National Institutes of Health
NIH...Turning Discovery Into Health

U.S. Department of Health & Human Services

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

COPR Alumni

CLASS OF 2005

- Nancye W. Buelow (North Carolina)
- Debra S. Hall (Kentucky)
- Kimberley Hinton (Missouri)
- Ted Mala (Alaska)
- Lawrence B. Sadwin (Rhode Island)
- John Shlofrock (Illinois)
- Donald E. Tykeson (Oregon)

Nancye W. Buelow

Term: 2002–2005

Ms. Nancye Buelow has been an advocate for the rights of people with genetic conditions since she was diagnosed in 1993 with alpha1-antitrypsin deficiency, known as Alpha-1, and placed on weekly plasma protein infusion therapy. Alpha-1 is a genetic disorder that may predispose affected individuals to illnesses such as lung disease, liver disease, and a skin disease called Panniculitis. Following her diagnosis, Ms. Buelow quickly became an outspoken advocate for people with Alpha-1 and other genetic disorders at the local and, later, national levels. She spends much of her free time advocating for genetic research and treatment issues so her children, grandchildren, and future generations will be spared the same concerns and challenges that she has faced. A coordinator of the Carolina A1A Support Network, Ms. Buelow is Past President of the Alpha-1 Association and an active member of the Genetic Alliance's Executive Board. Currently, she serves as the Alliance's Vice President for Consumers and as a representative on the Consumer Coalition for Health Privacy, the March of Dimes GENE Project, and the National Patient Safety Foundation Accountability in Clinical Research Balancing Risk and Benefit Committee. She also helped to found and build the Coalition for Genetic Fairness in Washington, DC. She frequently participates in meetings sponsored by the National Human Genome Research Institute in Bethesda, Maryland, where public input is one of the primary goals. In 2000, the ECKERD and Points of Life Foundations named Ms. Buelow one of the "100 Women Volunteers Making a Difference." In addition to her volunteer work, Ms. Buelow works as consultant for the health care home infusion industry, where she represents consumer concerns. She and her family live in the mountains of western North Carolina.

Debra S. Hall

Term: 2002–2005

Dr. Debra Hall is a Registered Nurse who works as the Clinical Nursing Researcher at the University of Kentucky Hospital. The hospital serves geographically underserved populations in which cardiovascular disease, diabetes mellitus, and tobacco use are major health issues and includes individuals from the Appalachian culture. Prior to this position, she worked as a Critical Care Staff Development Specialist for staff who provided care to patients with neurosurgical, trauma, burn, and other medical problems. She also worked as a staff nurse with patients that had medical, general surgical, oncological, and cardiac health problems. Dr. Hall is also a Lieutenant Commander in the Navy Reserve Nurse Corps and has served as staff nurse, division officer, and department head of training and administration for her reserve unit. She is comfortable working with many different audiences, having presented to laypersons, military personnel, unlicensed staff, nurses of various backgrounds, and multidisciplinary health care providers both locally and nationally.

As a Clinical Nursing Researcher, Dr. Hall works with nursing staff from all adult areas of the University of Kentucky Hospital to provide guidance, education, and general support in the development and conduction of nursing research activities aimed at improving patient outcomes and delivery of patient care. Her role encompasses program and process evaluation, clinical practice improvement, and research. Dr. Hall's primary area of interest is occupational stress, including organizational interventions and work redesign for health care workers with a focus on registered nurses. Dr. Hall, who earned her doctoral degree from the University of Kentucky's College of Nursing, has received grant funding and has completed pilot research studies on work-related stressors affecting registered nurses.

Kimberley Hinton

Term: 2002–2005

Ms. Kimberley Hinton has a long history of service to a diversity of philanthropic organizations in which she has held positions and participated in leadership capacities. These have included the United Way, the Glimmer Fund, the National AIDS Fund in Washington,

DC, and most recently, the AIDS Council of Greater Kansas City. While at the United Way, in the organization's Washington, DC, offices, Ms. Hinton worked with more than 25 different not-for-profit agencies around the DC, Maryland, and Virginia regions and managed the distribution of more than $9 million for essential community programs and services. Ms. Hinton's work with the staff and board leadership of these organizations helped them support vital community services such as emergency food and health services, safe houses for battered women, and local and national crisis-response services. Ms. Hinton's recent involvement includes her participation as a member of the advisory board of the Glimmer Fund, an organization based in Pennsylvania that is dedicated to supporting research on pregnancy loss. She is also a member of the Dartmouth Black Alumni Association.

Ms. Hinton is currently a full-time public health graduate student at John Hopkins University. Formerly, Ms. Hinton served as Executive Director of the AIDS Council of Greater Kansas City. She is considered an authority on grant-making and effective prevention programs, especially in the area of HIV and with programs designed to reach women and people of color. She is a trained facilitator of the Positive Workplace, a cutting-edge video training tool for workplace AIDS education. Prior to her position in Kansas City, Ms. Hinton was a Senior Program Officer for the National AIDS Fund in Washington, DC, where she managed more than $2 million in grants and provided training and development support to its 32 community partners, and she was also actively involved in planning and executing numerous national conferences.

Ted Mala

Term: 2002–2005

Dr. Ted Mala is an Alaska Native who has dedicated his career to improving health care services for Native Americans. An enrolled member of the Buckland Tribe and the Northwest Arctic Native Association in Kotzebue, Alaska, Dr. Mala currently serves as Director of Tribal Relations for the Southcentral Foundation, a nonprofit Alaska Native health corporation under the tribal authority of the Cook Inlet Region, Inc. In this capacity, he coordinates health initiatives for 53 villages served by the Alaska Native Medical Center and serves as Director of the Medical Center's Traditional Healing Program. Dr. Mala has also served as an Associate Professor of Health Sciences at the University of Alaska, Anchorage, where he founded the Institute for Circumpolar Health Studies. He made history when he served as Alaska's first Native State Commissioner of Health and Social Services, a position he held from 1990 to 1993. In this role, he directed seven divisions of government and oversaw a budget in excess of a billion dollars. Current President of the (national) Association of American Indian Physicians, Dr. Mala was most recently elected into the Russian Academy of Polar Medicine. Dr. Mala earned his M.D. from the Autonomous University of Guadalajara, his M.P.H. from the Harvard School of Public Health, and his A.B. from DePaul University in Chicago. His home village is Buckland, Alaska.

Dr. Mala is committed to the integration of Traditional Healing with allopathic medicine. He has lectured extensively on the subject and has been involved in research in the circumpolar countries Russia (Siberia), Sweden, Denmark, Iceland, Greenland, Norway, Finland, Canada, and the United States (Alaska) and was the first Secretary General of the International Union of Circumpolar Health. He is fluent in Spanish and conversant in Russian. He works with many tribes and on reservations throughout the United States and Canada. His hobbies include hiking, camping, traveling (especially Guatemala), and photography. He has three grown children.

Lawrence B. Sadwin

Term: 2002–2005

Mr. Larry Sadwin is a business and community leader. He is a strong advocate for health education, conducting effective community service programs to encourage personal behavior change and increasing funding for biomedical research. Mr. Sadwin's 20-year commitment to non-profit leadership at the local, regional, and national levels is rooted in his personal victory over heart disease, coupled with an extensive family history of cardiovascular disease. He is involved with Mended Hearts, a national support group for heart disease survivors, and is currently completing his term as Chairman of the Board of the American Heart Association, the chief volunteer executive officer responsible for the overall administration of the association's business affairs, public relations, and development. He is committed to furthering the cause of illness prevention and cure by putting a face to heart disease. This was uniquely demonstrated when Mr. Sadwin was the model for an interpretive sculpture called "A Fine Line Between Hope and Despair" by the internationally known artist Christiane Corbat, whose work explores the relationship between art, medicine, and healing. Mr. Sadwin is also a member of the National Leadership Council of Research!America, an organization dedicated to increasing funding for medical research.

