76th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Building 31, Room 11A01
NIH Campus
Bethesda, Maryland

Thursday, June 21, 2018

Members Present

Mr. David Arons, Chair
Mr. Rick Bangs
Dr. Senaida Fernandez Poole (by telephone)
Ms. Julie Fleshman
Dr. Sue Friedman (by telephone)
Ms. Shelley Fuld Nasso
Ms. Danielle Leach
Dr. June McKoy (by telephone)
Mr. Roberto Vargas (by telephone)
Dr. Regina M. Vidaver (by telephone)

Speakers

Mr. David Arons, Chair, NCRA; Chief Executive Officer, National Brain Tumor Society
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations, NCI
Ms. M. K. Holohan, Director, Office of Government and Congressional Relations, NCI
Ms. Laurie Mignone, Budget Officer, Office of Budget and Finance, NCI
Dr. Meg Mooney, Branch Chief, Clinical Investigations Branch, Cancer Therapy Evaluation Program, NCI
Dr. Nita Seibel, Head, Pediatric Solid Tumors Section, Cancer Therapy Evaluation Program, NCI
Dr. Ned Sharpless, Director, NCI
Dr. Malcolm Smith, Associate Branch Chief for Pediatric Oncology, Cancer Therapy Evaluation Program, NCI
Ms. Amy Williams, Acting Director, Office of Advocacy Relations; Executive Secretary, NCRA, NCI

Contents

Welcome and Meeting Goals
Mr. Arons, Ms. Williams

Ms. Williams opened the meeting by welcoming members and guests at 9:45 a.m.

Ms. Williams and Mr. Arons reviewed the meeting agenda and Mr. Arons read an opening statement regarding conflict of interest guidelines for the meeting.

Budget and Legislative Update
Ms. Gibbons, Ms. Holohan, Ms. Mignone

Ms. Gibbons, Ms. Holohan and Ms. Mignone provided an overview of the budget process and the status of fiscal years 2018 – 2019.

- FY 2018 appropriation ("Omnibus") was announced on March 23, 2018 following five continuing resolutions (CR) and two government shutdowns.
- The FY 2018 Omnibus includes a $3 billion increase for NIH, a $275 million increase for NCI.
- The NCI also received $300 million for the Cancer Moonshot as authorized by the 21st Century Cures Act of 2016.
- Ms. Holohan shared an update from the House Appropriations L-HHS Subcommittee hearing on the FY 2019 NIH budget, held on April 11, 2018, which Dr. Ned Sharpless, NCI Director, attended and testified.
- Ms. Holohan also shared an update from the Senate Appropriations L-HHS Subcommittee hearing held the following month on May 17, 2018. Dr. Sharpless also testified.
- The chairs of the Appropriation subcommittees (Senator Roy Blunt [R-MO] and Congressman Tom Cole [R-OK) appear to be in lock-step about NIH issues and have been positive about endorsing basic research.
- Ms. Gibbons provided an overview of recent relevant legislation, including the RACE for Children Act and the Childhood Cancer STAR Act.
- Ms. Gibbons also shared updates from recent congressional visits to NIH campus, including those by Sen. Jack Reed (D-RI), Sen. Maggie Hassan (D-NH), and the House Cancer Survivors Caucus, which includes Reps. Rick Nolan (D-MN), Mark DeSaulnier (D-CA) and Ted Poe (R-TX).
- Ms. Mignone provided an overview of the budget execution process and reviewed budget considerations and reporting for FY 2018.
- Ms. Mignone also described the NCI's activities in executing appropriations authorized by the 21st Century Cures Act of 2016.

<u>Discussion</u>

- Mr. Arons asked how preparations for the FY 2019 budget are progressing and what NCI expects will be "zeroed out" or cut. Ms. Mignone explained that she is unaware of any plans to "zero out" current programs and the NCI has enjoyed strong bipartisan support to support cancer research.

