87th Meeting of the National Cancer Institute (NCI) Council of Research Advocates (NCRA) National Institutes of Health (NIH)

Virtual Meeting September 28, 2022

Members Present

Mr. Yelak Biru Ms. Jaqueline Smith

Ms. Melissa Buffalo Mr. Kevin Stemberger

Ms. Annie Ellis, *Chair* Ms. Joya Delgado Harris

Mr. Nathaniel Ferre Dr. Nicole Willmarth

Speakers

Ms. Andrea Denicoff, Head of Clinical Trials Operations, National Clinical Trials Network, NCI

Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI

Dr. Douglas Lowy, Acting Director, NCI

Dr. Diane Palmieri, Acting Director, Center for Research Strategy, NCI

Ms. Maureen Clark Szemborski, Program Analyst, OGCR, NCI

Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

Dr. Catharine Young, Associate Director, Cancer Moonshot Engagement and Policy, White House Office of Science and Technology Policy

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Welcome and Opening Remarks

Ms. Amy Williams and Ms. Annie Ellis

Ms. Williams opened the meeting at 12:01 p.m. and welcomed Council members and attendees. Ms. Ellis called the meeting to order, reviewed the conflict-of-interest rules for the meeting, read the public comment statement, confirmed that a quorum of members was present, and provided brief opening remarks.

Ms. Williams invited attendees to share questions for presenters via the chat function in Zoom.

Acting NCI Director's Update

Dr. Douglas Lowy

Dr. Lowy welcomed new and returning members to the NCRA and provided an overview of NCI news and updates. Recent and upcoming activities include:

- The appointment of Dr. Monica Bertagnolli to the role of NCI Director. Dr. Bertagnolli is expected to be sworn in and begin work during the first week of October.
- The White House Forum on Childhood Cancer on September 23, 2022. The forum was hosted by
 the White House Office of Science and Technology Policy and included lively panel discussions
 featuring NCI representatives and stories from people whose lives had been touched by childhood
 cancers.
- The 15th American Association for Cancer Research (AACR) Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved in Philadelphia from September 16 to 19. Dr. Lowy was the keynote speaker. He highlighted several themes from his address, including the progress to date but the need to continue working on this important issue; the necessity of inclusion in research and the cancer research workforce; and the fact that roles in this work can span a wide spectrum of research, from technology development aimed at reducing health disparities to research on affected populations.

Research Advances

Dr. Lowy highlighted recent cancer research publications. Published this month, a paper authored by NCI-supported researchers found a dramatic increase in cancer survivorship over the last 30 years, with survivors now representing 18 million people, or more than 5 percent of the U.S. population. By 2040, the number is projected to reach 26 million.

A <u>study published in August</u> by NCI intramural researchers identified a significant association between physical activity and a decreased risk of death for older adults. Regardless of the activity, 2.5 hours per week of moderate physical activity was associated with lower rates of all-cause mortality, cardiovascular mortality, and cancer mortality.

<u>Another study by NCI researchers</u> concluded that former smokers who maintain healthy lifestyle habits such as a healthy diet and getting regular physical activity have a lower risk of all-cause mortality than those who do not.

Dr. Lowy also coauthored an NCI monograph titled <u>Treating Smoking in Cancer Patients: An Essential Component of Cancer Care</u>. He noted that many people don't realize that current smokers can improve their cancer prognosis by quitting smoking. On average, their response to treatment will be better.

Results from the NCI-supported KEYNOTE-355 trial indicate that adding pembrolizumab to chemotherapy can help women with advanced triple-negative breast cancer live longer—on average, several months longer. Dr. Lowy noted that even a few months of added life can make a big difference in a person's remaining days.

Cancer Moonshot

On September 12, the 60th anniversary of President John F. Kennedy's famous Moonshot speech, President Biden spoke about the reignited Cancer Moonshot. In his speech, President Biden emphasized the importance of working together to end cancer as we know it.

