

## DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

### COPR Alumni

#### CLASS OF 2008

- [Craig T. Beam](#) (California)
- [Wendy Chaite](#) (New York)
- [Nicolas Linares-Orama](#) (Puerto Rico)
- [Michael Manganiello](#) (Washington, DC)

#### Craig T. Beam

Term: 2004-2008



Mr. Craig T. Beam, a partner with the health care development firm Hammes Company, oversees the development and management of real estate, especially health care and institutional projects. He is a member and former chairman of the American Heart Association (2002-2003) and serves on the boards of Riverside Community Hospital in California and AllHealth, a company sponsored by the Hospital Council of Southern California.

Mr. Beam's interest in the American Heart Association stems from his family's health history, and he strongly supports national efforts on behalf of health care research in general. His active participation in health care issues and his professional experience have given him insight into the dynamic changes occurring in the industry. He has been a board member for several health care firms and chairman of Martin Luther Hospital in Anaheim, California. He has also served in governance capacities at hospitals in New Jersey and California.

Mr. Beam's understanding of health care trends has brought him major clients, including several health care systems. He has worked with several hospitals and major medical groups such as Harriman Jones, San Jose Medical Group, St. Joseph Medical Foundation, and Buenaventura Medical Group.

Mr. Beam graduated from California State University, Fullerton, with a degree in business administration and started his real estate career in 1977 as chief financial officer of Concordia Development. In 1983 he became president of Beam & Associates, with responsibility for the firm's consulting, development, leasing, and brokerage divisions. The firm merged with Hammes Company in 1999 to form the largest U.S. health care development firm. Mr. Beam has received numerous professional and volunteer awards, including the 2003 American Heart Association Distinguished Leadership Award, and was appointed an Endowed Fellow by the National Health Foundation in 1998. He resides with his family in Orange County, California, where his ancestors settled in the late 1800s.

#### Wendy Chaite

Term: 2004-2008



Ms. Wendy Chaite serves as the COPR Liaison to the NIH Advisory Committee to the Director. Ms. Chaite, whose daughter was born with systemic visceral and peripheral lymphatic disease and lymphedema, left her professional career in July 1998 to found the Lymphatic Research Foundation (LRF). LRF is a not-for-profit organization dedicated to promoting and supporting lymphatic research and to fostering an interdisciplinary field of research. Ms. Chaite played a central role in establishing a trans-NIH Coordinating Committee for lymphatic research and disease, an international peer-reviewed scientific journal, a prestigious Gordon Research Conference series devoted to lymphatic research and biology, and the creation of the first ever Endowed Chair in Lymphatic Research and Medicine at Stanford University School of Medicine, among other achievements. She is a Board Member Emeritus of Research!America, the nation's leading research advocacy organization and was appointed to a four-year term on the National Advisory Research Resources Council.

After graduating from law school in 1988, Ms. Chaite served as a federal judicial law clerk in the U.S. District Court, Southern District of New York. From 1990 to 1995, she worked as a corporate litigator with Mudge Rose Guthrie Alexander & Ferdon, a major Wall Street law firm. From 1995 to 1998, Ms. Chaite taught courses as an adjunct professor at Pace University School of Law. Prior to her legal career, Ms. Chaite was a corporate fundraiser for the United Way of Tri-State and spent years working with special needs populations, including the disabled, blind, deaf, and geriatric populations.

Ms. Chaite has received numerous awards for her efforts in promoting lymphatic research, including "Exceptional Contributions as a Volunteer Advocate" from Research!America, "Humanitarian of the Year" from the University of Maryland, and "Love of a Lifetime" from Achat Hadassah of the Nassau Region. She has been named an "Everyday Hero" by *Newsday* and included in the lists "Women of Achievement" by the Junior League of Long Island, "Women of Distinction" by *Newsday's Distinction* magazine, "Long Island's Top 50 Women" and "Healthcare Heroes" by *Long Island Business News*, and "Fortune 52 Women of Achievement" by *Long Island Press*.

Ms. Chaite resides in Roslyn, New York, with her husband, Bennett, and their two young children.

## Nicolas Linares-Orama

Term: 2005-2008



Dr. Nicolas Linares-Orama is Director of the FILIUS Institute of Disability and Rehabilitation Research at the University of Puerto Rico. FILIUS is a research center that conducts outreach to Latino/Latina audiences and organizations. Dr. Linares-Orama is a Professor of Language Pathology at the Medical Sciences Campus of the University of Puerto Rico and has developed many research and training projects, including the Assistive Technology Project, the Center for Interdisciplinary Intervention, the Infantile Autism Project, and the Initiative for Correctional Interdisciplinary Services. He served as Director of the Department of Communicative Disorders at the University of Puerto Rico for 12 years.

He served on the Advisory Council of the National Institute on Deafness and Other Communication Disorders (NIDCD) and was a founding member and liaison for the NIDCD Partnership Program with the University of Puerto Rico. Dr. Linares-Orama volunteers his time to a variety of NIH initiatives to improve communications with the Hispanic community.

Dr. Linares-Orama is a leader in Puerto Rico health care circles. As a speech-language pathologist, he is concerned about the development of Latino children who have language disorders, as well as those who are born deaf or with hearing loss, and with the prevention of noise-induced hearing loss in families and workers. He leads research and training projects on childhood autism, incarcerated youth and adults, emotional assessment, and gifted children. Dr. Linares-Orama is a special consultant to the Puerto Rico Secretary of Education on related services for students with disabilities and University Coordination Official for local Special Education Law 51. He is a member of the Advisory Board of the National Center on Education, Disability and Juvenile Justice. He is a member of the Executive Committee of AARP-Puerto Rico.

Dr. Linares-Orama obtained a Ph.D. in speech and hearing science from the University of Illinois at Urbana-Champaign. He holds a master's degree in language pathology from the University of Puerto Rico. His wife, Marta, and their three children have provided Dr. Linares-Orama with support in pursuing his academic and professional goals. He enjoys Spanish "baladas" and classical and Broadway music and recently began writing poetry.

## Michael Manganiello

Term: 2005-2008



Mr. Michael Manganiello is a principal in the health policy practice of Whyte Hirschboeck Dudek Government Affairs (WHDGA). Before joining WHDGA, he was Senior Vice President of Government Affairs at the Christopher Reeve Foundation (CRF), which he co-founded. Mr. Manganiello authored and introduced to Congress the Christopher Reeve Paralysis Act and played an integral role in passage of the Research Review Act of 2004, the first piece of legislation to specifically address the needs of Americans suffering from spinal cord injuries. At CRF, he served as director of the Hope Network and chaired the Paralysis Task Force, a joint program with the Centers for Disease Control and Prevention. He has a close working relationship with the National Institute for Neurological Disorders and Stroke and acted as an advisor to U.S. Department of Health and Human Services Secretary Tommy Thompson on HIV and HIV prevention.

Mr. Manganiello is a past president, co-founder, and current board member of the Coalition for the Advancement of Medical Research, which comprises nearly 100 patient organizations, research universities, scientific societies, and advocates for breakthrough research and technologies in regenerative medicine, including stem cell research and somatic cell nuclear transfer. He is on the board of the National Association for Biomedical Research, the advisory panel of the Mayo Clinic National Symposium on Health Care Reform, and a member of the Advisory Council to Proposition 71, the California bond initiative to fund stem cell research.

Mr. Manganiello graduated from Villanova University with a bachelor's degree in political science and received his M.P.A. from Columbia University's School of International and Public Affairs in 2001, where he was the recipient of the Harvey Picker Public Service Award. He is currently a member of the Advisory Board of the Executive Master of Public Affairs Forum for Columbia University and of the Federal Club of the Human Rights Campaign, America's largest gay and lesbian organization.

National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, Maryland 20892

NIH...Turning Discovery Into Health

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

**MEETING MINUTES**

October 31, 2008

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

**Fall 2008 Meeting**  
**Building 31, C-Wing, Conference Room 6, NIH Campus**  
**Bethesda, Maryland**

**October 31, 2008**

***NIH Participants***

Elias A. Zerhouni, M.D., Director, NIH  
Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH  
John T. Burklow, Associate Director for Communications and Public Liaison, Office of the Director, NIH  
Marin Allen, Ph.D., Deputy Associate 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.  
Micah Berman, J.D.  
Lora M. Church  
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, Ph.D., J.D., R.N.  
Nicole Johnson, M.A., M.P.H.  
Cynthia A. Lindquist, Ph.D., M.P.A.  
Matthew Margo, LL.M.\*  
Anne Muñoz-Furlong  
Eileen Naughton, J.D.  
Ann-Gel S. Palermo, M.P.H.  
Carlos Pavão, M.P.A.  
John Walsh  
James H. Wendorf, M.A.  
James Wong, Ph.D.

\*Participated by telephone

***COPR Members Not Present***

Brent M. Jaquet  
Marjorie K. Mau, M.D., M.S.

***ACD Liaison***

John C. Nelson, M.D., M.P.H., FACOG, FACPM

***Speakers***

Vence Bonham, J.D., Senior Advisor to the Director on Societal Implications of Genomics and Chief, Education and Community Involvement Branch, National Human Genome Research Institute, NIH

Patricia Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research, NIH

Alan E. Guttmacher, M.D., Acting Director, National Human Genome Research Institute, NIH

Yvonne Maddox, Ph.D., Deputy Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH

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## **EXECUTIVE SUMMARY**

The 20th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) took place on October 31, 2008.

NIH Director Elias A. Zerhouni, M.D., expressed his appreciation to the COPR for its guidance over his six and a half years as NIH Director. He also recognized and thanked the six retiring COPR members: Christina L. Clark, M.A., M.B.A.; Valda Boyd Ford, M.P.H., M.S., R.N.; Nicole Johnson, M.A., M.P.H.; Cynthia A. Lindquist, Ph.D., M.P.A.; Marjorie K. Mau, M.D., M.S.; and James H. Wendorf, M.A.

Dr. Zerhouni reported that the 110th Congress has shown substantial interest in NIH, introducing more than 200 bills of interest to the agency. The President has signed the Breast Cancer and Environmental Research Act of 2008 into law, and NIH is implementing Title VIII of the Food and Drug Administration Amendments Act of 2007.

On September 30, 2008, the President signed a fiscal year 2009 stopgap continuing resolution to fund most of the government until March 6, 2009. The 2009 House and Senate budgets call for an increase in the NIH budget.

Additional announcements were:

- NIH supports an increase in the number of young investigators through a new policy.
- The Human Microbiome Project will support the comprehensive characterization of the human microbiome.
- The Roadmap Epigenomics Program will support research on how the genome is regulated.
- The NIH Director's Pioneer Award supports creative scientists who propose exceptionally innovative approaches that could have substantial impact on biomedical and behavioral science.

- The Transformative R01 program supports innovative, high-risk, original, and unconventional research with the potential to create new or challenge existing scientific paradigms.
- NIH has issued a total of 38 Clinical and Translational Science Awards.
- NIH has increased access to information on research funding by creating the Research, Condition, and Disease Categorization system.
- The NIH process to make critical changes and improvements in its peer-review system is now in the implementation phase.

Mr. Wendorf and Elmer R. Freeman, M.S.W., co-chairs of the COPR Agenda Work Group, began the COPR reports with acknowledgments to Dr. Zerhouni for his years of service to NIH. They noted Dr. Zerhouni's commitment to and support of the COPR. Four presentations were made to recognize Dr. Zerhouni, including presentations of a replica of the new COPR fact sheet signed by the COPR members; a Rhode Island House of Representatives Resolution and Citation from Eileen Naughton, J.D.; a spirited solo verse by Ms. Ford; and a Native American special presentation and blessing for Dr. Zerhouni and Raynard S. Kington, M.D., Ph.D., respectively, by Dr. Lindquist, a member of the Spirit Lake Dakota Nation, and Lora M. Church, a member of the Navajo Nation. Dr. Zerhouni and Dr. Kington expressed gratitude for these kind mementos.

As the first item of COPR business, Syed M. Ahmed, M.D., Dr.P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H., reported that the Role of the Public in Research Work Group completed three deliverables: definitions and operating principles of "community engagement" and "public participation," guidelines for educating researchers and the lay public on community engagement, and guidance for peer-review panels in gauging community engagement. Dr. Kington proposed that NIH form an internal NIH working group to develop strategies for implementing the framework.

