74th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Building 40, Room 1201/1203
NIH Campus
Bethesda, Maryland

Friday, June 9, 2017

Members Present

Mr. David Arons, Chair
Dr. Gregory Aune
Ms. Mary Ann Battles
Ms. Julie Fleshman (by telephone)
Dr. Sue Friedman (by telephone)
Ms. Shelley Fuld Nasso (by telephone)
Dr. June McKoy
Ms. Kimberly Newman-McCown
Ms. Heather Ortner (by telephone)
Dr. Roberto Vargas
Dr. Regina M. Vidaver

Speakers

Mr. David Arons, Chair, NCRA; Chief Executive Officer, National Brain Tumor Society
Ms. Michelle Canady, Deputy Budget Officer, Office of Budget and Finance, NCI
Dr. Jason Cristofaro, Intellectual Property Program Manager, Division of Cancer Treatment and Diagnosis, NCI
Ms. Andrea Denicoff, Nurse Consultant, Division of Cancer Treatment and Diagnosis, NCI
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations, NCI
Ms. M. K. Holohan, Director, Office of Government and Congressional Relations, NCI
Dr. Warren A. Kibbe, Director, Center for Biomedical Informatics and Information Technology, NCI
Dr. Douglas R. Lowy, Acting Director, NCI; Chief, Laboratory of Cellular Oncology, NCI
Dr. Karlyne Reilly, Director, Rare Tumors Initiative, NCI
Ms. Kristen Santiago, Senior Director, Policy & Advocacy, Cancer Support Community
Dr. Tom Stackhouse, Associate Director, Technology Transfer Center, NCI
Ms. Amy Williams, Acting Director, Office of Advocacy Relations; Executive Secretary, NCRA, NCI

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Welcome, Introductions, and Opening Remarks
Mr. Arons, Ms. Williams

Ms. Williams opened the meeting by welcoming members and guests at 9:04 a.m. She noted that the meeting would focus on partnerships with the federal government, updates on the Cancer Moonshot, the Blue Ribbon Panel recommendations, budget and legislative updates, and an update from Dr. Lowy.

Mr. Arons announced that that Dr. Lowy will remain acting director of NCI.

Partnerships in Cancer Research
Ms. Lubenow, moderator

Ms. Lubenow introduced the panel members and opened the discussion.

Intellectual Property Program, Division of Cancer Treatment and Diagnosis
Dr. Cristofaro

- The Division of Cancer Treatment and Diagnosis (CTAD) is the largest sponsor of cancer clinical studies in the world and specializes in clinical trial agreements.
- Dr. Cristofaro described a virtual drug formulary, a direct initiative of the Cancer Moonshot, that will shorten the time needed to start cancer treatment trials. CTAD created agreements with various companies to provide pharmaceutical agents to academic research sites. Currently, eight companies are participating. More than half of the 26 available agents are investigational agents that cancer centers might not be able to access otherwise.
- CTAD facilitated agreements between NCI and United Therapies to bring to market Unituxin™, currently indicated for pediatric brain cancer.
- The MATCH (Molecular Analysis for Therapy Choice) study, NCI's first foray into precision medicine, involves a number of cooperative groups. A pediatric version of the MATCH program is in development.

Biomedical Informatics and Information Technology
Dr. Kibbe

- Dr. Kibbe discussed data sharing and its relevance to the Cancer Moonshot.
- The Genomic Data Commons went live last June and involved a number of different groups, including the Multiple Myeloma Research Foundation and Foundation Medicine, a commercial company that collects and sequences tumors, that use and share data sets.
- Dr. Kibbe described efforts to make data from the Genomic Data Commons accessible to the community through cloud pilots.
- Dr. Kibbe also described a partnership with computational scientists at the U.S. Department of Energy (DOE) to use data for simulation and prediction.

Policy and Advocacy for the Cancer Support Community
Ms. Santiago

- Ms. Santiago described the Cancer Support Community, which provides psychosocial support to patients and families through 170 physical locations, as well as wellness programs and online access.
- Information learned is used to help influence policy and research.
- One project relates to dispelling myths and misperceptions about clinical trials. For example, patients often believe that "placebo" means they will get no treatment, when in fact they will be receiving the standard of care (SOC) but without the addition of the study drug.
- The Cancer Support Community will host the "Cancer Moonshot: One Year Later" on June 27, 2018, in Washington, D.C., in partnership with six other organizations.