For the next phase of the Cancer Moonshot, NCI is jump-starting three programs: the Cancer Moonshot Scholars program, telehealth and cancer care, and multi-cancer detection. More information about each of these programs is available on the NCI website and in presentations from past NCRA meetings.

- The Cancer Moonshot Scholars program aims to increase the diversity of early-stage cancer investigators from underrepresented minorities. The program has already begun, and NCI hopes to select the first set of Moonshot Scholars in late fiscal year (FY) 2023.
- In September, NCI made awards to four academic institutions—NYU Grossman School of Medicine, Northwestern University, the University of Pennsylvania, and Memorial Sloan Kettering Cancer Center—to establish centers of excellence to conduct research on how telehealth can contribute to improved cancer-related healthcare.

The new phase of the Cancer Moonshot will also focus on increasing enrollment of underrepresented groups in NCI clinical trials. Three goals under this umbrella include developing a cancer study that mimics at-risk groups for the cancer in question; greater investment with community engagement; and more diversity among healthcare providers. Over the last three decades, the NCI Community Oncology Research Program (NCORP) has increased minority enrollment in NCI clinical trials from 14 percent in 1999–2001 to 25 percent in 2017–2019. These numbers have continued to rise in the last 3 years, despite the global COVID-19 pandemic. Most of the increase has been among Black/African American and Hispanic populations. To continue the discussion, in November NCI will host a summit on increasing diversity, equity, and inclusion in early-phase clinical trials.

Another top priority for NCI is supporting more R01 research grant awards. Dr. Lowy shared an <u>infographic</u> illustrating the importance of R01 awards to the advancement of cancer research and discovery.

Budget Update

Dr. Lowy explained that Dr. Palmieri, presenting after his remarks, will go into more detail about the NCI annual plan and budget proposal. NCI is proposing a substantial funding increase in order to reignite the Cancer Moonshot without neglecting NCI's important ongoing work.

Discussion

Ms. Ellis thanked Dr. Lowy for his report.

• Ms. Ellis expressed her appreciation for the attention given in the annual plan to persistent poverty and its association with cancer. Regarding Dr. Lowy's speech at the AACR conference, Ms. Ellis asked which issues advocates can help support. Dr. Lowy responded that while all the issues he mentioned are important, advocates could help bring attention to health disparities beyond racial and ethnic lines in demographic groups, including areas such as persistent poverty.

He also emphasized NCI's work on cancer care telehealth and multi-cancer detection tests, as these, ideally, will help reduce disparities in under-resourced areas.

- Dr. Willmarth said she is pleased to see the Cancer Moonshot's focus on screening and multicancer detection, as routine screenings save lives, and early diagnosis often results in better outcomes. She asked if the Cancer Moonshot is focusing on metastatic cancer, in which patients typically experience poorer outcomes. Dr. Lowy highlighted two Cancer Moonshot research areas relevant to metastatic cancer: expanding the pipeline of new drugs, and the NCI Molecular Analysis for Therapy Choice (NCI-MATCH) trial, a precision medicine cancer treatment trial, which soon will be expanding to a new trial investigating combinations of cancer treatments.
- Ms. Smith asked if Dr. Lowy could direct her toward shareable information about the Cancer
 Moonshot Scholars program. Dr. Lowy responded that information can be found on both the
 Cancer Moonshot Scholars page and a blog post. Ms. Smith asked if psychosocial researchers
 will be considered for inclusion in the Cancer Moonshot Scholars program. Dr. Lowy responded
 that there is no restriction on the kind of research the grantees perform so long as it is cancer
 relevant.
- Ms. Ellis asked Dr. Lowy if there is a specific definition of the phrase "ending cancer as we know it" as those words might mean different things to different people. Dr. Lowy agreed and responded that, in his view, the phrase has two parts: to make the experience better for patients, from prevention to screening, diagnosis, and treatment; and to make progress on cancers that have seen limited progress until now. Ms. Ellis commented that, for her, the phrase also evokes changing the paradigm of cancer from a terminal illness to something that can be survived. Dr. Lowy agreed and said that advances in controlling multiple myeloma and lung adenocarcinomas are good examples of that shift.

