

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

COPR Alumni

CLASS OF 2006

- [Rafael Gonzalez-Amezcu](#) (California)
- [Jim Jensen](#) (Nebraska)
- [Dawna Torres Mughal](#) (Pennsylvania)
- [Ellen V. Sigal](#) (Washington, DC)

Rafael Gonzalez-Amezcu

Term: 2003-2006



As part of his commitment to help the Hispanic community, Dr. Rafael Gonzalez-Amezcu hosts a weekly, live TV medical segment of the evening newscast for Univision's 14 KDTV in San Francisco, California, covering a range of medical topics from diabetes to bioterrorism. He is also a clinical instructor in medicine at the University of California at San Francisco School of Medicine and a staff physician for On Lok SeniorHealth, which offers comprehensive medical and support services to the frail elderly via an interdisciplinary team approach.

His involvement in the delivery of care to the frail elderly in a predominantly Hispanic community has led him to participate in other areas of health care delivery. One of the biggest challenges he sees his patients face is Alzheimer's dementia. This discovery culminated in his becoming one of the founding members of the Medical Scientific Advisory Committee to the Alzheimer's Association of the Greater San Francisco Bay Area, where he was also nominated to serve on the Board of Directors. He has taken part in several community forums to educate providers, patients, and families about Alzheimer's dementia through his involvement in the Alzheimer's Association and the Family Caregiver Alliance.

Dr. Gonzalez-Amezcu serves on the Advisory Board of a Quality of Care Initiative for the San Francisco Network of Adult Day Health Centers and was recently selected to serve on the National Advisory Board to the Robert Wood Johnson Foundation State Solutions, which is a program that seeks to maximize Medicare saving plans to better serve Medicare beneficiaries. He is a member of the National Hispanic Medical Association (NHMA), serving on its National Advisory Committee and actively participating in its annual conferences. In fact, it was through the NHMA that he took part in New York University's Wagner School of Public Service Leadership/Health Policy Fellowship. He also participated in the 2002 Hispanic Health Leadership Agenda Conference, which was held in San Antonio, Texas.

He received his undergraduate degree in Psychology from the University of California at Davis and his M.D. from the Finch University of Health Sciences/Chicago Medical School. Dr. Gonzalez-Amezcu and his wife, a pediatrician, have a 3-year-old daughter and a 7-year-old son, whose soccer team he coaches.

Jim Jensen

Term: 2003-2006



Senator Jim Jensen was elected to the 20th District of Nebraska in 1994 and has since worked to improve the health care of all Nebraskans. He has introduced significant health care legislation as the chairperson of the Health and Human Services Committee of the Nebraska Legislature, which is currently involved in a broad evaluation and planning study of publicly funded health and human services in the state. Much of Senator Jensen's work is devoted to Medicaid-related issues; for instance, he is the chair of the Medicaid Reform Task Force, which he established in response to the increasing Medicaid costs and Nebraska's budgetary shortfalls, and is a member of the Nebraska Medicaid Infrastructure Grant Project Advisory Committee.

Senator Jensen's work in the Nebraska Legislature has given him extensive experience working with groups of various sizes and very diverse interests to mediate legislative compromises in the best interests of the people of his state. He has served on the Banking, Commerce, and Insurance Committee and serves on the Nebraska Women's Health Advisory Council, Nebraska's Minority Public Health Initiative Task Force, Nebraska Newborn Screening and Genetics Advisory Committee, Nebraska Partners in Prevention for Addictions, and Nebraska Mental Health Housing Coalition. Among the many health awards Senator Jensen has received, he has been named the Nebraska Family Council Statesman of the Year and has received the Legislative Appreciation Award from the Nebraska Association of Hospitals and Health Systems. He has been married to his wife, Joan, for 44 years and they have 5 children and 16 grandchildren.

Dawna Torres Mughal

Term: 2003-2006

Dr. Dawna Torres Mughal is Associate Professor and Dietetics Program Director at Gannon University in Erie, Pennsylvania, as well as



director of the Consortium Coordinated Program in Dietetics of three neighboring academic institutions. She is a registered dietitian and is certified as a charter Fellow of the American Dietetic Association (ADA).

Dr. Mughal values education as an agent of change, collaboration as a tool for making things happen, and volunteer work as an important investment in the community and its future. Her research and professional interests in foods and nutrition include aging, cardiovascular diseases, diabetes mellitus, intellectual disabilities, patient/client education, and women's health. Her doctoral research on type 2 diabetes mellitus and dietary adherence received the ADA's New Researchers Award, and her more recent research has focused on nutrition screening of free-living older adults and of adults with intellectual disabilities who live in community-based homes.

Dr. Mughal served on the board of the Pennsylvania Dietetic Association (PADA) and as PADA's delegate to the House of Delegates of the ADA. She has held various leadership positions in the ADA as well. Dr. Mughal has also extended her volunteer work to the international community as the secretary and a member of the Steering Committee of the Special Interest Research Group on Aging and Intellectual Disabilities (SIRGAID), which is composed of international members. As charged by the World Health Organization, this association developed recommendations for healthy aging of individuals with intellectual disabilities. Her work with SIRGAID has taken her to conferences around the world and has increased her awareness of international issues on aging and intellectual disabilities.

Dr. Mughal is also devoted to community service. She is a graduate of the Leadership Erie Program and has held leadership positions on boards of local and non-local organizations. As a board member of the Erie County United Way, she chaired the Health and Healing Impact Area and is the present chair of the Community Building committee. She also served as board president of the local International Institute.

