

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

**MEETING MINUTES**

April 20, 2007

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

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

**April 20, 2007**

***NIH Participants***

Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH  
John T. Burklow, M.S., Director for Communications and Public Liaison, Office of the Director, NIH  
Jennifer E. Gorman, M.P.A., COPR Coordinator and NIH Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, NIH  
Kelli Carrington, M.A., COPR Special Associate, 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.  
Nicole Johnson Baker, M.A., M.P.H.  
Wendy Chaite, Esq.  
Christina 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.  
Beth Furlong, R.N., Ph.D., J.D.  
Brent Jaquet  
Nicolas Liñares-Orama, Ph.D., M.P.A.  
Cynthia Lindquist, M.P.A., Ph.D.  
Michael Manganiello, M.P.A.  
Matthew Margo, LL.M.  
Marjorie Mau, M.S., M.D.  
Anne Muñoz-Furlong  
Ann-Gel S. Palermo, M.P.H.  
James H. Wendorf, M.A.

***COPR Member Not Present***

Craig T. Beam

***ACD Liaison***

Annelise Barron, Ph.D.

***COPR Special Expert***

John C. Nelson, M.D., M.P.H., FACOG, FACPM, NIH Advisory Committee to the Director

***COPR Alumnus***

Vicki Kalabokes

***Speakers***

Elena Bastida, Ph.D., Professor and Director, Center on Aging and Health, University of Texas-Pan American

Joe Coulter, Ph.D., Associate Dean, University of Iowa College of Public Health

David S. Forbes, Ph.D., Professor and Dean, College of Health Professions and Biomedical Sciences, University of Montana

Doug Hussey, Acting Director, Division of Scientific Strategic Planning and Policy Analysis, National Center for Minority Health and Health Disparities, NIH

John Niederhuber, M.D., Director, National Cancer Institute, NIH

Giang Nguyen, M.D., M.P.H., Assistant Professor in Family Medicine and Community Health, School of Medicine, University of Pennsylvania

John Ruffin, M.D., Director, National Center for Minority Health and Health Disparities, NIH

Francisco Sy, M.D., Dr.P.H., Program Director, Community Based Participatory Research Program and Loan Repayment Program, National Center for Minority Health and Health Disparities, NIH

Derrick Tabor, Ph.D., Program Director, Centers of Excellence Program, National Center on Minority Health and Health Disparities, NIH

Stephen B. Thomas, Ph.D., Director, Center for Minority Health, University of Pittsburgh

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## **EXECUTIVE SUMMARY**

The meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 20, 2007. Elias A. Zerhouni, M.D., NIH Director, was unexpectedly called to the White House and could not attend the meeting. Raynard S. Kington, M.D., Ph.D., NIH Deputy Director, welcomed and introduced the six new COPR Appointees: Naomi Cottoms, M.S., Elmer R. Freedman, M.S.W., Beth Furlong, R.N., Ph.D., J.D., Brent Jaquet, Matthew Margo, LL.M., and Anne Muñoz-Furlong. Dr. Kington introduced John Nelson, M.D., M.P.H., FACOG, FACPM, Special Expert to the COPR, and Annelise E. Barron, Ph.D., NIH Advisory Council to the Director (ACD) Liaison to the COPR.

Dr. Kington provided updates in a number of areas. He singled out the creation of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director, as the most significant outcome of the NIH Reform Act of 2006. Given the challenging prospect of a reduced budget, NIH has made tough but necessary choices to ensure that the investment in and momentum of biomedical research continues. Dr. Kington stressed the importance of supporting new investigators as they make the transition to becoming independent. On March 3, 2007, NIH announced the NIH Director's New Innovator Award. It will support research by new investigators who propose highly innovative projects with the potential for exceptional influence on biomedical or behavioral science.

Dr. Kington announced several staff changes. Alan Krensky, M.D., is the Director Designee for the NIH Office of Portfolio Analysis and Strategic Initiatives (OPASI). Dr. Krensky, a leading scientist and recognized expert in pediatrics, comes to NIH from the Stanford University School of Medicine. Barbara Alving, M.D., is the new Director of the National Center for Research Resources and Griffin P. Rodgers, M.D., is the new Director of the National Institute of Diabetes and Digestive and Kidney Diseases – both effective April 1, 2007.

Dr. Kington recognized NIH advances over the past six months, including the increase in NIH Funding by \$637 million, which will add another 1,000 research project grants, provide funding for high risk grants, and funding for young investigators. Hearings for the President's budget request for fiscal year 2008 for NIH began on March 6 with an NIH overview hearing before the House Appropriations Subcommittee on Labor, HHS, and Education. Dr. Kington also addressed the Stem Cell Research Enhancement Act and the Hope Offered Through Principled and Ethical Stem Cell Research Act. He related his discussions of NIH issues in recent Congressional hearings and reported progress with the Director's Pathway of Independence Program for innovative research.

