

**81ST Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)**

Virtual Meeting

September 14, 2020

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

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Welcome and Meeting Goals

Ms. Anjee Davis and Ms. Amy Williams

Ms. Amy Williams opened the meeting at 1:00 p.m., 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.

Budget and Legislative Update

Ms. Holly Gibbons

Ms. Gibbons provided a brief update on congressional operations amidst the pandemic, recapping a few highlights from the prior meeting's updates, and also shared a few updates on the appropriations process.

- Ms. Gibbons shared that Congress has yet to agree on negotiations for the next pandemic-relief package. She shared that it is unclear at this point whether relief can be addressed in a continuing resolution (CR), because lawmakers have expressed a desire for a “clean CR.”
- She also reviewed recent NIH participation at various congressional hearings, including one on September 23 featuring Dr. Tony Fauci.
- It is unclear what the final CR package will look like, specifically, whether it will carry over into the next congressional session.

Discussion

- Ms. Williams asked Ms. Gibbons to elaborate about federal actions surrounding telemedicine. Ms. Gibbons mentioned that HHS and Congress are currently reviewing multiple policy proposals to allow for additional and appropriate flexibilities for telemedicine during the pandemic.
- Mr. Bangs asked for clarification around terms “telemedicine” and “telehealth.” He described telemedicine as being more descriptive of video visits with a provider whereas telehealth is using digital tools to organize and manage health data. Ms. Gibbons shared that some of the policy proposals use different terms. Ms. Williams added that it may be helpful to use those definitions moving forward, as many use them interchangeably in conversation.
- Ms. Leach asked about reviews of licensure rules. She described the issue around practitioners in one state not being allowed—or covered—to practice in a different state. She shared that some practitioners have expressed concern about engaging in telemedicine because of that. Ms. Santiago echoed that, saying some institutions and providers have expressed worry. Ms. Gibbons added that there is a bipartisan bill that has been introduced in the Senate specifically looking at these issues.

NCI Director's Update

Dr. Ned Sharpless

Dr. Sharpless thanked the Council for the opportunity to speak and previewed a few of the subjects he will cover.

He began by reminding the Council that a FY 2021 budget is unclear at this time, echoing updates shared by Ms. Gibbons. He continued that FY 2020 saw an increase in funding for NCI, including continued funding for the Cancer Moonshot. He expressed cautious optimism for NCI's budgetary future.

He recalled an article he authored in *Science* in June 2020 which modeled the cumulative excess deaths from colorectal and breast cancers through 2030 as a result of the pandemic. He described that the effect would be an excess one percent death, which he described as "conservative." Since the publication of that model, many other publications have found similar results, indicating the pandemic will yield a higher cancer mortality rate over ten years. He expressed disagreement with some investigators who cite projected decreases in cancer diagnoses as being indolent disease; he encouraged the Council members to consider these data as an "alarm bell." He emphasized that he is interested in the advocacy community's perspective on these issues.

Dr. Sharpless went on to describe some of NCI's efforts to respond to the pandemic. He reviewed the NCI COVID-19 in Cancer Patients Study (NCCAPS) which was introduced during the 80th meeting. The trial has been activated 49 states and Puerto Rico. To date, 136 patients have been screened and 96 enrolled. He described efforts to adapt clinical trials during the pandemic, including the allowance of remote informed consent, shipping drugs to patients directly, and transferring patient care to different participating study sites. He predicted that some of these flexibilities will hold when the pandemic subsides, given how positively some of them have been received. The NCI's Clinical Trials Advisory Committee will look at these issues more closely.

Dr. Sharpless teed up a later discussion for the Council by describing the opportunities presented by the pandemic to assess how telehealth can and should be leveraged for patients with cancer. NCI has issued a Request for Information (RFI) to address scientific gaps related to the delivery of cancer care via telehealth. He also mentioned that more than \$1 million have been administered as supplements by NCI to cover the salaries of postdoctoral fellows whose stipend support from a nonprofit funder has been cut due to financial constraints brought on by the pandemic.