Dr. Mughal's awards include the PADA's Keystone Award for leadership; the ADA's Madge Myers Fellowship, New Researchers Award, and Outstanding Dietetics Educator Award; Honoree, as a good role model for other women in her community, Erie Center for Women; and Distinguished Alumna, Central Philippine University. Dr. Mughal earned her Ph.D. in Nutrition from Penn State University. In her free time, she enjoys various kinds of music, travel, and spending time with her two grown children, Saleem and Yasmin.

Ellen V. Sigal

Term: 2003-2006



Dr. Ellen Sigal is the founder and chairperson of Friends of Cancer Research, as well as President of the Creative Community Task Force for Cancer Research. Her philanthropic and public pursuits for these two organizations are aimed at the eradication of cancer through public awareness, education, and advocacy on the benefits of cancer research.

Dr. Sigal serves on the National Cancer Institute's Board of Scientific Advisors, which counsels the director of NCI and division and deputy directors for extramural science on a wide variety of matters concerning scientific program policy, progress, and the future direction of extramural research programs of each of the divisions. She is also a member of the American Association for Cancer Research (AACR) and has been appointed to serve on their Strategic Planning and Development Committee. In addition, Dr. Sigal is a board member of the ASCO Foundation and serves on the National Dialogue on Cancer (NDC), where she is a member of the cancer research team. NDC is chaired by former President Bush, Mrs. Barbara Bush, and Senator Diane Feinstein and encourages the cancer community to work together on overriding issues of interest to prevent, treat, and educate the public on the importance of the community working together to eradicate this terrible disease.

She was a Presidential appointee to the National Cancer Advisory Board from 1992 to 1998, where she served as Chair of the Budget and Planning Committee of the Board for more than five years until her term expired. This committee has oversight of the federal cancer budget, which is in excess of two billion dollars, and advises on strategic issues, priorities, and on the Presidential Bypass Budget.

Dr. Sigal has served as chairperson of the Board of Overseers at the Duke Comprehensive Cancer Center and on the Board of Visitors of the Medical Center. She currently serves on the board of the Duke Comprehensive Cancer Center and the Johns Hopkins Cancer Center Advisory Council.

For her efforts on behalf of cancer research advocacy, she received the 1998 American Association for Cancer Research National Leadership Award, the 1999 Sidney Kimmel Cancer Center National Leadership Award, and the 2002 American Society of Clinical Oncology Special Recognition Award.

Dr. Sigal received her Ph.D. from Rutgers University in Russian History.

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

NIH...Turning Discovery Into Health



DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

April 21, 2006 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
- Marin Allen, Ph.D., Deputy Director for Communications and Public Liaison, Office of the Director, NIH
- John Burklow, M.S., Director for Communications and Public Liaison, Office of the Director, NIH
- Jennifer E. Gorman, M.P.A., NIH Director's Council Coordinator and Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, NIH

COPR MEMBERS ATTENDING:

- Syed M. Ahmed, M.D., Dr.P.H., M.P.H.
- James J. Armstrong
- Craig T. Beam
- Ruth C. Browne, M.P.H., M.P.P., Sc.D.
- Barbara D. Butler
- Wendy Chaite, Esq.
- Christina Clark, M.A., M.B.A.
- Linda Crew, M.B.A., R.N.
- Frances J. Dunston, M.D., M.P.H.
- Valda Boyd Ford, M.P.H., M.S., R.N.
- R. Mike Hill
- Nicole Johnson Baker, M.A., M.P.H.
- James Kearns
- Nicolas Linares-Orama, Ph.D.
- Cynthia Lindquist, M.P.A.
- Michael Manganiello, M.P.A.
- Marjorie Mau, M.S., M.D.
- Ann-Gel S. Palermo, M.P.H.
- James H. Wendorf

ACD LIAISON:

- Annelise Barron, Ph.D.

COPR ALUMNA/SPECIAL EXPERT:

- Dawna Torres Mughal, Ph.D., R.D.

OTHER SPEAKERS:

- Andrew C. Baldus, Acting Associate Director for Budget, NIH

- Francis S. Collins, M.D., Ph.D., Director, National Human Genome Research Institute, NIH
- Mark L. Rohrbaugh, Ph.D., J.D., Director, Office of Technology Transfer, NIH

EXECUTIVE SUMMARY

The meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on April 21, 2006. NIH Director Elias A. Zerhouni, M.D., welcomed four new COPR members, Syed M. Ahmed, M.D., Dr. P.H., M.P.H., Linda Crew, M.B.A., R.N., Ann-Gel Palermo, M.P.H., and Mr. James H. Wendorf.

Dr. Zerhouni provided updates in a number of areas. The NIH continues to develop the new Office of Portfolio Analysis and Strategic Initiatives (OPASI), which Dr. Zerhouni characterized as "an intellectual venture space, offering funds for shared needs and affording adaptability."

NIH has a strong bio-defense effort and the National Institute of Allergy and Infectious Diseases (NIAID) will make use of the new C.W. Bill Young Center on the NIH campus to expand its research on diagnostics, vaccines, and treatments for diseases caused by infectious agents that might be released into civilian populations or re-emerging infectious diseases.

NIH is concerned about encouraging new investigators. The NIH Pathways to Independence Award Program, announced in January 2006, will help to enhance the ability of new scientists with fresh ideas to enter the competitive world of NIH funding. The program will provide postdoctoral candidates with funding to bridge between mentored research and a first independent research award.