Mr. Sadwin's business career began as a senior in college, when he took over his family's textile manufacturing business after the untimely death of his father to heart disease. He then served as the company's CEO for the next 30 years. As a local community leader, he has assisted in the development of more than $25 million in urban renewal projects and has raised millions of dollars for local and national philanthropic and religious organizations. He serves as Vice-Chairman of both Landmark Medical Center and the Rehabilitation Hospital of Rhode Island and has held numerous other positions on the boards of his synagogue, the New England Region of the Anti-Defamation League, and his local YMCA. Mr. Sadwin also holds an Honorable Discharge as a First Lieutenant in the United States Army Reserve. He and his wife, Joan, have two children and two grandsons.

John Shlofrock

Term: 2002–2005

Mr. John Shlofrock is dedicated to improving health care and quality of life for senior citizens and people with mental illness. He has worked closely with state and local governments to implement innovations in delivering care to residents of long-term health care facilities. Currently, he serves as the Chief Executive Officer of Barton Management, Inc., a Northfield, Illinois-based company that manages long-term care facilities for people with Alzheimer's disease and mental illness, people in need of rehabilitative services, and a variety of additional health care needs. He is also Vice President of the Illinois Council on Long-Term Care, a trade association that represents 38,000 senior citizens, and has worked with the government and the private sector to create innovative programs that

benefit residents of Illinois nursing homes.

Mr. Shlofrock has worked for the past 16 years with health care centers that treat people with mental illness. He currently serves as a board member for three such centers and is president of a fourth outside the Chicagoland area. In addition, Mr. Shlofrock oversees the operations of four health care facilities in downstate Illinois that provide different levels of care in a campus setting. He has also been involved in running a supportive living facility with Rush-Presbyterian Hospital, a major Chicagoland medical center. This facility is part of a pilot program that uses government funding to provide lower-income senior citizens access to assisted-living services. Mr. Shlofrock received his bachelor's degree in psychology from George Williams College in 1986. His hobbies include exercising, listening to music, riding motorcycles and horses, and traveling.

Donald E. Tykeson

Term: 2002–2005

Mr. Don Tykeson balances business with philanthropy and advocacy. A pioneer in the communications industry, Tykeson built a small television station in Eugene, Oregon, into a multimillion-dollar, nationwide communications company that is now owned by AT&T. He is now managing partner of Tykeson Associates / Enterprises, the parent company of several communications companies in Oregon. He has also served as a founding Director of C-SPAN, a past Director of the National Cable Television Association, and President of the Oregon Cable Television Association.

Mr. Tykeson has been actively involved in and extended his support to numerous civic and charitable organizations from the beginning of his career. He serves as the founding Director and President of the Tykeson Foundation, which funds health care and medical research, education and arts initiatives, and children's programming. A total of 59 grants and gifts were made during 2001. He also advocates on behalf of people with neurological disorders. Diagnosed in 1957 with multiple sclerosis, he serves as a national board member and Western area Vice Chair of the National Multiple Sclerosis Society, where his efforts have focused on securing increased funding to find the cause and cure for neurological disorders. He has also served as a board member of the National Coalition of Research in Neurological and Communication Disorders. Mr. Tykeson has served on several committees and boards within his community, including as a trustee and Investment Committee member of the University of Oregon, his alma mater; as a trustee of the Sacred Heart Medical Center Foundation; as a member of the Investment Committee of the Oregon Health Sciences Foundation; and as Vice-Chair of the Oregon Investment Council of the Public Employees Retirement System. An avid golfer, Mr. Tykeson was an early advocate and shareholder in a company that developed the first single-rider golf cart for people with disabilities. The Tykesons have three children and six grandchildren, who range in age from preschool to college.

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DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

April 28, 2005 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 T. Burklow, Associate Director for Communications and Public Liaison, NIH
- Marin P. Allen, Ph.D., Deputy Associate Director for Communications and Public Liaison and Director of Public Information, NIH
- Jennifer E. Gorman, COPR Executive Secretary and NIH Public Liaison Officer, Office of Communication and Public Liaison, NIH
- Shelly Pollard, Advisory Committee to the Director (ACD) Coordinator and OD Public Liaison Officer, Office of Communications and Public Liaison, NIH

COPR MEMBERS ATTENDING:

- James J. Armstrong
- Craig T. Beam
- Barbara D. Butler
- Wendy Chaite, Esq.
- Christina Clark, M.A., M.B.A.
- Frances J. Dunston, M.D., M.P.H.
- Valda Boyd Ford, M.P.H., M.S., R.N.
- Rafael Gonzalez-Amezcua, M.D.
- R. Mike Hill
- Jim Jensen
- James Kearns
- Nicolas Linares-Orama, Ph.D.
- Cynthia Lindquist, M.P.A.
- Michael Manganiello, M.P.A.
- Marjorie Mau, M.D.
- Ellen V. Sigal, Ph.D.
- Dawna Torres Mughal, Ph.D., R.D.
- Donald E. Tykeson
- Thomas J. Ansfield, Ph.D., ACD Member and ACD Liaison to the COPR

COPR MEMBERS NOT PRESENT:

- Nicole Johnson Baker, M.A., M.P.H.
- Ruth C. Browne, Sc.D., M.P.H.

SPEAKERS:

- John T. Burklow, Associate Director for Communications and Public Liaison, Office of the Director, NIH
- Bruce A. Fuchs, Ph.D., Director, Office of Science Education, Office of the Director, NIH
- Timothy C. Hays, Ph.D., Public Access Policy Implementation Project Manager, Office of Extramural Research, Office of the Director, NIH
- Patricia Grady, Ph.D., R.N., F.A.A.N., Director, National Institute of Nursing Research

- Yvonne Thompson Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development
- Beverly Laird, Ph.D., Member, NCI Consumer Advocates in Research and Related Activities and Member, NCI Director's Consumer Liaison Group
- Cary Zahrbock, M.S.W., LICSW, Member, NCI Consumer Advocates in Research and Related Activities
- Sally Rockey, Ph.D., Deputy Director, Office of Extramural Research, Office of the Director, NIH

EXECUTIVE SUMMARY

The 13th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on April 28, 2005. NIH Director Elias A. Zerhouni, M.D., introduced the following new members of the Council: Ms. Nicole Johnson Baker, Ms. Christina Clark, Ms. Valda Boyd Ford, Ms. Cynthia Lindquist, Dr. Nicolas Linares-Orama, Mr. Michael Manganiello, and Dr. Marjorie Mau.

Dr. Zerhouni described NIH highlights over the past six months, including the opening of the Mark O. Hatfield Clinical Research Center, the awarding of Nobel Prizes to four NIH grantees, the announcement of the new NIH conflict-of-interest regulations, and continuing work in the development of a new NIH Office of Portfolio Analysis and Strategic Initiatives (OPASI). He related his discussions of NIH issues in recent Congressional hearings and expressed satisfaction with progress in the new Director's Pioneer Award Program for innovative research.

Mr. John T. Burklow reviewed ongoing efforts by the NIH to disseminate research-based information to the public, emphasizing the expansion of media efforts. Dr. Bruce A. Fuchs described a program of the NIH's Office of Science Education to develop school curricula and promote science careers through use of the Internet.

Dr. Timothy C. Hays reported progress in the development of a Congressionally mandated archive of all peer-reviewed articles for NIH-sponsored research. The primary purpose of the archive is to increase the public's access to NIH research results. The first manuscripts were to arrive beginning May 2, 2005.

Dr. Thomas Ansfield reported on current activities of the Advisory Committee to the Director (ACD). Drs. Patricia Grady and Yvonne Thompson Maddox, Co-Chairs of the NIH Public Trust Initiative, reported on the program's progress, including development of an inventory of NIH activities relating to public trust.

Dr. Beverly Laird and Ms. Cary Zahrbock described the Consumer Advocates in Research and Related Activities (CARRA) program, of the National Cancer Institute (NCI). The program now includes about 200 consumer members (comprising cancer survivors, caregivers, family members of survivors, and professionals), who review NCI communication and educational materials, review Web sites, and help plan public workshops. Trained CARRA members are also recruited to serve as public members in the NCI grant review process for clinical trials.

Dr. Sally Rockey addressed the complexities of the process in which clinical researchers interact with communities. She stressed the potential effectiveness of clinical research networks and efforts by the new NIH National Clinical Research Associates Initiative, which is currently in the planning and feasibility stages.

