

**83<sup>rd</sup> Meeting of the National Cancer Institute (NCI)  
NCI Council of Research Advocates (NCRA)  
National Institutes of Health (NIH)**

**Virtual Meeting**

**June 16, 2021**

**Members Present**

Ms. Anjee Davis, Chair  
Ms. Malinda Bachini  
Mr. Rick Bangs  
Mr. Yelak Biru  
Ms. Annie Ellis  
Ms. Danielle Leach

Ms. Jennifer Pegher  
Ms. Kristen Santiago  
Ms. Jaqueline Smith  
Mr. Kevin Stemberger  
Dr. Nicole Willmarth

**Speakers**

Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI  
Dr. Ned Sharpless, Director, NCI  
Ms. Maureen Clark Szemborski, Program Analyst, Office of Government and Congressional Relations (NCI)  
Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

## **Welcome and Opening Remarks**

*Ms. Anjee Davis and Ms. Amy Williams*

Ms. Williams opened the meeting, welcomed the Council members, and reviewed the meeting agenda. Ms. Davis reviewed the conflict of interest rules for the meeting and confirmed that a quorum of members was present. She provided brief opening remarks and elaborated on a few of the agenda items, specifically how the Council can address equity in advocacy, and how members can leverage their experiences and relationships to contribute to the discussions. Ms. Davis then introduced Dr. Sharpless to deliver his Director's Update.

## **NCI Director's Update**

*Dr. Ned Sharpless*

Dr. Sharpless began by remarking that he appreciated and shares Ms. Davis's encouragements to the Council and why these issues need to be addressed to advance cancer research.

He went on to describe recent fiscal year (FY) appropriations to NCI, including the important distinctions between NCI's base funding and funding for the National Childhood Cancer Data Initiative (CCDI) and funding from the 21<sup>st</sup> Century Cures Act. NCI appropriations for FY 2021, which included funding for the Cancer Moonshot initiative and the second year of funding for the Childhood Cancer Data Initiative (CCDI), increased by \$119 million. He then described the recent budget put forward by the President, including a 2.7 percent increase in funding over last year for NCI, and compared it to recent FYs. He forecasted that inflation and costs related to increasing paylines may be slowed by this proposal. Dr. Sharpless emphasized the importance of raising the payline to 15 percent by 2025. He also briefly described the proposed agency ARPA-H, which would be housed at NIH and cover multiple diseases including cancer. He cited recent testimony by Dr. Francis Collins and Dr. Eric Lander featuring more details on ARPA-H.

Dr. Sharpless highlighted President Biden's recent trip to the U.K. and meeting with Prime Minister Boris Johnson to discuss a bilateral cancer summit. The summit would be the first of its kind, and Dr. Sharpless pointed out NCI has a handful of existing partnerships and direct scientific collaborations with the U.K. The summit would illustrate additional opportunities for both nations to work together to advance cancer research.

Dr. Sharpless reiterated some of NCI's investments and activities related to the COVID-19 pandemic, including the NCI COVID-19 in Cancer Patients Study (NCCAPS), which has enrolled more than 1,100 patients across 875 sites in the U.S., Puerto Rico, and Canada. He pointed out that accrual has slowed as infection rates have decreased and vaccinations have increased. NCI is having ongoing conversations with investigators and advocacy groups about ongoing concerns regarding COVID-19 vaccine efficacy in patients, especially some blood cancer patients. The NCI is also examining data on hospitalizations of patients with cancer and COVID-19, which will help illustrate natural history of patients with cancer and COVID-19. Dr. Sharpless then described SeroHub, a tool, a dashboard to organize seroprevalence data collected from a variety of settings. Finally, he pointed to some data illustrating COVID-19's impact on cancer care, including the impact on screening for breast and colorectal cancers, and alluded to similar data for cervical and lung cancer screenings. However, one colorectal cancer modality (FIT) did not show the same decrease as others. NCI estimates in total, 10 million screening events were missed, which may impact cancer mortality over the next decade.

Dr. Sharpless then moved onto NCI's expansion of the SEER program, which now covers roughly half the U.S. population, and how useful the program has been in cancer research since its establishment following the passage of the National Cancer Act of 1971. He added that SEER's capabilities now include linkages to pharmacies, and NCI is exploring partnerships with the Department of Energy's machine learning capabilities to enhance SEER reporting.