Anne Muñoz-Furlong reported that the Communications Work Group will support NIH's strategic planning activities to enhance the agency's health communications efforts by issuing a request for information (RFI) on health information-seeking behaviors. The work group

recommended that COPR members introduce the RFI in plain language and disseminate it to constituents by e-mail, mail, and telephone.

Alan E. Guttmacher, M.D., described the accomplishments of the Human Genome Project. The project produced the human genome sequence; spurred new technologies; helped spawn the new field of genomics; and provides new knowledge, technologies, and approaches for understanding health and changing health care. He discussed the International HapMap Project, which is mapping variations in the human genome across various populations around the world. He also cited several examples of current genomic research under way.

John T. Burklow described the ways in which NIH disseminates health and science information to the public. Through the Office of Communications and Public Liaison (OCPL), the agency manages media outreach and communicates health information through a number of channels, including a monthly consumer newsletter; an electronic research update; and web-based strategies, including Web sites, podcasts, vodcasts, RSS feeds, and the NIH YouTube channels. As part of NIH's effort to enhance collaborative communications efforts across the agency, OCPL hosted a workshop with outside experts and communication directors representing the NIH Institutes and Centers on September 9, 2008. Outcomes include plans for working groups to address such areas as new media, shared resources, and capacity building in science communications among researchers.

In a special presentation, Vence Bonham, J.D., described the National Human Genome Research Institute's efforts to disseminate information about genetics and genomics to the public. Dozens of companies now provide genetic testing directly to consumers. NIH is determining its role in providing accurate and appropriate information about these services to the public and health professionals.

Patricia Grady, Ph.D., R.N., FAAN, and Yvonne Maddox, Ph.D., reported that the NIH Partners in Research program is the newest NIH Public Trust Initiative program. Research partnerships between community leaders and NIH-supported scientists will study methods to engage and

inform the public about health science, improve public understanding of the benefits of publicly funded research, and increase scientists' understanding of and outreach to the public.

The COPR heard public comments from Leo Hallan of Yankton, South Dakota, and Margo Michaels, Executive Director of the Education Network to Advance Cancer Clinical Trials.

John C. Nelson, M.D., M.P.H., FACOG, FACPM, summarized the presentations and discussions at the last meeting of the Advisory Committee to the Director.

Dr. Kington closed the meeting, thanking the COPR members for their support for Dr. Zerhouni, who only speaks of the COPR using superlatives.

## **WELCOME AND INTRODUCTIONS**

**Elias A. Zerhouni, M.D.**  
**Director, National Institutes of Health**

The 20th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) took place on October 31, 2008. NIH Director Elias A. Zerhouni, M.D., welcomed the COPR members and presenters. Dr. Zerhouni welcomed Elmer R. Freeman, M.S.W., as the new Agenda Work Group Co-Chair.

Dr. Zerhouni explained that this was his last day in office. He expressed his appreciation to the COPR for its guidance on many important issues over his six and a half years as NIH Director. In particular, the COPR has made major contributions to NIH's communications, public access policy, and efforts to involve the public in research. He noted that the COPR can also take credit for the addition of the fourth "P," for "participatory," to the original three "Ps" (for "predictive," "personalized," and "preemptive" medicine) in the NIH strategic vision. Dr. Zerhouni said he valued the COPR's commitment to analyzing problems before identifying solutions. He expressed his appreciation for the COPR's thoughtful approach to the many issues it has addressed.

Dr. Zerhouni recognized and thanked the six retiring COPR members: Christina L. Clark, M.A., M.B.A.; Valda Boyd Ford, M.P.H., M.S., R.N.; Nicole Johnson, M.A., M.P.H.; Cynthia A. Lindquist, Ph.D., M.P.A.; Marjorie K. Mau, M.D., M.S.; and James H. Wendorf, M.A. He noted that in addition to their individual contributions, all of these members had participated in the NIH Roadmap consultation meetings and the NIH Public Trust Initiative.

## **NIH DIRECTOR'S UPDATE**

**Elias A. Zerhouni, M.D.**  
**Director, NIH**

### **Legislative Update**

Dr. Zerhouni reported that the 110th Congress has shown substantial interest in NIH, introducing more than 200 bills of interest to the agency. These bills have addressed a range of issues and

diseases, including expansion of research on tuberculosis, pain, muscular dystrophy, arthritis, breast cancer and the environment, pulmonary hypertension, and pediatric cancer.

Legislation is pending to renew the Small Business Innovation Research and Small Business Technology Transfer programs. The President signed the Breast Cancer and Environmental Research Act of 2008 into law on October 8. This act requires the Secretary of Health and Human Services to establish an Interagency Breast Cancer and Environmental Research Coordinating Committee to organize research, develop a strategy to solicit proposals, summarize breast cancer research advances, and recommend improvements to the NIH research portfolio.

NIH is also implementing Title VIII of the Food and Drug Administration Amendments Act of 2007, which mandates a significant expansion of the ClinicalTrials.gov database, expanding the number of trials required to be registered. It will also require the inclusion of some results information about trials for approved drugs and devices.

### **NIH Budget**

On September 30, 2008, the President signed a fiscal year (FY) 2009 stopgap continuing resolution to fund most of the government until March 6, 2009. The continuing resolution provides \$29 billion in funding for NIH, at the same rate and under the same terms and conditions as in 2008. The 2009 House and Senate budgets call for an increase in the NIH budget of 3.9 and 3.5 percent, respectively. If Congress enacts this legislation, NIH funding will keep pace with the biomedical inflation rate for the first time in six years. This legislation would also increase funding for the National Children's Study.

### **Support for Young Investigators**

NIH has a new policy that establishes a minimum number of new investigators who will receive NIH funding. In FY 2009, the goal is to award grants to approximately 1,650 new investigators. This policy will help ensure that more young people enter the biomedical research field. NIH is hopeful that this new policy will nurture a new cadre of promising scientists and provide the continued expertise needed to foster the next generation of biomedical research. NIH expects

this new policy to level the playing field, allowing new investigators to achieve success rates comparable to those of established scientists submitting new grant applications. Achievement of a comparable success rate should permit NIH to support 1,650 or more new investigators across all Institutes and Centers in FY 2009, a number equivalent to that achieved in FY 2008.

### **New Initiatives**

Two new Roadmap projects that will support biological research could have a substantial impact on the understanding of how diseases develop. The Human Microbiome Project will support the comprehensive characterization of the human microbiome, which is the full collection of microbes—bacteria, fungi, viruses, etc.—that exist naturally in the human body. Scientists believe that these microbes have a profound influence on many biological processes. The Roadmap Epigenomics Program will support research on epigenetic changes, which control normal growth and development across many genes in a cell or entire organism. This program is based on the hypothesis that health and susceptibility to disease are, in part, due to epigenetic regulation of the genetic blueprint.

Two more new programs support high-risk, high-reward approaches to major biomedical questions. The NIH Director's Pioneer Award supports creative scientists who propose exceptionally innovative approaches that could have substantial impact on biomedical and behavioral science. The Transformative R01 program supports exceptionally innovative, high-risk, original, and unconventional research with the potential to create new or challenge existing scientific paradigms.

NIH has now issued 38 Clinical and Translational Science Awards (CTSAs). The CTSA program is an effort to create a new paradigm in how clinical research is conducted, including creating partnerships with patient groups. The program is training a new generation of clinical investigators, enhancing the clinical research enterprise, developing more effective translational research methods, and establishing linkages through bioinformatics systems.

NIH has made a point to focus on rare and neglected diseases in the new budget. Recognizing the lack of financial incentive for industry to focus on this area of research, NIH has advocated for

an initiative on rare and neglected diseases to create and make available resources for scientists conducting related research.

### **Transparency and Accessibility**

NIH is working to improve transparency and access to information on research funding through creation of the Research, Condition, and Disease Categorization (RCDC) computer-based system, which will sort and report the amount of funding NIH provided in each of 215 historically reported categories of disease, condition, or research area. RCDC provides consistent and transparent information to the public about NIH-funded research. For the first time, a complete list of all NIH-funded projects related to each category will be available. COPR members have been connected with this effort since its conception, providing perspectives on usability and communication with the public. NIH's first RCDC reports will be a part of the release of the President's 2010 budget request. The RCDC system will generate Web-based summary tables that the public can view and download.

### **Peer Review Reform**

NIH's process to make critical changes and improvements in its peer-review system is now in the implementation stage. The new plan calls for an increased commitment to investigator-initiated high-risk, high-impact research to prevent a slowdown of transformative research in spite of the difficult budgetary situation.

Dr. Zerhouni thanked the COPR members for their contributions to this effort, including Dr. Mau and Syed M. Ahmed, M.D., Dr.P.H., M.P.H., for their participation in the Advisory Committee to the Director Working Group on Peer Review. He also thanked Ann-Gel S. Palermo, M.P.H., for her testimony at an NIH regional consultation meeting and the other COPR members who asked their constituents to provide feedback during the request for information (RFI) process.

## **New NIH Policy on Application Resubmission**

NIH recently announced a new policy that will speed up the funding of meritorious science. Starting in January with applications being considered for funding in FY 2010, investigators will be able to resubmit grant applications only once. Under the previous policy, which allowed investigators to resubmit their applications twice, many meritorious applications did not receive fundable scores during the first submission, perhaps because reviewers knew that the investigators would have one more opportunity to resubmit and improve their applications. As a result, funding for many meritorious applications was delayed by one or even two years. The new policy will increase the number of high-quality applications funded after the initial submission process. The guide notices are available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-016.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>.

## **Recognition for NIH Leadership**

Three NIH employees received Presidential Rank Awards on September 30 for their outstanding and longtime service to the federal government. Colleen Barros, Deputy Director for Management, received the Distinguished Executive Award. Don Christoferson, Associate Director for Administrative Management at the National Heart, Lung, and Blood Institute, and Maureen Gormley, Clinical Center Chief Operating Officer, received the Meritorious Executive Award. In addition, Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, received the Presidential Medal of Freedom.

## **Discussion (COPR Members)**

Dr. Ahmed praised Dr. Zerhouni for his leadership during the past six and a half years and asked him to comment on one of the greatest challenges he faced as NIH Director and how he addressed the challenge. Dr. Zerhouni replied that the greatest challenge today is the tremendous burden of disease; the high cost of providing care to prevent and treat disease is endangering the nation's economy. Medicine must be transformed to produce much more effective ways of preventing and preempting disease, delivering care to the public, and helping people maintain

their health. To support this transformation, the public needs to understand that NIH funding is an important public investment—possibly the most important investment in this century.

Mr. Wendorf asked Dr. Zerhouni to comment on the future of behavioral research. Dr. Zerhouni explained that behavioral research is related to the preemptive and personalized components of the NIH strategic vision. Behavioral and social sciences will play a major role, but they need to become an intrinsic part of all biomedical research. Integrated approaches to research are the key to success.

Ms. Palermo asked Dr. Zerhouni for his thoughts on the COPR's future over the next decade. Dr. Zerhouni asked the COPR to continue to deepen its activities. He also asked the COPR to distinguish between its advisory role and the NIH staff implementation role. Advisory bodies, such as the COPR, focus on guiding policy and shaping the agency's thought processes, whereas staff has operational responsibility for implementing policies.

John C. Nelson, M.D., M.P.H., FACOG, FACPM, asked how the COPR might best help the new Director understand the Council's role and take on his or her new responsibilities. Dr. Zerhouni suggested that the COPR brief the new Director on the COPR and how it can assist him or her.

Several COPR members made presentations to Dr. Zerhouni to thank him for all of his work as NIH Director. On behalf of the COPR, Mr. Wendorf and Mr. Freeman presented Dr. Zerhouni with a copy of the new COPR fact sheet surrounded by signatures of the COPR members. The fact sheet serves as a communications tool for the Council to use as part of its outreach activities. Ms. Ford sang a verse from a rhythm and blues song. Eileen Naughton, J.D., presented a proclamation from the State of Rhode Island recognizing Dr. Zerhouni's accomplishments, a picture of a lighthouse, and a certificate. Dr. Lindquist, a member of the Spirit Lake Dakota Nation, presented Dr. Zerhouni with a remembrance quilt made by the Dakota people, and Lora M. Church, a member of the Navajo Nation, gave a blessing to Dr. Zerhouni for his journey into his next role. Ms. Church also blessed Raynard S. Kington, M.D., Ph.D., as he assumes the responsibilities of NIH Acting Director.