John Ruffin, Ph.D., Director of the National Center on Minority Health and Health Disparities (NCMHD), described four minority health initiatives: the Health Disparities Centers of Excellence Program, the Endowment Program Award, the Loan Repayment Program, and the Community-Based Participatory Research Program.

John E. Niederhuber, M.D., Director of the National Cancer Institute (NCI), talked about NCI's efforts to build patient access to science. He described the NCI Community Cancer Centers Program, a pilot program designed to bring science, early-phase clinical research, and evidence-based therapies to patients in community-based locations. Sites will be linked to national databases supporting basic, clinical, and population-based cancer research.

Christina Clark, M.A., M.B.A., and James Wendorf, M.A., Co-Chairs of the COPR Meeting Agenda Work Group, provided an overview of the COPR's Work Group Day. Ms. Clark noted that COPR members participated in a question-and-answer session with Dr. Zerhouni. Select COPR members reported on the following topics:

- Diversity Information Gathering Meeting and Discussion with NIH Staff
- Research, Condition, and Disease Categorization (RCDC) Initiative
- The COPR's two editorials—"The Future Is Now: Enhancing the Role of the Public in Medical Research" and "What Is Trust Worth?"

- Communicating the COPR's Messages—New Media Tools

Ms. Christina Clark reported the results of the consensus-building and priority-setting session from the previous day. COPR confirmed the continuation of the Role of the Public in Research Work Group and selected one area for future efforts: Identify ways to encourage researchers to involve the public including, but not limited to health disparities, diversity, community engagement, and behavioral and social context in research.

COPR members received updates from the liaison to the Advisory Committee to the Director (ACD) and heard public comments.

## **WELCOME AND INTRODUCTIONS**

**Raynard S. Kington, M.D., Ph.D.**  
**Deputy Director, National Institutes of Health**

The 17th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 20, 2007. Elias A. Zerhouni, M.D., NIH Director, could not attend due to an unexpected required meeting at the White House. Raynard S. Kington, M.D., Ph.D., NIH Deputy Director, welcomed the COPR members and presenters, and recognized COPR Special Expert John Nelson, M.D., M.P.H., FACOG, FACPM, member of the NIH Advisory Committee to the Director, and Annelise E. Barron, Ph.D., NIH Advisory Council to the Director (ACD) Liaison to the COPR.

Dr. Kington introduced the six new COPR Appointees: Naomi Cottoms, M.S., Director of the Tri County Rural Health Network, Inc.; Elmer R. Freeman, M.S.W., Executive Director of the Center for Community Health Education Research and Service, Inc., and an adjunct assistant professor and Director of Urban Health Programs and Policy for Bouvé College of Health Sciences at Northeastern University; Elizabeth Furlong, J.D., Ph.D., R.N., associate professor at Creighton University's School of Nursing and a faculty associate in the university's Center for Health Policy and Ethics; Brent Jaquet, Senior Vice President at Cavarocchi-Ruscio-Dennis Associates; Matthew Margo, LL.M., Senior Vice President of Program Practices, New York, for CBS Television Network; and Ms. Anne Muñoz-Furlong, CEO of the Food Allergy and Anaphylaxis Network. Dr. Kington acknowledged that COPR member Craig T. Beam could not attend the meeting and recognized Alan Krensky, M.D., Director Designee for the Office of Portfolio Analysis and Strategic Initiatives at NIH, who attended the meeting.

## **NIH DIRECTOR'S UPDATE**

**Raynard S. Kington, M.D., Ph.D.**  
**Deputy Director, National Institutes of Health**

Dr. Kington reported that during the past year, Dr. Zerhouni and his office have reached out to many groups around the country and around the world, speaking with scientific

associations, advisory councils, and other constituencies offering transparency about the challenges that the current budget poses to NIH, researchers, and the public who ultimately benefits from NIH research.

### **Status of the NIH Budget**

Congress recently passed the Fiscal Year (FY) 2007 Joint Funding Resolution, which increased NIH funding by \$637 million over FY 2006 (post supplemental transfers). This increase supported an additional 1,000 research project grants over the FY 2006 level, provided additional funding for high risk grants, funding for young investigators, and allowed continuation of the National Children's Study. The National Children's Study received \$69 million in the Office of the Director. Base funds of \$11 million for the study were shifted from the National Institute of Child Health and Human Development to the Office of the Director for the National Children's Study.

The Joint Resolution fully funds the NIH Roadmap and Common Fund in the Office of the Director, which resulted in the expected contribution monies remaining in the Institutes and Centers. There was also an allocation of about \$34 million to the National Center for Research Resources for a number of one time projects. Additionally, \$7 million was provided to support implementation of the NIH reauthorization bill. Small increases were also provided to the National Center on Minority Health and Health Disparities and to the National Library of Medicine.