NIH DIRECTOR'S UPDATE

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

The 13th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on April 28, 2005. NIH Director Elias A. Zerhouni, M.D., welcomed the COPR members and presenters. He thanked those who had participated in the previous day's awards ceremony of the use of plain language and he thanked those COPR members who participated in the evaluation and selection process for the plain language awards. He introduced the following new members of the Council: Ms. Nicole Johnson Baker, Ms. Christina Clark, Ms. Valda Boyd Ford, Ms. Cynthia Lindquist, Dr. Nicolas Linares-Orama, Mr. Michael Manganiello, and Dr. Marjorie Mau. Dr. Thomas Ansfield attended the meeting as the liaison from the Advisory Committee to the Director (ACD). COPR member Ms. Wendy Chaite is now serving as the COPR's liaison to the ACD, replacing former member Mr. Larry Sadwin in that role.

Dr. Zerhouni welcomed National Cancer Institute (NCI) advocates Mr. Douglas Ulman, Ms. Vernal Branch, Ms. Cary Zahrbock, and Dr. Beverly Laird, stating that the NCI has been an active program in the area of improving public participation and outreach. Finally, Ms. Rosemary Barber was welcomed to the meeting. Ms. Barber attended the meeting as a representative of the United Kingdom Medical Research Council's Advisory Group on Public Involvement.

In his updates, Dr. Zerhouni announced that the Mark O. Hatfield Clinical Research Center opened in September 2004. At a time when state-sponsored clinical research facilities are experiencing fiscal pressures, this new state-of-the-art research center on the NIH campus can take the lead in supporting bold, large-impact clinical research.

Dr. Zerhouni also announced four NIH grantees became Nobel Laureates in October 2004. They are Dr. Richard Axel, of Howard Hughes Medical Institute, Dr. Linda Buck, of the Fred Hutchinson Cancer Research Center, Dr. Irwin Rose, of the University of California, Irvine, and Dr. Avram Hershko, of the Technion-Israel Institute of Technology in Haifa, Israel.

In addition, since the last COPR meeting, Dr. Zerhouni stated that the NIH has moved forward with its initiative on conflicts of interest, developing new ethics rules for NIH staff. These interim regulations, unveiled in February 2005, will serve the goal of making the NIH the most trusted source of scientific information in the United States. They will ensure that NIH information is accurate and allow healthy exchanges and interactions among all persons involved. The process will adapt over time.

Recognizing that research is not a linear process and much overlap exists among agencies and institutes, Dr. Zerhouni described the new Office of Portfolio Analysis and Strategic Initiatives (OPASI) that NIH is creating to assess and plan its work. The OPASI will address issues such as coordinating trans-NIH initiatives, setting cross-cutting priorities, reducing redundancy, and analyzing the NIH research portfolio. Dr. Zerhouni expressed his intention for OPASI to support a transparent process and to foster better decision-support tools.

Dr. Zerhouni discussed the NIH Roadmap for Medical Research, the NIH Strategic Plan for Obesity Research, the NIH Neuroscience Blueprint, and OPASI at the Appropriations Overview Hearing, House Appropriations Subcommittee on Labor, HHS, and Education on March 9, 2005. He participated in a discussion of the NIH research portfolio and reauthorization at a hearing of the House Committee on Energy and Commerce, Subcommittee on Health, on March 17, 2005. Dr. Zerhouni and several NIH Directors attended a Senate Appropriations Subcommittee Hearing on the FY 2006 Budget on April 6, 2005.

Dr. Zerhouni announced that Dr. David A. Schwartz will be the new Director of the National Institute of Environmental Health Sciences (NIEHS), replacing Dr. Kenneth Olden. Dr. Elizabeth G. Nabel will become the new Director of the National Heart, Lung, and Blood Institute (NHLBI), and Dr. Antonio Scarpa will become the new Director of the Center for Scientific Review. Dr. Judith L. Vaitukaitis stepped down as Director of the National Center for Research Resources (NCRR) and now serves as Senior Advisor on Scientific Infrastructures and Resources in the Office of the Director. Dr. Barbara Alving is currently Acting Director of the NCRR.

Dr. Zerhouni described the NIH, with its incorporation of new directors in leadership roles, many from outside the NIH, as a vibrant agency. He celebrated the proactive strategic coordination that is occurring. The NIH's new Director's Pioneer Award Program, which supports scientists who exhibit exceptional creativity and innovative approaches, has completed its first year and will present approximately 5 to 10 new awards in September 2005.

MOVING SCIENTIFIC DISCOVERY TO THE PUBLIC: HOW SCIENCE INFORMATION GETS FROM THE LAB TO THE PUBLIC

Mr. John T. Burklow, Associate Director for Communications and Public Liaison, NIH

Reminding the meeting participants that science is the basis of health education, Mr. John Burklow provided examples of ways in which the NIH disseminates scientific information to the public, including underserved populations. For years, the NIH has worked to increase its accessibility to reporters and to be known as the place from which reporters can obtain research-based information from scientists. The NIH has a large-scale communications plan and publishes and disseminates a wide spectrum of science-based health education documents, many in Spanish and other languages. Mr. Burklow gave examples of recent large campaigns to translate scientific findings into public action in areas such as eye health, heart disease, and diabetes. Partnerships play an increasing role in these efforts.

The COPR members suggested that clearly highlighting the NIH's role in these efforts could help to advance the understanding and progress of the NIH is this area. It was also suggested that the NIH might expand on strategic initiatives to emphasize its contribution to some scientific results. All agreed that working on the grassroots level is most effective.

HOW THE NIH TAKES BASIC SCIENCE AND TURNS IT INTO TOOLS THE PUBLIC CAN USE: A CASE STUDY

Bruce A. Fuchs, Ph.D., Director, Office of Science Education, Office of the Director, NIH

Dr. Bruce Fuchs described how the NIH develops educational products based on scientific research. Decisions by young people to focus on fields of science are often made in middle-school years. On a percentage basis, U.S. schools are lagging behind those of many other countries in fostering scientific careers. The NIH Office of Science Education (OSE) features a Web site [www.science.education.nih.gov] that offers educational resources. Traffic for the site has been growing rapidly. The site features a popular component called “LifeWorks” for the benefit of young students, which describes scientific careers and profiles scientists.

In the NIH Curriculum Supplements Program, individual institutes produce curricula that focus on specific areas of scientific expertise. For example, the National Human Genome Research Institute (NHGRI) created a curriculum on the human genome project. The NIH employs strategies to make such tools applicable to hard-to-reach audiences, and it markets them to teachers rather than schools. The OSE has been increasing the sophistication of the presentations of these products that are distributed to teachers.

Dr. Fuchs noted that the topic of science would be added to the No Child Left Behind Program in a few years, but would be considered an optional subject. In response to a question regarding partnering with commercial agents such as the Disney Channel, Dr. Fuchs responded that it is often very difficult because of such issues as rights to the materials developed. Parents are also eligible to receive NIH educational materials if they homeschool their children.

UPDATE ON PUBLIC ACCESS

Timothy C. Hays, Ph.D., Public Access Policy Project Manager, Office of Policy for Extramural Research Administration, Office of Extramural Research, Office of the Director, NIH

Dr. Timothy Hays reviewed the progress of the new policy for public access to archives of publications funded by the NIH, which is to go into effect on May 2, 2005. NIH-funded researchers are asked to submit a copy of their final manuscripts upon acceptance for publication to the National Library of Medicine's PubMed Central (PMC) at http://nihms.nih.gov. The authors specify when the articles should be made available publicly on PMC after the final date of journal publication. After receiving thousands of public comments, the NIH set a policy for the timing of submission ranging from immediately upon journal publication to 12 months afterwards. The longer 12 month delay was implemented to accommodate the needs of smaller specialized journals of learned societies.

The policy applies to all publications of research from currently funded NIH research (grants, cooperative agreements, contracts, and other mechanisms) or from previously funded research if the paper is accepted after May 2, 2005. The articles submitted for the archive are final versions, as accepted for publication, and containing all changes resulting from the journal's peer review process. NIH will also accommodate corrections from authors that occur during copyediting or post publication.