He then described the Cancer Grand Challenges, a partnership between NCI and Cancer Research UK. The initiative will bring together international, multidisciplinary teams to address research questions which are expected to be accepted from October 2020 to April 2021.

Dr. Sharpless introduced the NCI Equity Council, which will examine several key issues, including: 1) enhancing research to address cancer health disparities; 2) ensuring diversity of thought and background in the cancer research workforce; and 3) promoting an inclusive and equitable community at NCI. He shared that the NCI Equity Council would be looking at long-term, durable solutions to these issues and that he is interested in learning what organizations in the advocacy community are hearing and doing related to these issues.

Dr. Sharpless proceeded to update the Council on the NCI Cancer Research Data Commons. Dr. Sharpless reminded the group what the CRDC is, and encouraged them to seek out and watch a

new video detailing updates from the CRDC. He specified one of these updates is the Integrated Canine Data Commons, developed at the Frederick National Lab, and will be used for comparative studies and the creation of new animal models. Users will be able to query open-access data.

Dr. Sharpless continued with a brief description of the Annual Plan and Budget Proposal for Fiscal Year 2022 (FY 2022). NCI has taken an all-digital approach for the FY 2022 version, and he forecasted a few of the major themes, including molecular diagnostics for cancer treatment, obesity and cancer, drug resistance, and cancer survivorship. He closed his remarks with a forecast of next year's 50th anniversary of the National Cancer Act of 1971. Dr. Sharpless shared that NCI will be commemorating this milestone with a few communications throughout 2021 and that he looks forward to sharing more with the Council as those activities take shape.

Discussion

- Ms. Leach mentioned the FY 2022 Annual Plan and Budget Proposal's emphasis on survivorship and asked how the community will be engaged in those issues. Dr. Sharpless responded that Dr. Emily Tonorezos, Director of NCI's Office of Cancer Survivorship, will be meeting with the community in the coming months to discuss various priorities and research opportunities. Ms. Williams added that she recently connected with Dr. Tonorezos, who has expressed interest in speaking with community leaders soon.
- Ms. Santiago shared that LUNGeVity has not been able to continue funding grantees throughout the pandemic, and they are also interested in supporting NCI efforts to address equity in cancer research. Dr. Sharpless appreciated hearing about the organization's operations during the pandemic and went on to say that NCI expects many early career investigators to experience challenges obtaining funds elsewhere.
- Ms. Davis asked how NCI envisions support of early career investigators who perhaps have a research focus on cancer health disparities. Dr. Sharpless clarified that he sees multiple issues: there are issues of underrepresented minority scientists across cancer research, some of whom study cancer health disparities, but there are others who do not. There are issues with funding cancer health disparities research and ensuring a diverse and equitable workforce that each require unique solutions. Dr. Sharpless also described programs the NCI invests in to help ensure young people pursue and are supported in scientific research careers, which he described as a proof-of-concept in developing a strong career pipeline.
- Mr. Bangs shared that SWOG has developed a methodology to address representation in the clinical trial population. It will be available as a training early next year. Dr. Sharpless mentioned that NCI has observed some successful results regarding minority enrollment in clinical trials through the NCORP sites compared to industry-sponsored trials. He mentioned that this is an issue FDA is actively working to improve also.
- Ms. Pegher thanked Dr. Sharpless for his emphasis on improving paylines and went on to ask about timing for some of the NCI Equity Council's milestones or outputs. Dr. Sharpless shared that the working groups he described are developing rosters and expects each to have their operating plans complete by the end of the year. He went on to say that he does not expect these groups to develop a single report and wrap up but rather constantly assess and reassess their progress in an enduring way.