Dr. Sharpless described the progress of the Cancer Moonshot, an effort that includes 240 research projects and initiatives. He noted funding for the Cancer Moonshot will end in 2023 and the continuation of infrastructure will then be supported by NCI's general budget. A significant number of Moonshot investigators had no prior NCI funding and are new or early-stage investigators, an accomplishment that aligns with NCI's objective of training cancer researchers. He highlighted a recent commentary he co-authored with Dr. Dinah Singer describing the effort's progress. Dr. Sharpless described two projects under the Cancer Moonshot, including the Human Tumor Atlas Network, which has led to 10 papers in various stages of publication, highlighting NCI's commitment to making data available from Moonshot projects as soon as possible. The second example cited was the NCI Cancer Center Cessation Initiative, which has reached more than 50,000 oncology patients with sustainable tobacco cessation programs.

The recent American Society of Clinical Oncology meeting featured several NCI studies, and he pointed out one example of a clinical trial for breast cancer which showed an additional adjuvant modality can improve survivorship. He added that it fits with other diseases that have showed promising response to PARP inhibitors in the adjuvant setting. He also highlighted recent publications in both adult and pediatric brain tumors, which also helped illustrate new ways to categorize different gliomas that will be important for further appreciation of the heterogeneity of these diseases.

Dr. Sharpless updated the Council on the CCDI, which has established four new working groups that will focus on different topics including 1) developing the infrastructure for enhancing data sharing and aggregation of new and existing data, 2) gathering data from every child diagnosed with cancer, 3) developing a national strategy to offer clinical grade sequencing and research of molecular characterization, and 4) developing guidelines and approaches to address crosscutting issues. These working groups will be overseen by a Steering Committee, which will be informed by an Engagement Committee.

He reiterated NCI's commitment to improving DEI efforts in cancer research and described NCI's Equity and Inclusion Program. The effort will include an Equity Council overseeing five different working groups examining different issues. He described different challenges in improving the equity of the scientific workforce, as well as among NCI staff, as well as improving research into cancer health disparities. Dr. Sharpless will co-chair the NCI Equity Council with the Director of the Division of Extramural Activities, Dr. Paulette Gray. He shared some data from the pool of researchers who have applied to NCI R01 grants, as well as those who were awarded those grants, indicated both a pipeline and awardee problem that has remained consistent over time. One of NCI's immediate actions to address this includes a program to transition early career investigators into independent investigators.

Dr. Sharpless reiterated the launch of NCI's communications for the commemoration of the 50<sup>th</sup> anniversary of the National Cancer Act of 1971 (NCA-50) is an opportunity to inspire cancer researchers and supporters of cancer research. He acknowledges a commitment from the White House and hopes this campaign will highlight cancer research progress as well as areas where progress is needed.

*Discussion*

- Mr. Bangs asked about rural health disparities vis a vis SEER's coverage and asked whether there are plans to improve SEER's capabilities to capture data in those communities? Dr. Sharpless responded that the registries are state-level so they are capturing data from both rural and urban communities within those states but also added that SEER has improved data collection in Hispanic/Latino communities.
- Ms. Davis asked about turnaround time for SEER. Dr. Sharpless responded that the machine-learning response is about 18,000x faster than human analysis, and that with automated data capture, it is possible to get down to "near real-time," especially for pathology reports. He cautioned that the publicly-facing version will need to include privacy considerations to protect patients' identifies.
- Mr. Biru asked Dr. Sharpless when he expects to have new guidance for blood cancer patients regarding COVID-19. Dr. Sharpless responded that NCI does not offer clinical guidance, and that there are other entities more equipped to do that, including ASH. NCI has a role to play in providing the research foundation for those guidelines, including the NCCAPS study, and added there are other registries with relevant data.
- Dr. Willmarth asked about COVID-19's impact on cancer screening may also impact patients with cancers that don't have standard screenings. She cited patients who maybe didn't seek treatments for brain tumors and whether there is an impact there? Dr. Sharpless agreed this is an important issue that isn't getting media coverage, because most cancers are not diagnosed on screening, but on symptoms, and that SEER and CMS data will particularly be helpful. Dr. Willmarth added that if the data becomes available, she would like to see it.
- Ms. Davis added that the colorectal cancer community is experiencing additional disruptions due to follow-up colonoscopy for diagnosis. Dr. Sharpless added that he agrees, and there are opportunities to address new research questions based on the pandemic's impact on cancer care.
- Ms. Davis shared that patients are getting caught between states with different telehealth regulations, specifically related to patients trying to enroll on trials across stateliness and asked what NCI's role is in addressing this. Dr. Sharpless agreed with her point that telehealth has largely been a benefit to patients and NCI's focus is to better understand the empirical utility of telehealth but that NCI does not advise policymakers, such as CMS.
- Dr. Willmarth asked if the HTAN will follow "previvors," those with high-risk mutations but have not developed cancerous lesions. Dr. Sharpless shared that the tool focuses on a lesion, but there are other efforts to follow those populations.
- Ms. Leach asked if there have been any discussions in the context of ARPA-H about developing more sophisticated imaging technology for different cancers. Dr. Sharpless shared that the presentations he's heard about the agency is high-level and there aren't many specifics. But the idea of technology development looms large.
- Ms. Davis asked how Dr. Sharpless sees ARPA-H aligning with NCI. Dr. Sharpless shared that NCI does some things well, like funding basic science and sustaining a clinical trial infrastructure, but there are other things requiring nimble contracting or interactions with industry that ARPA-H may be well-suited to do. He added that the proposal to have the agency housed in NIH is smart and that NCI has a strong history of working with the NIH Common Fund and NCATS. She followed-up with a question about how patient voices will be including in the planning. Dr. Sharpless agreed the advocacy community would be central to this and that patients would be the north star of this, with a formal engagement process.

