

NATIONAL INSTITUTES OF HEALTH
DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES (COPR)

MEETING MINUTES

October 26, 2007

**NATIONAL INSTITUTES OF HEALTH (NIH)
OFFICE OF THE DIRECTOR
DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES (COPR)**

**Fall 2007 Meeting
Building 31, C-Wing, Conference Room 6, NIH Campus
Bethesda, Maryland**

October 26, 2007

NIH Participants

Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH
John T. Burklow, Director for Communications and Public Liaison, Office of the
Director, NIH
Kelli L. Carrington, M.A., Executive Secretary, COPR, and Public Liaison Officer, Office of
Communications and Public
Liaison, Office of the Director, NIH

COPR Members Attending

Syed M. Ahmed, M.D., Dr. P.H., M.P.H.
Craig T. Beam
Christina L. Clark, M.A., M.B.A.
Naomi Cottoms, M.S.
Linda Crew, M.B.A., R.N.
Valda Boyd Ford, M.P.H., M.S., R.N.
Elmer R. Freeman, M.S.W.
Elizabeth Furlong, R.N., Ph.D., J.D.
Brent M. Jaquet
Nicole Johnson, M.A., M.P.H.
Nicolas Linares-Orama, Ph.D.
Cynthia A. Lindquist, Ph.D., M.P.A.
Matthew Margo, LL.M.
Marjorie K. Mau, M.D., M.S.
Anne Muñoz-Furlong
Ann-Gel S. Palermo, M.P.H.
James H. Wendorf, M.A.

COPR Members Not Present

Wendy Chaite, Esq.
Michael Manganiello, M.P.A.

ACD Liaison

Annelise E. Barron, Ph.D.

Speakers

Barbara Alving, M.D., Director, National Center for Research Resources, NIH

Jeremy M. Berg, Ph.D., Director, National Institute of General Medical Sciences, NIH

Patricia A. Grady, Ph.D., Director, National Institute of Nursing Research, NIH

Alan I. Leshner, Ph.D., Chief Executive Officer, American Association for the Advancement of Science

Yvonne T. Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development, NIH

Lawrence A. Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research, NIH

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EXECUTIVE SUMMARY

The meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on October 26, 2007. Elias A. Zerhouni, M.D., NIH Director, could not attend the meeting because of unexpected family commitments. Raynard S. Kington, M.D., Ph.D., NIH Deputy Director, welcomed the COPR members and presenters; in addition, he recognized Ms. Kelli L. Carrington as the new Executive Secretary for the COPR.

Dr. Kington thanked Christina L. Clark, M.A., M.B.A., and James H. Wendorf, M.A., COPR's Meeting Agenda Work Group Cochairs, for their extensive support of both the Council and the NIH staff during the Council's recent transition period.

Dr. Kington recognized and thanked the four retiring COPR members: Wendy Chaite, Esq.; Craig T. Beam; Michael Manganiello, M.P.A.; and Nicolas Linares-Orama, Ph.D., M.P.A. Dr. Kington gave a special thanks to COPR member Marjorie K. Mau, M.D., M.S., for agreeing to participate in the Director's Advisory Council's Working Group on Peer Review and on the newly established NIH Council of Councils.

Dr. Kington thanked Matthew Margo, LL.M., for helping NIH produce a 30-minute interview with Dr. Zerhouni and CBS reporter Charles Osgood for the CBS Cares radio program. He also noted that Annelise E. Barron, Ph.D., liaison to COPR from the Director's Advisory Council (ACD), would be retiring in December and thanked her for working so well with Wendy Chaite, COPR liaison to ACD, to enhance communications between the two committees.

Dr. Kington provided updates in a number of areas.

First, he reported that in September 2007, NIH launched the New Innovator Award with 30 recipients; these awards reinforce the notion that novel ideas and new investigators are essential ingredients for scientific progress.

Also in September, 12 new Pioneer Award recipients were announced; these awards support scientists at any career stage.

Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, received three distinguished honors this year: National Medal of Science, Lasker Prize, and George M. Kober Medal.

Nobel prizes were awarded to two longtime NIH grantees, Mario R. Capecchi, Ph.D., of the University of Utah School of Medicine, and Oliver Smithies, Ph.D., of the University of North Carolina at Chapel Hill.

The National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse were honored with the prestigious Governor's Award by the Academy of Television Arts and Sciences.

The NIH Public Trust Initiative recently launched the Partners in Research program to identify and encourage innovative models of community partnerships in research.

On September 12, in a ceremony in the U.S. Capitol, NIH and the National Aeronautics and Space Administration (NASA) signed a memorandum of understanding that will help American scientists use the International Space Station to answer important questions about human health and disease.

This past summer the Biomarkers Consortium launched a Web site (www.biomarkersconsortium.org) as part of its efforts to encourage researchers to submit projects that involve possible biomarkers.

Earlier this month, Dr. Zerhouni traveled to India and Japan, where he participated in meetings with high-level scientists and officials and delivered three major presentations. He was accompanied by Roderic I. Pettigrew, M.D., Ph.D., Director of National Institute of Biomedical Imaging and Bioengineering (NIBIB), and Roger I. Glass, M.D., Ph.D., Director of the Fogarty International Center (FIC). These meetings underscore NIH's commitment to enhancing global collaboration in biomedical research and to improving global health.

Dr. Kington took time to reflect on the NIH's loss of the Director of the National Center for Complementary and Alternative Medicine (NCCAM) Stephen E. Straus, M.D, who died of brain cancer on May 14, 2007 after a valiant struggle.

Dr. Kington announced the August 2007 release of the NIH Genome Wide Association Policy, which promotes data sharing to identify common genetic factors that influence health and disease. The NIH continues to implement the policy on enhancing public access to archived publications resulting from NIH-funded research (Public Access Policy), which took effect on May 2, 2005 (<http://publicaccess.nih.gov>).

David A. Schwartz, M.D., Director of the National Institute of Environmental Health Sciences, has stepped down from his position so that a comprehensive management assessment of that institute could be conducted. Sam H. Wilson, M.D., is the Acting Director.