In spite of these additional resources, Dr. Kington stressed the need to strike a balance between maintaining the value of ongoing research and providing opportunities for researchers with new ideas to receive research grants to help surmount public health challenges. This requires a focus on three categories of vulnerable scientists who are integral to continued public health advancements: new investigators, first time grantees

applying for their first renewal, and well established investigators with insufficient other support. NIH plans to support about 10,000 competing research project grants in FY 2007.

In terms of other budget decisions, NIH funded the second cohort of awards in the Pathway to Independence Program. This is a program specifically designed to target young investigators and support their transition towards the status of independent principal investigator.

Dr. Kington also noted that NIH has provided a slight increase in the FY 2008 President's Budget of about \$3 million for the Roadmap, in addition to a total of \$136 million that will be invested in the repair of many of the old buildings on the NIH campus.

### **Legislative Update**

Since the last COPR meeting, Congress passed, and the President signed, the NIH Reform Act of 2006. This legislation reauthorizes NIH programs for the first time since 1993 and provides significant authorities for the agency. Dr. Kington singled out the creation of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the NIH Office of the Director, as the most significant outcome of the Reform Act. The legislation also establishes:

- The Common Fund in statute, with no formula for growth and the requirement for a review when the Common Fund reaches 5 percent
- A Council of Councils to advise on research proposals that would be funded by the Common Fund
- A Scientific Management Review Board (SMRB) to conduct periodic organizational reviews of NIH and to make recommendations on the use of NIH organizational authorities

- It also authorizes—but does not appropriate—an increase in NIH funding for each of the next 3 years (\$30.3 billion for FY 2007, \$32.8 billion for FY 2008, and such sums as may be necessary for FY 2009)

Hearings for the President's Budget request for FY 2008 began on March 6 with an NIH overview hearing before the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Representative David Obey [D-WI], Chairman). The NIH Director was accompanied by directors of NHLBI, NCI, NIAID, NICHD, NCMHD, NHGRI, NINDS, Acting Director for NIDDK, Deputy Director for NIEHS, and Acting Director for NCRR. The Senate overview hearing was held on March 19. Major issues raised by Subcommittee members at the overview hearings were the adequacy of the FY 2008 President's Budget request for NIH, funding for the National Children's Study, stem cell research, health disparities (House only), and cost savings resulting from research.

In regards to stem cell research, Dr. Kington reported that on April 11<sup>th</sup> the Senate passed two stem cell bills, S. 5 (Senate Bill ), the Stem Cell Research Enhancement Act, and S. 30, the Hope Offered Through Principled and Ethical Stem Cell Research Act, which passed by a vote of 63-34 and 70-28, respectively.

The S. 5 would required the Secretary of HHS to conduct and support research using human embryonic stem cells regardless of the date on which such cells were derived and to conduct and support research involving methods of obtaining pluripotent stem cells that do not involve the use of human embryos. The White House has issued statements of administration policy in opposition to S. 5 and in opposition to a similar House measure.

The S. 30 would require the Secretary to support research to develop pluripotent stem cells using methods that do not involve either the creation of, harm to or the destruction

of human embryos, and the White House has issued a statement of administrative policy in support of S. 30.

### **NIH Director's Bridge Award (NDBA)**

On March 14, 2007, Dr. Zerhouni announced the launch of the NIH Director's Bridge Award (NDBA). The program will provide a single year of bridge funding for more than 200 competing R01 renewal applications. The awards will be at a level approved by individual Institutes and Centers up to total of \$500,000.

### **NIH Pathways to Independence Awards**

NIH continues to support the NIH Pathways to Independence Awards. Dr. Kington stressed the importance of supporting new investigators as they move toward becoming independent researchers. NIH received almost 900 applications and issued between 150 and 200 awards for this program this year. NIH expects to make the same number of awards for each of the next 5 years. During this time, NIH will provide almost \$400 million in support of this program.

### **National Consortium to Transform Clinical Research**

Dr. Kington described the NIH National Consortium to Transform Clinical Research as an effort to reinvigorate the clinical research enterprise in our country. The NIH funded 12 academic health centers as part of the consortium in the past year and plans to award planning grants to 52 additional centers so that they have support to develop proposals for future rounds. These academic health centers will act as central hubs for pulling together academic researchers, local clinicians, community medical centers, professional societies, industry, and the public at large.

Dr. Kington and other members of NIH leadership have heard repeatedly that one of the most important impacts of this Request for Applications (RFA) is that it provides a strong incentive for diverse components of large complex academic centers to communicate

with each other so that they can coordinate a proposal to the NIH. Dr. Kington also noted that previous discussions with COPR on the role of the public were used in framing that part of the RFA.