NCI Annual Plan for FY 2024

Dr. Diane Palmieri

Dr. Palmieri shared an overview of the NCI Annual Plan & Budget Proposal for Fiscal Year 2024 and the scientific opportunities highlighted by the Plan.

The Annual Plan, released every September, comprises the Plan itself and a professional judgment budget, which Dr. Lowy presented earlier in this meeting. The professional judgment budget is an aspirational document that is designed to inform President Biden as he develops his budget proposal to Congress.

The Annual Plan also highlights several scientific opportunities that represent NCI's research portfolio. These opportunities are selected by NCI leadership and developed by staff across the Institute. The scientific opportunities identified in this year's Annual Plan include persistent poverty and cancer, asymptomatic multi-cancer detection, cell therapy to treat cancer, and undruggable cancer targets.

Persistent Poverty and Cancer

An area of persistent poverty is one in which 20 percent or more of the population has lived below the poverty line for the past 30 years. Counties with persistent poverty have cancer death rates that are 12 percent higher than those of other areas of the United States. NCI is funding research to understand how factors associated with persistent poverty—such as increased exposure to cancer-causing agents, stress, and lack of healthcare access—intersect to influence cancer outcomes. In addition to understanding the

problem, NCI also is working to test interventions at the individual, community, and population levels. This includes telehealth interventions and partnerships with community health providers.

Asymptomatic Multi-Cancer Detection

Progress on multi-cancer detection technology has reached the assay development stage. These assays are now ready for large-scale clinical testing to determine their benefits and harms. Whether these tests will reduce deaths from cancer or lead to unnecessary diagnostic procedures that may cause undue harm remains unknown. Also unknown is how these tests will compare to effective screening tests already in use for common cancers and whether the tests will benefit all populations equally. NCI recently launched a cancer screening research network, which will allow researchers to answer these questions and more.

Cell Therapy to Treat Cancer

Cell therapy is a personalized treatment that uses a patient's own immune cells to treat their cancer. Patients who respond to this treatment often see strong and durable responses, yet not all patients respond, and cell therapy options do not yet exist for most cancers. Although 90 percent of all cancer diagnoses are solid tumors, there are currently no U.S. Food and Drug Administration (FDA)-approved cell therapies for solid tumors. Cell therapy is also expensive and difficult to provide at scale to large numbers of patients at a time. To advance this research, NCI has launched the Cancer Adoptive Cellular Therapy Network.

Undruggable Cancer Targets

Long-term investments in targeted cancer therapies now are paying dividends. Advances in cancer biology, medicinal chemistry, computational biology, and microscopy and imaging techniques are enabling a vision for the future in which no target is considered undruggable. The Annual Plan includes a personal story from a patient with von Hippel-Lindau disease, which is caused by a gene mutation that previously was considered an undruggable target. Last August, FDA approved a drug for this target, and the patient reports that the drug "changed his life." Dr. Palmieri urged NCRA members to read the full story and more about each of these areas of scientific opportunity in the Annual Plan.

In addition to these specific areas of opportunity, the Annual Plan includes NCI's broad research portfolio, which spans the cancer continuum from basic research to public health interventions.

Discussion

- Ms. Ellis observed that Dr. Palmieri used the term "asymptomatic multi-cancer detection
 (AMCD)" in her presentation and asked whether this is the currently preferred term. Dr. Palmieri
 clarified that MCD is still the preferred term but that in some instances the tests may be used in
 asymptomatic screening, at which time AMCD would be appropriate.
- Regarding cell therapies, Ms. Ellis asked what the biggest obstacle is to making them more
 broadly accessible and widespread. Dr. Palmieri invited cell therapy expert Dr. Marc Ernstoff to
 respond. Dr. Ernstoff listed several opportunities for growth, including expanding beyond the
 focus on solid tumors, identifying targets, identifying personalized mutations, identifying
 mechanisms of cell traffic within the tumor microenvironment, and developing resistant
 pathways.
- Dr. Willmarth expressed excitement about the future of cell therapy, especially with durable responses. She noted that if a cell therapy can evolve with a tumor, it could improve treatment efficacy over time. Dr. Ernstoff agreed that this will expand the spectrum of available treatment

