National Institutes of Health
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U.S. Department of Health & Human Services

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

# COPR Alumni

## CLASS OF 2002

- Michael D. Anderson (Oklahoma)
- Melanie C. Dreher (Iowa)
- Roland McFarland (California)
- Thomas Vaalburg (Michigan)
- Pam Fernandes (Massachusetts)
- Joan Lancaster (Tennessee)

### Michael D. Anderson

Term: 1999–2002
Dr. Anderson was Senior Minister of the Westminster Presbyterian Church in Oklahoma City. Under his leadership, the church became the city's most extensive community-based service organization, working to improve the health and welfare of the local community through outreach to schools, nursing homes, and other community facilities. He is presently serving on the Comprehensive Cancer Research and Treatment Center Committee, to which he was appointed by the Speaker of the House of the Oklahoma legislature. He also serves on the Future of Genetics Symposium Committee of the Presbyterian Health Foundation and the University of Oklahoma Health Sciences Center. He is a co-founding trustee of the Presbyterian Health Foundation, which funds more than 700 programs to improve health and to foster medical research in Oklahoma. Dr. Anderson received his Ph.D. in theology from the University of Edinburgh in Scotland, where his studies focused on the relationship between religion and science. In Oklahoma, his interest in aligning these disparate fields led him to organize an influential series of panel discussions about science and religion. Videotapes of the dialogues have been shown at churches throughout the United States. He also attracted some of the nation's most prominent scientists to Oklahoma for a symposium on DNA, genes, and molecular biology, to which 4,000 of the state's brightest high school students were invited. Convinced that "local and global health concerns are cut from a single fabric of life," Dr. Anderson has worked with the United Nations and other world health organizations to provide free eye exams and medical care in Honduras, to assess the critical needs of hospitals in Africa and China, and to evaluate agricultural programs in Kenya. As a member of the COPR, Dr. Anderson served on the NIH Human Pluripotent Stem Cell Review Group (HPSCRG), which was supervised by the Office of Science and Policy. He is married to Joanna Arneson Anderson, a science teacher. The couple has four daughters and several grandchildren.

### Melanie C. Dreher

Term: 1999–2002
Dr. Dreher is a nurse and an academic medical anthropologist, and she has held faculty and administrative positions as Dean of Nursing at private and public universities in New York, Massachusetts, Florida, and Iowa. She is currently Dean and Professor at the College of Nursing, University of Iowa, and is one of five deans who comprise the academic leadership of the University of Iowa Health Sciences Center. Her research interests have focused on maternal and child health in underserved and vulnerable populations and on the cultural impact of substance use and abuse, particularly in the West Indies and Jamaica. She also advocates for comprehensive health services and high-quality nursing care for the burgeoning rural elderly population in Iowa. Dr. Dreher previously served as President of Sigma Theta Tau International Honor Society for Nursing, which has more than 120,000 active members in 400 chapters worldwide, and she developed projects still used by the society today, including a communication network and the "Nursing Leadership in the 21st Century" project, which serves as a framework for the Society's International Leadership Institute. As the godparent of several children from Jamaica, Dr. Dreher has a personal as well as professional sensitivity to the social and health problems that emerge from cultural pluralism.

### Pam Fernandes

Term: 1999–2002
Ms. Fernandes is an advocate for people with diabetes and a champion tandem bike racer. She has devoted the last eight years to athletic training and achievement, both for the joy it brings her and to inspire others with serious health problems. At the age of four, Ms. Fernandes was the first member of her family to be diagnosed with Type 1 diabetes. Several years later, a brother was diagnosed with Type 1 diabetes, and he eventually died from the disease. Other members of her extended family have also been diagnosed. Because of diabetes, Ms. Fernandes lost her sight when she was 21, spent five years on dialysis to treat diabetes-related complications, and underwent more than 30 operations. In 1987 she had a kidney transplant that changed her life, allowing her to participate more actively in athletics. In 1991 she was encouraged to try tandem bicycle racing. In her first competitive race, Ms. Fernandes and her partner gave it all they had?and finished last. Since then she has been in more than 80 bike races, won national championships every year, and won four international medals. She was named Athlete of the Year for 1994 by the U.S. Olympic Committee. She is a spokesperson for, and was coordinator of, The Hartford's Team Ability, the first corporate-sponsored team of athletes with disabilities, and she helps spread the message that people with disabilities can excel in athletics and other fields. Ms.

Fernandes graduated from Wheelock College in Massachusetts and worked for nine years in community relations for the Massachusetts Association for the Blind and for four years at Hartford Life. In 1997, Ms. Fernandes and her partner rode her tandem bike to the top of Mt. Washington; it was the first time a blind cyclist had reached the summit. Pam recently returned from the 2000 Sydney Paralympic Games, where she and her partner, Al Whaley, raced their way to both a gold and a silver medal. They also set one world record and two Paralympic records. They are the first tandem team from the United States to ever earn a gold medal or set a world record in Paralympic history.

