84th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Virtual Meeting

September 29, 2021

Members Present

Ms. Anjelica Davis, Chair
Ms. Melinda Bachini
Mr. Yelak Biru
Ms. Victoria Buenger
Ms. Melissa Buffalo
Ms. Annie Ellis
Ms. Jennifer Pegher
Ms. Kristen Santiago
Ms. Jacqueline Smith
Mr. Kevin Stemberger
Dr. Nicole Willmarth

Speakers

Dr. Danielle Carnival, Senior Advisor to the Director, White House Office of Science and Technology Policy (OSTP)

Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences (DCCPS), NCI

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

Ms. Maureen Clark Szemborski, Program Analyst, Office of Government and Congressional Relations, NCI

Dr. Ned Sharpless, Director, NCI

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

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Welcome and Opening Remarks

Ms. Anjee Davis and Ms. Amy Williams

Ms. Williams opened the meeting at 12:00 p.m., welcomed Council members and attendees, and reviewed the meeting agenda. Ms. Davis reviewed the conflict-of-interest rules for the meeting, confirmed that a quorum of members was present, and provided brief opening remarks.

DCCPS Director's Update

Dr. Robert Croyle

Dr. Croyle announced that he will be retiring at the end of the calendar year, and Dr. Katrina Goddard will take on the role on October 11. He then previewed the topics he would cover, emphasizing the breadth of the DCCPS mission, the role DCCPS plays as a bridge between NCI and other U.S. Department of Health and Human Services (HHS) agencies and public health activities, and DCCPS's diverse portfolio, which has built unique areas of research.

Dr. Croyle provided an overview of the role, history, and organizational leadership of DCCPS. Key DCCPS leaders include the new Director of the Office of Cancer Survivorship, Dr. Emily Tonorezos; the Deputy Director for Implementation Science, Dr. David Chambers; the Senior Advisor for Health Disparities, Dr. Shobha Srinivasan; and leaders of the programmatic mission areas. The Healthcare Delivery Research Program—the first of its kind at the National Institutes of Health (NIH) and headed by Dr. Paul Jacobsen—was created to ensure adequate support for cancer care. He highlighted expansion of the Surveillance, Epidemiology, and End Results (SEER) Program, involvement in the Cancer Moonshot℠, and creation of the Office of Cancer Survivorship.

Existing and future DCCPS Centers of Excellence initiatives aim to accelerate progress in new research areas or re-energize areas of research and reflect the scientific priorities of DCCPS. DCCPS efforts are embedded with interagency collaboration; for example, DCCPS participates in coordinated tobacco control efforts across HHS through the Transdisciplinary Tobacco Use Research Centers because tobacco use remains a leading cause of cancer death in the United States. DCCPS is the only NIH Division with a branch focused on health communication research—the Centers of Excellence in Cancer Communications Research. Applications are under review for the new Centers on Telehealth Research and Cancer-Related Care initiative, which was launched in response to the shift to telehealth due to COVID-19 and the need for cancer-related telehealth research.

To date, 261 administrative supplements across 18 initiatives have been awarded since Fiscal Year (FY) 2014 by leveraging NCI-designated Cancer Centers for cancer control. These supplements have helped ramp up multiple efforts, including increasing human papillomavirus (HPV) vaccination uptake, supporting tobacco cessation efforts, and collecting cannabis use data. Future supplements may focus on cannabis use, nicotine reduction in cigarettes, and support for Health Resources and Services Administration (HRSA) clinic collaborations for cancer screening.

DCCPS funding in health disparities research has doubled in the last 4 years, which will provide data to help address this challenging problem. A large proportion of health disparities in the U.S. are geographic—including large rural-urban disparities in cancer incidence—and NCI must target cancer control efforts toward specific geographic areas in addition to ethnic groups in need. Future opportunities include additional research on cancer control among American Indians/Alaska Natives (AI/AN), sexual and gender minorities, and regions of persistent poverty, as well as collaboration with the Advanced Research Projects Agency for Health (ARPA-H).

