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

U.S. Department of Health & Human Services

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

COPR Alumni

CLASS OF 2003

- Luz Claudio (New York)
- Vicki Kalabokes (California)
- Barbara B. Lackritz (Missouri)
- Debra R. Lappin (Colorado)
- Robert Martin (Arizona)
- Isaac Montoya (Texas)
- Rosemary B. Quigley (Texas)
- Bob Roehr (Washington, DC)
- Douglas Q.L. Yee (Hawaii)

Luz Claudio

Term: 1999–2003

Dr. Claudio balances a research focus on neurobiology and environmental medicine with leadership in community outreach, education, and health policy development in New York City and her native Puerto Rico. As Assistant Professor of Neuroscience at the Mount Sinai School of Medicine, she works closely with local hospitals that serve Harlem and the Bronx and directs a community outreach and education program that connects community organizations with medical researchers to combat local health problems. She recently engaged graduate and postgraduate students in a project to document and map the incidence of asthma in New York City, which has one of the highest asthma rates in the country. She serves as Director of the Community Outreach and Education Program at Mt. Sinai's Center for Children's Health in the Environment, and she regularly speaks to community groups about the effects of environmental pollution on health, providing the scientific information communities need to protect themselves against toxic chemicals. Claudio is a graduate of the University of Puerto Rico and holds a Ph.D. from the Albert Einstein School of Medicine. Her laboratory investigations focus on the study of cellular and molecular aspects of the blood-brain barrier in the attempt to determine its role in immunologic conditions, such as multiple sclerosis, and in environmental exposure, such as lead poisoning. Still in the early years of her own career, Claudio devotes her personal time and resources to providing fellowships for scientifically gifted youngsters from inner-city and disadvantaged neighborhoods to work under her tutelage at Mt. Sinai. Her dedication to underserved populations extends to designing community-based environmental health education programs, one of which recently won an award from the U.S. Environmental Protection Agency. On the basis of her work with communities, Claudio was invited by the U.S. Agency for Toxic Substances and Disease Registry to join its Board of Scientific Counselors and co-chair the Community/Tribal Subcommittee that addresses health issues of African Americans and Native Americans.

Vicki Kalabokes

Term: 1999–2003

Ms. Kalabokes, a health educator, coalition builder, and advocate for medical research, is Chief Executive Officer of the National Alopecia Areata Foundation, a nonprofit agency that promotes research on and raises public awareness of a disease characterized by sudden unexplained hair loss. Believed to be an autoimmune disease, researchers are finding that results from research on alopecia areata can carry implications for a host of other diseases. Kalabokes is past co-chair of the Coalition of Patient Advocates for Skin Disease Research and a member of key standing committees of the American Academy of Dermatology and the Society for Investigative Dermatology, and she contributes to a newly formed Coalition of Autoimmune Patient Groups. Her coalition-building efforts are geared to increasing understanding and strengthening ties among diverse patients, medical professionals, researchers, and legislators. She and the skin diseases coalition are credited with spurring interest in creating the six skin disease core centers under the purview of NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). She also managed her Foundation's collaboration with NIAMS in jointly sponsoring the first three international research workshops on alopecia areata, at which scientists and medical professionals developed universal criteria and guidelines for future clinical and laboratory studies on this disease. Ms. Kalabokes is active at the community level?recently directing a public education campaign for increased funding in three California school districts?and she has served as a state legislative chair covering women's health, among other issues, for the American Association of University Women in California. She brings to her work as a health advocate an array of talents developed in earlier careers as a teacher, a community college public information officer, and a writer of screenplays. She has used her knowledge and skills to help family members and friends deal with heart disease; high blood pressure; fibromyalgia; lung, bladder, and ovarian cancer; Crohn's disease; multiple sclerosis; depression; and alcoholism.

Barbara B. Lackritz

Term: 1999–2003

Deceased

Ms. Lackritz was a speech/language pathologist for a suburban St. Louis public school district. When she retired, she had been working in the field for 40 years. She was diagnosed with chronic lymphocytic leukemia in 1989 and underwent treatment that included chemotherapy, radiation, and a bone marrow transplant. She passed away in 2003 soon after the completion of her term on the COPR. She provided others with information on hematological malignancies and the illnesses associated with them through her work with the American Cancer Society's Cancer Survivor's Network and as a director of the Association of Cancer Online Resources (ACOR) and the Chronic Lymphocytic Leukemia Foundation. Lackritz was the author of Adult Leukemia: A Comprehensive Guide for Patients and Families (O'Reilly and Associates, March 2001). Lackritz created and managed e-mail cancer support lists that include 45,500 members from 36 countries. These include all hematological cancer lists, cancer support lists, and some solid tumor lists. ACOR hosts over 130 patient lists serving thousands of patients, caregivers, and health professionals. Lackritz ensured that NIH information was disseminated to ACOR's entire online cancer community as well as to local and national health organizations. She also managed Leukemia Links, a Web site that has won awards for its effectiveness in providing information to help patients research their own cancer. Lackritz received a Master's degree in special education from the Columbia University Teacher's College. She was a former member of the City Council of Town and Country, Missouri, and was named Missouri Woman of Achievement in 1986 and Teacher of the Year in 1997. She worked professionally with children who had cerebral palsy, verbal apraxia, hearing and vision impairment, and other neurological and psychological disorders. Because of her husband's illness, she also followed research advances in Parkinson's disease and heart disease.

Debra R. Lappin

Term: 1999–2003

Ms. Lappin has brought a public voice to national health and science policy issues for two decades. Appointed to the NIH Council of Public Representatives at the time of its formation in 1999, Ms. Lappin chaired the Council's first working group on Human Research Protections, which presented a comprehensive report to the NIH Director in April 2001. Ms. Lappin has served as a member of ad hoc advisory committees to the NIH Director addressing NIH Oversight of Human Gene Transfer Research and Trans-NIH Pediatric Research and as an invited public guest at the NIH Budget Retreat. From 1991 to 1995, Ms. Lappin served as a member of the Advisory Committee for the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

In other areas of government, Ms. Lappin currently serves as a member of the Institute of Medicine's (IOM's) Committee on NIH Organizational Structure. She has participated in the IOM's public forum, Clinical Research in the Public Interest, and served as a member of the IOM Committee, Changing Health Care Systems and Rheumatic Diseases. At the Agency for Healthcare Research and Quality, she has served as a member of an advisory committee to examine future directions for the Center for Outcomes and Effectiveness Research.

Ms. Lappin presented the opening address in May at the American Psychiatric Association's annual meeting in a symposium addressing informed consent in global psychiatry. She lectures regularly at the University of Colorado Health Science's Center in the Graduate Program for Clinical Sciences on informed consent, a public perspective.

From 1996 to 1998, Ms. Lappin was the chair of the Arthritis Foundation. During this time, she was instrumental in creating the National Arthritis Action Plan, through a cooperative agreement with the Centers for Disease Control and Prevention, and in founding the Alliance for Lupus Research, through a partnership with Robert Wood Johnson IV. Subsequently, she served as the Arthritis Foundation's senior chair for Health Policy, and in this capacity, organized a public/private think tank to examine cost and access to medications, and served as a founding member of both the Board of the Canadian Arthritis Network and the Board of the Musculoskeletal Research and Education Institute. Today she remains active as an Emeritus Trustee of the Arthritis Foundation.

Robert Martin

Term: 2001–2003

Dr. Martin is a member of the Cherokee Nation of Oklahoma. He became President of Tohono O'odham Community College, located in Sells, Arizona, in 2001. He received his Doctorate from the University of Kansas and served on the faculty of the American Indian Studies program at the University of Arizona. Prior to his appointment at the University of Arizona, he served for ten years as the President of Haskell Indian Nations University. Under his guidance, Haskell made the transition from junior college to a university offering baccalaureate programs.

Dr. Martin has extensive experience in higher education both as an instructor and as an administrator. He served as President of Southwestern Indian Polytechnic Institute in Albuquerque, New Mexico, for eight years before assuming the presidency at Haskell. Dr. Martin served as a member of the Indian Nations at Risk Task Force and on the Advisory Board to the White House Conference on Indian Education. He also served on the Commission on Minorities in Higher Education for the American Council on Education. He is a graduate of the Department of Interior's Senior Executive Development Program, the John Heinz II School of Public Policy and Management, Carnegie-Mellon University, and the Center for Creative Leadership's Development Program.

Dr. Martin was awarded the Liberty Bell Award by the Douglas County (Kansas) Bar Association. The award is bestowed on Law Day USA to recognize individual contributions to human rights. He was also awarded an honorary doctorate from Baker University.

Isaac Montoya

Term: 1999–2003

Dr. Montoya is the Chief Executive Officer at Affiliated Systems Corporation, a Houston 500 company that is the region's leading think tank and research organization. Dr. Montoya earned his Ph.D. at New Mexico State University and is a behavioral scientist with experience in health services administration and in health services research. He has been principal investigator on several federally funded studies of HIV/AIDS prevention and risk behavior change and on NIH-funded grants that examine the motivational behaviors of drug users and the resulting impact on their health and daily lives. He has served as Director of the Department of Laboratory Medicine for several major teaching hospitals, has been a consultant to health sciences centers at Stanford and Vanderbilt Universities, and has been an advisor on Federal projects for community and migrant health centers, family planning clinics, and black lung clinics. Dr. Montoya has studied Hispanic cultures in the southwestern United States and has worked extensively with migrant workers, economically disadvantaged women living on public assistance, and indigent drug users. Currently, he is also a professor at the University of Houston College of Pharmacy, where he is responsible for research and health services courses. Dr. Montoya previously coordinated the health care management MBA program at the Houston campus of Our Lady of the Lake University.

Rosemary B. Quigley

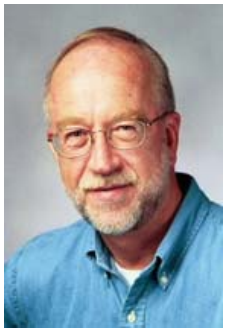
Term: 1999–2003

Deceased

Ms. Quigley was most recently a law clerk to Judge Kermit Lipez on the United States Court of Appeals for the First Circuit. She received her J.D. and M.P.H. (health management and policy) from the University of Michigan in 2000. Quigley embarked on this academic challenge after graduating from Harvard College and working as a senior research associate with the American Medical Association (AMA) Division of Ethics Standards on policy issues affecting medical research and health care delivery. Her experiences in health care ranged from interviewing transplant recipients in Northern Europe to holding the hand of a comatose boy with a brain tumor while on hospice duty, and from counseling people with disabilities about Medicare coverage for experimental therapies to authoring policy on genetic testing of children for the AMA Council on Ethical and Judicial Affairs. She also drafted a report on subject selection criteria in clinical research protocols for the Association. Ms. Quigley, who was diagnosed with cystic fibrosis at the age of six months, had personal experience with clinical research as a participant in a double-blind, placebo-controlled clinical trial. She also provided staff support for the Michigan Governor's Commission on Genetic Privacy and served on the Human Research Subjects Committee at the Veterans Administration Hospital in Ann Arbor. Previously, Ms. Quigley worked as a summer law intern with the U.S. Department of Justice and conducted research for an NIH-funded project on genome technology and reproduction. In 2002, she served on the Advisory Committee to the Director Working Group on Oversight of Clinical Gene Transfer Research. She also was part of the COPR working group on protection of human research subjects.

Bob Roehr

Term: 1999–2003



Mr. Roehr is a freelance journalist and medical reporter who has written extensively on the matrix of medical research, drug approval, and the government's role in setting health policy and paying for medical services. He has written in depth on HIV/AIDS, hepatitis, tuberculosis, vaccine development, and genetics. He regularly reports on meetings of the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration. Mr. Roehr has written for both medical providers in publications such as those of the International Association of Physicians in AIDS Care (IAPAC) and for consumers in magazines such as POZ. He is the Washington correspondent for the Bay Area Reporter (San Francisco) and a dozen other gay and lesbian newspapers, as well as producing radio and television programming.

Mr. Roehr received an M.S. degree in Foreign Service from Georgetown University and was the only member of his class invited to join the State Department. He served as vice consul and commercial attaché in Porto Alegre, Brazil, and later as press officer and acting spokesman for the Department under Secretary Henry Kissinger. He has received two study fellowships at the Knight Center for Specialized Journalism at the University of Maryland. As a member of the COPR, Roehr's focus of interest has been to better integrate patients and the public as full partners in all aspects of biomedical research. He sees openness of information as crucial to informed consent, and he is working to create mechanisms to facilitate communication between public members serving on the various NIH advisory bodies. At the request of former NIH Director Harold Varmus, Mr. Roehr served on a working group that reviewed NIH policy on gene transfer research.

Douglas Q.L. Yee

Term: 1999–2003

Mr. Yee is a First Vice President of Morgan Stanley Dean Witter in Honolulu, Hawaii, and has earned a solid reputation in his community for his work as a financial advisor and his service in civic organizations. He has earned a B.S. and a M.B.A. from the Wharton School of Finance and Commerce at the University of Pennsylvania, and he applies his business background to helping reduce health disparities, particularly in the alleviation of respiratory diseases, among Hawaii's varied racial and ethnic population. Mr. Yee has been on the Board of Directors of the American Lung Association of Hawaii for 15 years, and he helped to form its Research Committee, on which he served as Chair for three years. He has been particularly effective in building a research program for this organization, which has successfully completed studies of Legionnaire's disease, asthma, and tuberculosis. On the national level, Mr. Yee is a member of the Council of the American Lung Association, where he has served two terms on the Board of Directors, and he currently serves on the organization's Finance and Audit Committee. Mr. Yee is President of the Hawaii Chinese Civic Association, President of the University of Pennsylvania Alumni Club of Hawaii, and an active member and past president of the Rotary Club of West Honolulu. He and his wife, Caroline, have one daughter.