The policy does not apply to book chapters, editorials, reviews, conference proceedings, and publications resulting from non-NIH-funded research. NIH hopes to add about 60,000 articles to the archive each year. This new program addresses current general trends such as the new developments in information technology tools, the public's increasing use of the Internet to obtain medical information, and the interest of the U.S. Congress. The system should ensure the preservation of

NIH-funded publications, allow scientists, NIH, and the public to mine publications for information, and help the NIH monitor scientific productivity and establish priorities.

The NIH Policy should not affect copyright since it explicitly recognizes and upholds the principles of copyright. Authors and journals can continue to assert copyright in NIH-funded scientific publications, in accordance with current practice.

Dr. Hays also discussed the benefits to principal investigators (PIs) for participating in the Policy. First, PIs and institutions can use the manuscript submission as an alternative means to fulfill the existing requirement to provide publications as part of progress reports. Second, by adding their manuscripts to PMC, which is a comprehensive, integrated, biomedical information technology system, authors will benefit from the modern information technology tools already available in PMC (e.g., PubMed, GenBank, Molecular Database, MedlinePlus, Clinical Trials, Small Molecules (PubChem), etc.). Lastly, authors will have the ability to ensure timely public access to their research manuscripts. Once their manuscripts are electronically available through PMC, authors will benefit from higher visibility of their research and the potential for increased citations.

ADVISORY COMMITTEE TO THE DIRECTOR (ACD) LIAISON REPORT

Thomas J. Ansfield, M.D., Member, ACD, and Liaison to the Council of Public Representatives

On behalf of the ACD, Dr. Thomas Ansfield expressed his appreciation for the window into the work of the Council of Public Representatives. He welcomed Ms. Wendy Chaite as the new liaison from the COPR. The ACD recognizes the importance of both ensuring that the public is part of the decision-making process and of making the work of the NIH transparent. At its December 2004 meeting, ACD members received reports on the NIH Roadmap for Medical Research, COPR activities, behavioral and social science research, the process for approving outside awards for NIH employees, issues pertaining to postdoctoral fellows, conflict of interest, the NIH Director's Pioneer Award Program, and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Dr. Ansfield stressed that the ACD and COPR can act as complementary sounding boards for issues of importance to NIH.

UPDATE ON THE NIH PUBLIC TRUST INITIATIVE

Patricia A. Grady, Ph.D., R.N., F.A.A.N., Co-Chair, NIH Public Trust Initiative, and Director, National Institute of Nursing Research

Yvonne Thompson Maddox, Ph.D., Co-Chair, NIH Public Trust Initiative, and Deputy Director, National Institute of Child Health and Human Development

Drs. Patricia Grady and Yvonne Thompson Maddox, co-chairs of the NIH Public Trust Initiative, reviewed the program's ongoing philosophy, goals, and plans. The initiative encourages activities within the Institutes and Centers (ICs) and across the NIH in the following areas: involving and protecting human participants in clinical research, including the public in IC business, promoting the visibility of NIH information for the public, teaching and developing curriculum materials for various levels of science education, and educational and outreach programs for clinical and basic research communities funded by NIH.

Participants in the initiative have been creating an inventory of NIH activities relating to the issue of trust and have been in contact with all ICs. This will eventually result in a formal document for public reference. One activity of note was a unique outreach effort by NIH Public Liaison Officers (OPLs), who traveled to Anchorage, Alaska, to participate in a health fair and learned about special health and research issues in geographically isolated villages. This produced a better understanding of Alaskan health care delivery—including traditional methods—and the building of bridges to support clinical research activities.

A MODEL FOR PUBLIC INPUT AND PARTICIPATION INTO RESEARCH AND RELATEDACTIVITIES: THE NCI CARRA PROGRAM

Beverly Laird, Ph.D., Member, NCI Director's Consumer LiaisonGroup (DCLG), and Member, NCI Consumer Advocates in Research and RelatedActivities (CARRA)

The National Cancer Institute (NCI) created the Consumer Advocates in Research and Related Activities (CARRA) program in 2001, to draw upon the experience of people affected by cancer to represent the views of cancer survivors and family members in NCI's daily work. Approximately 200 highly qualified, pre-screened individuals from many different cancer types, age groups, and ethnic groups across the nation comprise the CARRA membership. NCI staff request their service as members of peer review groups for clinical and translational proposals, work group participants for initiatives such as caBIG (cancer Biomedical Informatics Grid), reviewers for NCI communication and educational materials in development, and roles in many other activities in research and the communication of research. Dr. Laird described the program's rationale and operation, including the role of the NCI Director's Consumer Liaison Group (DCLG) in the initiation of CARRA. She also illustrated connections between CARRA's goals and the goals of COPR recommendations, as well as relevance to the Public Trust Initiative and the NIH Roadmap. The CARRA Web site is located at http://carra.cancer.gov/.

Dr. Zerhouni described the CARRA program as very important, one which could perhaps serve as a consumer-involvement model for the NIH as a whole.

PUBLIC PARTICIPATION IN THE PEER REVIEW PROCESS: THE NCI CARRA PROGRAM

Ms. Cary Zahrbock, Member, NCI Consumer Advocates in Research and Related Activities (CARRA)

Ms. Cary Zahrbock highlighted the training and involvement of CARRA members in the peer review process for clinical and translational research at NCI. The patient advocate role focuses on reviewing patient recruitment, procedures (protocols), and human subjects protection. In collaboration with the NCI Division of Extramural Activities (DEA), the CARRA program has developed a Peer Review Training Workshop, conducted jointly by NCI staff, CARRA members, outside scientists, and a facilitator. CARRA members then participate in peer review meetings as full voting members—including extensive preparation prior to the meeting, submitting a critique online, and participating in the discussion and scoring. The CARRA members are equally accountable for all policies, including confidentiality and conflict of interest policies.

Ms. Zahrbock listed several benefits of involving CARRA members in peer review, including the increased likelihood that research studies eventually funded by NCI would be able to recruit and retain study participants, reach diverse populations, incorporate sound human subjects protections, and be adaptable to healthcare provider practices. She also emphasized how CARRA members carry back to their communities an increased understanding of and confidence in the research prioritization process, and positive perceptions of and support for clinical research.

HOW DOES THE NIH WORK WITH THE SCIENTIFICCOMMUNITY TO BUILD TRUST WITH PATIENTS?

Sally Rockey, Ph.D., Deputy Director, Office of Extramural Research, Office of the Director, NIH

Dr. Sally Rockey reviewed the issue of trust in light of the recent COPR report and recommendations on public trust in clinical research. The report stressed building relationships, partnerships, patient communities, and networks. Yet, she noted, we must address complexities. Clinical researchers need different and expanded expertise to assume a role that interacts with communities. Training and the new NIH National Clinical Research Associates initiative, a component of the NIH Roadmap, could address this need.

The NIH ICs have robust relationships with advocacy groups. We need processes of harmonization that streamline and optimize by knowing what does and does not work in communities, and that can foster actions that strengthen the process. One strategy is the use of clinical research networks, which employ informatics and other technologies to broaden the scope of research and reduce duplications. A problematic issue is the desire of researchers to pursue and define their own careers, at the same time that the research program requires substantial collaboration.

Dr. Raynard Kington noted that his office has contracted with the RAND Corporation to study the feasibility of the NIH National Clinical Research Associates Program. A representative from that effort could be asked to report on progress at the next COPR meeting.

PUBLIC COMMENTS

Three public visitors offered comments to the COPR. Mr. Rogelio Lopez, a Senior Public Health Programs Administrator from Southern California, praised the goals presented in the COPR report on trust and cautioned that many consumers are not familiar with issues such as confidentiality and privacy. Dr. Trevor Marshall, of the Autoimmunity Research Foundation, described that group's efforts to increase the visibility of a therapy for the idiopathic disease sarcoidosis, relating the effort in terms of public trust. Ms. Rosemary Barber, of the United Kingdom Medical Research Council Advisory Group on Public Involvement, expressed her desire to engage COPR members to discuss issues of public trust.

FINAL THOUGHTS AND FUTURE MEETING DATES

The meeting resulted in the recognition of a need to improve the interactions of researchers and communities and to seek greater rigor in the tools used to integrate information. One key is to institutionalize new processes. Based on the COPR recommendations, an accountability process has begun. The COPR should identify a method for increasing NIH recognition in a substantial way.