## **AGENDA WORK GROUP PRESENTATION**

**James H. Wendorf, M.A., and Elmer R. Freeman, M.S.W.**

Mr. Freeman described recent activities of COPR members, including giving presentations on the COPR and NIH at scientific meetings, participating in peer-review panels, and taking part in NIH panels and meetings.

Participants viewed a public service announcement (PSA) developed by Matthew Margo, LL.M., for CBS Cares. The PSA, which first aired during the show *60 Minutes* on July 27, 2008, promotes prostate cancer screening and publicizes the National Cancer Institute's (NCI's) toll-free information hotline.

## **ROLE OF THE PUBLIC IN RESEARCH WORK GROUP PRESENTATION**

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

Ms. Palermo and Dr. Ahmed reported that the Role of the Public in Research Work Group ended with this meeting. The work group has completed three deliverables:

1. Definitions and operating principles of “community engagement” and “public participation.”
2. Guidance for educating researchers and the lay public about community engagement.
3. Criteria and/or guidance that peer-review panels can use to gauge community engagement.

These deliverables were based on the work group's charge to identify ways to encourage researchers to involve the public in research, with emphasis on community engagement. The impetus for the work group stemmed from five key items: limited opportunity for community involvement in research beyond recruitment in clinical trials; limited research competency for community engagement in research; lack of incentives for community engagement in research; limited guidance available for peer-review panels to evaluate proposals involving community engagement; and the need to identify how to operationalize the fourth “P” (participatory research), which is part of the NIH strategic vision.

The definition of “community engagement” was modified in response to Dr. Zerhouni’s comments to better express how the term is operationalized. Below is the definition as presented.

**COPR ROLE OF THE PUBLIC IN RESEARCH WORK GROUP  
PRESENTED TO NIH DIRECTOR, OCTOBER 31, 2008**

**I. DEFINITION OF “PUBLIC PARTICIPATION”**

**Public participation** is based on the belief that those who are affected by a decision have a right to be involved in the decision-making process. Public participation is the process by which an organization consults with interested or affected individuals, organizations, and government entities before making a decision. Public participation is two-way communication and collaborative problem solving with the goal of achieving better and more acceptable decisions.

*Sources:*

International Association for Public Participation. (2007). *IAP2 Core Values*. [On-line], Available: <http://www.iap2.org/> .

Creighton & Creighton, Inc. (2008). *What is Public Participation?* [On-line], Available: <http://www.creightonandcreighton.com>.

**II. DEFINITION OF “COMMUNITY ENGAGEMENT”**

**Community engagement** is a dimension of Public Participation. In research, community engagement is a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus.

Community engagement is a core element of any research effort involving communities. It requires academic members to become part of the community and community members to become part of the research team, thereby creating a unique working and learning environment before, during, and after the research.

**OPERATING PRINCIPLE FOR COMMUNITY ENGAGEMENT**

Community engagement is a process that requires power sharing, maintenance of equity, and flexibility in pursuing goals, methods, and time frames to fit the priorities, needs, and capacities within the cultural context of communities. Community engagement in research is often operationalized in the form of partnerships, collaboratives, and coalitions that help mobilize resources and influence systems; change relationships among partners; and serve as catalysts for changing policies, programs, and practices.

*Sources:*

Jones L, Wells K. Strategies for academic and clinician engagement in community-participatory partnered research. *JAMA* 2007;297:407–410. p. 408.

Fawcett SB, Paine-Andrews A, Francisco VT, Schultz JA, Richter KP, Lewis RK, Williams EL, Harris KJ, Berkley JY, Fisher JL, Lopez CM. Using empowerment theory in collaborative partnerships for community health and development. *Am J Community Psychol* 1995;23:677–697

Ms. Palermo presented the work group's second deliverable, describing it as a template for developing educational guidelines for researchers. The template includes values, strategies, and outcomes for investigators who want to engage the community in their research. The 13 values are grounded in the experience presented and discussed during meetings with experts and in published and unpublished literature. The full template is available at <http://copr.nih.gov/reports.asp>.

Dr. Ahmed presented the work group's third deliverable, guidance for peer-review panels assessing community engagement. The template outlines 2 criteria for reviewers and 10 for grant applications. Dr. Ahmed explained the importance of having peer reviewers understand what community engagement means and how to evaluate public input as part of the researchers' community engagement design. The full template is available at <http://copr.nih.gov/reports.asp>.

Following the Role of the Public in Research Work Group's presentation, the co-chairs sought approval, requested guidance/response on implementation for the recommendations, and offered support from the Council where needed. The co-chairs also reported on plans to prepare manuscripts on the frameworks for publication in peer-reviewed literature.

### **Discussion (COPR Members)**

Dr. Kington said that he was delighted to accept the work group's recommendations and suggested that NIH consider them through the formation of an internal NIH working group, modeled after the implementation process used for the Peer Review Enhancement Initiative. This process seems more appropriate than a new COPR work group, as the Council suggested, because the COPR is not involved in implementation of NIH operations, as Dr. Zerhouni noted earlier in the day. He proposed that the Office of Communications and Public Liaison (OCPL), directed by John T. Burklow, take responsibility for forming a working group.

Dr. Nelson expressed concern about how his colleagues on the Advisory Committee to the Director (ACD) might respond to the work group's frameworks. Dr. Kington said that his staff could discuss the frameworks at a future ACD meeting; COPR members could also be invited to present and explain the frameworks.

## **COMMUNICATIONS WORK GROUP PRESENTATION**

### **Anne Muñoz-Furlong**

Anne Muñoz-Furlong reported on the activities of the Communications Work Group. She began by noting that in April, the work group suggested a communications roadmap, modeled after the NIH research-focused roadmap, which ultimately led to the COPR's proposal for an integrated, unified communications and Web strategy across the agency. Over the summer, Ms. Muñoz-Furlong explained, the NIH communications staff began a study of health communications to look at new media usage and health information-seeking behaviors.

During the Work Group Day, the Communications Work Group discussed how the COPR could support a broader public input effort using an RFI to gain insight on how the public wants to obtain information about health and research from NIH. Although the work group members appreciate the constraints that NIH is under to conduct mass public input activities, such as surveys, they noted several issues with the use of an RFI geared toward general public response.

Target audiences for the RFI are unlikely to read the *Federal Register*, responses are more likely to come from organizations than individuals, and RFIs are not consumer friendly. The work group therefore recommended that the COPR and COPR alumni:

- Introduce the RFI in plain language to make it more consumer friendly.
- Disseminate the RFI to constituents by e-mail, mail, and telephone.

This approach will ensure that the questions quickly reach a wide and diverse group of health consumers and stakeholders. The work group also considered that conducting this type of communication study annually could become a core COPR responsibility.

Additional strategies for overall communications efforts were:

- Communicate through a variety of methods directly to health consumers and to consumer and advocacy groups.
- Encourage NIH to develop a formal communications network that any nonprofit or advocacy group can join to receive information for its constituents.
- Partner with groups that interact with large numbers of health consumers (such as the American Medical Association and pharmacy and nursing organizations).
- Partner with state groups that set health policy and legislation.
- Communicate through establishments that exist in every community (e.g., pharmacies, grocery stores, and barbershops), and tailor communication vehicles to target audiences (e.g., places of worship and small or ethnic newspapers).
- Link the NIH Awareness Month campaign to high-powered television exposure, such as arranging for the NIH Director to appear on *The Oprah Winfrey Show*.
- Provide lapel pins to COPR members, COPR alumni, physicians, health care providers, advocacy groups, and others that say “Ask me about NIH.” These pins will stimulate frequent and informal dialogues about the agency.
- Create a group on Facebook or MySpace to attract interest and encourage dialogue.

### **Discussion (COPR Members)**

Dr. Nelson expressed concern that the RFI could miss groups of people not usually reached using this public input mechanism.

Marin Allen, Ph.D., explained that NIH has used RFIs successfully in the past. She hoped that the COPR would disseminate the questions beyond the general NIH constituent contacts and databases to ensure a broad-based public input opportunity. This will ensure an equal opportunity to express interest and ideas.

Dr. Kington explained that NIH could use evaluation funds to determine the mechanism’s effectiveness. The agency could also use focus groups and other strategies to collect the

information, especially if it identifies gaps in the information collected. John Walsh reported that some voluntary organizations can support the costs of focus groups.

## **THE SCIENCE OF GENOMICS**

### **Alan E. Guttmacher, M.D.**

Alan E. Guttmacher, M.D., described the accomplishments of the Human Genome Project, which produced the human genome sequence; spurred new technologies; helped spawn the new field of genomics; and provides new knowledge, technologies, and approaches for understanding health and changing health care.

The International HapMap Project is mapping variations in human genomes across various populations around the world. This project provides the information necessary to enable the selection of optimal sets of approximately 500,000 gene variants to make genome-wide association studies (GWAS) possible. Genotyping now costs less than 1/12 of a cent, so the total cost of studying 1 billion genotypes is now often less than \$800,000 per disease.

One HapMap-based study examined age-related macular degeneration, one of the leading causes of major vision loss. The researchers found two genes involved in this disease, which many had not previously even considered to be heavily genetic in its etiology. These two genes account for approximately half of a person's risk of developing the disease and—because they are both involved in the complement pathway—also suggest that this may be an inflammatory disease, an important new insight into the biology of the disease process. This study demonstrates the power of GWAS. However, GWAS do not yet explain most of heritability, which will require more research using current tools and the development of new scientific approaches.

Dr. Guttmacher offered some other examples of current genomic research:

- The Encyclopedia of DNA Elements (ENCODE) Project is determining how the entire human genome functions.
- Researchers are using chemical genomics to validate new drug therapy targets more rapidly and to move these targets and compounds into the drug-development pipeline.

- NIH is investigating the interest of healthy young adults in genetic susceptibility testing for eight common conditions.
- The Cancer Genome Atlas, sponsored by NCI and the National Human Genome Research Institute (NHGRI), is identifying unique genomic alternations in tumor samples.
- The Electronic Medical Records and Genomics (eMERGE) Network is developing, disseminating, and applying approaches to research that combine DNA biorepositories with electronic medical record systems for research.
- The 1,000 Genomes Project will produce a detailed catalog of human variants for different populations around the world.

Dr. Guttmacher reported that after 13 years of debate, Congress passed the Genetic Information Nondiscrimination Act and the President signed it into law.

#### **Discussion (COPR Members)**

In response to a question from Ms. Ford, Dr. Guttmacher explained that several genes are involved in obesity, although behavioral factors also play a role. Understanding the biology of obesity can help scientists find ways to interfere with the pathways that lead to obesity.

Mr. Walsh asked whether NIH will continue to support GWAS. Dr. Guttmacher replied that the agency will continue supporting these studies, which are becoming cheaper because the cost of genotyping is dropping. Many NIH Institutes and Centers are using this kind of information to study acute and chronic diseases.

Ms. Clark asked about the role of the pharmaceutical industry in GWAS. Dr. Guttmacher explained that the industry cosponsored the first large collaborative GWAS after several conditions were established for industry participation. For example, pharmaceutical companies received the data at the same time as everyone else and could not select the diseases to be studied. Pharmaceutical companies understand that this type of research could produce new drug targets more quickly and at a lower cost.

## CHARTING THE FUTURE OF NIH COMMUNICATIONS: UPDATE

**John T. Burklow**

Mr. Burklow described the ways in which NIH disseminates health information to the public. OCPL processes more than 3,000 press calls a year and issues many more news releases than any other agency in the Department of Health and Human Services. The office distributes *NIH News in Health*, a monthly consumer health newsletter, and *NIH Research Matters*, which provides brief research summaries. NIH has also launched a network for public information officers at the agency's 3,000 grantee institutions.

OCPL recently hosted a workshop, "Relevance and Credibility in a Changing Environment: Charting the Next Course for NIH Communications" (September 9, 2008), for the communication directors of the NIH Institutes and Centers as part of its strategic planning activities to enhance NIH health communications efforts. A consumer panel including a teen, a Gen-Xer, a health advocate, and a senior citizen discussed the kinds of health information the groups they represent seek and how they obtain that information. The teen described going straight to Google to answer a question and said that her friends on Facebook numbered more than 300. The senior citizen favored the newspaper and spent part of his day on the Internet. He described his role in a close-knit, face-to-face community.

