90th Meeting of the National Cancer Institute (NCI)

Council of Research Advocates (NCRA)

National Institutes of Health (NIH)

In-Person Meeting

October 4, 2023

Members Present

Mr. Yelak Biru

Ms. Melissa Buffalo

Mr. Marty Chakoian

Ms. Annie Ellis, *Chair*

Mr. Nathaniel Ferre

Ms. Joya Delgado Harris

Mr. Lee Jones

Dr. Brittany McKelvey

Mr. Robert Riter

Ms. Kristen Santiago

Ms. Jacqueline Smith

Mr. Kevin Stemberger

Dr. Nicole Willmarth

Speakers

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

Dr. Douglas Lowy, Principal Deputy Director, NCI

Ms. Kelli Marciel, Associate Director, Cancer Content, Office of Communications and Public Liaison, NCI

Dr. Meg Mooney, Chief, Clinical Investigations Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI

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

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Welcome and Opening Remarks

Ms. Amy Williams and Ms. Annie Ellis

Ms. Williams opened the meeting at 12:00 p.m., welcomed Council members and attendees, provided brief opening remarks, and reviewed the day's agenda.

Ms. Ellis called the meeting to order, reviewed the conflict-of-interest rules, read the public comment statement, and confirmed that a quorum of members was present.

NCI Principal Deputy Director's Update

Dr. Douglas Lowy

Dr. Lowy provided an overview of cancer research initiatives and advances, cancer policy, and NCI budget.

- Dr. Lowy began by presenting cancer mortality trends from 2000 to 2019 by race and ethnicity, and statistics indicating increasing uterine cancer death rates among Black women in the U.S.
- Dr. Lowy noted the key takeaways from the NCI Workshop held on June 22–23, 2023 on the diverse aspects of uterine serous cancer (USC). The takeaways included (1) spreading the word to new investigators and grant reviewers, (2) developing syngeneic, clinically relevant mouse models of USC is critical to understanding its biology and evolution, (3) identifying the crucial molecular signatures, undiscovered targets, and disparities among defined populations, and (4) developing organoids and patient-derived xenografts (PDX) from diverse patients could be useful to advance USC research.
- Dr. Lowy shared female breast cancer mortality rate trends from 2000 to 2020 by race and ethnicity in the U.S. There has been a steady decrease in female breast cancer mortality in Black women, although they continue to remain the group with the most deaths.
- Dr. Lowy mentioned the FDA-approved breast cancer treatments from March 2022 to March 2023 including olaparib, fam-trastuzumab, elacestrant, sacituzumab govitecan-hziy, and abemaciclib.
- Dr. Lowy explained the goals of the reignited Cancer Moonshot, which are to reduce the U.S. cancer death rate by 50% in the next 25 years, overcome cancer disparities, and end cancer as we know it, for all. To accomplish these goals, the scientific community must (1) widen dissemination of current standards of care, (2) ensure that everyone benefits, (3) conduct implementation research, (4) prioritize more research advances, and (5) include cancers that currently have a poor prognosis, rare cancers, and childhood cancers.
- Dr. Lowy shared that President Biden and the First Lady met with the Cancer Cabinet on September 13, 2023, to announce new actions federal agencies are taking to advance the goals of the Cancer Moonshot.
- Dr. Lowy noted the eight goals of the National Cancer Plan and common themes and priority areas from the *President's Cancer Panel: National Cancer Plan Initial Stakeholder Meeting* held on September 7, 2023. Themes and priority areas included recruiting and retaining a diverse cancer research and care workforce, providing accessible care regardless of a patient's geographic location or insurance status, enhancing data sharing and interoperability, and integrating social determinants of health into research and the cancer care continuum.