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

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DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

April 24, 2003 Meeting Minutes

NIH PARTICIPANTS:

- Elias A. Zerhouni, M.D., NIH Director
- Raynard S. Kington, M.D., Ph.D., NIH Deputy Director
- John Burklow, Associate Director for Communications, Director, Office of Communications and Public Liaison
- Ruth Kirschstein, M.D., Senior Advisor to the Director
- Jennifer Gorman Vetter, M.P.A., COPR Executive Secretary, NIH Public Liaison Officer, Office of Communications and Public Liaison

NIH ATTENDEES:

- Mary C. Dufour, M.D., M.P.H., Deputy Director, National Institute on Alcohol Abuse and Alcoholism
- Ellie Ehrenfeld, Ph.D., Director, Center for Scientific Review
- Judith H. Greenberg, Ph.D., Acting Director, National Institute of General Medical Sciences
- Gerald T. Keusch, M.D., Director, John E. Fogarty International Center
- T.K. Li, M.D., Director, National Institute on Alcohol Abuse and Alcoholism
- Roderic I. Pettigrew, M.D., Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering
- Lana Skirboll, Ph.D., Associate Director for Science Policy
- Stephen E. Straus, M.D., National Center for Complementary and Alternative Medicine
- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse
- Institute and Center Officers of Public Liaison

COPR MEMBERS ATTENDING:

- Evelyn Bromet, Ph.D.
- Nancye W. Buelow
- Ellen E. Grant, Ph.D.
- Debra S. Hall, Ph.D.
- Kimberley Hinton
- Ted Mala, M.D., M.P.H.
- Rodrigo A. Muñoz, M.D.
- Lawrence B. Sadwin
- John Shlofrock
- Leonard J. Tamura, Ph.D.
- Zelda Tetenbaum, Ed.D., M.Sc.
- Donald E. Tykeson

COPR SPECIAL CONSULTANTS:

- James J. Armstrong
- Ruth C. Browne, Sc.D., M.P.H.
- Barbara D. Butler
- Frances J. Dunston, M.D., M.P.H.

- Rafael Gonzalez-Amezcua, M.D.
- Jim Jensen
- William D. Novelli
- Ellen V. Sigal, Ph.D.
- Dawna Torres Mughal, Ph.D., R.D., FADA

NIH Director's Report

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

Dr. Zerhouni welcomed all those present to the 9th meeting of the Director's Council of Public Representatives (COPR). He recognized the COPR Special Consultants, individuals who are expected to rotate onto the Council later this year. He reminded attendees that the meeting was open to the public and introduced Raynard S. Kington, M.D., Ph.D., newly appointed Deputy Director of the National Institutes of Health (NIH), who briefly addressed the meeting.

Remarks of Dr. Kington

Dr. Kington explained that the NIH Deputy Director provides oversight to the Office of the Director in scientific priority setting, strategic planning, committee appointments, and other activities that facilitate agency operations. He said the NIH faces many scientific, financial, and managerial challenges, and that his primary goal as Deputy Director is to help the agency more efficiently and effectively accomplish its scientific mission. Since his appointment in February, he has met with the Directors of NIH Institutes and Centers (I/C), and with representatives from external agencies, professional organizations, and the larger scientific community. He noted that the COPR plays an important role in ensuring that the NIH addresses the health issues most relevant to Americans, and that he looks forward to COPR input.

Update from the Director

Staff Changes

Dr. Zerhouni welcomed the opportunity for new COPR members to meet some of the I/C directors and welcomed those who were present. He noted recent NIH staff changes, including the appointment of new I/C directors. These appointments include that of Nora D. Volkow, M.D., as Director of the National Institute on Drug Abuse (NIDA). Dr. Volkow previously served as Associate Director for Life Sciences, Director of Nuclear Medicine, and Director of the NIDA—Department of Energy Regional Neuroimaging Center at Brookhaven National Laboratory. She also served as a professor in the Department of Psychiatry and as associate dean of the School of Medicine at the State University of New York (SUNY)—Stony Brook.

Other recent appointments include those of Thomas R. Insel, M.D., as Director of the National Institute of Mental Health (NIMH); T.K. Li, M.D., as Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA); and Roderic I. Pettigrew, M.D., Ph.D., as Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Efforts are underway to fill vacancies at the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of General Medical Sciences (NIGMS).

Changes in the NIH Office of the Director include the departure in December of Wendy Baldwin, Ph.D, former Deputy Director for Extramural Research. Dr. Baldwin left the NIH to accept a position as vice president for research at the University of Kentucky. Belinda Seto, Ph.D., now serves as Acting Deputy Director for Extramural Research. Additional changes include the appointments of Mark Rohrbaugh, Ph.D., J.D., as Director of the Office of Technology Transfer; Mr. Don Poppke as Associate Director for Budget; and Mr. John Burklow as Associate Director for Communications.

Noteworthy Events

On April 14, 2003, the NIH celebrated the landmark completion of the human genome map, Dr. Zerhouni noted that April 2003 also marked the 50th anniversary of the discovery of the structure of the DNA molecule. Dr. James Watson, who, along with Dr. Francis Crick, made the original discovery of DNA's structure, attended the NIH celebration. Also present were many pioneers of advances in molecular biology whose work made the sequencing possible, among them Dr. Marshall Nirenberg, an NIH Nobel Laureate who unraveled the genetic code.

President Bush visited the NIH on February 3, touring the Vaccine Research Center and delivering an address at the Natcher auditorium. He expressed appreciation for the NIH's work, particularly in the biodefense area. Project BioShield, for example, is a comprehensive effort to ensure access to modern, effective drugs and vaccines to protect against biological and chemical attacks. The NIH has responded to the president's biodefense agenda by expanding research strategies for chemical, nuclear, radiological, and psychological biodefense. The NIH also has formed a Biodefense Committee to oversee such research and define a strategic plan.

Dr. Zerhouni formed a Stem Cell Task Force when he became NIH Director. The task force has worked with the scientific community for many months to identify roadblocks, challenges, and opportunities in stem cell research. A June 12th symposium will summarize the state of the science and research challenges.

Director's Formal Presentation

Dr. Zerhouni began his formal presentation by noting that the NIH is the foremost federal agency conducting, supporting, and stimulating biomedical research in the United States. NIH supports the largest concentration of biomedical researchers in the world who are committed to public health emergencies and rare diseases that are not addressed elsewhere.

Dr. Zerhouni reviewed the allocation of the NIH budget, emphasizing that the agency's research program is competitive and self-adapting. Of the country's $54–$57

billion investment in civilian, nondefense research, the NIH makes up about 47 percent, or approximately $25.4 billion. In 2002, extramural research accounted for 84 percent of the NIH budget. Less than 4 percent of NIH grantees have had ongoing grants for more than 20 years. Only about 50 percent of renewal applications are granted. About 10 percent of the NIH budget is spent on intramural research, which includes programs housed at the NIH and conducted by NIH scientists. About 3 percent of the NIH budget is used to manage and support in-house research programs, and the remaining 4 percent goes to the National Library of Medicine for information sharing and dissemination as well as the Office of the Director, and NIH facilities infrastructure.

Several offices within the NIH Office of the Director (OD) have their own budgets. These include the Office of AIDS Research, the Office of Research on Women's Health, and the Office of Behavioral and Social Sciences. These programmatic offices are not designated as intramural or extramural research entities. Historically, some of these offices—for example, the former Office of Minority Health and Health Disparities—become Centers over time.

Dr. Zerhouni presented a graph showing changes in the NIH budget between 1970 and 2000. In 1970, the Federal Government supported more than 80 percent of biomedical research. Today, it supports about 50 percent. This change is not due to a decreased federal investment—the NIH budget increased during this time and will double over the next five years. Rather, the change is due to greatly increased investment by others, particularly the pharmaceutical industry, in biomedical research. Spurred by Federal investments in the 1970s, such industry investment surpassed that of the NIH in 1991 and now grows at a commensurate rate. Biomedical research is also a top priority for the 21st century among scientific foundations, philanthropies, and academic institutions.

Science itself is changing as a result of discoveries in proteomics and molecular biology, becoming increasingly multi- and interdisciplinary. Expertise from many disciplines is required to address the scope, scale, and complexity of biological research today. Academic faculties also reflect the changing nature of science. The number of Ph.D. faculty in universities will have increased from 18,000 in 1990 to 27,000 by the end of 2003, and the majority are in clinical science departments. These trends reflect a growing understanding that biomedical research today requires multidisciplinary teams with multiple skill sets.

The recent doubling of the NIH budget enabled the NIH to expand its grant pool by about 37 percent, from about 27,000 in 1998 to 37,000 in 2003. This number will be even higher by the end of 2004 and ultimately will increase by 45–50 percent. The number of grant applications received each year has grown by 46 percent. The 30 percent success rate of applicants is expected to remain about the same.

Dr. Zerhouni then discussed megatrends and the challenges that will affect the NIH as the landscape of the U.S. health care system evolves. Most prominent among these trends is a shift in emphasis from acute, lethal diseases to chronic, long-term diseases. In many cases, this shift has resulted because research advances have increased the survival times of patients suffering from lethal conditions such as AIDS. Chronic diseases constitute about 75 percent of the national disease burden. Other contributing factors are the aging population, health disparities, emerging diseases such as severe acute respiratory syndrome (SARS) and West Nile virus, and the newly significant health concerns related to biodefense.

An example of the shift from acute to chronic disease is the increased survival rate of patients who have coronary heart disease (CHD). The age-adjusted CHD death rate has declined by nearly 60 percent in the past 50 years. AIDS, another major health burden with increasing rates of long-term survival, has benefited from the development of 80 new drugs and a 3-fold increase in the number of vaccines in Phase I trials since 2001.

Dr. Zerhouni emphasized the need to regularly review the NIH research portfolio to assure it is appropriately diversified and it addresses future challenges. For example, we know the population is aging, and we know the top six disability-causing conditions among older adults—arthritis and other musculoskeletal disorders, heart disease and other circulatory conditions, vision and hearing problems, fractures and joint injuries, diabetes, and mental illness. Thus, as life expectancy increases, we need to consider research strategies that can prevent or delay those age-related diseases and disabilities.

Reducing health disparities is a priority and a challenge. Although progress has been made in many diseases among minority populations, such as heart disease among black males, health differences and disparities persist.

Dr. Zerhouni noted the importance of looking not only at the current burden of disease, but also downstream to the future implications of current trends. For example, rates of obesity and diabetes are increasing among U.S. adults and, if they continue to rise, will constitute an enormous health burden.

Compared to the relatively slow growth during the years 1994–1999, national health expenditures in the United States have increased at an accelerated rate in more recent years, and between the years 2000 and 2011 they are projected to more than double. Consequently, national health care expenditures as a percentage of GDP are projected to increase from 13.1 percent of GDP in 2000 to 17.0 percent of GDP in 2011). If this growth curve continues at its present rate, there may be no room in the budget for research.

The growing burden of disease requires the adoption of new approaches and the acceleration of the pace of scientific discovery. The sequencing of the human genome has ushered in a new era in health research and health care that requires a paradigm shift, from curative medicine to proactive intervention before disease occurs. This changing health care landscape is the context for the COPR's actions, advice, and integration of public input.

Dr. Zerhouni detailed three major themes of the NIH Road Map Initiative, which identifies scientific challenges and roadblocks to progress and indicates directions for future research. The first is the development of new pathways to discovery. The genomic era offers unprecedented opportunities for understanding biological systems. Novel approaches must replace outdated reductionist views of disease. A new view is that disease arises from multiple factors; this view requires an understanding of biological disease pathways and their controls and interactions. Future research will require investment in new technologies, bioinformatics, and molecular libraries. Advances in novel research methodologies, such as biomedical imaging, also are needed.

The second theme of the NIH Road Map is to promote research teams of the future whose scale and complexity will require new organizational models for team science. Research teams of the 21st century must be large, coordinated, multidisciplinary, and resource sharing to preserve investigator-initiated strategies.

The third theme is a re-engineering of the clinical research enterprise. The nation needs a common research informatics base, training that is more cohesive, national networks to improve the effectiveness and efficiency of research, efforts to harmonize the many regulations while maintaining human subjects protections, approaches to measure clinical outcomes and improvements in translational research. The goal is to develop a more efficient, national, bench-

to-bedside clinical research system.

Dr. Zerhouni concluded that, if not addressed, the rapidly changing nature of health care and the challenges facing young researchers could threaten the discovery process. The plan for the NIH is to continue to gather the best ideas and the best and brightest people, and ensure adequate resources to meet these challenges.

Comments and Discussion

Ms. Tetenbaum noted the importance of NIH brainstorming and think tank activities as an integral part of the discovery process, asking for comments on how such exchanges take place. Dr. Zerhouni said that each I/C organizes such activities in accordance with its mission. In addition, the Office of the Director (OD) holds weekly information-exchange meetings, and 21,000 people advise the NIH each year. This has been deemed the most effective and open approach to strategizing for the NIH's future.

Dr. Mala inquired about the NIH role in public and international health emergencies, such as the SARS outbreak in China. Dr. Zerhouni said that several NIH programs are designed to quickly identify and respond to emerging disease outbreaks. For example, the causative agent of SARS was originally identified by an NIH grantee in Hong Kong who was a member of an Asian-flu-tracking network. Once it was recognized that SARS was a new virus, the Centers for Disease Control and Prevention (CDC) began investigating. With a gene array of viruses available at the NIH, scientists were able to identify the genetic structure of the SARS virus.

Dr. Sigal complimented Dr. Zerhouni on the stewardship of the NIH budget and his strategic planning initiative. She observed that the NIH budget seems relatively static in an era of big science and wondered about flexibility within the budget to fund new research areas.

Dr. Zerhouni explained that the NIH grants process ensures a commitment to existing, promising research and as a result, only about one quarter of the budget is available to fund new areas. The 50 percent renewal rate of funded research means that about 10 percent of the NIH budget goes to new research, and these opportunities must be identified well in advance. Partnerships and collaborations (for example, among I/Cs and with industry and the NIH Foundation) are another way to fund new research.

Dr. Dunston asked about the mix of dollars for behavioral versus medical research. Dr. Zerhouni explained that an estimated 10 percent of the NIH budget is committed to behavioral research. At the same time, increasing numbers of research teams are integrating behavioral science in their pool of expertise. In addition, several I/Cs are developing new initiatives in behavioral research and view it as a core part of their work.