## Joan Lancaster

Term: 1999–2002

Ms. Lancaster lives, works, and volunteers in her hometown of Johnson City, Tennessee, where she focuses on issues affecting underserved and low-income rural Americans, the elderly, and families coping with severe chronic illness. Born and raised in the mountains of East Tennessee, she has a personal and professional understanding of these issues. She and her family are, and have been, coping with chronic life-limiting diseases. She has cared for elderly grandparents and parents in their homes, in her home, and later in nursing homes. Today, as Director of Government Relations at the Mountain States Health Alliance, Ms. Lancaster is a liaison between community health providers and vulnerable people in need of health care. She is assisting her health care system, East Tennessee State University's Division of Health Sciences, the City of Johnson City, the Veterans Administration, and the Public Housing Authority with identifying concentrations of high-risk, chronically ill, and elderly populations in the region as a first step toward selecting sites for new day care centers and health care sites. Two cooperative rural clinics and one in the City of Johnson City have opened to date. As a former regional planning commissioner for the City of Johnson City, Ms. Lancaster sought to expand sustainable job opportunities and to develop new health care initiatives, particularly in the areas of telemedicine, advanced visualization, and biotechnology. She has been involved in the planning and development of the Regional Med-Tech Center, a project that will link the development of health care delivery systems and related research with high technology businesses that serve the health industry and other related businesses. A graduate of East Tennessee State University, Ms. Lancaster has served as a public housing commissioner for the past 17 years. She has also served as a board member of the Children's Advocacy Center, and she currently serves as a public representative on the State Judicial Council. Ms. Lancaster is a sponsor as well as a member of the Steering Committee for the annual Family Re-Union Conference moderated for the past seven years by Vice President Al Gore and his wife, Tipper. This conference is a partnership of The Children, Youth, and Family Consortium of the University of Minnesota and the Child and FamilyPolicy Center at Vanderbilt Institute for Public Policy. This year's topic was Families and Seniors.

## Roland McFarland

Term: 1999–2002

Mr. McFarland is a broadcast executive and veteran in the field of network television programming. In his career, he has reviewed the content of tens of thousands of hours of television programming, assessing its accuracy, appropriateness for various audiences, and potential for positive or negative impact. The experience has given him in-depth understanding of the interface between messages and their intended audiences, the power of the communications media as a vehicle to reflect contemporary society, and the role that broadcasters can play as corporate citizens. Currently as Vice President for Broadcast Standards and Practices at the FOX Broadcasting Company, Mr. McFarland directs a staff of seven executives who review the content of all FOX prime time and late night programming, as well as ongoing comedy and drama development. His analyses influence the portrayal of sensitive and controversial social or public health issues on Beverly Hills 90210, The X-Files, Party of Five, King of the Hill, The Simpsons, Ally McBeal, That 70's Show, Malcolm In the Middle, Boston Public, Dark Angel, and other FOX series seen by millions of Americans. He has a particular interest in promoting insights into serious health problems affecting the African American community, including hypertension, heart disease, high blood pressure, and prostate cancer. A graduate of San Diego State University, McFarland serves on the boards for the San Diego Film Festival, Boys and Girls Club of America, and Chrysalis Foundation for the Homeless. He is former Chairman of the NAACP's National Image Award and Vice President of the National Committee for Youth Opportunity. He was a jury member for the 1999 PRISM Awards, an initiative sponsored jointly by the Entertainment Industries Council and NIH's National Institute on Drug Abuse to recognize and reward the accurate depiction of drug, alcohol, and tobacco use and addiction in television programming and feature films. He is married to Paulette McFarland, a pre-kindergarten Spanish teacher.

## Thomas Vaalburg

Term: 1999–2002

Mr. Vaalburg is a retired health care executive and engineer who contributed to the development and marketing of medical devices, including several heart-lung systems for use in open heart surgery, infusion pump systems, and blood separation devices. Mr. Vaalburg is a graduate of MSG Technical College and of the Instrument Makers School of the University of Leiden in The Netherlands. He began his career as an engineer with a physiology background and held progressively more responsible positions over the years, which culminated in his appointment as Research and Development Manager and later as Business Development Manager for 3M Health Care. In these capacities, he represented 3M on the NIH Artificial Heart Program Contract, working in collaboration with Pennsylvania State University. His business development experience included the evaluation of technologies and businesses resulting in several acquisitions made by 3M.

In addition to his technological and business expertise, Mr. Vaalburg has a strong interest in nursing care and has served on the Nursing Research Advisory Board of the University of Michigan, helping to refine the overall research agenda for the School of Nursing. He has also served on the Advisory Board of the Ann Arbor Community Dental Center, which provides care for needy families and individuals. In retirement, Mr. Vaalburg remains active in community services at Holland Family Hope Ministries in Holland, Michigan, which is a faith-based organization serving the needy. He teaches personal and family finances at this organization. He is also involved with consultant work in the health care field.

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DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

# April 15, 2002 Meeting Minutes

The Council of Public Representatives (COPR) convened its seventh meeting at the National Institutes of Health (NIH) campus in Bethesda, Maryland, at 8:30 a.m., on Monday, April 15, 2002. The meeting was open to the public. Dr. Ruth Kirschstein, Chair of COPR and Acting Director of NIH, presided.

## NIH DIRECTOR'S REPORT

**Ruth Kirschstein, M.D.**

Dr. Kirschstein opened the meeting by welcoming several new COPR members:

- Nancye Buelow, Clyde, North Carolina
- Debra Hall, Ph.D. (c), Lexington, Kentucky
- Kimberley Hinton, Kansas City, Missouri
- Ted Mala, M.D., M.P.H., Anchorage, Alaska
- Lawrence Sadwin, Warren, Rhode Island
- Zelda Tetenbaum, M.S., Hinsdale, Illinois

New member Donald Tykeson, of Tykeson Associates, Eugene, Oregon, joined the group by teleconference. New member, John Shlofrock, of Barton Management, Northfield, Illinois, was unable to be present.

Dr. Kirschstein informed the participants of several changes that had occurred since the last meeting. On December 6, 2001, President Bush announced the nomination of Andrew von Eschenbach, M.D., as Director of the National Cancer Institute (NCI). Before coming to the NIH, Dr. Eschenbach, a nationally recognized urologic surgeon, was at the M.D. Anderson Cancer Center in Houston, Texas. Dr. Kirschstein expressed the hope that Dr. Eschenbach would join a future meeting of the COPR.

Dr. Kirschstein also informed those present of the nomination of Elias A. Zerhouni, M.D., as the new Director of NIH. Dr. Zerhouni is currently Chair of the Department of Radiology and Associate Dean at Johns Hopkins Medical School in Baltimore, Maryland.