- Dr. Lowy explained the mission and focus areas of MyPART: My Pediatric and Adult Rare Tumor Network, shared the new artificial intelligence engagement series, and announced NCI's new funding opportunity: NCI Worta McCaskill-Stevens Career Development Award for Community Oncology and Prevention Research.
- Dr. Lowy noted that many women are overdue for cervical cancer screening; the overdue rates increased from 14% in 2015 to 23% in 2019.
- Dr. Lowy shared the cervical cancer incidence and mortality in the U.S. from 2000 to 2019 based on age-adjusted incidence rates; the Hispanic and Black populations have the highest cancer incidence and mortality. He also mentioned NCI's cervical cancer Last Mile Initiative and announced the new Cancer Screening Research Network (CSRN) to conduct trials and studies specifically related to cancer screening; CSRN is funded in part by the Cancer Moonshot. The purpose of CSRN is to save lives by establishing systems that detect asymptomatic cancers; due to current budget constraints, only seven centers have been funded.
- Dr. Lowy then provided an overview of NCI's appropriations and paylines over an 8-year period (2016–2023) and the President's NCI budget proposal for fiscal year (FY) 2025, which includes a $1.478 billion increase. He highlighted that this and other proposed budget increases may be in jeopardy due to the debt ceiling agreement.
- Dr. Lowy shared a breakdown of NCI spending and noted that NCI's research buying power is $1.1 billion less than 20 years ago. He mentioned that the percentage of modular awards has decreased progressively from 63% in 2012 to 17% in FY 2022. President Biden's NCI budget proposal for FY 2025 and FY 2026 is proposing a further increase of about $1.45 billion each FY.
- Dr. Lowy explained the implications of a "flat" FY 2024 budget. It is necessary to add $250 million to the research project grants pool in FY 2024 to maintain the 12th percentile payline to fund new grants. The NCI budget could be adversely affected by a flat budget, including the need to increase the payline for new awards, decrease new cancer training awards and SPORE grants, and cut the intramural research program awards as much as extramural awards.

Discussion

- Ms. Ellis highlighted the disparities and confusion in cancer care due to frequently changing guidelines, particularly affecting underserved populations in accessing timely cervical cancer screenings. She advocated for focused, targeted efforts to help these populations benefit more from cancer research, aiming to reduce mortality rates more swiftly. She also encouraged a nuanced interpretation of "ending cancer," tailoring its meaning to various individual experiences and outcomes, suggesting that clarity in this definition could enhance the effectiveness of cancer care goals. Dr. Lowy acknowledged Ms. Ellis' comments and noted that cancer care often focuses on individual cancer types, resulting in isolated advancements. He emphasized the need for broader applicable advances, citing the success of immune checkpoint inhibitors as an example. There is a need for progress in areas like endometrial cancer, where outcomes are worsening. He also advocated for enhanced efforts and a more equitable distribution of standard cancer care to improve overall outcomes.
- Ms. Santiago asked about the roles of caregivers and navigation in cancer care, expressing that NCI has been more involved in developing evidence for the utility of navigation in cancer care. Dr. Lowy noted the complexity of cancer care, and the difficulty patients face in managing it

alone, suggesting that navigation could be enhanced using digital or technological enhancements to improve efficiency and reduce costs. Moreover, caregivers and navigation play vital roles in cancer prevention and cancer screening, especially in explaining and interpreting the complexities of care to patients.