Dr. Grant said she was glad to see that heart disease in women is a research priority in the NIH portfolio. She noted a recent NIH conference on the topic and described an article in the *New York Times* about differences between randomized clinical trials and observational studies. She also asked about NIH self-evaluation mechanisms to determine whether outcomes are being met. Dr. Zerhouni explained that outcomes evaluation at the NIH is a multi-tiered process. Institute Directors are reviewed every 5 years as are intramural Scientific Directors. External Boards of Scientific Counselors review intramural researchers every 4 years. In addition, the NIH works with the Office of Management and Budget (OMB) to meet requirements of the Government Performance Results Act (see Dr. Skirboll's presentation for details). Other measures include naming an ad hoc blue-ribbon panel to evaluate the intramural clinical research program.

Dr. Hall asked about the status and progress of the National Clinical Research Program. Dr. Zerhouni said that multiple Institutes have established subsystems on related areas in clinical research. For instance, the NIAAA has a subsystem on cancer research, and new subsystems are being established in other areas. One barrier to subsystems is the lack of a common database, language, or infrastructure. A first step to enhancing this research approach will be to harmonize regulatory issues and informatics, perhaps by developing a single national medical dictionary that is comprehensive and interchangeable across disciplines.

Dr. Bromet asked about the NIH's international relationships and partnerships. Dr. Zerhouni described his participation in the Heads of International Research Organizations, which meets twice yearly, once in Europe and once in the United States. Representatives of major industrialized countries attend to discuss coordination of policies and integration with the World Health Organization (WHO) programs. Dr. Zerhouni said he believes the most fruitful international interactions take place between individual scientists.

Dr. Keusch explained that the NIH is unique in its acceptance of research proposals from around the world. Many universities that conduct NIH-supported research are engaged in collaborative projects with institutions abroad, and this is an increasing part of the NIH budget. NIH gives strong consideration to global health disparities and developing countries, investing not only in research but also in building research capacity. As an example, Dr. Keusch described the Fogarty International Center Multilateral Initiative on Malaria, initiated in 1998 by Dr. Zerhouni's predecessor, Dr. Harold Varmus. Interested in exploring areas in which science could make a significant difference in a global health problem, Dr. Varmus chose malaria because tools for combating the disease were inadequate. He created a malaria initiative that focused on Africa, home of the most lethal form of the disease. The program's purpose is to conduct research and enhance the ability of African scientists to conduct research through the investments of multiple agencies. The first secretariat was Wellcome Trust, the NIH became secretariat in 1999, and Sweden now holds the position. The NIH organized a meeting on malaria in Arusha, Tanzania, in November 2002. A total of 1,200 people attended, of whom about 700 were from or were working in Africa. The project's growing involvement with young African scientists is a measure of success.

International relationships and partnerships are an important part of the NIH mission. The agency spends about $300 million on international research and works with the Pan American Health Organization, WHO, the Gates Foundation, and others. The NIH also has a visiting scientists program and contributes about 40 percent of the international research budget to global research and development. The influence of such collaborations exceeds dollars spent.

Dr. Torres Mughal asked about health disparities in relation to data being collected on subgroups in minority populations. As an example, she cited the demographics of Pacific Islanders, whose makeup has changed significantly in recent years. She asked about the amount of money spent by the NIH on research for these groups, and how to make research a priority in a developing country where hunger and poverty are overriding problems. Dr. Zerhouni said that, in global terms, addressing hunger and other basic needs could eclipse spending money on research. However, research can become a mechanism by which a country creates the intellectual capital and capability it needs to handle such problems. Global health disparity is of great concern because of its potential to lead to fundamental disruptions worldwide. Addressing the first question, he said that, domestically, the quality of data on subgroups in minority populations varies, partly because of the extraordinary range of differences in minority subgroups. He said there is a need to move away from the simplistic approach of taking a

single snapshot of a subgroup. Dr. Kington added that substantial data have been collected on African Americans but, even in this largest subgroup, differences are created by an increased influx of immigrants. He said the quality of data on Hispanic subgroups is reasonable but data on Asians/Pacific Islanders are inadequate.

Dr. Browne asked for further information on NIH capacity-building initiatives, globally and in domestic minority populations. Dr. Zerhouni said three areas are important to capacity building and eliminating health disparities: increasing the representation of minorities in research, cultural competence, and cultural tailoring of health messages. He described an NIH initiative to help African American, and now Hispanic, students become biological scientists and build an infrastructure of African American colleges and universities. In 1972, when the Department of Health, Education, and Welfare oversaw the project, the NIH brought new faculty to participating schools. Today, many students in those colleges and universities major in the biological sciences.

Dr. Kington also described the Minority Supplement Program, which provides administrative funds for research projects to support high school students, undergraduate students, and faculty. The purpose of the funding is to add staff members to NIH grants who could eventually become independent investigators.

Mr. Sadwin asked for an update on the NIH restructuring being reviewed by the Institute of Medicine (IoM). Dr. Zerhouni reported that a policy decision was made at the NIH that "it is more important to preserve people than bricks and mortar." He said the NIH wants its research community to understand the agency's commitment to their future. He added that the IoM restructuring committee is now writing the report it must deliver by next year.

Senator Jensen asked how the Government facilitates the process by which discoveries are translated into practice. Dr. Zerhouni observed that the first stages of clinical trials are fairly quick, consisting of toxicity studies. The next stages, which involve thousands of patients and are the point at which the regulatory process comes into play, are slower. The slower pace is due less to government regulation than to the scientific complexity of research at this stage. The NIH is trying to work with the Food and Drug Administration (FDA) to better integrate the discovery and regulatory processes.

Ms. Butler asked about continued funding of basic research, the recruitment of young M.D. investigators, and whether pressure to move discoveries from bench to bedside affected basic molecular biology research. Dr. Zerhouni noted that the research portfolio must be balanced with continued investment in basic research. There is also a need to accelerate the investment in systems. For instance, pharmaceutical industry researchers use systems with an array of targets, allowing more efficient identification of those that are effective. It is important for the NIH to have a balanced, proactive, and prospectively determined portfolio that relates to strategic areas in health.

Dr. Bromet noted that the number of young M.D. investigators has dwindled over the past 20 years. Dr. Zerhouni said that he sees the root of the problem as being disincentives in the current research enterprise. Training for clinical research, for example, is fragmented. Emerging leadership among young M.D.s needs to be encouraged.

Presentation on the National Institute of Alcohol Abuse and Alcoholism

T.K. Li, M.D., Director, NIAAA

Dr. Li explained that the NIAAA provides leadership in the national effort to reduce alcohol-related problems by conducting and supporting research in scientific areas that include genetics, neuroscience, epidemiology, health risks and benefits of alcohol consumption, and alcohol-related problem prevention and treatment. The NIAAA collaborates and coordinates with other research institutes and Federal programs on a range of alcohol-related issues. The Institute also collaborates with international, national, state, and local institutions, organizations, agencies, and programs engaged in alcohol-related work. NIAAA research findings are translated and disseminated to health care providers, researchers, policymakers, and the public.

The NIAAA vision is that research and education will remove the stigma associated with the disease of alcoholism. The effects of alcohol consumption are known to vary among individuals, and research will reveal the genetic, biological, and sociocultural origins of these variations. Prevention and treatment of alcohol-related problems address physical, behavioral, and social risks attributable to excessive and underage alcohol consumption, and the chronic relapsing and remitting nature of alcoholism.

Dr. Li described NIAAA outreach efforts, beginning with the Web site (www.niaaa.nih.gov), which is visited by about 800,000 people each month. Of primary interest to visitors are NIAAA publications and the frequently-asked-questions link. Publications include pamphlets and other materials for the public and the scientific community.

April is Alcohol Awareness Month, and National Alcohol Screening Day (NASD) was April 10, 2003. This activity is sponsored by the NIAAA, the Substance Abuse and Mental Health Services Administration (SAMHSA), and Screening for Mental Health, Inc. The NASD program provides free, confidential, educational screening and brief intervention at sites that include hospitals, primary care physicians' offices, clinics, military installations, and community settings. The sites offer educational publications for consumers and care providers. Brief intervention ranges from advice about reducing drinking to recommendations for formal treatment programs. This activity is increasingly important for several reasons: research shows that 36 percent of the U.S. population older than age 18 exhibits risky drinking behavior related to alcohol consumption quantity and frequency, and alcohol screening still is not a part of routine practice in health care delivery, although screening and brief intervention are known to effectively reduce harm. This year there were more than 4,500 NASD registration sites in all 50 states.

Fundamental questions addressed in alcohol research are why some people drink while others do not, why some drink more than others, and why some drink excessively despite negative consequences. To understand the etiology of alcohol problems, researchers examine genetic and other biological and sociocultural origins of varying responses to alcohol. Based on answers to these questions, researchers seek to develop effective treatment and prevention strategies, address the physical behavior and social risks attributable to excessive and underage alcohol consumption, and understand the chronic, relapsing nature of alcoholism.

Alcohol problems are related to drinking quantity and frequency and to underage drinking. A standard drink consists of one beer, one glass of wine, or one shot of liquor. Binge drinking is popularly defined as the consumption on one occasion of five or more standard drinks for men and four or more drinks for women. Underage drinking is a problem in the United States. In a recent survey, 11 percent of 6th graders and 30 percent of 12th graders reported binge drinking, and 21 percent of 8th graders reported having been drunk at least once. Adolescents who begin drinking at an earlier age have been shown to have smaller hippocampal

volumes. Memory problems are common among adolescents in treatment for alcohol detoxification. An NIAAA epidemiological study showed that age at drinking onset influences the later development of alcoholism. Those who start drinking at age 13, for example, are four times more likely to become alcoholics than those who start at age 18.

The Leadership to Keep Children Alcohol Free program is a public-private, federal-state initiative that is part of the NIAAA's efforts to address underage drinking. Co-founded by the Robert Wood Johnson Foundation, it is the only national initiative that focuses on preventing alcohol use by children ages 9–15. Collaboration and support for the program is provided by other Federal agencies, including SAMHSA, and by NIH Institutes. The program provides research evidence to governors' spouses to support state outreach and education activities. Forty states participate in the program. This new research-based initiative will address underage drinking in a community context from childhood through college. The program will help test new research hypotheses and build community research, prevention, and treatment capabilities. It will support partnerships with leaders in academic health centers, public health arenas, local communities, and educational settings. The result will be well-tested, cost-effective, multifaceted strategies for addressing underage drinking.

Comments and Discussion

Dr. Grant asked about the status of fetal alcohol syndrome (FAS) research. Dr. Li reported that research has shown that FAS, the leading preventable cause of juvenile retardation, is more related to binge drinking than to constant low-level drinking by pregnant women. The prevalence of FAS is high among Native Americans, and research in this group is a high priority in the NIAAA portfolio. The Institute also supports FAS research in other populations. One study showed that the prevalence of FAS among vineyard workers in Cape Town, South Africa, was 1 in 60–1 in 100, due to cultural and genetic factors.

Dr. Bromet asked about NIAAA co-funding with other Institutes. Dr. Li said cofunding is an effective way to implement programs, especially in a time of budget restrictions; for example, similar research groups from each Institute could join forces to procure and share expensive equipment. NIAAA co-funding efforts deal with high-risk behavior in general to identify comorbidities that can exist with alcohol-related problems. Such associated behaviors may include early sexual activity, tobacco use, conduct disorder, and antisocial personality disorder. In the Leadership to Keep Children Alcohol Free initiative, the NIAAA agreed to be a partner in the Transdisciplinary Research Initiative cofunded by the National Cancer Institute and NIDA.

Ms. Butler asked about NIAAA programs for addressing alcohol problems in pediatric and older populations. Dr. Li said the NIAAA supports the need to address alcohol-related problems in all age populations. The NIAAA is developing ways to provide advice about harm reduction to pediatricians and others, and is developing literature for use by social workers, pediatricians, and primary care physicians.

Ms. Tetenbaum commended Dr. Li and Dr. Calhoun, NIAAA Associate Director for Collaborative Research, on the toolkit provided to COPR members for drinking among college-aged youths. She emphasized the importance of delaying the onset of drinking in children and asked about outreach methods used in the Leadership to Keep Children Alcohol Free program. Dr. Li replied that the research evidence provided to governors' spouses was the first step in reaching out to other state programs. It will also be important to establish partnerships among researchers, states, and communities.

Ms. Tetenbaum asked whether FAS statistics have changed since it was first identified. Dr. Li said it is difficult to detect changes in FAS incidence because studies that use intervention and control groups show changes in drinking patterns of the control groups. This suggests that the intervention has an effect even on the group not receiving it, perhaps by raising subjects' awareness of drinking levels.

Dr. Mala noted the impact of alcohol consumption and alcohol-related problems on Native Americans and inquired about the status of research on an alcohol dehydrogenase gene. Dr. Li said this gene seems to protect against heavy drinking and is not present in Native Americans, possibly because their ancestors were from Siberia. He cited the need for more research in this area. In response to Dr. Mala's suggestion that members of minority medical associations be included on NIAAA review boards, Dr. Li said the work of these coalitions is very important and the Institute would be happy to work with them.

Dr. Sigal asked about public service campaigns targeting children more specifically. She inquired whether efforts are under way to involve media experts in reaching younger audiences. Dr. Li noted that no advocacy group currently focuses on underage drinking. A pilot study would help demonstrate the feasibility of reaching children through community organizations and schools. It is important to involve media experts early in this process.

Dr. Tamura also praised the toolkit and requested an overview of the NIAAA strategic plan for addressing health disparities. Dr. Li said NIAAA researchers are acutely aware of the importance of understanding that alcohol use and abuse is intimately tied to cultural aspects of drinking practices. Gender differences are also important. Such research is a major part of the NIAAA portfolio. Culturally appropriate messages are also important, and the NIAAA has worked in this area with Hispanic populations. Similar efforts are in development for Asian populations. Another NIAAA program is directed at African Americans in the Washington, DC, area and focuses on FAS prevention.

