

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

COPR Alumni

CLASS OF 2004

- Evelyn Bromet (New York)
- Ellen E. Grant (New York)
- Rodrigo A. Muñoz (California)
- William D. Novelli (Maryland)
- Leonard J. Tamura (Colorado)
- Zelda Tetenbaum (Illinois)

Evelyn Bromet

Term: 2001-2004



Dr. Bromet is Professor of Psychiatry and Behavioral Science at the State University of New York at Stony Brook. She is an epidemiologist whose work focuses on the psychosocial and somatic aftermath of exposure to traumas, like the nuclear power plant accidents at Three Mile Island and Chernobyl, as well as the consequences of having a severe psychiatric illness. With funding from the National Institute of Mental Health, she is currently studying the prevalence of mental disorders and substance abuse in Ukraine and the natural history of schizophrenia and affective disorders in a cohort residing in eastern Long Island. She has been a consultant to the World Health Organization, UNESCO, the Institute of Medicine, and projects ranging from the health of Persian Gulf veterans to the mental health of American Indian populations. After being diagnosed in 1995 with Sjogren's syndrome, a chronic inflammatory autoimmune disorder in which the immune system attacks the body's moisture-producing glands, she brought her expertise in psychiatric epidemiology to the study of this disease. As a professor of psychiatry, she is sensitive to the emotional repercussions of having a chronic disease and what it means for overall quality of life. She is currently Vice President of the Sjogren's Syndrome Foundation, which is dedicated to educating patients and their families about the disease and its associated features, increasing awareness about the disorder among public and

healthcare providers, and encouraging and supporting research into its etiology and course. She is a graduate of Smith College and earned her Ph.D. in epidemiology from Yale University. She is an amateur pianist and lover of classical music, and an avid reader of mysteries.

Ellen E. Grant

Term: 2001-2004



Dr. Grant began her career as a licensed practical psychiatric nurse. She is currently Director of Operations, Liberty Health Care. She is the Former CEO of Niagara Falls Memorial Medical Center, a multi-faceted health care system in Niagara Falls, New York. She is also the former Commissioner of Mental Health in Erie County (1988-2000). There, she monitored mental health, alcoholism, substance abuse, mental retardation/developmental disabilities, forensic mental health, and family court. She has experience as a private therapist and as a Clinical Assistant Professor in the State University of New York at Buffalo (SUNY-UB), Department of Psychiatry. She has authored articles in professional journals on mental health disabilities and served as a monthly journalist for the publication, Health World. She co-chaired the Behavioral Health Subcommittee for the National Association of Counties. She has served on several local boards as well as the New York State Governor's Board for Alcohol and Substance Abuse. She is also a member of the Advisory Board, Black Women's Health Study, School of Medicine, Boston University.

She earned a B.A. in Sociology, a Master's in Social Work, and a Ph.D. in Communication and Organizational Behavior, all from SUNY-UB. She has several credits toward an M.B.A. Dr. Grant was awarded an honorary Doctorate from Medaille College, Buffalo, for exemplary community service. She was President, National Association of Social Workers, NY State (2002-2003). She has also served as President of the New York State Association of Counties (1996-1997), which acts as a liaison between the governor's office and state lawmakers. Dr. Grant has represented Erie County at the 1999 White House Conference on Mental Health. She is also an Executive Coach, and she has written a publication, *Managing in Black and White*.

Rodrigo A. Muñoz

Term: 2001-2004



Dr. Muñoz served as the 127th President of the American Psychiatric Association and was the last APA President to complete his term in the 20th century. He presided upon a transformation of the organization which included the creation of the American Psychiatric Institute on Research and Education, the consolidation of the American Publishing Group, and the initial implementation of a corporate change that will commit the APA more closely to its members. He obtained training in psychiatry at Washington University in St. Louis,



Missouri. While there, he participated in research that led to his being one of the co-authors of "Diagnostic Criteria for Using Psychiatric Research," the most quoted psychiatric paper in the last decades of the century.

Dr. Muñoz has published scientific papers in the American Journal of Psychiatry, the Archives of General Psychiatry, and most of the leading psychiatric journals in the country. Of the four books he has published, *Boarding Time – A Psychiatric Candidate's Guide to Part II of the ABPN Examination*, has helped more than 10,000 psychiatrists in taking the ABPN. Dr. Muñoz is a Delegate to the House of Delegates of the American Medical Association; President-Elect of the San Diego County Medical Society; Advisory Board Editor, Clinical Psychiatry News and Chief Editor of the Latin American Journal of Psychiatry. Dr. Muñoz is very active in programs for the indigent, the homeless, and patients who suffer from chronic mental illness. Dr. Muñoz has a full time private practice in San Diego, California, and is a Clinical Professor of Psychiatry at the University of California at San Diego.

William D. Novelli

Term: 2003-2004



Mr. Bill Novelli is Executive Director and CEO of AARP, a membership organization of more than 35 million people aged 50 and older, half of whom remain actively employed. He joined AARP in January 2000 as Associate Executive Director, Public Affairs.

Prior to joining AARP, Mr. Novelli was President of the Campaign for Tobacco-Free Kids, whose mandate is to change public policies and the social environment, limit tobacco companies' marketing and sales practices to children, and serve as a counterforce to the tobacco industry and its special interests. He now serves as chairman of the board. Previously, he was Executive Vice President of CARE, the world's largest private relief and development organization, where he was responsible for all operations in the U.S. and abroad.

Earlier, Mr. Novelli co-founded and was President of Porter Novelli, now one of the world's largest public relations agencies and part of the Omnicom Group, an international marketing communications corporation. He directed numerous corporate accounts as well as the management and development of the firm. Porter Novelli was founded to apply marketing to social and health issues and grew into an international marketing/public relations agency with corporate, not-for-profit, and government clients. He retired from the firm in 1990 to pursue a second career in public service. He was named one of the 100 most influential public relations professionals of the 20th century by the industry's leading publication.

Mr. Novelli is a recognized leader in the international practice of social marketing and managed programs in cancer control, diet and nutrition, cardiovascular health, reproductive health, infant survival, pay increases for educators, charitable giving, and other programs in the U.S. and the developing world.

He holds a B.A. from the University of Pennsylvania and an M.A. from Penn's Annenberg School for Communication, and he pursued doctoral studies at New York University. He taught marketing management for 10 years in the University of Maryland's M.B.A. program and also taught health communications there. He has lectured at many other institutions. He has written numerous articles and chapters on marketing management, marketing communications, and social marketing in journals, periodicals, and textbooks.

He began his career at Unilever, a worldwide packaged-goods marketing company, moved to a major ad agency, and then served as Director of Advertising and Creative Services for the Peace Corps. In this role, Mr. Novelli helped direct recruitment efforts for the Peace Corps, VISTA, and social involvement programs for older Americans.

Mr. Novelli serves on a number of boards and advisory committees. He and his wife, Fran, reside in Bethesda, Maryland. They have three adult children and three grandchildren.

Leonard J. Tamura

Term: 2001-2004



Dr. Tamura is a full-time licensed clinical psychologist in Denver, Colorado. He earned his Ph.D. from Biola University in Southern California, and completed his internship at the University of Colorado Health Sciences Center. Formerly, he divided his time between working as a staff psychologist at the Counseling Center at the University of Denver, and a private practice. While providing clinical services to students, faculty, and staff at the University of Denver, Dr. Tamura also provided training and supervision to psychology graduate students and pre-doctoral interns. He oversaw the primary care rotation within the internship and worked to develop an integrated care model for the student health center, wherein behavioral science practitioners worked right in the medical clinic. In that setting they contribute to a more holistic approach to treatment, by providing direct clinical services to the health center patients as well as consultation and support to the medical providers.

Dr. Tamura has also been appointed by the Governor to serve as one of the professional members on the Colorado State Board of Psychologist Examiners, the board that oversees the licensing and discipline of psychologists in the state. Another area of particular interest is multi-culturalism and cross-cultural psychology. Prior to his current positions, he worked for many years in community mental health, serving a variety of underserved populations. In particular, he was instrumental in developing the psychology training programs at the Asian Pacific Center for Human Development, a specialty clinic serving the Asian and Pacific Islander population in the Rocky Mountain region. He speaks and teaches frequently on topics related to Asian-American mental health as well as ethics and mental health law. Prior to becoming a psychologist, Dr. Tamura earned a Master's degree in rehabilitation counseling from the University of Northern Colorado, and worked for the State of Colorado for several years as a rehabilitation counselor. He and his wife, Leslie, have two daughters.

Zelda Tetenbaum

Term: 2002-2004



Ms. Tetenbaum, a science and health educator, saw her life change profoundly in 1996 when her 42-year-old son was diagnosed with a brain tumor, glioblastoma multiforme. Ms. Tetenbaum's son, a husband and father of two small children, survived for two years following his diagnosis. In her search for information about her son's illness, Ms. Tetenbaum became involved with the Central Brain Tumor Registry of the United States, an organization that centralizes and compiles incidence and survival rate data on primary brain tumors, and the North American Brain Tumor Coalition (NABTC), a network of 13 charitable organizations dedicated to eradicating brain tumors. Currently, Ms. Tetenbaum serves as NABTC chairperson.

In addition to her volunteer and advocacy work, Ms. Tetenbaum has devoted much of her professional life to education. She was a science teacher at a junior high school in Illinois for 21 years. When she retired in 1990, Ms. Tetenbaum worked on a National Science Foundation Teacher Enhancement Program at the U.S. Department of Energy's Argonne National Laboratory. Ms. Tetenbaum consults for her local school district in Illinois in the field of substance abuse prevention. Ms. Tetenbaum and her husband, a retired scientist who continues to work at the Argonne National Laboratory, have two daughters and two grandchildren.