- pathways.
- Mr. Stemberger asked whether there are limitations to NCI's ability to engage the Frederick National Laboratory for Cancer Research. Dr. Palmieri replied that there are no real limitations because most of NCI-Frederick's focus is cancer research.
- Mr. Ferre asked if Dr. Palmieri could provide any updates on cancer vaccine research. Ms. Williams said that he might direct that question to Dr. Young later in the meeting and that she would follow up with Mr. Ferre after the meeting with more information.
- Mr. Chakoian asked how a multi-cancer early detection approach would work in conjunction with existing early detection strategies. Dr. Palmieri said that this is still to be determined, as rigorous clinical trials and testing will be required to prove that the MCD tests perform better than current standardized tests. She noted that because cancer is relatively rare in the general population, validating screening tests may take a long time. In the near future MCD tests will be integrated into screening guidelines and compared with existing tests. Ms. Ellis commented that Dr. Castle delivered a presentation on the MCD tests during the last NCRA meeting and that NCRA might invite Dr. Castle back to provide an update in the future.

NCI COVID-19 in Cancer Patients Study (NCCAPS)

Ms. Andrea Denicoff

Ms. Denicoff, Head of Operations for NCI's National Clinical Trials Network, presented on the <u>NCI</u> <u>COVID-19 in Cancer Patients Study (NCCAPS)</u>, including its history, progress, and preliminary results.

Background and Study Design

Early in the COVID-19 pandemic, Dr. James Doroshow recognized the need to study how the new virus was affecting cancer patients. Dr. Doroshow and Ms. Denicoff connected with a team of collaborators, including two patient advocates who accepted volunteer positions. Due to the urgent nature of the subject, the protocol for the study was written and accepted by the central Institutional Review Board (IRB) in a matter of weeks. Enrollment opened in May 2020, with input and support from experts around the United States, including Principal Investigators Dr. Brian Rini of Vanderbilt University Medical Center and Dr. Larissa Korde of NCI.

The objectives of the longitudinal study are twofold:

- Characterize patient factors associated with short- and long-term outcomes of COVID-19 in adult and pediatric cancer patients undergoing active treatment.
- Describe cancer treatment modifications made in response to COVID-19, including dose adjustments, changes in symptom management, and temporary or permanent cessation.

Patients were eligible to enroll in the study if they were actively being treated for cancer and had either tested positive for COVID-19 or were awaiting the results of a COVID-19 test. If the test results were negative, the patient exited the study; if the results were positive, NCCAPS began data collection. The goal was to accrue up to 2,000 patients and follow them for at least 2 years to monitor outcomes.

The study plan is to collect data, imaging scans, and research specimens:

• Among the data captured are cancer type and treatment, demographic factors, preexisting comorbidities, COVID-19 course and severity, COVID-19 treatment, and quality-of-life data.

- Imaging scans include a patient's most recent pre-COVID-19-infection cancer imaging study, imaging studies clinically indicated for cancer, and imaging studies clinically indicated for COVID-19.
- Biospecimen (blood) collection will allow researchers to look at factors associated with severe
 disease, the development of immune response, and the trajectory of immune response. NCI's
 Division of Cancer Epidemiology & Genetics will perform genome-wide association studies on
 the samples. A sub-study also has been added for patients who have both had COVID-19 and
 been vaccinated.

Advocates are an essential component of NCCAPS, from study design to protocol to patient communications. Two volunteer advocates joined NCCAPS meetings two or three times per week, served on the study working group, and served on additional correlative substudy groups developing quality-of-life research objectives. Ms. Denicoff noted that having patient voices has been crucial to the study's success.