Ms. Buelow asked about programs for children of alcoholics. Dr. Li said this is one of the NIAAA's highest priorities. The problem is difficult because, although alcoholism affects approximately one-quarter of American families, not everyone with a positive family history develops alcohol problems. Identifying a trait marker for alcoholism is a high NIAAA research priority.

Dr. Torres Mughal noted an apparent disconnect between research on the hazards of alcoholism and the way the public perceives drinking, partly due to mixed public health messages about alcohol consumption. For example, the fact that low alcohol consumption levels can improve lipid profiles may be misinterpreted as meaning that drinking alcohol is beneficial to health. Consistent, clear messages are needed and education in school curricula is important.

Presentation on the National Institute of Biomedical Imaging and Bioengineering

Roderic Pettigrew, M.D., Ph.D., Director, NIBIB

Dr. Pettigrew's presentation emphasized the importance of technological innovation in advancing scientific discovery. Biomedical research is becoming more interdisciplinary and synergistic. Part of the NIBIB mission is to find the optimal interface between the physical sciences and the fields of biology and medicine.

Signed into law on December 29, 2000, by President Clinton, the NIBIB is the result of combined efforts by the biomedical and bioengineering communities. The Institute has a 40-member staff and, at the time of this presentation, administers 650 funded grants totaling about $250 million. The NIBIB issued 10 Requests for Applications (RFAs) in its first 6 months and received a very robust response.

The NIBIB research portfolio includes cellular and molecular imaging, nanotechnology, image-guided interventions, tissue engineering, bioinformatics, biosensors, biomaterials, telemedicine, 3D tomographic imaging, optical imaging, computation biology, and interdisciplinary training. Dr. Pettigrew offered several examples of this work.

In the area of imaging at the cellular level, researchers have developed a smart probe for cancer. A molecule is configured in such a way that the chemical bond prevents light from being emitted in the infrared range. In the presence of a protease that resides on cancer cells, the bond is lysed and light is emitted, indicating the presence of cancer.

Cardiovascular disease is a major cause of morbidity in the United States. A persistent challenge is to detect it early enough to prevent heart attack and stroke. Another molecular imaging technique uses nanosize particles targeted against fibrin, a key agent in the development of heart attack and stroke.

In the areas of bioengineering and tissue engineering, Dr. Pettigrew showed a photograph of a scaffolding-type construct to promote wound healing in burn victims. The construct contains cellular growth factors to promote wound healing. Over time this technology may be applied to the development and replacement of critical subunits of severely diseased organs. He also showed a brief movie about advances in developing prosthetic limbs. The example showed an intelligent prosthetic knee containing sensors that allow it to respond and flex like a normal knee.

In the area of bioinformatics, Dr. Pettigrew described a brain-computer interface system that allows paraplegics or quadriplegics to operate computers and simple prosthetic devices.

In the area of cellular modeling, the NIBIB, in collaboration with the NIGMS, is conducting research to understand cell-signaling pathways. This research may one day lead to computer modeling to evaluate cell behavior under a variety of conditions to evaluate disease and the impacts of various interventions.

The NIBIB is also engaged in research on image-guided interventions. Magnetic resonance imaging (MRI) of tumors in rat models is being used to reveal areas that contrast agents do and do not enhance. Microarray technology showed different levels of gene expression in enhanced and non-enhanced areas of the tumor. These experiments have indicated that tissue in tumor masses is not homogeneous, not only from one patient to another, but also within the same tumor mass. This information can help guide therapies modeled on genetic behaviors.

Intravascular catheterization is an emerging technology that allows *in vivo* visualization inside arteries. Early detection of plaque accumulation may one day make it possible to treat localized areas by injecting chemical agents or by using gene-based therapy to reduce or stabilize the plaque, circumventing a catastrophic event such as a heart attack or stroke.

Three-dimensional imaging techniques increasingly are used in operating suites. Neurosurgeons can view 3-dimensional images during surgical procedures to obtain important information about incision locations and stimulator placement. Dr. Pettigrew showed a brief movie demonstrating the effect of a stimulator placed in the brain of a Parkinson's disease patient who could then walk normally. This technology also yields new information about brain function.

In summary, Dr. Pettigrew reviewed the important areas of NIBIB-supported research, including biosensors, tissue engineering, drug and gene delivery systems and devices, and micro- and nanotechnology. He concluded with two slides showing a microelectronic motorized system and a device that will be able to detect the presence of viruses in an air sample. NIBIB's guiding principle is to pursue technologies whose application will yield new discoveries and advance disease understanding, prevention, and treatment.

Comments and Discussion

Dr. Muñoz asked about the screening potential of technologies used to detect vascular disorders. Dr. Pettigrew said the cost-benefit ratio of such technologies is an important factor. The accuracy and expense of such tests would be major considerations in using the technologies for screening.

Dr. Sigal asked about opportunities for collaboration with industry, given the large industry investment in many of the technologies described. Dr. Pettigrew said there are synergistic opportunities for collaboration with industry and he hopes to be able to report on such activities by next year.

Dr. Mala noted the potential importance of telemedicine in remote areas such as Alaskan villages. He noted that the Centers for Medicare and Medicaid Services reported that the primary use of telemedicine has been in radiology and psychiatry and asked about potential new areas for applying the technology. Dr. Pettigrew said one of the earliest applications was in geographic areas where expertise was needed to interpret images and that the technology can be used in areas where specific expertise or equipment is lacking to consult with experts. An exciting advance that may hold promise is the development by the National Aeronautics and Space Administration of a robonaut with manual dexterity similar to that of a human. It may one day be possible to couple this technology with a global positioning system so that, in areas where specific surgical expertise is not available, sensors on a surgeon's hand can direct the movements of a surgical robot to perform surgery at the remote site.

Update on the Government Performance and Results Act

Lana Skirboll, Ph.D., Associate Director for Science Policy, NIH

Dr. Skirboll began her presentation with a brief history of the Government Performance and Results Act (GPRA) and a summary of decisions made at the NIH to comply with its requirements. The GPRA was passed in 1993 with three main goals: to improve program management, effectiveness, and accountability by focusing on results; to improve congressional decision making and affect budgets; and to improve public confidence in government.

The GPRA generated much discussion and debate in the NIH scientific community. Of primary concern was that goal setting in science is different than in other institutions because of the inherent unpredictability of science. It was considered important to devise a planning process for GPRA compliance that did not hinder scientific creativity or discovery. The resulting plan consists of three broad areas that encompass the NIH budget: the research program, research training and career development, and research facilities[1]. Under these categories, goals are set for research outcomes and for communicating results, technology transfer, grants administration, peer review, management, training, and buildings and facilities. The previous method for evaluating outcomes and goals was qualitative. The new goals must be representative, meaningful, specific, objective or quantitative, reportable, and not obviously attainable. Goals are set and placed in a matrix that represents a continuum of the time to achieve the goal and its level of difficulty (i.e., low to high risk).

Matrix for NIH GPRA Scientific Research Outcome Goals

Risk	*Time*
High	7–10 Years
Med	4–6 Years
Low	1–3 Years

The ICs submitted a total of 240 goals. Ultimately, 27 scientific research outcome goals were selected for inclusion in the GPRA Plan/Report that was published in February 2003. It presents a clear picture of how the NIH does its work—what goals have been set, what progress has been made in attaining them, and which goals have been met.

Dr. Skirboll referred those present to the NIH GPRA Plan/Report for examples of goals submitted with the current year's budget. One goal is as follows: "By 2006, develop one or more prototypes for a low-power, highly directional hearing aid microphone to help hearing-impaired persons better understand speech in a noisy background." This goal meets the criteria of being specific, meaningful, and observable, and falls into the categories of intermediate risk and short time frame (1–3 years). A high-risk, longer-term (4–6 years) goal is: "By 2007, develop an HIV/AIDS vaccine."

Non-research components of the NIH GPRA Plan are also being aligned with GPRA requirements. These include communication of results, technology transfer, grants administration, agency management, training, and buildings and facilities. The plan describes goals in each area that are also placed in a matrix.

Dr. Skirboll then described President Bush's Management Agenda, overseen by the OMB, which tracks how federal agencies are managed and ties this to performance and, ultimately, budget. GPRA research outcome goals are part of the agenda, as are two other activities. The first is research and development criteria being developed by the Office of Science and Technology Policy. The second is the Program Assessment Rating Tool (PART), which consists of assessments for each type of federal agency activity. For purposes of the FY 2005 PART, the NIH will be assessed under the Research and Development. With these tools, the OMB evaluates program performance and gives each agency a weighted score. GPRA goals are broadly linked to the NIH budget because most are trans-NIH with no single budget line and many sources of funding across the Institutes and Offices.

The process of planning and goal-setting can be likened to that of Lewis and Clark, who, when requesting funding for their expedition from Congress, did not promise what they would discover but proved that they could plan for the trip. The GPRA plan is similar in that it relies on concrete goals to equip the process of discovery.

Since the time of the presentation, NIH has streamlined its GPRA program planning and reporting. Every activity at NIH is carried out under one program —Research—in support of NIH's single mission: *To uncover new knowledge that will lead to better health for everyone*. To achieve the best possible scientific results, NIH carries out research activities in five functional areas: Scientific Research Outcomes, Communication and Transfer of Results, Capacity Building and Research Resources, Strategic Management of Human Capital, and Program Oversight and Improvements.

Comments and Discussion

Mr. Armstrong asked how often the list of goals is updated. Dr. Skirboll said the list will be evaluated annually and the total number will vary accordingly. Every year, as part of the budget process, these goals are included as part of the NIH congressional justification.

Dr. Sigal asked what percentage of the NIH budget is devoted to the goals. Dr. Skirboll said the GPRA Plan is more reflective of the kinds of basic and clinical research performed at the NIH. The plan therefore does not require that the goals constitute a certain percentage of the budget. As a follow up, Dr. Sigal asked about the response from the OMB to the NIH GPRA Plan. Dr. Skirboll said the OMB and Congress have responded positively about the NIH's willingness to set such goals, and enabled NIH not be rated until FY 2003. She is hopeful the agency will continue to be well rated as the goals are put in place and OMB conducts its evaluation on the AIDS program.

Dr. Zerhouni offered clarification by explaining that, before the GPRA passage, the NIH set five qualitative research outcome goals so broad that one area or another would always be successful. A tool for aligning goals, strategic plans, and operational plans was lacking. Because it was not possible to look at every NIH program, a sampling methodology was used: a few Institutes were examined in depth, and goals were chosen that cut across all NIH competencies. As a result, many goals were identified that could be stratified according to the time needed to accomplish them and the level of risk (difficulty) involved in meeting them. An example of a low-risk, short-term goal was to create a map of the human genome by 2005. A negative aspect to this approach is that some may wonder about the inclusion of specific diseases. When the goals are examined in combination, however, together they test all aspects of the NIH. Dr. Zerhouni said COPR input was critical to this process.

Report on the NIH Communication Plan

Mr. John Burklow, Associate Director for Communications, NIH

Mr. Sadwin introduced Mr. John Burklow, recently appointed Associate Director for Communications, who developed an NIH Communications Plan to ensure clear,

consistent, and integrated communications across the agency to provide a clear perspective when communicating with public audiences.

Mr. Burklow began his presentation with results from a survey showing that only about six percent of Americans know what the NIH does. At the same time, those surveyed were highly supportive of scientific and biomedical research. The benefits of strategic communication include conveying the relevance of medical research and the NIH leadership role to audiences ranging from policymakers to the public. Another important goal is to demonstrate accountability for the public's continued investment in medical research. NIH's impact as the world's foremost health institution can be maximized by coordinating I/C communications about medical research discoveries that touch people's lives. It is also important to reinforce in the public audience the link between the NIH and the Department of Health and Human Services (DHHS).

The goal of the NIH communications plan is to convey to the public how NIH-supported research helps improve health. The objective is to enhance public awareness of the NIH as a trusted, credible source of health and medical information. Intended audiences include direct and gateway audiences. Examples of the former are the public, minority and underserved populations, patients and their families, health care providers, science opinion leaders and policymakers, and scientists and students. Gateway audiences include the media; scientific, professional, and academic organizations; voluntary health organizations; and NIH staff.

Strategies for implementing the plan include working with the NIH Office of the Director and the I/Cs to develop clear, consistent, and integrated communications; conducting proactive media outreach to communicate NIH messages to the public; and undertaking collaborations with science, medical, voluntary, and private organizations to engage their members and the interested public. A first step in implementing these strategies is improving and widely distributing the NIH home page.

A new NIH brochure is currently awaiting DHHS approval and will soon be finalized. Next steps for the first strategy include developing policy guidelines on consistent identities for the NIH and DHHS, developing a speaker's kit and traveling exhibit to tell the NIH story, and enhancing grantee communication about NIH support.

Action steps in the second strategy include conducting outreach to top-tier media such as prominent newspapers, radio and television news programs, scientific publications, and journalist associations. These media will present opportunities for developing television programs and documentaries about medical research. The NIH will develop a regular health segment for radio stations.

As part of the third strategy, arrangements will be made for NIH leadership to deliver keynote addresses at national conferences of voluntary and professional organizations. Partnerships will be pursued with outside organizations to develop an exhibit about the NIH. Other activities include establishing an NIH e-newsletter and enhancing activities of the Offices of Public Liaison.

Mr. Burklow explained that the approach to developing the NIH communication plan consists of situational analysis, planning and programming, implementation, and evaluation. Between December 2002 and March 2003, a needs assessment and an environmental scan were completed to assess how the NIH affects public understanding of medical research. The assessment included analyzing media coverage and use of the NIH Web site, evaluating NIH products, and conducting focus groups and an awareness and attitude survey.

In a survey of internal stakeholders, I/C directors and staff were asked to describe the NIH role, its unique contribution, and attributes that should be communicated to various audiences, including the public. According to these stakeholders, the NIH role was to conduct medical research that led to disease detection, treatment, or prevention, or that improved health. They cited improving health and supporting and funding research as important attributes that should be communicated. The unique NIH contribution was seen as its ability to conduct research without a financial or profit motive.