- Ms. Davis continued to echo other members' comments that the Council and wider advocacy community would appreciate staying apprised of the NCI Equity Council's progress would be helpful as external organizations stay aligned with their internal work. She also asked about the CRUK challenge and how NCI envisions the community engaging in the work. Dr. Sharpless mentioned that the CRUK has included the community in developing the challenge questions and the way the process would play out and Dr. Sharpless does not expect the U.S. approach to be different. Ms. Williams shared that the Office of Advocacy Relations is working with CRUK to set up engagement mechanisms that are aligned with the CRUK approach, including adding advocates to the steering committee and to each of the research teams.

Advocacy and COVID-19 Discussion

Ms. Anjee Davis and Ms. Amy Williams

Ms. Davis introduced the next discussion, continuing a thread begun at the 80th meeting, examining the ways the community is responding the pandemic. Ms. Williams added that NCI wants to better understand how members perceive the pandemic effecting individual patients and how the pandemic is affecting organizations responsible for supporting large constituents of patients.

- Mr. Bangs led by describing his concern that there needs to be a plan to convene stakeholders in a broad way to address the myriad issues the pandemic is raising. Dr. Sharpless agreed it is a fair suggestion given how many federal agencies have a role to play in addressing the issues patients face, but has not been made aware of any single meeting. He added that he believes CMS has the largest role to play and has been encouraged by the efforts CMS has made to respond quickly and implement solutions that potentially could last, specifically telemedicine. Dr. Sharpless continued that the NCI is not able to weigh in on some of the pending legislation addressing licensure and other issues.
- Ms. Leach asked whether a landscape analysis could be done looking at what the advocacy community is doing to provide patient support, specifically looking at clinical trials. Dr. Sharpless responded that NCI had a Request for Information (RFI) seeking input research opportunities which is now closed, but hopes that the community submitted perspectives. He added that he agreed there are additional things NCI could pursue. Ms. Williams asked a clarification and Ms. Leach responded that there are several programs being stood up within the advocacy community that NCI might not be aware of but would be helpful in communication with federal agency partners. She added that the RFI was specific to research and her encouragement would include looking at resources and other non-research services patient groups are now offering their constituents in response to the pandemic.
- Dr. Willmarth shared that research grants administered by the American Brain Tumor Association (ABTA) will be negatively affected in 2021, and that funding is specifically designed to support early career investigators. She asked Dr. Sharpless whether or not NCI plans to continue supplementing funding for those investigators who lost stipend funding from nonprofits beyond 2021. Dr. Sharpless said that he expects that additional

assistance will occur beyond 2021. NCI staff have had several conversations with foundations to better understand their financial circumstances, but that it was not a formal survey. Even through these informal conversations, Dr. Sharpless stated that it is clear many foundations are struggling and those conversations would need to continue so as to better understand circumstances as they evolve. He asked Council members to be proactive in sharing their circumstances with NCI leadership, including Dr. Oliver Bogler, so collaborations can occur early. He closed by reminding the Council that any additional assistance NCI would be able to provide in the future would be contingent on the availability of emergency funding. Dr. Willmarth added that she will consider the ways she and her organization can make their grantees available.