Other changes include the departure of some members of the NIH office staff, including Sue Quantius, Director of Budget, who is leaving to work on Capitol Hill with the House Subcommittee on Appropriations for Labor and Health and Human Services. Anne Thomas, Associate Director of Communications and the Executive Secretary of COPR, is leaving the NIH to join the Sloan-Kettering Memorial Cancer Center at the end of April.

Also leaving the NIH for other positions are the directors of five of the Institutes: the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the National Institute of General Medical Sciences (NIGMS), the National Institute of Mental Health (NIMH), and the National Institute of Neurological Disorders and Stroke (NINDS). Search committees have been formed to find replacements for these positions. In addition, the director of the newest Institute, NIBIB, is expected to be announced in the very near future. Dr. Kirschstein said that the new Institute has just awarded its first research grants to Yale University School of Medicine; the University of California at San Francisco; and Tribofilms Research, Inc., in Raleigh, North Carolina.

Dr. Kirschstein briefed the meeting attendees on the President's $27.4 billion budget proposal for 2003, which emphasizes cancer, biodefense, and clinical research. The portion of the budget for cancer research will be increased to $5.5 billion. Dr. Kirschstein reported that 80% of this amount, or $4.7 billion, will go to the National Cancer Institute (NCI), and the remainder will be allocated to other Institutes that also contribute to cancer research.

Funding was announced in August 2001 for the National Center on Minority Health and Health Disparities (NCMHD) program for clinical research loan repayment for medical students. A portion of the FY 2002 budget has been carved out for 250 slots for students who are in the end stages of their medical training and are beginning to move into careers in research. Because clinical trials have become more wide ranging, more representative of the population, and much larger, additional emphasis will be placed on clinical trials in FY 2003. The Loan Repayment Program will be expanded from the initial 250 slots to 500 slots, and $23 million over the 2002 estimate will be provided.

The 2003 budget proposal represents the final installment of the increase promised by Congress and fulfilled by the President, in which the NIH budget was to be doubled over 5 years. Dr. Kirschstein said that this increase will enable the NIH to take advantage of the broader and deeper opportunities to understand disease and improve health and opens the way for continued future progress.

Dr. Kirschstein provided the group with an update on developments in the registry for stem cell research. The NIH has created the Human Embryonic Stem Cell Registry, which allows scientists to apply for grants under the stipulation of the policies announced by President Bush in August 2001. Supplemental funding has

begun to be awarded to researchers who are already engaged in work in this area to enable them to expand their work. In April 2002, the NIH signed a memorandum of understanding with ES Cell International of Singapore and Melbourne, Australia, for research use of six existing stem cell lines that meet the President's criteria. This agreement is the federal government's first international agreement involving the distribution of human stem cell lines. Scientists at the NIH and elsewhere will have access to these cell lines to explore new areas of research in this emerging field of technology. In compliance with the NIH guidelines for the transfer of research materials, this agreement permits NIH scientists to freely publish the results of their research. The NIH will retain its ownership of any new intellectual property that might arise from the conduct of research in this area. The NIH will provide grants to public and private organizations to enhance the growth of these cell lines so that they will eventually become more widely available to researchers.

## RECOGNITION OF R. ANNE THOMAS

**Isaac Montoya, Ph.D. and Debra Lappin, J.D.**

Dr. Isaac Montoya and Ms. Debra Lappin presented a plaque on behalf of all COPR members to Ms. R. Anne Thomas in recognition and appreciation of Ms. Thomas's contribution to COPR. Ms. Lappin read the plaque aloud to those present:

The members of the National Institutes of Health's Council of Public Representatives recognize and thank R. Anne Thomas for her exemplary support, wisdom, and guidance.

In 1999, Ms. Thomas was instrumental in the establishment of COPR. In the years that have followed, Ms. Thomas has continued to guide the development of COPR with an ever-steady and trusted hand. Ms. Thomas has nurtured the COPR through its infancy, prompted the COPR to mature and to develop its unique culture, and ensured that COPR assumes a position of lasting prominence within the National Institutes of Health.

For these many efforts, and for countless hours of service, the members of COPR, past and current, thank and salute R. Anne Thomas.

*Presented this 16th day of April, 2002.*

Ms. Thomas expressed her gratitude in response to this recognition, noting the great progress that the Council has made since its inception. She noted that COPR began as an experiment whose original members and staff charted new ground. She expressed her appreciation for the members' recognition of her efforts and her confidence that the group will continue to evolve and grow in her absence.

## REPORT ON BIODEFENSE RESEARCH

**Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases**

Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), reported on biodefense research supported by the NIH. He began his presentation by elucidating the distinction between biowarfare and bioterrorism, a distinction which is important in informing the NIH research agenda. He pointed out that the U.S. military has been involved in the defense against biowarfare for many decades, dealing with a homogeneous population of healthy men and women in the Armed Forces. In contrast, bioterrorism must be defended against in the civilian population, which is much more broadly varied in age and health status. Whereas defending against biowarfare focuses mostly on vaccines, the complexity of protecting against bioterrorism entails the development and use of diagnostics and therapeutics as well as vaccines. Dr. Fauci further pointed out that, whereas the agents used in biowarfare are intended to be efficiently lethal both tactically and strategically, those used in terrorist acts have only to disrupt the population to achieve the perpetrators' ends.

Dr. Fauci presented a list of potential bioterror agents classified as "Category A" by the Centers for Disease Control and Prevention (CDC). The agents given top priority in this list are smallpox, anthrax, plague, botulism, tularemia, and the hemorrhagic fever viruses, including Ebola virus. Dr. Fauci mentioned that this list was developed prior to the attacks of September 11. He then presented some results from studies of the 11 cases of inhalational anthrax that occurred in the fall of 2001 and reviewed some of the lessons learned from those cases. For instance, inhalational anthrax was found not to be universally fatal, as had previously been thought. Individuals who were treated early for inhalational anthrax in the fall of 2001, he said, had a fairly high survival rate. In addition, much was learned about the chain of vulnerability with regard to an anthrax attack.

