrence, with the exception of Ruth L. Kirschstein National Research Service Awards. (2) Applications above the 20th percentile will not have summary statements presented to the NCAB unless the Institute is considering an award of such an application, or other special consideration is requested or required by NCI or NIH policy, or for special consideration by an appointed member of the Board. (3) For applications assigned raw scores that are not percentiled, the cutoff will be a priority impact score of 50 for all mechanisms except R41, R42, R43, and R44 awards; for the latter, all scored applications will be included.

Expedited Concurrence: (1) For R01 and R21 applications with percentiled or raw scores that fall within the NCI paylines for that mechanism, a process of expedited concurrence will be used and (2) the Executive Secretary will alert Board members with responsibility for expedited concurrence when review outcomes for eligible applications are available on the Electronic Expedited Concurrence portion of the Electronic Council Book.

Administrative Adjustments: (1) Permission is delegated to the Director, NCI, to allow staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards. (2) Administrative requests for increases in direct costs that are the result of marked expansion or significant change in the scientific content of a program after formal peer review will be referred to the Board for advice and recommendation. (3) Actions not requiring Board review or advice, such as change of institution, change of principal investigator (PI), phase-out of interim support, or additional support, need not be reported to the Board. (4) NCI staff may restore requested time and support that were deleted by the initial review group when justified by the PI in an appeal letter or when restoration is in the best interest of the NCI and the project is of high NCI programmatic relevance.

To continue responsible stewardship of public funds, the NIH has instituted a policy of Special Council Review of applications from well-funded investigators. Applications from PIs who have \$1 M or more in direct costs from active NIH Research Project Grants (RPGs) must be given additional consideration. Immediately following this meeting, applications from PIs who have \$2 M in total costs from active NIH RPGs must be given additional consideration. The \$2 M will be a threshold, and investigators who have additional research support may still receive additional awards as warranted. This revised consideration will occur when the grants are considered in the NCAB closed session during the 14–15 June 2022 meeting.

Motion. A motion to approve the NCI Annual Delegations of Authority was approved unanimously.

VI. TRIENNIAL GENDER AND MINORITY IN CLINICAL TRIALS INCLUSION REPORT—DR. MARGARET MOONEY

Dr. Margaret Mooney, Chief, Clinical Investigations Branch, Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), presented the NCI Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY 2019 – FY 2021. The NIH is mandated by the Public Health Service Act to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal is to ensure that research findings can be generalizable to the entire population.

The NIH Revitalization Act of 1993 (P.L. 103-43), amended by the 21st Century Cures Act, requires the advisory board of each NIH Institute to prepare a triennial report describing the manner in which the Institute has complied with NIH inclusion guidelines and tracking requirements. The NIH inclusion data for NIH-defined clinical research studies include patient-oriented research, in which an investigator interacts directly with human subjects for the research; epidemiological and behavioral studies; and outcomes research and health services research. Grantees must report the information annually as part of their Research Performance Progress Report. Clinical research supported by grants or an intramural NCI program also are reported annually. Several NCI Divisions, Offices, and Centers (e.g., CCR and DCTD) account for their clinical research in the inclusion reporting.

Dr. Mooney described four strategies the NCI uses for ensuring compliance. Strategy 1 is peer review, in which reviewers evaluate applications for the appropriateness of the inclusion plans and analyses. The NCI staff work with investigators to resolve any issues. Strategy 2 involves program

monitoring and grants management oversight. Program staff monitor the enrollment progress with annual progress reports and address issues as necessary. Grants management staff ensure appropriate terms and conditions are included and documented for the grant, intramural review, and training. Strategy 3 relates to the IRP; intramural investigators provide inclusion plans that are considered during scientific review. The enrollment progress is reviewed as part of annual scientific and institutional review board review, and any issues are resolved. Strategy 4 involves regular training, during which inclusion instruction is provided to program and review staff.