Technology Transfer Center
Dr. Stackhouse

- Dr. Stackhouse provided an overview of technology transfer at NCI and how ideas are brought to the marketplace.
- The Technology Transfer Center (TTC) manages patents that result from the discoveries of about 120 new invention reports each year in the intramural program.
- TTC is involved with sharing research resources within the research community and managing data sharing and collaborations with extramural nonprofits, universities, and industry.
- TTC was recently reorganized to find ways to develop patents more quickly and transfer them to commercial companies to benefit patients earlier. A focused effort is being made to move some of NCI's technologies to startup companies and train teams worldwide. To date, 38 inventions are out there, and 24 startups are still in existence.
- TTC is aiming to interact more with the community to spread the word about new technologies and their benefits to public health.

Discussion

Ms. Lubenow cited the need for the cancer community to draw on different disciplines to tackle the cancer challenge and asked the panel members to comment on the keys to successful partnerships. Dr. Kibbe said that each partner needs to understand the value that the partnership has for them. Dr. Stackhouse said that having a common goal in mind and thinking about what the other party needs are important. Ms. Santiago agreed that it is important to have a shared mission for the Moonshot; all organizations are equal partners. Dr. Cristofaro added that trust and consistency are important so that all parties know what to expect. Ms. Lubenow added that a partnership is beyond just "giving us money"; it means giving access to agents, expertise, and relationships.

Mr. Arons asked whether nonprofits should think about NCI as an option if they have a project and are looking for a fit. Mr. Cristofaro said yes and mentioned the NCI Experimental Therapeutics (NExT) program, which does development work from basic to clinical trials, is open to anyone, and has an easy application process. NCI provides resources for scale-up. Dr. Stackhouse said that NCI has many resources that people are not aware of. Dr. Kibbe

said yes also but noted that it is sometimes difficult to find the right partner. He said that partnering is not only about clinical trials and acute therapy but also about prevention, early detection, and long-term outcomes. A partner may need to work with different people at NCI rather than just one group, and NCI can facilitate these opportunities. Dr. Kibbe also noted that NCI is making an effort to make clinical trials more accessible to patients and that new partners are always needed to help.

Dr. Vidaver asked whether NCI is trying to model screening that determines which cancers are indolent and which are aggressive. Dr. Kibbe agreed that the problem across all cancers is predicting which patients do not need treatment, which patients might respond, and which patients may need more aggressive treatment. The current collaboration with DOE is not focusing on that issue, although there is a need.

Dr. McKoy asked whether partnerships with pharma are possible so that the onus is on them to not overcharge patients. Dr. Stackhouse said that the pricing issue is difficult, and if NCI tries to exert too much control over pricing, it will be difficult to attract partners from pharma. However, partners need to understand that the common goal is treating patients and improving public health. Dr. McKoy suggested adding a congressional representative as a partner. Ms. Nasso asked whether there are policy barriers that need to be addressed to give NCI better leverage over pricing. Dr. Kibbe said that drug development is very costly for pharma and there are many factors and stakeholders to consider when negotiating. He cited a need to consider where the country is headed, a discussion that is much too big for NCI to have alone. He suggested that the advocacy community may help with changing the framework. Dr. Cristofaro added that it is challenging to establish collaborations with pharma if pricing language is included in the agreement.

Ms. Newman-McCown asked how NCI might interact with 501(c)(3) and 501(c)(4) organizations. Ms. Lubenow said that NCI has made several efforts to collaborate more effectively with nonprofit funders of research, but there are some barriers due to policy, legal, and peer review issues. NCI has limitations on collaborations on certain aspects of the research process but is currently discussing options to address roadblocks in this area. Startup challenges often involve nonprofits, but the challenge is the community's willingness to work together. Ms. Williams added that discussions should start with an understanding of the organization's priorities; the structure of the organization matters less than the content and ideas. Ms. Santiago said that the Cancer Support Community has been making progress, and she stressed the importance of having multiple organizations come together.

Dr. Aune said that, as a pediatric oncologist, he feels that progress is accelerating for adult initiatives but lagging behind for pediatrics. Dr. Cristofaro said that it is more challenging to bring in pharma for pediatric MATCH trials because of concerns about adverse events and health challenges. Advocacy organizations as partners can help, given the importance of pediatric research. Dr. Aune said that his community is ready to help get the pediatric MATCH trial started if there are specific companies NCI would suggest. Dr. Kibbe said he is part of a steering committee that has made progress in this area, and he anticipates a summer date for the pediatric MATCH trial. Dr. Cristofaro noted that liability is not the main issue.