Dr. Fauci also described the depth and breadth of the problem that occurred with the anthrax infections in fall 2001. He noted that the attacks overall had a minimal biological effect but a major disruptive societal effect in terms of closings of facilities, millions of dollars spent on clean-ups, and ongoing anxieties and concerns about contamination.

Dr. Fauci next discussed smallpox, a historically important disease that was eventually eradicated from the world population as a result of concerted public health efforts. The last reported case of smallpox in the United States was in 1949. In 1971, the last case was reported in the Americas, in Brazil, and routine vaccinations for smallpox were discontinued in 1972. The last endemic smallpox case in the world occurred in Somalia in 1977, and two accidental cases occurred in England in 1978. In 1980, smallpox was declared to have been globally eradicated. Although samples of the virus do exist and are kept under guard at the CDC and in Russia, it is also clear that large amounts of smallpox were produced as bioweapons by the Soviet Union during the 1970s and early 1980s. These latter stocks of smallpox were supposed to have been destroyed after the collapse of the Soviet Union. However, it is possible that samples from these stocks were obtained by individuals and organizations that might use them for nefarious purposes.

Dr. Fauci spoke of the public protection strategies against bioterrorism currently being developed by various agencies of the Department of Health and Human Services, including the NIH. The portion of the NIH budget that is allocated to protection against bioterrorism was increased in the FY 2003 President's Budget by $1.5 billion, which represents the largest single-year increase in NIH history of any discipline or institute. Dr. Fauci noted that this increased funding confers increased responsibility to use this resource responsibly and well, to develop concrete products and milestones, and to extend capabilities in the overall arena of public health, emerging diseases, and other potential threats.

Dr. Fauci indicated that the NIAID has developed a strategic plan that is based on two primary areas of research. The first of these is basic research into microbes with the potential for use as bioterrorism agents and into the specific and nonspecific host defense mechanisms against these agents. The second area is applied and translational research with predetermined milestones and the ultimate production of new and improved diagnostics, vaccines, and therapies. In addition, plans include the expansion of biodefense research capabilities extramurally, on the NIH campus, and at the Institute's Rocky Mountain Laboratories in Hamilton, Montana. In addition, Centers of Excellence for Biodefense and Emerging Diseases Research will be established throughout the country.

Dr. Fauci closed by saying that concerns about infectious disease epidemics go beyond the deliberate propagation of threats by humans. Stating that "nature might be seen as the worst 'terrorist,'" he cited naturally occurring diseases such as West Nile virus, hantavirus, and resistant strains of tuberculosis and staphylococcus as important targets of research. He expressed the hope that the research now being directed to bioterrorism might prove beneficial in the future, not only for the public's protection but also in furthering knowledge about naturally occurring diseases as well as those intentionally perpetrated on the public.

*Questions and Answers*

Mr. Bob Roehr made the observation that, at the outset of the AIDS epidemic, it was difficult to recruit new researchers into the field of HIV research until they could be assured that funding for this research would continue and could sustain them in their careers. He asked Dr. Fauci whether a similar problem was being found in the field of bioterrorism research. Dr. Fauci replied that the research agenda of the NIH expanded and evolved along with the evolution of the AIDS problem and that he anticipated that this same process would be seen in the area of bioterrorism research.

In response to a question from Dr. Ellen Grant Bishop about the timeline for completion of the strategic plan, Dr. Fauci responded that it has been completed and that efforts are now under way to incorporate the contributions of other NIH Institutes. The plan has been presented to at least three Congressional committees thus far, to the National Academy of Sciences, and to the Institute of Medicine.

Responding to a question from Dr. Ted Mala, Dr. Fauci described plans to strengthen the infrastructure of public health in addition to developing vaccines. He described the approach to addressing bioterrorism as, first, surveillance by the CDC; second, the local and state public health infrastructure; and third, research and development for vaccines, diagnostics, and therapeutics.

Dr. Isaac Montoya raised the question of what was being done on the behavioral side of bioterrorism. Dr. Fauci replied by acknowledging the distinction between the biological and the psychological effects of bioterrorist activities. As an example, the anthrax incidents in the fall of 2001 had, in relation to the U.S. population as a whole, only a very minor biological effect in that they did not affect large segments of the general population, but had far greater-reaching psychological impacts in terms of causing fear and concern. Dr. Fauci said that the National Institutes of Mental Health will be an important part of the strategic plan.

Ms. Zelda Tetenbaum asked about the existence of mechanisms or plans to recognize a microorganism before a bioterrorist event occurs. Dr. Fauci replied that the NIH's aim is to reduce the time it takes to identify an organism and to determine its microbial sensitivity from the current time, which is measured in weeks, to days, and ideally to less than 24 hours.

## COPR DISCUSSION

**COPR Members and Dr. Kirschstein**

Mr. Doug Yee told the group about a visit made by Dr. Yvonne Maddox, Acting Deputy Director of NIH, to Hawaii in November 2001. During her visit, Dr. Maddox paid an impromptu visit to Ms. Tsuda's fourth-grade class in Honolulu and subsequently arranged for each of the NIH Institutes to send a box of educational materials and supplies to the class each month. In response, the class sent to Dr. Maddox's office a photograph of the students at the elementary school.

COPR members discussed the various educational efforts at the NIH, which include visits by faculty and staff to schools in the Washington metropolitan area to give lectures and presentations. Dr. Kirschstein mentioned that the Advisory Committee to the Director will meet in June and will include a session on science education. As a pilot for a program on science education by the National Center for Research Resources, students from the CityLab School in Boston will visit the NIH campus. CityLab is a biotechnology learning laboratory for students and teachers at the Boston University School of Medicine. The school is supported by NIH's Science Education Partnership Award program and the Howard Hughes Medical Institute. During their visit, CityLab students will make presentations and receive Presidential Career Awards.