Dr. Kington recognized numerous NIH advances during the previous 6 months, including the participation of NIH staff in 31 congressional hearings on topics including Alzheimer's disease, pandemic influenza, stem cell research, emergency preparedness, postpartum depression, and drug-resistant tuberculosis. President Bush has vowed to veto both the House and Senate fiscal year (FY) 2008 appropriations bills, which include \$110.9 million for the National Children's Study, a \$300 million transfer for global AIDS (the amount for fiscal year 2007 was \$99 million), and direct funding for the Common Fund (\$495.153 million in the House and \$531.3 million in the Senate); these bills include language on mandatory public access.

In all, 10 appropriations hearings were held on the FY 2008 NIH budget—3 in the House and 7 in the Senate. NIH continues to move forward with implementing the requirements of the NIH Reform Act. In FY 2008, the NIH plans to spend a combined \$30 million from the Common Fund on the first year of funding for two new initiatives associated with the general theme of “new pathways to discovery”—the Human Microbiome Project and the Epigenomics Program.

Patricia A. Grady, Ph.D., Director of the National Institute of Nursing Research, and Yvonne T. Maddox, Ph.D., Deputy Director of the National Institute of Child Health and Human

Development, talked about the innovative, new NIH Partners in Research program, a part of the NIH Public Trust Initiative that grew from the Public Trust Workshop, hosted by COPR in October 2004.

Jeremy M. Berg, Ph.D., Director of the National Institute of General Medical Sciences provided an overview of the NIH Director's Pioneer and New Innovator Awards, which evolved out of the NIH Roadmap.

Barbara Alving, M.D., Director of NCRP, reviewed NCRP's efforts in community engagement, including the Clinical and Translational Science Award, Institutional Development Award, and the Research Centers in Minority Institutions programs.

Alan I. Leshner, Ph.D., Chief Executive Officer of the American Association for the Advancement of Science and former director of the National Institute on Drug Abuse, talked about the evolving relationship between science and society.

Lawrence A. Tabak, D.D.S., Ph.D., Director of the National Institute of Dental and Craniofacial Research, discussed the efforts of NIH to enhance the peer review process.

Christina L. Clark, M.A., M.B.A., and James H. Wendorf, M.A., cochairs of the COPR Meeting Agenda Work Group, provided an overview of the COPR's Work Group Day.

Syed M. Ahmed, M.D., Dr. P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H., cochairs of the COPR Role of the Public in Research Work Group, reported the recommendations and the action items discussed during the breakout session of their work group the previous day:

- Develop proposed criteria and/or guidance for review panels to use for gauging community engagement.
- Create broad guidelines for educating researchers and the lay public on community engagement.
- Identify and propose definitions for community engagement and public participation.

Anne Muñoz-Furlong and Brent M. Jaquet, cochairs of the COPR Communications Work Group, reported communications strategies discussed during the breakout session of the Communications Work Group on the previous day:

- Embrace the NIH “Ambassador Program” to promote bilateral communication.
- Promote the Ad Council Campaign in partnership with nonfederal groups.
- Support a NIH community engagement activity modeled after AmericaSpeaks.
- Examine the NIH Internet strategy and make suggestions to increase NIH’s visibility among the public.
- Explore opportunities for alliances with national civic organizations.
- Increase activities aimed at children.

COPR members received updates from Annelise E. Barron, Ph.D., the Advisory Committee Director liaison to COPR. Public Comments were presented by Vlady Rosenbaum, Ph.D. of COPD-ALERT.

WELCOME AND INTRODUCTIONS

Raynard S. Kington, M.D., Ph.D.

Deputy Director, National Institutes of Health

The 18th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on October 26, 2007. NIH Director Elias A. Zerhouni, M.D., could not attend because of unexpected family commitments. NIH Deputy Director Raynard S. Kington, M.D., Ph.D., welcomed the COPR members and presenters, and he recognized the new Executive Secretary for the COPR, Kelli L. Carrington, M.A., and thanked her for her hard work. Dr. Kington acknowledged Christina L. Clark, M.A., M.B.A., and James H. Wendorf, M.A., the COPR's Meeting Agenda Work Group cochairs, for their support of both the Council and the NIH staff during the Council's recent transition period.

Dr. Kington recognized and thanked the four retiring COPR members: Wendy Chaite, Esq.; Craig T. Beam; Michael Manganiello, M.P.A.; and Nicolas Linares-Orama, Ph.D., M.P.A. Dr. Kington reported that Ms. Chaite and Mr. Manganiello were unable to attend because of a family emergencies. Dr. Kington gave a special thanks to COPR member Marjorie K. Mau, M.D., M.S., for agreeing to participate in the Director's Advisory Council's Working Group on Peer Review and on the newly established NIH Council of Councils. Dr. Kington thanked Matthew Margo, LL.M., for helping NIH to produce a 30-minute interview with Dr. Zerhouni and CBS reporter Charles Osgood for the CBS radio program CBS Cares.

NIH DIRECTOR'S UPDATE

Raynard S. Kington, M.D., Ph.D.

Deputy Director, National Institutes of Health

Dr. Kington reported that during the past year Dr. Zerhouni and his office reached out to many groups around the country and around the world, speaking with scientific associations, advisory councils, and other constituencies in an effort to offer transparency about the challenges that the current budget poses to NIH, researchers, and the public, which ultimately benefits from NIH research.

Status of the NIH Budget

The President has vowed to veto both the House and Senate fiscal year (FY) 2008 appropriations bills, which include \$110.9 million for the National Children's Study, a \$300 million transfer for global AIDS (the amount for FY 2007 was \$99 million), direct funding for the Common Fund (\$495.153 million in the House and \$531.3 million in the Senate), and language on mandatory public access. Dr. Kington stressed the need to remain "cautiously optimistic" during a time of uncertain budgets. In all, 10 appropriations hearings were held on the FY 2008 NIH budget—3 in the House and 7 in the Senate.