- Mr. Lee expressed gratitude for Dr. Lowy's efforts in cancer care and shared personal experiences of participating in a clinical study and undergoing screenings. He explained that real-world factors contributing to the emergence of early onset cancers, such as colorectal and breast cancers, should be closely monitored. He also underscored the importance of NCI's survivorship programs, acknowledging the ongoing quality-of-life issues faced by cancer survivors, and the continuous needs of the increasing survivor population.
- Mr. Ferre articulated a need for more straightforward and accessible screening approaches, such as blood tests, to improve adherence. He noted that evolving and confusing guidelines, especially in cervical, prostate, and breast cancer screenings, complicate the process, particularly for those in rural areas or without advanced primary care. He urged NCI to simplify guidelines and focus on approaches that enhance accessibility and clarity in the cancer screening process. Dr. Lowy agreed with prioritizing cancer care accessibility, especially in rural areas, and mentioned initiatives like telehealth to improve services in underserved communities. However, he emphasized that local and at-home screening tests also introduce complexity, necessitating proper follow-up care. Therefore, despite the convenience of local screenings, establishing a robust connection with healthcare providers for appropriate follow-up is essential to make these screenings meaningful and effective.
- Mr. Riter asked how a government shutdown would impact NCI. Dr. Lowy explained that the effects would be more significant in Bethesda, where NCI is located, causing disruptions like the cancellation of peer review meetings and new work prohibitions. The impact would be lesser externally, as ongoing grants at universities would continue, but delays would occur in new award applications due to rescheduling of study sections. Patient care would continue, but new patient admissions would be limited, with a few exceptions requiring substantial justification.
- Ms. Smith asked whether NCI has identified additional screening tests—beyond blood tests—for the Vanguard Study on Multi-Cancer Detection. Dr. Lowy discussed the challenge of balancing the efforts to identify new screening tests and refine known, well-established tests in medical diagnostics. He stressed the need to validate these approaches before selecting tests for implementation. Ms. Ellis noted uncertainties such as the appropriateness of cancer detection timing, available interventions, and the potential outcomes of detected cancers. However, she expressed hope that experts, possibly from the Vanguard Study, will clarify these aspects, recognizing the complexity of these issues and looking forward to more defined and directed outcomes in cancer screening processes.
- Ms. Buffalo noted that Dr. Lowy's presentation was both refreshing and frightening for her, as an American Indian/Alaska Native, to hear the stark statistics that reflect their reality. She discussed the underfunding of the Indian Health Service and the lower life expectancy of 65 years for their communities, in contrast to the national average of 77 years. She also underscored the significance of including more representation from underserved populations in these conversations. Dr. Lowy acknowledged that the difficulties for American Indians begin with rural accessibility but are amplified by numerous other factors. He noted that NCI is committed to

advancing initiatives that serve American Indians and Alaska Natives, focusing on implementation research. For example, in colorectal cancer screening for rural communities, Dr. Lowy recommended training non-gastroenterologists—physicians, nurse practitioners, and physician assistants—to conduct screenings with efficacy comparable to specialists. This strategy aims to deliver cancer care to patients in their communities.

- Mr. Biru shared that by examining lessons learned from disparities in cancer treatment studies, researchers may gain insights to improve equitable access to more effective treatments. He pondered whether this is challenging because it is a systemic issue. Dr. Lowy noted that while nationwide solutions are ideal, practical implementation is complex due to varying regional problems not limited to isolated pockets. However, he shared that he is optimistic about the advancement of technology and new interventions, which have contributed to reduced mortality rates and dampened disparities since 2000, despite persisting inequities. Dr. Lowy said he believes that the continual development and equitable application of new technologies and interventions will expedite improvements in the standard of care.

Update on the NCI National Clinical Trials Network (NCTN)

Dr. Meg Mooney

Dr. Mooney provided an overview of NCI's Extramural Clinical Trials Networks and NCTN, evaluation of the NCTN Program, budget and funding considerations, and next steps.

- Dr. Mooney began by highlighting the current NCI Extramural Clinical Trials Networks and the transformation of the former Cooperative Group program to NCI NCTN in 2014. She also described the NCTN program organizational structure and the Cancer Therapy Evaluation Program (CTEP) CORE for clinical trials that helps support NCTN and other NCI-funded CTNs.
- Dr. Mooney shared the adult and pediatric intervention for each trial phase and cancer type from March 1, 2019, to October 31, 2022; 65% of all trials were with an investigational new drug (IND), and 35% were with a non-IND.
- Dr. Mooney highlighted that the NCTN's quarterly data on patient enrollments for treatment trials between 2019 and 2022 was significantly affected by the COVID-19 pandemic. Notably, there was a sharp decline in enrollments during the second quarter of 2022. However, enrollments rebounded in the third and fourth quarters, thanks to the adoption of telemedicine. Dr. Mooney outlined the continued lower proportion of accrued participants who were non-White compared to those who were White in NCTN 2019 and 2020, as well as the NCTN study components and accrual across two project periods; the first period was across 60 months and the second period was across 44 months; accruals for the second period decreased by 10.8% due to the pandemic. She also described the NCTN accrual by enrolling site types: lead academic participating sites (LAPs), NCI Community Oncology Research Program, and rostered.
- Dr. Mooney highlighted the Program's key accomplishments including the conduct of collaborative trials in special populations; progress of PROSPECT: Alliance N1048; and other selected recent key accomplishments and impact from three successful trials.
- Dr. Mooney shared that the satisfaction from key NCTN participants has significantly improved by approximately 25% from 2016 to 2022.