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

NIH...Turning Discovery Into Health



DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

April 29, 2004 Meeting Minutes

NIH PARTICIPANTS:

- Elias A. Zerhouni, M.D., Director, National Institutes of Health (NIH)
- Raynard S. Kington, M.D, Ph.D., Deputy Director, NIH
- Patricia A. Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research
- Yvonne Thompson Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development
- John Burklow, Associate Director for Communications and Public Liaison, Office of the Director, NIH
- Jennifer Gorman Vetter, COPR Executive Secretary and NIH Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, NIH
- Shelly Pollard, Coordinator for the Advisory Committee to the Director, Office of Communications and Public Liaison, Office of the Director, NIH

COPR MEMBERS ATTENDING:

- James J. Armstrong
- Craig T. Beam
- Ruth C. Browne, Sc.D., M.P.H. (*participated via telephone*)
- Barbara D. Butler
- Wendy Chaite, Esq.
- Frances J. Dunston, M.D., M.P.H.
- Debra S. Hall, Ph.D. R.
- Mike Hill
- Kimberley Hinton
- Jim Jensen
- James Kearns
- Ted Mala, M.D., M.P.H.
- Lawrence B. Sadwin
- John Shlofrock
- Ellen V. Sigal, Ph.D.
- Dawna Torres Mughal, Ph.D., R.D., FADA
- Donald E. Tykeson

COPR ALUMNI:

- Leonard J. Tamura, Ph.D.
- Zeldia Tetenbaum, M.Sc.

COPR MEMBERS NOT PRESENT:

- Nancye Buelow
- Bill Novelli
- Rafael Gonzalez-Amezcuca, M.D.

NIH DIRECTOR'S REPORT

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

Dr. Zerhouni welcomed participants to the 11th meeting of the Director's Council of Public Representatives (COPR). He noted the progress shown at each COPR meeting. He then introduced four new COPR appointees in attendance as ad hoc participants: Mr. Craig T. Beam, Regional Partner, Hammes Company, and former Chairman, American Heart Association; Ms. Wendy Chaite, Esq., President, Lymphatic Research Foundation; Mr. R. Mike Hill, Executive Director, Northwest Florida and Big Bend Health Councils, and President, Florida Association of Health Planning Agencies; and Mr. James Kearns, President, River Falls Productions, Ltd.

Dr. Zerhouni extended a special welcome to Dr. Thomas Ansfield, a member of the Advisory Committee to the Director (ACD) who serves as the ACD liaison to the COPR. COPR member Mr. Larry Sadwin serves as the COPR liaison to the ACD. Dr. Zerhouni thanked Dr. Ansfield and Mr. Sadwin for their time and commitment to the liaison effort.

Two COPR members were unable to attend the meeting: Mr. Bill Novelli and Ms. Nancye Buelow. Dr. Ruth Browne joined the meeting via teleconference. Two COPR alumni also attended the meeting: Dr. Len Tamura and Ms. Zelda Tetenbaum.

UPDATE FROM THE DIRECTOR

Meetings and Events

Dr. Zerhouni highlighted noteworthy meetings and events. The third meeting of the NIH Blue Ribbon Panel on Conflict of Interest Policies was held April 5-6, 2004. After review, the Panel made recommendations for improving existing rules and procedures governing real and apparent conflicts of interest for the NIH staff. It also made recommendations regarding requirements and policies for reporting NIH staff financial interests. The panel is a working group of the ACD and will provide recommendations to the ACD at the May 6, 2004, meeting. The ACD will deliberate and approve final recommendations to go to the NIH Director. Bruce Alberts, Ph.D., President of the National Academy of Sciences, and Norman R. Augustine, Chairman of the Executive Committee of the Lockheed Martin Corporation, co-chair this panel. Mr. Sadwin also serves on the panel. COPR members were invited to attend the May 6 meeting. In addition to Mr. Sadwin, Ms. Barbara Butler, Dr. Dawna Torres Mughal, and Ms. Wendy Chaite will attend.

Dr. Zerhouni, Dr. Alberts, and Mr. Augustine will testify before the House Energy and Commerce Subcommittee on Oversight and Investigations at a May 12, 2004, hearing on conflict of interest issues.

Congressional Hearings

Dr. Zerhouni testified before the Senate and House Labor, Health and Human Services, and Education Appropriations Subcommittees on April 1, 21, and 22, respectively, regarding the Fiscal Year (FY) 2005 Budget. He also presented the NIH Roadmap and Management Initiatives at the hearings.

The Director testified on clinical research before the House Energy and Commerce Subcommittee on Health on March 25 and briefed congressional staff on the Biosecurity Initiative on March 4. More information on these issues is available in the NIH Director's Update.

NIH Budget

Dr. Zerhouni commented on the budgetary environment. Congress is aware that the NIH is under pressure and must make difficult choices. At the appropriations hearings in early April, he presented the President's FY 2005 Budget for the NIH of \$28.8 billion, an increase over FY 2004 of 2.6 percent. In addition to the request for the NIH, the HHS budget includes \$47 million for nuclear/radiological countermeasures research at the NIH, which brings the total increase in the NIH budget to \$764 million, or a 2.7 percent increase.

COPR Member Activities

Dr. Zerhouni noted recent activities of COPR members at the NIH. Many COPR members have served on NIH Institute and Center (IC) Director Review Panels and Work Groups. Eight members have served on these review panels since COPR formed in 1999. Twelve members recently served as ad hoc members of the NIH Plain Language Evaluation Subcommittee. They were charged with judging consumer-oriented products entered in the NIH Plain Language Program. The Director thanked the following COPR members and alumni for their time and commitment to this effort: Mr. James Armstrong, Dr. Ruth Browne, Ms. Barbara Butler, Dr. Frances Dunston, Dr. Rafael Gonzalez-Amezcuca, Dr. Ellen Grant, Dr. Debra Hall, Dr. Ted Mala, Dr. Rodrigo Munoz, Dr. Leonard Tamura, Ms. Zelda Tetenbaum, and Mr. Donald Tykeson. Mr. Sadwin has also given of his time and talent in service to the NIH through his participation on numerous work groups and in his capacity as the COPR liaison to the ACD.

Update on the NIH Roadmap

The Director reviewed key Roadmap activities. These activities are also described in the NIH Director's Update:

- The Nanomedicine Roadmap Initiative Project meeting was scheduled for launch on May 4, 2004, on the NIH campus.
- The Molecular Libraries Screening Centers Network (MLSCN) Request for Applications (RFA) was released April 21, 2004.
- The NIH hosted a Roadmap Initiative meeting on February 27, 2004, that included briefings by the NIH Director and senior staff.
- The NIH Director's Pioneer Award Program was launched January 20, 2004. The program received more than 1,400 applications and will give 10-20 awards.

Gene Transfer Research

Dr. Zerhouni updated participants on a program launched by the NIH and the Food and Drug Administration (FDA) for a new Human Gene Transfer Research Data System on March 26, 2004. It is called Genetic Modification Clinical Research Information System (GeMCRIS) and is a unique public information resource. NIH and

FDA staff have worked for two years to ensure that adverse events in this program can be reported quickly. GeMCRIS allows users to access an array of information about human gene transfer trials registered with the NIH, including medical conditions under study, institutions where trials are being conducted, investigators carrying out these trials, gene products being used, route of gene product delivery, and summaries of study protocols. The pilot Web site for the project is <http://www.gemcris.od.nih.gov>.

Selected NIH Research Advances for 2003-2004

Dr. Zerhouni highlighted recent NIH scientific advances, including the following:

- The National Institute of Mental Health has a new program to explore the genetics of schizophrenia. For the first time, researchers have discovered half a dozen vulnerability genes possibly associated with this condition.
- Several months ago, international research teams that included NIH researchers (National Human Genome Research Institute) found variants in a gene called hepatocyte nuclear factor 4-alpha (HNF4A) that may predispose people to type II diabetes, the most common form of the disease. Finding a gene that may increase susceptibility to type II diabetes and may be a master switch for pancreatic beta cells is a major breakthrough.
- Remarkable progress is being made in research on Severe Acute Respiratory Syndrome (SARS). NIH-supported researchers identified the virus that causes SARS. It is a new strain of coronavirus, a virus formerly associated only with the common cold in humans. Isolating the virus aided the rapid sequencing of its genome and investigations into diagnostic tests and treatments including two candidate vaccines. Historically, in the genetics of infectious diseases, the process of finding the gene responsible for a condition takes time. It took 20 years to find the poliovirus and develop treatment approaches in the 1950s-1960s. The identification process now is occurring much faster. Scientists took nine years to find the mutation that leads to cystic fibrosis. For Parkinson's disease, researchers were able to identify the gene in just nine days and understood it in nine months. It took four weeks to learn that the coronavirus causes SARS. The National Institute of Allergy and Infectious Disease developed two candidate SARS vaccines. Thanks to genomics advances, trials of these vaccines will begin in August 2004, not quite two years after the disease appeared. Vaccine design is being revolutionized because of knowledge of the gene responsible for virulence. The investment in basic biology helps researchers find cures and treatments.