Current Status

NCCAPS closed to accrual on February 2, 2022. A small number of patients already have completed 2 years of follow-up. NCCAPS submitted abstracts to the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and presented posters on preliminary results of the study. The team has also submitted an abstract to the American Society of Hematology (ASH) meeting, where they hope to present preliminary results of coagulation studies.

More than 2,000 patients were screened for the study and 1,833 enrolled, including 171 children. Patients joined from all over the United States, with study sites in all 50 states, the District of Columbia, and Puerto Rico.

One difficulty that arose during the study was the national phenomenon of the so-called Great Resignation, in which significant proportions of the workforce were leaving their jobs. This resulted in a staffing shortage that affected the ability of NCCAPS study sites to keep up with enrollment and data collection.

Preliminary Results and Future Directions

The results presented at the July ASCO meeting included only patients for whom NCCAPS had complete datasets: 780 adults and 47 children. For adult patients, breast, lung, and GI cancers were the most common diagnoses; for children, leukemia was the most common cancer diagnosis.

Around 50 percent of adult participants with cancer had cardiac and pulmonary comorbidities, and 20 percent were taking anticoagulant medication when they contracted COVID-19. One patient, or less than 1 percent of the cohort, was pregnant.

Of the symptoms present at study enrollment, fatigue was the most common—a finding in line with symptom frequency among the general public as well. Symptoms typically declined over a 3-month period.

All-cause mortality among the 780 adult patients was 9.7%. Of the patients who died, 25 (3.2%) died of COVID-19, 33 (4.2%) died of cancer, and 18 (2.3%) died of other causes. Approximately 170 patients were hospitalized for COVID-19, and 31 of those patients had multiple COVID-19-related hospitalizations. Among the 47 pediatric patients, one child died of malignancy, but none died of COVID-19.

The NCCAPS team now is conducting a major effort to collect and clean the full datasets for all enrolled patients. Other tasks include ongoing analysis of data from correlative studies, including cytokine profiles, immune cell phenotyping, and serology/neutralizing antibodies; an assessment of long COVID in the patient cohort; further research in the pediatric population; and the publication of imaging findings.

Discussion

- Ms. Ellis expressed her admiration for how rapidly NCCAPS came together. She asked whether the NCCAPS team had difficulty distinguishing which symptoms were attributable to COVID-19 and which were attributable to cancer and cancer treatment, as significant overlap exists. Ms. Denicoff said this was true, especially for symptoms like fatigue and shortness of breath. She said that NCCAPS simply will report the data rather than trying to parse specific symptom causality. One possible avenue may be looking at an increase in symptoms among patients with COVID-19, but it will be difficult to do.
- Ms. Ellis was also pleased to learn about NCCAPS' exploration of COVID-19 vaccines and long COVID. With the availability of vaccines and boosters, people are now less afraid of dying of COVID-19, but long COVID remains a real risk and an unknown.
- Mr. Ferre asked if any of the difficulty NCCAPS experienced with enrollment in some parts of
 the country was related to sentiments regarding COVID-19 and unwillingness to be involved in
 related research. Ms. Denicoff said no resistance was encountered for these reasons, although
 some patients dropped out of the study due to the burden of participating while sick with both
 cancer and COVID-19.

Budget and Legislative Update

Ms. Holly Gibbons and Ms. Maureen Szemborski

As FY 2022 reaches its end, appropriations for FY 2023 have not yet been finalized. The status within each house of Congress:

- A \$290 million increase for NCI from the Senate, and a \$460 million increase from the House
- A \$3 billion increase for NIH from the Senate, and a \$2.5 billion increase from the House
- Flat funding at \$1 billion for the Advanced Research Projects Agency for Health (ARPA-H) from the Senate, and a \$1.75 billion increase from the House.

Significant disagreements on funding levels remain. Bipartisan support for both NIH and NCI remains strong, but neither proposal had minority support, making it unclear where final appropriations will land.