In a survey of external stakeholders, COPR members and directors of communications, public affairs, and public relations offices in professional and voluntary organizations and universities were asked to describe the NIH role and how its activities benefited the public, and to identify three health priorities that the NIH should address. These stakeholders also said the NIH role was to conduct medical research that led to disease detection, treatment, and/or prevention. They believed that NIH activities benefited the public by improving health and preventing and curing disease. They were more likely to identify specific diseases such as cancer, cardiovascular disease, and HIV/AIDS as NIH health priorities. Outside organizations were more likely to have contact with individual I/Cs rather than with the NIH as a whole. They welcomed more frequent communication from and with the NIH, preferably via electronic communication or in-person meetings, and prepackaged information describing the broader implications of research findings.

The environmental scan indicated that, although the NIH is known for conducting research, its leadership role and direct benefits to its target audience are generally not communicated. The name "National Institutes of Health" or "NIH" often comes up on the topic of medical research or studies, but the agency is typically mentioned only briefly as the research funder. Many I/Cs are mentioned without affiliation to the NIH. When the news media report on scientific discoveries, they are more likely to mention the institution conducting the research than NIH as the funding source. An analysis of NIH media coverage showed that news stories on medical research mention the NIH only briefly. NIH-referenced stories cover a variety of health topics but quote mostly non-NIH affiliations, usually an academic institution. The abbreviation "NIH" is also rarely defined in news stories.

An analysis of NIH Web site use showed people search it primarily for disease-specific information. The site is visited more often than those of the CDC, the FDA, or the DHHS. In NIH publications and other products, communications staff found that more than half the I/Cs clearly identified themselves as part of the NIH, although they did not describe the agency in their publications or Web sites. Most I/Cs use some combination of NIH, DHHS, and/or individual I/C graphic logos.

Members of consumer focus groups thought medical research was very important and should be increased. They viewed the personal benefits of medical research as including "improved quality of life" and "longer and healthier life." Some terms were more familiar to the public than others; for example, most people were unsure of the meaning of "biomedical," although they recognized the term "medical." Most people were unfamiliar with the term "basic research," and most were less familiar with the NIH than with the CDC or FDA.

Mr. Burklow said that an important lesson learned from these activities was that, in the public's mind, the NIH is not positioned as a cohesive entity with a single voice. Although this is not always achievable, given the diversity of I/Cs, more could be done to this end. Immediate next steps are to develop an operational plan

and develop and institutionalize guidelines for enhancing the NIH identity. Refining NIH messages will involve examining the consistency of agency communications with the public and other audiences about its activities. A traveling exhibit and media training should be made widely available to NIH scientists.

Comments and Discussion

COPR members advanced many ideas for the communications plan and next-step strategies.

- Create and disseminate ready-to-print inserts in minority newspapers to educate the public about the NIH role and mission.
- Air advertisements on the Black Entertainment Television network.
- Notify news service entities when NIH-funded research is about to be published.
- Conduct outreach to specific communities to help implement the communication plan.
- Develop partnerships with traveling representatives from drug companies or cooperative extension networks who could distribute pamphlets to clients that provide information about the NIH.
- Emphasize health promotion and disease prevention; promote individual, family, and community health rather than reporting only on research articles.
- Reflect the changing language of consumer health groups; for example, human subjects are more appropriately referred to as research participants. Such language can help people see themselves as partners in the research enterprise.
- Rather than creating more brochures, add I/C-specific inserts to existing brochures.
- Create monthly boilerplate articles that can be mailed to associations for use in their newsletters. Create a predictable product with a consistent identity and standard format.
- C-SPAN has a regular weekly program dealing with a specific topic, accompanied by information on its Web site. Mr. Tykeson offered to explore with colleagues at C-SPAN the possibility of giving the NIH time to promote its message. Give each I/C a chance to participate and create a useful, informative format.
- Make patient brochures more identifiable.
- Position the NIH with major media newsbreaks; have a speaker explain the NIH contribution to important scientific and medical advances. Also explore the use of minority networks; for example, there are at least three U.S.-based Spanish networks.
- Create camera-ready articles that newspaper or newsletter publishers can freely use as sidebars or boxes.
- Conduct a multifaceted public relations campaign to reach all members of society. Put a human face on a disease or disorder to make a strong statement about NIH-supported research.
- Identify the NIH as the supporter of research in television news stories on hot topics such as the protein diet or hormone replacement therapy.
- Ms. Butler described an event that took place 50 years ago in which science reporters from three major networks were given direct access to NIH Building 1 for any information they wanted. Most stations did stories on the NIH as a starting point.

Dr. Zerhouni noted that these ideas would fit well into a GPRA-like matrix, and that the communications strategy could be a COPR work group topic.

COPR Work Group Co-Chair Reports and Discussion

Dr. Zerhouni and COPR Members

Mr. Sadwin, co-chair of the COPR Agenda Issues Working Group (AIWG), and Dr. Tamura, co-chair of the COPR Public Input and Participation Working Group (PIPWG), recapped the history of the two work groups and described work group plans for the following day.

Mr. Sadwin explained that, at the October 2002 meeting, it was decided to form two project specific working groups. An Agenda Issues Work Group will address important COPR issues for each meeting and serve as primary liaison with the Director for meeting agenda development and related issues. This group will document the institutional memory for high-priority topics, track and document long-term initiatives to ensure follow-up between meetings, as well as develop meeting agendas.

Dr. Tamura said the PIPWG will focus on enhancing public input and participation; specifically, by gathering information on broad-based mechanisms of public input. The work group will target specific categories of input that it has identified as having the greatest potential for eliciting meaningful input.

The work group will focus on the thoughts and needs of the public audience, and how these affect the research priority-setting process, as well as how health research results are disseminated to the public and how the public understands and perceives the NIH. The group also will address intra-NIH issues such as how the I/Cs communicate with each other and how public members of NIH advisory bodies are trained.

The work group has held several conference calls since the October meeting to clarify their direction. One call included some I/C Officers of Public Liaison (OPL) and Communication Directors (CD), after which the OPLs and CDs developed an outline of mechanisms for public input into the NIH. One work group task would be to review that document and determine next steps.

Ms. Tetenbaum noted a discrepancy between the number of hits received on the NIH Web site and participation of the public on advisory groups and study sections. She suggested the work group consider the training needs of public members of these bodies.

Dr. Tamura noted that COPR members previously raised the issue of holding another yearly meeting and were asked to justify the need. He suggested that interim work group meetings could be held between full COPR meetings. Dr. Zerhouni suggested that members who wished to hold an interim meeting develop a work plan

to determine the need.

Dr. Sigal pointed out that the IoM report on NIH restructuring would be released in June 2003 but the COPR is not scheduled to meet again until October 2003. She said the COPR should have a mechanism for responding to the report in June rather than in October.

Action Item: Work group teleconferences will be held to determine the COPR's response to the IoM report.

Dr. Zerhouni said the most common questions he hears about the NIH relate to its priority-setting process. Public input comes from many sources, including large organizations, patient advocacy groups, foundations, and universities. The process is influenced by many factors but is not transparent or deliberative. Clarifying this process for the public would be a significant task that would benefit the NIH and the public. COPR can help by crystallizing the process, finding a way to rationalize it, and carrying that message back to the general public.

At this point, individual members expressed their reactions to the day's meeting.

- One member said the agenda did not include some topics raised in previous meetings and suggested that a more abbreviated form be used to hear from I/C Directors. Dr. Muñoz said the AIWG would enumerate subjects the group considers important.
- Another member, who called the previous day's orientation "wonderful though daunting," liked the collaborative meeting format and the opportunity for input after presentations. The member added that two meetings a year may not be enough to accomplish COPR business and that more subcommittees and work groups may be needed.
- It was suggested that, rather than meeting more often, COPR meetings could be extended from 2 days to 3. The formal, public meeting could be held on the first day, and the next two days could be used to process new information. Work groups could collaborate to determine the information to present to the full COPR membership. Dr. Kirschstein noted that during its first several meetings, the Council heard from each I/C Director. There was concern that continuing to hear from all I/C Directors would become repetitive for long-time members and generate too much information to adequately process. She suggested that the AIWG and PIPWG work together to solve this issue and make a recommendation about it.
- In response to Mr. Burklow's presentation, one member recommended follow-up for these items: distributing camera-ready sidebars to newspapers and newsletters to encourage the media to promulgate NIH messages, encouraging NIH to act as a biomedical watchdog for the public, and wider distribution of information about NIH contributions in specific health areas.
- One member commented that COPR members need time to distill meeting information before they can formulate recommendations. Dr. Zerhouni suggested that a mandate for the agenda work group could be to summarize and synthesize meeting information.
- Another member said that two major meetings might be adequate if the group could conduct more business electronically. Materials distributed to members in advance of meetings should include a focused agenda and background papers.
- One member suggested that the group take greater advantage of mentor relationships to orient and inform new members.

Wrap-Up and Scheduling of Upcoming COPR Meetings

The following future meeting dates were set:

2003:

- October 20–21

2004:

- April 29–30
- October 25–26

The meeting was adjourned at 4:08 p.m. on Thursday, April 24, 2003.

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

U.S. Department of Health & Human Services

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

October 20, 2003 Meeting Minutes

NIH PARTICIPANTS:

- Elias A. Zerhouni, M.D., NIH Director
- Raynard S. Kington, M.D., Ph.D., NIH Deputy Director
- John Burklow, Associate Director for Communications, Director,Office of Communications and Public Liaison
- Ruth Kirschstein, M.D., Senior Advisor to the Director
- Jennifer Gorman Vetter, M.P.A., COPR Executive Secretary, NIH Public Liaison Officer, Office of Communications and Public Liaison

COPR MEMBERS ATTENDING:

- James J. Armstrong
- Ted Mala, M.D., M.P.H.
- Ruth C. Browne, Sc.D., M.P.H.
- Rodrigo A. Muñoz, M.D.
- Nancye W. Buelow
- William D. Novelli
- Barbara D. Butler
- Lawrence B. Sadwin
- Frances J. Dunston, M.D., M.P.H.
- John Shlofrock
- Rafael Gonzalez-Amezcua, M.D.
- Ellen V. Sigal, Ph.D.
- Ellen E. Grant, Ph.D.
- Leonard J. Tamura, Ph.D.
- Debra S. Hall, Ph.D.
- Zelda Tetenbaum, M.Sc.
- Kimberley Hinton
- Dawna Torres Mughal, Ph.D., R.D., FADA
- Jim Jensen
- Donald E. Tykeson

NIH Director's Report

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

Dr. Zerhouni welcomed attendees to the 10th meeting of the Director's Council of Public Representatives (COPR). He extended a special welcome to Dr. Thomas Ansfield, a member of the Advisory Committee to the Director (ACD), who serves as the ACD liaison to the COPR. Dr. Zerhouni added that Mr. Sadwin serves as the COPR liaison to the ACD and observed that Mr. Sadwin's and Dr. Ansfield's presence further a vital synergy between the Office of the Director (OD) and the COPR by promoting information sharing and a common purpose.

Update from the Director

Staff Changes

Dr. Zerhouni announced new directors who have taken their positions since the last COPR meeting. Story C. Landis, Ph.D., accepted an appointment as Director of

the National Institute of Neurological Disorders and Stroke (NINDS). She previously served as Scientific Director of the NINDS intramural program.

Jeremy M. Berg, Ph.D., accepted an appointment as Director of the National Institute of General Medical Sciences (NIGMS). He was previously Director of the Institute for Basic Biomedical Science, and Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins University School of Medicine. Dr. Berg also directed the Markey Center for Micromolecular Structure and Function, and co-directed the Keck Center for the Rational Design of Biologically Active Molecules.

Dr. Zerhouni also announced resignations and retirements. Claude Lenfant, M.D., retired on Aug. 30 as Director of the National Heart, Lung, and Blood Institute (NHLBI). Dr. Zerhouni noted Dr. Lenfant's exceptional impact on the NHLBI during his long and distinguished tenure. A search team, co-chaired by Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. T.K. Li, Director of the National Institute on Alcohol Abuse and Alcoholism, is soliciting recommendations for candidates. Dr. Zerhouni said COPR member Dr. Rafael Gonzalez-Amezcua agreed to serve on the search committee, and stressed the importance of COPR's presence in major searches. Dr. Barbara Alving, former NHLBI Deputy Director, is Acting Director.

Kenneth Olden, Ph.D., stepped down as Director of the National Institute of Environmental Health Sciences and the National Toxicology Program on July 29 but will serve until a replacement is found. Dr. Zerhouni commended Dr. Olden on a remarkable job and added that Dr. Olden will remain at NIH and continue his research.

Dr. Ellie Ehrenfeld resigned as Director of the Center for Scientific Review (CSR) in September. Dr. Zerhouni commended Dr. Ehrenfeld for an outstanding job in reshaping the NIH peer review system. Brent B. Stanfield, Ph.D., CSR Deputy Director, was named Acting Director effective Oct. 1.

Appointments of NIH Senior Staff

Richard Turman was appointed Associate Director for Budget after the retirement of Don Poppke. Mr. Turman was a longstanding leader at the Office of Management and Budget and has also worked in the private sector.

Dr. Norka Ruiz-Bravo replaces Dr. Wendy Baldwin as Deputy Director for Extramural Research. Dr. Ruiz-Bravo was chosen after an extensive review and search for an outstanding candidate who would understand the need for change in managing the grants portfolio and accelerate NIH's advance toward a more user-friendly way of applying for, reviewing, and awarding grants. She previously served as the NIGMS Deputy Director of Extramural Research.

Noteworthy Events

Dr. Zerhouni reported on the rollout of the NIH Roadmap for Medical Research at a press conference on September 30. More than 50 reporters attended, making it one of the largest NIH press conferences in recent years. A briefing of more than 150 public constituents preceded the press conference.

Developed with input from more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides a framework of the priorities the NIH as a whole must address in order to optimize its entire research portfolio, and lays out a vision for a more efficient and productive system of medical research. In the post-genome era, the NIH must adapt its technologies to better address current research challenges and opportunities. The resulting 28 Roadmap initiatives are designed to speed the transfer of research discoveries from bench to bedside. They will also help make the nation's medical research capabilities more responsive to the changing scientific landscape and the demands of public accountability.