Meeting Theme—Public Trust

Dr. Zerhouni returned to the meeting theme—public trust. Public trust has emerged as an important issue for the clinical research enterprise and also for the NIH. In the process of developing the Roadmap, Dr. Zerhouni involved NIH staff, scientists, the public, and more than 300 outside scientists. The group found that preserving and enhancing public trust in research is a strategic need. This theme also emerged in the context of increasing discoveries that require public participation. Translating research from animal to human models has worked well in the past. Today, however, chronic diseases are an important focus of research. Such conditions do not have one cause; they evolve due to complex interactions between genes and environment, diet, and other components that are not fully understood. It is difficult to develop a comprehensive model for a complex disease. It is unlikely that scientists will make progress against these diseases without a vibrant clinical research enterprise to investigate these conditions. At the core of such an enterprise is public trust.

Dr. Zerhouni recently announced the creation of the NIH Public Trust Initiative (PTI) to improve public health by promoting activities and attitudes that instill confidence in the NIH's work as the premier biomedical and behavioral research enterprise. He asked Dr. Patricia Grady, Director of the National Institute of Nursing Research, and Dr. Yvonne Thompson Maddox, Deputy Director of the National Institute of Child Health and Human Development (NICHD), to co-chair the initiative. He said there is no better topic on which to receive input from COPR than ways to further the PTI. This is a critical time in the NIH's history to look at the issue of public trust. The PTI is important to the Roadmap but extends beyond that effort.

Dr. Zerhouni asked Mr. Sadwin to act as COPR meeting manager for the morning session, then introduced NIH staff attendees: Drs. Grady and Maddox; Duane Alexander, M.D., Director, NICHD; Lawrence Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research; Judy Vaitukaitis, M.D., Director, National Center for Research Resources; Roderic Pettigrew, Ph.D., M.D., Director, National Institute of Biomedical Imaging and Bioengineering; Francis Collins, M.D., Ph.D., Director, National Human Genome Research Institute; James Battey, M.D., Ph.D., Director, National Institute on Deafness and Other Communication Disorders, and Chair, NIH Stem Cell Task Force; Sharon Hrynkow, Ph.D., Acting Director, Fogarty International Center; Ruth Kirschstein, M.D., Senior Advisor to the NIH Director; Michael Gottesman, M.D., Deputy Director for Intramural Research, NIH; Dushanka Kleinman, D.D.S., M.Sc.D., Associate Director for NIH Roadmap Coordination; and Alan Rabson, M.D., Deputy Director, National Cancer Institute.

OVERVIEW OF COPR PUBLIC TRUST EFFORTS

Debra Hall, Ph.D. and Lawrence Sadwin, COPR Members

Mr. Sadwin and Dr. Debra Hall co-facilitated the meeting. Mr. Sadwin noted the COPR Public Trust Steering Work Group began planning for the April COPR meeting in November 2003. Their aims were to coordinate a workshop on public trust and write a white paper/report on the subject. Mr. Sadwin introduced Dr. Hall, who provided an update on COPR efforts.

Dr. Hall told attendees that the COPR had agreed the first priority was to enhance public trust in clinical research, so they focused on devising strategies for exploring trust and its effect on clinical research. The COPR used a literature review to find key concepts related to trust, including the following:

- Transfer of trust between the individual researcher and the institution is important.
- Trust involves surrendering some control to the researcher.
- Dimensions of trust include fidelity, competence, confidentiality, and honesty.
- Components of institutional trust include shared goals, research oversight, and ethics training.

The review also revealed that some minority groups reported feeling like guinea pigs with regard to research, and this feeling led to a lack of trust. Lack of trust is manifested, Dr. Hall said, by the following:

- Decreased enrollment in clinical trials.
- Demand for referrals.
- Litigation.
- Poor adherence to treatment.
- Increased focus on negative events.

There is a lack of public understanding about research, she added. Members of the public do not always recognize that a research protocol may differ from standard treatment. Some participants, however, view research as their only opportunity to receive medical treatment. The public thinks the Government is responsible for protecting people in research, but they also want to be personally empowered. They scrutinize health-related research more than other types of research.

Dr. Hall detailed COPR's findings, which were based on their literature review of research and trust. With regard to the public, the COPR's findings were as follows:

- Community involvement is needed in research.
- Networking between advocacy organizations and government officials, councils and work groups would be helpful.
- The public needs to be educated about research benefits and the impact of the Bayh-Dole Act.
- Racial and ethnic diversity on advisory committees is recommended.
- Research results should be disseminated to the public.

With regard to the NIH Roadmap, COPR recommended the following:

- Joint research between clinicians and researchers.
- Interpersonal training for researchers.
- Demonstrating the effect of research findings on treatment effectiveness.

Dr. Zerhouni thanked Dr. Hall for an excellent analysis and summary of the literature findings. He then introduced Drs. Grady and Maddox, co-chairs of the NIH Public Trust Initiative. The NIH leadership thought it important to have this initiative involving the scientific perspective to complement COPR's work on trust from the public perspective.

NIH Public Trust Initiative

Patricia A. Grady, Ph.D., R.N., FAAN, Director, NINR

Dr. Grady expressed gratitude to Dr. Zerhouni and COPR, and opened her presentation with the PTI goal: "To improve the public's health by promoting public trust in biomedical and behavioral research."

She defined the public as "individuals, patients, families, and communities," and trust as "confidence placed by the people in an institution or process."

The NIH can improve communication and its interactions with the public. The PTI is critical to the NIH Roadmap, Dr. Grady said. The PTI fits into the broader framework of why people should care about the NIH and how it does its work. It is very important that the NIH translates research knowledge into practice and disseminates findings through the Internet and other vehicles.

Dr. Grady described the COPR-planned workshop as an important complement to the PTI. She mentioned areas in which public participation could be improved, such as the use of interdisciplinary teams, public-private partnerships, and new paths to discovery. Some new, exciting Roadmap paths such as Nanomedicine also entail addressing new legal and ethical issues.

Dr. Grady closed by emphasizing that the audience included leaders of the NIH and important members of the PTI Steering Committee who were listening keenly to COPR recommendations and were eager to work with COPR.

Yvonne Thompson Maddox, Ph.D., Deputy Director, NICHD

Dr. Maddox outlined current PTI activities. Those involved with the PTI learned from the COPR report on enhancing public trust that an inventory is needed of current public outreach and education activities among the various NIH Institutes and Centers. The PTI has asked the Institutes and Centers to send information on current programs, and PTI staff members are working on a national survey to ascertain the issues involved in public trust. Suggested survey questions include: Does the public trust their investment in research? Do they understand research? What are their expectations and concerns with regard to research? The PTI will work with COPR to develop additional survey questions.

Dr. Maddox noted the PTI Steering Committee is in place and that many members were in attendance.

Dr. Maddox also noted that the research enterprise should be viewed as a continuum, from discovery to translation to dissemination. The PTI will review models and may also find gaps. Survey results may lead to action items and possible initiatives to create programs that engage the public to a greater extent in biomedical research. The NIH cannot solve all problems, but some solutions may be translated to other research organizations. One idea is to send scientists to work in communities. Another idea is to establish an NIH Biomedical Research 101 course to teach science and present research positives and negatives.

Dr. Maddox pointed out that the PTI has a wide array of participants from the NIH community. The Steering Committee will review inventory results and develop guidelines, criteria, and new programs to be used in the Initiative.

Dr. Maddox closed by saying that the ultimate goal for the PTI is a tall one: To establish for the NIH a trusted reputation.

Discussion

Dr. Zerhouni thanked Drs. Grady and Maddox and opened the meeting for questions.

Dr. Mala asked how the NIH is publicizing its public trust efforts. Dr. Grady said that the PTI is starting with the inventory of current activities in this area to see what is already being done. NIH Officers of Public Liaison are the PTI voice for taking the message to the many constituencies of the Institutes and Centers. They are the intermediaries. The PTI also will use every opportunity to publicize the NIH through societies and organizations that represent each institute's mission.

Ms. Chaite asked if other COPR members could participate in the PTI Steering Committee. Dr. Grady responded that Ms. Jennifer Gorman Vetter, COPR Executive Secretary, is the COPR representative to the PTI. As projects are identified, the PTI will form subgroups and working groups that will fit more closely into COPR's work. Such developments will offer opportunities for participation. Dr. Maddox noted PTI is a far-reaching, long-term initiative that will need many ambassadors to the public.

Dr. Zerhouni added that the PTI is a large initiative whose boundaries are at the outer edge of the NIH interface with the public, including campaigns to educate the public about research, public health goals, and achievements. A key question voiced by a Steering Committee member was: "Why should the public trust us?" NIH must be able to answer that question first. The PTI eventually will develop best practices for public trust.

The Director reiterated that the PTI would receive input from public members of Institute and Center advisory councils. He asserted the NIH would consider how to better educate the public about the conduct of research. There is an important disconnect in the communication and education process. Dr. Raynard Kington, Deputy Director, NIH, agreed and suggested that the NIH might develop a Biomedical Research 101 course to help the public understand the research process. That could lead to communities of research. Mr. James Kearns offered to use his writing skills to help in the effort to get information to the public.

Dr. Zerhouni suggested that a comment from Ms. Barbara Butler about partnering with public members of other advisory councils should be investigated on a council-to-council basis.

The Trust Perception: Building a Reputation that Communities *Really* Know and Trust

David Shore, Ph.D., Associate Dean and Director of the Trust Initiative at Harvard University School of Public Health

Mr. Sadwin introduced Dr. David Shore, Associate Dean and Director of the Trust Initiative at Harvard University School of Public Health.

Dr. Shore opened his presentation with a comment made by Harvey Feinberg, M.D., President of the Institute of Medicine (IOM). When asked what is necessary to have better treatment options five years in the future, Dr. Feinberg answered, "Research." The consensus of opinion among those in Dr. Feinberg's audience, however, was that there is little trust in research.