- Ms. Davis asked Mr. Bangs to outline a few of the issues he's noticed from patients specifically. He described concerns about deferring screening and missing early diagnoses. He continued that he has been thinking about long-term solutions like conducting surveillance without requiring in-person medical visits but cautioned that would be aspirational.
- Mr. Biru shared that some of the trials he works on have observed up to 40 percent reductions in enrollment and he is concerned about the patients who would be missing treatments because of this and long-term, how the community can support trials making up these losses over time.
- Ms. Davis shared that her organization is hearing myriad questions from patients regarding the use of telemedicine and navigating care during the pandemic. She added that some patients are wondering if trials will continue accruing and are struggling to learn updates about various trials' status.
- Ms. Williams followed to say this NCI is eager to continue hearing what questions patients have to make sure resources are being used and/or developed. She mentioned NCI has been working to promote the Cancer Information Services and redirect some patients to various Cancer Centers which have been offering resources.
- Ms. Santiago contributed that patients in her constituency have shared that they are concerned with some obvious issues, such as traveling for care, etc., but are also sharing concerns about the status of research and FDA activities. She asked Ms. Williams if there is the opportunity for NCI to develop new educational materials?
- Ms. Williams responded that yes, when appropriate NCI is able to create materials but also connect patients to existing information they may not be aware of via the Cancer Information Service.
- Ms. Fleshman added that all virtually any organization serving patients have already had to create information to guide patients through the pandemic. She continued that any effort to push patients to that existing information is helpful so as not to duplicate efforts, but chiefly that it is important for all patients to continue seeking care, and that NCI is uniquely positioned to push that message.
- Ms. Davis asked Dr. Sharpless about the opportunity to leverage social media, specifically messages from the Director, to encourage patients to not delay treatment would be valuable. Dr. Sharpless agreed this is an important discussion for patients and that delaying care is dangerous for some but it's important to have a nuanced discussion and not give patients the impression, "no matter what, get a mammogram," because COVID-19 does pose a threat. He continued that he wants to focus on how it is possible to provide excellent cancer care, even under these circumstances, and is looking to the

extramural research and advocacy communities for counsel on how to engage. Dr. Sharpless shared that he has been heartened by what he has seen from the advocacy community so far. Going back to an earlier part, Dr. Sharpless added that he agrees the patient community's concern about the status of clinical trials is a real challenge for the NCI, and NCI is watching accrual data carefully.

- Ms. Fleshman wondered whether the national research conversations around vaccine trials is contributing to patient confusion around cancer trials, which are much different. Dr. Sharpless agreed, saying this is likely a boost in education to vaccine science but using that knowledge to talk about cancer trials is misguided.
- Dr. Sharpless responded to Mr. Bangs that NCI is assessing its entire trial portfolio, and has a particular scrutiny on prevention and screening trials right now, given the pandemic's effects.
- Ms. Davis thanked Dr. Sharpless for his time and discussion. Dr. Sharpless shared likewise, and encouraged members to reach out to OAR with any additional questions.
- Ms. Davis then teed up the next session focused on telehealth and a discussion about next steps for the NCRA, and adjourned the meeting for a ten-minute break.

Telemedicine Discussion

Ms. Anjee Davis and Ms. Amy Williams

Ms. Davis introduced the final session of the meeting acknowledging that telehealth has come up a bit throughout the day and asked if members had any initial questions to layer into the conversation.

- Ms. Ellis shared that she believes there is an opportunity to include exploration of how telehealth can be used to address some of the psychosocial effects the pandemic is causing patients with cancer.
- Ms. Santiago added that telehealth be framed as an option for patients. She has heard from many patients that the option is great, but some family members have expressed concern for wanting in-person visits per usual.
- Ms. Williams thanked both members for the additional comments to help the NCI and the NCRA be aware of what issues are emerging as priority for patients.
- Ms. Bachini shared that some patients her organization serves have benefited from more access to second opinions via telehealth, but that policy matters related to licensing would threaten that benefit and disproportionately harm patients with rarer cancers.
- Ms. Santiago echoed that concern saying licensure is critical to allowing for second opinions.
- Ms. Leach asked how closely NCI is working with FDA to ensure funded PIs have the most current FDA guidelines? Ms. Davis shared this question too.

Ms. Davis shared a brief summary of the issues highlighted throughout the day and transitioned the group to address next steps by asking what they think the NCRA can consider doing next based on the conversations to date.