Dr. Zerhouni announced several staff changes. Roger I. Glass, M.D., Ph.D., has been named the new Director of the Fogarty International Center and Associate Director of NIH for International Programs. He is a leading scientist and recognized expert in the development and introduction of rotavirus vaccines. Allen Spiegel, M.D., is leaving the NIH to become Dean of the Albert Einstein College of Medicine. Dr. Spiegel served more than 6 years as Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Dr. Zerhouni shared with COPR members the slide-presentation that he gave at the April 6, 2006 hearing on the [FY 2007 Budget Request before the House Subcommittee on Labor](#). His testimony emphasized the return on investment that the NIH provides for Americans. For example, a 63 percent decrease in mortality from coronary heart disease during a recent 30-year period accounted for about 1 million early deaths averted and \$2.6 trillion in economic return to the public.

Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, described advances in genomic research, focusing on the current HapMap consortium, which is applying a whole genome-association approach to analyzing DNA SNPs for diseases. Other large genome-analysis programs underway include the Genetic Association Information Network (GAIN) and the Genes and Environment Initiative (GEI).

Mr. Andrew C. Baldus, Acting NIH Budget Officer, provided an update on the NIH budget, which represents about 1 percent of the FY 2007 U.S. budget and, at \$28.6 billion, continues a flat trend that has followed the period in which the budget was doubled. Priorities in the FY 2007 budget include biodefense-related activities, the NIH Roadmap for Medical Research, the genes, environment and health initiative, pandemic influenza activities, and support for new investigators.

Mark L. Rohrbaugh, Ph.D., J.D., reviewed activities of the NIH Office of Technology Transfer (OTT), which identifies, evaluates, protects, and markets technologies derived from NIH intramural laboratories. The OTT supports about 6,000 scientists and their laboratories at the NIH. Dr. Rohrbaugh described the process by which his office develops patents and licenses for NIH researchers, sometimes involving collaborative arrangements with private companies.

Frances J. Dunston, M.D., M.P.H., F.A.C.P., reported the final activities and results of the COPR Performance Review Work Group. She presented two products of the Work Group's efforts: a Planning Table to help the COPR with internal processes and a Post-Report Evaluation of Effectiveness Tracking Table to follow the results of reports and recommendations.

Nicole Johnson Baker, M.A., M.P.H., and Michael Manganiello, M.P.A., reviewed recommendations of the October 2005 COPR meeting on issues before the Communications Work Group, which they co-chair. In addition to praising ongoing and accelerating communication efforts by NIH, they focused on additional opportunities to unify the NIH identity, increase efforts to educate Congressional staff and increase communication efforts about NIH research activities. They recognized recent efforts by the NIH, including discussions between Dr. Zerhouni and IC directors to consider combined communication efforts, Dr. Zerhouni's testimony to Congress, and the development of Institute and Center communication plans.

Christina Clark, M.A., M.B.A., presented to Dr. Zerhouni a list of recommendations developed by the COPR members in the April 20 work group session. These included:

- Continue efforts in knowledge management, including the development of OPASI and a strategic communications plan. Create a COPR liaison to work with OPASI.
- Continue efforts to increase public involvement in research through peer review and IRBs.
- Educate researchers about public involvement in the research process. Promote researcher awareness about the potential benefits of public involvement in the research process. Develop a work group to explore the possibilities.
- Promote and affirm public participation in the entire research process from beginning to end, including community-based participatory research.
- Promote collaboration between community entities and large academic institutions.
- Pursue partnerships with voluntary groups, clinics, and community organizations.
- Add a fourth "p" for "participation" to the list of future research emphases.

WELCOME AND INTRODUCTION

Elias A. Zerhouni, M.D.

The 15th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives was held on April 21, 2006. NIH Director, Elias A. Zerhouni, M.D., welcomed the COPR members and presenters and expressed gratitude for the fresh perspectives that the COPR representatives have offered in past meetings.

Dr. Zerhouni formally presented four new COPR appointees: Syed M. Ahmed, M.D., Dr.P.H., Director of the Center for Healthy Communities, Medical College of Wisconsin; Linda Crew, M.B.A., R.N., Director of the Joseph F. Sullivan Center at Clemson University; Ann-Gel Palermo, M.P.H., Associate Director of Operations at the Center for Multicultural and Community Affairs, Mount Sinai School of Medicine; and Mr. James H. Wendorf, Executive Director of the National Center for Learning Disabilities in New York City.

Dr. Zerhouni thanked five members of the COPR who rotate off the Council this year, and who attended the meeting to offer their expertise: Mr. James Armstrong, Ruth Browne, Sc.D., M.P.H., M.P.P., Ms. Barbara Butler, Frances Dunston, M.D., M.P.H., and Dawna Torres Mughal, Ph.D., R.D. He stated that the experiences and collective knowledge of the COPR members have brought much insight to NIH staff and efforts to enhance the public's perspective in the research process.

DIRECTOR'S UPDATE

Dr. Elias A. Zerhouni [NIH Director's Update](#)  (PDF - 4.8MB)

OPASI

The Office of Portfolio Analysis and Strategic Initiatives (OPASI) is both a platform and a process. OPASI allows all NIH institutes to come together to discuss the broad needs of science and medicine and consider what must be done. Including a knowledge-management effort, OPASI represents a far-sighted approach to understanding science and advancing the frontiers of science, leading to translation at the bedside.