The fall meeting of the COPR is scheduled for October 24–25, 2005. The next spring meeting is scheduled for April 19–21, 2006, with a new-member orientation on April 19, 2006. In 2006, the fall meeting is scheduled for October 23–24.

ADJOURNMENT

Dr. Kington thanked the participants and adjourned the meeting at 4:45 p.m.

LIST OF ABBREVIATIONS AND ACRONYMS

- ACD—Advisory Committee to the Director
- CARRA—Consumer Advocates in Research and Related Activities
- COPR—Council of Public Representatives
- DCLG—Director's Consumer Liaison Group (NCI)
- FY—fiscal year
- HHS—Department of Health and Human Services
- IC—Institutes and Centers
- NCI—National Cancer Institute
- NCRR—National Center for Research Resources
- NHGRI—National Human Genome Research Institute
- NHLBI—National Heart, Lung, and Blood Institute
- NIAAA—National Institute on Alcohol Abuse and Alcoholism
- NICHD—National Institute of Child Health and Human Development
- NIEHS—National Institute of Environmental Health Sciences
- NIH—National Institutes of Health
- NINR—National Institute of Nursing Research

- OCPL—NIH Office of Communications and Public Liaison
- OPASI—NIH Office of Portfolio Analysis and Strategic Initiatives
- OSE—NIH Office of Science Education
- PI—Principal Investigator

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

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U.S. Department of Health & Human Services

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

October 25, 2005 Meeting Minutes

Building 31, C-Wing, Conference Room 6, NIH Campus
Bethesda, Maryland

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
- Jennifer E. Gorman, NIH Director's Council (COPR) Coordinator and Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, NIH

COPR MEMBERS ATTENDING:

- James J. Armstrong
- Nicole Johnson Baker, M.A., M.P.H.
- Craig T. Beam
- Ruth C. Browne, Sc.D., M.P.H.
- Barbara D. Butler
- Wendy Chaite, Esq.
- Christina Clark, M.A., M.B.A.
- Frances J. Dunston, M.D., M.P.H.
- Valda Boyd Ford, M.P.H., M.S., R.N.
- Rafael Gonzalez-Amezcua, M.D.
- R. Mike Hill
- Jim Jensen
- James Kearns
- Nicolas Linares-Orama, Ph.D.
- Cynthia Lindquist, M.P.A.
- Michael Manganiello, M.P.A.
- Marjorie Mau, M.D., M.S.
- Dawna Torres Mughal, Ph.D., R.D.

COPR MEMBERS NOT PRESENT:

- Ellen V. Sigal, Ph.D.

OTHER SPEAKERS AND DISCUSSANTS:

- Antonio Scarpa, M.D., Ph.D., Director, Center for Scientific Review, NIH
- James F. Battey, Jr., M.D., Ph.D., Director, National Institute on Deafness and Other Communication Disorders
- Patricia Grady, Ph.D., R.N., F.A.A.N., Director, National Institute of Nursing Research
- Sally Rockey, Ph.D., Deputy Director, Office of Extramural Research, Office of the Director, NIH
- Yvonne Thompson Maddox, Ph.D., Deputy Director, National Institute on Child Health and Human Development

EXECUTIVE SUMMARY

The meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on October 25, 2005. NIH Director Elias A. Zerhouni, M.D., thanked the COPR members for their commitment and dedication. He also announced that on September 29th, the NIH named 13 new recipients of the NIH Director's Pioneer Award. In addition, on October 12, the NIH announced the recipients of the Institutional Clinical and Translational Science awards (CTSAs).

The NIH continues to develop the new Office of Portfolio Analysis and Strategic Initiatives (OPASI) to better manage NIH's large and complex scientific portfolio, to coordinate trans-NIH initiatives, and to develop better tools and information for decision-making. Dr. Zerhouni announced the final conflict-of-interest regulations on August 25th. These are intended to protect the NIH's integrity and its ability to provide the public with unbiased information.

Dr. Zerhouni and other NIH staff testified at Congressional budget hearings. Given the numerous issues the nation is dealing with the NIH budget likely will not increase in 2006. Dr. Zerhouni called on the NIH community to maintain its forward momentum regardless.

Dr. Zerhouni reported that two NIH-supported scientists, Robert H. Grubbs, Ph.D., of Caltech, and Richard R. Schrock, Ph.D., of MIT, received the Nobel Prize. He named three new NIH directors-David Abrams, Ph.D., (Office of Behavioral and Social Sciences Research), Antonio Scarpa, M.D., Ph.D., (Center for Scientific Review), and David Schwartz, M.D., M.P.H., (National Institute of Environmental Health Sciences).

Ms. Christina Clark and Dr. Marjorie Mau facilitated a discussion on the topic of the inclusion of trained public reviewers participating in the NIH peer review process and presented results of their information gathering on the issue. Dr. Scarpa presented a perspective of peer review issues from the Center for Scientific Review. COPR members discussed ways in which public participation in the research process currently occurs at the NIH and could occur in the future. COPR members encouraged the dialogue on this topic to continue and encouraged the work group to continue gathering information about where public input and participation could be included in the peer review process and even more broadly in the grant and research process.

Dr. Frances Dunston and Dr. Nicolas Linares-Orama reported on progress in developing a process for evaluating the COPR's internal activities, usefulness, and effectiveness. They presented outlines of proposed guidelines for post-report feedback and a post-report tracking check list, developed by the Performance Review Work Group. This led to a general discussion of performance issues, including suggestions such as seeking the counsel of former COPR members, extending the COPR members' term of service, and ensuring wide representation on the Council.

Ms. Nicole Johnson Baker and Mr. Michael Manganiello reported on recent efforts of the Communications Work Group. They identified three areas in which the Work Group recommended that the NIH enhance communication efforts: the NIH identity, public outreach and increasing education and awareness efforts to Congressional offices. They presented a list of recommendations for enhancing education and awareness of the NIH, such as streamlining communications to enhance a unified NIH identity and encouraging grantees to identify the NIH in their research publications. The COPR members discussed the recommendations and challenges to communicating the NIH's work to the public.

Ms. Wendy Chaite presented highlights of the June 2, 2005, meeting of the Advisory Committee to the Director (ACD), on behalf of absent Dr. Thomas J. Ansfield, the ACD's liaison to the COPR.

Drs. Patricia Grady and Yvonne Thompson Maddox reported progress in the NIH Public Trust Initiative, which has as its overarching goal enabling the public to understand and have full confidence in the research that the NIH conducts and supports. They presented a list of proposed activities that the NIH's Institutes and Centers (ICs) might apply to help earn and increase the public's trust in the research process. The initiative itself plans to conduct a series of activities to earn and advance feelings of trust in the research process, such as conducting small-scale outreach to communities and identifying incentives to encourage ICs to adopt activities that earn and build trust in the research process.

The COPR members noted two letters of comment from the public. One was on Preparing Public Members to Participate in Peer Review, from Sarena D. Seifer, Executive Director, Community-Campus Partnerships for Health and the other was from William Ash who served as the co-chair for the Los Angeles Breast Cancer Alliance who also affirmed his belief that public members bring a different and important aspect to the peer review process. After the public comment session, COPR members agreed on future COPR meeting dates.

WELCOME AND INTRODUCTION

Dr. Elias A. Zerhouni

The 14th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on October 25, 2005. NIH Director Elias A. Zerhouni, M.D., welcomed the COPR members and presenters and noted that, since its inception, the COPR has witnessed more than 30 presentations, updates, and reports from Institute and Center directors and their senior staff, and from the Office of the Director. The Council has held a major workshop on building trust and has drafted six reports.

Dr. Zerhouni thanked the Council members for volunteering their time and for their dedication. He described that for this meeting, the COPR instituted a new format and that by scheduling a series of focused work group sessions the day before, the new format allowed for longer discussion periods in this daylong open meeting.

NIH DIRECTOR'S UPDATE

Dr. Elias A. Zerhouni

Office of Portfolio Analysis and Strategic Initiatives

The NIH has been in the process of establishing the new Office of Portfolio Analysis and Strategic Initiatives (OPASI) to better manage NIH's large and complex

scientific portfolio, to coordinate trans-NIH initiatives, and to develop better tools and information for decision-making. Changes in science and health (for example, the increase in chronic conditions) are requiring that the NIH have a mechanism that looks across the Institutes and obtains input from a wide spectrum of stakeholders as it plans. The NIH Roadmap for Medical Research serves as a prototype for such a strategy. The OPASI will feature public input and strive to be a bottom-up process, to remove barriers to science, and to increase cross-fertilization.