- Ms. Ellis replied that she would like to pursue Ms. Leach’s suggestion to survey what cancer organizations are already doing and whether NCRA would be able to that.
- Ms. Williams explained that NCI has an opportunity to work with NCRA as a convener in the community and wants to take the idea back to the NCI Office of the Director.
- Ms. Davis shared that the Cancer UK partnership could be helpful in modeling how organizations can engage.
- Ms. Leach elaborated that the webinar suggestion was a bit different than the survey one in that the webinar would be aimed at investigators to help promote opportunities but that a survey would be more specific to how organizations are navigating the pandemic.
- Dr. Willmarth added that it would be important to include how the pandemic is affecting external organizations’ grantees in any survey.
- Ms. Williams shared that a survey does carry a few federal restrictions that would need to be discussed.
- Mr. Bangs added that any survey would have to be narrowly defined to something that is actionable.
- Mr. Biru suggested that another area of exploration would be the availability of and access to wearables or mobile technology for implementing telehealth widely and also who owns the data those touchpoints collect. Ms. Williams asked if what he was describing would be a request to learn more about NCI-sponsored research in that area and he responded yes.
- Ms. Santiago suggested reexamining the notion of using NCI leadership social media as a communication tool and asked whether NCI participates in PSA-type campaigns to help encourage patients to seek resources for navigating the pandemic. She acknowledged that something like this would be laborious but meaningful to patients. Ms. Williams clarified that NCI’s communication mandate is to explain research and not provide medical advice, but can help elevate resources to help patients find more information about when and how to seek care, or seek information on clinical trials.
- Ms. Davis summarized she is hearing the members describe the need for any survey to be actionable for NCI, but that it would also be helpful to use the survey to identify resource or educational gaps. She posed the question to NCRA: what can this group do to inform both those questions?
- Ms. Williams offered that the board could consider two parallel actions: one is to explore what questions CIS is receiving and what exists in the community so we can find gaps in information, and second to create a sharing mechanism to understand what existing organizations are doing to address the pandemic.
- Ms. Fleshman added that it’s important to consider how that information is going to be used and her organization has had several questions about what they’re doing to respond but it’s not always clear what’s done with the information provided.
- Ms. Davis wondered whether it would be more fruitful to have the board convene a group of stakeholders rather than solicit information via a survey? Mr. Bangs agreed, adding whether NCAR could convene a group of federal partners (FDA and CMS) to learn more about what’s being done to expand telehealth.
- Ms. Ellis suggested that a conversation like that that addressed hurdles to implementation could be used by the community to pursue change.

- Ms. Leach wondered how a convening would collect all the necessary information from the relevant organizations already doing work in this area and feels strongly that there is a great deal of parallel work without any sharing.
- Ms. Williams suggested that a convening could accomplish more information sharing.
- Ms. Davis asked the board about timing and what seems feasible to remain relevant with this conversation?
- Ms. Williams reminded the group that the next scheduled NCRA meeting is March 2021.
- Ms. Fleshman said that the situation will be different by then.
- Mr. Bangs suggested that if the scope of this were to be narrowed, for example, just the adaptations NCI made to address the pandemic's effects, early in the new year would be ideal.
- Ms. Davis asked if the March 2021 meeting could be moved up and Ms. Williams said that she would check, but a convening like what Mr. Bangs is suggesting would not have to happen as part of the March 2021 NCRA meeting.
- Ms. Davis then added that the board needs to consider how focusing on a select set of issues is the most important next step and members can exchange information in the coming weeks and months.
- Ms. Williams offered that a small subset of members who are interested could gather to identify a process for pursuing next steps.
- Ms. Ellis and Mr. Bangs explained that the Clinical Trial Working Group process could serve as a model for developing a scope for NCRA's next steps.

Closing Remarks

Ms. Anjee Davis and Ms. Amy Williams

- Ms. Williams proposed a summary statement that the group is considering two separate items: the need for additional patient information/communication and exploring what policies or practices related to the pandemic should be tackled, accompanied by a potential convening to discuss those matters. Ms. Davis agreed and encouraged members to share additional thoughts after the meeting.
- Ms. Williams shared that members will have access to Dr. Sharpless's presentation and the archived videocast of the day's discussion. A meeting summary will follow and it may be helpful to brainstorm possible tactics between meetings.
- Ms. Davis and Ms. Williams thanked members for their time and attention.
- The meeting was adjourned at approximately 3:50 p.m. EST.