A panel of experts, including the CEO of a major public affairs firm dealing with health; the author of *The Paradox of Choice*, Dr. Barry Schwartz; Pew Foundation Internet expert Susannah Fox; Rick Weiss, a former *Washington Post* science writer who is now with the Podesta firm; and Pere Estupinya, an international media expert experienced in video and blogging with Spanish-language audiences, discussed emerging needs and how to serve those not connected to social media. Some of the key findings from the group included:

- NIH must adapt to the ever-changing media landscape.
- Information overload is leading to confused, overwhelmed consumers.
- E-patients can be both a critical audience and communicators of NIH messages.
- Many health stories are information, not news, in today's 24/7 news cycle.

- Journalists may spend more time developing articles for mainstream media and may feel that they are more complete and better written, but their blog posts may be more influential—or at least seem to generate more interest.
- Content should be customized to the medium and the demographic group.

After the panel discussions, the communication directors met privately to develop recommendations. Among the takeaway action steps was the plan (now under way) to form four working groups on (1) new media; (2) shared resources across the Institutes and Centers; (3) NIH identity; and (4) internal/external communication to make NIH leadership and NIH-based scientists stronger partners in science-based health and science information dissemination to the full spectrum of NIH audiences.

Facebook and MySpace are popular information sources for adolescents and young adults. OCPL is exploring the use of social networking sites and Wikipedia to disseminate its information. In addition, the Institutes and Centers have agreed to a moratorium on developing new logos.

### **Discussion (COPR Members)**

Elizabeth Furlong, Ph.D., J.D., R.N., asked about NIH's interactions with Wikipedia. Dr. Allen explained that OCPL identified the appropriate contact person at Wikipedia. Mr. Margo reported that a new Wikipedia-related Web site targets people in public relations, communications, and the media. Perhaps NIH could create an analogous partnership that focuses on health and health research.

Dr. Furlong mentioned a group of five major health and medical universities developing an online resource with information from credentialed health providers. Dr. Kington noted that some other universities are also involved and this might be an appropriate discussion topic for the COPR's next meeting.

Ms. Church asked about NIH efforts to communicate with communities that do not have access to the Internet. Mr. Burklow replied that NIH does not plan to abandon the traditional communications vehicles or even word-of-mouth communications.

Linda Crew, M.B.A., R.N., asked about the health resource information kiosk in Jackson, Mississippi. Yvonne Maddox, Ph.D., reported that this center provides publications and brochures from all 27 Institutes and Centers describing the research supported by NIH. The center is located in the Jackson Medical Mall, a former shopping center that now houses physician offices and care facilities.

## **GENOMICS IN THE PUBLIC DOMAIN**

### **Vence Bonham, J.D.**

Vence Bonham, J.D., described NHGRI's efforts to disseminate information about genetics and genomics to the public. These programs include:

- Developing Community Based Models for Education and Utilization of Family Health History Information: A Demonstration Project in Urban Appalachian Communities, a model program to educate urban Appalachian women about the collection and use of their family health histories.
- The Brigham and Women's Hospital Family History Project, which provides tools to organize health history information.
- The National Council of La Raza, which uses lay health care workers to communicate to people with low literacy levels about the importance of family health history.

Dozens of companies now provide genetic testing directly to consumers, and several companies are marketing genetic ancestry tests. NIH is determining its role in providing accurate and appropriate information to the public and health professionals about these services.

Mr. Burklow reported that Dr. Zerhouni has emphasized the need to educate the public about genomics and direct-to-consumer genetic testing. In response, a new trans-NIH committee has been formed to determine what information the agency should present to the public and how to

present this information. The committee is conducting a literature review, focus groups, and an environmental analysis to determine what information is available and what studies have been or are being conducted. The committee will also create a Web site for the public.

### **Discussion (COPR Members)**

Micah Berman, J.D., asked whether NIH is exploring the ethical, legal, and social implications of GWAS. Mr. Bonham responded that the trans-NIH committee is considering these issues.

Dr. Ahmed asked how NIH communicates with children about genetic issues. Mr. Bonham replied that NHGRI reaches out to teachers and students across the country. On National DNA Day, for example, NIH researchers visit schools across the country to share information and excite students about careers in genetics and genomics.

Dr. Nelson wondered how genetic testing could be of practical use in medicine. Mr. Bonham explained that NHGRI's Genomic Healthcare Branch works with health care organizations to educate practitioners. Researchers are studying how health professionals will use new genetic and genomic information.

Ms. Palermo asked about efforts to educate communities on environmental changes that affect genetics. Mr. Burklow replied that the trans-NIH committee will discuss this issue. The group is establishing a system to disseminate information quickly through its Web site when confusing, controversial, or misleading news is published. Mr. Bonham added that NHGRI is examining the roles of environmental, cultural, social, and genetic issues.

Ms. Church asked about the information that the new Web site will provide to consumers about genetic-testing companies. Mr. Bonham replied that the Web site will list questions to ask these companies, and research is ongoing to determine the utility, validity, and accuracy of the tests. Mr. Burklow noted that the Web site will not provide a "Good Housekeeping Seal of Approval" for any test. Instead, it will provide assistance in making good decisions about testing.

## **PUBLIC TRUST INITIATIVE: UPDATE ON PARTNERS IN RESEARCH AWARD PROGRAM**

**Patricia Grady, Ph.D., R.N., FAAN, and Yvonne Maddox, Ph.D.**

Patricia Grady, Ph.D., R.N., FAAN, reported that the NIH Partners in Research (PIR) program is the newest NIH Public Trust Initiative program. The program was inspired, in part, by the 2004 COPR workshop on public trust. The PIR program will develop research partnerships between community leaders and NIH-supported scientists. These partners will study methods to engage and inform the public about health science, improve public understanding of the benefits of publicly funded research, and increase scientists' understanding of and outreach to the public. The PIR program recently awarded 74 grants to 37 partnerships for two years.

Dr. Maddox explained that during its first phase, the program solicited and reviewed applications and awarded grants to successful pairs of applicants. The second phase will include a workshop to provide an update on partner progress and experiences as well as opportunities to network and share ideas about successes and challenges.

### **Discussion (COPR Members)**

Mr. Wendorf commented on the strong shared mission between the COPR and the PIR program. Ms. Palermo served on a peer-review panel for the PIR applications. She suggested that NIH evaluate the peer-review process for the program and that COPR representatives attend the PIR workshop.

Dr. Brady explained that NIH is establishing a steering committee for the workshop and would like the COPR's input. Ms. Palermo offered to provide a COPR overview at the workshop. Carlos Pavão, M.P.A., Mr. Freeman, and Dr. Ahmed also volunteered to join the steering committee.

Mr. Pavão asked about the two-year funding limit. Dr. Maddox explained that this limit is due to the amount of funding available and NIH's desire to fund as many partnerships as possible. Mr. Pavão wondered how to promote a learning community after the grants end. Dr. Grady explained

that the workshop would address project sustainability. Dr. Maddox added that Institute and Center program staff will help partners develop applications for funding through regular NIH grant mechanisms after the PIR grants end.

Dr. Grady commented that almost half of the reviewers were community members. Perhaps some lessons learned could be developed in collaboration with the Center for Scientific Review.

## **PUBLIC COMMENT**

Mr. Wendorf reminded the COPR that the topics brought forward during the public comment period are for information only. These comments are not presented for deliberation or action by the Council.

Leo Hallan of Yankton, South Dakota, sent a letter to the COPR in support of the Christopher and Dana Reeve Paralysis Act. Margo Michaels, Executive Director of the Education Network to Advance Cancer Clinical Trials (ENACCT), described a new report (*Communities as Partners in Cancer Clinical Trials: Changing Research, Practice, and Policy*) issued by ENACCT and Community-Campus Partnerships for Health.

## **ACD LIAISON REPORT**

**John C. Nelson, M.D., M.P.H., FACOG, FACPM**

Dr. Nelson explained that the ACD is one of four advisory committees to the NIH Director. At its last meeting, the ACD heard about the NIH Blue Ribbon Panel to advise the Director on risk assessment for the Boston University National Emerging Infectious Diseases Laboratories. The ACD plans to make recommendations to the NIH Director based on an upcoming report at its December 5 meeting.

The ACD has also discussed NIH's efforts to enhance peer review. The ACD is particularly interested in four core priorities:

- Engaging the best reviewers.

- Improving the quality and transparency of reviews.
- Ensuring balanced and fair reviews across scientific fields and scientific career stages and reducing the burden on applicants.
- Developing a permanent process for continuous review of peer review.

The ACD has also discussed the following programs:

- The Public-Private Partnerships Program, which sponsors partnerships to promote public health.
- The Foundation for NIH, which develops public-private partnerships that build on existing NIH programs to take advantage of new scientific opportunities, enables private partners to expand the number of funded NIH grants, and develops partnerships for clinical and public health studies to collect data in support of improved prevention of or interventions for childhood diseases.
- The National Center for Research Resources, whose mission is to accelerate research from basic discovery to improved patient care.

Dr. Nelson believes that the ACD would support some of the strategies proposed by the Role of the Public in Research Work Group. He will discuss the work group's recommendations with the ACD.

## **CLOSING**

As outgoing co-chair for the Agenda Work Group, and speaking on behalf of the six retiring members, Mr. Wendorf described his service on the COPR as an honor. Dr. Kington thanked the COPR members for their support for Dr. Zerhouni, who only speaks of the COPR using superlatives. Dr. Kington asked for the COPR's assistance in delivering an agency in top form to the next NIH Director.

## **ADJOURNMENT**

Dr. Kington adjourned the meeting.

## **LIST OF ABBREVIATIONS AND ACRONYMS**

ACD	Advisory Committee to the Director
COPR	Council of Public Representatives
CTSA	Clinical and Translational Science Award
eMERGE	Electronic Medical Records and Genomics
ENACCT	Education Network to Advance Cancer Clinical Trials
ENCODE	Encyclopedia of DNA Elements
FY	Fiscal year
GWAS	Genome-wide association studies
ICs	Institutes and Centers
NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
NIH	National Institutes of Health
OCPL	Office of Communications and Public Liaison
PIR	Partners in Research
RCDC	Research, Condition, and Disease Categorization
RFI	Request for information

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

**MEETING MINUTES**

**April 18, 2008**

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

**Spring 2008 Meeting  
Building 31, C-Wing, Conference Room 6, NIH Campus  
Bethesda, Maryland**

**April 18, 2008**

***NIH Participants***

Elias A. Zerhouni, M.D., Director, NIH  
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***

Christina L. Clark, M.A., M.B.A.  
Naomi Cottoms, M.S.  
Linda Crew, M.B.A., 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.  
Cynthia A. Lindquist, Ph.D., M.P.A.  
Marjorie K. Mau, M.D., M.S.  
Ann-Gel S. Palermo, M.P.H.  
James H. Wendorf, M.A.

***COPR Members Not Present***

Syed M. Ahmed, M.D., Dr. P.H., M.P.H.  
Valda Boyd Ford, M.P.H., M.S., R.N.  
Anne Muñoz-Furlong  
Matthew Margo, LL.M.

***2008 COPR Appointees Present***

Micah L. Berman, J.D.  
Lora M. Church  
Eileen Naughton, J.D.

Carlos A.O. Pavão, M.P.A.  
John W. Walsh  
James S. Wong, Ph.D.

***ACD Liaison***

John C. Nelson, M.D., M.P.H, FACOG, FACPM

***Speakers***

Jeremy M. Berg, Ph.D., Director, National Institute of General Medical Sciences, NIH  
Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH  
Melanie Modlin, Public Affairs Specialist, National Library of Medicine, NIH  
Elizabeth G. Nabel, M.D., Director, National Heart, Lung, and Blood Institute, NIH

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## **EXECUTIVE SUMMARY**

The 19th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 18, 2008. Elias A. Zerhouni, M.D., NIH Director, welcomed the COPR members and guests.