The SEER program recently was expanded to cover a larger portion of the U.S. population and include more data (e.g., biomarker status) and more members of population subgroups (e.g., white, black, AI/AN, and Asian subgroups). He described the percent increase of U.S. population subgroups resulting from the SEER expansion; as of May 2021, the largest increase is seen in the Hispanic subgroup. The Centers for Disease Control and Prevention (CDC) is an important partner in this effort; however, the SEER registries provide major research support to cancer investigators.

Dr. Croyle provided a brief overview of the Office of Cancer Survivorship, which was created as a result of advocacy. NCRA is an important source of input to Dr. Tonorezos as she re-envisions the Survivorship research program. The definition of *cancer survivor* has been updated to include those living with cancer and reflects the growing number of survivors with advanced and metastatic cancer.

Future challenges for DCCPS include revitalizing key partnerships (e.g., with American Cancer Society [ACS], CDC, and the National Institute of Environmental Health Sciences [NIEHS]) and the need for more epidemiological evidence on the U.S. Latino population. The decrease in cigarette use and increase in cannabis use and vaping by 12th graders emphasizes the need for additional cannabis research, which DCCPS is addressing (e.g., expansion of Cancer Center Supplements in FY22).

Dr. Croyle briefly described funding opportunities such as the new initiatives awarded in FY21 and noted that more information about DCCPS can be found through newsletters, listservs, blogs, and social media. He thanked NCRA members for their service and dedication and encouraged collaboration between NCRA and the Office of Cancer Survivorship.

Discussion

Ms. Williams thanked Dr. Croyle for highlighting DCCPS' work on issues that NCRA board members and advocates are addressing in the community.

- Ms. Santiago asked how the advocacy community can encourage other states to participate in SEER. Dr. Croyle clarified that it is up to the states' health departments to apply (through a Request for Proposals [RFP]) to participate in SEER. Currently, cancer is a reportable disease in every state, but in the recent SEER expansion, several states chose not to apply because they have funding from CDC or would prefer not to co-lead with an academic institution on surveillance. Another challenge is determining which cancer center in the state will lead the effort. Dr. Croyle added that participation in SEER provides additional funding opportunities to cancer investigators.
- Ms. Davis thanked Dr. Croyle for the work he has done for the cancer community, applauded the impact of his leadership at DCCPS, and asked how NCRA can support Dr. Goddard as the new DCCPS Director. Dr. Croyle responded that NCRA is uniquely poised to inform, educate, and orient Dr. Goddard on issues and perspectives of the cancer patient and advocacy communities. He will suggest to Dr. Goddard that she follow up with Ms. Davis and Ms. Williams. Dr. Goddard has unique expertise on healthcare delivery in large healthcare organizations, which can be leveraged for science and research.
- Ms. Williams asked Dr. Croyle to outline the purpose and goals of the Centers of Excellence in Cancer Communications Research because this is a vehicle for bringing patients into advocacy, and advocates need to be aware of and may want to participate in these efforts. There may be potential synergy between the next generation of advocates and these centers. Dr. Croyle recommended engaging Ms. Jennifer Pegher (Association of American Cancer Institutes [AACI]) and Drs. Henry Ciolino (Director, Office of Cancer Centers) and Robin

Vanderpool (Chief, Health Communication and Informatics Research Branch [HCIRB]) in discussions to bridge NCRA with the cancer centers' community advisory boards and activities.

NCI Director's Update

Dr. Ned Sharpless

Dr. Sharpless celebrated Dr. Croyle's innovative thinking and the importance of his leadership across all NCI areas and welcomed new DCCPS Director Dr. Katrina Goddard. He provided a brief update on the commemoration of the 50th anniversary of the National Cancer Act of 1971 (NCA-50) and showed a public-facing video that is part of the NCI commemoration material.