Ms. Davis thanked Dr. Sharpless for his time and willingness to field questions. Dr. Sharpless thanked the Council for their time and attention, and Ms. Davis transitioned to the Budget & Legislative Update and introduced Ms. Holly Gibbons and Ms. Maureen Szemborski from NCI's Office of Government and Congressional Relations (OGCR).

### **Budget and Legislative Update**

*Ms. Holly Gibbons and Ms. Maureen Clark Szemborski*

Ms. Gibbons began by describing current congressional activities, including the hope that biomedical research will continue to be an issue with bipartisan support. She shared reviewed recent House and Senate hearings on federal appropriations, as well as President Biden's budget proposal, but forecasted that an FY 2022 budget is not expected on October 1. Ms. Gibbons also emphasized both hearings featured several questions about ARPA-H.

Ms. Gibbons continued by reviewing some of the highlights in the President's Budget, including a proposed increases in funding for NIH of \$9B and \$174M for NCI. The \$9B increase for NIH includes the proposed \$6B for ARPA-H.

Ms. Gibbons then introduced Ms. Szemborski to wrap up OGCR's update.

Ms. Szemborski reviewed recent congressional events with NCI, including virtual briefings hosted by the Personalized Medicine Caucus and the Littlest Tumor Foundation. She closed by detailing pending legislation focused on science and technology, focused on enhancing U.S. abilities to compete with China, and legislation aimed at protecting patients' access to telehealth.

### *Discussion*

- Ms. Davis asked if there will be any ongoing research related to a telehealth framework. Ms. Gibbons responded that she would need to take a closer look at some of the PARs Dr. Sharpless outlined but that this is of interest to NCI staff. Ms. Williams added that NCI program staff have been working with staff at the Department on this issue.

Ms. Davis and Ms. Williams thanked OGCR staff for their time and updates and transitioned to a brief break.

### **Equity and Advocacy Discussion**

*Ms. Anjee Davis and Ms. Williams*

Ms. Williams transitioned the group to a continuation of the discussion that began at the 82<sup>nd</sup> NCRA meeting with presentations from NCI and NIH and shared that the NCI would like the Council's feedback and perspectives on how to bring more equity into the advocacy community. She continued that NCI recognizes there are many ways advocates enter the community and many ways they can engage in cancer research, but that it is a community-owned, pipeline issue that NCI cannot address alone.

Ms. Williams reiterated some of Dr. Sharpless's comments about including the advocacy community in its work to build equity into the cancer workforce. Ms. Davis echoed this and shared the goal of the NCI Equity Council in this area, and that the Council should organize its conversation in the context of advocate recruitment, development, and sustainability.