- Dr. Mooney noted that the NCTN was assessed by an external evaluation panel; the entire panel (including patient advocate representatives) was highly supportive of other NCTN components, including LAPs, imaging core centers, and integrated translational science awards. She outlined the external panel's key concerns and recommendations, as well as the population, clinical, and societal impact of NCI's NCTN.
- Dr. Mooney elaborated on the budget considerations and highlighted that the comparable estimate for NCTN's estimated "per patient" cost is between $9,500 and $15,000. The costs are funded by industry and national cooperation group sponsors.
- Dr. Mooney noted that NCTN continues to make significant progress, although robust progress will be diminished due to funding delays, including delaying the request for applications (RFA) for one year to a more favorable financial environment. Moreover, she emphasized that NCI has notified current grantees of the delay so that there will be no lapse in funding.

Discussion

- Ms. Ellis commended NCTN's impressive, interconnected landscape, particularly the active participation of patients, advocates, and oncologists dedicated to ensuring accessible community solutions.
- Mr. Jones noted that NCTN is in late phase trials but asked the status of the experimental therapeutics trials. Dr. Mooney responded that the experimental therapeutics CTN focuses on earlier phases, and the central Institutional Review Board (IRB) reviews these early-phase studies. Dr. Willmarth asked whether there are patient advocates in each of the groups and IRBs. Dr. Mooney reassured that patients are well represented, including in the central IRBs.
- Mr. Biru speculated about what can be done to compress the clinical trials timeline. Dr. Mooney noted that NCI is relentlessly working on this question and established the Operational Efficiency Working Group to accelerate and streamline the development of clinical trials, following specific guidelines for operational efficiency. Even though NCI starts the timeline early, collaborations, especially with multiple companies, can prolong the trials. An example is the Pragmatica-Lung study, which took 200 days to activate despite having sufficient prior data. However, continuous monitoring and evaluation are conducted to ensure trials remain relevant, attractive for accrual, and valuable in providing significant information, even if they do not fully accrue.
- Dr. Smith noted that frequent travel is burdensome for patients and asked how this can be alleviated, as well as how implementation of CTEP IND oral agents impacts ongoing accrual and trial participation. Dr. Mooney explained that NCI is working to make the use of CTEP IND oral agents a permanent part of the program, despite challenges with intravenous experimental agents. Collaboration with local investigators is possible in some cases, even for IND studies, ensuring compliance with FDA guidelines. NCTN aims to facilitate participants' access to trials, allowing transfers to closer centers when necessary, enhancing the flexibility and accessibility of the trials.
- Dr. McKelvey asked what proportion of studies lead to regulatory approvals. Dr. Mooney elaborated that every phase 3 trial NCI conducts aims to impact clinical practice. Approximately 58% of these trials are under IND, but only about 40% intend to register. IND-exempt trials are easier to streamline due to fewer monitoring and data collection requirements, while industry often explores specific questions without intending to file for marketing application.

- Ms. Ellis requested clarification on whether NCTN groups will get separate gap funding because of the RFA delay. Dr. Mooney clarified that NCTN has been approved a 1-year funding extension at the current level.

Modernizing NCI's Consumer-Focused Cancer Content

Ms. Kelli Marciel

Ms. Marciel described NCI's consumer-focused information and content modernization, as well as its results and impact.