When the CTSA Awards reach full implementation in 2012, they are expected to provide a total of approximately \$500 million annually to 60 academic centers. These CTSA's were a key initiative within the NIH Roadmap and they were paired with an ongoing program of the Clinical Research Centers funded by the National Center for Research Resources (NCRR).

### **The NIH Roadmap and Office of Portfolio and Strategic Analysis (OPASI)**

Dr. Kington introduced Alan Krensky, M.D., the Director Designee for the NIH Office of Portfolio and Strategic Analysis (OPASI). Dr. Kington described OPASI as creating an incubator space for supporting complex programs that cut across the missions of institutes and centers and that have broad relevance to the NIH mission. The NIH Roadmap for Medical Research, which Dr. Kington referred to as the “brainchild of Dr. Zerhouni,” is housed within OPASI.

OPASI, in consultation with the institutes and centers, is finishing the concept development stage for the next wave of Roadmap initiatives to be selected and funded. As part of this phase, NIH received more than 300 proposals of suggested Roadmap initiatives from around the world. The concept development phase focused on the following areas:

- Inflammation as a common mechanism of disease
- Proteome/protein capture tools
- Training and careers
- Health disparities
- Science of science administration

Dr. Kington noted that a number of COPR members participated in roundtables with scientists from across the country to solicit ideas for potential areas for funding. Over the summer, these specific initiatives will inform new RFAs. These will in turn lead to innovative new research projects that hold great promise for the future of American's health.

### **NIH Director's New Innovator Award**

On March 3, 2007, NIH announced the NIH Director's New Innovator Award, which will support research by new investigators who propose highly innovative projects with the potential for exceptional influence on biomedical or behavioral science. NIH expects to fund 14 awards in September 2007. Each grant will be for five years and up to a total of \$1.5 million in direct costs. The National Institute of General Medical Sciences, under the leadership of Jeremy M. Berg, Ph.D., coordinates this effort.

### **Leadership Update**

Barbara Alving, M.D., is the new Director of the National Center for Research Resources and Griffin P. Rodgers, M.D., is the new Director of the National Institute of Diabetes and Digestive and Kidney Diseases – both effective April 1, 2007. Alan Krensky, M.D., a leading scientist and recognized expert in pediatrics, is the Director Designee for OPASI.

Dr. Kington asked for comments.

### **COPR Member Discussion**

Mr. Wendorf asked Dr. Kington what COPR could do to help communicate the NIH mission and priorities to the public. As a starting point, Dr. Kington encouraged COPR members to use the NIH 101 slides to educate the public about NIH. Dr. Kington reminded members that a COPR representative will participate on the "Council of Councils" that was created by the NIH Reform Act of 2006. He noted two recent NIH

communications successes: *Parade Magazine*'s series on NIH research and the new *NIH NLM MedLine Plus Magazine*, which is appearing in physicians' offices around the United States.

Syed M. Ahmed, M.D., Dr.P.H., M.P.H., asked if community engagement was a requirement for CTSA awardees. He noted that CTSA awardees showed responsiveness to community engagement and that this will be included in the NIH evaluation of the CTSA Awards. Dr. Kington emphasized building bridges between academic and surrounding communities as integral to the CTSA Awards.

Mr. Jaquet suggested that NIH develop an educational workshop for research investigators to learn about community engagement approaches. Dr. Kington responded enthusiastically and noted that this could be an opportunity to merge the activities and interests of COPR with NIH-funded investigators. Dr. Kington referred to past discussions about COPR preparing guidance material on different ways the public has input (serving on councils, study sections, and community advisory committees). He plans to discuss this suggestion with NCRR.

During a COPR member inquiry about trans-NIH activities, Dr. Kington remarked that some of the best science advances have come from overseas. Roger I. Glass, M.D., Ph.D., Director of the Fogarty International Center (FIC) at NIH, encouraged COPR members to think about results and discoveries overseas that benefit the American public. FIC works with many NIH Institutes and Centers (ICs).

Michael Manganiello, M.P.A., asked Dr. Kington for clarification on the role of the new Common Fund. Dr. Kington reviewed the purpose of the Common Fund: to support trans-NIH research that pushes the frontiers of science and cuts across the missions of individual institutes and centers. The Common Fund was created to address broad cross-cutting public health challenges.

## **DIALOGUE WITH THE DIRECTOR OF THE NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES**

**John Ruffin, Ph.D.**

John Ruffin, Ph.D., Director of the National Center on Minority Health and Health Disparities (NCHMD), provided an overview of NCMHD programs and initiatives. Dr. Ruffin invited the following members of his senior staff to present: Derrick C. Tabor, Ph.D., Director, NCMHD Centers of Excellence Program; Francisco Sy, M.D., Dr.P.H., Director, NCMHD Community-Based Participatory Research and Loan Repayment Programs; and Douglas Hussey, Acting Director, Division of Scientific Strategic Planning and Policy Analysis, NCMHD.