Dr. Montoya talked about the success of two ongoing health education programs from the National Institute on Deafness and Other Communication Disorders (NIDCD). The Wise Ears Program comprises a coalition of 85 national organizations that includes teachers, students, industry, voluntary organizations, the Girl Scouts of America, the American Association of Retired Persons (AARP), 4-H, and others in all 50 states. The program's objective is to increase awareness of hearing loss and related issues through education and focus groups. Focus groups were recently held in West Virginia, North Dakota, and Houston, Texas. Materials are now available in Spanish, and articles about the program are appearing in local newspapers and other media. The health education campaign aims to test newborns and to educate parents about the importance of testing at birth. The community response to these programs, said Dr. Montoya, has been extremely positive.

Dr. Kirschstein reiterated the importance of programs such as the ones described by Dr. Montoya in bringing research findings "from the bench to the bedside." The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies has allowed the NIH to hold four theme meetings each year, one of which will focus on translational research. The committee's chairman, Rep. Ralph Regula (R-OH), and its ranking minority member, Rep. David Obey (D-WI), will travel to each other's congressional districts to lead town hall meetings in which NIH staff will present activities for a day.

Dr. James Battey, Jr., Director of NIDCD, reported that the efforts described by Dr. Montoya were primarily the work of Dr. Marin Allen, who has also developed an initiative with the Office of Science Education to provide curricula for middle-school students on the connection among the auditory system, language, and cognition. Dr. Battey said that the connection among these systems defines what the Institute views as hearing impairment, which is ultimately a communication disorder.

Mr. Roehr thanked the NIH for assisting with the conference of the Association of Health Care Journalists held recently in Bethesda, Maryland. Dr. Fauci gave his presentation on bioterrorism at the conference, and the National Cancer Institute (NCI) held a day-long workshop on cancer issues that was very well attended. Dr. Barry Kramer of the NIH Office of Medical Applications of Research conducted some educational programs for journalists to help them understand how to evaluate the results of clinical trials. A number of NIH staff from other Institutes participated in other sessions. Mr. Roehr expressed appreciation to the NIH for its help in better communicating to the American public some of the work that science in general, and NIH in particular, is doing.

Ms. Rosemary Quigley thanked COPR staff for providing more background materials for the current meeting, as requested at the last COPR meeting. She praised the way in which staff compiled useful information for COPR members on health disparities, research priorities, and materials from the Institute of Medicine and the President's Cancer panel report, which she said helped the members before the meeting to start thinking about the issues to be addressed.

Mr. Yee asked about the appropriateness of having a COPR member represent NIH at certain functions, such as the awarding of grants. Dr. Kirschstein advised the members that in cases deemed to be of sufficient importance, the Secretary of the Department of Health and Human Services (DHHS) may be accorded the privilege of making such announcements. In addition, the U.S. Congressperson or Senator in whose district the university or academic institution is located may wish to make such an announcement. Dr. Kirschstein said that Mr. Yee's question would be taken under advisement and that, if COPR members do represent the NIH in this regard, a number of issues would have to be considered. For example, the COPR member would have to be considered a special employee of NIH for the day and to abide by the restrictions that this status confers.

Ms. Quigley asked Dr. Kirschstein about the plans for centralizing communications within the DHHS. Dr. Kirschstein answered that DHHS Secretary Tommy Thompson has a very strong interest in having the DHHS speak with one voice and has decided to restructure and centralize a number of activities, particularly in regard to the media in certain policy issues. Dr. Kirschstein said that, along with the DHHS, the NIH believes firmly that communication to the public about health and science should be closely associated with the scientists who have direct oversight over the scientific and health matters in question. The DHHS has been working closely with the NIH, and this issue is still under ongoing discussion.

Dr. Montoya acknowledged Glen Hanson, Acting Director of the National Institute on Drug Abuse (NIDA), for his role in procuring funding for a fellowship on writing grant applications. Under the program, six faculty members from New Mexico State University will be sent to Houston for the summer of 2002 to learn how to prepare grant applications. Dr. Kirschstein noted that many of the other Institutes are also involved in similar summer activities. As an example, she described a special program to work with universities in 23 states and the Commonwealth of Puerto Rico that receive little or none of the funds appropriated to NIH. Under one of these programs, the Biomedical Research Infrastructure Network, a total of $48 million will be divided up equally among these 23 states and Puerto Rico over 3 years to form consortia of community colleges, professional schools, medical schools, colleges of arts and sciences, and other institutions of higher learning. These consortia will develop planning grants to identify activities that can be developed into pilot programs. The first awards were made in FY 2002, and the 2003 budget will be enhanced in this area.

## THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

**Kenneth Olden, Ph.D., Director**

Dr. Kenneth Olden, Director of the National Institute of Environmental Health Sciences (NIEHS), gave a presentation entitled "The Complex Relationship Between Poverty, Pollution, and Health Status." He described a public health or societal approach to reducing morbidity and mortality in which environmental and societal factors are evaluated for their contribution to disease.

Dr. Olden began by making the case that three factors primarily account for the occurrence of disease: genetics, environment, and behavior. To prevent disease, one must understand the contributions of and interplay among all three of these factors. Genetics alone, for example, does not sufficiently account for the emergence of disease: a person can inherit a predisposition to a disease but never contract it if one is never exposed to the environmental conditions that trigger it.

The NIEHS defines "environment" in broad terms as not only the chemical, physical, and biological agents to which people are exposed but also as social, economic, and behavioral factors. Dr. Olden said that one of the most important functions of any government is to protect the health of its people by preventing illness and improving the quality of life. In this regard, he listed some examples of NIEHS grantees whose work has made important contributions to fundamental science as well as the diagnosis and treatment of disease. NIEHS grantees have made many important discoveries in cell communication and signaling, oxidative stress, DNA repair, and advances in the neurosciences, developmental biology, and genetics. A former scientific director of NIEHS was awarded the Nobel prize for work in signal transduction. A team of researchers isolated the first breast cancer gene, BRCA-1, in 1994. Another investigator at NIEHS developed important animal models (estrogen receptor knockout mice, which lack three estrogen receptor genes) for studying breast cancer.