Dr. Zerhouni stressed that OPASI is not an administrative structure. Rather, it is an intellectual venture space, offering funds for shared needs and affording adaptability. Such a concept will characterize knowledge-based organizations in the 21st century. OPASI will make the work of the NIH more transparent.

The C.W. Bill Young Center

The bio-defense mission of the NIH received a large part of the increase in funding that occurred during the doubling of the NIH budget. The National Institute of Allergy and Infectious Diseases (NIAID) has served as the lead institute in the use of these funds and will use the integrated research facility in the new C.W. Bill Young Center (Building 33) on the main NIH campus. The Center will allow the NIAID to expand its research programs for developing new and improved diagnostics, vaccines, and treatments for diseases caused by infectious agents that might be released into civilian populations and re-emerging infectious diseases.

The Pathways to Independence Award Program

On January 27th, 2006, Dr. Zerhouni announced the NIH Pathways to Independence Award Program, which targets and supports new investigators. In a period of transition, including an increased capacity for research and constrained budgets, the category of investigator most at risk is the group of scientists who are just beginning their careers. The Pathways to Independence Award Program will help to enhance the ability of new researchers with fresh ideas to enter the competitive world of NIH funding. The program will provide postdoctoral candidates with funding to bridge between the time when they are doing mentored research and when they win their first independent research award. This should result in the funding of 150 to 200 additional scientists each year.

An initial 1- to 2-year phase will allow investigators to complete supervised research, publish results, and search for an independent research position. A second, 3- to 5-year phase will allow awardees who secure an assistant professorship or equivalent position to establish a research program and apply for an NIH investigator-initiated grant (R01).

Investigators are at a disadvantage early in their careers because they do not have as much experience and data as seasoned investigators. To counter this, Dr. Zerhouni has proposed that reviewers consider the potential of an investigator in addition to the proposed project. Also, the NIH will attempt to inform investigators whether their applications have succeeded within 4 or 5 months, thereby allowing them to reapply at the 9-month mark.

Leadership Update

The NIH recruited Roger I. Glass, M.D., Ph.D., to be the new Director of the Fogarty International Center and Associate Director of NIH for International Programs. Dr. Glass is a leading scientist and a recognized expert in the development and introduction of rotavirus vaccines in the developing world. Dr. Zerhouni noted that Sharon Hrynkow, Ph.D., has performed an outstanding job as acting director and in representing the NIH internationally during the search for a new director.

Allen Spiegel, M.D., who served more than 6 years as Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), will become Dean at Albert Einstein College of Medicine of the Yeshiva University. Griffin Rodgers, M.D., M.A.C.P., has agreed to serve as the Acting Director of the NIDDK.

Status of the NIH Budget

On April 6th, Dr. Zerhouni presented the FY 2007 Budget Request to the House Subcommittee on Labor. He will make the request to the Senate on May 19th. The NIH is working in a tight budgetary environment now.

Testimony Given at the House Appropriations Hearing

Dr. Zerhouni shared with COPR members the slide-presentation that he gave at the April 6, 2006 hearing on the [FY 2007 Budget Request before the House](#)

Subcommittee on Labor. His testimony emphasized the return on investment that the NIH provides for Americans. For example, a 63 percent decrease in mortality from coronary heart disease during a recent 30-year period accounted for about 1 million early deaths averted and \$2.6 trillion in economic return to the public.

On average, each American made an investment of about \$110 toward this goal during the 30-year period (about \$3.70 per year). Reasons for the decreased mortality included new, effective treatments, prevention strategies, and medical discoveries. Dr. Zerhouni's presentation provided a similar analysis and result for increased cancer survivorship during the 30-year period. For the first time in recorded history, annual cancer deaths in the United States have fallen. NIH funding is the seeding and leveraging that leads to such results.

During the period of doubling of the budget, the NIH was able to rapidly respond to critical issues such as the anthrax attack and SARS. In part because of that investment, it has been able to develop vaccine trials to counter the potential avian flu. The Vaccine Research Center developed more than 14 new vaccines in 5 years. The NIH has also been able to move into new areas such as genomics and bioinformatics. Between 1998 and 2004, the increased funding of the NIH helped to bring more than 3,000 new technologies to market, with the help of 185 research institutions across the nation.

Dr. Zerhouni presented to the House subcommittee a vivid example of a benefit of NIH research that involved interdisciplinary efforts. Showing a before- and after-treatment video clip of a patient suffering from Parkinson's disease who was treated successfully using deep brain stimulation, he described the process that was developed by neurophysiologists, neurologists, engineers, and computer specialists to produce this extremely powerful result.

He noted also that during the past 20 years, the disability rate for elderly Americans decreased by 30 percent. People are living longer, as the most recent data on life expectancy showed. The NIH is making medical progress across the board. The investment in the NIH is about \$95 per American citizen per year.

One fallacy that must be rebutted is that more research leads to a more expensive health care system. Deploying medical procedures more widely leads to increased overall expense, yet new technologies and approaches lead to lower unit costs and better quality of life. The medicine of the future must go beyond curing to become predictive, personalized, and preemptive. As such, it will be transformed.