Dr. Zerhouni outlined three concepts in furthering Roadmap goals: (1) Effecting a fundamental change in the way research is conducted by promoting an interdisciplinary model, which involves importing and cross-stimulating many disciplines to solve complex problems; (2) Stimulating high-risk research by funding exceptional people with original ideas that are in the early stages of formulation; and (3) Re-engineering clinical research to create a better network of academic centers and community-based physicians to work jointly on clinical trials.

Dr. Zerhouni said the Roadmap has the support of the NIH Institute and Center (ICs) directors, who agreed to allocate IC funds to a common pool as part of NIH's new research direction; Roadmap initiatives are projected to account for 0.9% of the NIH budget over the next several years. The initiative recognizes that many missions are too complex to be accomplished by a single Institute, and that all ICs have a vested interest in combining resources.

Success in developing the Roadmap was due in large part to extraordinary efforts by NIH staff, whose work was complicated by a difficult budget year in 2003. He noted that COPR member Larry Sadwin participated in one of the Roadmap work group meetings and that this kind of participation from COPR members is a valuable part of COPR's work.

Dr. Zerhouni announced that, on Oct. 15, NIH received a Diversity Best Practices Leadership Award at the 2003 Diversity and Women Leadership Summit in recognition of NIH's efforts to ensure a diverse medical research workforce. NIH was the only Federal agency to receive this competitive award. Other recipients included companies such as the Boeing Company, Eli Lilly and Company, Lockheed Martin Corporation, and Booz Allen Hamilton Inc. The NIH is proud of this award and acknowledges the outstanding work of Larry Self, Director of the NIH Office of Equal Opportunity and Diversity Management (OEODM).

NIH grantees were among the winners of the 2003 Nobel Prizes for Chemistry and Medicine. The Nobel Prize for Physiology or Medicine was awarded to Drs. Paul C. Lauterbur and Peter Mansfield for discoveries involving magnetic resonance imaging. Dr. Lauterbur is a longtime NIH grantee; a majority of his funding comes from the National Center for Research Resources.

The Nobel Prize for Chemistry was awarded to NIH-funded basic scientists Drs. Peter Agre, a biologist/physician, and Roderick MacKinnon, also an M.D./Ph.D., for discoveries involving cell membrane channels.

Dr. Zerhouni said these awards illustrate the impressive advances that come from interdisciplinary research, adding that it is noteworthy that the winners in chemistry are not typical Ph.D. chemists. These awards validate NIH initiatives that seek to accelerate research advances by using interdisciplinary teams.

The Grand Challenges in Global Health initiative was recently announced, a $200 million research effort funded by the Gates Foundation in partnership with NIH

and the NIH Foundation to accelerate research on grand challenges in global health. Dr. Zerhouni said this allows unappropriated funds to be used for exploring nontraditional NIH areas. Next steps include publication by the scientific board of specific scientific challenges, and issuance of a request for applications (RFA) for up to $20 million in grants.

Dr. Zerhouni reported forming a blue-ribbon panel in June to review the Intramural Clinical Program. Dr. Joel Goldstein and Dr. Ed Benz, President of the Dana Farber Cancer Institute, are conducting the review in conjunction with Dr. Michael Gottesman, Deputy Director for Intramural Research. Their recommendations will be forthcoming.

Legislative Update

Dr. Zerhouni testified on October 2 before a rare joint hearing of the Senate Health, Education, Labor, and Pensions Committee and the House Energy and Commerce Committee to present the NIH Roadmap for Medical Research. He identified several areas of congressional interest, including:

- Setting research priorities. How to set priorities in a complex institution to ensure that NIH invests in the right projects is an on-going challenge. An example of current congressional interest includes grants on sexuality research. Another area of interest was the on-going questions related to the NIH structure and organization (i.e., the issue of the proliferation of new institutes because there is a perceived need for research in a particular area or a powerful group lobbying for this specific issue). Discussion included whether this kind of proliferation was in the public interest? The public must be part of examining how NIH does business in this regard, and part of COPR's mission is to address this issue.

- Outsourcing initiative. A natural tension exists because it is not easy to outsource NIH's sophisticated services, and because NIH is responsible to taxpayers for ensuring competitive outsourcing. In a recent outsourcing competition NIH has shown the benefit from internally controlling grants management; competition is on-going in the area of facilities management.

- Changes to NIH. Congress will continue to be interested in the implementation of the Roadmap for Medical Research initiatives. Transparency is the best bulwark against inappropriate change, and COPR has a role in bringing transparency to the process.

Another topic raised was the issue of stem cell research. Dr. Zerhouni acknowledged the testimony at the hearing of the former Director of the NIH, Dr. Harold Varmus, who was extremely helpful in providing historical background about the NIH organization, and Dr. Harold Shapiro, who fairly represented the work of his committee in terms of the IoM recommendations.

Comments and Discussion

Ms. Tetenbaum asked about the process of changing NIH research grant funding from primarily single scientist grants to multidisciplinary grants. Dr. Zerhouni said the Roadmap initiatives call for interdisciplinary centers, which represents a change in the culture of institutions that receive grants.

Dr. Sigal asked about next steps after the IoM report. Dr. Zerhouni said impetus for change began before the IoM report, when NIH sought the help of several hundred scientific leaders in planning the Roadmap. There is a demonstrated need for transparency and for a disciplined agency-wide process to fund common areas, and the IC Directors have been supportive in this effort. Dr. Zerhouni said the lack of a specific process causes anxiety about the state of science and the progress that needs to be made; the improvement process must be on-going.

Dr. Mala requested elaboration on the outsourcing issue. Dr. Zerhouni agreed that the process is complicated. The intent of outsourcing is to assure taxpayers that NIH is using public funds efficiently. The initiative reviews NIH processes and puts them up for competition. If NIH is doing the best work, the processes are kept in-house. NIH is outsourcing such work as computer programming.

Mr. Tykeson suggested that the amount of money transferred to the Director's control from the ICs seems small in relation to the NIH budget and asked if it is sufficient. Dr. Zerhouni replied that the amount of money isn't as important as the fact that scientific disciplines have converged enough to focus on common areas. It is difficult in these tough economic times to ask, in midstream, to reapportion a significant portion of the budget. But Dr. Zerhouni said he is satisfied that the amount serves as seed funds. He noted that the molecular library initiative, which will cost $250–$300 million over 5 years, is something that no single institute could undertake. Dr. Zerhouni agreed that NIH must transition from where it is to where it wants to be, but the amount is not as important as the change in culture.

Dr. Zerhouni stressed the cooperation of the ICs on this issue. A steering committee of nine of 27 directors streamlined the decision process and resolved the issue of funding in two days. Thanks to the directors' impressive leadership, 27 institutes are now heading in the same direction.

Ms. Butler raised concerns about future funding of past grants, and constituency group fears that their diseases will be slighted because each institute must give money to the pool. Dr. Zerhouni emphasized that this money will serve the entire community through corporate decision making on initiatives such as the molecular library. Constituency groups must be educated to understand that this funding is synergistic with their interests and that it is for a minimum set of important NIH activities.

Dr. Zerhouni thanked the departing COPR members for their dedicated service—Drs. Grant, Muñoz, Tamura, and Bromet, and Ms. Tetenbaum—and presented certificates of appreciation.

COPR Work Group Co-chair Report and Discussion

Dr. Zerhouni and COPR Members

Ms. Hall, co-chair of the COPR Agenda Issues Working Group (AIWG), and Dr. Tamura, co-chair of the COPR Public Input and Participation Working Group (PIPWG), recapped work group activities over the past year and outlined plans for the following day.

Ms. Hall described the evolution of AIWG's thinking in preparing the meeting agenda, noting that the group refined its focus from concentrating on how research results translate to health benefits for a specific disease (metabolic syndrome), to conducting a panel discussion to examine how to enhance public trust in the clinical research enterprise, with an emphasis on understanding the relationship between health disparities, research practices, and building trust. There would also be a report from Dr. Sigal, chair of the IoM Response subgroup. Ms. Hall recapped lessons learned from the agenda-setting process: 1) it takes time, 2) flexibility must be built in, 3) communication via teleconference and e-mail is vital and ongoing, and 4) the job could not be accomplished without the interest of Drs. Zerhouni and Kington, the leadership of Dr. Tamura and Ms. Tetenbaum, and the efficient support of Ms. Jennifer Gorman Vetter and Ms. Shelly Pollard.

Dr. Zerhouni said he was impressed by the progress made in a year on the meeting agenda and commended the co-chairs.

Mr. Sadwin asked Dr. Zerhouni to use the program as a lens for suggesting appropriate next steps.

Dr. Tamura said that PIPWG saw itself as part of the process of engaging the public in the clinical research enterprise by referencing Dr. Zerhouni's three priorities —trust, bi-directional communication, and education - keeping in mind that even the perception of a lack of transparency can erode public trust. The work group worked with many Institute Officers of Public Liaison (OPLs) to find examples of how public input is obtained, and identified specific practices that effectuate public input in the research priority-setting process. The group interviewed OPL and IC staff and amassed information. Future efforts for the group include distilling this information to identify best practices that can be recommended for replication across the Institutes and Centers. The group will also examine how the research priority-setting process works in the context of facilitating public input into that process by identifying points of public access. The focus will be on transparency, i.e., asking, how clear is this process to the public.

Dr. Zerhouni asked if the group considered meeting with public members of the advisory councils. Dr. Tamura replied that the group is investigating such meetings.

Dr. Tamura reported that the communications subgroup had developed relationships with C-SPAN and the Discovery Channel, and that Mr. Burklow would present an update. Dr Tamura expressed appreciation to Mr. Burklow, Ms. Gorman Vetter, and Ms. Pollard for their efforts and support.

Dr. Zerhouni said that communication has improved but that an ongoing strategy was needed to let the public know about NIH activities.

Mr. Tykeson suggested that, although Dr. Zerhouni has a busy schedule, it would be beneficial if Dr. Zerhouni could participate in the communications effort because greater visibility by the Director would be a valuable catalyst.

Dr. Zerhouni said that it cannot be the Director alone in this effort—multiple strategies are necessary.

Dr. Grant told Dr. Zerhouni that COPR had received tremendous cooperation from the Officers of Public Liaison in many of the Institutes.

Dr. Zerhouni introduced Mr. Marc Smolonsky, the NIH legislative liaison with Congress.

Update from the Office of Legislative Policy and Analysis

Marc Smolonsky, Associate Director for Legislative Policy and Analysis, Office of the Director, NIH

Mr. Smolonsky gave a brief legislative history, tracing NIH roots from the establishment of the Marine Hospital Service in 1798 to the passage of the Public Health Service Act (PHSA) in 1944, which created the first National Institutes of Health. The NIH Revitalization Act was enacted in 1993. There have been no major omnibus reauthorizations since then, predominantly because NIH is driven by the appropriations process.

The NIH is not self-sustaining; congressional appropriators dominate the NIH legislative universe and set NIH's course. From 1998 to 2003, the NIH budget doubled to $27.2 billion. Pending legislation contemplates much more modest increases, a situation that is expected to continue into the future.

Mr. Smolonsky identified key appropriators in the Senate and House and stressed that in 2004 there will be a significant shift from appropriations to the authorization process.

The key NIH authorities (i.e., prioritizing research through the ICs, biomedical research, grant making, peer review, training, disseminating information, human subjects protections, and soliciting public advice) come through the PHSA.

Through the authorization process, Congress authorizes programs (usually in a 3-year cycle, but programs can continue without being reauthorized if funds are appropriated), may change existing programs, may add prohibitions to the PHSA, and can create institutes at NIH without going through the standard legislative process (e.g., debate).

In 1993, Congress sent a message through the NIH Revitalization Act that NIH did not focus enough on certain populations. The Act created the offices of Alternative Medicine, Women's Health, Minority Health, and Behavioral and Social Sciences Research. It also created the National Center for Human Genome Research and expanded the authority of the Office of AIDS Research. Among other provisions, Congress established the NIH Director's discretionary fund and the IDeA program.

Only 3 years later, Congress tried but failed to set new priorities for NIH in the 1996 reauthorization attempt. It is instructive, however, to look at the proposals. The legislation would have, among other things, created an Office of Rare Disease Research, elevated the Center for Genome Research to an institute, and established a Pain Research Consortium (which was later created administratively). Congress also proposed increased research funding for Parkinson's disease and increased support for diabetes and pediatric research. These were all enacted separately as amendments to the PHSA.

Mr. Smolonsky identified congressional committees involved in the process, key players in the Senate and the House, and congressional caucuses with interests in specific diseases or research. The congressional process, as it relates to NIH, is truly bipartisan.

The 108 th Congress has already held three authorization hearings for a reauthorization bill that will be considered in the spring. One of these was Dr. Zerhouni's appearance at a rare joint House/Senate hearing, which was a success for NIH.

Controversial issues before Congress are stem cell research, cloning, fetal tissue research, sexuality studies, and politics and science. Of concern is the Toomey Amendment, which was introduced on the House floor and focused on five sexuality study grants. It lost by two votes. This was important because Congress was considering defunding peer-reviewed research; i.e., grants that had already been awarded.

Potential issues that will be addressed in the reauthorization process are:

1. DARPA-like authority. Should the NIH have Defense Department-like authority that allows it to cut through red tape in research and fund studies more directly and quickly?
2. Bioterrorism. A big issue in the reauthorization process.
3. Priority setting. Congress is constantly concerned with how NIH sets its priorities; for example, why the NIH funds one disease over another.
4. Director's authority. Congress will examine whether it is sufficient to manage corporate NIH in a system where each center or institute receives its own appropriations.
5. Peer review. Congress will ask whether the process is too cumbersome and prevents high-risk research.
6. Structure. The focus will be on the number of institutes and centers.
7. Small states. Many states do not receive funds; often they may not have research hospitals or university research centers that are successfully competing for NIH grants.
8. Recruitment and training.
9. Human subjects protection.
10. Centers of Excellence. A common congressional solution to areas of research it considers underfunded.