In addition to supporting basic research, the Institute emphasizes public health. The field of environmental science grew out of public health, and both fields focus mainly on populations. The field of environmental science in general, and the Institute in particular, have made some important contributions to environmental policy in recent years. Dr. Olden presented several "success stories" of legislation enacted on the basis of NIEHS-supported scientific findings concerning health hazards among economically disadvantaged communities.

A recent debate concerning a proposed amendment to the Clean Air Act focuses on the regulation of exposure to 2.5-micron particulates. The bulk of the research on which this legislation was proposed was supported by the NIEHS. A recent study published in JAMA confirmed findings that 2.5-micron particulates cause lung cancer.

The NIEHS also supported research that was the basis for a recent, highly publicized decision to remove polychlorinated biphenyls (PCBs) from the bed of the Hudson River in New York. The research showed that PCBs in the riverbed were not turning over at the rate that had been predicted by previous laboratory studies. As a result, PCBs were accumulating in the food chain and were being passed along to people eating fish caught from the river. These findings encouraged the federal government to remove the PCBs from the riverbed.

The federal government also recently decided to support a reduction of arsenic in drinking water from 50 parts per billion (ppb) to 10 ppb. This decision was also based on research supported by NIEHS.

Despite remarkable improvements in environmental quality over the past several decades, massive quantities of toxic agents remain in the environment. These include chemical and physical agents that cause cancer, Alzheimer and Parkinson diseases, asthma, osteoporosis, juvenile diabetes, and immune and nervous system impairment. Whether, and in what proportion, these agents contribute significantly to the burden of disease is one of the challenges confronting the NIH.

The concept of "environmental justice" was introduced in the 1980s to explain the disproportionate burden of disease and death that is seen among socioeconomically disadvantaged populations and racial and ethnic minorities. Although the relationship among poverty, pollution, and health status is generally unknown, it is clear that poor and minority communities have higher exposure to environmental health hazards and therefore are at increased risk for diseases.

In the 1970s and 1980s, there was little evidence that living and working in a polluted environment caused disease. The only case in which evidence was clear was that of lead poisoning, which was more common among children in poor, urban environments where lead paint had been used in residential environments. Today it is clearer that certain environmental exposures lead to disease. For example, exposure to beryllium and asbestos in the construction industry have been found to lead to lung disease. Another disease emerging as an environmental justice issue is asthma, which is directly related to living in inner-city, highly polluted urban neighborhoods.

The development of effective environmental justice programs requires the involvement of informed consumers, who are the stakeholders in this issue. To that end, the NIEHS uses a citizen-based priority-setting process in developing its priorities, sponsoring brainstorming sessions and town hall meetings in various locations across the United States. These meetings are attended by local, state, and county health officials; public interest groups; U.S. Senators and Congresspersons; members of the lay public; and personnel from the regional offices of federal agencies such as the Agency for Toxic Substances and Disease Registry, the NIH, and the Environmental Protection Agency.

In addition to the citizen-based approach to priority setting, the NIEHS has also developed community-based prevention/intervention programs that provide accurate information to enable members of the public to make informed decisions about their health. Whereas prevention/intervention programs are typically imposed on communities by researchers and government agencies without citizen buy-in, programs developed with citizen participation are almost always more effective in achieving desired behavioral modifications. To reconcile differences of opinion between scientists and members of communities about the appropriate goals for research related to environmental pollution, poverty, and health disparities, the NIEHS insists on the active participation of community members in the design, conduct, and translation of research. This approach helps to ensure that the community perspective is incorporated.

An example of this philosophy of community inclusion can be seen in an NIEHS-supported center at the University of California at Davis, which conducted a program to monitor workers for pesticide toxicity. Researchers there discovered serious flaws in the assay used to monitor levels of acetylcholinesterase in the blood, the marker used to measure pesticide exposure. Scientists worked with state regulators to develop a more accurate assay to protect the health of farm workers. A grantee at the University of California, Los Angeles, demonstrated that an open-air dump site consisting of concrete and asphalt debris and ground glass was causing episodes of asthma, other respiratory problems, and nosebleeds. These findings were used to convince the City Council to remove the debris and remediate the site.

The ultimate goals of community-based research are to reduce morbidity and mortality and health care costs, enhance productivity, increase employment opportunities, and strengthen community infrastructures to address public health problems as well as other issues affecting the community by translating research into public policy. Community-based research is supported by two major grants from the NIEHS. Environmental Partnerships for Communication stimulates community outreach training and education, linking community members, health care providers, and scientists to ensure that the community remains informed and aware of environmental health concepts. Community-Based Prevention/Intervention Research aims to advance the design of prevention and intervention methods to develop community-based public health research approaches. The NIEHS also supports community outreach workshops with the Conference of Chief Justices of the United States to acquaint them with current concepts in genomics and environmental sciences.

Dr. Olden listed the critical principles of community-based research, which include promoting the development of prevention/intervention methodology, developing community-based public health research approaches, bridging gaps between basic and clinical researchers and between researchers and community members, and promoting research that is culturally relevant and responsive to the community. Community-based research, he said, must recognize the community as a geographically confined group of people who share values, common interests, and needs and must acknowledge and use the strengths and resources within the community.

Dr. Olden said that he would argue that we have a responsibility to engage in research to reduce inequities in health outcomes. He said that the views of identified subgroups, such as the poor, minorities, seniors, children, women, men, and residents of particular communities, deserve special attention as the nation establishes its priorities in research, public health policy, and other matters. The interaction between proponents of the community perspective and the scientific perspective has led to an awareness of a common purpose and shared objectives and provides a means for scientists to demonstrate that they are members of the community. Dr. Olden cautioned against the substitution of advocacy for science, however. Exciting new innovations in biomedical research and their potential to cure disease and revolutionize the practice of medicine also raises concerns that the gap between the rich and the poor with respect to health status will grow wider.