Pharma is concerned about effects on the population downstream, because a long-term effect in children may affect the regulatory status of adult agents.

Ms. Battles said that the new administration has proposals for regulatory changes, and she asked about the role of NCI in working with accessibility and extension of treatments. Mr. Cristofaro said that the U.S. Food and Drug Administration (FDA) has a voucher program for rare pediatric conditions, which serves as an incentive for work in these areas, but FDA does not want to get involved in pricing discussions. He felt that this was a broad issue that needs to be dealt with in a political arena. Ms. Battles said that the regulatory framework needs to include a social justice element and asked whether genomic data should be provided directly to patients. Dr. Kibbe said that the Global Alliance for Genomics and Health has a policy group and has created a framework document indicating that every citizen has a right to participate in and benefit from research, and this is being considered from a data-sharing standpoint.

Dr. Vargas asked about ways to ensure that underrepresented populations are being engaged to participate in clinical trials. He said there are opportunities for strengthening accessibility in this area for patients and advocates, noting that the University of California, San Francisco (UCSF), has improved in this area. He also said that it is important to have people who can sit down with patients and families and help explain the trial, and he asked how barriers can be overcome and addressed in agreements. Dr. Kibbe said that NCI has been discussing health disparities that predate the Cancer Moonshot and addressing incentives and requirements to put in place regarding underrepresented groups. He noted that 60% of cases that come to MATCH have less common or rare cancers but that figures for diversity (12%) are not high enough. Mr. Cristofaro said that he was hesitant to add language about diversity, since most studies have difficulty reaching full accrual, but he agreed that the issue of low representation needs to be addressed.

Blue Ribbon Panel Recommendations Discussion
Ms. Denicoff, Dr. Reilly

- Ms. Williams said that the portion of the Cancer Moonshot that involves prioritizing the science has been completed and efforts are now focused on implementation.
- The Cancer Moonshot Blue Ribbon Panel has made several recommendations. Two initiatives, management of patient-reported outcomes (PROs) and the Rare Tumor Patient Engagement Network, were presented and discussed at this meeting.

<u>Patient-Reported Outcomes</u>

- Ms. Denicoff described her roles as head of operations for NCI's national clinical trials network and as scientific liaison for PROs and discussed the goals of an RFA (Request for Application) for reporting and managing PROs.
- Variability exists in how patients and clinicians report grades of reports. Patients might underreport or overreport.
- Improved efforts are needed for using data and sharing information about long-term tolerability.

- NCI has developed a tool for assessing safety and tolerability reported for the CTCAE (Common Terminology Criteria for Adverse Events), as well as a patient-reported assessment tool.
- One hurdle to implementing an effort across studies is that NCI has five funded groups. All embed PROs in studies but report them differently.
- The goal of the RFA is to create a shared community of researchers (including behavioral, information, and statistical researchers).
- Patients using an app on a cellphone can report adverse events that can be downloaded and transmitted to two different databases.

Dr. Vidaver asked about privacy protection. Ms. Denicoff cited products (Medidata Rave®, Patient Cloud™ ePRO) that have been purchased and implemented to protect privacy. She said that the goal is to share analytic approaches. FDA is interested in having outcomes in labeling to improve treatment tolerability over time. There is also an interest in using pharmacokinetic data to inform dose and schedule and in tracking patients who stop taking treatment.

Ms. Battles asked whether PROs are immediately available to the investigator. Ms. Denicoff said that this is a long-term aim, but they are currently focused on engaging clinical sites.

Mr. Arons asked whether the study will look at the use of cellphones versus paper for gathering data. Ms. Denicoff said yes and also noted that patients are sometimes too sick to report the most important information, so it is necessary to work with a family member or friend as well.

Dr. Vargas said that even after language is simplified for low-literacy populations, patients still like to have a person sit with them and explain. He asked whether the RFA addresses having health workers for this role and whether health literacy experts helped develop the app. Ms. Denicoff said that the program funded by NCI was developed over a number of years and used ARRA (American Recovery and Reinvestment Act) funding to test health literacy specifically. She said a large study evaluated the tool, and she felt confident with the language. The Medidata Rave® tool has been used worldwide for years and is easy to use on a smartphone. The clinics will also have tablets available. Ms. Denicoff said that issues remain, and the clinics are working with staff education.