The passage of the Minority Health and Health Disparities Research and Education Act of 2000, Public Law 106-525 established NCMHD, which works to promote minority health and to eliminate health disparities. NIH defines health disparities as differences in the incidence, prevalence, morbidity, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups.

Since its creation in 2001, NCMHD has provided more than \$300 million to support several hundred research, training, community-outreach, and capacity-building projects around the United States (including Puerto Rico and the U.S. Virgin Islands).

Dr. Ruffin introduced Dr. Tabor, who heads the NCMHD Centers of Excellence Program. Dr. Tabor told COPR members that at its peak, NCMHD funded 76 centers of excellence, the first of which focused on partnerships for community outreach, research on health disparities, and training. New centers will focus on research excellence; specifically research for improving minority health and eliminating health disparities.

Dr. Francisco Sy described the NCMHD Research Endowment Program that builds research and training capacity in institutions that make significant investments in the education and training of individuals from health disparity populations. Awards range

from \$300,000 to \$5 million per institution. NCMHD funds 13 institutions across the United States.

Dr. Ruffin told COPR members about the NCMHD Loan Repayment Programs. Dr. Sy added to the presentation. The NCMHD Loan Repayment Programs seek to recruit and retain highly qualified professionals with doctoral degrees to pursue health disparities or clinical research by repaying their educational loans. The Loan Repayment Program for Health Disparities Research encourages health professionals to engage in basic, clinical, behavioral, community-based, and health services research that is directly relevant to health disparities. The Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds aims to recruit highly qualified health professionals from disadvantaged backgrounds to and retain them in clinical research careers.

All of these programs aim to increase the pool of researchers in the health disparities field. NCMHD provides individual loan repayments of \$35,000 a year for 2 years, including taxes and interest. Since 2002, when the program began, NCMHD has funded 1,100 individuals.

The NCMHD Community-Based Participatory Research Program promotes collaboration between researchers and the communities. The initiative has three phases: a pilot or planning phase, a competitive 5-year research intervention phase, and then a 3-year research dissemination phase. In 2005, when this initiative was launched, NCMHD received 188 applications and has funded 25 grantees.

Dr. Ruffin introduced Mr. Hussey, Acting Director, Division of Scientific Strategic Planning and Policy Analysis, NCMHD, who reported on the NIH Health Disparities Strategic Plan and Budget. The FY 2002-2006 plan is available on the NCMHD Web site at [http://www.ncmhd.nih.gov/our\\_programs/strategic/volumes.asp](http://www.ncmhd.nih.gov/our_programs/strategic/volumes.asp). The Strategic Plan focuses on three major goals: research, research infrastructure, and public information and community outreach. It includes objectives, priorities, action plans, and time frames.

The NCMHD also contracted with the Institute of Medicine (IOM) to assess the implementation of the plan at NIH. The 2006 IOM Report, *Examining the Health Disparities Research Plan of the National Institutes of Health: Unfinished Business*, was the result of the assessment. NIH is awaiting Departmental clearance of the second iteration of the strategic plan which covers FY 2004-2008. After receiving public comment on the second version of the strategic plan, the NIH will begin developing the third strategic plan, taking into account the recommendations of the IOM and all other public comments received. In addition, during fiscal years 2007 and 2008, NCHMD, in collaboration with the other NIH ICs, will convene forums to identify best practices to further enhance Institute and Center activities, as a part of NIH's response to the IOM report.

To illustrate how each of the NCMHD programs are working and what is being accomplished, Dr. Ruffin invited five NCMHD program award recipients to briefly contribute to the presentation: Elena Bastida, Ph.D., professor and director, Center on Aging and Health, University of Texas-Pan American; Joe Coulter, Ph.D., associate dean, University of Iowa College of Public Health; David S. Forbes, Ph.D., professor and dean, College of Health Professions and Biomedical Sciences, University of Montana; Giang Nguyen, M.D., M.P.H., assistant professor in family medicine and community health, School of Medicine, University of Pennsylvania; and Stephen B. Thomas, Ph.D., director, Center for Minority Health, University of Pittsburgh.

### **COPR Member Discussion**

Dr. Nelson asked about NCMHD collaboration with outside organizations. "We set aside 20 percent to 30 percent of our budget for collaboration," said Dr. Ruffin. NCMHD works with many governmental agencies including the Indian Health Service (IHS), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicaid and Medicare Services (CMS), and others. Since its creation in 2001, NCMHD has provided more than \$300 million to

support several hundred research, training, community outreach, and capacity-building projects.

COPR members wondered how NCMHD receives public input. Dr. Ruffin noted that the NIH Health Disparities Strategic Plan provides an excellent way for both NIH and NCMHD to receive public input. Wendy Chaite, Esq., suggested that the collaboration demonstrated by Dr. Ruffin and NCMHD could be used as a model for all of NIH, including the new OPASI initiative.