Comments and Discussion

Dr. Sigal asked how Congress will set priorities and if there is anything COPR can do. Mr. Smolonsky said Congress is influenced by constituency groups, which should work together and think about how they interact with NIH. There is more risk than benefit to a reauthorization bill.

Dr. Mala asked for more information about the relationship between the IDeA program and small states. Mr. Smolonsky explained that the IDeA program is designed to help small states by providing seed money for developing institutional skills to help organizations in those states compete for NIH funding. Congress has been reluctant to force NIH into a geographic distribution of money, but legislators are frustrated by the lack of geographical distribution.

Mr. Sadwin said that all states benefit from good research. Mr. Smolonsky suggested that the Roadmap for Medical Research will help resolve geographical inequities.

Senator Jensen suggested that acceptance comes from not pushing too hard on controversial issues and letting them evolve. Mr. Smolonsky agreed that this is true in the ideal world but in Congress political evolution has reached a ceiling for certain areas of research; it is incumbent on NIH to be engaged to make things to happen.

Dr. Torres Mughal asked for advice on how to effectively reach and talk to legislators. Mr. Smolonsky replied that what would be more effective is to have biomedical advocacy and constituency groups collaborate and work together among one another.

Dr. Sigal suggested that there are overarching issues important to all advocacy groups. She said COPR is uniquely suited to encourage collaborative thinking. She added that NIH is where it is today because of constituency groups but, for some large reauthorization issues, group thinking is absent. Mr. Smolonsky agreed that constituency groups have played and will continue to play a vital role for NIH, but cooperative group thinking is necessary to be effective in the current political climate.

Ms. Hall raised the issue of the importance to the public and health care providers of the Roadmap as it relates to translating research into clinical practice.

Dr. Zerhouni said that when something new arises it is natural to try and fit it into existing frameworks. But NIH is not interested in responding with structures (e.g., ICs). The changing research paradigm is relationships and information transfer. Academic health centers were effective in dealing with acute health problems, but chronic health problems around the globe require a system of information transfer to share the benefits of research with physicians at each site. In this process, trust and best practices must be maintained and transferred easily across networks so participants can be recruited for research. This represents a philosophical change that will revolutionize the way research is done.

Dr. Muñoz raised the issue of the relationship among the research establishment, patients, and clinicians, suggesting that distance among these three groups must be decreased through collaboration.

Dr. Zerhouni replied that there are effective models, citing the Cystic Fibrosis Foundation, which works with 190 clinical sites in communities that connect to one data registry. This takes great cooperation from physicians. It is a best practice model that has led to increased life expectancy each year. NIH must create new research partnerships—a base of communities willing to partner with NIH and a base of credentialed specialized physicians who are qualified for such a partnership.

Dr. Zerhouni introduced Debra Lappin, an attorney and founding COPR member and a former member of the NIAMS Advisory Council. Calling her committed to the

mission of NIH and an alumnus emeritus of COPR, Dr. Zerhouni said that Ms. Lappin, a member of the IoM Committee, would give an inside look at the IoM report and the issue of NIH organizational change.

Presentation on National Research Council/Institute of Medicine (IoM) of the National Academies Report

Debra Lappin, J.D., A COPR Alumni and IoM Committee Member

Ms. Lappin explained that Congress commissioned the NIH-funded study in response to rising concern about the NIH organizational structure. The Committee was composed of distinguished members with a wide breadth of expertise. Ms. Lappin noted that, despite the Committee's independent thinkers, there was a remarkable convergence with the NIH Roadmap for Medical Research.

The Committee's charge was to consider the following questions: How should NIH be organized to identify and respond with greater agility to emerging public need and scientific opportunity, is NIH equipped to be accountable to the pubic and Congress, and how can we ensure that public input informs strategic planning and research priority setting? The study was driven by three concerns: whether NIH had become too large and decentralized to respond to the needs of a rapidly changing science; that Congress felt the need to develop a new institute when there was a perceived research need; and that science was changing so dramatically that new infrastructures were required in which the multidisciplinary and multi-institutional concepts must be augmented with new interdisciplinary and inter-institutional concepts.

The Committee, recognizing that an organization can become entrenched in its own culture and lose the ability to adapt, confronted the major question: How should the NIH be optimally configured to meet 21st century scientific needs?

The Committee rejected the idea of a major consolidation of ICs, concerned that clustering the ICs would add a new layer of management. The Committee also found no ready set of natural dimensions for clustering, concluding that a loose federation of units with a high degree of autonomy and close ties to its constituency is NIH's bedrock.

The Committee explored new organizational strategies that included a trans-NIH capacity for response, a program to encourage high-risk/high-reward research, a major reorganization of clinical research activities, and strengthening of the Office of the Director. These were seen as ways to enhance NIH's ability to respond to science and new opportunities.

Ms. Lappin elaborated on each strategy:

1. Trans-NIH capacity for planning and implementation to allow NIH-wide responses to compelling emerging areas. This entails regular NIH-wide planning and priority setting, and increased accountability of the Director to Congress. The Director must therefore have increased responsibility and authority, some of which will be accomplished by ongoing and stable funding from the ICs at an initial rate of 5%, increasing to perhaps 10% in 5 years. This funding, which does not take away from R01s but allows reprioritization to address public needs, will represent a new NIH acting as a whole. This new approach will demand that advocacy groups come forward as a new kind of NIH partner.
2. High-risk/high-reward research that envisions creating a Director's Special Projects Program (DSPP) and urging the intramural research program (IRP) toward higher risk and innovation. The DSPP and IRP would complement the peer review system for the substantive body of NIH research.
3. Clinical research. NIH is seen as the leader in balancing scientific opportunity against public need. NIH is the convener for orchestrating the removal of translational blocks. The NIH goal is to facilitate the passing on of information—to the next partner in clinical research—to ease the way for research teams to take a scientific concept through the clinical research passage to improve public health. Appointing a deputy director of clinical research is recommended to facilitate the process of coordinating intramural and extramural activities, and to build on and consolidate existing units and programs.
4. Strengthen the OD. If the Director is to be held accountable, he must have the leverage to lead. This requires giving the Director an adequate budget to support the management role, operations budget, and the DSPP, and the budget authority to organize trans-NIH strategic planning.

Areas of accountability and administration include measuring COPR's impact and using data and information management systems to estimate spending priorities.

The advisory council system must be strengthened dramatically to gain consistency and independence. Members should be selected based on expertise, not a political agenda, that fairly represents the public; councils should include scientific members from organizations not funded by NIH institutes. There should be members from outside institutions who will push for new directions.

Centralization of administrative functions must proceed slowly and cautiously and not undermine the ability to administer, oversee, and conduct science. Among the administrative issues to be addressed is the tenure of IC and NIH Directors. There was support in the Committee for a 5-year, 360° review of directors in a new formalized way. The NIH Director should have a 6-year renewable term.

Structural changes (i.e., changing the number of institutes and centers) should revolve around a public process; there should be no sacred cows in terms of combining or changing the status of existing institutes. The Committee recommended a merger of the National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), and suggested combining the National Human Genome Research Institute and the NIGMS. Another suggestion involved examining the National Cancer Institute's special status.

The Committee concluded that what makes NIH great is its ability to attract outstanding leaders and scientists. Congress and the public anticipate a new level of accountability from NIH and the NIH must be ready to respond. Ms. Lappin suggested that COPR should be able to give Dr. Zerhouni important advice in light of this report.

Comments and Discussion

Dr. Browne asked what COPR's response should be in educating the public at this critical juncture for NIH. Ms. Lappin said this is up to COPR.

Ms. Tetenbaum asked if the Committee was on-going. Ms. Lappin said the Committee's work is complete.

Ms. Hall asked for more elaboration on removing translational blocks and leadership. Ms. Lappin said it is a tough question but trust in the enterprise means something is being done that makes a difference in people's lives. NIH is the obvious organization to orchestrate public trust in the clinical enterprise.

Mr. Tykeson, acknowledging the Committee's conclusion that it would be too expensive to change the structure of NIH , asked Ms. Lappin what the Committee would have suggested if it had the luxury of starting from scratch in organizing the NIH. Ms. Lappin said the structure most considered was clustering but that was finally rejected because it might lead to a subset of clusters that would demand even more money for a growing bureaucracy.

Mr. Armstrong asked Ms. Lappin to estimate how much weight the report will carry with Congress regarding high-risk research. Ms. Lappin said congressional scrutiny is driven by what serves the public need and that it remains to be seen whether this will stimulate Congress to allocate funds for trans-NIH planning.

Dr. Tamura asked how the Committee assessed the state of the system. Ms. Lappin referred him to the back of the report, which lists public testimony. Town meetings were also held.

Dr. Kington introduced the afternoon panel discussion, "Examining How to Enhance Public Trust in the Clinical Research Enterprise," with an emphasis on understanding the relationship among health disparities, research practices, and building trust.

Presentation on "Race, Trust, and Tuskegee: Professional Ethics, Broken Trust, and Health Disparities"

Matthew Wynia, M.D., M.P.H., Director, the Institute for Ethics, American Medical Association

Dr. Wynia recounted a story about the study of an AIDS vaccine in 5,009 people at high risk. Among vaccine recipients, 5.7% contracted the infection, in contrast to 5.8% of placebo recipients, so the vaccine did not work. But among African Americans the vaccine reduced infection rates from 8.1% to about 2%. The catch: only 314 African Americans enrolled in the study and only 13 became infected, so this may have been a statistical anomaly.

There are many reasons why minorities may be less likely to participate in research, and mistrust of the health care system and the research enterprise is one of them. Minorities more often mistrust the health system and this mistrust is grounded in realities that medical researchers need to acknowledge as valid. Mistrust has many negative effects throughout health care, including increased litigation, increased disenrollment, and possibly lower health status.

The integrity of the medical profession depends on trustworthiness. Relationships in health care and medical research are based on trust because of patients' vulnerability. We build trustworthiness in the hope that trust will follow.

There is a reciprocal relationship between interpersonal trust (between individual doctors and patients) and institutional trust (such as trust in the medical profession and medical research). Patients will not see a doctor if there is not some baseline institutional trust, and trust in institutions grows through positive interpersonal interactions. Building personal trust with the doctor validates initial institutional trust and builds on it.

Numerous studies have shown that African Americans commonly have a profound mistrust of medical research and a concern that they will be used as guinea pigs. This mistrust occurs in highly educated African American populations and reflects a collective memory of a history of unethical experimentation on African Americans such as the Tuskegee study of untreated syphilis. A significant minority of African Americans hold extreme levels of mistrust of the medical profession; believing, for example, that sickle cell screening is done to reduce the African American population.

The Tuskegee study (1932–1972) is an example of the failure of professional ethics in research on African Americans. Participants were lied to about the nature of the study. They were told they would receive free treatment for "bad blood," despite the fact that the objective of the study was to prevent subjects from receiving treatment and bring the men to necropsy (post-mortem) to evaluate the "effects of untreated syphilis on the negro male." The legacy of the Tuskegee study endures, researchers have concluded, in part because "the racism and disrespect for black lives that it entailed mirror black people's contemporary experiences with medicine." Today, 80% of minorities are more likely to believe that health professionals, whether they mean to or not, treat minority patients differently than they treat white patients.

In summary, Dr. Wynia suggested:

- Trustworthiness is central to professional integrity and trust confers health benefits.
- Many minorities mistrust medical research.
- There are historic and contemporary reasons for this mistrust that reflect profound failures of professional ethics.
- To improve outcomes, reduce health disparities, and build integrity, medical researchers must work to demonstrate their trustworthiness to minority populations.

Ways to demonstrate trustworthiness include:

- Recognize and focus on the issue.
- Develop standard, well-validated tools to assess trust in the research enterprise.
- Build on personal trust, which is still strong; people tend to trust their own doctors.
- Involve the community, such as through community-based participatory research (CBPR).
- Communicate the value of research within minority communities.

Finally, note that the Tuskegee Study could not enroll enough research subjects until advertisements said that "government doctors" were conducting the study. Never forget that trust in medicine, research and the government has been quite strong in the past, but it must be re-built.

Dr. Kington then introduced Vence Bonham, who recently joined the National Human Genome Research Institute from Michigan State University.

Presentation on Enhancing Trust in the Clinical Enterprise

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

Mr. Bonham focused on research he was involved in at Michigan State University, representing about 250 individuals.

Mr. Bonham said the research, Communities of Color and Genetics Policy Projects, provides insights for enhancing trust in the clinical enterprise and biomedical research. The project aimed to engage African American and Latino communities of diverse socioeconomic levels in dialogs relating to genome research and its resulting technology, and to develop recommendations for laws, professional standards, and policies on the use and application of genome research and technology.

Dialog groups were identified and engaged in public discourse over 5 weeks. Their recommendations were outlined and the groups met again to review the dialog report. All 15 individual dialog reports were distilled into a summary report that was presented in meetings with policy groups (such as legislators) around the country.

Areas of concern identified by the dialog groups included education and trust.

Education:

- Must be in a culturally relevant language and form.

Trust:

- Found that the entity most trusted was the government. Most concern was with private enterprise because of a belief that the mission of private enterprise is to benefit shareholders, not the public.
- There is a need for researchers and public communicators who are people of color.
  Mr. Bonham shared comments made by participants as part of his promise that their voices would be heard. The comments indicated a general wariness on the part of minorities regarding genetic research.

The following recommendations came from the study:

Education:

- It is the responsibility of the Federal government to fund broad public education efforts regarding genetic technologies, research, and current policy issues.

Trust:

- There is a need for more racial and ethnic diversity in advisory committees for lay and scientific members.
- There is a need for networking between advisory groups and advocacy organizations to share findings and recommendations.
- Federal funding must be maintained at a high enough level related to private funding to minimize the profit motive's impact.
- Institutional Review Boards (IRBs) must address the protection of groups (i.e., communities and populations) and individuals, with an emphasis on minorities. This raises a question about how these different groups should be identified.