Dr. Zerhouni recognized the new COPR appointees: Micah M. Berman, J.D., Columbus, Ohio; Lora M. Church, Albuquerque, New Mexico; Representative Eileen Naughton, J.D., Providence, Rhode Island; Carlos A.O. Pavão, M.P.A., Chamblee, Georgia; John W. Walsh, Miami, Florida; and James S. Wong, Ph.D., San Jose, California.

Dr. Zerhouni recognized the two new Advisory Committee to the Director (ACD)-COPR liaisons: John C. Nelson, M.D., M.P.H., FACOG, FACPM, from the ACD, and Elizabeth Furlong, R.N., Ph.D., J.D., from the COPR.

Dr. Zerhouni congratulated Marjorie Mau, M.D., M.S., and COPR alumnus Douglass Yee, M.B.A., on their article about the importance of public participation in research that was published in the January 2008 issue of *Hawai'i Medical Journal*.

Dr. Zerhouni thanked the COPR members serving on other working groups and councils: Dr. Mau and Syed Ahmed, M.D., Dr.P.H, M.P.H., on the ACD Working Group on Peer Review, Dr. Mau on the NIH Council of Councils, and Cynthia Lindquist, Ph.D., M.P.A, on the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies.

Dr. Zerhouni also thanked COPR members Valda Boyd Ford, M.P.H., M.S., R.N., Brent Jaquet, Anne Muñoz-Furlong, and James Wendorf, M.A., as well as COPR alumnus Michael Manganiello, M.P.A., for participating on the Public Review Working Group for

the Research, Condition, and Disease Categorization system.

Dr. Zerhouni announced that Ann-Gel Palermo, M.P.H., and Dr. Mau would be participating on a review panel for the newly established Partners in Research Awards Program.

Dr. Zerhouni provided updates in a number of areas. The fiscal year (FY) 2008 Budget for NIH remains flat; however, NIH directors continue working hard to maintain their priorities and look to Congress to sustain biomedical research given the enormous discoveries that are occurring at a very fast pace.

Two priority areas for NIH directors are to: 1) continue support of 9,700 investigator-initiated research projects, which is the same number as in FY 2007, and 2) continue investment in more than 1,500 early-stage investigators, the average of the past five years.

A comprehensive peer review analysis has been conducted with input from the public, and a preliminary report with recommendations has been presented to the Director.

The NIH Public Access Policy, which ensures that the public has access to published results of NIH -funded research, has been implemented.

Two initiatives that are part of the NIH Roadmap for Medical Research and critical to scientific progress and discovery are being launched: the Human Microbiome Project and the Epigenomics Program.

Dr. Zerhouni discussed the growing concern about the increasing number of attacks on researchers who use animals in research, which he described as a form of terrorism. He

further noted that this act of violence threatens the dedicated scientists working to improve serious health problems facing this country.

Josephine Briggs, M.D., has been appointed Director of the National Center for Complementary and Alternative Medicine. Samuel Wilson, M.D., has been appointed Acting Director of the National Institute of Environmental Health Services. Christine A. Bachrach, Ph.D., is serving as the Acting Associate Director for Behavioral and Social Sciences Research and Acting Director of the Office of Behavioral and Social Sciences Research.

The National Institute of Child Health and Human Development (NICHD) has been renamed the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The ceremony on March 3, 2008, commemorated Mrs. Shriver's role in the establishment of the NICHD and her work with and founding of the Special Olympics. NICHD also has renamed its Mental Retardation and Developmental Disabilities Research Centers Program in honor of Mrs. Shriver. The program is now known as the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers Program.

Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, received the Presidential Medal of Freedom from President George W. Bush.

Vivian Pinn, M.D., Associate Director for Research on Women's Health, received the Silver Plain Language Award for her "Pinn Point on Women's Health" podcast series.

Raynard Kington, M.D., Ph.D., announced that on April 10, 2008, French President Nicolas Sarkozy presented Dr. Zerhouni with France's highest honor, the French National Order of the Legion of Honor, at the Elysée Palace in Paris.

Dr. Zerhouni presented data showing that investigators are being funded at later ages and stages of their careers, and he discussed the long-term implications of flat budgets that increase the difficulty of sustaining established investigators and of funding early-stage investigators who have vigorous new ideas that will transform health and medicine.

Michael M. Gottesman, M.D., Deputy Director for Intramural Research, discussed the NIH Intramural research program and outlined new trans-NIH initiatives.

Jeremy M. Berg, Ph.D., Director of the National Institute of General Medical Sciences, presented an update on the Peer Review Enhancement Initiative.

Melanie Modlin, Public Affairs Specialist at the National Library of Medicine (NLM), presented on the library's outreach program, including NLM's work with the National Network of Libraries of Medicine.

Elizabeth G. Nabel, M.D., Director of the National Heart, Lung, and Blood Institute, presented an update on the Genome-Wide Association Studies Policy, which promotes data sharing to identify common genetic factors that influence health and disease. More information is available at <http://grants.nih.gov/grants/gwas.index.htm>.

Christina Clark, M.A., M.B.A., and Mr. Wendorf, co-chairs of the COPR Agenda Work Group, provided an overview of the COPR's Work Group Day.

Ms. Palermo, co-chair of the COPR Role of the Public in Research Work Group, reported on the initiatives of the Work Group and action items discussed during the sessions the

previous day.

Mr. Jaquet, co-chair of the COPR Communications Work Group, reported on the recommendations discussed during the Work Group sessions on the previous day.

COPR members received updates from Dr. Nelson, the ACD liaison to COPR. Public comments were presented by Taylor Werner, who spoke on behalf of patients with Traumatic Brain Injury, and submitted by Diane Bargonetti, N.D., of New York and B. Sachau of New Jersey.

## **WELCOME AND INTRODUCTIONS**

**Elias A. Zerhouni, M.D.**

**Director, National Institutes of Health**

The 19<sup>th</sup> meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 18, 2008. NIH Director Elias A. Zerhouni, M.D., welcomed the COPR members and presenters.

Dr. Zerhouni recognized the new COPR appointees: Micah L. Berman, J.D., Executive Director and Visiting Professor of Law, Tobacco Public Policy Center of the Capital University Law School, Columbus, Ohio; Lora M. Church, Senior Program Manager, Acoma-Canoncito-Laguna Teen Centers, University of New Mexico, Albuquerque; Representative Eileen Naughton, J.D., State Representative of Rhode Island, Providence; Carlos A.O. Pavão, M.P.A., Community Administrator, DeKalb County Board of Health, Chamblee, Georgia; John W. Walsh, President and Chief Executive Officer, Alpha-1 Foundation, Miami, Florida; and James S. Wong, Ph.D., Senior Advisor, Strategy and Product Planning, Hitachi Global Storage Technologies, San Jose, California.

Dr. Zerhouni also recognized the two new Advisory Committee to the Director (ACD)-COPR liaisons: John C. Nelson, M.D., M.P.H., FACOG, FACPM, from the ACD, and Elizabeth Furlong, R.N., Ph.D., J.D., from the COPR.

Citing the important contributions that the COPR has made since last October, Dr. Zerhouni congratulated Marjorie Mau, M.D., M.S., and COPR alumnus Douglass Yee, M.B.A., for publishing an article on the importance of public participation in research on behalf of the COPR in the January 2008 issue of *Hawai'i Medical Journal*.

Dr. Zerhouni thanked COPR members who have joined ACD working groups: Dr. Mau and Syed Ahmed, M.D., Dr.P.H., M.P.H., members of the ACD Working Group on Peer Review, and Cynthia Lindquist, Ph.D., M.P.A., a member of the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies. He noted the importance of the COPR in bringing the public's perspective to the important process of privacy and protection that these working groups are addressing.

Dr. Zerhouni also recognized COPR members Valda Boyd Ford, M.P.H., M.S., R.N., Brent Jaquet, Anne Muñoz-Furlong, and James Wendorf, M.A., as well as COPR alumnus Michael Manganiello, M.P.A., for participating on the Public Review Working Group for the Research, Condition, and Disease Categorization system.

Dr. Zerhouni announced that Dr. Mau has been appointed to the newly instituted NIH Council of Councils, which was established under the 2006 NIH Reform Act and advises the NIH Director on cutting-edge trans-NIH priorities and matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives.

Dr. Zerhouni noted that directly following the COPR meeting, Ann-Gel S. Palermo, M.P.H., and Dr. Mau would be participating on review panels for the newly established Partners in Research Awards Program, which is a part of the NIH Public Trust Initiative supported by the COPR and co-led by Patricia Grady, R.N., Ph.D., FAAN, Director of the National Institute of Nursing Research, and Yvonne Maddox, Ph.D., Deputy Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The initiative's goals are to increase public trust in and understanding of NIH research and to foster a new paradigm for the future of medical and behavioral research. NIH has committed \$3 million to the program in fiscal year (FY) 2008 to

support two small pilot grant and feasibility studies.

Dr. Zerhouni thanked the COPR for its contributions and participation in this phase of the program. He also recognized and thanked all COPR members for their personal outreach efforts on behalf of NIH.

Dr. Zerhouni welcomed two former COPR members in the audience, Nicolas Linares-Orama, Ph.D., from Puerto Rico, and Ted Mala, M.D., M.P.H., from Alaska.

## **NIH DIRECTOR'S UPDATE**

**Elias A. Zerhouni, M.D.**

**Director, NIH**

Dr. Zerhouni presented the status of the FY 2008 budget for NIH, noting that the budget remains flat with no real increase planned and inflation continuing. NIH directors continue working hard to maintain their priorities and look to Congress to sustain biomedical research given the enormous discoveries that are occurring at a very fast pace.

Two priority areas for NIH directors are to: 1) continue support of 9,700 investigator-initiated research projects, which is the same number as in FY 2007, and 2) continue investment in more than 1,500 early-stage investigators, the average of the past five years.

The intent is to organize priorities to meet the budget crisis and allow for flexibility of immediate scientific investments, which will determine long-term competitiveness.

### **Enhancing Peer Review**

Dr. Zerhouni noted that one of the most important issues for NIH is the effort to enhance the Agency's peer -review system. the key question: How do we adapt Peer Review to

the changing landscape of science in changing times and ensure the highest quality review with the lowest administrative burden to both the investigators and NIH?

As part of NIH's longstanding commitment to supporting promising and meritorious biomedical and behavioral research using diverse approaches, strategies, and mechanisms, the agency has begun a comprehensive analysis of the Peer -Review Process lead by Lawrence Tabak, D.D.S., Ph.D., Director of the National Institute of Dental and Craniofacial Research, and Jeremy Berg, Ph.D., Director of the National Institute of General Medical Sciences (NIGMS). A preliminary report with recommendations has been presented to the Director, and the COPR will be briefed on the priorities of the new program as decisions are finalized.

### **Public Access Policy**

The NIH Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research went into effect January 11, 2008. Dr. Zerhouni noted that the policy represents a fundamental shift in the way scientific and public health information is distributed and used to enhance the research process. NIH is currently working to implement the policy from voluntary to mandatory status. As of April 7, 2008, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. It is a phased-in approach, allowing authors time to learn the new process. Public comments were being sought from March 31 to May 31, 2008. Dr. Zerhouni recognized Betsy Humphreys, M.L.S., Deputy Director of the National Library of Medicine (NLM), for her leadership on this effort and COPR members for promoting the public input opportunities.

### **Scientific Projects Initiated Through the Roadmap and the Common Fund**

Two initiatives that are part of the NIH Roadmap for Medical Research and critical to scientific progress and discovery are being launched: the Human Microbiome Project,

which will use genomic technologies to explore the role of microbes in human health and disease, and the Epigenomics Program, which will accelerate understanding of how the genomic code is regulated. A small portion of the budget, about 1.7%, is set aside for projects such as these, which are seen to be critical to scientific progress. More information on the Microbiome Project is available at <://nihroadmap.nih.gov/hmp> and information on the Epigenomics Program is available at <://nihroadmap.nih.gov/epigenomics/initiatives.asp>.

### **Use of Animals in Research**

Dr. Zerhouni cited growing concern about the increasing number of attacks on researchers who use animals in research. NIH treats animals in research with respect, even as every effort is being made to reduce the use of animals. Dr. Zerhouni pointed out that 85% of all treatments for animal diseases come from research using animals. These attacks on scientists, which are a form of terrorism, are not in the public interest or in the interest of the animals themselves.