Discussion

The COPR members pointed to recent advances in promoting the NIH and its work, and Dr. Zerhouni gave credit to the Institute and Center (IC) directors who have rallied their staffs in that area. He noted that the slide show presented to the congressional subcommittee is available on the [NIH Web site](#). COPR members and others should feel free to download it and use it. One challenge in promoting the NIH is that funded investigators are not in the habit of crediting the NIH and often are not natural communicators. Dr. Zerhouni stressed that communication must be local and multi-channel. A sense of community is important—we never know where progress may occur. Ms. Wendy Chaite emphasized a need for participation, suggesting that the word might be added to the list of guiding principles (predictive, personalized, preemptive) AND "participatory"—for medical research in the future.

UNLOCKING THE SECRETS OF COMMON DISEASES: THE GENES AND ENVIRONMENT INITIATIVES

Francis S. Collins, M.D., Ph.D.

Francis S. Collins, M.D., Ph.D., provided an overview of advances in genomic research, reflecting on his work and that of others. The human genome project was completed in April 2003. On April 25, 2006, the anniversary of the publication of Crick and Watson's paper on the structure of DNA, scientists will visit high school biology classrooms to discuss their research with students. Also, scientists at the NIH will conduct a live Web chat with classrooms across the country, focusing on work in genomics.

The DNA instruction book—the reference sequence—is available on the Internet. Of great interest now are the variable parts of DNA—those pieces that make us different and hold the clues to hereditary disease. Virtually all diseases have some hereditary influence. A great challenge will be the discovery of the genetic basis for diseases that result from the complex influence of multiple genes. Genetics plays a role even in infectious diseases. Discovering the genetic variants that play roles in disease raises the possibility of preventing disease by indicating preventive measures and by pointing to drug targets.

The variants in DNA, called single nucleotide polymorphisms or SNPs, are subtle. There are about 10 million SNPs, and the cost of performing a controlled scientific study to genotype all DNAs for all SNPs for a single disease would be prohibitive. For that reason, stated Dr. Collins, the HapMap consortium was developed to apply a whole-genome-association approach to analyzing DNA SNPs for a disease. This method, being conducted internationally and led by the NIH, identifies and employs a smaller set of "tag" SNPs, reducing the cost of genotyping for a disease from about \$10 billion to about \$2 million. The first HapMap success story was the identification of SNPs for age-related macular degeneration. Dr. Collins serves as project manager of HapMap. The project is benefiting from previous NIH-funded studies that had collected DNA samples on various diseases.

Another initiative, the Genetic Association Information Network (GAIN), is a private-public partnership involving the NIH, the Foundation for NIH, and a number of pharmaceutical companies. It will support the genotyping of seven common diseases (to be determined in the grant application process) through whole-genome association studies. The research will begin in the summer of 2006, and the eventual results will be made available on the Web. Information is available at www.fnih.org.

Yet another effort, the Genes and Environment Initiative (GEI), is a synergistic program proposed in President Bush's FY 2007 budget and strongly supported by HHS Secretary Michael Leavitt. The program will use \$40 million to increase understanding of both genetic and environmental contributions to disease. It will include a GAIN-like genomic initiative and innovative projects to measure environmental exposures, dietary intake, and physical activity.

Dr. Collins predicted that the major genetic risk factors for common diseases, including diabetes, cancer, heart disease, autism, hypertension, bipolar illness, asthma, Alzheimer's disease, osteoporosis, and others, will be identified in the next 2-3 years. This will make possible future advances in diagnostics, pharmacogenomics, and therapeutics.

Discussion

Dr. Collins remarked that, although genomic science is compelling, it also raises ethical, legal, and social concerns. The possibility of genetic information leading to discrimination (as in health insurance) is real, and the Federal Government must provide protections. Some scientists opt out of genetic research because of ethical concerns.

The emergence of a research culture that encourages cross-Institute collaborations has benefited genomic studies such as HapMap. In some ways, the environmental contributions to disease are more difficult to understand than the genetic contributions. For example, people respond uniquely to environmental exposures. However, recent advances in measures of environmental exposure (chips, nanotechnology) offer great promise. The environment could offer the best opportunity to prevent and treat disease. The National Institute of Environmental Health Sciences (NIEHS) is creating a training program in genomic environmental science that will develop leadership. Annelise Barron, Ph.D., suggested that the NIH partner with the Environmental Protection Agency (EPA) to perform activities such as profiling toxins in cities.

UPDATE ON THE NIH BUDGET

Mr. Andrew C. Baldus [Update on the NIH Budget](#)  (PDF - 89KB)

Mr. Andrew C. Baldus provided an update on the NIH budget, which represents about 1 percent of the FY 2007 U.S. budget. The FY 2007 NIH budget of \$28.6 billion continues the flattening that has followed the period in which the NIH budget was doubled.

Mr. Baldus showed how the NIH budget will be apportioned among the NIH Institutes, Centers, and other operations, ranging from the National Cancer Institute (\$4.754 billion) and National Institute of Allergy and Infectious Diseases (\$4.396 billion) to facilities (\$81 million) and the Fogarty International Center (\$67 million).

Priorities in the FY 2007 budget include the following:

- Biodefense-related activities (\$1.891 billion).
- The NIH Roadmap for Medical Research (\$443 million).
- The genes, environment, and health initiative (\$40 million).
- Pandemic influenza (\$34 million).
- Support for new investigators (the Pathway to Independence Program) (\$15 million).

Research project grants (RPGs) account for 52.9 percent of the FY 2007 budget. In addition, about 10 percent will support research centers, and 2.7 percent will support research training. Intramural research at the NIH will account for 9.7 percent of the budget. Mr. Baldus noted that 84 percent of NIH funding will support work outside the NIH, including more than 200,000 scientists and more than 3,000 organizations worldwide.