Dr. Mooney explained the limitations on the data, noting that inclusion data records, or inclusion enrollment reports (IERS), provide an indicator of the volume but do not represent a count of total studies or trials. Inclusion data do not represent the enrollment for a single year but are cumulative for the entire span of the project. Grants that are recomputed in a fiscal year are not included in the data for that year, such as Type 2 grant applications, which provide only planned (i.e., not actual) enrollment data for a specific year. In addition, the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) grants were recomputed in FY 2019, and those data were not included. Dr. Mooney called attention to a one-time data entry error that occurred in FY 2021. The FY 2021 data from the FY 2019–FY 2021 Triennial Report included an erroneous record identified after the data tables were locked to changes by the NIH. This error resulted in the inclusion of significantly higher FY 2021 enrollment counts in the Report. Corrected data are noted in the Report.

Dr. Mooney described the overall NCI FY 2019–FY 2021 reporting data. The summary of IERS and enrollment for all clinical research studies indicate total enrollment that ranged from 3.2 to 3.7 million participants. More than 80 percent of participants who enrolled in clinical research studies were from the United States. In clinical research studies by sex and gender, data show a higher percentage of women enrolled than men. A large number of these studies investigate malignancies seen in women, particularly breast cancer. Excluding all-female and all-male studies (e.g., gender-specific), enrollment data show a relative balance of gender. Inclusion data for all clinical research studies by minority participants (i.e., non-white, Hispanic, or Latino) show stable participation averaging 20 percent over the 3-year period. Enrollment data by race/ethnicity show stable minority accrual of Hispanic and Latino populations of 9 percent. The number of participants with unreported ethnicity was high and could reflect large-scale studies (e.g., observational studies), in which significantly high numbers of unknown or non-reported participants have been observed. Inclusion data for all clinical research studies by race show highest accrual in the White population (60 percent).

Although not included in the Triennial Report, Dr. Mooney noted the inclusion data for all clinical research studies by NCI extramural and intramural programs. Enrollment was robust in terms of millions of participants for both programs, with slight differences by gender, race, and ethnicity. For all NCI NIH-defined Phase III clinical trials, total enrollment doubled in FY 2020 and FY 2021, a direct reflection of NCTN and NCORP data that were not included in FY 2019. U.S.-only enrollment over the three fiscal years ranged from 74 percent to 78 percent. NIH-defined Phase III clinical trials by sex and gender show a higher percentage of women enrolled than men, with higher percentages reported in FY 2020 and FY 2021. This increase was driven largely by the NCORP Tomosynthesis Mammographic Imaging Screening Trial (TMIST). Excluding all-female and all-male studies in NIH-defined Phase III clinical trials, enrollment data show a relative balance across genders, because large-scale breast cancer trials also enroll men.

Inclusion data for all NIH-defined Phase III clinical trials of minority participants by race and ethnicity show stable enrollment of 40 percent over the three fiscal years. Enrollment data in NIH-defined Phase III clinical trials by race/ethnicity show increases in minority accrual of Hispanic and Latino participants, also due partly to the participation in TMIST in U.S. and non-U.S. clinical sites. Inclusion data for all NIH-defined Phase III clinical trials by race show a decrease in the percentage of Asian

participation in FY 2021 and an overall decrease in the percentage Black/African American participation. Dr. Mooney pointed out that the one-time error of category of reporting more than one race could not be corrected for today's presentation, but estimates that those data likely will reflect the FY 2019 data and prior triennial reports.

Questions and Answers

Dr. Paskett expressed interest in helping to address the high percentage of unknown enrollees in the NCI NIH-defined Phase III trials. She suggested restructuring the Triennial Report presentations that are made to the NCAB so they review data that are representative of the clinical trial demographics across the United States to better assist the Cancer Centers in their activities.