### **Leadership Update**

Dr. Zerhouni introduced Josephine Briggs, M.D., the new Director of the National Center for Complementary and Alternative Medicine (NCCAM), calling her an accomplished researcher and physician who brings a focus on translational research to the study of complementary and alternative medicine. In 1997, Dr. Briggs served as Director of the Division of Kidney, Urologic, and Hematologic Diseases in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Dr. Briggs described the two-fold mission of NCCAM as (1) bringing the rigor of science to the evaluation of the safety and efficacy of widely used interventions for health and (2)

serving as a public information resource. She invited the COPR's input and advice.

Dr. Zerhouni thanked John (Jack) Killen, M.D., for his contributions to NCCAM and Ruth Kirschstein, M.D., who was the Acting Director of NCCAM and who remains a senior advisor to the NIH Director.

Samuel Wilson, M.D., was appointed Acting Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program. Dr. Wilson joined NIEHS in 1996 as Deputy Director and Chief of the DNA Repair and Nucleic Acid Enzymology Group in the Intramural Division. He will oversee a proactive analysis of the institute.

Dr. Zerhouni noted that Christine A. Bachrach, Ph.D., is the Acting Director of the Office of Behavioral and Social Science Research and Acting Associate Director of Behavioral and Social Science Research at NIH.

Dr. Zerhouni announced the renaming of the National Institute of Child Health and Human Development (NICHD) to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in a ceremony on March 3, 2008, to honor Mrs. Shriver's role in the establishment of the NICHD and her work in and founding of the Special Olympics.

NICHD also has renamed its Mental Retardation and Developmental Disabilities Research Centers Program in honor of Mrs. Shriver. The name change acknowledges the contribution of Mrs. Shriver and replaces the outmoded term "mental retardation" with "intellectual disabilities." The program is now known as the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers Program.

Duane F. Alexander, M.D., NICHD Director, addressed the Council, noting that other than the John E. Fogarty International Center, NICHD is the first institute at NIH to have the name of a person associated with it in its title. He recalled Mrs. Shriver's advocacy for an institute at the NIH focusing on maternal and child health and human development, lobbying both her brother, President John F. Kennedy, and the Congress until NICHD was established. Mrs. Shriver was also inducted into the Institute's Hall of Honor, which recognizes outstanding individuals who have made major contributions to the Institute and public health. In addition, the Mental Retardation and Developmental Disabilities Research Centers were renamed in her honor and are now the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers.

Guests of the event included Mrs. Shriver's brother, Senator Edward Kennedy, her sister, Jean Kennedy Smith, her daughter Maria and her husband, Governor Arnold Schwarzenegger, members of Congress, federal officials, as well as extended family and friends.

### **NIH Directors Receive Awards**

Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, received the Presidential Medal of Freedom from President George W. Bush at a White House ceremony on November 5, 2007, in honor of his leadership in revolutionizing genetic research.

Vivian Pinn, M.D., Associate Director for Research on Women's Health, received the Silver Plain Language Award for her very successful "Pinn Point on Women's Health" podcast series, which provides the latest news in women's health research and includes conversations with expert guests on a variety of subjects. Podcasts are located on the Office of Research on Women's Health web site at

[://orwh.od.nih.gov/podcast/podcast\\_archive.html](http://orwh.od.nih.gov/podcast/podcast_archive.html) .

### **Dr. Zerhouni Discusses Grants to Young Scientists**

Dr. Zerhouni noted his concern about the long-term effect of not encouraging and supporting talented young scientists early in their careers. Through a series of slides, he illustrated that the average age for receiving independent grants has risen from early 30 years to early 40 years. Dr. Zerhouni expressed concern that as a result of lengthening training periods, compounded by the demographic impact of the baby boom generation, today more scientists are in late-stage than early-stage careers, a trend that is expected to continue over the next decade.

Tight budget times penalize new investigators more than established investigators, and there has been a significant decrease in first-time Research Project Grants (RO1s) from a high of more than 1,600 as the budget has gone flat. The NIH directors have instituted successful policies to maintain the number of new investigators at about 1,500 in the face of falling budgets. But the long-term risk of these flat budgets is the difficulty of sustaining the established investigators and still funding early-stage investigators who have vigorous new ideas that will transform health and medicine.

### **Dr. Zerhouni Honored by the President of France**

Raynard Kington, M.D., Ph.D., announced that on April 10, 2008, Dr. Zerhouni received France's highest honor in a ceremony at the Elysée Palace in Paris. French President Nicolas Sarkozy made him a Knight of the National Order of the Legion of Honor "in recognition of his brilliant professional career and his remarkable contribution to Franco-American exchanges in life sciences research."

### **Discussion (COPR Members)**

Mr. Wendorf thanked Dr. Zerhouni and Dr. Kington for their comments.

Dr. Nelson asked whether any specific demographic explained why certain laboratories did not receive bridge awards. Dr. Zerhouni said that because it takes about \$300,000–\$400,000 to fund a lab for a year, the institutes focused on helping labs that had less than that and would have to close without a bridge award. He offered to provide information about the areas of research that needed these awards.

Christina Clark, M.A., M.B.A., asked Dr. Zerhouni to comment about careers in knowledge management and the strategic thinking process that would transition into 21<sup>st</sup> century opportunities. Dr. Zerhouni replied that the complexity of analyzing new information involves knowledge management, an evolving field of science. He noted Dr. Kington's view that more must be done to understand not only the knowledge management but also the social and behavioral aspects involved. Alan Krensky, M.D., Director of the Office of Portfolio Analysis and Strategic Initiatives (OPASI), added that OPASI is focusing on this issue both in the knowledge management of portfolio analysis and the lesser-known "science of science." A workshop with a wide range of experts is being scheduled to discuss these issues, particularly the role of NIH in knowledge generation for public health. Ms. Humphreys observed that knowledge management is considered a core activity within the general discipline of biomedical informatics. She noted that NLM, which has been supporting academic research training in biomedical informatics for more than 30 years, currently has programs funded at 18 universities across the country.

Mr. Pavão asked whether the gender gap has closed in the past 25 years and what strategies are planned for the future. Dr. Zerhouni stated that the numbers are going in the right direction, with 25%–30% of chairs and top science positions held by women. The gap is closing, but not fast enough, and more needs to be done.

Mr. Jaquet, referring to violence against scientists, asked whether grants include a requirement that universities must protect scientists. Dr. Zerhouni said that policies and support mechanisms are being developed to ensure that the public understands the

problem and that universities support their scientists. There is also outreach to mainline animal rights organizations. Dr. Kington added that the Office of Extramural Research is developing toolkits and a Web site to help universities respond to threats.

Dr. Mau asked whether NIH had a mentorship program for young scientists. Dr. Zerhouni said that although NIH does not provide direct mentoring, it supports and provides indirect mentoring through the peer -review process and fellowship awards. He noted that this area is best addressed by medical schools.

## **THE NIH INTRAMURAL RESEARCH PROGRAM: NEW TRANS-NIH INITIATIVES**

**Michael M. Gottesman, M.D.**

Dr. Gottesman, Deputy Director for Intramural Research, explained that the mission of the intramural Research program is to conduct distinctive, high-risk, high-impact laboratory, clinical, and population-based research in a unique and fostering environment and to train a diverse population of outstanding young researchers. The intramural budget is slightly less than 10% of the overall NIH budget.

The majority of institutes and centers have intramural programs that involve more than 8,000 scientists and students. The main focus of the intramural training activity is the postdoctoral fellowship program. Although most intramural research is conducted on the NIH campus, there also is an NIH intramural presence in other states, including North Carolina, Montana, Arizona, Michigan, and other areas in Maryland.

Several factors make the NIH intramural Research program distinct:

- A high degree of intellectual freedom that supports the ability to do high-risk, high-impact research with a predominantly retrospective review system.
- Stable resources and funding for new technology and long-term projects.
- A critical mass of talent.
- Leadership that recognizes and preserves the unique features of the program.

- The Clinical Center, which is the largest hospital in the world dedicated to research.

Dr. Gottesman stated that trans-NIH initiatives are being undertaken to encourage researchers to interact in a more cooperative process that transcends the individual institutes and centers and takes advantage of the special features of the intramural research program in new and creative ways. These initiatives include:

- Center for Human Immunology, Autoimmunity, and Inflammation—This program, headed by Neil S. Young, M.D., of the National Heart, Lung, and Blood Institute (NHLBI), is designed to tap the talent of the 400 (out of 1,200) intramural principal investigators (PIs) who work primarily with immunologic systems. It will bring clinical investigators together with the basic immunology community to advance the study of human immunology in a major way that could become a model for NIH translational research.
- Imaging Initiative—This project will combine all the various imaging initiatives across NIH to foster the development of new probes and chemistry that will provide scientists with access to cutting-edge technology.
- Systems Biology Initiative—This initiative will support a comprehensive integration of basic biological and quantitative information with the goal of creating a computer-based model that is predictive about how cells respond to various stimuli.
- Various other initiatives, which include funding opportunities for collaboration between the laboratory and the clinic, a new obesity center, and the use of adult stem cells in research in clinical practice.

### **Discussion (COPR members)**

Mr. Walsh noted the positive impact of the NIH intramural Research program, especially on rarer diseases. He asked about the possibility of “connecting the dots” between the Systems Biology Initiative and the Chemical Genomics Center. Dr. Gottesman agreed that the Genomics program would be useful in developing chemical probes for use in

systems biology studies. He added that the immunology studies would also use the Chemical Genomics Center and stated that the Center would continue to be funded after its Roadmap funding expired.

Mr. Wendorf asked what plans were being made to communicate the results of these initiatives for maximum impact both within NIH and to the public. Dr. Gottesman cited the *Catalyst*, an NIH-based magazine published from his office and read by intramural scientists, and the technology that allows him to access investigators quickly with messages. The public will learn about some results through the normal process of publication, but Dr. Gottesman asked for the COPR's help in disseminating information that is especially important to the public. Dr. Gottesman agreed that more work needs to be done to educate the public about the work being done at NIH, both intramurally and extramurally.

Naomi Cottoms, M.S., asked about the ranking of the obesity initiative in light of the flat budget. Dr. Gottesman said that it is ranked at the highest priority because the obesity center, containing state-of-the-art equipment such as the metabolic chamber, has been completed and research has already begun. He invited COPR members to tour the new facility (new members toured the facility as part of orientation on April 16). Dr. Zerhouni added that the obesity research budget has tripled, and he referred to a strategic research plan on obesity that was developed in 2003 that could be shared with the COPR. He noted the difficulty of obesity research and the need to undertake it in a highly sophisticated facility, such as that at NIH.

## **UPDATE ON ENHANCING PEER REVIEW AT NIH**

### **Jeremy M. Berg, Ph.D.**

Dr. Berg, Director of NIGMS, described the peer -review process as advancing Dr. Zerhouni's directive to "fund the best science, by the best scientists, with the least administrative burden."

The diagnostic phase of the review, which included outreach to the public and scientific community to identify the challenges of the current peer -review process and potential solutions, is complete. Some of the recommendations include:

- Reducing the administrative burden on applicants, reviewers, and staff who are inundated with too many applications and submission rounds. Solutions include adding a “Not recommended for resubmission” category and eliminating the special status of amended applications.
- Enhancing the rating system for usefulness and consistency by adding more early interaction between reviewers and applicants, rating multiple criteria to provide better-defined feedback instead of using a single overall score, and shortening and restructuring the applications and the reviews.
- Enhancing review quality, with more emphasis on the broad impact of the research, and the use of editorial board models and electronic reviews.
- Enhancing reviewer quality through training of study section chairs and scientific review officers, building in more flexibility, and linking board service to NIH awards to help attract top-quality reviewers.
- Optimizing support at different career stages by funding early-career investigators and giving established investigators longer periods of support.
- Optimizing support for different approaches to science by setting aside a percentage of funding for transformative (high risk/high reward) research, piloting use of patients or their advocates to review clinical research, and enhancing support for interdisciplinary research.
- Reducing stress on the support system by requiring a minimum percentage (20%) of effort by PIs, and analyzing the incentives in the funding system.
- Meeting the need for continuous review of peer review by identifying what is working and what might cause unintended consequences.

Dr. Berg stated that a report has been sent to Dr. Zerhouni about the feasibility of implementing these various ideas. When Dr. Zerhouni has made a final decision, phased implementation of selected actions will begin.