The top congressional priority for the week was passing a continuing resolution (CR), which would provide funding at FY 2022 levels through December 16, 2022. Voting on the CR was held up in negotiations with Senator Joe Manchin, who eventually withdrew his demands and allowed the vote to proceed. Both the House and Senate were expected to vote on the CR by the end of the week.

Reauthorization of the user fees for the Food and Drug Administration (FDA) is attached to the CR. Several provisions attached to the reauthorization—including the Give Kids a Chance Act and provisions aimed at increasing diverse enrollment in FDA clinical trials—were removed amid negotiations. These provisions may be reconsidered after the CR ends in December.

While several authorizing bills for ARPA-H have been introduced, no bill has yet been through a vote and signed into law, and a consensus proposal has yet to be developed. One unresolved issue is whether

ARPA-H will remain part of NIH or become a separate operating division of the Department of Health and Human Services (HHS). President Biden has announced his intent to appoint Dr. Renee Wegrzyn as the first Director of ARPA-H.

Other Legislation and Issues to Watch

Ms. Szemborski provided an update on several additional legislative issues:

- The CHIPS and Science Act of 2022 was negotiated in tandem with the Inflation Reduction Act this past summer. While neither act contains provisions directly related to NIH, both are of interest to the scientific community. The CHIPS and Science Act was bipartisan. It will spur investment in the U.S. semiconductor industry and reauthorize the National Science Foundation (NSF) at a higher level with provisions related to expanding geographic diversity among NSF grantees. The partisan Inflation Reduction Act reflects Democratic priorities, with energy and tax provisions. The act also allows Medicare to negotiate on certain prescription drug prices and extends Affordable Care Act (ACA) subsidies for insurance through 2025.
- The latest authorization for FDA user fees will expire with the CR in December and negotiations will resume. Of note in the reauthorization is the ability for FDA to regulate dietary supplements and cosmetics, as well as changes to the accelerated approval process for therapies.
- Congress also will be voting on the reauthorization for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) programs. This standalone bill would reauthorize the programs through the end of FY 2025.
- Other pending legislation concerns pandemic preparedness and ARPA-H authorization; telehealth continuation and expansion; and clinical trials access and inclusion.

Recent Events

A federal delegation including HHS Secretary Xavier Becerra, HHS Region 3 Director Dr. Ala Stanford, Senators Ben Cardin and Chris Van Hollen, and Representative David Trone visited the NCI laboratory in Frederick, Maryland on July 22.

On September 12, NCI presented a webinar on the Institute's progress implementing the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act of 2018. A recording of the webinar and slides are available on the NCI Office of Advocacy and Relations (OAR) website.

On September 22 and 23, NCI representatives presented at the 13th Annual Congressional Childhood Cancer Caucus Summit and the White House Cancer Moonshot Childhood Cancer Forum.

Discussion

Ms. Ellis thanked Ms. Gibbons and Ms. Szemborski for their presentation.

Update from the White House Office of Science and Technology Policy

Dr. Catharine Young

Dr. Young presented on the reignition of the Cancer Moonshot. She opened with a quote from President Biden's Cancer Moonshot speech on February 2, 2022: "I committed to this fight when I was Vice President. It's one of the reasons why, quite frankly, I ran for President. Let there be no doubt: now that I am President, this is a presidential White House priority—period." These words from President Biden demonstrate his personal and presidential commitment to the Cancer Moonshot.

The reignition of the Cancer Moonshot included what Dr. Young referred to as two audacious goals: to reduce the death rate from cancer by 50 percent over the next 25 years, and to improve the experience of people and their families living with and surviving cancer. While these goals are ambitious, the Cancer Moonshot team and President Biden believe they are achievable. This belief is bolstered by the remarkable biomedical advances that have been spurred by the COVID-19 pandemic, the cultural changes beginning to occur in science and medicine, and the innovation and technical advancements of the past two decades.