Mr. Arons asked about opportunities for the greater cancer community to participate. Ms. Denicoff said that there were many questions at the American Society of Clinical Oncology (ASCO) meeting on how to engage patients. Questions about using technology to improve literacy for patients remain.

Dr. McKoy said that older patients are more likely to mistrust gadgets or have problems with eye–hand coordination, so surrogates or family members need to be included in beta testing. Ms. Denicoff agreed, adding that data on whether patients are filling in the information themselves will be captured.

<u>Rare Tumor Patient Engagement Network</u>

- Dr. Reilly introduced herself and three other team members involved with the network: Mark Gilbert, Terri Armstrong, and Brigitte Widemann.
- Rare tumors (<40,000 new cases per year) make up 27% of cancers diagnosed each year and lead to 25% of cancer-related deaths.
- The goals of the Rare Tumor Patient Engagement Network are to develop a shared infrastructure across national/international sites to study select rare tumors; to collect, analyze, and share all available data on these tumors; and to develop a network to translate findings to new clinical trials and improve access to existing clinical trials.
- The network's success depends on partnerships with advocacy groups to promote patient engagement.
- The program's current design involves engaging patients through social media and advocacy; collecting clinical, environmental exposure, and family history data as well as biospecimens; providing education and support to build a community; and disseminating data rapidly into research community to advance new therapies and model systems.
- Current collaborators include the Brain Tumor Collaborative Consortium (26 sites) and the Pediatric and Adult Rare Tumor Consortium (6 U.S. sites and 2 European sites).
- Meeting participants were asked for feedback on engaging underrepresented populations, using social media to spread the word, providing virtual support, understanding barriers to patient participation, determining the amounts and kinds of data that patients want, and maintaining patient engagement over time.

Mr. Arons asked for a definition of "participation" and what specifically is being asked of patients. Dr. Reilly said that there will be several layers. The first level involves finding out who is using the website and how to get people from other areas involved. Then there will be a need to connect to share clinical data and imaging. Dr. Armstrong said that they want to understand what led patients to the doctor and what their issues are. They have questionnaires to help understand the disease trajectory, and this should help better educate and target patients. By engaging patients, the hope is to bring them into the centers, collect samples, and have them stay in the community and develop networks. In some cases, coming to NIH allows patients to meet other patients with a tumor like theirs for the first time. Dr. Gilbert said that it is symbiotic: "We learn from them, and they get support."

Mr. Vargas said that there is a tremendous distrust of medical institutions and research, and he is looking for opportunities to engage around areas other than research. He cited the development of partnerships with faith-based African American communities to increase peer health educators. Also, transportation and housing are major issues for rural populations. Dr. Widemann said the issue is dealing not only with diversity but also with rareness, and there is a need to relate to small numbers of patients. Dr. Gilbert said that there is an opportunity to provide resources and education to patients who have rare cancers. If patients have a positive experience, they will become stewards and share information about how the group came together and helped.

Ms. Newman-McCown said that patients may not have resources in their state or may not be able to get access to them. Dr. Reilly said that an important component of the program is that patients can travel to the NIH campus and stay there at no cost.

Ms. Newman-McCown asked about the program's web presence, social media efforts, and accessibility to the centers. Ms. Armstrong said that this process is still being built. She said that the program partners with local oncologists who can administer treatment. The centers are helpful for people who do not want to travel to NIH, and these centers are continuing to expand.

Dr. McKoy said that for underrepresented populations, the way to start is by reaching out to the primary care doctor or clinic. While they may not be experts in the area, they will know how to direct patients to the Rare Tumors Initiative at NCI. Dr. Gilbert said that there are sections in place to address this. Dr. Reilly said that the program needs to determine how patients with specific tumors get directed to the program; they are unlikely to search for "rare tumor."

Dr. Aune asked about considerations for pediatrics. Dr. Widemann said that the program is working with other institutions to connect with their networks and cited St. Jude Children's Research Hospital as an example.

Action Item: Ms. Williams will work with people interested in becoming advisors and will create a structure for getting involved.