Dr. Shore commended the NIH, COPR, and the PTI for their work on trust. Trust is good business, good leadership, and good medicine. It is one thing to build capacity around trust, however, and another to have a perception of trustworthiness among the public. He suggested that researchers think of patients and the public as customers. Health seekers are essentially customers; they want to be cured and be well cared for in the process.

Health care is consumer driven, Dr. Shore contended. If the patient is a consumer, the NIH should treat the patient as a partner. The challenge is that people think like consumers when they are well but like patients when they are sick.

There is mistrust among minority groups but there are also significant trust issues with other groups based on socioeconomic status, geography, and health status. Dr. Shore contended that a better question is: Why do minorities participate at all in clinical research? He suggested not asking why patients don't trust researchers, an approach that blames the victim. Focusing on distrust puts the onus for change on health seekers rather than on health providers.

It is essential to build trustworthiness. Biomedical research is intangible to most of the public, and trust is intangible. Dr. Shore advised that if the NIH wants to be known in the community, it needs something that is proprietary in the public mindset. The public is now mistrustful of many things related to health, such as health insurance companies. They also hear news reports of increasing medical errors in hospitals. The movie, *John Q*, did not inspire trust in the system. Although there are regulatory safeguards, most of the public does not believe the safeguards will ensure safety. The public does not trust the regulators. Dr. Shore suggested that the phrase, "Trust me. I am from the NIH and I am here to help you," has no meaning. People do not recognize the NIH as a trustworthy enterprise.

Medicine has a strange language, strange customs, and a strange culture. Doctors hold all the power and patients feel at their mercy. People trust their own personal doctor but not doctors in general. It is too painful to say that they don't trust their own personal physician.

Dr. Shore emphasized that there is very little trust among the public. There is even less trust for things related to health and medicine, which extrapolates to a lack of trust in clinical research. Trust is a proxy for competence and confidence.

He recommended that NIH learn how to think differently. Dr. Shore stated that trust is not an end in itself but is needed to achieve the ends of a profession or of an organization. The NIH needs public trust to successfully conduct clinical research and improve public health.

Trust is built. Because much clinical research is conducted without high visibility, investigators must be of good conscience. Deep personal trust, according to Dr. Shore, is one part perceived competence and two parts conscience. The word *science* is contained in the word *conscience*. A reputation is an intangible that is

connected to acting competently with good conscience. Integrity is another key component of trust, as is performance. Doing the right thing, Dr. Shore asserted, is as important as doing things right.

People also want consistency and predictability. Dr. Shore used Coca Cola as an example. Among other comments, he said people can trust that the brown liquid in the container will taste the same every time. It is not the same in a health care system in which patients experience the system anew each time they encounter it.

Dr. Shore quoted Warren Buffet on trust: "Trust is like the air we breathe. When it's present, nobody really notices. But when it's absent, everybody notices." A good reputation is a proxy for belief in an organization and is critical to an organization's success. Buffet went on, "If you lose dollars for the firm, I will be understanding, but if you lose reputation for the firm, I will be ruthless." Reputation is almost more important than the product. In polls, General Electric ranks in categories for which they have no products. People think of the company as having a reputation for good products. Princeton University ranked among the top 10 business schools in the United States, even though it has no business school. Princeton is synonymous with quality. Success, Dr. Shore contends, is more an issue of who you are—that is, reputation—than what you know. Why would someone trust you if they don't know you? Dr. Shore ended with a quote from *Alice in Wonderland*: "The keys are on the table. All you have to do is pick them up."

Discussion

Mr. Sadwin thanked Dr. Shore for his presentation and opened the floor for discussion. Senator Jim Jensen asked where the Health Insurance Portability and Accountability Act of 1996 (HIPAA) fit into Dr. Shore's accounting of trust. Dr. Shore said that HIPAA is a manifestation of a lack of trust that the Government (and those involved with an individual's health care) will keep medical information private. Privacy guidelines were not needed in the past. HIPAA shows that people now think external oversights are needed for providers and organizations. HIPAA is more about confidentiality than about privacy.

Mr. Kearns commented on Dr. Shore's references to Coca Cola. He noted that the public did not like reformulated Coke; the new formulation failed. Americans find failure to be antithetical. "Are we now reality averse?" he asked. Dr. Shore responded that the issue of risk is an important one. Trust is necessary for people to take a risk. Trust is important in the clinical research enterprise because people won't reveal important information if they don't trust. They also won't participate unless they trust.

Dr. Shore also mentioned the related issue of trust in the "health care family." Nurses and doctors generally don't trust each other. This leads to a disruptive organization. An organization cannot convey a public persona of trust without having trust internally.

What Does the Public Think? A Review of Current Data

Ms. Mary Woolley, President, Research! America

Dr. Zerhouni introduced Ms. Mary Woolley and complimented her work as important. Ms. Woolley characterized herself as an advocate for research, for the NIH, and for maximum public participation in all aspects of research. Ms. Woolley wants researchers to engage with the public whose interest they serve. She wants researchers to convey that they work for the public. She anticipates helping to make the NIH Roadmap and the COPR goals a reality.

Ms. Woolley provided information about her organization and its research in public perceptions. She presented the survey methodology and described the population sampled. She gave detailed research results on factors that impact the public's perception of research, including trust of research and researchers. The findings were as follows:

Research

- Most people polled think the United States should maintain its role as a world leader in medical and health research.
- The public strongly supports all kinds of research, including basic research.
- People value health research but don't know what it is.
- People strongly support prevention research.
- Clinical research in terms of clinical trials is valuable.
- Many said that they would participate in clinical trials.
- Most of those surveyed (88 percent) thought it was important to do medical/health research to help eliminate health disparities.

Factors affecting research participation (in order of importance)

- The greatest factor (76 percent) was the institution's reputation.
- Improve health of self or other.
- Privacy, confidentiality.
- Physician's recommendation.
- Other incentives to participate.

Factors impacting research participation

- People are not sure where clinical and health research take place.
- There is uncertainty about who pays for clinical research.

- Most people do not talk to doctors about medical research.
- Most do not recognize NIH as the government agency that funds most medical research.
- Most do not recognize the National Science Foundation or the Centers for Disease Control and Prevention (CDC).

Other research-related factors important to Americans

- Most think that a national Institutional Review Board should certify universities involved in clinical research.
- Most people would like to see government, universities, and pharmaceutical companies work together in developing new treatments and cures.
- People do not like regulatory barriers to research.
- People think that the research and development tax burden is too high.
- Electronic medical records would be acceptable if confidentiality could be guaranteed.

Ms. Woolley summarized that people in America want positive research results more quickly and they do not want to see waste or fraud in research. These issues, she asserted, would be good starting points for the public trust efforts because medical research helps deal with them both. Controlling health care costs and making sure that all have access to care are also of concern to Americans. Americans want more information about medical research. Research needs to have a public face, Ms. Woolley emphasized.

Ms. Woolley concluded that she and her organization "stand ready" to help increase public outreach.

Mobilizing Communities of Research

Neil S. Calman, M.D., Co-Founder and President, Institute for Urban Family Health

For 25 years, Dr. Calman had a family practice in the Bronx and Manhattan, New York. He has a long history of public health service and has received three national awards for his work. Dr. Calman's Institute is a nonprofit organization that provides community health services, health services research, and health professional education in New York. He directs the Bronx Health REACH project, which is funded by the CDC. The project is designed to eliminate disparities in health outcomes among minorities.

According to Dr. Calman, it is important to look at how people view the health care system when thinking about public trust in medical research. People think of medical research as part of the health care system, which they distrust. People generally distrust the medical system for many reasons, among them ever-changing recommendations about treatment. People read that doctors are more likely to kill them than guns in the home. These issues, coupled with disparities in access and treatment, further exacerbate mistrust. The data show that among minorities, African Americans have the worst health care outcomes.

Dr. Calman then detailed the Bronx REACH consortium and its activities. The project involves and employs the community in its research. Residents are trained to conduct research-related activities. The principal investigators have established relationships with health agencies, community organizations, and faith organizations. The project conducted focus groups to help understand the gaps in health outcomes and how best to involve the community in the research project. Findings were as follows:

- Trust is the number one issue. Dr. Calman reported huge gaps between how people feel about the health care delivery system and the care they receive.
- Payment for services: Medicaid and Medicare payments differ. The Government pays more for Medicare than for Medicaid, which says something about how America views the poor who are on Medicaid. Disparities, Dr. Calman said, begin with the Government.
- Research funding: The project found that research funding goes to academic medical centers. They studied six such centers and found that:
 - Academic research centers discriminate in giving care based on insurance.
 - Faculty practices treat the insured and clinics treat the uninsured. These are separate, not equal.
 - Persons of color are 2.5 times more likely to be uninsured. This results in *de facto* discrimination based on race. This situation is clear to the community.
 - People of color go to the municipal hospitals next door to the academic research centers and wait long hours to be seen because they are seen by "their own people," which they prefer to receiving secondary care in the private hospital.
 - This situation therefore affects medical research in academic hospitals.
- Language barriers: Project leaders went back to the community to solicit solutions. They worked with the community to develop a seven-point plan to alleviate health care disparities. The plan included universal health insurance, mandatory cultural competence training for health professionals, enforcement of translation mandates for health facilities and offices, increasing resources for public health education through community organizations, and social marketing and increasing diversity in New York's health profession schools.

Implications for Community-Based Research

Key points learned from this research that affect public trust are as follows:

- Trust must be earned. This can be done in part by learning what health research is important to a community and planning a research agenda around those needs.
- Community research must be based on relationships with organizations and groups in that community.