COPR members inquired how they could assist NCMHD in reducing health disparities. Dr. Ruffin suggested that COPR could help NCMHD recruit candidates for the loan repayment programs. “I can think of no better way to build a health disparity workforce than through the Loan Repayment Program,” said Dr. Ruffin. He recommended that NCMHD develop a career development track to retain this new workforce.

COPR members shared their passion about health disparity issues with Dr. Ruffin and thanked him for NCMHD’s hard work in the community.

## **BUILDING PATIENT ACCESS TO SCIENCE**

### **John Niederhuber, M.D.**

John Niederhuber, M.D., Director of the National Cancer Institute (NCI), reviewed the NCI’s efforts to build patient access to science. He described the NCI Community Cancer Centers Program, a pilot program designed to bring science, early-phase clinical research, and evidence-based therapies to patients in community-based locations. Currently only approximately 16 percent of cancer patients in the United States have access to the 61 NCI-designated cancer centers. Community hospitals and physician offices care account for the remaining 84 percent. For most Americans, especially senior citizens and minorities, who bear a heavy burden of cancer, an NCI-designated cancer center may be too far away or economically out of reach. “I firmly believe that access to health care and to good cancer care will actually be a greater determinant of cancer

mortality in the decades to come than any of the things that we commonly consider to be risks, such as tobacco,” said Dr. Nieberhuber.

The NCI Community Cancer Centers Program aims to bring state-of-the-art cancer research and treatment to communities where people live. It will support multiple pilot sites (for a total of \$9 million over a 3-year period) to identify the critical factors that define a state-of-the-art community center, which will be incorporated into a future program. Year one will focus on infrastructure development and refinement of pilot program research questions. Implementation and evaluation of the model takes place in years two and three.

The selection criteria for sites are broad. NCI hopes to fund centers in settings with underserved populations such as Appalachia and Indian reservations. The program seeks to bring more patients into clinical trials in community-based settings, reduce health care disparities, prepare sites for standardizing the collection and storage of biological specimens for cancer research, and link sites to national databases supporting basic, clinical, and population-based cancer research.

Dr. Niederhuber views this program as a tremendous resource for genomic and proteomic research, which depends on quality tissue specimens. Participating community-based hospital systems will provide these tissue resources. Dr. Niederhuber also noted that this program gives NCI an opportunity to make progress on HHS Secretary’s agenda to establish electronic medical records.

### **COPR Member Discussion**

COPR members asked about community involvement in the NCI Community Cancer Centers Program. Dr. Niederhuber responded that NCI plans to have community members involved in planning the pilot sites. An incentive for community involvement is built into the contract process.

Dr. Niederhuber suggested that COPR assist NCI in answering questions critical to the success of this program: What methods are effective to increase accrual of patients into clinical trials especially for our minority populations? How can we reduce disparities in cancer care? And, can NCI's biorepository guidelines be implemented at the community level?

Valda Boyd Ford, M.P.H., M.S., R.N., expressed concern about medical records and patient privacy and protection issues. Dr. Niederhuber responded that NIH is aware of these fears and that pending legislation addresses these concerns. Dr. Kington agreed that patient privacy is important. He noted that a trans-NIH Working Group on Bioinformatics was formed to weigh the benefits of genetic databases against privacy concerns and issues.

Nicolas Liñares-Orama, Ph.D., M.P.A., asked about research progress on environmental factors that influence cancer. Dr. Niederhuber responded that the NCI Community Cancer Centers Program will help researchers learn more about the effect of environmental factors on cancer because they will have access to tissue samples from cancer patients around the United States.

## **COPR WORK GROUP DAY OVERVIEW AND REPORT FOR THE NIH DIRECTOR**

**Christina Clark, M.A., M.B.A. and James Wendorf, M.A.**

James Wendorf, M.A., and Christina Clark, M.A., M.B.A., Co-Chairs, Spring 2007 Meeting Agenda Work Group, provided Dr. Kington with an overview of the Work Group Day that took place the previous day (April 19). Ms. Clark noted that COPR members participated in a question-and-answer session with Dr. Zerhouni, which informed COPR's consensus-building and priority-setting process. Mr. Wendorf summarized the agenda:

- Report from the COPR Sub-Work Group on the April 18th information-sharing discussion with NIH staff on diversity training, underrepresented scientists, and health disparities research training
- An update by Timothy Hays, Ph.D., on the NIH Research, Condition, and Disease Categorization (RCDC) initiative
- A communications update by John Burklow, M.S., and an invitation to brainstorm about using new media to amplify the COPR voice
- A review by Jennifer Gorman, M.P.A., of COPR accomplishments as a context for the work group session
- A consensus-building and priority-setting session with facilitator Sue Harris, M.S.
- An update by Dr. Alan Krensky on the Office of Portfolio Analysis and Strategic Initiatives