Introduction to NCI's Office of Budget and Finance
Ms. Canady

- Ms. Canady reviewed the budget process, noting that most funding for NCI comes from individual income taxes.
- NCI receives its appropriation from Congress as part of the overall federal budget process. The budget requires congressional justification and testimony from the NCI director.
- The NCI budget for fiscal year (FY) 2016 was $5.2 billion and increased by 5% over the previous year; 41.2% of the total budget was allocated for research.
- The NCI Budget Fact Book provides a summary of the distribution of the FY 2016 budget among the various NCI research programs and funding mechanisms and is available online: https://www.cancer.gov/about-nci/budget/fact-book.
- Funding for the Cancer Moonshot (2017–2023) has been authorized but is not guaranteed; spending for this initiative must be appropriated each year. For FY 2017, $300 million was appropriated in December 2016 and made available in June 2017.
- Sources of non-appropriated funds include gifts, royalties, Cooperative Research and Development Agreements (CRADA), sale of research substances, and sale of breast cancer stamps (which have raised $84.4 million since 1998).

Legislative Update
M.K. Holohan, Ms. Gibbons

- Ms. Holohan reviewed the NCI/NIH budget process and how the Office of Government and Congressional Relations (OGCR) facilitates the relationship with Congress.

- The President's budget for FY 2018 was released on May 23, 2017. It calls for more than a 20% cut to NIH's budget compared to the FY 2017 appropriated level.
- The process for FY 2018 is later than usual. NIH presented to the House Appropriations Committee on May 17 and will present to the Senate on June 22. Dr. Lowy will be present to answer questions.
- Seven representatives and their staff from the House Appropriations Committee visited NIH in February 2017.
- Nine senators and their staff from the Senate Appropriations Committee visited NIH in June 2017 and spent time with researchers.
- Ms. Gibbons added that congressional staff visited the NCI Pediatric Oncology Branch in May 2017 and spent time discussing extramural research.
- The Senate is currently under pressure to repeal or replace the Affordable Care Act before the August recess.
- A return of sequestration in FY 2018 would result in a reduction of funds.

Discussion

Ms. Battles asked whether unused funds are forwarded to the following year. Ms. Canady said that funds can carry over for the Cancer Moonshot but not for the annual spending.

Dr. Vidaver asked what happens when a 5-year grant is not guaranteed for a full 5 years. Ms. Canady said that if the FY 2018 budget comes in with a significant cut, money is subject to appropriation.

Dr. McKoy asked about the impact of not using the money appropriated. Ms. Canady said that there is a risk of Congress determining that the money is not needed; every federal agency faces this issue. Ms. Williams said that NCI tracks spending very closely all year and that lapses are few.

Mr. Arons asked about the impact of reductions to NCI's budget and how advocates can help with accurately communicating the implications externally. Ms. Holohan said that the results of the congressional hearing will shape the narrative. She said it is difficult to specify now exactly how ambassadors can engage, but advocates can present their personal views. The senators are most interested in the patients and met a patient during their NCI visit.

Update from the NCI Acting Director
Dr. Lowy

- An increased effort is needed to further decrease cancer mortality rates; prevent cancer; detect cancers earlier, when they are most treatable; and develop more effective and less toxic treatments.
- A balanced research approach to addressing cancer considers long-term (>15 years), intermediate-term (~5 to 15 years), and short-term (~5 years) factors.
- NCI appropriations have done well in recent years, with $5.39 million appropriated in FY 2017.

- Appropriation for the Cancer Moonshot is an augmentation to regular appropriations. Authorized funding for the Moonshot is:

Fiscal Year	Dollars (in millions)
2017	$300
2018	$300
2019	$400
2020	$195
2021	$195
2022	$194
2023	$216