Dr. Zerhouni cited a debt of gratitude to Dr. Dushanka Kleinman for her work in guiding the NIH Roadmap for Medical Research (she has returned to her position at the National Institute of Dental and Craniofacial Research). Dr. Lisa Colpe has taken the position of Acting Assistant Director for Roadmap Coordination.

NIH Director's Pioneer Awards

On September 29th, Dr. Zerhouni announced the 13 new recipients of the NIH Director's Pioneer Award. This was the second round of awards. The Pioneer Awards reward scientists who take innovative approaches to address major challenges in biomedical research. The program received positive feedback following its first year. The new awardees represent diverse fields, including neuroscience, genetics, epidemiology, chemistry, stem-cell biology, behavioral science, infectious diseases, and technology development.

Translational Research

Dr. Zerhouni announced that Dr. Barbara Alving had completed her report on progress in the Institutional Clinical and Translational Science Awards (CTSAs) program, and awardees were announced on October 12. Led by Dr. Alving and Dr. Anthony Hayward, the CTSA program seeks to transform clinical and translational research, in order to close the gap between scientific research and clinical work. Reengineering the clinical research enterprise is a centerpiece of the NIH Roadmap for Medical Research. Dr. Zerhouni stressed that translational research itself is a science. The NIH wants to generate new knowledge and perform research using the best knowledge, at the bedside and as a tool of discovery.

NIH Ethics Regulations

Following publication in April of the interim NIH ethics regulations and the receipt of comments from the NIH staff, the public, and scientific organizations, Dr. Zerhouni announced on August 25th the final conflict-of-interest regulations. Because the NIH provides advice to the nation, it must abide by rules to ensure that it functions in the public's best interest and retains its confidence. The new rules will protect the NIH's integrity and ability to provide the public with unbiased information. The model for conflict-of-interest regulations will evolve over time to address issues such as databases and transparency. At the same time, the NIH will strive not to become overly bureaucratic.

Congress and the Budget

Dr. Zerhouni and others from the NIH testified at a recent Congressional hearing for the reauthorization of the NIH. Goals to consider in the reauthorization are to institutionalize the process of the NIH common fund and to improve NIH decision-making. Dr. Zerhouni assured the COPR members that the overall goal of Congress is to ensure that the NIH is operating as efficiently and effectively as possible.

The NIH continues to operate under a continuing resolution, which holds NIH at the FY 2005 operating level. Hurricane relief and reconstruction likely will result in cuts to final FY 2006 budgets, including that of the NIH. Dr. Zerhouni emphasized the need for the NIH to be ready to find ways to maintain the forward momentum of research in spite of such a result. In particular, human capital-for example, the next generation of scientists-must be supported.

Personnel Highlights

On October 5, 2005, two NIH-supported scientists received the Nobel Prize. Robert H. Grubbs, Ph.D., of Caltech, and Richard R. Schrock, Ph.D., of MIT, were honored for developing metal-containing molecules that are now used daily in the chemical and pharmaceutical industries to manufacture important compounds.

Dr. Zerhouni announced that David Abrams, Ph.D., is the new Associate Director for Behavioral and Social Sciences Research and Director of the Office of Behavioral and Social Sciences Research (OBSSR). Antonio Scarpa, M.D., Ph.D., is the new Director of the Center for Scientific Review (CSR), and David Schwartz, M.D., M.P.H., is the new Director of the National Institute of Environmental Health Sciences (NIEHS). Dr. Schwartz played a leadership role in NIH's relief efforts following Hurricane Katrina. Thomas Gallagher, Ph.D., recently left the post of Director of the Office of Community Liaison, and Mr. John Burklow was chosen to serve as that office's Acting Director.

Discussion

In response to a question about the shift to an emphasis on trans-NIH processes, Dr. Zerhouni cited new understandings of scientific processes that span different diseases, such as the roles that signaling cells play in cancer, heart disease, and more. Scientific work in genomics and proteomics must span the disease spectrum and not be contained within individual medical-research silos.

The budgetary cuts required to meet the expenses of recent events such as Hurricane Katrina likely will cause a slowdown in development of the OPASI program. Regardless, the NIH will continue implementing the NIH Roadmap for Medical Research. As for continuing to nurture young investigators, Mr. Michael Manganiello encouraged the NIH to work with voluntary health agencies. Dr. Zerhouni reminded the group that the NIH budget is an investment in the future. The NIH must be specific and accountable-educating the public about its support for medical/scientific advances.

The NIH balances work in the sciences, including psychosocial and environmental sciences. Nevertheless, there is a need for more work in basic behavioral science. The understanding of behavioral science can help to advance the work in other medical sciences. The NIH must support the development of, for example, new measures and tools to study gene/environment interactions and exposures.

Dr. Zerhouni recognized the following members of the COPR, who were retiring from the Council, each having served for 3-years: Mr. James Armstrong, Dr. Ruth

Browne, Ms. Barbara Butler, Dr. Frances Dunston, Dr. Rafael Gonzales-Amezcua, Senator Jim Jensen, Dr. Dawna Torres-Mughal, and Dr. Ellen Sigal. He remarked on their accomplishments and thanked them for their public service.

COPR members attending the meeting were provided copies of recent NIH news releases about the NIH Roadmap for Medical Research, the NIH Director's Pioneer Awards, and the NIH program to transform clinical and translational science.

OVERVIEW OF COPR'S WORK EFFORTS SINCE THE APRIL 2005 COPR MEETING

Mr. Craig T. Beam and Ms. Christina Clark

Mr. Craig T. Beam noted that the work session included presentations on OPASI, the NIH Roadmap for Medical Research, the CTSAs, and the National Electronics Clinical Trials and Research Network (NECTAR).

The COPR members strongly support efforts to reach out to communities, especially recent efforts through the CTSAs. Although they recognized a capacity to prepare the public to engage in the clinical research process, they wondered about better preparation and education of the scientific community about the role of the public in the research process. It was pointed out that the request for proposals (RFP) for the CTSAs included a requirement for ideas on engaging communities. Success at training scientists to communicate with communities will depend in part on the fields of research (that is, in some fields the process is more difficult).

EXPLORING THE INCLUSION AND TRAINING OF PUBLIC MEMBERS IN PEER REVIEW: A Discussion with NIH Leadership

Facilitators: Ms. Christina Clark and Dr. Marjorie Mau

Ms. Christina Clark thanked the many people who had helped to gather information and data on the issue of incorporating public reviewers in the peer-review process. She indicated that she and Dr. Mau had provided background materials to the COPR members in advance of the meeting. This information was meant to provide important background information on the topic. These background materials included information that provided baseline understandings and premises about the qualifications and roles of public members in peer review.

Dr. Mau began by further clarifying COPR's interest in this topic. She confirmed that COPR recognizes peer review at CSR and NIH as the gold standard in the field. Within that context, she acknowledged some of the challenges related to this topic, such as the need to recruit and train the best reviewers; to effectively evaluate a broad range of clinical research; and to increase the system's transparency, accountability, and uniformity. Based on what COPR has learned from its previous collaborative work on appropriate involvement of the public in the NIH research process, and noting the expressed challenges in peer review, COPR was initiating a dialogue with NIH leadership on this topic and seeking to continue it, as needed, for the next few COPR meetings.

Dr. Mau noted that terminology is still emerging, but for now the term "study participant expert" (SPE) would describe the proposed participants/ trained public reviewers. The intent would be a carefully defined and structured involvement in reviews of research applications involving human subjects (not basic research); and the purpose of involvement would be to provide value-added perspective of the target population to be recruited for studies, which would ultimately help achieve research goals.

She emphasized that the SPEs would need to be carefully selected, and trained or experienced in addressing issues such as the adequacy of the recruitment plan, relation of the study design and requirements to participant retention, adequacy of human subjects' protection, and representation of minority populations.