- Training those in the community to work in the research effort helps them become advocates for the research.
- Coerciveness of clinical trials: Trials are sometimes the only way people have access to treatment. Those who do not have insurance may never benefit from trial results, even if they participated in the trials.

Dr. Calman said the work of building trust in the NIH and in clinical research nationally is linked to building a health care system that people trust, and to which there is nondiscriminatory access.

Panel Discussion—Questions and Answers

Dr. Hall reminded attendees of the meeting mission statement:

- Develop a framework for describing and identifying "trust cues."
- Understand the importance of building a reputation for trust from the public perspective.
- Uncover factors that enhance the capacity for trust in research participation.

Dr. Hall suggested that the themes emerging from the morning presentations were:

- Reputation - credibility builds trust.
- Community - research needs to address the needs of the community.
- Team Work and Collaborations - Joint research between providers and researchers.
- Communicating Results - Translation of research into practice.

Dr. Calman emphasized access to health care, but Dr. Hall reminded attendees of the need to keep the NIH mission in mind.

Dr. Kington explained the Tuskegee experience and its impact on minority trust in research was well publicized but he was bothered that only one side of the issue is discussed. The flip side of the negative argument is accountability. Is the research community addressing the community's problems?

Ms. Woolley agreed with Dr. Kington. The advocacy community, she said, wants change. They want research and regulatory environments that address issues of concern to the community. The research community is eager to learn how it can use its skills to help with problems defined by the community. This is the difference between a missionary and a Peace Corps approach. The Peace Corps goes into the community and says, "How can we help you?"

Dr. Calman seconded this approach, citing his research experience. His project partnered with well-established health care researchers. They went to the community and asked community members what types of health-related research they felt needed to be done. He advised attendees that the model to follow is to let the community-based research agenda be driven by community-based organizations.

Dr. Grady addressed the issue of bringing trust back into the health care system. She said if the NIH could inspire trust in the research enterprise, it might translate into trust in the health care system. She added that Dr. Calman had given the audience clues about how to do that.

Dr. Maddox added that the NICHD has examples of when it partnered with community members to design an agenda and identify problems. NICHD trained the trainers: those trained in methods to reduce infant mortality due to Sudden Infant Death Syndrome went into the community to teach community members to help themselves. Once involved, the community feels they have to help find solutions.

Dr. Ruth Browne suggested that dialogue is needed on changing the research-funding paradigm. The dialogue needs to center on community readiness to participate in research, which requires capacity building. Capacity building involves a shift toward sharing resources with the community.

Dr. Grady identified as a recurring issue the need to translate research to underserved populations; i.e., geographically or socially isolated populations, minorities, and rural residents, among others. Partnering with researchers like Dr. Calman could help the NIH develop strategies for reaching such groups. Potential partners include groups who implement research and health care agendas. The effort could capitalize on the positive public attitude toward nurses. Nursing research is at times translational. The NIH needs to find groups to move research ideas and results forward.

Dr. Calman suggested the following potential partners:

- National Association of Community Health Centers.
- National Coalition of Public Hospitals.

He described these groups as bright and interested in local communities. They have credibility in the communities. He said they are not like the advocacy groups with whom the NIH generally interacts and are trusted and established in the communities.

Ms. Woolley added that institutions do not presently encourage researchers to become involved in the community. That mindset needs to change. Leadership should recognize researchers for public outreach services to the community and show that they value outreach.

Mr. Kearns asked why the NIH did not fund Dr. Calman's work. Dr. Zerhouni responded that there are differences in the mission statements of different government agencies. The CDC is the appropriate funding agency for Dr. Calman's work, but his work highlights an important disconnect between the evolution of the health care system and its impact on discovery science. This is a fundamental structural defect and the NIH may have to find interventions to change the fact that academic research centers receive most of the medical research funds. Those institutions train people, leading to the "ivory tower" mystique. Community research using community intermediaries is an undeveloped area. Dr. Zerhouni suggested that Dr. Calman's identification is revealing about the evolution of the health care

system vis-à-vis the pressures that academic health care systems experience and how that process affects the NIH's ability to be recognized by public constituencies. Dr. Zerhouni said this issue may require further study.

Dr. Zerhouni closed the session, referring to the NIH Roadmap that addresses transforming clinical research via better contacts with the community. He remarked that diseases have been reduced from the acute challenge they presented 40-50 years ago. Today, people deal with chronic conditions like heart disease rather than acute diseases. Life expectancy has increased. Therefore, the role of the academic health center is not as critical in the area of chronic disease as the role of the community health care center. Most cancer patients, for example, are treated in outpatient settings. This is a system issue. Dr. Zerhouni suggested this system issue could be tackled with interventions, such as having academic centers relate to communities in the way Dr. Calman describes. This is a large problem, he said, and it needs to be addressed.

ACD AND COPR LIAISON UPDATE

Dr. Zerhouni introduced Thomas J. Ansfield, M.D., member of the Advisory Council to the Director (ACD) and liaison to COPR. Dr. Ansfield thanked Dr. Zerhouni for the opportunity to attend COPR meetings and for instituting open communication between the ACD and COPR. He said he trusts that cross-fertilization of ideas between the two groups will provide sound advice and direction to the Institutes and Centers and their leadership.

Dr. Ansfield gave a brief history of the ACD. It began in 1965 when President Johnson appointed a committee under Dr. Dean Wooldridge to study NIH operations. The Wooldridge Committee recommended establishing an advisory group to help the NIH Office of the Director make "major plans and policies pertinent to the NIH mission in the conduct and support of biomedical research, medical science, and biomedical communications." The committee may make recommendations on program development, resource allocation, administrative regulation, and policy. The Secretary of the Department of Health and Human Services appoints members of the general public and the academic and private sectors in overlapping terms of four years.

At the January 2004 meeting, the ACD reviewed the Blue Ribbon Panel *Report on the Future of Intramural Clinical Research*. Recommendations included the following:

- Revise the NIH intramural clinical research oversight structure.
- Develop new training and career pathways in patient-oriented research.
- Emphasize the study of rare diseases at the Clinical Research Center by the Intramural Clinical Research Program.
- Create translational, multidisciplinary intramural and extramural partnerships.
- Reduce barriers and impediments to clinical research.

The ACD also recommended creating a single, high-level oversight committee and strengthening the roles of the Office of the Director and the Institute and Center leadership in clinical research.

Ed Benz, M.D., and Joseph Goldstein, M.D., will co-chair the NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research to recommend how best to use the Mark O. Hatfield Clinical Research Center, due to open in 2004.

Dr. Ansfield detailed other ACD work group activities. Linda Waite, Ph.D., is serving as chair of the Basic Behavioral and Social Sciences Research Working Group, which is examining areas of opportunity in basic behavioral and social science, consistent with the NIH mission. They are also examining barriers to the submission and peer review of grant applications in the basic behavioral and social sciences. The working group will complete its work by fall 2004.

Ruth Kirschstein, M.D., Senior Advisor to the NIH Director, and David Burgess, Ph.D., of the ACD are co-chairing the working group on Postdocs: Training and Career Opportunities in the 21st Century.

Dr. Ansfield explained the ACD will hear and consider recommendations of the Blue Ribbon Panel on Conflict of Interest Policies at its meeting on May 6, 2004. Panel co-chairs Dr. Alberts, and Mr. Augustine will present an overview of the panel's work. They also will facilitate discussion of the panel's findings with ACD members.

Dr. Ansfield closed his presentation with comments concerning its ties to COPR. ACD embraces principles that Mr. Sadwin presented at the last ACD meeting—that "public input into the NIH process of research choices is critical and that it is essential to consider the interests of the public in the decision-making process. To ensure this happens, the public must be able to understand and access the NIH decision-making process. The process must be transparent to the public." Dr. Ansfield said that, together, the COPR and the ACD provide a critical ear and serve as complementary sounding boards for scientific and public review in support of the Director and the Institutes and Centers and staff. He said he looked forward to providing counsel to ensure the development of science and research that enhance health issues most relevant to all Americans.

Mr. Sadwin next thanked COPR members who commented on the recommendations of the Blue Ribbon Panel on Conflict of Interest. Their views were expressed to the Panel.

Dr. Zerhouni noted the ACD, like COPR, is working hard, as evidenced by the number of working groups and reports. They are addressing important issues. The issue of postdoctoral training and the development of young scientists will receive more attention in the future. The ACD will keep COPR updated.

Enhancing Public Input and Transparency in the Research Priority Setting Process at the NIH (COPR report)

Leonard J. Tamura, Ph.D., and Zelda D. Tetenbaum, M.Sc., Immediate past Co-Chairs, Public Input and Participation Work Group, COPR, COPR Alumni Members

Mr. Sadwin introduced Dr. Leonard J. Tamura and Ms. Zelda D. Tetenbaum, immediate past co-chairs of the COPR Public Input and Participation Work Group (PIPWG). They are COPR alumni members who then presented the COPR report on "Enhancing Public Input and Transparency in the Research Priority Setting Process at the NIH."

Dr. Tamura explained the PIPWG spent many hours on the report. He quoted Dr. Zerhouni—"Engaging the public is a major priority, it is a national priority, it is not an option"—and said that the COPR agrees with Dr. Zerhouni on the importance of this issue.

Dr. Tamura acknowledged many who helped develop the report, including the Public Liaison Officers of many Institutes and Centers, Palladian Partners staff, and PIPWG members.