Lessons learned about enhancing individual participation and building trust in the research enterprise:

- It is important to reach out directly and work with targeted communities. Researchers must engage the community to understand how to work in that community.
- Long-term relationships must be developed with organizations and community leaders; parachuting in does not work.
- It is necessary to go beyond obvious community leaders to include individuals who represent important grassroots coalitions.
- Issues of trust as part of the research structure must be continually examined.

Presentation on Building Trust: Engendering Research Communities

Sharon B. Wyatt, R.N., C.S., Ph.D., Co-Principal Investigator, Jackson Heart Study Examination Center, Professor of Nursing, University of Mississippi

Dr. Wyatt cited former Surgeon General Dr. David Satcher as saying that none of us can argue with the national fact that we must do better to reach those with disparities in health: the uninsured, the uninformed, the uninspired, and the untrusting. How we do that is the issue at hand.

Noting that only in the last decade has the research enterprise made substantive and serious efforts to assure that the traditionally disenfranchised are equitably included in research to overcome health disparities, Dr. Wyatt suggested that research has become increasingly difficult to conduct and, as the NIH Roadmap has identified, requires new approaches and partnerships.

Dr. Wyatt described the Jackson Heart Study (JHS), the largest epidemiological cohort study of heart disease risk factors and causes in African Americans, as an exemplar of current approaches in building trust and overcoming disparities in health through use of a community driven model (CDM):

- The study extended the reach of researchers beyond the building to form partnerships among minorities and majority institutions in the community. The challenge was the time required to forge this partnership. Research outcome is driven by data; community outcome is driven by relationships.
- The CDM is generalizable to other sites. The CDM engages the community and researchers/practitioners as co-investigators; i.e., partners in planning, not ancillary reactors to preconceived plans.
- The CDM involves three overarching themes illustrated in the JHS study:

1. Interpreting the concerns of the JHS family, particularly the guardedness that is a reflection of the way this population lives. Appreciating these concerns affects issues of consenting, the amount of study information that should be provided, and the community's need to have (and trust) guarantees about the researchers' intentions.
2. Gathering the community as co-investigators. Researchers need to collaborate with their community co-investigators to identify and develop protocol elements. In the JHS, the consent brochure is extensive and there is a video and a signed commitment by the investigator that the data will only be used as listed in the consent form. Researchers must be aware that family is special in the African American community and an emphasis is needed on building a family-like relationship between the community and the researchers and institution. To this end, a Council of Elders was formed to provide a supportive presence for the community and the researchers.
3. Community outreach. Taking newly gained knowledge back to the community redefines the traditional researcher/subject relationship and forges another level of partnership; a partnership for community health education and awareness.

Throughout the presentation, Dr. Wyatt shared the thoughts of participants, using their own words in the vernacular.

Despite this effort, there has been a mixed level of success:

- On the positive side, gaining knowledge for themselves and their families gives community members an incentive to participate and creates a sharing atmosphere that overcomes differences. The annual follow-up response is greater than 95%.
- On the negative side, recruitment is always a problem.
- Obstacles to building trust remain. There is a built-in inequitable power distribution that makes shared control in a CDM difficult. The nature of the scientific enterprise, which is data driven, often gives participants the sense that "all you want is our data." In addition, the difficulty of changing researchers' methods of inquiry, timetables, and resource allocation can preclude investment in community building. Finally, although building trust is on-going, trust remains fragile. Once established, trust can never be taken for granted and requires constant vigilance. Conflicts over meaning, language, values and beliefs, assumptions, and promises are inevitable, necessitating the on-going joint development of operational norms.

Community-driven possibilities for engendering trusting research communities:

- Develop models for community-driven research and multi-method evaluations.
- Fund studies that attend to how researchers build their research communities.
- Provide training for investigators and NIH staffand reviewers to facilitate broad-based, multiethnic studies.

Next, Dr. Kington introduced Myrl Weinberg, President of the National Health Council.

Presentation on Introducing Research into Communities

Myrl Weinberg, C.A.E., President, National Health Council

Ms. Weinberg described the National Health Council (NHC) as a nonprofit umbrella organization of 110 health-related organizations representing 100 million people. The NHC also numbers among its members pharmaceutical biotech companies, the AARP, and Hospice.

Rather than repeat ideas advanced by previous speakers, Ms. Weinberg highlighted major points:

Literacy and trust:

- Trust and trustworthiness are closely tied to communication. Health literacy issues (people cannot read, or they use words differently in their cultures or in rural areas) can account for recruiting difficulty because people do not know about the studies.
- The NHC conducts market research and asked people how they viewed genetic research to find out which words are effective. The research found that people did not have the language to process such technical concepts.

Building trust in the community:

- It takes a serious time commitment to develop the respect of people and their families.
- Identify community leaders, the most valuable community resource.
- Get involved in the community. Going beyond medical research to general issues that are important to the community is the basis of building trust.
- Create new roles. Identify and train people who can serve as trusted intermediaries between researchers and the community, such as social workers. This can be more effective than a legalistic consent document; it will improve the researchers' knowledge of the patients' perspective and what is important to them.
- Involve the community from the beginning. Every IRB should include people from the community. They are among the most valuable resources and they

should be involved in the initial stages of research in their communities.

Research our own research:

- Find good models so we know what activities work when we recruit, and try to engage the community in research. An organization that does this is the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which works to identify how communities and potential research participants are involved, how are they kept safe, and how their information is kept confidential.

Dr. Zerhouni thanked the speakers and asked them to define trust. The speakers gave the following definitions:

- Dr. Wynia: Trust is an expectation of future cooperation. Domains of trust include knowing that you are dealing with someone who is competent, will ensure confidentiality, encourages shared decision-making, and makes full disclosure. But this does not help us measure trust; it would be valuable to develop mechanisms for measuring trust. As new ways are developed to conduct community-based research, it would be helpful to be able to see if they affect trust in a measurable way.
- Dr. Wyatt: Trust is the expectation of being safe as predicated on past experience.
- Mr. Bonham: Trust is the faith, the belief, and the knowledge that you will not be harmed.
- Ms. Weinberg: Trust is feeling safe because of knowing that the doctor/researcher "has my best interests at heart."

Dr. Zerhouni, quoting a Japanese philosopher, added that trust is the ability to predict someone's behavior. It is a short word encompassing a complex reality.

Panel Discussion Question and Answer

Dr. Sigal recounted recent difficulty recruiting an African American who had been in a clinical trial to be an advisor to another clinical trial. It was difficult to find such a person and medical directors told her that it was exceptionally difficult to recruit African Americans for clinical trials. Dr. Sigal found that there was a collective memory about Tuskegee, and a potential recruit told Dr. Sigal that her entire family asked her not to volunteer.

Dr. Kington said the reported racial distrust has not led to a consistent failure to enroll. Statistics have shown that there is not a big difference in response rates by race; so there is a disconnection between reports of distrust and the lack of a consistent failure to enroll in studies.

Dr. Grant agreed that there are positive enrollment experiences, citing the Boston Black Women's Study. She said HHS has its own faith-based initiative and some lessons learned were that barber shops and beauty salons are valuable sites for educating the community. After holding a meeting that no one attended, it was clear that a first step is going into the community and engaging involvement. Dr. Grant said she liked the Council of Elders idea but suggested that participants' words should not have been left in the vernacular. Dr. Wyatt said the participants requested this, saying, "Don't whitewash our dialect."

Mr. Bonham gave an example of the African American community's involvement in genetics research, citing the NHGRI prostate cancer family project, which was done with African Americans.

Dr. Zerhouni recognized Dr. Stephen Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and recalled that Dr. Katz had suggested that there is no such thing as one community of African Americans, but that many factors are involved from community to community.

Dr. Wyatt agreed, having seen this in the Jackson Heart Study, which involves three diverse counties.

Dr. Katz added that a critical element in building community infrastructure is building trust, a process that involves an on-going series of interactions. The success of the Roadmap for Medical Research section on clinical re-engineering depends on building trust in communities, something that will take time and commitment. NIH is concerned with public trust at all levels and with all communities.

Ms. Butler asked about work being done in the area of researcher bias. Dr. Wynia said there is much interest in improving physician communication, and last year physician accreditation required cross-cultural communication skills for new physicians. Dr. Wynia sees this as the least threatening way to approach this sensitive issue. Stereotyping can occur because physicians are rushed and this can appear to be racism. Physicians shut down if this is called racism but will talk about cross-cultural communication skills.

Ms. Weinberg suggested that research institutions develop systematic, organized ways of interacting with communities that have measurable objectives. Institutions must cull these successful strategies and replicate them.

Ms. Hall noted that this morning the group spoke of human subjects research and this afternoon it is speaking of people. She added that notions of mistrust can cut across a wide group of people of all ethnicities. She described a need to educate community researchers and called for the community to be a partner in research.

Dr. Mala acknowledged that "every researcher must pay for the sins of his or her forebears," and emphasized the problem he has seen in the Native American community of researchers who come into the community, do the research, and are never heard from again. He suggested that mistrust will be overcome when research results are brought back home.

Dr. Dunston said that, to promote public trust in clinical trials, researchers must demonstrate competency in dealing with participants and engendering trust. Should this be a core competency related to funding grant proposals?

Dr. Gonzalez-Amezcua said socioeconomic considerations often drive involvement in research. Such disparity should not exist, and this topic should be addressed.

Dr. Torres Mughal asked whether there is information on trust in minority groups.

Dr Wynia said there was some, but there is more information about trust in terms of how individuals view personal physicians. Among Latinos, for example, there appears to be a high level of trust in doctors and too much trust in Latino physicians. All minorities have a lower level of trust in the health care system. They tend to trust their doctors, but not researchers. This is why the distinction between trust and trustworthiness is so important; the research enterprise must be trustworthy.

Mr. Bonham said there is limited data on trust and research.

Dr. Muñoz said he had anecdotal evidence that the Latino population in his area evidences mistrust of clinical research.

Ms. Hinton expressed appreciation to the speakers for their presentations and said her own experience has been in HHS service organizations with AIDS. She felt the key is to respect the person sitting in front of you; this is not so much a trained competence but an innate respect. She added that, despite her own education and understanding of the research process, she sees Johns Hopkins trying to recruit and something inside tells her that she should not volunteer because, "What if?" As an African American woman, she added, when she visits the doctor the first thing that builds trust is respect. If professionals don't listen because she does not have an M.D. after her name, it does not work.

Dr. Dunston noted that the group had been discussing trust at a relational level (person to person) and wanted to know about the broader sense of public trust—confidence from the public in the NIH as an institution.

Ms. Weinberg suggested that they are intertwined. Building trust from the ground up at the relational level leads to trust in institutions.

Dr. Mala described his visit to Dr. Katz's inner-city clinic. The clinic was established because patients weren't coming to NIH, so the researchers took the clinic to the community. Dr. Mala reported being impressed with the staff and the positive attitude about this effort to bring NIH to the community.

Dr. Katz thanked Dr. Mala and said that it was Dr. Peter Lipsky of the Intramural Research Program who realized that NIAMS is an institute that deals with women and minority health, but sensed that this minority population was not reflected in patients being seen in the Clinical Center. He decided to go out into the community. He met with Hispanic and African American community leaders, including representatives from Howard University, to explain that NIH wanted its intramural program to be accessible to the community. This was a good practice and could be broadened to other initiatives.

Dr. Zerhouni said that the dimension of public trust is greater than the minority context. He said there are delays and recruiting problems across the board and charged COPR with taking the larger view and looking at broad generic problems that stifle the discovery pipeline.

Ms. Tetenbaum noted that patient accrual is not the only problem.

Dr. Zerhouni agreed, saying patient accrual was an example. He added that NIH must do the experiment because that is how science advances.

Dr. Wynia suggested that education is weakly related to trust because sometimes an educated person is less trusting. He mentioned the difficulty of framing a research program for grant funding for CBPR when you are not sure of the questions because you have not had the money to go out into the community. He felt there was no obvious way to do CBPR with traditional funding procedures.

Ms. Hall returned to the question of consent forms, saying that researchers need to be educated about what language works in the community.

Ms. Butler asked about the feasibility of approaching nonprofits and teaching them how to explain research projects.

Ms. Weinberg considered this an excellent idea because nonprofits are trusted community sources, but suggested it is limited because what works and what doesn't have not been identified. She wished that plain language could be used for guidelines like HIPAA *(The Department of Health and Human Services (HHS) issued the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to provide the first comprehensive Federal protection for the privacy of personal health information.)*. She gave an example of the Alpha-1 Registry. Individuals with alpha-1 can register confidentially, and volunteers from patient groups contact these individuals and explain available research. Then it is up to the individuals to contact the researcher if they want to participate. The Registry successfully recruits participants because it is a trusted intermediary.

Dr. Katz mentioned two initiatives germane to the discussion:

1. Harmonizing and simplifying research regulatory language to do away with 15-page consent forms. Dr. Zerhouni is using the power of his office in this effort, and the community must get involved.
2. Support for the idea that volunteer organizations are important partners in this effort. This does not require money, it requires time and commitment.

Wrap-up and Next Steps

Dr. Zerhouni said it is clear that the evolving core issue of trust must be addressed and asked for next steps.

Dr. Sigal suggested that outreach efforts by the institutes be integrated in this effort.

Dr. Gonzalez-Amezcua suggested that more education is needed for the public to realize NIH's impact on their lives. Trust will increase as the public learns more about NIH.

Dr. Zerhouni thanked all participants.

Ms. Gorman Vetter asked COPR members to put the following tentative dates on their calendars for upcoming meetings:

2004

- April 29–30, with the reminder that a new member orientation must be scheduled on Wednesday, April 28
- October 25–26

2005

- April 21–22 or 28–29
- October 17–18 or 24–25

Ms. Gorman Vetter will check the Director's schedule and get back to all members.

Dr. Mala commended the *Anchorage Native News* to members and said that it contained a picture of COPR. Copies were available.

Dr. Zerhouni called the meeting one of the best and well focused that he had attended. He said COPR has an important role to play, that much rests in its hands, and that he appreciates the time that members give NIH.

The meeting adjourned at 4:28 p.m.