## **DIVERSITY INFORMATION GATHERING MEETING AND DISCUSSION REPORT**

**Marjorie Mau, M.D., and Ann-Gel Palermo, M.P.H.**

Marjorie Mau, M.S., M.D., and Ann-Gel Palermo, M.P.H., reviewed the agenda and lessons learned from the April 18 informational meeting with NIH staff. COPR requested this meeting to learn about diversity training and health disparities research at NIH. Topics covered included underrepresented scientists in training and recruitment; the research infrastructure and minority health; clinical trials recruitment and retention for minority and health disparity issues; and the research agenda for minority health and health disparities. COPR participants learned the following about diversity at NIH:

- Equal employment opportunity (EEO) is different from diversity management
- EEO data and comparative relevant labor force
- There is a lack of consensus on the definition of diversity
- All NIH Institutes and Centers have strategic plans targeting health disparities
- Current efforts have varying levels of effectiveness
- COPR can assist NIH in addressing health disparities
- Effective management strategies are critical for advancing diversity

- The 2006 Institute of Medicine Report *Examining the Health Disparities Research Plan of the National Institutes of Health: Unfinished Business* is a good starting point
- Accountability across the NIH needs to be recognized
- Education and training pipeline programs are critical to addressing diversity and health disparities
- NIH requests that COPR keep asking questions

COPR selected diversity training and health disparities research as two possible separate target areas for the Role of the Public in Research Work Group.

### **RESEARCH, CONDITION, AND DISEASE CATEGORIZATION (RCDC) INITIATIVE REPORT**

**James Wendorf, M.A. and Christina Clark, M.A., M.B.A.**

Mr. Wendorf shared COPR's perspective on the RCDC initiative. COPR views RCDC as an important project for both Congress and the public. The RCDC reporting approach offers a method for consistent reporting across all of NIH. It will promote transparency, accountability, and expedite the reporting process for NIH.

The COPR recognizes that RCDC can result in two key outcomes: (1) increasing public access to federal investment in medical research and (2) providing NIH with a powerful tool to communicate with the public. COPR agrees to give input to NIH on development and implementation of RCDC and to assist in informing and engaging the public on this new reporting tool. Introduction of the RCDC to the public will take place in early 2008.

## **THE COPR'S TWO EDITORIALS: VALUE OF THE ROLE OF THE PUBLIC IN RESEARCH**

**Syed Ahmed, M.D., Dr.P.H., M.P.H., and Cynthia Lindquist, M.P.A., Ph.D.**

Syed Ahmed, M.D., Dr.P.H., M.P.H., and Cynthia Lindquist, M.P.A., Ph.D., reviewed COPR's two proposed editorials: "The Future Is Now: Enhancing the Role of the Public in Medical Research" and "What is Trust Worth?" Dr. Ahmed reviewed considerations for advancing the role of the public in research:

- Educate researchers about potential public roles
- Provide guidance to applicants and grantees and enhance training programs
- Create tools to educate researchers on community involvement and engagement
- Identify and disseminate best practices of community engagement
- Establish a baseline of NIH community participation
- Bridge gaps between organizations and research institutions
- Build partnerships that expand community involvement in research

Dr. Lindquist reported on COPR's intention to create awareness and inspire action for greater public involvement in research. A strong public research partnership will enhance dissemination and application of research findings. COPR members agreed that a diverse spectrum of public voices enriches the research process.

## **COMMUNICATION THE COPR'S MESSAGES WORK GROUP REPORT**

**Nicole Johnson Baker, M.A., M.P.H., and Michael Manganiello, M.P.A.**

Nicole Johnson Baker, M.A., M.P.H., and Michael Manganiello, M.P.A., reviewed recent communications successes:

- Development of COPR Editorials
- Initiation of NIH Ambassadors Program
- Increased visibility of NIH in the media (vodcast)
- Development of Grantee Public Information Officers Network

Continued recommendations include exploring new ways to enhance NIH visibility, continuing to produce COPR editorials, and exploring ways to reach youth (NIH Kids Web site and new media). New recommendations include:

- Co-branding NIH with network public service programs
- YouTube videos of families that put a face on NIH
- TV spots focused on children and health habits
- A phase II editorial that includes a literature review on the value of public participation in research
- Expanding the Discovery project
- Create incentives for the media by establishing an excellence award
- Collaboration with the Foundation for the NIH

**OUTCOMES AND NEXT STEPS FOR THE COPR**  
**Christina Clark, M.A., M.B.A., and James Wendorf, M.A.**

Ms. Clark reported the results of the consensus-building and priority-setting session from the previous day. During this session, COPR members discussed four broad topics: community engagement, diversity and health disparities, disenfranchised areas, and emerging issues. Ms. Harris facilitated the discussion and the COPR reached consensus on priority issues and next steps. COPR confirmed the continuation of the Role of the Public in Research Work Group and selected one area of exploration for future efforts: Identify ways to encourage researchers to involve the public including, but not limited to:

- health disparities
- diversity
- community engagement
- behavioral and social context in research

Next steps for COPR include identifying the specific activities and potential deliverables to support this action item.