- For FY 2017, $140 million of the Cancer Moonshot funds will be used for first-year awards.
- The initial goals of the Cancer Moonshot are to accelerate progress in cancer prevention, screening, treatment, and mechanisms; encourage greater cooperation and collaboration within and among academia, government, and the private sector; and enhance data sharing.
- The Cancer Moonshot Blue Ribbon Panel has made 10 recommendations for achieving the goals of the Cancer Moonshot. The complete Blue Ribbon Panel report is available online: https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel.
- Cancer Moonshot implementation teams are currently developing scientific proposals, which will be reviewed by the NCI Scientific Leaders in May 2017 and by the Board of Scientific Advisors in June 2017. Funding Opportunity Announcements (FOAs) for 2017 will be released in September/October of 2017.
- Implementation teams for new awards in FY 2018 to FY 2023 are aligned with the Blue Ribbon Panel recommendations and composed of staff from NCI and other institutes. They are charged with developing and proposing initiatives for FY 2018 and beyond, seeking input from the cancer research community, and providing oversight and coordination of funded initiatives.
- Opportunities for potential collaborations are needed with other institutes and agencies, private philanthropy, pharma and biotech, other countries, and international donors.
- The International Cancer Proteogenome Consortium, a self-assembled group of 11 countries and 18 institutions, will have a website available soon. Each country will study one or more cancers of importance to them and detail the relevant genomics and proteomics. Countries will support their own research and follow NCI standard operating procedures (SOPs). Data will be entered in a single NCI database and made available to researchers throughout the world.
- A balanced approach to addressing cancer depends on determining where each of us can make the biggest impact.

Discussion

Mr. Arons asked how ambassadors might describe in an "elevator speech" the initiatives that NCI is carrying out to help Americans. Dr. Lowy said that the effort to understand and improve immunotherapy is a signature initiative within both the Cancer Moonshot and regular appropriations. Industry and private philanthropy have invested heavily in this area. Other important areas are efforts to better understand why some patients respond and others do not and to study new approaches to immunotherapies that have not stood the test of time (e.g., vaccines). Dr. Lowy also said that remarkable findings have been made in supporting immunotherapy for uncommon cancers. One example is an improved response to new checkpoint inhibitors for Merkel cell carcinoma, which has a higher mortality rate than melanoma. Another important area is pediatric cancer. Dr. Lowy noted that people get more excited hearing about treatments than prevention efforts.

Ms. Nasso said that the Pancreatic Cancer Action Network will be hosting about 150 advocates in Washington, D.C., soon, and she asked whether there were any specific messages to relay regarding appropriations for NIH and NCI. Dr. Lowy said that strong support for immunologic approaches to pancreatic cancer is warranted. He suggested emphasizing the RAS initiative, because the development of interventions against mutant KRAS has been challenging.

Dr. McKoy asked about the Biomarkers Consortium managed by the Foundation for the National Institutes of Health (FNIH). Dr. Lowy said that this effort is not specifically devoted to cancer but is trying to identify and validate biomarkers associated with a wide variety of diseases. Proposals are coming from extramural researchers who often work with data developed through clinical trials; a limited number have been related to cancer. Funding from pharma is needed in addition to public funding. NCI tries to proceed only when certain that the biomarker is really likely to make progress and is likely to receive funding from pharma.

Mr. Arons asked for more information about FNIH. Dr. Lowy said that this foundation is an independent entity headed by Maria Freire, the first head of technology transfer at NIH, and provides support for a wide range of public–private partnerships not necessarily limited to industry. Dr. Collins is working to find support for research in immunological biomarkers and development of standard immunoassays. Tens of millions of dollars have already been invested in this area, but progress can be faster if pharma contributes.

Dr. Aune asked whether NCI applies a model for pharma–public partnerships for pediatric diseases similar to the model used for Unituxin®. Dr. Lowy said that NCI tries to partner with other groups both in the U.S. and abroad. He has discussed pediatric cancer fusion proteins with Cancer Research UK.

Dr. McKoy asked how the late appropriations for FY 2018 will affect the payline for research grants. Dr. Lowy said that NCI "always runs out of money before running out of good ideas that can be tested" and will be as strategic as possible if there is less money.

Mr. Arons asked Dr. Lowy to discuss NCI's partnerships and interactions with human papilloma virus (HPV) vaccination and the Bill & Melinda Gates Foundation. Dr. Lowy said that NCI is doing a clinical trial to see whether one dose of HPV vaccine in adolescents is

sufficient to give multiple years of protection. If this could be done in the developing world, it would make vaccination much easier and less expensive. The Gates Foundation is co-funding a vaccine trial in Costa Rica, where cervical cancer is the #1 cancer in women. NCI is interested in promoting development of regional vaccine production and making biosimilar vaccines. Dr. Lowy also said it should be possible for all future trials to simply use immunogenicity rather than efficacy, because immunogenicity is simpler and less expensive. The Gates Foundation and NCI are also supporting the standardization of a serology laboratory at NCI's Frederick National Laboratory for Cancer Research.