In closing, Dr. Olden pointed out that if prevention/intervention programs do not result in behavioral change or reductions in morbidity and mortality, then they cannot be considered successful. He said that the goals of the NIEHS's community-based research are measured in terms of public health improvement. What is needed is a revaluing of public health in which field science, laboratory research, and sociological disciplines are brought together to improve our understanding of how to control disease.

*Questions and Answers*

In a lengthy question-and-answer discussion following his presentation, Dr. Olden responded to questions from COPR members on a wide array of environmental

health issues, including lead poisoning, environmental molds and asthma, and agricultural trauma (i.e., injury from farm machinery), briefly describing the Institute's activities in these areas. Other topics discussed included privacy and confidentiality issues in employment, recruitment of underprivileged populations in environmental health research, and exposure to antibiotics used in livestock and antibiotic resistance.

In response to comments and questions from the group, Dr. Olden also described community outreach efforts to work with grassroots organizations in communities, churches, and other local organizations. He alluded to the Institute's town hall meetings, whose aim is to make community leaders aware of environmental health issues.

## NIH RESPONSE TO THE COPR REPORT ON HUMAN RESEARCH PROTECTIONS

**Wendy Baldwin, Ph.D., Deputy Director for Extramural Research**

Dr. Baldwin presented the preliminary response from NIH to the report of the COPR Working Group on Human Research Protections. She said that the report was obviously the product of careful deliberations of the working group and that she appreciated the analysis of the issues in the report. She described ongoing activities and programs at the NIH that relate to many of the concerns outlined in the report.

Regarding the report's recommendation that Institutional Review Boards (IRBs) have some sense of the research literature in a particular area of science, Dr. Baldwin said that until recently this ability was handicapped by the fact that the National Library of Medicine's (NLM's) Medline database contained records dating back only as far as 1966. She reported that the NLM will soon expand the database to include articles back to 1956. She acknowledged that IRBs are under a great deal of stress and are overburdened and that the NIH is looking at ways to address this problem.

In relation to issues of confidentiality and privacy elucidated in the report, Dr. Baldwin said that safeguarding the confidentiality of research subjects is a top priority of the NIH. She pointed out that, to comply with the Health Insurance Portability and Accountability Act (HIPAA), research institutions and investigators must not only abide by privacy rules but must also safeguard the actual physical processes used to keep data secure. In the matter of confidentiality, Dr. Baldwin informed the group that the NIH has recently taken steps to help investigators understand the appropriate use of certificates of confidentiality, which prohibit the forced release of confidential information in court cases. She also alluded to an amendment to the Treasury Postal Bill by Senator Richard Shelby (R-AL) that applies the rules of the Freedom of Information Act to data collected under grants. The DHHS has prepared a Notice of Proposed Rulemaking (NPRM) that will modify certain standards in the final Privacy Rule that was published in December 2000. The NPRM was published in the Federal Register in March 2002 and called for a 30-day comment period, during which time COPR has an opportunity to provide input to the DHHS. Dr. Baldwin pointed out that confidentiality and data sharing are not necessarily at odds with one another and that the NIH has been focusing on both of these issues in order to allow researchers to gain access to data when this is appropriate while still protecting the confidentiality of subjects.

Oversight of adverse events in clinical trials, said Dr. Baldwin, can be complicated because of the different ways in which these events can be defined and reported. She pointed out that, because different legislative frameworks guide different government agencies, such as the NIH, the Food and Drug Administration (FDA), and the Veterans Administration, it will take time to find appropriate common ground among these potentially conflicting perspectives. She said that in some cases it is difficult or impossible to interpret an adverse event within the context of a study. She said that part of the challenge regarding this issue is the need for very specific and sophisticated skills in interpreting adverse events, skills that are now more likely found on DSMBs (Data Safety Monitoring Boards) than on an IRB.

Concerning the issues surrounding conflicts of interest raised in the report, Dr. Baldwin acknowledged that this topic has generated a great deal of interest in recent years. Regulations governing conflicts of interest have been in place for extramural investigators at the NIH since 1995. Discussions are progressing on the issue of institutional conflicts of interest, which are far more difficult to address than individual conflicts. At the end of September, NIH's Office of Extramural Research will convene a meeting on financial conflicts of interest. Included in that meeting will be policy statements on this issue from the American Association of Medical Colleges and the American Association of Universities. Dr. Baldwin extended an invitation for interested COPR members to attend that meeting. In addition, the General Accounting Office has surveyed five institutions on their adherence to regulations concerning conflicts of interest. In response to an article appearing in the New England Journal of Medicine reporting that 15 institutions receiving NIH funds had no conflict of interest policies in place, an additional Federal review found that in 299 of the 300 reviewed institutions did have such policies.

Dr. Baldwin told the group that the NIH shares COPR's concerns about communicating with the larger community about the NIH's expectations of investigators, participants, and others involved in clinical research. She observed that many of the report's recommendations did not necessarily require new policies or a new understanding of informed consent so much as they called for ensuring adequate communication of policies and principles that are already in place at the NIH. She said that the issue of communicating to the public was a topic at last year's leadership forum and that the NIH shares the working group's concerns in this regard.

Dr. Baldwin reported that the National Center for Research Resources has instituted a research subject advocacy program with their general clinical research centers. Each of the centers is funding a full-time employee to assist research subjects in gaining access to resources to help them understand issues concerning participation in clinical trials. In addition, the NIH's Human Subjects Research Enhancement Award is a 1-year program that provides funds to institutions to help them improve their human subject protection activities. The program is available to the 174 institutions that are responsible for 90% of NIH's clinical research; awards will be made later this year. Some of the possible uses of this funding by the institutions include educational programs for IRB members, investigators, or community members on human subject protections; data systems for adverse event reporting; and developing an infrastructure for data safety monitoring activities. Also written into the Request for Application (RFA) is encouragement for larger institutions to form partnerships with smaller institutions to work together on these issues.