Dr. Sharpless provided an overview of the NCI Professional Judgment Budget proposal for FY23. The cost of cancer care is immense; given their success, cancer research efforts are worthwhile, and the Federal Budget being sought by NCI in 2023 is apt. NCI appropriations for FY2015–2021 showed a gradual increase of funding for NCI that reflects bipartisan support for cancer research. The largest components of NCI's budget are Research Project Grants such as R01s, R35s, and U mechanisms (43%); the portfolio is divided between extramural (75%) and intramural funding (25%).

Current cancer programs and studies include a webinar on the Childhood Cancer Data Initiative (CCDI), a Blue Ribbon Panel Report Anniversary seminar on the Cancer Moonshot℠, and promising results from the Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors study, a prospective, open-label, multicenter phase II clinical trial of ipilimumab plus nivolumab for angiosarcoma. The Sherlock Lung Study, which tracks lung cancer mutational processes in never-smokers through genomic sequencing analysis, has revealed that there is no signature associated with tobacco smoke in tumors from subjects exposed to second-hand tobacco smoke. This result may be due to the detection limit of the signature algorithm or the need for a larger sample size. This type of molecular approach may allow linking of carcinogens to specific cancers.

Cancer screening rates and clinical trial enrollment have been affected by the COVID-19 pandemic. Epic Health Research Network has found that colon cancer screening rates are lagging, and NCI is aiming to understand the pandemic's effects on cancer screening and diagnosis to try to mitigate an increase in advanced cancer diagnoses. The pandemic also has slowed the clinical trials process, affecting accrual, which will lead to delayed development of cancer treatment and diagnosis approaches. NCI's SARS-CoV-2 serology activities include antibody test performance evaluation with the Food Drug Administration (FDA), work with the All of Us research program on the timeline of early seroconversion, the COVID-19 Seroprevalence Studies Hub database, the first demonstration that antibody status correlates with reduced risk of infection, and creation of the NCI Serological Sciences Network for COVID-19 (SeroNet).

NCI's recent efforts to promote health equity include two recent Requests for Applications (RFAs) for the Connecting Underrepresented Populations to Clinical Trials Network, announcement of the first round of awardees of the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative, and NCI's collaboration on the Cancer Diagnostics Devices (CD2) Interagency Task Force with HRSA, FDA, and the Centers for Medicare and Medicaid Services (CMS) to address regulatory and technical challenges to translation and implementation of cancer screening and diagnostic devices.

NCI's Center for Global Health is promoting equity in global cancer research by developing resources and supporting independent scientific capacity of investigators within low- and middle-income countries. NCI will participate in the first U.S.-U.K. Cancer Summit to bring together researchers, patients, and stakeholders to identify opportunities for collaboration and promote progress for cancer patients.

Dr. Sharpless shared updates to NCI training programs to support cancer researchers. He acknowledged the excellent service of two departing NCRA members—Mr. Rick Bangs and Ms. Danielle Leach—and welcomed new NCRA members Dr. Vickie Buenger and Ms. Melissa Buffalo.

Discussion

Ms. Davis expressed appreciation for the advocacy of Mr. Bangs and Ms. Leach and their work and mentorship.

- Dr. Buenger commented that as a member of CCDI's engagement committee, she could be a resource for communicating with the scientific and broader communities. Dr. Sharpless mentioned that CCDI is addressing data access, privacy, and sharing issues and emphasized the importance of patient engagement and community participation and input in this effort.
- Ms. Davis asked whether CD2 will be considering healthcare delivery from a cost perspective (e.g., acceleration of coverage, impact of costs on the patient) for patients. Dr. Sharpless noted that a new track for coverage must be considered. He clarified that CMS is acting in an advisory capacity and not signing the memorandum of understanding (MOU). CD2 has great potential, and he is optimistic about this effort to accelerate device development, FDA authorization, and usage. Ms. Davis commented that due to the high cancer incidence in rural and impoverished communities, ensuring that the task force is focused on implementation that includes cost coverage (including screening) is essential. She hopes NCRA can be involved in discussions about care in rural communities.
- Mr. Biru asked about the impact of COVID-19 on clinical trial accrual and data maturity or readout. Dr. Sharpless responded that data collection from various sources (e.g., Clinical Trials Reporting Program, NCI's National Clinical Trials Network [NCTN]) is ongoing and indicated that the analysis of these data is difficult because only some trials have recovered after the large drop in accrual during March, April, and May 2020. Thus, there is a need to aggregate the data and determine which types of trials and patients have been affected. The impact is clear and will lead to delayed therapy development. NCI is attempting to find approaches to accelerate clinical trial accrual.
- Dr. Buenger asked whether conclusions will be made about differences in the impact of COVID-19 on screening and clinical trials relative to variations in state reopening plans. Dr. Sharpless responded that NCI has considered how to use the modifications (e.g., telehealth implementation) in cancer care delivery that have occurred during the pandemic. He commented on NCI efforts to study how cancer care (e.g., cancer health disparities, policy decisions) has been affected by the use of telehealth, which has been used widely in clinical trials and been embraced by both patients and researchers. Unsurprisingly, telehealth has been embraced more in urban areas than in rural areas. He emphasized that NCI does not control licensing or payer rules, barriers that are reappearing after being relaxed during the pandemic.