Legislative Update

NIH staff participated in 31 congressional hearings on such topics as Alzheimer's disease, pandemic influenza, stem cell research, emergency preparedness, postpartum depression, and drug-resistant tuberculosis. NIH continues to move forward with implementing the requirements in the NIH Reform Act of 2006.

The centerpiece of the act is the creation of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), which empowers NIH to move nimbly and quickly to address issues that will have an effect on the broader field of biomedical research. The new law restructured the reporting of NIH to Congress, eliminating many reports and creating several others, including a new biennial report that is intended to provide a more comprehensive, transparent, and accessible portrait of NIH. This report is due to Congress in January 2008.

The act establishes the Council of Councils to advise the NIH Director on matters related to DPCPSI policies and activities, including making recommendations on trans-NIH research that would be supported by the Common Fund, and establishes a Scientific Management Review Board to review the organizational structure of NIH every 7 years.

In the House, in addition to the NIH Overview Hearing under the chairmanship of Representative David R. Obey (D-WI), a single-theme hearing was held: "Substance Abuse and

Mental Health.” In the Senate, Senator Tom R. Harkin (D-IA) held an NIH Overview hearing and six thematic hearings, which allowed each NIH Institute and Center to testify before his subcommittee. This marked the first time in more than a decade that such hearings have been held in the Senate.

New Common Fund Initiatives

The two initiatives to be launched in fiscal year 2008—the Human Microbiome Project and the Epigenomics Program—are associated with the general theme of “New Pathways to Discovery.” These programs both respond to the Common Fund goals of advancing basic knowledge and developing new tools or resources that will be broadly applicable to many research fields. The Human Microbiome Project will support the development of new technologies and improve our knowledge of how changes in the microbiome (e.g., bacteria, fungi, viruses) correlate with changes in human health. The Epigenomics Program will facilitate the development of new tools to more efficiently detect epigenetic changes in the human genome structure and correlate them with specific diseases or health conditions.

Dr. Anthony S. Fauci Receives the National Medal of Science, the Lasker Prize, and the George M. Kober Medal

Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, received three distinguished honors this year. On July 27, 2007, President George W. Bush awarded Dr. Fauci the 2005 National Medal of Science “for pioneering the understanding of the mechanisms whereby the human immune system is regulated, and for his work on dissecting the mechanisms of pathogenesis of human immunodeficiency virus that has served as the underpinning for the current strategies for the treatment of HIV diseases.” Earlier this year, Dr. Fauci also received the George M. Kober Medal of the Association of American Physicians for his work in clinical medicine. On September 28, 2007, Dr. Fauci received the 2007 Mary Wood Lasker Award for Public Service for his role in developing two major U.S. public health programs in AIDS and biodefense: the President’s Emergency Plan for AIDS Relief and Project Bioshield. Upon the announcement, Dr. Zerhouni said, “As a clinician, researcher, and scientific leader, Dr. Fauci has channeled his intellect, compassion, and vision into discoveries and

research programs that have transformed medicine and public health. NIH is extremely proud of him.”

Nobel Prize Winners

The 2007 Nobel Prize in physiology or medicine was shared by two longtime NIH grantees, Mario R. Capecchi, Ph.D., of the University of Utah School of Medicine, and Oliver Smithies, Ph.D., of the University of North Carolina at Chapel Hill. The two researchers were honored, along with Sir Martin J. Evans, Ph.D., of Cardiff University (Wales, United Kingdom), for developing the powerful technology known as “gene targeting.”

NIDA and NIAAA Receive Emmy Award

The Academy of Television Arts and Sciences honored the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) with the prestigious Governors Award for their work with HBO (Home Box Office) on the Addiction Project. This documentary television series reveals the science of addiction and its treatment, recovery, and costs to families and society. The award was displayed for the Council members and meeting attendees.

Public Trust Initiative: Partners in Research Program

The NIH Public Trust Initiative recently launched the Partners in Research program to identify and encourage innovative models of community partnerships in research to facilitate the discovery of new knowledge about the causation, treatment, and prevention of disease. This innovative, new program solicits applications for research grants to develop partnerships between scientific or research institutions and their community organizations. COPR, through its work with the PTI and the 2004 Public Trust Workshop, played an integral role in developing the program.

NIH and NASA Partner for Health Research in Space

On September 12, 2007, in a ceremony at the U.S. Capitol, NIH and the National Aeronautics and Space Administration (NASA) signed a memorandum of understanding that will help American scientists use the International Space Station (ISS) to answer important questions about human health and disease. Dr. Zerhouni and NASA Administrator Michael D. Griffin, Ph.D., welcomed scientists, astronauts, and senators to the event, including Senators Kay Bailey Hutchison (R-TX), Barbara A. Mikulski (D-MD), and Bill Nelson (D-FL). Senator Hutchison was responsible for the legislation that formally designated the U.S. portion of the ISS as a national laboratory. NIH is not funding NASA research; instead, it is publicizing to the scientific community the availability of the space station as an environment for research. NASA, in turn, will advise researchers on implementing NIH-funded projects.

Biomarkers Consortium Update

During the summer of 2007, the Biomarkers Consortium launched a Web site (www.biomarkersconsortium.org) as part of its efforts to encourage researchers to submit projects that involve possible biomarkers. Biomarkers can measure the risk for disease and the status of disease. They can be genetic, biochemical, or immunological measurements of health, images, and cognitive measures, among others.

