# 70<sup>th</sup> Meeting of the National Cancer Institute (NCI) NCI Council of Research Advocates (NCRA) National Institutes of Health (NCI)

NCI and the Vice President's National Cancer Initiative

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

Monday, April 11, 2016

#### **Members Present**

Mr. David Arons, Chair Dr. Gregory Aune Ms. Mary Ann Battles Dr. Sue Friedman Ms. Shelley Fuld Nasso Ms. Martha Gaines Dr. June McKoy Ms. Kimberly Newman-McCown Ms. Heather Ortner Dr. Senaida Fernandez Poole Mr. Roberto Vargas Dr. Regina M. Vidaver

#### Speakers

Mr. David Arons, Chair, NCRA; Chief Executive Officer, National Brain Tumor Society

- Ms. Holly Gibbons, Program Analyst, Office of Government and Congressional Relations, NCI
- Ms. M. K. Holohan, Director, Office of Government and Congressional Relations, NCI Dr. Elizabeth Jaffee, Professor and Deputy Director for Translational Research, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University
- Kimmel Comprehensive Cancer Center, Johns Hopkins University
- Dr. Douglas R. Lowy, Acting Director, NCI; Chief, Laboratory of Cellular Oncology, NCI

Ms. Nancy Siebert Murphy, Office of Communications and Public Liaison, NCI

Dr. Dinah Singer, Acting Deputy Director, NCI; Director, NCI Division of Cancer Biology

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

# Contents

| Welcome and Opening Remarks  |
|--|
| National Cancer Institute Update   |
| NCI Budget Outlook   |
| The Vice President's Cancer Initiative   |
| Discussion 4   |
| Overview: The Vice President's Cancer Initiative   |
| Discussion   |
| Scientific Vision: The Vice President's Cancer Initiative7                               |
| NCRA Discussion and Public Comment Period  |
| Legislative Update   |
| Discussion   |
| Public Engagement in the Vice President's Cancer Initiative                              |
| Discussion 11  |
| The Role of the Research Advisory Community in the Vice President's Cancer Initiative 11 |
| Closing Comments and Wrap-Up   |

# Welcome and Opening Remarks

Mr. Arons, Ms. Williams

Ms. Williams welcomed the attendees and explained that this meeting would focus mainly on the Vice President's Cancer Initiative. She congratulated those present who will be serving on the Blue Ribbon Panel of scientific experts, cancer leaders, and patient advocates that will inform the scientific direction of the Vice President's Cancer Initiative. Panel members include Mr. Arons, Dr. Ellen Sigal, Dr. Lowy, Dr. Singer, and Dr. Jaffee. Dr. Singer and Dr. Jaffe will serve as two of the co-chairs of the Blue Ribbon Panel. After being updated on the Vice President's Cancer Initiative, NCRA members discussed the role of advocates and how the advocacy community can engage and contribute moving forward.

Mr. Arons welcomed all participants and stated NCRA is fortunate to have Dr. Lowy, Dr. Jaffee, and Dr. Singer present to provide a detailed briefing about the initiative to help frame the NCRA's discussion.

# National Cancer Institute Update

Dr. Lowy

#### NCI Budget Outlook

There is strong bipartisan support for cancer research funding. The advocacy community has a key role to play in helping reach the goal of making faster progress in helping cancer patients. In addition to federal funding, the need for private and philanthropic contributions should be recognized.

The NCI budget remained fairly level between 2005 and 2015, with the exception of the increased funding from the American Recovery and Reinvestment Act in 2009 and 2010. This decade of level funding resulted in progressively decreasing purchasing power. The fiscal year (FY) 2016 and FY 2017 budgets indicate a more encouraging trend, with a 5 percent and 13 percent increase, respectively, to the NCI budget.

The vast majority of the 5 percent total increase (about \$265 million) in the FY 2016 budget will be used for the President's Precision Medicine Initiative in Oncology, which was initiated in pilot form in 2015 and will move forward both clinically and pre-clinically. The remainder of the increase will be used for investigator-initiated research project grants (RPG pool), support grants for 21 of the 69 NCI-Designated Cancer Centers, and overhead and inflation costs.