Dr. Tamura reminded attendees that the 1998 IOM Scientific Opportunities and Public Needs Report noted research priority setting and public input as areas that needed attention at the NIH. COPR itself evolved from a recommendation in that report. The PIPWG focused in its report on public input and transparency in the research priority-setting process at the NIH. Core assumptions behind the report are:

- Public input is an essential part of the research priority-setting process.
- The public must be able to access and understand the process; that is, transparency is necessary.
- Public input would strengthen public trust in the NIH.

The public is everyone outside the NIH, including patients, family members, advocates, and health care providers, among others. The NIH, PIPWG commented, should realize that it has many publics and tailor activities as appropriate for each one.

The report reflects a sampling of many best practices that are ongoing among the NIH Institutes and Centers. Its 11 recommendations were categorized in terms of public input, transparency, and funding, as follows:

1. Go beyond the NIH campus. This can be done via such opportunities as town meetings and regional forums.
2. Partner with communities.
3. Use varied proactive outreach such as the Internet and other ways to solicit public input.
4. Foster cross-Institute communication.
5. Create a dialogue with the community.
6. Ensure that decision makers receive and consider public input.
7. Make full use of advisory councils and their public members.
8. Develop tools and materials to educate the public.
9. Seek new ways to obtain public input.
10. Actively solicit information.
11. Provide adequate resources.

Ms. Tetenbaum, PIPWG co-chair, presented recommendations 8 through 11. She said that public trust is at the core of the research enterprise. Making adjustments to enhance transparency and public input will require funding and NIH must find the resources to show that it is committed to involving the public in its priority-setting process.

Ms. Tetenbaum closed by thanking Dr. Ruth Kirschtein and Dr. Zerhouni for their support in developing the report. She also gratefully acknowledged the work of Ms. Jennifer Gorman Vetter, Ms. Shelly Pollard, Institute and Center Public Liaison Officers and Communication Directors, and COPR members.

Discussion

Dr. Frances Dunston asked for information regarding the extent to which the Institutes and Centers are practicing the positive outreach efforts cited in the report.

Actual figures are not yet known. The intent of the report is to encourage those who are not engaged in such activities to become more active in public outreach. Dr. Dunston remarked that establishing some baseline knowledge about existing Institute and Center activities would later allow COPR to measure the impact of its recommendations on the NIH.

Dr. Ellen Sigal applauded the recommendation that the NIH leadership and researchers spend time beyond the NIH campus. She cited the many opportunities to attend town hall meetings and partner with community organizations. She mentioned the Director's e-mailed *Weekly Update*, which can be found on the NIH Web site. The communication is well done and reaches a broad audience of lay people and academics. She wondered if the NIH had measured the effectiveness of this communication.

Dr. Tamura asserted that Dr. Sigal's comment highlights a difficulty in measuring NIH outreach activities—so much is being done. He advocates a bidirectional form of communication to solicit input from the targeted audiences.

Dr. Sigal noted the National Cancer Institute (NCI) includes a component at large national cancer meetings called NCI Listens. This is an opportunity for the community to give feedback.

Dr. Ted Mala expressed hope that this COPR report would be woven into NIH Roadmap activities and act as a benchmark for the effectiveness of Institute and

Center outreach programs. He said he hoped the NIH would move these recommendations forward and recognize positive public outreach efforts.

Elliot R. Siegel, Ph.D., of the National Library of Medicine (NLM) commented that the NLM has been doing outreach since 1989 and has found it important for NLM staff and leadership to go on the road. Getting out among the public has helped the NLM learn which programs matter to the public. This is important in tailoring effective programs.

Dr. Zerhouni called for a vote on formally accepting the COPR report. Dr. Sigal moved to approve the report and Dr. Dunston seconded the motion. The report received unanimous approval.

Next Steps and Action Items for COPR Efforts on Public Trust

Dr. Zerhouni applauded the PIPWG's trans-NIH research to find best practices across Institutes and Centers. He suggested cross-fertilization improves the process. He then asked COPR for the next step in implementing the recommendations.

Ms. Butler answered that COPR will work on distribution methods for the report to different publics, then measure what has been done a year from now. This measurement will help ascertain the report's effectiveness. COPR also will develop a presentation to be given to advocacy groups. The goal is broad dissemination of the report.

Dr. Zerhouni suggested presenting the report to the Institute and Center Directors at their monthly meeting on May 27. COPR could describe current positive activities at NIH and recommend improvements. He especially liked the recommendation to include public representatives on Institute and Center advisory councils. It is important for COPR to engage the Directors in this work.

Dr. Zerhouni also recommended sending the report to each Institute and Center communications staff. The NIH has many publics, which vary by Institute and Center. Even strategic planning does not cut across Institutes and Centers. The Roadmap is one exception. It is therefore important to define and reach the various publics.

According to Dr. Zerhouni, the report evaluation should be done in the context of a feedback loop. To judge whether or not an action is effective, the action should be seen in the context of reaction and input. Some Institutes and Centers are very active in their outreach programs but they are not necessarily receiving public input. The requirements vary. The NCI is most involved with the public, probably due to its Cancer Control and Prevention Program, which requires much public input. The Director concluded that COPR should talk to the Institute and Center Directors and then develop operational strategies that may require meeting with a group of advisory council public members to share ideas.

In addition, Dr. Zerhouni remarked that the COPR has provided leadership in contributing to the National Research Council/Institute of Medicine of the National Academies report to study the NIH organizational structure and determine whether the current organization and structure of NIH are optimally configured for the scientific needs of the twenty-first century.

Dr. Zerhouni thanked Dr. Tamura and Ms. Tetenbaum. He reiterated that he was pleased with the report, which is a proactive, thoughtful analysis with a strategy for change. He added that he is impressed with how much COPR has accomplished since he first attended a COPR meeting two years ago. According to the Director, the COPR work is in line with his best expectations for the Council.

Dr. Zerhouni asked if there were a sense of where to go next. Should COPR look at a broad spectrum of issues related to health care restructuring—the issue raised in Dr. Calman's presentation—or should it look at a smaller set of issues?

Dr. Mala answered that he heard a call for more community involvement in the research process. There is a need to engage the public in the idea that research will improve their health.

Ms. Wendy Chaite thought that perhaps the vision could be expanded within the Department of Health and Human Services. There is a need to create a mechanism for dialogue because all the agencies are interconnected in their public health work.

Dr. Dunston added that NIH grantees are mediators of public trust for the NIH. Their public interactions determine whether or not there is public trust. The NIH could facilitate their ability to engender public trust. Ms. Kimberly Hinton agreed, saying the public could make the connection between the investigator and the NIH. The NIH has an image problem, however. People do not think of the NIH when they are treated at Johns Hopkins University, for example. The NIH should be the "Good Housekeeping" seal of quality in research. Those who receive money from the NIH should have information on their letterhead crediting the NIH for the funding. Ms. Hinton suggested sending them NIH logos to put on their correspondence.

Dr. Hall agreed that this suggestion is a good idea and would promote transparency.

Dr. Zerhouni proposed that the planned COPR workshop (October 2004) should include grantees for an interactive discussion. The NIH has 2,800 grantees.

Mr. John Burklow suggested adding to the COPR workshop agenda ways to improve NIH visibility with NIH grantees and their communities; perhaps this could be accomplished in the longer-range plan. Dr. Zerhouni agreed. The recommendation could be translated into an analysis of how to better link the NIH grantees and their communities. The Roadmap mentions facilitation of translational research, such as in diseases that have gone from acute to chronic. There is a strong scientific rationale for reinventing the system. The pending October COPR discussion is synergistic but requires some thought. The topic is provocative but good to attempt as part of both the workshop and the NIH Public Trust Initiative (PTI). This means the PTI should look externally, not just internally, and involve intramural and extramural components to see where the NIH may be putting up obstacles.

Dr. Dunston expressed that, in working with grantees, there is a need to improve the quality of their engagement with the public. The workshop could facilitate that capacity in the grantees. It should also include community members to facilitate dialogue in a manner similar to Dr. Calman's model. The workshop's intent,

she explained, would be to have grantees and community members develop a set of strategies together that would allow the dissemination of best approaches to engender public trust throughout the clinical research enterprise. An outcome could be the development of a set of strategies.

Dr. Zerhouni suggested starting on a small scale with pilots and components. COPR could take what is successful in the pilots and replicate those components, using several approaches rather than top-down research that dictates a single path. Scientific meetings could subsequently be organized to use the successes to move the effort forward. The task is possible but cannot be accomplished overnight.

Dr. Sigal commented that the NIH has a rich network in its local area to begin the effort. Dr. Zerhouni ended this discussion by noting that the NIH already promotes partnerships with academic centers and others nearby.

NIH Plain Language Initiative

Ms. Ann Brewer from the Office of the Director presented awards to several COPR members for their work on the NIH Plain Language Evaluation and Awards Subcommittee evaluating products and entries. The following members were honored with a token of appreciation: Dr. Hall, Dr. Dunston, Dr. Mala, Dr. Browne, Dr. Tamura, Ms. Butler, Ms. Tetenbaum, Dr. Rafael Gonzalez-Amezcuca, and Mr. Donald Tykeson. Alumni members Drs. Ellen Grant and Rod Munoz were not present to receive their awards.

Wrap-up and Final Comments

Dr. Zerhouni asked if any COPR members wished to provide input independent of the day's issues.

Dr. Mala wondered about the implementation of COPR's ideas as presented in the PIPWG Report. He was particularly interested in the discussion about favorably weighting criteria for evaluating grant applications if the grantees included in their research plans strategies for mentoring community members as part of the research process. Dr. Mala emphasized the importance of this strategy among racial/ethnic populations in which health disparities exist.