Dr. Zerhouni Travels to India and Japan

Roderic I. Pettigrew, Ph.D., M.D., Director of National Institute of Biomedical Imaging and Bioengineering (NIBIB), and Roger I. Glass, M.D., Ph.D., Director of the Fogarty International Center (FIC), accompanied Dr. Zerhouni on a trip to India and Japan earlier this month. In India, they met with the Prime Minister, Manmohan Singh, Ph.D., D.C.L. (hon), and the Minister of Science & Technology, Kapil Sibal, LL.M., M.A. Dr. Zerhouni spoke with representatives from the Department of Biotechnology, and the Indian Council of Medical Research. Two agreements were signed, the Letter of Intent on Translational Research and the Joint Statement on the Development of Low-Cost Diagnostic and Therapeutic Medical Technologies. The latter agreement, which will be spearheaded by Dr. Pettigrew, is based on a shared commitment to

improve the health and well-being of the people of both countries by encouraging collaborations and cooperation on the development of diagnostic and therapeutic medical technologies that are inexpensive and operate at the initial point of physician contact, or point of care. Directly following the trip to India, they traveled to Kyoto, Japan, to participate in the Science and Technology in Society (STS) Forum's fourth annual meeting. These meetings underscore NIH's commitment to enhancing global collaboration in biomedical research and to improving global health.

Genome-Wide Association Studies

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease and is working to ensure that GWAS data are used ethically and with the highest possible standards for protecting the privacy and confidentiality of participants. The final GWAS policy was released in August. NIH had received more than 200 comments from the public during development of the policy. The NIH GWAS policy will advance science for the benefit of the public through the creation of a centralized data repository; this policy becomes effective January 25, 2008. NIH has established a working group to serve as the Advisory Committee to the Director; this group will provide independent advice on protecting participants as well as the data. A member of the COPR will be asked to participate in the working group. A full update will be provided to the COPR at the Council's meeting in April 2008.

Leadership Update

Dr. Kington memorialized for those present "an extraordinary leader, outstanding scientist, and close friend to many," Stephen E. Straus, M.D., former Director of the National Center for Complementary and Alternative Medicine (NCCAM), who succumbed to brain cancer on May 14, 2007. As the first director of NCCAM, Dr. Straus was instrumental in establishing it as a credible, rigorous scientific center. On June 11, NIH held a memorial service in remembrance of Dr. Straus, his accomplishments, and his contributions to science and public health. Ruth L. Kirschstein, M.D., is acting Director of NCCAM.

David A. Schwartz, M.D., Director of the National Institute of Environmental Health Sciences, stepped down from his position so that a comprehensive management assessment of the institute could be conducted. Samuel H. Wilson, M.D., is the Acting Director during this process. Dr. Kington asked for comments.

Discussion (COPR Members)

Brent M. Jaquet asked Dr. Kington for an update on the scientific management review board. Dr. Kington explained that this new board, created under the NIH Reform Act of 2006, will create a forum to provide advice related to NIH structure and functions. NIH IC (Institute or Center) directors will hold 9 spots on the board, and the remaining 12 spots will be filled by members of the public. This committee will develop a series of initiatives over the next year that could benefit from the input of the advisory committee.

Mr. Wendorf asked Dr. Kington to identify the NIH programs that will receive cuts in the coming year. Dr. Kington responded that NIH does not expect to make cuts in the coming year, but that the increases will vary widely across NIH. Dr. Kington pointed out that every NIH IC has its own process for setting priorities and that NIH research moves more slowly with less funding. However, it is unusual for NIH to completely stop research in a particular area. Ms. Clark asked for science and research highlights within the NIH intramural programs. Dr. Kington emphasized that the NIH intramural program is a responsive, flexible, and unique resource. It includes the NIH Clinical Center, which helps to translate research from the bench to the bedside. Dr. Kington suggested that COPR members receive a tour of the NIH Clinical Center at a future COPR meeting.

Alan M. Krensky, M.D., NIH Deputy Director for the Office of Portfolio Analysis and Strategic Initiatives, reported on discussions from a recent NIH intramural retreat. More than 400 members of the NIH immunology community came together as part of the NIH autoimmunity initiative to discuss how to apply the current understanding of the immune system to various diseases. Dr. Kington concluded by saying that NIH hopes to develop initiatives in autoimmunity to allow synergy across NIH.

Retiring member Dr. Linares-Orama read a poem he composed for the Council entitled *Diversidad Esplendidad (Splendid Diversity)*. See the Appendix.

NIH PUBLIC TRUST INITIATIVE: COPR UPDATE
Patricia A. Grady, Ph.D., and Yvonne T. Maddox, Ph.D.

Dr. Grady, Director of the National Institute of Nursing Research, and Yvonne T. Maddox, Ph.D., Deputy Director of the National Institute of Child Health and Human Development, described the NIH Partners in Research (PIR) program, a part of the NIH Public Trust Initiative (PTI). The mission of the NIH PTI is to enable the public to understand and to have full confidence in the research that NIH conducts and supports across the country and throughout the world. The PIR program promotes collaboration between community leaders and NIH-supported scientists to improve the public's understanding of the benefits of health care research. Researchers and community leaders apply as co-investigators to receive grant funds.

Dr. Grady expects the scientific community to develop a deeper and better understanding of what is important to the public and of how to work with the public. "If people in the community do not learn about health-related research findings, then we are not doing our job," said Dr. Grady. She stressed the importance of improving the communication of health-related findings to communities. In addition, NIH investigators need to learn about the research needs and interests of the community. Lastly, we expect our scientific community to have a deeper and better understanding of what is important to the public and how to work with the public area so that we can be better informed. Community leaders from voluntary or professional organizations, health groups, faith-based groups, and housing organizations will participate in research that addresses the health needs of their communities. They will play a key role in communicating health-related findings back to their communities.

Dr. Grady pointed out that the COPR, through its work with the PTI and the 2004 Public Trust Workshop, played an integral role in developing the program. A Request for Applications (RFA) was released October 12, 2007. Phase 1 of the initiative will provide grant support for innovative activities for the Community Leader-Scientist partnership.