## **PUBLIC COMMENT**

Vlady Rozenbaum, Ph.D., founder-administrator of COPD-ALERT, a national support and advocacy group for people suffering from chronic obstructive pulmonary disease (COPD), encouraged NIH to address the health disparities caused by COPD. He described the rising public health challenges associated with COPD. According to Dr. Rosenbaum, COPD is the fourth major cause of death in the United States, the second major cause of disability, and treatment options are inadequate. Dr. Rosenbaum suggested that the provisions of the NIH Reform Act support an increased commitment to COPD research.

Carlos Vázquez-Rivera, Ph.D., director of the Centro de Investigación y Refortalecimiento Comunitario, FILIUS Institute, University of Puerto Rico, presented a letter from his organization, encouraging NIH and COPR to increase diversity in science so that the health of all citizens can improve. He suggested that NIH promote diverse community participation in the design and implementation of research.

## **ACD LIAISON REPORT**

Annelise Barron, Ph.D., and Wendy Chaite, Esq., reported on the meeting of the Advisory Committee to the Director (ACD), which occurred on December 1, 2006. The ACD members also held a teleconference on February 21, 2007. The ACD welcomed three new members at the December 1, 2006, meeting: Mary-Claire King, Ph.D., American Cancer Society Professor, Departments of Medicine and Genome Sciences, University of Washington; Karen A. Holbrook, Ph.D., president, The Ohio State University; and Barbara L. Wolfe, Ph.D., professor, Departments of Population Health Sciences, Economics, and Public Affairs, and director of the Robert M. La Follette School of Public Affairs, University of Wisconsin-Madison.

ACD members and invited speakers discussed the Clinical Research Policy Analysis and Coordination Program (Amy P. Patterson, M.D.), a proposed NIH policy on data sharing

for NIH-supported genome-wide association studies (Elizabeth G. Nabel, M.D.), the electronic application system for NIH grants (Norka Ruiz Bravo, Ph.D.), a history of the Fogarty International Center (Roger Glass, M.D., Ph.D.), and a report on outside awards for NIH employees (Raynard S. Kington, M.D., Ph.D.).

ACD members discussed concerns about how NIH peer-review process would be affected in the current fiscal environment and ongoing NIH efforts to address this issue, including special funding and turnaround criteria for first-time grantees, Pathway to Independence and New Innovator Awards, and potential changes to the grant proposal guidelines. Ms. Chaite suggested increasing the synergy and exchange between the ACD and COPR.

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

Dr. Kington noted the development and accomplishments of the COPR over the past nine years. He encouraged COPR to continue to inform and advise NIH on matters of public interest and emphasized that NIH is committed to addressing diversity issues. He also acknowledged that NIH and COPR should consider ways to integrate activities of the COPR and ACD. Dr. Kington commented that NIH will have follow-up meetings on diversity and community engagement issues.

Dr. Kington thanked the COPR members for their input. The COPR meeting will take place October 25–26, 2007. Ms. Gorman noted that Kelli Carrington, M.A., will send out dates for the 2008 spring COPR meeting.

## **ADJOURNMENT**

Dr. Kington and Ms. Clark adjourned the meeting.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Kelli L. Carrington, MA  
Executive Secretary  
Director's Council of Public Representatives

Elias A. Zerhouni, MD  
Director  
National Institutes of Health

## **LIST OF ABBREVIATIONS AND ACRONYMS**

ACD	Advisory Committee to the Director
AHRQ	Agency for Healthcare Research and Quality
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CMS	Center for Medicaid and Medicare Services
COPD	Chronic Obstructive Pulmonary Disease
COPR	Council of Public Representatives
CTSA	Clinical and Translational Science Awards
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DHHS	Department of Health and Human Services
EEO	Equal Employment Opportunity
FIC	Fogarty International Center
FY	Fiscal Year
FNIH	Foundation for the National Institutes of Health
ICs	NIH Institutes and Centers
IHS	Indian Health Service
IOM	Institute of Medicine
IRB	Institutional Review Board
NCHMD	National Center for Minority Health and Health Disparities
NCI	National Cancer Institute
NCRR	National Center for Research Resources
NDBA	Director's Bridge Award Program

NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	National Institute of Child Health and Human Development
NIDDK	National Institute 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
OBSSR	Office of Behavioral and Social Sciences Research
OPASI	Office of Portfolio and Strategic Analysis
RCDC	Research, Condition, and Disease Categorization
RFA	Request for Applications
SMRB	Scientific Management Review Board