The FY 2007 budget will support 37,671 RPGs. This is a decrease of 656 from FY 2006. The budget will support 9,337 competitive RPGs, an increase of 275 over FY 2006. The success rate for grant applications will be about 19 percent, which is similar to that of FY 2006, although lower than the FY 2005 rate of 22 percent. The decrease in success rate is explained in part by a large increase in the number of applications during the past 3 years.

For the 30-year period 1977 to 2006, funding for the NIH represented an average investment per American of about \$44 per year (about \$ 1,334 for the entire period). Additional budget information is found at <http://officeofbudget.od.nih.gov/ui/homepage.htm>.

Discussion

The COPR members expressed concern about the effects of flat funding for the NIH. Mr. Baldus responded that, as a result, the directors of the ICs are challenged to make decisions about priorities. Dr. Barron noted that some grant amounts have been cut and some benefits (for training grants) capped. Dr. Zerhouni added that the Institutes managed, nevertheless, to increase the number of competitive grants for FY 2007.

NIH TECHNOLOGY TRANSFER

Mark L. Rohrbaugh, Ph.D., J.D. [NIH Technology Transfer](#)  (PDF - .5MB)

Mark L. Rohrbaugh, Ph.D., J.D., reviewed activities of the NIH Office of Technology Transfer (OTT), which identifies, evaluates, protects, and markets technologies derived from NIH intramural research program, which includes about 6,000 scientists and their laboratories. Technology transfer refers to the movement of information, materials, and technologies from research laboratories to the commercial enterprise and other laboratories. These products support additional research and lead to the development of new products that ultimately improve public health. The OTT uses intellectual property rights, such as patents, to stimulate commercial development of technologies through the use of license agreements. The OTT also licenses to companies unique materials, such as mouse models for particular diseases, for research purposes.

The OTT's goals are to improve public health, attract new research-and-development resources to technologies, obtain a reasonable return on public investment through the collection of royalties, and stimulate economic development. It reviews inventions received from ICs, handles their patenting, and administers licensing to companies. Each IC has its own Technology Development Coordinator, and some additional supporting staff, to negotiate collaboration agreements for intramural scientists and receive the initial invention reports that are forwarded to the OTT. License royalties flow back to the ICs of the NIH, and inventors receive a share of the funds.

Dr. Rohrbaugh described the process by which his office licenses technologies to companies for commercial development, sometimes involving collaborative arrangements between the inventor scientists and the company. He cited recent successes. Researchers at the National Cancer Institute discovered that

keratinocyte growth factor could be used as a treatment for oral mucositis, a side effect of chemotherapy treatment for cancer. The technology was licensed in 1992 to Amgen, which then developed it as the commercial product Kevivance. The OTT managed the licensing of a patent to a cardiovascular stent that is coated with the compound paclitaxel (embedded in a polymer), resulting in less scar tissue and less re-growth of blockages in arteries. Angiotech initially licensed this technology in 1996 and developed it in collaboration with Boston Scientific launched the product TAXUS Express last year. Patents were issued in 1997 and 2002.

More than 200 products that have reached the market include, in part, technologies developed in the NIH intramural research program. Many are research tools, such as mouse models and cell lines, but 24 are FDA approved drugs and vaccines. The OTT has more than 1,500 active licenses. These activities produced a return of about \$98 million in royalties for the NIH in FY 2005—funds that supported research and technology transfer programs. The ICs have executed more than 1,600 cooperative agreements with industry.

The OTT also licenses technologies internationally in many countries, including Brazil, China, Egypt, India, Indonesia, Korea, and Mexico. The Office hosts a Web site that focuses on neglected diseases and lists technologies available for licensing to address them. It also hosts technology training for people from institutions in developing countries and minority serving institutions in the U.S. The general Web site for the OTT is at www.ott.nih.gov.

Discussion

The COPR members encouraged the OTT to highlight its achievements, including eventual cost savings, as in the development and use of the coated stent. Dr. Zerhouni remarked on the phenomenon in which a new medical technology initially leads to higher total costs for care, even as unit costs decline and quality of life improves. Ms. Chaite proposed creating an awards program to encourage creative efficiencies. Dr. Ahmed proposed creating a platform that allows the public to be involved in technology transfer. Dr. Rohrbaugh noted that an effort to speed-up the approval of new technologies (reducing the 10-year period) is part of the NIH Roadmap for Medical Research. The law states that, for extramural work, researchers must assign inventions to their institutions, which then have the right to license them and receive royalties (a portion of which is returned to the inventors).

Dr. Rohrbaugh noted that the NIH has a policy and model agreement for bioprospecting in localities. When the NIH licenses an invention based on one of these locally derived materials, the company is required to come to an agreement with the authorities in that locale as to ways to bring a benefit to its population.

The COPR members discussed issues concerning the distribution of royalties and the difficulties of starting a company based on new technologies. Dr. Rohrbaugh stated that the OTT attempts to be flexible with start-up companies, for example, having them use limited funds for additional research rather than royalty payments at this early stage. The NIH Roadmap for Medical Research has initiatives to help start-up companies. Beginning about 15 years ago, the amount of royalty income to the NIH has grown dramatically. It leveled off a few years ago, then, in the past year, doubled. The institutes responsible for the inventions leading to royalties make the decisions about how to use the income after a share is paid to the inventors.