- Ms. Fleshman asked Ms. Mignone about "noncompete" grants and Ms. Mignone emphasized that the NCI always pays a portion of the commitment made to grantees regardless of the NCI's annual appropriation. Ms. Holohan added that describing "noncompete" grants is often challenging because they represent ongoing science.
- Ms. Leach asked if new initiatives outlined in the Childhood Cancer STAR Act have been planned for and Ms. Mignone responded that those conversations have just begun.
- Ms. Williams encouraged the NCRA members to share suggestions for how NCI communicates about budget and asked what questions the community has.
- Mr. Arons added that there are misperceptions in the community about how federal appropriations can be directed by leadership.
- Mr. Bangs encouraged the NCI to consider and evaluate the value that research advocates provide to the research process and how those investments can be communicated to the community and added that it would behoove the NCRA to consider how to better make those arguments.
- Ms. Leach added that there are opportunities to communicate the value of basic science and how it translates to disease-specific treatments and shared that she often has the conversations with her colleagues in the community. She continued that NCI's recent communication about Unituxin is a good example of the type of messaging she thinks the community needs.
- Ms. Fleshman offered that a clearer explanation of NCI's budget operations would help the community and shared that the majority of the funding comes through a competitive process that the full community rarely understands.
- Ms. Williams asked members about the preferred methods of communication, including additional meetings with the NCI Director, better engagement around the NCI's advisory boards?
- Mr. Bangs responded that there are a variety of opportunities, but that social media and in-person meetings are good methods. He also added that research advocates are often not considered when these plans are being made and that should change.
- Ms. Leach offered that there could be a need to identify "core principles" of research advocate engagement that explain how the community should be included in the process.
- Dr. Friedman agreed with the need for "principles" to engage at every level and shared that FORCE has resources for this effort.

Childhood Cancer Research Update
Dr. Smith and Dr. Seibel

Dr. Smith provided an overview of a few pediatric cancer research programs and Dr. Seibel shared updates on the Pediatric MATCH study.

- Dr. Smith began by describing two new projects stemming from the Cancer Moonshot Blue Ribbon Panel focused on pediatric fusion oncoproteins and pediatric immunotherapy.
- Dr. Smith defined fusion oncoproteins for the members and explained how the drive several pediatric cancers. He described an RFA that has been issued to fund a

consortium of institutions investigating these drivers of pediatric cancer and shared that he expects the RFA to be reissued in the fall of 2018.

- Dr. Smith then described the Pediatric Discovery and Development Network (PI-DDN), a translational science network aimed at facilitating the testing of novel immunotherapy approaches in childhood cancer.
- Dr. Smith closed by sharing results from two pediatric cancer trials presented at the American Society of Clinical Oncology's (ASCO) Annual Meeting in 2018: a trial of nelaribine in T-cell malignancy and a phase II study of selumetinib in children with neurofibromatosis type 1 (NF1).
- Dr. Nita Seibel then presented an update on Pediatric MATCH and noted that as of May 2018, the trial has enrolled 200 patients.
- Dr. Seibel also presented the results of trials shared at ASCO 2018 including a study of mortality following breast cancer in survivors of childhood cancer and a phase II study for relapsed or refractory neuroblastoma.

Discussion

- Ms. Leach asked how germline analysis reports collected during Pediatric MATCH would be made available to treating physicians. Dr. Seibel answered that the treating physicians receive the copies of the analyses and then decides how to provide that information to the families.
- Mr. Arons asked Dr. Seibel about the forward-looking strategy for the Pediatric MATCH study, particularly if a treatment arm indicates a drug should progress to approval. Dr. Seibel added that the results would be shared with the industry partner and with the Children's Oncology Group (COG) for further study.
- Mr. Bangs if Pediatric MATCH or any of the work presented will lead to adult discoveries the way adult studies have led to pediatric discoveries. Dr. Smith answered that it is possible, particularly with the fusion oncoprotein work as some adult cancers are driven by similar alterations.
- Mr. Arons added that in both the development of the Cancer Moonshot projects and Pediatri MATCH, advocates were deeply engaged and encouraged that model moving forward.

Adult Cancer Research Update
Dr. Mooney

Dr. Mooney provided an overview of large, NCI-sponsored clinical initiatives focused on adult cancers, as well as an update on the NCI National Clinical Trial Network.

- Dr. Mooney began with an overview of the NCTN, describing its origin, purpose, and current composition. She also introduced two new initiatives: NCTN/NCORP Data Archives and the Navigator Biospecimen program.
- Dr. Mooney then described NCTN accrual data, providing members with a sense of total accrual since the program began, where patients enroll, and demographic patient information.
- Dr. Mooney closed by sharing updates on a few clinical trials that were presented at the ASCO 2018 meeting, including the TAILORx and adult MATCH trials.