#### The Vice President's Cancer Initiative

The chief aim of the Vice President's Cancer Initiative is to make a decade's worth of progress in cancer research in five years. Vice President Biden said, "We have an opportunity to fundamentally change the trajectory." He emphasized the need to break down silos within and among academia, government, and the private sector. Data sharing is also critical for improving our understanding of cancer and making precision oncology a reality.

The opportunity for focused research to accelerate progress requires taking advantage of current advances and technological innovations and applying them to projects that will have a substantial impact. An example is the recently initiated project to develop therapies for cancers that are driven by *KRAS* gene mutations. These cancers, which do not respond well to chemotherapy and have a poor prognosis, account for more than 135,000 cases per year in the United States, more than 30 percent of human cancers.

The Vice President's Cancer Initiative proposes preventive interventions that include targeting pre-cancer and early cancer with a vaccine or other immunological approaches; developing screening tests that find new forms of cancer, not just recurrent ones; and improving the standard of care for prevention, screening, and treatment. It will be important to increase combination therapy trials; develop new treatments for pediatric cancer, which has been resistant to inhibitors; increase participation in clinical trials; develop a drug formulary to facilitate combination trials; expand various -omic analyses, including single-cell analysis to examine non-cancer cells surrounding the cancer; increase basic research; and develop an "exceptional opportunities" fund to encourage new and innovative research ideas. This would all be part of the FY 2017 budget.

#### **Discussion**

Dr. Lowy elaborated on the funding for only 21 of the 69 Cancer Centers. There are three categories of Centers with funding floors for each: Basic (\$1.2 million), Regular (\$1.4 million) and Comprehensive (\$1.5 million). Because 21 of the 69 Centers were below those minimal funding levels, \$10 million was allocated to bring them up to the base. Going forward, as the Centers apply for renewals, those that do well will get an increase in their budgets. Grants range from \$1.2 million to \$7 million, and even large grantees will get an increase if they score well.

Dr. Lowy explained the funding for the RPG pool for FY 2016. Grants that are ending in 2016 total \$447 million. NCI will provide an additional \$50 million for a total of \$500 million available for new and competing awards. Approximately 90 percent of this money will fund investigator-initiated projects outside of requests for applications. Funding will remain at the FY 2015 level. If funding increases in FY 2017, the RPG pool could be increased. If not, it would be necessary to add \$78 million to stay complete.

# **Overview: The Vice President's Cancer Initiative**

Dr. Singer

The goals of the Vice President's Cancer Initiative are to accelerate progress in cancer, including prevention and screening; encourage greater cooperation and collaboration within and among academia, government, and the private sector; and enhance data sharing.

The organizational workflow of the Vice President's Cancer Initiative begins in the Office of the Vice President and proceeds through the Initiative's Federal Task Force, NIH and NCI, the National Cancer Advisory Board (NCAB), the Blue Ribbon Panel, and the Blue Ribbon Panel's Working Groups. The Task Force is composed of federal agencies, including the Department of Health and Human Services, including NIH, NCI, and the Food and Drug

Administration (FDA); the Department of Commerce; the Department of Defense; the Department of Energy; the Department of Veterans Affairs (VA) and the National Science Foundation. The Task Force goals are to accelerate understanding of cancer, support greater access to new research and data, improve patient access and care, address unnecessary regulatory barriers, and identify opportunities for public-private partnerships. NCI will be involved mainly with supporting new research, but this component must be integrated with the other goals, such as access to care and removing barriers. NCRA can help create that bridge.