Dr. Howard J. Fingert, Consultant, sought clarity on whether these inclusion data also reflect those completing the clinical trial and whether an analysis could be conducted on the chosen primary endpoint relative to the demographic of the study. Dr. Mooney explained that enrollment can be assessed by the individual programs and trials after withdrawals for other reasons, but she could not speak to whether an analysis of withdrawal and reaching the primary endpoint had been carried out. Dr. Fingert commented on whether data on individuals completing the trial as defined by the protocol would complement the existing inclusion data, noting that it would be helpful to understand the trial design to mitigate the high number of unknowns.

Motion: A motion to accept the report of the Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research was approved unanimously.

VII. THE NATURAL PRODUCTS PROGRAM—DR. BARRY R. O'KEEFE

Dr. Barry R. O'Keefe, Director, Molecular Targets Program (MTP), CCR, and Chief, Natural Products Branch (NPB), Developmental Therapeutics Program (DTP), DCTD, NCI, presented an update on the NCI Program for Natural Product Discovery (NPNPD). Dr. O'Keefe informed members that although natural products comprise 25 percent of all approved drugs, they constitute only 1 percent of small molecules included in high-throughput drug screening efforts. Dr. O'Keefe pointed out several reasons for this discrepancy, including the difficulties associated with the purification and structural elucidation of these compounds. He described the need to address these challenges to efficiently access the unique chemical diversity in natural products.

The NCI Natural Products Repository hosts one of the world's largest libraries of crude natural product extracts and contains more than 230,000 samples originating from plants, marine organisms, and microbes. To utilize this resource, the NCI initiated the NPNPD, a joint effort between the DCTD and the CCR funded by the Cancer Moonshot. The NPNPD was designed to facilitate intramural and extramural research and address challenges in natural product-based drug discovery. The aims of the program are to (1) create a semi-purified (i.e., pre-fractionated) library of diverse natural chemicals that is amenable to high-throughput screening; (2) expand the chemical diversity available from culturable organisms to address resupply challenges; (3) provide the library to worldwide screening centers free of charge; (4) encourage high-throughput screening support for researchers to enable targeted discovery efforts; (5) provide faster analytical resources to researchers to expedite translational pipelines; and (6) provide bioinformatics resources and databases to increase the efficiency of the screening pipeline.

Dr. O'Keefe described the development of a library of semi-pure natural product fractions. Compound purification was based on polarity and optimized for mass yield, compound separation, and biological activity retention. Purification was automated to enable the efficient and reproducible production of an unprecedented volume of 150,000 fractions per year. Crude extract fractions were analyzed via total mass spectrometry and yielded an average of 20 to 25 compounds per fraction.

Dr. O’Keefe explained that 525,000 natural product fractions have been produced, and 325,000 of these fractions have been released to the research community. Another 175,000 fractions are anticipated to be released within the next 6 weeks. More than 5 million samples have been shipped, with an average of 150,000 fractions shipped per month. Protocols for generating the library and for screening compounds have been published and disseminated. Research groups in the United States, South Africa, and Sweden have adopted NPNPD methods and automated systems. South African researchers have purified fractions from tens of thousands of plants native to their region. A citizen science program at The University of Oklahoma has collected 24,000 fungal samples from across the United States to expand the chemical diversity of cultured organisms at the NCI. A new fermentation facility at the NCI at Frederick can culture and perform extractions on these organisms, which were catalogued (e.g., photographed, frozen, and sequenced) to ensure their availability to researchers.

To date, the NPNPD has implemented more than 40 material transfer agreements with research institutions and industry partners across the United States and the world. The NPNPD has a joint interagency agreement with the National Institute of Allergy and Infectious Diseases (NIAID) to screen the library against ESKAPE pathogens (i.e., *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter* species) for antibiotic discovery. The NPNPD has worked with the Walter Reed Army Institute of Research (WRAIR) and the DoD to screen the library against neglected tropical diseases, such as malaria and leishmaniasis. The National Center for Complementary and Integrative Health (NCCIH) and the National Center for Advancing Translational Sciences (NCATS) have collaborated to screen NPNPD library fractions against targets associated with the NIH Helping to End Addiction Long-term[®] Initiative, or NIH HEAL Initiative[®]. The National Oceanographic and Atmospheric Administration has funded the collection of marine organisms for biomedical research to be added to the program.