Discussion

- Mr. Bangs asked if it were possible to obtain demographic data for accrual in trials coordinated by the different cooperative groups and Dr. Mooney answered that two divisions—DCCPS and DEA—pull that together every few years and expects the next cycle to be in about a year. She added that typically when the data is reported, it's very consistent with national demographics for race and ethnicity.
- Dr. McKoy asked about accrual of rural populations in NCI-sponsored trials and Dr. Mooney said that she didn't have those figures on hand but would follow up.
- Mr. Arons asked if there is site-by-site monitoring of the MATCH trial to track approaches and progress to accrue underserved populations and Dr. Mooney described a program at multiple sites—not just for MATCH—that is examining the use of patient navigators to accrue underrepresented patients in precision medicine trials and the results are still being collected.
- Dr. Friedman asked about MSI-high patients and whether or not there is a process for letting them know about their screening results and Dr. Mooney explained that the FDA accelerated approval for pembrolizomab across histologies for that target and that since, testing is being incorporated more into standard of care.

Update from the NCI Director
Dr. Sharpless

Dr. Sharpless presented to the NCRA for the first time and reviewed a few key priorities. Before he delivered his remarks, the members introduced themselves to him for the first time.

- Dr. Sharpless opened with a few statistics from the Annual Report to the Nation indicating the overall decline in cancer death rates between 1999 and 2015. He emphasized that while this is good news, there is still much work to do for patients.
- Dr. Sharpless outlined his key focus areas individually, beginning with basic science, emphasizing that as NCI Director he hopes to continue the commitment and investment in basic science that fuels all cancer research.
- Dr. Sharpless then described his second key focus area: developing a strong and diverse cancer workforce capable of tackling emerging issues and opportunities in cancer research, including big data, machine learning, and biostatistics.
- Dr. Sharpless shared with the board his vision for comprehensive and national data aggregation in cancer and talked a bit about the improvements he'd like to see made to the Surveillance, Epidemiology, and End Results (SEER) Program.
- Dr. Sharpless closed his prepared remarks by outlining his vision for improving the national cancer clinical trials system to be more adaptive to patient needs and innovative in design. He described a few promising approaches, including MATCH and TAILORx, and emphasized what he would like to see improved within the NCTN program.

Discussion

- Mr. Bangs initiated the question-and-answer session by thanking Dr. Sharpless for sharing his key focus areas with the board and asking about whether or not research advocates would be included in the workforce development area. He added that the only funding available for professional development is through philanthropy and

believes that NCI is missing an opportunity to create a pipeline of research advocates. Dr. Sharpless agreed that training—in addition to being expensive and necessary—is highly visible. He also added that many of the NIH Institutes and Centers are working on developing strategies to improve the research workforce, particularly early-stage investigators.

- Ms. Williams added that research advocate training and compensation are evergreen issues in the community and the Office of Advocacy Relations is always assessing the opportunities to provide more resources to the community, including looking at what large advocacy organizations offer to their constituents.
- Mr. Bangs added that there is no funding to do any sort of training at the NCI or within the NCTN for cooperative group advocates. Ms. Williams shared that the funding that NCI provides to the cooperative groups is then coordinated by the cooperative groups.
- Dr. Friedman echoed Mr. Bangs' point about advocate training and needing to ensure that we create opportunities for advocates to develop a career pipeline where they can continue their work, share with the next generation of advocates, and encourage researchers to engage advocates in their work. She added that identifying what the needs/gaps are in training would be a preferred first step.
- Ms. Williams shared that this conversation is reflective of work NCRA addressed a few years ago and will share the output of that work with the current members.
- Dr. Sharpless asked the board for suggestions of what NCI ought to be focusing on and Ms. Leach replied that looking at how advocates are currently engaged at the NCI would be an appropriate first step. She also added that it is helpful to look outward and examine what organizations are doing with advocates to see if there are strong models for engagement.
- Ms. Fleshman added there are two issues: 1) in order to engage on an individual level, an advocate needs to be trained how to engage and 2) what role do organizations have in partnering with NCI to advance cancer research.
- Dr. McKoy shared that partnering with institutions that already have successful models of advocate engagement should be considered.
- Dr. Vidaver echoed Ms. Williams by sharing that this work was done by NCRA a few years ago and perhaps should be dusted off.
- Dr. Sharpless summarized the discussion by saying that these are important issues to examine for NCI and OAR.
- Mr. Arons continued the conversation by saying that he hopes Dr. Sharpless can challenge the NCRA with issues that the board should tackle on NCI's behalf.
- Dr. Sharpless shared that continued and sustained relationships between the community and NCI that feature candid communication are essential. He encouraged members to be frank and share when they are supportive and unsupportive of NCI approaches.
- Ms. Leach asked what Dr. Sharpless would like to see NCI staff do differently to engage organizations and other funders when developing new programs. Dr. Sharpless explained that the majority of NCI programs are implemented through competitive grants and asked what organizations would like NCI to do and how they see themselves fitting into the competitive process.