NCI is charged to create a Blue Ribbon Panel composed of scientific experts, cancer leaders, and patient advocates to develop scientific opportunities that could be accelerated. The Blue Ribbon Panel will generate working groups on various topics and engage a wide representation of leaders in the cancer community. The working groups will report back to the Blue Ribbon Panel, which will in turn report their findings and recommendations to the NCAB, which will use the information to provide final recommendations to the NCI Director. Possible topic areas for the working groups include prevention and cancer vaccine development, early cancer detection, cancer immunotherapy and combination therapy, genomic analysis of tumor and surrounding cells, enhanced data sharing, pediatric cancer, and exceptional opportunities funding.

There will be active outreach to the advocacy community and the public to ensure the broadest possible participation in the Vice President's Cancer Initiative. Approaches for contacting the Blue Ribbon Panel include an online public idea repository, emails, workshops, and professional meetings.

The Blue Ribbon Panel timeline is very aggressive. Working groups will be generating recommendations by May 2016, and the Blue Ribbon Panel will present a report to the NCAB by August. Funding of awards is expected to occur in the summer of 2017.

Patient participation is critical. There are two representatives of this group on the Blue Ribbon Panel (Mr. Arons and Dr. Sigal), and there will also be patient representation in the working groups. NCRA is a natural channel for engaging the patient and advocacy community, particularly in the areas of dissemination, standard of care, and policy issues that must be addressed to accelerate research.

#### Discussion

Upcoming opportunities for public and advocacy engagement include the American Association for Cancer Research meeting later in April, a planned mid-summer workshop, a summit to be sponsored by the White House, and occasional open sessions of the Blue Ribbon Panel.

Better screening brings the danger of overtreatment, which raises the need for better medical and patient education. Dr. Singer agreed that this is a concern and noted the launch of a new molecular and cellular screening process to distinguish benign lesions from malignant lesions with greater accuracy.

NCRA members offered the following suggestions:

- Include payers in the Vice President's Cancer Initiative to address policy and access areas.
- Consider a working group on access from a consumer perspective.
- Consider including scientists whose labs are now closed but who can offer a wealth of good information as mentors.
- Leverage the expertise of international researchers. Dr. Lowy noted that he is meeting with international leaders about opportunities for co-funding and is involved with data-sharing discussions at the international level.
- Involve engineers to bring new and different approaches to existing problems. Dr. Singer noted that NCI has programs that involve engineers, physicists, and mathematicians to develop predictive algorithms. The working groups will have representatives from other disciplines, particularly for new technologies.
- Create a working group specifically on disparities. Dr. Lowy noted that two BRP members (Dr. Edith Mitchell and Dr. Maria Elena Martinez) are very active in this area and will ensure that this is part of the focus.

Two issues related to diversity were raised: (1) Would the Vice President's Cancer Initiative encourage equity in the pool of researchers entering cancer research? (2) Will there be a specific commitment to ensure that under-resourced communities are connected to and served by the Vice President's Cancer Initiative?

Dr. Singer noted that there would be considerable overlap in the working groups that would address the need to maintain a robust and diverse cancer research community through a variety of different mechanisms. Dr. Lowy stated that NCI is supporting research that provides more insight into biological, lifestyle, and environmental factors in health care access and use. The working groups will look explicitly at how to improve cancer care for people who have fewer resources, including underrepresented populations and those in rural locations. At the level of the Task Force, there are also other agencies beyond NIH that can serve as catalysts.

Increasing funding for young investigators, especially to bring more into pediatric research, is not an explicit topic for the Vice President's Cancer Initiative, but it might be addressed with the exceptional opportunities fund. Dr. Lowy noted that NIH is trying to implement new ways to increase participation of young physicians in research. The single most important driver is a sustained increase in the NIH budget over a long period of time.

Dr. Lowy addressed the issue of funding. The Blue Ribbon Panel's job is to identify the most important opportunities in research and then for NCI to develop a plan, based on the assumption that it will receive the full appropriation. With full funding, NCI will be in a position to accelerate progress; otherwise, research will be restricted.

Mr. Arons invited Dr. Sigal, a member of the Blue Ribbon Panel, to address the group.