High-throughput systems were built by the NPNPD to assist researchers lacking natural products chemistry expertise. An automated second-stage purification system was designed to purify up to 500 samples of interest into 22 subfractions and to subsequently aliquot the subfractions into high-throughput screening plates. This system, which already has been implemented with such partners as Baylor College of Medicine, The University of Texas, and WRAIR, can ship more than 10,000 subfractions to screening laboratories within 2 weeks, reducing costs for screening tests and conserving library extract samples. The process generates valuable chemical information (e.g., data from nuclear magnetic resonance, mass spectrometry, and Fourier transform infrared spectroscopy), reduces the overall time needed for chemical analysis, and uncovers novel chemical diversity. As determined by principal component analysis, the purified NPNPD compounds largely overlap with the chemical space of approved natural product drugs, indicating their potential for drug development. Dr. O’Keefe noted that web-accessible and secure data systems have been developed to track all elements of library compound purification and analysis, including such details as source of each organism, the global positioning system coordinates of sample collection sites, organism photographs, and the chemistry and biology associated with each organism.

Dr. O’Keefe described recent outcomes from NPNPD efforts. Biophysical assays have been used to screen compounds for their ability to alter macromolecular stability. In a differential scanning fluorimetry assay, natural product extracts were added to a temperature gradient to assess their ability to alter the melting temperature of pre-microRNA-21 (pre-miR-21). One compound, butylcycloheptyl prodiginine (bPGN), modified the melting temperature of pre-miR-21 by 3.4°C by inducing the formation of an alternative RNA structure. Colon cancer cells cultured in the presence of bPGN exhibited increased cellular levels of miR-21 targets, such as programmed cell death 4 (PDCD4) and phosphatase and tensin homolog (PTEN), and improved cell death in response to chemotherapeutic treatment. Another assay investigated the effects of compounds on the activity of tyrosyl-DNA phosphodiesterase 1 (TDP1), which alters cancer resistance to topotecan and other topoisomerase-inhibitor treatments. A peptide identified in

the library was shown to be an allosteric TDP1 inhibitor that binds to the regulatory domain of the protein. This class of peptides has been patented and is in active licensing by the NCI for therapeutic development. Dr. O’Keefe added that NCI-60 Human Tumor Cell Lines Screen (NCI-60) cytotoxicity data associated with NPND extracts are being analyzed using bioinformatic self-organizing map technologies to further drive anti-cancer drug discovery.

In closing, Dr. O’Keefe noted that the NPND program is becoming a central hub for natural products research. He suggested utilizing the Innovation Grants to Nurture Initial Translational Efforts (IGNITE) Program to fund NPND library screening efforts and build on foundational NPND technologies and resources.

Questions and Answers

Dr. Friese inquired about the NPND’s dissemination and outreach efforts to developmental therapeutics programs at Cancer Centers or other institutions. Dr. O’Keefe commented that he has been invited to speak at the American Association for Cancer Research (AACR) Annual Meeting in April 2022. He noted that, despite being impeded by the COVID-19 pandemic, outreach efforts are worthwhile and should be encouraged. NCAB Chair Dr. Carpten suggested that NPND efforts be presented to lay audiences.

Dr. Heimberger asked about the potential for high-throughput screening of the natural product extracts for immuno-oncology effects (e.g., reversing immune exhaustion, increasing direct tumor cytotoxic activity). Dr. O’Keefe described a collaboration with an intramural NCI program to investigate immunological endpoints. He added that immune-oncology target proteins tend to localize to the cytosol, rather than the cell surface, and that natural product extracts are likely to be active against these targets. He noted that these assays might be technically challenging to perform in a high-throughput manner.

Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro-Oncology, Professor Emeritus of Neurosurgery, Duke University Medical Center, commented that natural product extracts should be assayed for their effects on the early stages of cancer. Dr. O’Keefe answered that he has presented these results to the NCI Division of Cancer Prevention (DCP), which is interested in funding assays to be used in conjunction with the NPND library. He described NPND efforts to generate a library of pre-fractionated aqueous medicinal plant extracts that might be useful in chemoprevention.

VIII. ONGOING AND NEW BUSINESS—DR. JOHN D. CARPTEN

NCAB *ad hoc* Subcommittee on Global Cancer Research. Dr. Ali-Osman, Chair of the NCAB *ad hoc* Global Cancer Research Subcommittee, presented the report of the 10 February 2022 meeting. NCI Director Dr. Sharpless attended the meeting. Dr. Ali-Osman explained that the Subcommittee first heard presentations from Center for Global Health (CGH) leadership focusing on the accomplishments since the last meeting. CGH Director Dr. Satish Gopal provided a brief overview of the CGH and an update on implementation of the [Center for Global Health Strategic Plan 2021–2025](#). Dr. Gopal, in his update, highlighted the primary goals for CGH-led programs in low- and middle-income countries (LMICs) and the upcoming events, including the 10th Annual Symposium on Global Cancer Research that is organized with other cancer organizations (e.g., AACR). Dr. Gopal informed the Subcommittee that this year’s symposium, for the first time, will include an Early-Career Investigator Day. Dr. Paul Perlman, Program Director and Lead for Global Health Technology Research, CGH, provided an overview of the Affordable Cancer Technologies (ACTs) Program, highlighting the funding opportunity announcements and Program accomplishments. The Subcommittee discussed how effective the ACTs Program has been in translating some of the technologies to commercialization and how well it engages

with the NCI SBIR program and industry partners. Dr. Ali-Osman reminded the NCAB members that the ACTs Program is managed by other NCI Divisions and Offices in addition to the CGH, including DCCPS, DCP, and DCTD.

Dr. Ali-Osman noted that invited speakers, who were ACTs Program investigators, provided research updates to the Subcommittee. Dr. Aggrey Semeere, Physician and Clinical Research Scientist, Infectious Diseases Institute, Makerere University, Uganda, reported on early-stage diagnosis of Kaposi sarcoma (KS) in limited-resource settings using point-of care diagnosis. Dr. Semeere and his colleagues collaborated with Dr. David Erickson at Cornell University on the KS-Detect technology, which has resulted in the Tiny Isothermal Nucleic acid quantification sYstem (TINY) device. TINY is being evaluated in sub-Saharan Africa. Dr. Hannah Simonds, Associate Professor and Head, Division of Radiation Oncology, Stellenbosch University, South Africa, described a radiation planning assistant for radiation therapy planning in LMICs, FDA approval of which is pending.

In closing, Dr. Ali-Osman commented on the success of the ACTs Program and encouraged the NCAB members to visit the CGH website to review the various funded projects.

Questions and Answers

Dr. Hayes-Jordan asked about the United States' readiness to implement micro-biopsy technology that provides a readout of the DNA and whether it could be operated remotely. Dr. Ali-Osman explained that TINY can provide such a readout, but the device will require beta testing and subsequent FDA approval prior to its dissemination to the clinical community.

Motion. A motion to accept the report of the 10 February 2022 NCAB *ad hoc* Subcommittee on Global Cancer Research meeting was approved unanimously.

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

IX. ADJOURNMENT OF OPEN SESSION—DR. JOHN D. CARPTEN

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

X. CLOSED SESSION—DR. JOHN D. CARPTEN

“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 2,550 NCI applications were reviewed requesting direct cost support of \$1,006,764,573 and three FDA applications requesting direct cost support of \$1,334,756.

XI. ADJOURNMENT—DR. JOHN D. CARPTEN

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

There being no further business, the 16th virtual meeting of the NCAB was adjourned at 5:30 p.m. on Thursday, 10 February 2022.

Date

John D. Carpten, Ph.D., Chair

Date

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