## **Discussion (COPR members)**

Ms. Palermo asked whether the goals of the Peer -Review process to reduce the administrative burden and focus on the merit of the science would exclude community engagement and participation. She also asked for Dr. Berg's thoughts as the COPR begins to develop guidance for peer -review panels to help them evaluate community engagement. Dr. Berg stated that institutes should, and do, consider community participation for funding projects that depend critically on community involvement. Dr. Berg noted that some institutes have piloted the use of public members in the first level of peer review, and he emphasized the importance of public representatives having adequate training. He asked the COPR to consider the type and structure of training that would be helpful.

Ms. Palermo suggested that the transparency of the process from a community perspective appeared to be missing from the goals of the peer -review process and asked that this be included as a goal. Dr. Berg agreed that the process must be as transparent as possible to avoid misunderstandings about how projects are funded. Dr. Zerhouni emphasized that peer review at the first level is a technical review; funding decisions are made at the advisory level, at which one-third of the members are public members, thereby giving the public a tremendous impact on these decisions.

Linda Crew, M.B.A., R.N., asked for a clarification of the "editorial board model." Dr. Berg explained that there are many variations, but the basic concept is to have a large number of people independently involved in the first level of review with their input going to an editorial board that integrates the various input and compiles a final list of ratings, which go to the advisory councils for the next level of review.

Dr. Mau asked for comment about peer review for applications that are looking at community engagement and translation, such as the Clinical and Translational Science Awards or the partners in research Awards. She also inquired about the scientific expertise required for those kinds of applications. Dr. Berg said that this had not been

discussed because the focus was on scientific initiatives. He noted that institutes and centers have their own review offices in addition to the peer review conducted by the Center for Scientific Review, and he suggested that there is a need to find people with expertise in how to engage appropriate communities effectively in the research.

Ms. Church asked about the timeline for assessing the new review process and wondered about recruiting more community members to serve on review panels. Dr. Berg said that the timeline and evaluation plans are linked to specific actions. Some, such as providing scores to reviewers, are easy to implement and can be assessed quickly. Others, like changing the structure of the application, are complicated and will take considerable time to implement. The biggest challenge will be measuring whether better science is being funded, which is hard to do in a reasonable time scale. With respect to recruiting public members, Dr. Berg welcomed input from the COPR.

Ms. Clark cautioned against having too narrow a focus on the appropriate roles for the public and thus failing to involve the public in basic biomedical protocols from the start. She asked whether Dr. Berg thought it valuable to revisit where the public belongs in the peer review continuum in light of what may be artificial distinctions between basic and clinical research. Dr. Berg replied that the reviews of basic research are stronger when there is a broad review panel and that it is tremendously helpful to have sufficient breadth to counteract the more narrowly focused study sections.

## **NATIONAL LIBRARY OF MEDICINE OUTREACH INITIATIVES**

### **Melanie Modlin**

Ms. Modlin, Public Affairs Specialist for NLM, gave an overview of the outreach services available from NLM, the world's largest medical library, with resources in 150 languages. She noted that in a typical two-day period, NLM users download the equivalent of an entire Library of Congress of data. Providing this level of information is one way that NLM magnifies the positive impact of NIH's investment in scientific and clinical research.

The main NLM outreach tools include:

- MedlinePlus—An online resource, in English and Spanish, that links consumers to reliable, up-to-date, easy-to-read public and private health information.
- *NIH MedlinePlus* magazine—a quarterly publication designed to provide the public with the gold standard of consumer health information from NIH. NLM distributes 300,000 copies free of charge to doctor's offices, libraries, community health centers, and other locations. Ms. Modlin invited the COPR's suggestions about topics for articles and celebrities to feature on the cover. There will also be a bilingual version of the magazine, in Spanish and English.
- National Network of Libraries of Medicine—This is an effort to provide all U.S. health professionals with equal access to biomedical information and improve the public's access to information that will enable consumers to make informed decisions about their health. The network is comprised of eight regional libraries (hubs), 159 resource libraries located primarily at medical schools, and 4,700 primary access libraries.
- ClinicalTrials.gov—A centralized, comprehensive database for clinical trials that includes 54,000 trials in the United States and 154 nations.

Smaller outreach initiatives include:

- DeBakey Science Events—A program of reaching out to high school students to encourage medical careers.
- Pow Wows—An outreach to Native American populations.
- Exhibitions—The current exhibition is *Against the Odds: Making a Difference in Global Health*. A previous exhibition, *Changing the Face of Medicine*, on America's women physicians, is traveling throughout the country until 2010. There are also Web sites associated with the exhibits, which include detailed teaching and lesson plans.

## **Discussion (COPR members)**

Dr. Lindquist recounted how her small tribal college in North Dakota, with the help of the NLM outreach program, created a section in the school public library dedicated to various diseases and health issues that affect the community. NLM also helped provide the technology and computers to track usage. Dr. Lindquist noted the tremendous impact this network can make at small, more remote venues.

Dr. Wong asked whether the information on the NLM Web site or through links on that site is available at a variety of technical levels that can take patients from a first cursory look at a disease to more detailed research. Ms. Modlin stated that people could start with the basics on MedlinePlus, then move on to both PubMed, which offers biomedical knowledge, and PubMed Central, which includes 1.7 million printed medical articles. In addition, there is a toll-free line on the Web site, and the NLM staff is available and happy to answer questions. Ms. Modlin noted that NLM has about 75 databases, so there is a wealth of information available at various levels.

Ms. Church noted that she has found PubMed invaluable in her graduate work. She asked for NLM publications that she could distribute at the various Native American events. Ms. Church offered to open a COPR meeting with Native American culture and traditions to celebrate the diversity of public representation on the Council.

Dr. Furlong complimented her Nebraska area network representative that operates the listserv informing the public of so many resources. She wondered about getting NIH to become a top tourist attraction in Washington, D.C.

Ms. Palermo, noting that she works in East Harlem, suggested creating a program to help develop the capacity of community librarians to navigate these databases and help community residents access them. Ms. Palermo also suggested a partnership between NLM and the National Area Health Education Centers to facilitate the establishment of mini National Libraries of Medicine around the country in disadvantaged areas.

Mr. Jaquet asked about the scope of ClinicalTrials.gov. Ms. Modlin replied that it has become such a successful recruiting tool that private pharmaceutical companies have started posting trials. Elliot R. Siegel, Ph.D., Associate Director, NLM Health Information Program Development, added that as a condition of publication, many journals now require the registration of clinical trials in clinicaltrials.gov. NLM is also working with international organizations to acquire their trials through a partnership similar to that of the genomics community. Dr. Siegel announced that the next NLM exhibition, opening in 2010, would feature Native American concepts of health and illness.

Ms. Crew recalled that NLM had helped fund a project called The Health Connector Program that she implemented to bring reliable health information to rural communities. Her organization bought a computer, paid for the Internet connection, and trained a person from the community to show community residents how to access health information. Ms. Modlin expressed interest in the program, saying that it might fit into Ms. Palermo's suggestion about training librarians.

Mr. Berman asked for interdisciplinary outreach efforts to departments at schools and universities. Ms. Modlin agreed that outreach to nontraditional departments could help identify important areas that have been overlooked.

## **GENOME-WIDE ASSOCIATION STUDIES POLICY: AN UPDATE**

**Elizabeth G. Nabel, M.D.**

Elizabeth G. Nabel, M.D., Director of NHLBI, discussed the new policy, across all 27 institutes and centers, to coordinate sharing of data obtained in NIH-supported or -conducted genome-wide association studies (GWAS). More information is available at <http://grants.nih.gov/grants/gwas.index.htm>.

Dr. Nabel described how variations in genetic codes can predispose individuals to certain diseases. Genomics research takes advantage of new technology to isolate DNA to compare individuals who are affected with a certain variation that has caused a disease with those unaffected. These genetic studies are designed to determine how common the variance is in the population and its importance in causing disease.

This new technology can be applied to previous studies, such as the Framingham Heart Study, which NIH has funded since 1948. The 10,000 participants in that study agreed to have their DNA analyzed. The more than 5.5 billion pieces of genetic data (genotype), along with their clinical data (phenotype), are now contained in a database called Database Genotype and Phenotype (dbGaP), which allows researchers to conduct more than five trillion tests of association between genetic variation and clinical parameters.

Other institutes are assembling similar rich datasets for diabetes, cancer, and mental illness. Realizing the importance of sharing these data, especially with the proliferation of applications to do genome-wide associations, NIH drafted a policy for data sharing.

Dr. Nabel outlined the components of the policy. Submitting investigators gather information on participants, de-identify it, and submit this dataset for inclusion in the NIH central data repository, dbGaP. This process includes privacy safeguards and institutional review board (IRB) input about confidentiality issues. The NLM Web site, which is the homepage for dbGaP, lists the studies that are contained within the repository.

Investigators wishing to use dbGaP datasets (recipient investigators) apply and must be approved by a data access committee (DAC). Each institute has a DAC that consists of federal staff with expertise in science, bioethics, and privacy/confidentiality issues. The recipient investigator and the institution must agree to strict requirements about the use of

the data before receiving the dataset, which is sent in an encrypted manner.

The recipient investigator has a 12-month period of exclusivity for publication. NIH urges that genotype-phenotype associations remain available to all investigators, unencumbered by intellectual property claims.

For any grant to do GWAS that is funded after a submission date of January 25, 2008, the investigator must submit a data sharing plan that is consistent with the GWAS policy prior to receiving notice of the grant award. This ensures that the data from the grant will be added to dbGaP.

To provide adequate oversight for the implementation of this policy, a comprehensive trans-NIH governance structure has been established that includes technological protection for the information itself and confidentiality protection for human subjects.

Dr. Nabel noted the role of Dr. Lindquist, who is the liaison to the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies. She concluded by acknowledging the role of the participating institutes and centers.

#### **Discussion (COPR members)**

Mr. Walsh commended Dr. Nabel on the NHLBI chronic obstructive pulmonary disease (COPD) public awareness campaign, *Learn More, Breathe Better*. He added that as an individual affected by alpha-1 –related genetic COPD, he hoped for a reconsideration of the GWAS confidentiality policy to allow individuals in studies to be notified of a finding of a genetic predisposition to a disease. Mr. Walsh congratulated Dr. Nabel for her leadership on the COPD Genetic Epidemiology Study, which includes a GWAS with

more than 10,000 study subjects. Dr. Nabel stated that the issue of notification of individuals is a very complex one, involving the need for strong privacy safeguards to prevent misuse of the information. Currently, notification is being handled at the PI and IRB level.

Dr. Furlong asked what other limitations participants request, besides not wanting their information used in a proprietary way. Dr. Nabel replied that the other major limitation requested was to limit the type of studies for which the information could be used, such as for heart research but not mental illness studies.

Ms. Palermo asked how GWAS are initiated and what the implications are for participants in terms of understanding the scope of these studies and thus being less likely to put limitations on the use of information. She also asked about plans to disseminate the information from the studies to the community. Dr. Nabel explained that GWAS are initiated by institutes, as with the Framingham example, and by investigators who have datasets that could be enhanced by adding a genomic component. An important aspect is instilling pride in participants that they are furthering medical research that benefits others. In terms of disseminating information to the community, this education piece will be the subject of upcoming meetings. A public update component to the dbGaP web site is also being considered.

Dr. Nelson asked whether there is a “chilling effect,” both because of the project’s complexity and the possibility that it will raise the cost of research and actually reduce the amount of research being done. Dr. Nabel acknowledged that it is difficult to find the right balance between making the data available to foster creative research and yet still have enough privacy safeguards in place. At least in these early stages, there is probably a trend toward erring on the side of caution to avoid an incident that could jeopardize the entire program.

Dr. Zerhouni noted Dr. Nabel's great leadership in crafting a policy that addresses so many complex issues.

## **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., Co-Chairs**

Ms. Clark and Mr. Wendorf, co-chairs of the spring 2008 Agenda Work Group, provided Dr. Zerhouni with an overview of the Work Group Day that took place April 17.

Ms. Clark described the purpose of the Agenda Work Group as helping to translate the COPR's recommendations about the broad development of NIH programmatic and research priorities into action. Therefore, the Work Group Day was organized to more effectively carry out the COPR's dual functions of bringing the public's perspectives to NIH and identifying ways to help NIH deliver information to the public.