- Mr. Bangs shared his experiences from SWOG and PASC would lead to additional questions, such as defining “equity,” and that he defines it broadly to include not just race and ethnicity, but also disease expertise, gender, and socioeconomic status. He also added that he would be concerned with who would own the results of this work because there are structural impediments to overcome.
- Ms. Leach echoed Mr. Bangs’s concerns about process and shared that there are things that can be done to improve recruitment because there are current impediments to that. She added that there should be closer coordination with OAR and professionalization of advocates is something to be concerned about.
- Ms. Williams clarified that the Council is being asked to look at the broader community, not specifically advocates that work with NCI and not advocates who serve on PASC. She added that NCI does not think of equity as related to only race and ethnicity, but to many of the demographics Mr. Bangs outlined.
- Mr. Biru shared that he agrees the advocacy pipeline is limited because most advocates begin as patients so they either have a particular disease interest or a particular issue they’re interested in such as clinical trials. There is no formal job description or compensation and he continued that there should be a discussion of advocate compensation.
- Ms. Davis agreed and put forward whether budgeting for advocate engagement in research grants would ever be a possibility. She also shared that there are limited numbers of opportunities for advocates to engage in NCI steering committees and asked if there is something the Council can propose to better utilize the existing skill sets in the community.
- Ms. Williams reiterated that this discussion should not be limited to one NCI activity, such as PASC or steering committees, but should be broader than NCI. She agreed that broadening opportunities for advocates could be a necessary step to help advocates hone their skills.
- Ms. Ellis commented that she observes part of the problem is that investigators tasked with working with advocates build relationships with a few and continue to work with them over and over which removes the opportunity to have new advocates learn. She suggested that we consider ways to include novice advocates in more engagements. She also asked if NCI has a sense of the community’s current demographic breakdown.
- Ms. Smith agreed and continued that in her experience the advocacy community is sometimes exclusive within itself. She shared that she wasn’t always welcomed openly in her early career as an advocate, and that bridging those needs with the needs to develop the hard skills for novice advocates is essential.
- Dr. Willmarth added that a mentoring program could create the kind of information exchange and development that novice advocates may need.
- Ms. Bachini agreed that a mentoring program would be great and cited one operated by the Cholangiocarcinoma Foundation has observed success in preparing novice advocates for more technical engagements.
- Ms. Leach posed a question about what more specifically the Council can do related to recruitment?
- Ms. Williams asked Ms. Leach to share what she observes as barriers to bringing in more advocates to the community.
- Ms. Leach shared that many of the biggest barriers have been shared, specifically time, money, training. She also added that being clear about what the expectations of the engagement are for the research advocate are not always clear.
- Ms. Smith cited AACR’s Scientist to Survivor program is one of the existing resources for patient advocates to get involved in research.

- Dr. Willmarth shared that another barrier could just be the technical information or the assumption that a research advocate is going to have to fully understand the science, which is not always the case. She added that making that clearer to folks would potentially lower the barrier to entry to some.
- Mr. Biru shared one potential recruitment opportunity from the myeloma community is support groups.
- Mr. Bangs commented that SWOG attempted to create positions for advocates tasked with reaching underserved and it's proven very difficult in certain communities, specifically rural and LGBTQ populations. He continued that the advocacy community could benefit from understanding more about which populations are underrepresented but that would require more broad convening.
- Ms. Davis added that there may need to be some vetting or contingency planning to help novice advocates navigate the bumps early in the engagement could help keep them interested and pursuing further engagements.
- Ms. Williams asked if organizations are pursuing that kind of vetting?
- Ms. Davis shared that AACR did publish a summary review of advocacy efforts but there are groups that do that, including Fight Colorectal Cancer.
- Dr. Willmarth added that those conversations are essential because it helps identify and hone their interests.
- Mr. Bangs added that there is so much diversity among cancer organizations and there could be utility in better understanding their capabilities.
- Ms. Leach suggested there is a need to develop a landscape analysis of what the current community looks like and how we can provide more information about what resources exist for new or novice advocates.
- Ms. Davis agreed and asked whether it would be possible to solicit open opportunities quarter by quarter so the community can help circulate them?
- Mr. Stemberger shared that when he began engaging as a research advocate it was difficult to identify who the leaders or mentors were since there weren't any existing connections. He also added that the investigators he's worked with will often look to other populations, such as large donors, to fill advocate positions first, which further limits the abilities of new advocates to gain traction.
- Ms. Ellis echoed his statements, sharing that when she started, without mentorship, she could not have been effective and today, when recruiting others, she looks for individuals with a unique story to share because as the community is missing a lot of perspectives. She called back to a map Dr. Sharpless shared showing cancer mortality across the U.S. and wondered how many advocates are in those populations and could be contributing.
- Ms. Leach asked which organizations representing some of these populations may be options for partnerships.
- Ms. Williams agreed this is a unique approach to consider.
- Ms. Davis asked Ms. Williams to share a bit more about the desired outcomes for what this group could accomplish?
- Ms. Williams shared that it would be helpful to better understand what the community's representation looks like, specifically from different organizations working with research advocates. She continued that the goal is up to the Council, specifically what does the group want to pursue. She added that the Council is an appropriate convener for this conversation because it should be broad and open to as many voices as possible.

- Mr. Bangs reiterated that it would be helpful to better understand the current state of the community and that's as broad and aggressive a scope as appropriate.
- Ms. Davis added that it is a worthwhile endeavor for the Council.
- Ms. Leach asked if it would be possible for the group to put forward a set of principles for an equitable advocacy workforce.
- Ms. Ellis agreed and said it could be in line with the NCI Equity Council's work and there's nuance within the different types of diseases advocates represent.
- Ms. Davis agreed, specifically about creating some nuanced context around what equity can and should look like within the community.

### **Closing Remarks and Next Steps**

*Ms. Anjee Davis and Ms. Amy Williams*

Ms. Williams thanked members, the advocacy office, and Dr. Sharpless. Ms. Davis thanked everyone for their commitment.

The meeting adjourned at approximately 3:00 p.m. EST.