- Ms. Marciel began by noting that NCI's consumer-focused web content received 33 million visits in 2022. NCI continues to modernize its public health communications and confront health misinformation. She also explained each section of cancer.gov.
- Ms. Marciel shared that her team's work has shown that consumers: (1) use search engines to find what they are looking for; (2) want a one-stop source for trusted cancer information; (3) expect to quickly find answers to their questions posed in Google; (4) value content that is authoritative and accurate, yet approachable and warm; and (5) navigate within content to learn more.
- Ms. Marciel outlined the goals including: (1) making it easier for users to find the specific information they want; (2) using a data-informed approach to create a more cohesive, modern, and helpful user experience; and (3) presenting information with a voice and tone that are empathetic, authoritative, and trustworthy.
- Ms. Marciel described the iterative content modernization process composed of four major components: evaluation, discovery, content creation and updating, and publication.
- Ms. Marciel shared that impact is evaluated by search result ranking for the terms users are searching, page visits (i.e., traffic), time on site, and pages viewed per visit.
- Ms. Marciel noted that NCI has made substantial progress on modernizing content, including completing web sections on the following topics: liver and bile duct cancer, cervical cancer, stomach cancer, and bladder cancer. She also mentioned several topics in progress including breast cancer and rare childhood cancers, and the side effects of cancer treatment. For example, in cervical cancer, there was a 163% increase in visits to cervical cancer patient content since the content launch compared to the previous year; these data are only for the English content.
- Ms. Marciel noted several next steps including (1) modernizing NCI's consumer-focused content to meet the public's needs; (2) leveraging the observation that more individuals are finding and engaging with NCI content to answer their questions about cancer; and (3) applying these content modernization approaches across all NCI consumer-focused content. Ms. Marciel noted that although it is time and resource-intensive, it is worth the investment.

Legislative and Budget Update

Ms. Holly Gibbons

Ms. Gibbons provided an update on the debt limit deal, the ongoing FY 2024 appropriations process, and recent congressional briefings.

- Ms. Gibbons began by reiterating that the Biden administration raised the debt ceiling until January 2025. This agreement is part of the Fiscal Responsibility Act, which was signed into law by President Biden on June 3, 2023.

- Ms. Gibbons outlined the FY 2023 enacted funding and FY 2024 President's budget request. The funding proposals from the House and Senate are different. The President's budget request for FY 2024 would provide $716 million for the Cancer Moonshot and $2.5 billion for the Advanced Research Projects Agency for Health. Based on the subcommittee markup from July 14, 2023, the House plans to decrease NCI funding by $216 million, while the Senate plans to increase NCI funding by $60 million.
- Ms. Gibbons described the late Senator Diane Feinstein's role and impact on championing breast cancer research and noted that Senator Laphonza Butler was sworn in on October 3, 2023, to replace Senator Feinstein.
- Ms. Gibbons outlined how NCI receives its funding and noted the NCI Professional Judgement Authority: The National Cancer Act of 1971 gives the NCI Director special authority to submit an annual professional judgment budget directly to the President for review and delivery to Congress. This budget reflects NCI cancer research priorities and identifies areas of potential investment in cancer research. She also emphasized that Congress has enacted one or more continuing resolutions in all but three of the last 46 FYs.
- Ms. Gibbons explained the Antideficiency Act of 1950, which sets the rules for a government shutdown. Both House and Senate reached consensus that the government will remain open for another seven weeks; the next potential government shutdown would be on November 17, 2023, if Congress does not approve funding.
- Ms. Gibbons noted that former Speaker of the House McCarthy was the first speaker in history to be removed. She also described potential speaker candidates.
- Ms. Gibbons noted that the Senate will hold a Health, Education, Labor, and Pensions Committee Hearing for Dr. Monica Bertagnolli's nomination to serve as NIH Director.
- Ms. Gibbons shared a list of recent congressional visits and briefings with NCI leadership.

Closing Remarks and Board Administration

Ms. Amy Williams and Ms. Annie Ellis

Mr. Stemberger made a motion to approve the minutes of the 89th NCRA meeting. Ms. Smith seconded the motion. The motion passed unanimously.

Ms. Ellis thanked council members for their time, attention, and feedback and thanked OAR staff.

The meeting was adjourned at 3:26 p.m. ET.

Certification

I hereby certify that foregoing minutes are accurate and complete.

March 6, 2023
Date

\s\
Annie Ellis
Chair
NCI Council of Research Advocates

March 6, 2023
Date

\s\
Amy Williams
Executive Secretary
NCI Council of Research Advocates