To distill the vision and mission of the Cancer Moonshot, the White House team and stakeholders developed seven pillars of action:

- 1. Screening and early detection: We often diagnose cancer too late.
- 2. Prevention: We still have few effective ways to prevent cancer.
- 3. Addressing inequities prevention through survivorship: We have stark inequities based on race, region, and resources.
- 4. Targeting treatments to the right patients: We still know too little about why treatments work for some patients but not others.
- 5. Making progress on the deadliest and rarest cancers: We lack strategies for developing treatments for some cancers.
- 6. Supporting patients and caregivers: We don't do enough to help patients and families navigate cancer and its aftermath.
- 7. Learning from patients: We don't learn from most patients' experiences.

To execute these pillars of action, President Biden assembled what he calls the Cancer Cabinet: cabinet-secretary levels of more than 20 different U.S. agencies and departments, each of which offers unique resources, skills, and perspectives. The Cancer Cabinet has identified five areas in which they can execute either policy reform or activities and projects.

- 1. Close the screening gap: During the early days of the COVID-19 pandemic, nearly 10 million cancer screenings were missed. It is imperative that the government help speed the process of helping Americans catch up on those screenings.
- 2. Understand and address environmental and toxic exposures: Tackling environmental exposures will be an essential element of any cancer action plan.
- 3. Decrease the impact of preventable cancers: We presently have the tools to tackle certain preventable cancers, including vaccines for human papillomavirus and hepatitis C, but not all communities have equal access to them.
- 4. Drive innovation from discovery to patients: It is necessary to accelerate the pipeline from laboratory research to clinical treatment and community access. This area is specifically focused on the deadliest and rarest cancers, including childhood cancers.
- 5. Improve the experience for patients and caregivers: This includes not only navigating cancer care but also empowering patients with data and including patients and advocates in discussions and decision-making.

Dr. Young shared a list of Cancer Moonshot-related announcements from various U.S. agencies, including a \$250 million award through the U.S. Centers for Disease Control and Prevention (CDC) for cancer control and prevention programs; the Cancer Grand Challenges, a collaboration between NCI and Cancer Research UK; and the U.S. Centers for Medicare & Medicaid Services (CMS) expanding coverage for lung cancer screenings.

Since the official reignition of the Cancer Moonshot on February 2, 2022, the White House has made progress through many different channels, including a mention of the program in the State of the Union address; structured community conversations with advocates, researchers, patients, and families; the formation of the Cancer Cabinet; the signing of the Sergeant First Class (SFC) Heath Robinson Honoring our Promise to Address Comprehensive Toxics (PACT) Act and the Inflation Reduction Act of 2022, both of which will support cancer patients; President Biden's remarks at the John F. Kennedy Presidential Library and Museum; and the White House Childhood Cancer Forum. In October 2022, the White House will launch National Breast and Cervical Roundtables, and, in the future, more public-private partnerships will be announced.

Progress toward the President's vision includes:

- Recent NCI programs described earlier by Dr. Lowy such as the Telehealth Research Centers of Excellence, multi-cancer detection tests, and the Cancer Moonshot Scholars program.
- The signing of the Inflation Reduction Act, which caps out-of-pocket costs for Medicare beneficiaries at \$2,000, thereby reducing prescription costs for tens of thousands of cancer patients by thousands of dollars per year.
- Updated policy guidance from the Office of Science and Technology Policy, making the results of taxpayer-supported research immediately available to the American public at no cost. This guidance will affect the more than 200,000 federal studies published each year.

Additional White House community engagement efforts include:

- Working with the office of the First Lady
- Implementing a direct line of community access to the Cancer Moonshot where anyone can submit ideas, projects, and commitments
- Utilizing calls to action to curate commitments from the public and private sectors
- Encouraging and catalyzing public-private partnerships
- Engaging the President's Cancer Panel, a group of volunteers who come together to advise the President around cancer research and federal spending.