Dr. Vidaver asked why MATCH has had a greater impact in the Midwest than in the Southeast, the "cancer belt." Dr. Lowy speculated that many areas in this section have designated NCI cancer centers doing analogous trials and that it may not be as critical for those patients to have access.

Dr. Vargas asked whether NCI is collecting data about how patients end up in the MATCH study. Dr. Lowy said NCI has had discussions about developing that evidence.

Dr. McKoy asked whether NCI is engaged, interested, or involved in looking at complementary therapies as adjunctive or even primary treatments. Dr. Lowy said that NCI looks at preliminary evidence of efficacy beyond anecdotes and has the largest library on natural products in the world. Research tends to focus on isolated molecules, while complementary medicine very often is a mixture of different kinds of molecules. NCI is more focused on interventions that allow an understanding of the mechanism and can be characterized specifically.

Ms. Battles asked whether looking at nonresponders was built into the MATCH protocol and whether regulatory restrictions are in place now to extend label applications for drugs. Dr. Lowy said that nonresponders are offered a form of immunotherapy. If a signal is seen with some people and not others, a detailed genomic analysis may be performed. Most of the patients screened do not have a molecular abnormality.

Ms. Newman-McCown asked whether the NCRA members will receive copies of Dr. Lowy's presentation.

Action Item: Share copies of Dr. Lowy's presentation with NCRA.

Mr. Arons asked what NCRA can do to help with implementation of the Cancer Moonshot. Dr. Lowy said that the implementation groups have had limited input from advocates and would like to hear from them to avoid going down a path that may be ill-considered.

Mr. Arons asked whether NCI has initiatives to address cancers that do not have an early detection protocol. Dr. Lowy said that this has been an area of intense thought and that a number of biotech companies are oriented in this direction. He said that he personally feels enthusiastic about developing screening for cancers or improving existing screening. He said that it is important to recognize that the goal of screening is to save lives, but the problem is that early detection is not enough to reduce mortality rates. There is a need to show that

detection is clinically useful, and one should start with high-risk populations. Looking for biomarkers should be an ancillary approach, not a primary approach.

Mr. Arons asked whether there are screening initiatives that NCRA should be aware of. Dr. Lowy cited the Tomosynthesis Mammography Imaging Screening Trial (TMIST), a breast cancer screening initiative of about 150,000 women ages 45 to 75 years. One goal is to see whether new 3D mammography has an advantage over the standard. Another goal is to see whether postmenopausal women at normal risk can start to be screened every other year rather than annually. Dr. Lowy's hope is that this will lead to a change in the SOC and reduce lifetime mammograms by one-third for the average women. The U.S. is the only country with annual screenings.

Dr. Aune asked about the main messages that Dr. Lowy will convey to Congress so that the advocates can support them. Dr. Lowy said that only Dr. Collins will have a prepared oral statement. He expects to hear questions about the Cancer Moonshot, and he would say that NCI is supporting a great deal of research, trying to accelerate progress, and increasing data sharing.

Dr. Vidaver asked how the potential loss of health insurance for 23 million people might affect cancer deaths. Dr. Lowy said that any estimates would be highly speculative, but NCI is highly attuned to the issue. NCI is having discussions with the Centers for Medicare & Medicaid Services (CMS) about providing cancer screenings to populations younger than Medicare eligibility age and maintaining and increasing access to cancer services.

Mr. Arons asked about opportunities to enhance the collaboration of NCRA and NCI. Dr. Lowy said that partners can help by sharing information with their communities in ways that NCI cannot. He suggested talking about how clinical cancer research is trying to give people hope so that they do not view participation in clinical trials as being "guinea pigs." Research will help patients who do get cancer, as well as reducing the chances of getting cancer in the first place. It is very important to bring that message to a wide range of constituencies.

Mr. Arons asked whether the low percentage (6%) of patients entering clinical trials is a public health problem and whether partners need to stress recruitment for clinical trials. Dr. Lowy said that patient accrual is often limiting. For children with cancer, the assumption is that they will enter a clinical trial. Many people do not understand that much preliminary data is compiled before a study and that much science is involved. It is critical that patients understand that trials are not placebo-controlled but rather SOC versus SOC plus. The best group of people to discuss this with may be people who recently learned they have cancer.

Wrap-Up
Mr. Arons, Ms. Williams

Mr. Arons and Ms. Williams thanked Dr. Lowy and the participants.

Adjournment

The meeting adjourned at 3:40 p.m.