- Dr. Willmarth asked whether the factors that have caused clinical trial overaccrual during the pandemic are known. Dr. Sharpless indicated that research is ongoing, and it may be difficult to determine the impact of specific new practices (e.g., telehealth implementation) that have been implemented during the pandemic and resulted in an increase in accrual. Ms. Davis noted that this is an important effort. Some patients lost coverage (e.g., telehealth visits) due to unexpected policy changes as they were attempting to join a clinical trial.
- Ms. Ellis suggested that comparison of NCTN accrual strategy changes (e.g., adoption of telehealth) and resulting patient accrual with those of industry clinical trials, which may not have implemented the same accrual strategy changes, would be helpful in showing the approaches that are effective. Dr. Sharpless pointed to an industry shift toward greater transparency about their data, which would be helpful for studies of accrual, particularly minority accrual, during the COVID-19 pandemic. The advocacy community can help disseminate messages about the need for data transparency.

White House Office of Science and Technology Policy: Ending Cancer as We Know It

Dr. Danielle Carnival

Dr. Carnival, former CEO of I AM ALS—a patient advocacy organization—expressed gladness to be with like-minded colleagues who represent the direct experience of those who live with cancer. In addition to the important science and technology advances and investments by federal research agencies, the individuals affected by those advances are at the center of how OSTP perceives its role.

Dr. Carnival described the vision for the ARPA-H model and highlighted President Biden's support for NIH and NCI. ARPA-H reflects a bold vision for enhancing—not replacing—the federal government's capabilities to make progress to promote human health. The aim is to engage NIH and NCI in the application of successful aspects of the ARPA model to address unanswered questions about health.

ARPA-H structural elements include a flat and dynamic organization; a term-limited Director with technical and leadership skills; a creative, diverse cohort of Program Managers with broad autonomy; distinct project review and selection processes; convergence of scientific disciplines; and collaborations across academia, industry, and government. ARPA-H goals include supporting transformative research to speed application and implementation of health breakthroughs to serve all patients; fostering breakthroughs across various levels (e.g., molecular to societal); building capabilities and platforms to revolutionize prevention, diagnosis, treatment, and cures; converting use-driven ideas into tangible solutions; and overcoming market failures through critical solutions or incentives. Although many details remain to be defined, the vision is to make progress in challenging areas in collaboration with NIH and NCI.

In order to realize the ARPA-H vision and build upon lessons learned from the National Cancer Act and the Cancer Moonshot^{SM}, it is important to determine the best way to organize federal government efforts and collaborations with non-government groups. The principles of this approach include injecting urgency to end cancer as we know it; bringing all possible solutions and partners to the table; providing an avenue to understand and prioritize needs, ideas, and experiences that patients and caregivers consider most important; changing systems and culture to meet this moment; and delivering on the hope felt by millions facing cancer diagnosis.

Dr. Carnival is focused on defining how to accomplish these goals and ensure coordination for delivery of equitable support and care from prevention through survivorship for those living with cancer. She asked Council members to discuss how cancer is known (e.g., Is cancer diagnosed too late?) and identify the most important challenges as well as the areas best positioned for progress.