Ms. Clark noted that since the last meeting, the COPR has:

- Delivered an editorial to raise public awareness, published in Hawai'i Medical Journal.
- Developed definitions of community engagement and public participation.
- Developed recommendations to support trans-NIH communications strategies.
- Supported the strategic initiatives of the Office of the Director as they relate to public interest.

COPR members and alumni have also been active on several fronts. In addition to the activities noted by Dr. Zerhouni during his update to the Council, Ms. Clark reported on the following:

- Wendy Chaite, Esq., former COPR member, has been appointed to the National Advisory Research Resources Council.
- Nicole Johnson, M.A., M.P.H., who interacts with the public through her television show, dLife, recently visited the laboratory of David Harlan, M.D. at NIDDK.

## **UPDATE: THE ROLE OF THE PUBLIC IN RESEARCH WORK GROUP**

### **Ann-Gel Palermo, M.P.H., Co-Chair**

Ms. Palermo reported on activities for the Role of the Public in Research Work Group on behalf of its members and her Co-chair, Syed M. Ahmed, M.D., Dr. P.H., M.P.H., who was unable to attend the meeting. The purpose of the Work Group is to identify ways to encourage researchers to involve the public in research, with an emphasis on community engagement.

During the previous day, the Group held a roundtable session with experts from within and outside NIH to help build a framework for their efforts focused on researcher training and peer -review panels involving community engagement. Roundtable participants included:

- Amy Bany Adams, Ph.D., *Special Assistant to the NIH Director, Office of the Director, NIH*
- David Armstrong, Ph.D., *Chief, Scientific Review Branch, National Institute of Mental Health, NIH*
- Jared Jobe, Ph.D., FABMR, *Program Director, Clinical Applications and Prevention Branch, Division of Prevention and Population Sciences, NHLBI, NIH*
- Loretta Jones, M.A. *Founder and Executive Director, Healthy African American Families II*

- Donna Jo McCloskey, Ph.D., R.N., *Health Scientist Administrator, Division for Clinical Research Resources, National Center for Research Resources, NIH*
- Walter Schaffer, Ph.D., *Senior Advisor, Office of Extramural Research, NIH*
- Vivian Ota Wang, Ph.D., *Executive Office of the President, National Nanotechnology Coordination Office, National Science and Technology Council*

As a result of research undertaken since the last meeting and the valuable input from the roundtable discussion with experts during the Work Group Day, the Role of the Public in Research Work Group has:

- Crafted definitions of community engagement and public participation:  
 [DRAFT] *Community engagement in research is a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus.*  
*It is a process that requires power sharing, maintenance of equity, and flexibility in pursuing goals, methods, and time frames to fit the priorities, needs, and capacities within the cultural context of communities. Community engagement in research is often operationalized in the form of partnerships, collaboratives, and coalitions that help mobilize resources and influence systems; change relationships among partners; and serve as catalysts for changing policies, programs, and practices.*

*Community engagement is a core element of any research effort involving communities. It requires academic members to become part of the community and community members to become part of the research team, thereby creating a unique working and learning environment before, during, and after the research.*

*Adapted from:*

Jones L, Wells K. Strategies for academic and clinician engagement in community-participatory partnered research. *JAMA* 2007;297:407–410. p. 408.

Fawcett SB, Paine-Andrews A, Francisco VT, Schultz JA, Richter KP, Lewis RK, Williams EL, Harris KJ, Berkley JY, Fisher JL, Lopez CM. Using empowerment theory in collaborative partnership for community health and development. *Am J Community Psychol* 1995;23:677–697.

*Public participation is based on the belief that those who are affected by a decision have a right to be involved in the decision-making process. Public participation is the process by which an organization consults with interested or affected individuals, organizations, and government entities before making a decision. Public participation is two-way communication and collaborative problem solving with the goal of achieving better and more acceptable decisions*

*Sources:*

International Association of Public Participation. IAP2 Core Values.

<http://www.iap2.org/displaycommon.cfm?an=4>.

Creighton and Creighton, Inc. What is...?

<://www.creightonandcreighton.com/whatis.html#6>.

- Created a template of values, strategies/recommendations, and outcomes to be used for developing guidelines for educating researchers and the public about community engagement.
- Identified a process for developing guidelines that peer-review panels can use to gauge community engagement.

Next steps to be addressed between April 2008 and October 2008:

- Complete the template for use in developing guidelines for educating researchers about community engagement.
- Identify models/best practices for developing guidelines for peer-review panels.

Ms. Palermo asked the COPR to approve the definitions of community engagement and public participation.

### **Discussion (COPR Members)**

As Agenda Work Group Co-Chair, Mr. Wendorf presented the definitions of community engagement and public participation that represent the consensus of the COPR to Dr. Zerhouni for approval.

Dr. Zerhouni thanked Ms. Palermo and the Work Group members for their extensive work. He shared positive impressions on the definitions, but noted that the portion of the community engagement definition that states “It is a process that requires power sharing, maintenance of equity and flexibility...” was more of an operating principle or method of implementation than a definition. Ms. Palermo recognized the work group’s agreement with Dr. Zerhouni’s comments, as they discussed the need to operationalize the definitions as part of their next steps.

Dr. Zerhouni raised the question of whether the text might be considered “characteristics of positive community engagement” rather than a definition. He stated that he is officially in receipt of this text, calling it “terrific work.” He added that it could be implemented at many levels.

Ms. Clark noted that the COPR considers this definition a starting point to be further developed. Dr. Zerhouni characterized it as a definition of “desirable processes.”

## **UPDATE: COMMUNICATIONS WORK GROUP**

### **Brent M. Jaquet, Co-chair**

Mr. Jaquet described the role of the Communications Work Group as:

- Promoting awareness about NIH to the public.
- Acting as a vehicle for communication from the public to NIH.
- Recommending communications strategies that support the work of the COPR.

During the previous day, the Work Group held a panel session with experts in communications from within and outside NIH to gain insight on effective communications strategies that can be incorporated into the Council’s planning activities surrounding education and outreach efforts. Presentations included:

- *The Heart Truth*<sup>TM</sup> Campaign —Ann Taubenheim, Ph.D., M.S.N., and Diane Striar, NHLBI; Sarah Temple and Jennifer Wayman, M.H.S., Ogilvy Public Relations Worldwide
- *Nuts and Bolts of Campaign Advertising* —Kate Emanuel, M.P.H., M.A., Ad Council
- *Communications and New Media* —Jeff Gralnick, NBC News
- *NIH YouTube Update* —Jeff Dehoff, Office of Communication and Public Liaison, NIH

Building on previous initiatives, crystallizing the Work Group’s recommendations presented in the March 14, 2008, letter to Dr. Zerhouni, and incorporating the valuable input from the presenters on the Work Group Day, the Communications Work Group recommends implementation of a trans-NIH “Communications Roadmap” that will:

- Present NIH through an integrated, unified communications and Web strategy.

- Require budget and cultural changes and possibly include public/private partnerships.
- Represent the opportunity to devise a dual awareness and branding campaign focused on health consumers that would make NIH widely recognized as the “gold standard” for objective, evidence-based health information.
- Integrate the use and power of “new media” for maximum dissemination of information.

The COPR offered to take a leadership role in helping NIH obtain input about:

1. What the public wants to know.
2. How the public obtains health information.

Possible approaches they suggest include town hall meetings, internet activities, and large public deliberation activities.

### **Discussion (COPR Members)**

Mr. Burklow called this a timely project that would harness the resources of NIH to provide an integrated, valuable communications strategy.

Dr. Nelson complimented Mr. Burklow on his work to date in advancing the NIH communications strategy and endorsed the idea of moving to a new level.

Dr. Zerhouni called the presentation stimulating and timely. He asked whether the focus of the project is strategic distribution. Mr. Jaquet replied that the project’s goal is to raise awareness of NIH as an entity, rather than as many disparate parts, and that strategic distribution of information is a part of the process.

Dr. Zerhouni asked whether the current NIH Web presence and content is insufficient or whether the problem is that NIH is not positioned in a way to get maximum attention from consumers. Mr. Wendorf suggested a look at the consumers' ability to find information from many separate silos, which can be confusing, or if there is benefit in pursuing an integrated, strategic communication network at the NIH level. Mr. Jaquet added that to move from individual silos to an integrated trans-NIH Web site would require a dedication of resources.

Dr. Zerhouni stated that his understanding from the presentation was that both the NIH Web presence and the way NIH distributes information need to move to another level.

Ms. Church cautioned about forgetting the people who do not have access to the technology or resources to get information online. She added that literacy level must also be taken into account. Mr. Jaquet suggested that a fully developed awareness campaign would filter to the community level and include printed or other appropriate materials.

Ms. Johnson suggested having NIH alumni or others who have been associated with NIH write a blog to further disseminate the story of what NIH does.

Dr. Nelson suggested recounting some of the major NIH breakthroughs on the Web site and framed the ultimate goal as having the American public understand that NIH is the gold standard.

Mr. Burklow described new media as one component of an integrated, multipronged strategic approach and said that the communications directors are ready to consider a specific campaign to make information more accessible. He announced plans for a fall meeting of experts, including COPR representation, to discuss this issue.

Mr. Pavão asked whether other federal agencies, such as the Centers for Disease Control and Prevention, have information dissemination practices that could be used by NIH. Mr. Wendorf suggested looking at university models that have integrated communication networks without losing the individuality of their various schools.

Mr. Walsh suggested working with organizations such as the American Cancer Society or American Heart Association, asking them to refer to NIH, which funds much of their research, on their Web sites and in their literature.

### **PUBLIC COMMENT**

Public comments were presented by Taylor Werner, who spoke on behalf of patients with Traumatic Brain Injury, and submitted by Diane Bargonetti, N.D., of New York and B. Sachau of New Jersey.

### **ACD LIAISON REPORT**

**John Nelson, M.D., M.P.H., FACOG, FACPM, ACD Liaison to the COPR, and Elizabeth Furlong, R.N., Ph.D., J.D., COPR Liaison to the ACD**

Dr. Nelson reported on the December 2007 meeting of the ACD. The ACD members discussed the issue of supporting both established and new investigators and will continue to explore realistic ways within budget constraints to accomplish this issue. The ACD and invited speakers also discussed peer review (Lawrence Tabak, D.D.S., Ph.D., and Keith Yamamoto, Ph.D.), the National Institute of Diabetes and Digestive and Kidney Diseases Director's Report (Griffin Rodgers, M.D.), Participant and Data Protection for Genome-Wide Association Studies (Christine Seidman, M.D.), Roadmap 1.5 (Alan Krensky, M.D.), and the National Children's Study (Duane Alexander, M.D.), which is the largest long-term study of children's health and development ever conducted.

Dr. Zerhouni thanked Dr. Nelson for his work on both the ACD and COPR, and he stated that the input that he gets from the various advisory councils (ACD, COPR, Council of Councils, and the Scientific Management Review Board) is enriching, complementary, and makes a tangible difference to what happens at NIH.

### **NIH DIRECTOR AND COPR MEMBERS SUMMARY AND NEXT STEPS**

Ms. Clark recognized the efforts of Mr. Burklow, Marin Allen, Ph.D., and Kelli Carrington, M.A., in making the meeting a success. Dr. Zerhouni thanked Ms. Clark and Mr. Wendorf for their leadership and thanked the COPR members for the stimulating meeting and proposals.

Ms. Carrington announced that the next meeting of the COPR will take place October 30–31, 2008.

### **ADJOURNMENT**

The meeting was adjourned at 4:15 p.m.

## LIST OF ABBREVIATIONS AND ACRONYMS

ACD	Advisory Committee to the Director
COPD	chronic obstructive pulmonary disease
COPR	Council of Public Representatives
DAC	data access committee
dbGaP	Database Genotype and Phenotype
FY	fiscal year
GWAS	genome-wide association studies
IRB	institutional review board
NCCAM	National Center for Complementary and Alternative Medicine
NHLBI	National Heart, Lung, and Blood Institute
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development
NIDDK	National Institutes of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NLM	National Library of Medicine
OPASI	Office of Portfolio Analysis and Strategic Initiatives
PI	principal investigator
RO1	Research Project Grant