To receive funding, applicants must describe a proposed collaboration between community partners and investigators. Phase II will consist of the NIH Partners Workshop, where all the partners will meet at NIH to discuss their programs, looking at their successes and challenges along with their plans for the next project year. In 2008, 40 partner pairs will receive funding through the Small Research Grant mechanism (R03). Members of underrepresented groups are strongly encouraged to apply

Dr. Maddox described the NIH Partners Workshop and thanked the 27 NIH Institutes and Centers for their support and willingness to review applications. Community partners, research organizations, and program officials from NIH will attend the workshop, where participants will learn about true partnerships. Dr. Maddox provided examples of currently funded true partnerships: HIV/AIDS researchers collaborating with advocates on adherence to trials and researchers in behavior working with faith-based organizations to test methods for disseminating messages on preventing obesity. Partners will learn how to share research findings with the media. Dr. Maddox emphasized that progress in research depends on the community's understanding and endorsing the benefits of research. Her office plans to disseminate information on the needs of the researchers to communities. Dr. Maddox expects this will increase the community's willingness to partner with researchers.

Discussion (COPR Members)

Syed M. Ahmed, M.D., Dr. P.H., M.P.H., expressed concern that 1 year would not be enough time for the NIH PIR program grantees to demonstrate results; Dr. Grady agreed. She explained this is a pilot focused on starting small discrete projects that will ideally demonstrate new approaches for potential long-term studies.

Mr. Jaquet asked about NIH outreach plans to nonscientists unfamiliar with the NIH grant proposal process. He wondered whether NIH would depend on scientists in the community to spread the word. Dr. Grady responded that NIH is circulating the RFA widely to public groups. "More often the scientists will approach the community member, but we anticipate it can go either way," explained Dr. Grady. She also pointed out that the NIH PTI Web site includes a

Frequently Asked Questions section where community members can ask questions to NIH staff. Dr. Kington added that a number of medical schools are beginning to create dean-like positions at medical schools to facilitate community outreach, serving as common touch stones for the program.

Ann-Gel S. Palermo, M.P.H., expressed interest in participating in the NIH Partners Workshop to learn about the experiences of the grantees, because the program relates to the COPR's broad focus on the role of the public in research. Dr. Kington stated that NIH would plan to involve the COPR during that time.

COPR members shared their passion for disseminating research results to the public. Dr. Grady pointed out that the NIH Clinical Center is pioneering an effort to share information on research with trial participants sooner than was the case in past years.

Dr. Maddox added that NIH ICs are developing communications documents to increase the dissemination of research results to the public.

NIH PIONEER AND NEW INNOVATOR AWARDS

Jeremy M. Berg, Ph.D.

Jeremy Berg, Ph.D., Director of the National Institute of General Medical Sciences, talked about the NIH Director's Pioneer and New Innovator Awards. The Pioneer Award evolved out of the NIH Roadmap. "We are looking for innovative projects that probably would not be funded through the regular NIH peer-review process," reported Dr. Berg. The program seeks scientists with a track record of innovation who are interested in working on novel projects with potentially high impact.

Dr. Berg described the five-page essay included in the application as a critical component. Electronic reviewers independently evaluate applications. The first year, NIH received more than 1,300 applicants, interviewed approximately 20 finalists, and then made 9 awards in September 2004. The second year, NIH made adjustments to prepare for the large number of applications and to increase outreach to women and members of underrepresented groups. NIH

received more than 800 applications and ultimately made 13 awards in September 2005. This second cohort included a younger, more diverse group of scientists. In 2006, more than 400 applications were reviewed, and 13 awards were made. In 2007, NIH announced 12 awards. Information on the Pioneer Award, including details on the 47 awardees since the program's inception, is available at <http://nihroadmap.nih.gov/pioneer>.

A Joint Resolution of Congress in 2007 included funds to start a junior pioneer-like program called the NIH Director's New Innovator Award program. This program, launched in February 2007, funds exceptionally innovative research with a potential for significant impact.

Information on the 2007 NIH Director's New Innovator Award is at http://grants.nih.gov/grants/new_investigators/innovator_award/index.htm. Awards will total up to \$1.5 million in direct costs over 5 years. Only new investigators are eligible to apply (a new investigator is someone who received his/her most recent doctoral degree or completed medical internship and residency in 1997 or later). This person must never have been a principal investigator on an R01 or equivalent NIH grant; in addition, he or she must hold an independent research position at a U.S. institution. Applicants must submit a 10-page essay that describes the project's innovativeness, the investigator's qualifications (including evidence of creativity and innovativeness), a biographical sketch, and a list of current and pending research support. After receiving more than 2,100 applications, NIH announced 30 awardees in September 2007.

Discussion (COPR Members)

Annelise E. Barron, Ph.D., suggested that NIH broaden the Pioneer and New Innovator Awards programs and noted the potential global impact of these awards.

Ms. Clark asked how applicants responded to the concept of high-risk, high-return projects. Dr. Berg responded that future evaluations of outcomes may begin to answer this question. Dr. Kington pointed out the importance of considering the willingness of the agency to tolerate failure. If all projects succeed they are probably not high risk.

Dr. Mau asked whether New Innovator awardees could become Pioneer awardees in the future. Dr. Berg explained that both the New Innovator and Pioneer Awards are one-time opportunities

and are not renewable. However, New Innovator awardees could apply for Pioneer Awards in the future.

COPR members expressed their enthusiasm for the shortened application process. Dr. Kington added that NIH peer-review committees are considering a major proposal to shorten the grant application process.

NCRR COMMUNITY ENGAGEMENT ACTIVITIES

Barbara Alving, M.D.

Barbara Alving, M.D., Director of the National Center for Research Resources (NCRR), discussed the Center's community engagement activities. NCRR launched the Clinical and Translational Science Award (CTSA) program, funding 12 academic health centers in October 2006, to create an academic home for clinical and translational science at institutions nationwide. The CTSAAs (www.CTSAWeb.org) help to eliminate institutional barriers, integrate resources and training, speed up clinical and translational science, and enhance efforts to engage the community.

In 2007, NCRR funded an additional 12 academic health centers. Through the CTSA Consortium, grantees have the opportunity to collaborate with private and public organizations, research centers in minority institutions, underserved populations, National Primate Research Centers, and National Cancer Institute Centers. Developing outcomes for evaluating research in community engagement was identified as a priority by the CTSA Community Engagement Steering Committee. Dr. Alving described this steering committee as a trans-NIH strategy to ensure that efforts to engage the community are maximized and sustained over time.