In this next phase, the Cancer Moonshot will expand the mission globally. The White House is committed to supporting and developing concrete oncology solutions to the most pressing global challenges that will benefit patients from all backgrounds and in all geographic locations. The Cancer Moonshot's international work will contribute to its core value and pillar of equity, particularly as it relates to access to treatments, tools, and resources for all cancer patients and their families around the world.

In closing, Dr. Young provided a link to the White House <u>Cancer Moonshot website</u> and invited NCRA members to share those with their networks.

Discussion

Ms. Ellis thanked Dr. Young for presenting a comprehensive overview of the Cancer Moonshot.

• Ms. Ellis asked whether the Cancer Moonshot has ongoing relationships with advocates and whether the Cancer Moonshot includes representation from advocates in areas of persistent poverty or underserved populations. Dr. Young responded that while there are no formal partnerships in place, patients, caregivers, families, and advocates are included and consulted in everything the Cancer Moonshot does. She explained that the Cancer Moonshot team spends much of its time in conversations with these stakeholders and that the White House encourages

- members of the public to contact the Cancer Moonshot team with ideas or comments. Ms. Ellis commented that, for certain populations, an open door may not be enough—specific outreach may be required to ensure inclusion and engagement.
- Dr. Willmarth asked how the <u>Cancer Grand Challenges</u> fit into the Cancer Moonshot and whether these will continue. Dr. Young explained that the Cancer Grand Challenges are a component and partner of the Cancer Moonshot, with \$100 million put toward international cancer research, and that she is eagerly anticipating the results of that work.
- Mr. Biru commented that although Dr. Young works for the Office of Science and Technology Policy, the seven pillars of action she highlighted do not explicitly mention technology. He asked how technology could advance the goals of the Cancer Moonshot. Dr. Young replied that technology is inherent in many of the priorities, and it will be a player in driving acceleration of the cancer pipeline; advancing biotechnology integration in new and innovative treatments; and addressing rare, deadly, and childhood cancers, among many other things. In conversations with stakeholders, the White House team speaks to technologists from many different sectors, from app development to cancer treatments. They view technology as having a parallel role with science, and the two, hand in hand, will push the needle forward.

Closing Remarks and Board Administration

Ms. Amy Williams and Ms. Annie Ellis

Ms. Ellis made a motion to approve the minutes of the 86th Council meeting. Dr. Willmarth seconded the motion, and the motion passed unanimously.

Ms. Williams shared dates of the 2023 NCRA meetings, occurring on March 1, June 21, and October 4.

Ms. Ellis invited new and returning NCRA members to introduce themselves.

- Bob Riter is a survivor of both breast and prostate cancer who has long been active in local cancer support organizations. Mr. Riter currently works at Cornell University, connecting trainees in basic research with the local cancer community.
- Marty Chakoian is a prostate cancer survivor who facilitates prostate cancer support groups and chairs the Patient Advocates Committee for the Pacific Northwest Prostate Cancer Specialized Program of Research Excellence (SPORE).
- Brittany McKelvey is a survivor of pediatric thyroid cancer and is active in both pediatric and thyroid cancer spaces. With a Ph.D. in molecular biology and genetics, Dr. McKelvey now works at Friends of Cancer Research and is involved in several thyroid-specific groups and the NCI Technology Research Partnership (NTRAP).
- Joya Delgado Harris is part of the leadership team for the CEO Roundtable on Cancer. Prior to that, she worked in the extramural research department of the American Cancer Society for 9 years. A survivor of Stage 3 breast cancer, she appreciates combining her personal and professional passions in her work.
- Nathaniel Ferre has worked as a patient advocate and currently is working to improve access and engagement in clinical trials in American rural and frontier areas through his work at the Huntsman Cancer Institute.

Ms. Ellis thanked NCRA members for attending and her colleagues for their contributions and support. The meeting adjourned at 3:04 p.m. EDT.

Certification

I hereby certify that foregoing minute	es are accurate and complete.
Date	Annie Ellis Chair NCI Council of Research Advocates
Date	Amy Williams Executive Secretary NCI Council of Research Advocates