Dr. Sigal noted that outcomes for patients and survivorship are very important issues for the Blue Ribbon Panel. She emphasized the need for broad input from the advocacy community and assured all that she will be a voice for advocates and patients.

# Scientific Vision: The Vice President's Cancer Initiative

Dr. Jaffee

Dr. Jaffee began her talk emphasizing that in this endeavor, we are all a team, and the patient is the "North Star".

The topic areas presented today for the working groups to consider are preliminary suggestions that will be considered by the Blue Ribbon Panel. Other topics might be put forward when the Blue Ribbon Panel meets later today. The overarching goal is to identify barriers to progress. Rationales for choosing some of the potential topics included:

- **Prevention and cancer vaccine development.** This overlaps with cancer immunotherapy, which turns some cancers into chronic issues and enables long-term durable responses. Integrating with detection and prevention will be important. New models are needed to move from virally-associated cancers to genetically based cancers to understand what happens in the tumor microenvironment to promote cancer. New vector delivery systems will be needed. The other part of the immunotherapy piece is to look at antibodies that inhibit T-cells. Collaboration among technological experts, including experts in bioinformatics and imaging, will be needed so that tumors can be digitized into 3-D pictures.
- Early cancer detection, tumor evolution, and progression. Cancer genetics has improved the ability to find cancers by their -omics, not where they originate, which is moving us toward precision medicine. Tumor heterogeneity requires understanding the genetic make-up and the tumor microenvironment to understand how genes that have mutated into cancer-promoting cells can be turned on and off. Early detection will allow interventions at early stages. This will require imaging and predictive computational modeling for 3-D visualization.
- **Pediatric cancer.** Pediatric cancer differs biologically from adult cancers. It is very difficult to develop inhibitors of pediatric cancer. Technological advances are critical to begin to apply immunotherapy to pediatric cancers.
- Enhanced data sharing. Enhanced data sharing is a high priority, and it requires shared technologies that allow for integration of patient databases. Collaboration is needed with FDA and pharmaceutical companies. Overly restrictive regulations should be addressed and modified, and HIPAA (Health Insurance Portability and Accountability Act) requirements must be considered.
- Enhancing clinical trials. New trial designs are needed to move agents more quickly or to test two novel drugs at the same time. Multicenter studies with biologic endpoints are needed to help better understand how to combine treatments. How to ensure that more patients are eligible for clinical trials must be addressed, and technologies must be integrated to link databases and minimize HIPAA issues. Contracting is often the biggest barrier to moving things forward faster.

• **Dissemination and population science.** Health care delivery must be more standardized. Many physicians are not aware of the latest advances, which limit access for their patients. This working group will focus on the research aspects of how to address disparities such as determining the issues that prevent enrollment of more minorities into clinical trials and how clinical trials can be made more available to underserved populations. Research is needed to identify these gaps. More research is also needed on survivorship issues. People are living with cancer longer, and a better understanding is needed about how they can conduct normal life activities.

# NCRA Discussion and Public Comment Period

Dr. Singer, Dr. Jaffee, Mr. Arons, Ms. Williams

A theme that stood out was capacity to identify areas of opportunity for acceleration when the particular field may be under-developed. Dr. Jaffe said the BRP's job is to recommend priorities, perhaps in the first year prioritizing areas where fast progress can be made, then later funding areas that require more progress. The technologies exist, and the Blue Ribbon Panel must think broadly.

NCRA members discussed the Vice President's Cancer Initiative's approach to disparities, suggesting that disparities be addressed widely from the beginning, not just in the dissemination stage, and asking about possible research interventions that would help overcome disparities. Dr. Singer noted that integrating disparity research into policy considerations would be weighed at the Task Force level, through working groups on policy, disparities, and dissemination not related to research. Dr. Jaffee added that disparities must be addressed across working groups, for example, in the immunology and cancer progression components. Research is needed to define barriers, such as why some clinical trials have eligibility requirements that restrict certain populations, so actual changes can be made. Prevention screening must be available to all, and those who work with disparities and underserved populations must be represented in the working groups.