OVERVIEW OF COPR'S WORK GROUP DAY

Mr. Craig T. Beam [COPR Work Group Day Report for the NIH Director](#)  (PDF - 58KB)

Mr. Craig T. Beam outlined the agenda of the work-group program that took place the day before (April 20). This included:

- A review by Mr. John Burklow of a new NIH communication plan.
- Updates from the Performance and Communication COPR work groups.
- A briefing by Timothy Hays, Ph.D., on the NIH Knowledge Management initiative.
- A report by Norka Ruiz Bravo, Ph.D., on the Office of Extramural Research.
- An update by Mr. John Burklow on the Clinical Research Awareness and Education Campaign.
- An update by Raynard Kington, M.D., Ph.D., on the OPASI.
- Discussion of a possible curriculum on educating researchers about public involvement in the research process.
- Discussion of how to promote and encourage collaborations between community entities and large research institutions.
- Discussion of how to increase researcher awareness of the potential benefits of instituting practices for community-based research.

EFFORTS AND PROGRESS SINCE THE OCTOBER 2005 COPR MEETING

Frances J. Dunston, M.D., M.P.H., F.A.C.P., and Nicolas Linares-Orama, Ph.D. [Efforts and Progress](#)  (PDF - .3MB)

Frances J. Dunston, M.D., M.P.H., co-chair of the Performance Review Work Group, related the group's progress and presented to Dr. Zerhouni and the COPR its final products, including a Planning Table to help the COPR with internal processes and a Post-Report Evaluation of Effectiveness Tracking Table to follow the results of reports and recommendations. The work group had been charged with developing strategies to evaluate the performance and influence of the COPR.

The Performance Review Work Group recommended steps to orient new members regarding the status of COPR activities, to share COPR progress with former COPR members, to seek input from COPR alumni, to prepare a progress report, to debrief outgoing members, and to conduct self-assessments.

COPR WORK GROUP DAY REPORT FOR THE NIH DIRECTOR

Christina Clark, M.A., M.B.A. [COPR Work Group Day Report for the NIH Director](#)  (PDF - 58KB)

Christina Clark, M.A., M.B.A., presented to Dr. Zerhouni a list of recommendations developed by the COPR members in the previous day's work-group sessions.

These included:

- Adopt the planning and tracking tools developed by the Performance Review Work Group.
- Add a fourth "p" for "participation" to the current 3 "p's" list of guiding principles for the future of medical research.
- Continue efforts in knowledge management, including the development of OPASI and a strategic communications plan. Create a COPR liaison.
- Continue efforts to increase public involvement in research through participation in peer review and IRBs. Encourage public participation early in the grant application process, including the application preparation process.
- Establish recognition/award programs for public participation in research. Perhaps make involvement a criterion for grants.
- Promote and affirm public participation in the entire research process from beginning to end, including community-based participatory research. Develop a work group for this issue.
- Educate researchers about public involvement in the research process. Promote researcher awareness on the potential benefits of public involvement in the research process. Develop a work group for this issue.
- Promote collaboration between community entities and large academic institutions.
- Pursue partnerships with voluntary groups, clinics, and community organizations.
- Consider holding a community-academic summit.
- Provide technical assistance to Clinical and Translational Science Award applicants to support community engagement.

The COPR Agenda Work Group was tasked with developing an agenda for the fall 2006 COPR meeting. A subset of the Agenda Work Group will gather data on patient and health categories, emphasizing underserved and under-recognized populations. The COPR members noted that recent trends in the representation of women and minorities in clinical trials are good.

Dr. Zerhouni responded to the COPR members' list of recommendations. He stated that public participation in the research process, where appropriate, is an intention of the NIH. In fact, many research projects do feature public involvement. An award for such participation likely would be an insufficient strategy. The NIH is striving to increase the pool of minority researchers by offering competitive opportunities. The COPR members noted efforts by the National Academy of Sciences to address disparities and proposed inviting a member of that organization to address the COPR.

COPR COMMUNICATIONS WORK GROUP REPORT

Nicole Johnson Baker, M.A., M.P.H., and Michael Manganiello, M.P.A. [COPR Communications Work Group Report](#)  (PDF - 53KB)

Nicole Johnson Baker, M.A., M.P.H., and Michael Manganiello, M.P.A., reviewed recommendations of the October 2005 COPR meeting regarding issues for the Communications Work Group. These included focusing on the NIH identity, enhancing efforts to educate Congressional staff and increasing communication efforts about NIH research activities.

The following related activities have since occurred:

- Dr. Zerhouni met with IC directors to consider combined communication efforts.
- Dr. Zerhouni provided innovative testimony to Congress.
- The NIH held a series of State field hearings.
- Dr. Zerhouni gave an important interview in Research Policy Alert.
- The NIH developed communications plans involving personal narratives.

The Communications Work Group further affirmed the need for resources to communicate medical research to the public and stated its desire to play a larger and integral role in this effort. The work group could serve as a point of contact for the public perspective in the clinical research awareness and education campaign. It could work with the NIH to develop a COPR Community Ambassador Program and could plan COPR involvement in regional educational events.

Valda Boyd Ford, M.P.H., M.S., R.N., reported the success of a unique effort to reach out to local underserved women by holding a red dress affair, a dinner, attended by 400 women, which conveyed the importance of heart health and recognized the contributions of the NIH.