Discussion

- Ms. Santiago listed challenges related to early detection, screening, inequities, biomarkers, and clinical trials for lung cancer and asked how ARPA-H will involve patient advocacy organizations. Dr. Carnival responded that patient advocates and organizations will have ongoing input at ARPA-H, although the specific structure has not yet been determined.
- Dr. Willmarth shared that screening, early detection, and prevention are challenges in different cancers such as brain tumors. Incidence of metastatic brain tumors is increasing, but screening for metastatic brain tumors in higher risk patients is still limited.
- Ms. Davis asked whether ARPA-H will garner consensus around universal cancer issues (e.g., clinical trials) as well as work with specific cancer groups that have unique needs. Dr. Carnival responded there will be a balance. In addition to conducting investigation of major diseases, such as Alzheimer's disease, for which the specific challenges are well known, ARPA-H will take on important challenges in specific areas of cancer. Details of how ARPA-H will focus on specific cancer research areas are not yet defined. However, this work will be done with continued input from the broad disease and advocacy community as well as Congress.
- Mr. Biru commented that to make progress in cancer, the spectrum of care must be considered—prevention, diagnosis, disease progression and treatment, cure, and post treatment and living with cancer. The drug development pipeline, drug development research strategies, clinical trials, drug approval, and postapproval implementation also must be studied.
- Dr. Buenger noted that she perceives ARPA-H efforts as incentivizing and aligning missions on high-risk, high-reward projects. Thus, the advocacy community needs to be educated and become educators about the potential results—payoffs or disappointments—of such projects. It is important for ARPA-H to involve advocates early and educate them about the effort so that they can communicate with their communities. Dr. Carnival agreed and noted her hesitation to use high-risk, high-reward nomenclature because high-risk approaches may not be necessary to solve issues that the existing system has not resolved; rather, these issues may require different approaches. It is important to have a conversation with the recipients of ARPA-H products and advancements. FDA and CMS will be part of the conversation throughout the development process. Dr. Carnival acknowledged the importance of recognizing that patients and clinicians are the ones who decide whether the products (e.g., diagnostics, prevention methods) are used.
- Ms. Ellis commented on the progress (e.g., HPV vaccinations) that has occurred since her cancer diagnosis in 2004. Survivors want to live well with or without cancer; however, what patients are willing to do for cures and disease control can vary and should be part of the conversation. She added that many have not had direct access or benefited from the recent technology explosion and that patients want early detection—detection while the cure is still possible—to inform treatment. She thanked Dr. Carnival for her work and for including

people living with cancer. Dr. Carnival added that ARPA-H would like to expand efforts from outside organizations to combat the deficit in individuals receiving recommended screening due to the pandemic. She and her colleagues want to help spread that message and share the work on screening that other organizations, companies, and healthcare providers are conducting. She asked that Council members follow up with her on their ongoing efforts and willingness to work on this issue.

- Mr. Stemberg commented that ARPA-H is a concept of bold, exciting, and hopeful advancement as well as a daunting task. He asked what the next steps are for ARPA-H to fulfill its ambitions. Dr. Carnival responded that there are many aspects that have yet to come together and there is no definitive timeline; however, there is support for this project and full commitment from President Biden and NIH. ARPA-H could be initiated in the coming fiscal year, which starts October 1, and some projects could be initiated while the full plan, structure, and leadership are being determined. NIH could begin to obtain input from external groups to start to develop initial projects.
- Ms. Davis asked about NCRA's role in this effort. Dr. Carnival indicated that she and Dr. Tara Schwetz welcome input from NCRA members and would like to understand the Council members' preferred way to intersect going forward. They will gladly communicate that information to the ARPA-H leadership as it is developed.
- Dr. Carnival thanked NCRA members for their work and expressed excitement about broadening their engagement and beginning to work with this group on an ongoing basis. Dr. Sharpless expressed appreciation for Dr. Carnival's presentation and her advocacy for cancer patients at the White House. Ms. Williams thanked Dr. Carnival and noted that her contact information will be shared with Council members. Ms. Davis thanked Dr. Carnival for the ARPA-H update.