The Enhancing Clinical Trials Working Group should address decreasing participation in clinical trials; enrollment is less than 10 percent nationwide. It was noted that clinical trials rarely focus on the elderly.

The lack of drug development for pediatric cancer should be addressed, and it was suggested that payers could be helpful here. A separate working group would be needed for adolescent and young adult cancer because there are many different psychosocial issues for this population, and they do not have the same survival rate. Dr. Jaffee noted that the Vice President's Cancer Initiative is focused on research, but there will be a separate pharmaceutical-academic partnership to address drug development.

NCRA members offered the following suggestions:

- Capitalize on the technology through basic science, such as mouse modeling on how drugs affect the heart.
- For survivorship research, look at issues during (not just after) treatment because data are lacking on the measurable collateral damage of cancer treatments. It might be

possible to determine which patients are more likely to get complications like neuropathy, for example.

• Ensure that an infrastructure of resources is in place so that the findings of the Vice President's Cancer Initiative are things that are needed and can be used by a broad representative group.

Mr. Arons opened the floor for public comments and questions:

- Given the impending change in administrations, will the Vice President's Cancer Initiative be a permanent program? Dr. Lowy said he is heartened by the strong bipartisan support in Congress and believes the Vice President's Cancer Initiative will continue with a new administration.
- Will the working groups' recommendations be very specific things that can actually be implemented? Dr. Lowy said that the recommendations would cover a number of different areas within cancer research, but not *all* of cancer research. There will be specific recommendations identifying promising scientific opportunities.
- How will the Blue Ribbon Panel tackle areas with a significant increase in cancer rates, such as liver cancer? Dr. Lowy said that the Vice President's Cancer Initiative is focused on areas of cancer research rather than specific cancers. Liver cancer rates are high, and this area is critically important. To make real progress with liver cancer, we must focus on primary and secondary prevention, as well as better treatment. We are making key collaborative connections to look at areas such as hepatitis C, obesity, liver fibrosis, and cirrhosis because of the heterogeneity of liver cancer.
- A member of the public praised Dr. Lowy's work and urged NCRA members to work with their advocacy groups to let Congress know that this endeavor must not end with this administration.

# Legislative Update

Ms. Holohan, Ms. Gibbons

The FY 2016 budget included a \$2 billion increase for NIH (\$265 million increase for NCI). Authorizing bills are currently in play as authorizers consider NIH funding issues. The President's FY 2017 budget request increases NIH funding by 2.6 percent above FY 2016 and increases NCI funding by \$680 million above the FY 2016 level specifically to support the Vice President's Cancer Initiative. However, the increase being proposed for NIH and NCI is budgeted as mandatory funding as opposed to the discretionary funding typically used for the NIH budget. Medicare, Medicaid, and Social Security are examples of mandatory funding. Creating a new mandatory funding stream requires legislation to authorize the funding along with budget offsets to cover the new costs. The President's budget request included a \$1 billion cut to NIH discretionary funding.

At the March 16 NIH budget hearing before the House Appropriations Committee, many members mentioned their recent visit to NIH, with particular emphasis on the impact of meeting with patients. The members expressed broad bipartisan support for NIH and biomedical research and voiced concerns about the mandatory funding proposal. At the April 7 NIH budget hearing before the Senate Appropriations Committee, members also

expressed bipartisan concern about mandatory funding and the consequent diversion of \$1 billion in biomedical research funds.

Congress wants to find a way to fund NIH. Appropriators have a metric for spending increases, and their allocations (e.g., the amount they have to spend) have not yet been announced. Short-term fixes will not be adequate.

Ms. Gibbons described the work of NCI's Office of Government and Congressional Relations in arranging congressional briefings with professional societies and advocacy groups and bringing delegations to visit NIH to see how programs are being conducted. She invited NCRA members to reach out to OAR for ways to work together.

#### Discussion

Ms. Williams said that OAR invites questions and comments and is ready to help advocates with whatever they need. She added that as the work of the Blue Ribbon Panel progresses, she expects OAR will have a key role working with the advocacy community.