Ms. Clark further described that SPEs would be not self-selected, but rather would be chosen by the SRA because of their specific experience and background through a careful screening process. As with any new reviewer, they would receive formal training or individual orientation on the NIH peer review system and procedures, as well as on the key requirements of conflict of interest and confidentiality. They would be governed by the same rules and regulations as all other reviewers. She also emphasized that SPEs would not advocate for or against any particular research area during the review meeting, and they would not represent an advocacy organization or cause. An SRA would determine whether a particular review would benefit from SPE expertise, and would also select the specific SPE to participate. The Consumer Advocates in Research and Related Activities (CARRA) Program of the National Cancer Institute is one of several models of SPE involvement in peer review at the NIH. CARRA staff provides customized lists of screened, trained SPEs to SRAs, based on the specific needs of their review; then the SRA selects one or more individual(s) as needed.

Ms. Clark noted that COPR became interested in this subject through a series of its previous reports and previous discussion on various NIH initiatives including the NIH Roadmap (especially "Re-engineering the Clinical Research Enterprise") and the NIH Public Trust Initiative, as well as hearing about the Trans-NIH Dialogue on Public Members in Peer Review. She concluded by proposing that the NIH consider and examine the possible benefits for and feasibility of a pilot of SPE involvement in peer review meetings. She noted that the COPR meeting in April will be an opportunity to continue the dialogue on this concept.

Dr. Scarpa noted that the idea of public input into the peer-review process has been considered to some extent for about 10 years, and he outlined issues at the CSR. Most applications received by the CSR are for basic scientific research. The Center often must deal with the difficulty of finding reviewers to represent diseases and complaints from applicants that they were "not properly reviewed." He noted that these reviewers had not gone through a special training for public reviewers. Dr. Sally Rockey agreed that input by the public could have value in particular cases—for example, for research proposals that involve human subjects/clinical research. As the discussion proceeds, the NIH must seek public input where it will add the greatest value.

The idea for including trained public reviewers in the review process currently is in an exploratory stage. Ms. Clark commented, that as other Institutes and Centers learn more about these kinds of models for public participation, the concept has the potential of supporting the goal of trans-NIH training programs and activity. Dr. Rockey reminded the COPR that maintaining the integrity of the peer-review process is critical. It was agreed that training reviewer scientists to work with the trained public reviewers will be important. Dr. Scarpa volunteered to report at a future COPR meeting the results of discussions in the CSR's Advisory

Committee meeting and invited Ms. Clark and Dr. Mau to continue this dialogue at the January Peer Review Advisory Committee (PRAC) meeting. Issues to consider include whether trained public reviewers will be involved in the scoring of applications. It was noted that in the current model at the NCI, trained public reviewers participate in all aspects of the review including scoring.

The NCI's CARRA program features public participants who are cancer survivors, family members of cancer patients, and other persons close to the disease. Dr. Rockey indicated that for research that does not target a specific disease, the inclusion of public reviewers in peer review could be more difficult. COPR members noted that nevertheless, public participation may lead to transparency and better communication. Dr. Mau noted that, from her experience in observing the CARRA program, public representatives can offer advice on issues such as clinical trial recruitment and retention as well as transportation for persons participating in clinical trials.

Dr. Zerhouni emphasized the need to insulate the peer-review process from undue pressures. With that in mind, public input in peer review should be guided by the principle that it should occur where it can add value to the process. The COPR members recognized that peer review is only one instance of public input in processes at the NIH. Jennifer Gorman reminded everyone that each Institute and Center has an office of public liaison and avenues for public input. Dr. Zerhouni commented that beyond the peer-review process, the public should be allowed to help the NIH prioritize its work, in part by helping the NIH to understand the environments surrounding diseases and conditions. He mentioned that the public has provided input in the development of RFPs. He also cautioned against any attempt to revamp the peer-review process significantly. The efforts should seek instances in which public input would add a benefit, perhaps for research in specific institutes or for specific diseases.

Ms. Butler proposed that public representatives be assigned to the six NIH Advisory Councils responsible for second-stage reviews of applications. Dr. Zerhouni agreed that was an excellent idea, although it perhaps should depend on the Institute involved. Another proposal was to ensure that a communication pathway to inform communities of the results of research funding decisions is in place and includes the public. Dr. Zerhouni suggested holding a pilot program for public input in peer review, to analyze the results, including its impact (or lack of impact).

The NIH must examine the spectrum of long- and short-term research goals and how they intertwine, then determine where public input could play a role. Similarly, the NIH and the COPR should also study similar activities for public input that already exist to include determining where public input in peer review would add value, considering placing public representatives on the Advisory Councils, and enriching the public relations process in communities.

COPR PERFORMANCE REVIEW WORK GROUP REPORT

Dr. Frances Dunston and Dr. Nicolas Linares-Orama

Dr. Frances Dunston and Dr. Nicolas Linares-Orama reported on progress in developing a process for evaluating the COPR's internal activities, usefulness, and effectiveness. A proposed outline of the process includes the following areas:

- The rationale for selections of topics to address.
- The establishment of goals.
- The development of a work plan.
- The development of a strategy to reflect a broad public perspective.
- Defining processes for data and information collection.
- Defining end products and outcomes.
- A self-evaluation process.
- Generating COPR input during discussions.
- Reporting to former COPR members on the impact of recommendations they developed.

The work group also outlined proposed guidelines for post-report feedback and a post-report tracking check list. It generally observed that the COPR would like to be timely in providing its advice on emerging and developing issues and should obtain feedback that indicates how it can positively influence NIH developments.

The work group recommended a new meeting format, which would allow the COPR to provide immediate feedback to the Director. It recognized a potential benefit in obtaining input from former COPR members and a need for open communication to determine whether it is operating well. These points led to a discussion of performance issues, which led back to the issue of public involvement in the NIH.

Dr. Zerhouni emphasized a goal of identifying the drivers of outcomes and avoiding unnecessary staff and bureaucracy. He welcomed the Performance Review Work Group's report describing an evaluation process to close the performance loop and a structure that affords rapid feedback. Dr. Raynard Kington noted that another way to further tap the experience and knowledge of COPR members would be to extend the period of their service from 3 years to 4 years.

Defining a specific product (report, white paper, etc.) for the COPR to create to advise the NIH might be difficult, because of the dynamic nature of the NIH's work. A better role for the Council is selecting topics for NIH to address. Perhaps the COPR should develop ties with the many public representatives who currently serve the NIH in various capacities. The COPR might even evaluate the activities of those representatives, working with the NIH evaluation office.

Dr. Zerhouni noted that the Institutional Review Boards (IRBs) have a patient-advocate component. For a number of reasons (for example, the need to blind trials), he recommended not including public representatives on the Data Safety Monitoring Boards.

The COPR members suggested seeking ways to ensure that the COPR membership is sufficiently representative (types of diseases, types of health-system experience, etc.). Perhaps the Council should develop new ways to reach out to communities and bring views to the table.

The COPR might consider new ways to report NIH progress. One method would be simply to increase contacts and communication. Perhaps the COPR could help to distribute the inventory of NIH public trust activities being compiled by the NIH Public Trust Initiative. It was noted that the COPR already produced a Report on best practices for public input and participation around the NIH. Perhaps the Council could set up teleconferences with the public members of the IC Councils to share information and gather the collective input of public representatives from around the NIH. Dr. Zerhouni recommended that the COPR not develop lists of expectations but instead provide actionable advice.

COPR COMMUNICATIONS WORK GROUP REPORT

Ms. Nicole Johnson Baker and Mr. Michael Manganiello

Ms. Nicole Johnson Baker and Mr. Manganiello presented a rationale and suggestions to enhance NIH communications. The NIH's major efforts to transform its operations through the Public Trust Initiative, the NIH Roadmap, reengineering of the clinical research enterprise, and others, require a multiyear campaign to educate the public about clinical research.

In the previous day's discussion, the Communications Work Group identified three areas of interest. It recommended that the NIH continue to enhance its communication efforts: the NIH identity, public outreach, and that it increase education and awareness efforts to the Congress on NIH research efforts.

The work group recommended streamlining communications to enhance a unified identity for the NIH, holding a meeting with IC directors and communication directors to gain consensus on communication priorities, and urging grantees to acknowledge the NIH in their communications and public reports. Other recommendations included collaborating with voluntary health organizations to increase awareness of the NIH identity, convening a roundtable to evaluate perceptions about the NIH, and considering consultants, as needed, to assist in increasing public awareness of the NIH.