Dr. Zerhouni explained measuring the effectiveness of implementing change is a constant issue. He asserted the Office of Science Policy could address Dr. Mala's particular suggestion regarding applications. More broadly, COPR has been effective, such as in its comments to the IOM. The issue of measuring the effectiveness of implementation of COPR's work can be broken into two components—how effective COPR is in getting its recommendations implemented, and evaluating the effectiveness of those recommendations.

Mr. Sadwin noted that the COPR recommendations would first be presented to the ACD.

Dr. Zerhouni suggested that the COPR could discuss with ACD members the response to the report and how to implement it. The ACD may have suggestions and recommendations for the COPR to consider prior to making the report final. COPR members were invited to attend the ACD meeting on May 6 and the congressional hearing on May 12.

Dr. Zerhouni asked if there were other comments. Ms. Gorman Vetter noted the COPR Workshop on Trust and the next COPR meeting would be scheduled for the end of October 2004. The workshop and meeting date will be confirmed via email.

The April 2005 meeting is scheduled for April 28-29.

Dr. Zerhouni thanked Mr. Sadwin for co-chairing the meeting.

The meeting was adjourned at 4:30 p.m.

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

NIH...Turning Discovery Into Health



DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

October 27, 2004 Meeting Minutes

NIH PARTICIPANTS:

- Elias A. Zerhouni, M.D., Director, National Institutes of Health (NIH)
- Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH
- John Burklow, Associate Director for Communications and Public Liaison, Office of the Director, NIH
- Patricia Grady, Ph.D., R.N., F.A.A.N., Director, National Institute of Nursing Research
- Dushanka Kleinman, Associate Director, Roadmap Coordination, Office of the Director, NIH
- Yvonne Maddox, Ph.D., Deputy Director, National Institute on Child Health and Human Development
- Jennifer Gorman Vetter, COPR Executive Secretary and NIH Public Liaison Officer, Office of Communication and Public Liaison, Office of the Director, NIH
- Shelly Pollard, Coordinator for the Advisory Committee to the Director, Office of Communications and Public Liaison, Office of the Director, NIH

COPR MEMBERS ATTENDING:

- James J. Armstrong
- Craig T. Beam
- Barbara D. Butler
- Wendy Chaite, Esq.
- Frances J. Dunston, M.D., M.P.H.
- Rafael Gonzalez-Amezcuca, M.D.
- Debra S. Hall, Ph.D.
- R. Mike Hill
- Jim Jensen
- James Kearns
- Ted Mala, M.D., M.P.H.
- John Shlofrock
- Ellen V. Sigal, Ph.D.
- Dawna Torres Mughal, Ph.D., R.D., FADA
- Donald E. Tykeson

COPR MEMBERS NOT PRESENT:

- Ruth C. Browne, Sc.D., M.P.H.
- Nancye Buelow
- Kimberley Hinton
- Lawrence B. Sadwin

NIH DIRECTOR'S WELCOME

Dr. Elias A. Zerhouni

Dr. Elias Zerhouni welcomed the public to the 12th meeting of the NIH Director's Council of Public Representatives (COPR). He noted the importance of the previous day's workshop, *Inviting Public Participation in Clinical Research: Building Trust through Partnerships*, an event designed to solicit input from the various communities that have a role in conducting clinical trials in this country. Dr. Zerhouni thanked COPR members Dr. Debra Hall and Dr. Rafael Gonzalez-Amezcuca for serving as co-chairs for the workshop. Dr. Zerhouni also thanked Dr. Raynard Kington, Deputy Director, NIH, for presiding over the workshop and all of the COPR

members for their support of this event.

He then announced the passing of two former COPR members, Ms. Barbara Lackritz and Ms. Rosemary Quigley. Dr. Zerhouni acknowledged their passion and cited them as examples of the remarkable people who come to NIH because they want to give something to the larger medical community. He asked for a moment of silence in honor of Ms. Lackritz and Ms. Quigley. Following this moment of silence, Dr. Zerhouni suggested that their passion for advancing the mission of NIH must continue and that public discussion in the context of scientific investigation is essential to accomplishing that mission.

Returning to the topic of the workshop, Dr. Zerhouni recognized the more than 80 workshop participants, who had come from various regions in the country and represented diverse groups. He provided a brief history of the workshop, the planning of which began more than a year ago with COPR deliberations and a series of discussions about the NIH Roadmap for Medical Research vis-à-vis potential input from the public. Early in Dr. Zerhouni's tenure, he had directed the COPR to review opportunities for gathering the public's perspective, and subsequent discussions converged into the workshop and today's meeting.

Dr. Zerhouni also recognized the NIH Public Trust Initiative (PTI) as an important contributor to the workshop. He thanked the co-chairs of the NIH PTI, Dr. Patricia Grady, Director, National Institute of Nursing Research, and Dr. Yvonne Maddox, Deputy Director, National Institute of Child Health and Human Development. He introduced Dr. Dushanka Kleinman, Associate Director for Roadmap Coordination. Dr. Zerhouni then explained that both the Public Trust Initiative and the NIH Roadmap for Medical Research focus on improving public health. The NIH leadership understands that there is no perfect solution to today's public trust issues. The public is diverse, and thus "public trust" does not have a single definition. The previous day's workshop regarding public trust and clinical research helped to identify common factors that NIH leadership should consider, he noted.

Dr. Zerhouni reminded attendees that the COPR meeting was open to the public and that time would be set aside for comments and questions after the presentation by COPR members about the workshop.

Dr. Zerhouni then recognized seven outgoing COPR members—Kimberley Hinton, Nancye Buelow, Debra Hall, Ted Mala, Larry Sadwin, John Shlofrock, and Don Tykeson—for whom this would be the last COPR meeting. He thanked the departing members and recognized them as an extraordinary class. He also acknowledged Mr. Tykeson's role in discussions of ways to improve the NIH's ability to communicate its agenda to the public and the Congress. Dr. Zerhouni noted that recently developed NIH materials, such as brochures, carry the following tagline about NIH: "the nation's medical research agency." Mr. Tykeson had suggested this tagline to help raise awareness of NIH outside the Washington, D.C., area. Dr. Zerhouni thanked Mr. Tykeson and called the tagline his legacy to NIH.

COPR PRESENTATION OF PRELIMINARY FINDINGS OF THE WORKSHOP INVITING PUBLIC PARTICIPATION IN CLINICAL RESEARCH: BUILDING TRUST THROUGH PARTNERSHIPS

Dr. Debra Hall and Dr. Rafael Gonzalez-Amezcu

Dr. Rafael Gonzalez-Amezcu stated that, on behalf of the entire COPR, he and Dr. Hall would present the preliminary recommendations arising from Tuesday's workshop. He reported that the workshop had been successful and had yielded interesting results. He stated that COPR had embarked on this project a year earlier, with strong interest from COPR members, based on Dr. Zerhouni's request for public input on ways the NIH could enhance trust in clinical research. The workshop planning began as COPR learned about the NIH Roadmap for Medical Research initiative of reengineering the clinical research enterprise. This portion of the NIH Roadmap for Medical Research involves engaging the public in clinical research and building alliances to encourage public participation in clinical trials. This Roadmap initiative consists of three priorities: to build trust among members of the public, to promote communication between researchers and the public, and to educate the public about the value of clinical research.

Dr. Gonzalez-Amezcu acknowledged the contribution of the NIH PTI staff in planning the workshop. PTI staff represent a number of NIH Institutes and Centers (ICs). Dr. Gonzalez-Amezcu specifically thanked Dr. Grady, Dr. Maddox, and Dr. Kleinman for working closely with COPR to develop the foundations for the workshop.

Dr. Hall noted that COPR had prepared for this workshop over a period of several months, conducting literature searches, interviewing experts in clinical research, and working with NIH staff, and had identified three purposes for the workshop:

- To provide an overview of the current status of public participation and trust in medical research.
- To learn about past interrelationships and some proven strategies to build partnerships and engender trust.
- To explore the barriers to and opportunities for building public participation and trust in highly interactive sessions.

Dr. Hall elaborated that the goals of the workshop were also (1) to identify guiding principles that all involved communities could use to build participation and trust in medical research and (2) to develop initial recommendations for the Director, NIH, and partnering organizations. The workshop included participants who represented various backgrounds, geographical areas, races and ethnicities, conditions and diseases, patient populations, and the health and medical media. Dr. Hall reported that the day after the workshop, COPR members had reviewed what they'd heard during the workshop, spent some time identifying key themes and concepts, and converted them into a preliminary set of recommendations. These preliminary recommendations will be refined in the coming weeks.

Dr. Hall also reported that the workshop had generated tremendous energy and that the participants reflected the world in which we live. Based on their experience, they had provided specific ideas that could be translated into action, and had called for broad changes in the research culture. Most notably, many participants had identified the powerful link between community health care and public trust in clinical research, and asserted that the link could not be ignored. At the same time, COPR recognized that the NIH does not deliver community health care. With this preamble, Drs. Hall and Gonzalez-Amezcu presented the following preliminary recommendations:

Clear Communication of Intent Leads to Trust

- Explore and take inventory of existing training and look for ways to teach researchers how to communicate with communities.

- Explore and replicate best practices for communicating with patients and communities, and acknowledging them when research is done (e.g., conveying research results, thank-yous).
- Educate patients about the changing and evolving nature of research findings in the context of conflicting information.
- Ensure full disclosure of clinical trial outcomes to participants and the general public.
- Focus on educational strategies to help patients and communities better understand clinical research.