Ms. Holohan elaborated on the budget process, noting that finding the offset is the big issue. To this end, it is possible that there will be an amendment brought to the floor outside of the health committee. She emphasized the effect that meeting patients has on Congress members, recounting a recent meaningful visit congressional leaders had at NCI with two melanoma patients, one 12 years post-treatment and one just undergoing treatment. The Vice President's Cancer Initiative provides a great opportunity to come together with a clear and coherent voice.

# Public Engagement in the Vice President's Cancer Initiative

Ms. Murphy

The goal of the public engagement strategy is to encourage the best scientific ideas from a wide range of disciplines and the American public. The audience we want to reach includes cancer researchers and global health advocates, health care providers, industry groups, the data-sharing community, and the interested public (educators and students, citizen science communities, and community organizations). The Blue Ribbon Panel will be provided with regular summaries of the ideas received from this audience.

There are three ways to submit ideas: (1) online (<u>http://cancerresearchideas.cancer.gov</u>), (2) by email (<u>cancerresearch@nih.gov</u>), and (3) over the phone (1-800-4-CANCER). A digital toolkit, which includes items that can be put onto websites to spread the word, will be available, and a Google Hangout will be hosted. All will be live by April 25. The toolkit and Google Hangout information will be sent to NCRA members.

The online platform, using IdeaScale software, requires that users first register. There is an area to type in ideas and the capability to search for and comment on other ideas that have been submitted. There is a character limit, but there is also the ability to add an attachment. Users click on one of the research areas of interest listed on the homepage, which will align

with the working group topics. The research topic pages include a brief description about the state of the science. There is also a link to the "Tell your story to the White House" page.

# Discussion

Suggestions for the public engagement strategy include:

- Provide examples on the website of the kind of submissions being sought to help those who want to contribute but are intimidated by the process.
- Be prepared to adapt the online platform to concentrate the public input more narrowly or more specifically as the BRP refines its focus on particular categories.
- Tailor the messaging to the audience.
- Consider allowing voting on the various ideas to see which have the most positive buy-in.
- Consider using other social media strategies such as texts and mobile apps.
- Provide feedback on individual submissions both to validate good ideas and educate people about research.
- Consider posting the reports sent to the Blue Ribbon Panel on the public access website.
- Put specific questions on the website that NCI would like public input on.
- Continue the online platform even after the Blue Ribbon Panel makes recommendations to enable long-term engagement of the public with implementation.

This public engagement strategy is just one access point to connect with the public and the broader scientific community. The working groups will be very inclusive, and one of their roles is to bring together a wide range of participants to "connect the dots" with research and work being done by outside groups.

# The Role of the Research Advocacy Community in the Vice President's Cancer Initiative

#### Mr. Arons

Mr. Arons asked NCRA members to describe what they consider essential for the Vice President's Cancer Initiative to be successful in changing the trajectory and accelerating progress in cancer:

- Have a sense of urgency because there is a narrow window of time available to make the Vice President's Cancer Initiative move to such a point that it would be difficult for future administrations or Congress to pull back from it. We can't afford to stagnate by trying to satisfy everyone at the table.
- Concentrate on small projects that will yield success early to get buy-in and demonstrate the value of the Vice President's Cancer Initiative while building momentum.
- Tailor messaging to make clear that the Vice President's Cancer Initiative is really extraordinary.
- Make an explicit commitment to address disparities and access across the spectrum.
- Have the Blue Ribbon Panel evaluate other cancer research programs to identify what was successful, what failed, and what tools were used to prioritize.