The CTSA Supplement Awards provide funds for pilot projects focused on the health needs identified by diverse communities through interviews and surveys. These awards test the concept of recruiting and supporting practitioners to engage in community-based clinical research.

Dr. Alving also reported on two other NCRR-funded programs: the Institutional Development Award (IDeA) program (www.ncrr.nih.gov/RIidea) and the Research Centers in Minority Institutions (RCMI) program (www.ncrr.nih.gov/RIrcmi). The IDeA enables states, some without medical schools, to partner with medical schools and research-intensive universities to train rural and minority populations in biomedical research. The RCMI Translational Research Network facilitates both the bench-to-clinical-trial transition and community outreach.

In May and September 2007, NCRR held workshops on fostering collaborative community-based clinical and translational research. Recommendations from these workshops will help to prioritize future supplement awards. Key recommendations included:

- Develop a community-based research infrastructure to sustain partnerships.
- Fund training programs in community competence for academic health centers.
- Encourage communities to identify their research needs.
- Award grants to community-based organizations with academic health centers as partners.
- Build health outcome measures into protocols and evaluations.
- Ensure that accountability to the community extends beyond the initial stages of research.
- Work closely with health care funders to improve the translation of knowledge into practice.

Discussion (COPR Members)

Cynthia A. Lindquist, Ph.D., M.P.A., asked NIH to engage communities in a dialogue about their needs before starting their research. She also emphasized that research must be mutually beneficial. Dr. Alving suggested that communities take the initiative by explaining to investigators who they are and what they represent. She also noted that communities could bring new models of health care to the table.

Dr. Linares-Orama asked about NIH strategies to close the gap between knowledge and practice in health care. Dr. Alving responded that all NIH ICs actively work to close this gap. She

suggested that a systems approach to rethinking the health care system is needed. Dr. Kington added that the Clinical Associates Program helps to close the gap between knowledge and practice by connecting researchers to networks of practicing doctors.

Dr. Ahmed asked about NIH plans to evaluate the CTSA. Dr. Alving clarified that each CTSA applicant institution must describe how it plans to conduct evaluations. NIH also developed an evaluation committee for the CTSA consortium and is working on benchmarks. CTSA awardees will be asked to report on their progress during site visits and before their 5-year renewals.

Elmer R. Freeman, M.S.W., shared his conviction that community organizations need to build capacity and infrastructure to fully participate in community-based research.

Ms. Palermo asked to what extent the community engagement component was taken into consideration for the development of the CTSA and to what extent the NCRP will ensure that the community engagement experts work together. Dr. Alving noted that the structure is to include a community engagement group that comprises representation from all the CTSA and NIH. She also noted that sustainability must come from the community outreach experts funded across the United States.

David B. Abrams, Ph.D., Director of the Office of Behavioral and Social Sciences Research (OBSSR), noted that the community engagement steering committee is the most active of all the CTSA steering committees. Each CTSA has more than one representative on this steering committee, which is supported by an NIH subcommittee that meets on a regular basis and cuts across all the NIH institutes. The representative group is made up of both the community partners and the principal investors and the scientists in the CTSA.

Elizabeth Furlong, J.D., R.N., Ph.D., asked about what training programs for academics and community constituents were going to be funded and how communities were going to be encouraged to identify their research needs based on the recommendations made at the May workshop. Dr. Alving noted that the proceedings of the May workshop will be circulated for feedback in the coming weeks.

[A group picture with Dr. Kington was taken during the lunch break.]

FROM PUBLIC UNDERSTANDING TO PUBLIC ENGAGEMENT

Alan I. Leshner, Ph.D.

Alan I. Leshner, Ph.D., chief executive officer of the American Association for the Advancement of Science (AAAS), discussed the evolving science-society relationship and the need to move from public understanding of science to public engagement. Science and technology are embedded in every aspect of modern life. Tension between science and society results from conflicts between scientific findings and core human values and beliefs. Dr. Leshner suggested that society now wants to influence science rather than having a situation in which we have only science influencing society. The growing divide between science and the rest of society could have negative consequences for both science and society. Dr. Leshner quoted Abraham Lincoln: “Public sentiment is everything. With public sentiment, nothing can fail. Without it nothing can succeed.”

People need to know more about science as an enterprise. Dr. Leshner suggested that advocating for more public education in science is not enough, because not all problems result from a lack of understanding. Instead, greater efforts to engage the public would provide mutual benefit. What is public engagement? It involves listening and responding to the public about its concerns, priorities, and questions about science and technology. A recent Institute of Medicine roundtable on evidence-based medicine emphasized the need for the active involvement of patients in developing research questions, developing evidence, and disseminating findings. Receiving help from the public in forming the research agenda is a critical part of public engagement.

Public engagement can happen in a variety of ways:

- Holding public forums/town meetings.
- Visiting with community groups.
- Holding problem-solving sessions with small groups.
- Exploiting natural opportunities such as science museums, physician's offices, and everyday activities.

For example, the AAAS "Glocal Strategy" brings global issues to the local level by working with local opinion leaders. Dr. Leshner emphasized that governmental agencies should initiate public engagement activities because these agencies are accountable to the public. He suggested that scientists could contribute to public engagement efforts in several ways:

- Build relationships with stakeholders.
- Build communication around issues informed by science and technology.
- Practice openness by putting information, ideas, and debate in the public realm.

Dr. Leshner pointed out that researchers must be trained to engage with the public. Learning how to talk to the press about research results and how to reach out to neighbors and community groups are necessary skills. In efforts to engage the community, scientists should stick to facts and not express their personal values or go outside their field of study.

Discussion (COPR Members)

Mr. Margo wondered whether it was too late to educate scientists about community engagement after graduation. Dr. Leshner responded that it was not too late. He pointed out that because community engagement is an acquired skill, mechanisms to teach it must be in place.