- Mr. Arons pointed out that he is identifying both a communication issue and a strategy issue. Where there is a shift in strategy, the community and in particular, the relevant funders, want to be engaged. Where there is a communication challenge for the NCI, the community wants to be able to support additional promotion or increased understanding of scientific projects or programs sponsored by the NCI.
- Ms. Williams added that the NCRA is often engaging around clinical trials and big data in cancer research and asked Dr. Sharpless what his thoughts about advocate engagement would be on those issues.
- Dr. Sharpless shared that big data is a focus for him because it presents so many opportunities in cancer research and it becomes harder and harder to aggregate data each day. He added that engaging the community around issues of privacy and consent could be an initial step.
- Ms. Leach added that sometimes the engagement comes late in the discussion or planning, and she hopes that NCRA and NCI can work together to collaborate earlier in the process.
- Dr. Sharpless added that solutions for data aggregation and clinical trial accrual are available but require coordination and collaboration.
- Mr. Arons added that that type of collaboration is encouraged by the Blue Ribbon Panel and specifically Recommendation A which focuses on increased patient engagement.
- Dr. Sharpless shared that Recommendation A is in the process of being implemented and believes the first few ideas stemming from it are in line to be presented at the next Board of Scientific Advisors meeting.
- Ms. Fleshman asked if there are ways NCI can partner with organizations on programs of engagement and shared the example that pancreatic cancer patients who reach out to NCI would also benefit from being connected to PanCAN.
- Dr. Sharpless answered that there are opportunities especially when so many organizations in the community have robust resources for patients that complement many of NCI's resources. He also added that he hopes organizations—particularly those that field inquiries from patients seeking clinical trials—are referring patients to the Clinical Center when appropriate.
- Ms. Leach asked what the update on the search for the new Director of the Office of Cancer Survivorship.
- Dr. Sharpless replied that the search is for a key position within the NCI and the leadership of DCCPS is reassessing following the withdrawal of two candidates.
- Ms. Fuld Nasso added that as part of the search committee, she would like to be included in the conversations about reassessing the search and future directions for the Office of Cancer Survivorship.
- Mr. Arons asked if there are other issues top of mind for Dr. Sharpless that may require community support or feedback.
- Dr. Sharpless added that communication with the congress is essential and that communicating to all community constituents about opportunities in cancer research is helpful.

- Mr. Arons asked about Dr. Sharpless' vision for innovative clinical trial design. Dr. Sharpless replied that it requires a combination of approaches, including smaller, more tailored trials, but noted that large, practice-changing trials won't go away.
- Mr. Vargas asked about expanding workforce in genetic counseling for cancer research?
- Dr. Sharpless described his interest in this issue and described a few new training grants and programs aimed at improving the diversity of the cancer research workforce.
- Mr. Bangs commented on the opportunity to improve the transparency of the vision for expanding the workforce and how understanding the vision could better engage the community in supporting the implementation of that vision.
- Dr. Sharpless acknowledged the communication challenges facing the NCI and spoke to his desire to improve communication internally and externally.

Wrap-Up
Mr. Arons, Ms. Williams

Ms. Williams thanked Dr. Sharpless for his time and the members for their engagement throughout the day.

She acknowledged the next NCRA meeting date: September 17, 2018. And she also recapped a few of the discussion points throughout the day, including principles of advocate engagement, the Blue Ribbon Panel's Recommendation A, and some of the key focus areas Dr. Sharpless outlined.

Mr. Arons added that it might be helpful to outline principles prior to the September meeting and use the next meeting to discuss. Ms. Williams added that it would be helpful to see the output of NCRA's prior working group. Mr. Arons agreed and added that it would be helpful to know more about the progress of implementation of the Blue Ribbon Panel. Ms. Fuld Nasso agreed a progress report would be extremely helpful. His final point related to developing more resources to help the community communicate about the Clinical Center, as Dr. Sharpless requested.

Ms. Fleshman added that it sounds like the board needs to reevaluate some basic ideas, including "research advocates," and Ms. Williams added that that will be included in the prior work to be shared with NCRA. Mr. Bangs suggested it might be helpful to provide Dr. Sharpless with a more detailed overview of how advocates are engaging with NCI already.

Ms. Williams reiterated her thanks for all members' participation and Mr. Arons thanked the NCI staff and speakers for their participation.

Adjournment

The meeting adjourned at 3:45p.m.

Certification

I hereby certify that foregoing minutes are accurate and complete.

9-25-2018
Date

David Arons, Chair
NCI Council of Research Advocates

9/26/18
Date

Amy Williams, Executive Secretary