Mr. Wendorf proposed that, to increase visibility, the NIH disseminate to the public a document similar to an Annual Report, or something on a smaller scale that that would include important data about the NIH's activities.

ACD LIAISON REPORT

Annelise Barron, Ph.D.

Annelise Barron, Ph.D., member of the Advisory Committee to the Director (ACD), expressed her appreciation for becoming the new ACD liaison to the COPR. She summarized the topics of the ACD's December 2005 meeting, which included: implementing the Office of Portfolio Analysis and Strategic Initiatives (OPASI), initiatives for new scientists, accelerating the grant process at the Center for Scientific Review (CSR), and establishing rules governing outside awards for NIH employees.

Dr. Barron stated that she looked forward to offering the COPR her perspective as a researcher on the many issues the COPR will tackle and discuss during her

term. In particular, she wondered about the possibility of looking into options for voluntary organizations or other foundations to fund grant applications that nearly, but do not, receive funding by the NIH.

NIH DIRECTOR AND COPR MEMBER SUMMARY AND NEXT STEPS

Mr. Beam stated that the Communications Work Group will continue its efforts. The COPR will create a new work group to focus on the issue of the role of the public in research and promoting public participation in the research process from beginning to end, including community-based-research. A subset of the Agenda Work Group will be formed to consider minority issues.

Dr. Zerhouni thanked the COPR members for their many helpful ideas. He reminded the group that small ideas can lead to large results. The next meeting of the COPR will take place November 2 and 3, 2006.

ADJOURNMENT

Dr. Zerhouni adjourned the meeting.

LIST OF ABBREVIATIONS AND ACRONYMS

- ACD—Advisory Committee to the Director
- CSR—Center for Scientific Review
- COPR—Council of Public Representatives
- FY—fiscal year
- GAIN—Genetic Association Information Network
- GEI—Genes and Environment Initiative
- HHS—Department of Health and Human Services
- ICs—NIH Institutes and Centers
- IRB—Institutional Review Board
- NCI—National Cancer Institute
- NHGRI—National Human Genome Research Institute
- NHLBI—National Heart, Lung, and Blood Institute
- NIEHS—National Institute of Environmental Health Sciences
- NIH—National Institutes of Health
- OPASI—NIH Office of Portfolio Analysis and Strategic Initiatives
- OTT—NIH Office of Technology Transfer
- PI—principal investigator
- RPG—research project grant
- SNP—single nucleotide polymorphism

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

NIH...Turning Discovery Into Health

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

MEETING MINUTES

October 26, 2007

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

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

October 26, 2007

NIH Participants

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

COPR Members Attending

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

COPR Members Not Present

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

ACD Liaison

Annelise E. Barron, Ph.D.

Speakers

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

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

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

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

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

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

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Jeremy M. Berg, Ph.D.

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Barbara Alving, M.D.

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EXECUTIVE SUMMARY

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

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

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

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

Dr. Kington provided updates in a number of areas.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WELCOME AND INTRODUCTIONS

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

Deputy Director, National Institutes of Health

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

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

NIH DIRECTOR'S UPDATE

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

Deputy Director, National Institutes of Health

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

Status of the NIH Budget

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

Legislative Update

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

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

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

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

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

New Common Fund Initiatives

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

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

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

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

Nobel Prize Winners

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

NIDA and NIAAA Receive Emmy Award

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

Public Trust Initiative: Partners in Research Program

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

NIH and NASA Partner for Health Research in Space

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

Biomarkers Consortium Update

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

Dr. Zerhouni Travels to India and Japan

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

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

Genome-Wide Association Studies

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

Leadership Update

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

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

Discussion (COPR Members)

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

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

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

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

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

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

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

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

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

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

Discussion (COPR Members)

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

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

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

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

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

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

NIH PIONEER AND NEW INNOVATOR AWARDS

Jeremy M. Berg, Ph.D.

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

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

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

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

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

Discussion (COPR Members)

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

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

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

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

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

NCRR COMMUNITY ENGAGEMENT ACTIVITIES

Barbara Alving, M.D.

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

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

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

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

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

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

Discussion (COPR Members)

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

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

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

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

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

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

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

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

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

FROM PUBLIC UNDERSTANDING TO PUBLIC ENGAGEMENT

Alan I. Leshner, Ph.D.

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

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

Public engagement can happen in a variety of ways:

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

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

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

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

Discussion (COPR Members)

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

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

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

NIH PEER REVIEW

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

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

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

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

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

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

Discussion (COPR Members)

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

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

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

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

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

[insert “view the presentation (pdf)"]

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

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

Mr. Wendorf summarized the agenda:

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

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

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

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

[insert "view the presentation (pdf)"]

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

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

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

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

UPDATE: COMMUNICATIONS WORK GROUP

Anne Muñoz-Furlong and Brent M. Jaquet

[insert “view the presentation (pdf)"]

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

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

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

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

Discussion (COPR Members)

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

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

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

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

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

PUBLIC COMMENT

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

ACD LIAISON REPORT

Annelise E. Barron, Ph.D.

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

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

NIH DIRECTOR AND COPR MEMBER SUMMARY AND NEXT STEPS

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

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

ADJOURNMENT

Dr. Kington and Ms. Clark adjourned the meeting.

APPENDIX

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

DIVERSIDAD ESPLENDIDA

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

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

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

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

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

LIST OF ABBREVIATIONS AND ACRONYMS

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

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

RFI Request for Information