- Use the power of inspiration to change attitudes. People are often skeptical of politics, so our role as we take this back to our communities is to get people to sense the great excitement of the endeavor and inspire them to participate in the commenting phase, especially the younger generation.
- Solve the puzzle of the *RAS* gene mutations. Finding treatment for *RAS*-driven cancers would make a huge impact.
- Include the "hard-to-reach and hard-to-treat" populations from the beginning. This will have a valuable "trickle up" effect and send a strong sign to these groups that are often off the radar or not invited to the table that they will not be allowed to languish.
- Emphasize the "exceptional opportunity" component by soliciting unusual disciplines and venture communities to bring creative and innovative thinking to high-risk problems that are often ignored because of the difficulty in getting grants for highrisk studies.
- Support the recommendations. Don't get caught up on semantics. Keep all stakeholders informed. Use social media extensively.
- Be steady and don't hurry things. As a guiding question, ask: What can NCI do to contribute to the Vice President's Cancer Initiative by virtue of what it is that others cannot? It can call people together in an extraordinary way to shape this effort. If patients are indeed the "North Star," use the people in this room to bring patients in when that is needed. We have a legion of people who need this Initiative and can effectively communicate that.

Dr. Lowy thanked the NCRA members and addressed some of their comments:

- There are two very good opportunities for early wins that relate to the Vice President's emphasis on breaking down silos: (1) the encouraging movement among our academic, pharmaceutical, biotechnology, and international colleagues to coalesce around data sharing and (2) the possibility that the VA will sign on to a single institutional review board (IRB), which would mean we could access research they support.
- The "exceptional opportunities" component is not a dustbin. One area that might benefit from a focused effort is the *Myc* oncogene that involves a wide range of tumors.
- The disincentives for patients participating in clinical trials could be addressed by improving the reimbursement for the health care providers who see patients on clinical trials. This would be done at the level of private payers, not at the level of NCI. It is important to hear from NCRA about incentivizing involvement of patients in clinical trials and increasing dissemination of what we already know works.

NCRA members commented on Dr. Lowy's clinical trials thoughts:

- Only about 4 percent of eligible cancer patients nationwide are in clinical trials. A major public campaign is needed to educate the medical establishment and the public about clinical trials.
- Devise a way to ask patients a series of questions and then provide a report of what trials are specifically available for them.

- Re-think whether public education is effective. The most effective conduit to clinical trials is the doctor talking to the patient.
- Lack of participation is a cultural problem. Pediatric participation in clinical trials is much higher than the national average because enrollment in a clinical trial is considered standard of care in pediatrics. The realization that participation in a clinical trial provides state-of-the-art care, regardless of what group one is randomized to, needs to be more widely understood in the adult population.
- IRBs are very strict about what potential participants can be told and usually prohibit saying that participants will receive better care.

Ms. Williams described NCRA involvement as part of the scaffolding that builds beyond the BRP working groups. She asked how OAR could keep members invested and supplied with the tools they need for outreach to their communities. Members made suggestions about what NCRA could do to help advance the Vice President's Cancer Initiative:

- Initiate teleconferences with key persons in the various advocacy communities to share a summary of this meeting and encourage them to use the NCI public engagement tools to make their voices heard. As more information evolves, host additional webinars.
- Be available to assist the Blue Ribbon Panel as members of the working groups.
- Have OAR provide NCRA members with talking points so they can speak with a consistent voice. Update the talking points as the Vice President's Cancer Initiative evolves.
- Bring payers into the conversation so they can gain more insight into the research process and see clinical trials as value-based care. Payers should be at the table early to hear the messages.
- Schedule a conference call with NCRA in the next few weeks when more is known about the Blue Ribbon Panel's focus and where the overlay for policy is. At that point, NCRA could consider making its own formal recommendations.

# **Closing Comments and Wrap-Up**

Mr. Arons, Ms. Williams

Ms. Williams said she would convene a conference call when more information is available from the Blue Ribbon Panel so NCRA could consider its next steps. A meeting of NCRA will be convened this summer/fall at a date to be determined.

Ms. Williams thanked all the attendees for this very informative meeting, which was so valuable to the advocacy office. NCI recognizes the great need for community engagement, and OAR will be providing NCRA with the tools it needs to engage the advocacy community and bring information back to NCI.