Legislative Update

Ms. Holly Gibbons

Ms. Gibbons remarked on the daunting series of tasks Congress had for that week and the uncertainty of the outlook for some priorities. She is cautiously optimistic about prospects for a continuing resolution (CR).

Congress is considering four competing, intertwined, and urgent legislative priorities: FY22 appropriations, the debt limit, the $1.2 trillion bipartisan infrastructure framework, and the budget reconciliation package. A CR is expected to pass in both the Senate and the House, averting a government shutdown; this CR likely would expire December 3. The Treasury Secretary estimates that the debt limit will be reached by October 18; unless the debt limit is suspended or raised, this could have serious implications for the country and the global economy. Next steps on the debt limit are unclear. Democrats have begun the budget reconciliation process and crafted a reconciliation package that includes the Administration's human infrastructure priorities and provisions to establish ARPA-H.

Ms. Gibbons outlined the current proposals for FY22 funding for NIH. The President's Budget includes a $9 billion increase for NIH (including $6.5 billion to establish ARPA-H) and $174 million increase for NCI. The House proposed a $6.5 billion increase for NIH (including $3 billion for ARPA-H) and $434 million increase for NCI.

Additional authorizing bills that are being tracked include the U.S. Innovation and Competition Act, the Creating Opportunities Now for Necessary and Effective Care Technologies for Health (CONNECT) Act, and Cures 2.0. The CONNECT Act is a widely supported telehealth proposal that would result in waiving certain geographic requirements for telehealth services during public health emergencies and require HHS to conduct a study on telehealth utilization during the COVID-19 pandemic and test models to examine the use of telehealth under Medicare.

Ms. Clark Szemborski updated the Council on recent and future congressional events with NCI. These include visits by Maryland Congressional Staff to Frederick National Lab, a virtual briefing on childhood cancer research, and the Men's Health Network/Prostate Health Education Network briefing.

Closing Remarks

Ms. Anjee Davis and Ms. Amy Williams

Ms. Davis and Ms. Williams welcomed new NCRA Council members Dr. Buenger and Ms. Buffalo. Dr. Buenger is President Emeritus of the Coalition Against Childhood Cancer, an academic, and a bereaved parent. She expressed pride in being a part of the NCRA. Ms. Buffalo is an enrolled member of the Meskwaki Nation in Iowa and aims to be a voice for American Indians. She recently became Chief Executive Officer of the American Indian Cancer Foundation, through which she looks forward to addressing cancer burdens faced by indigenous relatives across the country. She feels honored and thankful to be part of NCRA and its work, which has both professional and personal impact for advocates.

Ms. Davis made a motion to approve the 83rd NCRA Council meeting summary. Ms. Willmarth seconded the motion, and the motion passed unanimously.

Ms. Williams noted that Council members will receive a meeting summary. She reminded Council members that the Office of Advocacy Relations (OAR) welcomes feedback and ideas.

Proposed NCRA meeting dates for 2022 are as follows: March 9, June 29, and September 28. OAR will issue save-the-dates and notify Council members whether these meetings will be held virtually or in person.

Ms. Davis thanked Council members for their engagement and reminded them that building equity in the cancer advocacy community will be included in the next NCRA meeting agenda. She asked Council members to share names of exceptional programs and organizations that are prioritizing research advocacy, as well as ideas and suggestions relating to research advocacy and addressing diversity within the research advocacy community, with her, Ms. Williams, or Mr. Patrick Mahoney. She emphasized that it is important to consider the next generation of research advocates and ensure that the research community reflects the values and needs of the cancer community. Ms. Williams echoed this and shared that the goals are to have a focused discussion, determine which organizations are addressing the equity issue successfully, and define NCRA work in this area. She thanked Council members and the advocacy office.

The meeting adjourned at approximately 3:15 p.m. EST.