Dr. Ahmed asked for suggestions on how to work with academic leadership on public engagement activities. Dr. Leshner responded that most university presidents know they need to interact more with their communities. However, senior-level department heads often question

the value of such interaction. He emphasized that ways to reward people for community engagement must be developed.

NIH PEER REVIEW

Lawrence A. Tabak, D.D.S, Ph.D.

Lawrence A. Tabak, D.D.S., Ph.D., Director of the National Institute of Dental and Craniofacial Research, described efforts to enhance peer review at NIH. The increasing breadth, complexity, and interdisciplinary nature of biomedical science are creating new challenges for the NIH system: peer review is a key component of this system. NIH must continue to adapt to the rapidly changing fields of science and to growing public health challenges. Dr. Tabak emphasized that NIH must work to ensure the processes used to support science are as efficient and effective as possible for both applicants and reviewers.

Dr. Tabak described a self-study by NIH in partnership with the scientific community to strengthen peer review (<http://enhancing-peer-review.nih.gov/>). Because NIH seeks input from the broadest scientific community possible, two committees were established: (1) the external Advisory Council to the Director Working Group on Peer Review and (2) the internal Steering Committee Working Group on Peer Review. NIH completed a request for information (RFI) as part of this self-study. In the RFI, NIH asked for input on the challenges in the peer review process and solutions to these challenges. Drs. Zerhouni and Tabak also held two teleconferences with deans from around the country to discuss issues regarding peer review. NIH conducted five regional town meetings on this topic.

Dr. Tabak shared emerging ideas of potential interest to the COPR:

- Criteria and focus of review.
- Many suggestions of how NIH should change its review criteria to increase risk taking and/or innovation and/or public health focus.
- Reviewing the project vs. the person.
- Need for new models of review that include more than the customary two or three primary reviewers.

- Suggestions on how to establish a dialogue between applicant and reviewer to correct factual errors during the review in real time.
- Different types of review are needed for different types of science.
- Improving the quality of review by having an ombudsperson on each study section.
- Some reviewers would benefit from more context.
- Possible need for a third level of review that assesses the impact on public health or on society.
- Need for reviewers to provide more useful feedback to applicants in addition to their application score.

Discussion (COPR Members)

Ms. Palermo emphasized the importance of redefining “peer” in peer review to extend beyond scientists.

Dr. Linares-Orama expressed concern about the importance of eliminating subjectivity in the peer-review process. Dr. Tabak responded that this issue was raised in the NIH self-study process. He also added that NIH is gathering information on possible solutions to this problem.

Mr. Jaquet asked whether common themes arose from the five town hall meetings. Dr. Tabak responded that the concept of the community as an equal partner in the peer review process arose again and again.

OVERVIEW OF THE COPR WORK GROUP DAY AND REPORT FOR THE NIH DIRECTOR

Christina L. Clark, M.A., M.B.A., and James H. Wendorf, M.A.

[insert “view the presentation (pdf)"]

Ms. Clark and Mr. Wendorf, cochairs of the fall 2007 Meeting Agenda Work Group, provided Dr. Kington with an overview of the Work Group Day that took place the previous day (October

25). Ms. Clark thanked COPR members for their public engagement activities during the year. She also thanked the NIH Public Liaison Officers and other NIH staff who attended and supported the Work Group Day.

Mr. Wendorf summarized the agenda:

- An update by Ezekiel J. Emanuel, M.D., on efforts by NIH to engage minority communities in clinical research.
- A presentation by Diane R. Brown, Ph.D., on the importance of social and cultural factors in population-based health research.
- An update by Sara A. Keim, M.A., M.S., on community engagement efforts in the National Children's Study.
- A description by Joseph P. Goldman, M.P.P., on AmericaSpeaks' efforts to engage citizens in public decision making.
- An overview by Jacqueline Dunbar-Jacob, Ph.D., R.N., FAAN, and Lee Hipps on the Clinical and Translational Science Institute (CTSI) Community PARTners (Partnering to Assist Research and Translation) Program at the University of Pittsburgh.
- A communications update by John T. Burklow.

Mr. Wendorf explained that through consensus building the COPR identified the following action item for the October 2007 COPR meeting: identify ways to encourage researchers to involve the public in research, with an emphasis on community engagement.

UPDATE: WORK GROUP ON THE ROLE OF THE PUBLIC IN RESEARCH

Syed M. Ahmed, M.D., Dr. P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H.

[insert "view the presentation (pdf)"]

Dr. Ahmed and Ms. Palermo reviewed the scope of work, recommendations, and deliverables for the Role of the Public in Research Work Group. The work group focused on the following action item: Identify ways to encourage researchers to involve the public, with an emphasis on community engagement. Ms. Palermo said that the work group supports the overarching principle of transforming the clinical research enterprise through discussion of the participatory

aspect of research, the 4th “P” described in Dr. Zerhouni’s framework for the *Future Paradigm of Medicine: Predictive, Personalized, Preemptive, and Participatory*.

Dr. Ahmed reviewed the work group’s action items to be addressed between October 2007 and October 2008:

- Develop proposed criteria and/or guidance for review panels to use for gauging community engagement.
- Create broad guidelines for educating researchers and the lay public on community engagement.
- Identify and propose definitions for community engagement and public participation.

UPDATE: COMMUNICATIONS WORK GROUP

Anne Muñoz-Furlong and Brent M. Jaquet

[insert “view the presentation (pdf)"]

Anne Muñoz-Furlong and Mr. Jaquet summarized the goals of the Communications Work Group:

- Promote awareness of NIH among the public.
- Act as a vehicle for communication from the public to NIH.
- Recommend communication strategies that support the work of the COPR.

Ms. Muñoz-Furlong and Mr. Jaquet reviewed the work group’s recommendations:

- Embrace the NIH “Ambassador Program” as a way to promote bilateral communication.
- Promote the Ad Council Campaign in partnership with nonfederal groups.
- Support a community engagement activity modeled after AmericaSpeaks that would involve NIH staff, grantees, and the public.
- Examine the NIH Internet strategy and make suggestions for greater visibility of NIH among the public.
- Explore opportunities for alliances with national civic organizations.
- Increase activities aimed at children.