The work group recommended instituting regular communications to educate and increase awareness of NIH research efforts and special initiatives with all congressional offices, helping congressional offices to coordinate initiatives in their districts in order to increase awareness of NIH resources, performing outreach to educate other elected policymakers (state and local) about the NIH, and taking advantage of established networks that include the public.

The work group recommended that the NIH increase resources for media outreach, including further development of a b-roll for mass distribution, increased public service announcements, and the use of NIH scientists as media contacts. The NIH could use more personal narratives to put a face on scientific research and could increase outreach to consumer-oriented media.

In discussion, the COPR members noted challenges to communicating the work and results of the NIH. Mr. Burklow reported recent successes in media outreach and noted the lingering problem of the lack of identification of the NIH in reports and discussions of research results. Yet, the NIH has increasingly been "getting its name out there." He did note that, public service announcements are very expensive. On the other hand, internal strategies, such as convening Institute directors, are not. Needed perhaps is a focus on how the NIH is presented, employing narrative or storytelling, and a sense of conviction. However, many scientists are not comfortable playing roles that are essentially public relations, and the main business of the NIH must be the support of research. Nevertheless, establishing an image of the NIH is important for increasing public trust and awareness of clinical research.

The COPR members suggested various ideas: using new names and plain language, reducing the use of initialisms and acronyms (which are off-putting), placing the "NIH" name and logo on more products. Dr. Zerhouni suggested emphasizing to the ICs that there is a strong value in their use of the "NIH" brand. He also suggested increasing the use of strategic communications at local levels to promote the NIH. Others proposed finding ways in which the public representatives within the Institutes could better promote the NIH locally.

Mr. Burklow noted that his office has a comprehensive strategic plan for communicating the NIH's work and results. Perhaps the NIH Clinical Center should be featured more in communication strategies, for example, being cited as the source of breakthrough health stories. Dr. James Battey encouraged the group to consider success stories that are accessible to the public. For example, work at the NIH Clinical Center was instrumental in saving the U.S. blood supply and making profound advances in the battle against childhood leukemia. The new effort to reengineer the clinical research enterprise could be seen as an opportunity to promote the NIH.

State Senator Jensen suggested that the NIH could make its campus more visitor-friendly and step up its accommodation of visitors/tourists. Former COPR members could be asked to report the number of contacts they make that represent NIH outreach. That could become part of the COPR evaluation.

ACD LIAISON REPORT

Ms. Wendy Chaite

Because Thomas J. Ansfield, M.D., the Advisory Committee to the Director (ACD) liaison to the COPR, was unable to attend the meeting, Ms. Chaite presented his prepared statement on his behalf. Ms. Chaite is the COPR's Liaison to the ACD.

Dr. Ansfield provided highlights of the June 2, 2005, ACD meeting. Dr. Zerhouni reported on progress in the Neuroscience Blueprint, the interim ethics regulations, and the NIH Roadmap for Medical Research. Nora Volkow, M.D., Director of the National Institute on Drug Abuse, reviewed issues and priorities of her institute. ACD member Arthur Ullian provided an overview of international trends in scientific research. Dr. Kington reviewed progress in developing the OPASI and developing a list of bona fide outside awards for NIH employees. Jeremy Berg, Ph.D., Director of the National Institute of General Medical Sciences, reviewed the NIH Director's Pioneer Award program and described the development of PubChem, the new publicly available NIH molecular database. Norka Ruiz Bravo, Ph.D., Deputy Director for Extramural Research, reviewed the new policy on public access to archived publications funded by the NIH, and Allen Spiegel, M.D., Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), reported on the NIH Strategic Plan for Obesity Research.

UPDATE ON THE NIH PUBLIC TRUST INITIATIVE AND RESPONSE TO THE COPR'S PUBLIC TRUST REPORT

Drs. Patricia A. Grady and Yvonne Thompson Maddox

Dr. Patricia Grady stated that the mission of the NIH Public Trust Initiative is to enable the public to understand and have full confidence in the research that the NIH conducts and supports. The initiative seeks to provide the public with information about how the NIH conducts and supports research, with opportunities to participate in priority-setting and clinical research, and with access to and an understanding of research results. COPR member Ms. Johnson Baker recently joined the steering committee of the Public Trust Initiative.

Dr. Grady presented a list of exportable, or adaptable, activities that the NIH's ICs could apply toward increasing public trust. The activities target the internal scientific community, the external scientific community, clinical trial participants, the general public, and the research advocacy community. Examples are intramural retreats (internal scientific community), grantsmanship and training in peer review (external scientific community), a mini-CARRA model for including public members in reviews (clinical trial participants), public education campaigns (general public), and coalitions (advocacy community). In addition, the initiative developed the CTSA, which features community input.

Dr. Yvonne Thompson Maddox listed next steps for the Public Trust Initiative. These include conducting small-scale outreach to communities, modeled on a recent outreach activity in Alaska; identifying incentives to encourage ICs to adopt public-trust activities; making presentations to science directors, clinical directors, and others; possibly including communities in grant-award decisions; and emphasizing public trust throughout the NIH campus (for example, using exhibits or publishing local articles). COPR members could act as spokespersons for the Initiative. The Web address for the Public Trust Initiative is http://publictrust.nih.gov.

The COPR members suggested that the Initiative track hits to its Web site and collect feedback. They also suggested that the Initiative seek ways to encourage program officers to promote the work of their grantees. The phrase "public trust" has developed a resonance in communities, suggesting that progress is being made. The COPR members proposed that the Initiative consider changing its name, replacing "initiative" with a word suggesting a result, such as "integration" or "transformation." Dr. Grady welcomed further suggestions.

PUBLIC COMMENT

Ms. Clark reported two letters received by the COPR. Mr. William Ash, of Santa Monica, California, co-chair of a local breast cancer organization, wrote that he supports the inclusion of public members on scientific review panels. Ms. Sarena D. Seifer, Executive Director of Community-Campus Partnerships for Health, also wrote that her organization supports the concept of public participation in research—encouraging the inclusion of public representatives in all NIH peer-review processes.

NIH DIRECTOR AND COPR MEMBER SUMMARY AND NEXT STEPS

Discussions for initiating the April 2006 Agenda work group will occur in conference calls and E-mail exchanges. That committee will welcome input for any further changes to the format for the COPR meetings. Dr. Zerhouni and the COPR members agreed that the new structure for the work group day and formal COPR meeting day worked very well. Some of the significant suggestions from the meeting included: highlighting the work of the NIH Clinical Center; emphasizing presentation and success stories in NIH communications efforts; using COPR members as communicators; expanding the efforts of the NIH Visitor's Center; creating a newsletter for congressional staff: strengthening the use of Web sites; possibly increasing the COPR member term to 4 years; and, including public members on advisory committees.

The spring meeting of the COPR is scheduled for April 20–21, 2006, with new-member orientation on April 19. The next fall meeting is scheduled for November 2–3, 2006. The spring 2007 meeting is scheduled for April 26–27.

ADJOURNMENT

Dr. Zerhouni thanked the participants and adjourned the meeting.

LIST OF ABBREVIATIONS AND ACRONYMS

- ACD—Advisory Committee to the Director
- CARRA—Consumer Advocates in Research and Related Activities
- COPR—Council of Public Representatives
- CSR—Center for Scientific Review
- CTSA—Institutional Clinical and Translational Science Award
- FY—fiscal year
- ICs—Institutes and Centers
- IRB—Institutional Review Board
- NCI—National Cancer Institute
- NICHD—National Institute of Child Health and Human Development
- NIDCR—National Institute of Dental and Craniofacial Research
- NIDDK—National Institute of Diabetes and Digestive and Kidney Diseases
- NIEHS—National Institute of Environmental Health Sciences
- NIH—National Institutes of Health

- NINR—National Institute of Nursing Research
- OBSSR—Office of Behavioral and Social Sciences Research
- OCPL—NIH Office of Communications and Public Liaison
- OPASI—NIH Office of Portfolio Analysis and Strategic Initiatives
- PI—principal investigator
- RFP—Request for Proposals

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