Building Capacity for Community Partnerships

- In the absence of Clinical Research Associates programs (See NIH Roadmap), provide resources (e.g., community preparatory research grants) for communities to work with grantee institutions and encourage grantee institutions to facilitate partnerships that educate communities about research and provide community members with education and access to research opportunities.
- Stimulate and facilitate education and training programs and the development of tools and resources that will help to build a strong infrastructure and associations with the community, such as, the following:
 - Develop special fellowships for researchers.
 - Develop curricula, targeted to grantees, for engaging communities.
 - Provide structures for teaching providers who live and work in the community about research.
 - Allocate resources to support these recommendations.
- Establish a community advocate/ombudsman who would have an important role in forming links between community members and local research institutions.
- Establish infrastructure to enable community providers and others to feed back information to and translate the benefits of research for the community.
- Ensure that this partnership development becomes a permanent, sustainable resource for the community.

Fostering Public Trust and Communication Is Everyone's Job

- Influence the research community and NIH staff to make public trust and communication a higher priority.
- Let all individuals demonstrate how their work will contribute to establishing public trust and communications.

Following this presentation, Dr. Zerhouni repeated a question that had arisen during the Spring 2004 COPR meeting: Why should the public trust us? He concluded that the NIH had to answer this question first, and reiterated that COPR had worked hard to bring together individuals with unique perspectives in the hope of generating ideas to overcome distrust. He expressed his hope that the workshop would spark a continuing dialogue leading to increased participation and greater trust in clinical research.

Question, Answer, and Discussion Session

Dr. Hall opened this session by asking attendees to consider:

- First impressions?
- What is missing?
- Suggestions for improving the draft?
- Perspectives and opinions?
- Reasons for disagreement?
- Identification of the strongest possibilities for encouraging public trust?
- Preferred formats for recommendations?

Dr. Gonzalez-Amezcuca introduced workshop facilitator Dr. Rob Williams and noted his instrumental role in ensuring that ideas and opinions generated by the workshop had moved forward. Drs. Hall and Gonzalez-Amezcuca then opened the forum for discussion.

One audience member remarked that the tagline for the NIH, "the nation's medical research agency," would help to establish and reinforce the identity of the NIH. At present, not many people made this connection, and the tagline might serve as a good starting point for other recommendations by providing a clear vision of what the NIH represents to the nation's health.

Dr. Steve Katz, Director, National Institute of Arthritis and Musculoskeletal Diseases (NIAMS), requested more elaboration on what COPR was recommending related to community involvement in research. NIAMS has gained a tremendous amount of experience through a health center in the District of Columbia that serves Hispanic and African-American communities. This center has facilitated interaction between community health care and the NIH, and has provided a forum for District patients to take advantage of the intramural research program at NIH. However, this center is highly labor intensive and expensive. Dr. Katz asked COPR to elaborate on this issue. Dr. Hall suggested that workshop participants were seeking ideas for community-involvement in research and efforts that involve stimulating partnerships between local communities and research institutions. What the participants expressed was a need to take steps toward building links with individuals in the community and providing resources for community members to participate in research. Dr. Katz reminded everyone that outreach was part of the NIH Roadmap for Medical Research, particularly the Clinical Research Associates program, and he asked whether people knew about this aspect of the initiative.

Another audience member asked about the full disclosure of clinical trial outcomes and noted that during the past few weeks, there had been some discussion at NIH of open access to applications. The audience member asked if in the preliminary recommendation, disclosure was limited to clinical trials or whether it would be expanded to other NIH-funded activity. Dr. Hall responded to the need to review information carefully but said that this recommendation was considered fairly broad.

Ms. Suzanne Pattee, of the Cystic Fibrosis Foundation, called for more specificity in the definition of clinical research and communities. She said that a disconnect existed between what researchers wanted to accomplish and what patients want. Ms. Pattee cautioned that the Centers for Disease Control and Prevention and the NIH have separate missions, and that NIH should not duplicate the CDC model. Instead, NIH should focus on basic and clinical research.

Dr. Dawna Torres Mughal informed audience members that the recommendations had been organized under broad themes, which should also be presented. She suggested that these broad themes would aid the discussion. Ms. Jennifer Gorman Vetter listed the themes. Dr. Torres Mughal also commented that several terms—medical research, clinical trial, and clinical research—were used interchangeably and that one term should be used for consistency. Ms. Barbara Butler responded that discussion should focus on the topic of the workshop: clinical research. Dr. Mala commented that research involves everyone. Everything that NIH does, every dollar it sends out, and every life it touches should be involved in the effort to increase public trust. Dr. Hall added that one problem with perception is that the public does not differentiate between NIH, NIH-funded researchers, and the medical community.

Dr. Zerhouni acknowledged that defining a community is a complicated task, because one person often belongs to many communities. Depending on the context, these preliminary recommendations could be implemented differently. For example, if the focus was on a geographical community, then a new infrastructure might need to be established. Dr. Gonzalez-Amezcuca suggested that defining "community" should serve as a starting point. He noted that when COPR members started to compress the notes from the workshop, they listed education and communication as priorities. Dr. Hall also noted that at the workshop, a presentation by Dr. Robert Beall, President and CEO of the Cystic Fibrosis Foundation, focused on patients and geographic communities.

Dr. Zerhouni congratulated COPR for pulling together a preliminary report based on the workshop. He noted that with more than 80 participants, it was not easy to crystallize the diverse comments. With so many people putting forth ideas, any summary sentence that COPR generated would most likely have several different interpretations. Dr. Zerhouni noted that COPR had focused on communication between the research world and the patient and public world, and that once this issue was addressed, the resulting changes should be institutionalized. He noted the need for a clear communication strategy and the adoption of best practices.

Dr. Gonzalez-Amezcuca noted that prior to the workshop, some COPR members had been trained as "weavers," who listened to breakout discussions and identified themes. He noted that communication and education were dominant themes and that there was a call for all of the NIH to understand that the community, however it was defined, needed education. The public couldn't trust what it didn't know. Dr. Hall also cited a tremendous hunger among the public for information related to health and research. Dr. Mala stated that public trust belongs to all involved in research and noted that a shift in culture that includes the grantee community would represent a new way of doing business at the NIH. Part of the evaluation for anyone who receives money from NIH should include a question about how the investigators have communicated trust to the public and how they have helped the goal of transparency.

Dr. Sally Anderson, of the National Institute on Alcohol Abuse and Alcoholism, also cautioned that the work of developing public trust involves many communities of various sizes and that all participants want more of a say in how research is done. However, one missing element is an understanding that the researcher-participant relationship differs from the doctor-patient relationship. Dr. Zerhouni agreed, and observed that community surveys about academic centers typically yield negative responses, but that research participants and others feel positively toward academic centers. The same is true for medicine. The overall trust factor for medicine is similarly low, but people feel good about their specific doctors. Dr. Zerhouni noted that the recommendation about better researcher training should focus on the researcher-participant relationship. For example, the recommendation of saying "thank you" to research participants is amazingly simple and the kind of best practice the NIH can readily implement.

CLOSING REMARKS

Dr. Zerhouni noted that, with the issue of public trust, people do not separate researchers from health care providers, which complicates the ability to address the issue. He stated that COPR had identified some preliminary recommendations that the NIH could work on and take under advisement. He noted that NIH is very interested in building public trust and that Institute and Center directors support the Public Trust Initiative. The identification of a common language and the implementation of changes in the way NIH does business could be a great outcome of the final recommendations. In both this set of recommendations and the NIH Roadmap for Medical Research, there is a clear message to train researchers to communicate with participants. Dr. Zerhouni spoke of a meeting he had attended in Kansas City, where members of the public posed questions to a representative of the Susan G. Komen Breast Cancer Foundation. He learned that 78 percent of women with breast cancer had never been asked to participate in clinical research, but that a great many did so when asked. He noted that the research community has a duty to provide transparency and that sometimes, even when a clinical trial *is* completely transparent, it can still be perceived as opaque. Anything that is not clear is often interpreted in the worst way.

Mr. Mike Hill noted that this need for transparency prompted the recommendation to establish two advocates/ombudsmen, one for patients and one for providers. Such liaisons could increase participant interactions with researchers. He added that although there is a database available to provide information on all active clinical trials, most physicians do not have time to go online and research clinical trials to recommend to patients.

Dr. Raynard Kington acknowledged the workshop as a valuable enterprise and noted that COPR members had devoted many hours over the past months to assembling the mix of diverse participants. He pointed out that the preliminary recommendations are just a first step in the process, and outlined the following next steps:

Develop a thorough synthesis of the notes from the workshop breakout sessions, including the full range of comments, who participated, and information from the speakers. Make this Workshop Proceedings available to the public online on the COPR web site at www.copr.nih.gov and on the www.getinvolved.nih.gov web site.

- Create a refined list of recommendations for NIH to explore in addressing the challenges raised in this workshop.
- Present these recommendations to the upcoming meeting of the Advisory Committee to the Director.

- Send a thank-you letter from Dr. Zerhouni to workshop participants and inform them that they will receive copies of the report when it becomes final.

Dr. Zerhouni reminded everyone that the COPR recommendations presented were a first draft and a further review by COPR would result in a more refined set that would be circulated to COPR members and participants as well as being posted on the COPR web site at: www.copr.nih.gov. Dr. Hall thanked the NIH leadership, the NIH Offices of Public Liaison, and Ms. Gorman Vetter for their help in coordinating the workshop.

The April 2005 meeting is scheduled for April 28-29.

Dr. Zerhouni thanked Dr. Hall and Dr. Gonzalez-Amezcuca for co-facilitating the meeting.

The meeting adjourned at 4:30 p.m.

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