Discussion (COPR Members)

COPR members agreed on the importance of making NIH information more accessible to the public. The members suggested that NIH make the COPR more visible on the NIH Web site.

Valda Boyd Ford, M.P.H., M.S., R.N., suggested that information on NIH needs to appear in places such as newspapers owned by African Americans. Mr. Margo described the COPR's work as "putting a human face on NIH research and bringing NIH into people's homes."

Ms. Muñoz-Furlong emphasized the importance of fueling the emotional aspects of health and disease that appeal to the public. She suggested that NIH create a place such as YouTube (<http://www.youtube.com>) where people could post their stories about illness.

Dr. Kington agreed that even though the NIH Web site receives popular ratings, many people do not access it.

Mr. Burklow thanked COPR for its input and emphasized how important it has been to have COPR's contributions during the meeting today and through the past few years, supporting NIH's communications strategies and bringing new ideas to the forefront.

PUBLIC COMMENT

Public comments were received in advance and made available to the Council members and to meeting attendees. Comments were presented at the meeting by Vlady Rozenbaum, Ph.D., founder and administrator of COPD-ALERT, a U.S. support and advocacy group for people with chronic obstructive pulmonary disease (COPD). Dr. Rozenbaum discussed his support of NIH efforts to build collaborations between scientists and communities and suggested that while the awareness campaign for COPD, sponsored by the National Heart, Lung, and Blood Institute, has made inroads, more efforts are needed. Dr. Rozenbaum concluded that rising health care costs and increasing morbidity and mortality rates make COPD a critical issue for research and hopes that public engagement in research efforts will help address COPD and other health conditions.

ACD LIAISON REPORT

Annelise E. Barron, Ph.D.

Dr. Barron reported on the meeting of the Advisory Committee to the Director (ACD), which occurred on June 8, 2007. Ms. Chaite was unable to attend the COPR meeting. The ACD members and invited speakers discussed the NIH Reauthorization (Dr. Kington), the progress of the NIH Working Group on Women in Biomedical Careers (Vivian W. Pinn, M.D.), updates on NIH peer review (Antonio Scarpa, M.D., Ph.D., and Dr. Tabak), progress in the NIH Director's New Innovator Award program (Dr. Berg), updates on the NIH Director's Bridge Awards (Norka Ruiz Bravo, Ph.D.), and a new "Facts and Figures" Web-based system to report data on NIH-funded research (Sally Rockey, Ph.D.).

The ACD members discussed a broad range of NIH issues and approved the NIH's interest in supporting young investigators and high-risk, high-impact research. Ms. Chaite suggested that the new Scientific Management Review Board include public representatives. In response to discussion on ACD and COPR interactions during the ACD meeting, Dr. Zerhouni proposed that ACD and the COPR hold a joint meeting sometime in the future.

NIH DIRECTOR AND COPR MEMBER SUMMARY AND NEXT STEPS

Dr. Kington noted that the COPR's efforts in the area of communications have had a direct impact on how NIH prioritizes its communication strategy. He thanked the COPR for its work on community engagement and noted that it will help NIH to develop more rigorous criteria for evaluating efforts in community engagement.

Dr. Kington thanked the COPR members for their input. Ms. Carrington noted that the next meeting of the COPR will take place April 17–18, 2008.

ADJOURNMENT

Dr. Kington and Ms. Clark adjourned the meeting.

APPENDIX

Retiring member Dr. Linares-Orama read a poem he composed for the Council entitled *Diversidad Esplendida (Splendid Diversity)*.

DIVERSIDAD ESPLENDIDA

From dissimilar upbringings,
We connect for one assertion,
And recognize unfair ill health,
Anguish, pain, solitude, despair,
With thoughts for remediation.

We turn down empty prejudice,
To converse shared mind options,
And seek a better humanity,
From a diverse capacity,
Of mixed memoirs and notions.

Along with the good will of all,
Accepting the want for variance,
To grasp tangled human natures,
And the joint need for our neighbor,
We shape a global acquaintance.

Towards a bright life for people,
By *participatory* plans,
We, melting pot constituents,
With essence pride as element,
Now claim our passage, grand!

By: Nicolás Linares-Orama
FILIUS Institute
University of Puerto Rico
NIH COPR Member
October 26, 2007

LIST OF ABBREVIATIONS AND ACRONYMS

AAAS	American Association for the Advancement of Science
ACD	Advisory Committee to the Director
AHRQ	Agency for Healthcare Research and Quality
CBPR	Community-Based Participatory Research
CC	Clinical Center
CDC	Centers for Disease Control and Prevention
CIT	Center for Information Technology
COPD	chronic obstructive pulmonary disease
COPR	Council of Public Representatives
CTSA	Clinical and Translational Science Awards
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DHHS	Department of Health and Human Services
FIC	Fogarty International Center
FNIH	Foundation for the National Institutes of Health
GWAS	genome-wide association studies
IC	institutes and centers
ISS	International Space Station
IHS	Indian Health Service
IdeA	Institutional Development Award
IOM	Institute of Medicine
IRB	institutional review board
NASA	National Aeronautics and Space Administration
NCCAM	National Center for Complementary and Alternative Medicine

NCHMD	National Center for Minority Health and Health Disparities
NCI	National Cancer Institute
NCRR	National Center for Research Resources
NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIBIB	National Institute of Biomedical Imaging and BioEngineering
NIDA	National Institute on Drug Abuse
NICHD	National Institute of Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
OBSSR	Office of Behavioral and Social Sciences Research
OPASI	Office of Portfolio Analysis and Strategic Initiatives
OMB	Office of Management and Budget
PIR	Partners in Research
PTI	Public Trust Initiative
RCMI	Research Centers in Minority Institutions
RFA	Request for Applications

RFI Request for Information