Dr. Baldwin told COPR members that the working group's report was very helpful in focusing on the public perspective. She referred to the letter of March 26, 2002, from Dr. Kirschstein, for more detailed responses to the specific issues raised in the report.

*Questions and Answers*

Dr. Bishop asked about the progress of plans to finalize the HIPAA Privacy Rule referred to by Dr. Baldwin. Her question was fielded by Dr. Lana Skirboll, Associate Director for Science Policy, who informed the group that the NPRM was released on March 27 with a 30-day period for comments. She said that the DHHS will then respond to those comments and will issue a final rule as soon as is feasible, depending on the volume of comments received. The compliance date of April 13th will remain the same. Dr. Skirboll also said that a large portion of the NPRM addresses changes to research that are significant in helping both research participants as well as investigators and institutions to implement the Privacy Rule with regard to research. Although the NIH will be central to the DHHS's efforts, it will not be central to efforts to implement the rule with regard to the delivery of health care. Ms. Julie Kaneshiro of the Office for Human Research Protections (OHRP) added that OHRP is also very concerned about the rule and how it will interact with existing OHRP and FDA regulations governing human research subject protections.

Ms. Lappin commented on the current dynamic in voluntary health agencies between the interests of researchers and the privacy concerns of participants. She said that this issue is a major one in these agencies concerning whether the National Health Council would respond on their behalf in order to avoid competing interests.

Having served as chair of the Working Group on Human Research Protections, Ms. Lappin continued by thanking Dr. Kirschstein and Dr. Baldwin for their interesting and thoughtful response to the working group's report. She said that the fundamental question underlying the report concerns whether the view of the participant in research can be elevated in some meaningful way over the course of the next few years. She said that the report's central purpose was to ask the NIH how this issue can be made paramount in its overarching mission. Ms. Lappin asked that the three main suggestions concerning conflict of interest in the report be incorporated into the plans for the September conference mentioned by Dr. Baldwin.

The overarching premise of the report, said Ms. Lappin, is that a cultural change must take place within institutions concerning human research protections. This point was taken up by the group in a discussion of effective ways in which to communicate with research participants. Also discussed was the report's suggestion that clinical trial participants have clear and direct access to whatever level of information is desired, as opposed to overly burdening the consent process. Some of the Institutes' activities in this area, such as the NCI's videos on clinical trials, were acknowledged. Regarding these videos, Dr. Baldwin observed that many of the Institutes have developed various ways in which to present information in this area, although they may not be shared as broadly or as uniformly as they could be.

Finally, Mr. Roehr raised the point that the use of the term subject in referring to those who participate in clinical trials is indicative of an aspect of the current cultural climate within institutions that he said must change if the premise of the report is to be fulfilled. COPR members discussed the ways in which various terms to describe research participants, such as patient and subject, reflect attitudes about and perspectives on research participants and the nature of their roles in clinical trials.

## THE NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES

**John Ruffin, Ph.D., Director**

Dr. John Ruffin, Director of the National Center on Minority Health and Health Disparities (NCMHD), described the Center's operations in accordance with Public Law 106-525 (PL 106-525), which established the Center under the Minority Health and Health Disparities Research and Education Act of 2000. Throughout his presentation, Dr. Ruffin emphasized that all of the details he presented concerning the structure and functions of the NCMHD are set forth in the public law that established the Center.

PL 106-525 established the purpose of the NCMHD to conduct and support research and training activities, disseminate research-based health information, and develop other relevant programs related to minority health conditions and other populations with health disparities. Target groups for these activities are racial and ethnic minorities, the medically underserved, and other groups with health disparities. The law defines "other health disparity populations" as "any group exhibiting significant disparities in the overall rate of disease compared to the general population, based on incidence and prevalence, morbidity and mortality, and survival rates."

The overarching mission of the NCMHD is to conduct basic, clinical, and behavioral research on minority health conditions. The responsibilities of the Center Director are to coordinate all NIH health disparities research, represent NIH on relevant Executive Branch task forces and committee planning activities, and work with other federal agencies to transmit research-based health information to relevant constituents. In consultation with the Director of NIH and the directors of NIH Institutes and Centers, the director also must establish a comprehensive strategic research plan and budget no later than 12 months after the enactment of P.L. 106-525, prioritize authorized health disparity activities, ensure that all appropriated health disparities funds are expended in accordance with the plan and budget, and ensure that the plan and budget are reviewed annually and revised as appropriate.

The comprehensive research plan must promote coordination and collaboration among the NIH Institutes and Centers, ensure their participation, and serve as a binding statement of policies. The Center Director must ensure that the plan provides for basic and applied research, including product research and development as well as behavioral and social sciences research (which includes cultural and linguistic research). The strategic plan is currently under review by the Director of NIH.

PL 106-525 also provides for the establishment of an NCMHD Advisory Council. Criteria for membership in the Council are expertise in minority health disparities and other disparity issues as well as membership in communities affected by disparities in health. Council members are to advise on strategic plan development, budget allocations, and center programs; review Center reports prior to their submission to the NIH Director; and provide a second-level review function. The Advisory Council membership slate is currently at the DHHS for approval, and it is hoped that the council's first meeting will take place in June.

When the NCMHD was the Office of Research on Minority Health (ORMH), the primary constituencies served by that office were racial and ethnic minorities. With the new Center, however, this constituency base has broadened to include all medically underserved populations, including whites in poor, rural areas. Another change from the ORMH is that the new Center has the authority to make grants, whereas formerly the ORMH transferred funds to the various Institutes and Centers, which in turn made awards.

New initiatives provided for in PL 106-525 include authorization to develop Centers of Excellence in Research Training, whose purpose is to support biomedical and behavioral research training for members of health disparity populations. Participating institutions must have a record of recruiting, enrolling, and graduating students from health disparity populations and of recruiting minority and other health disparity populations for faculty and administrative positions. Institutions that do not meet these criteria can still participate by forming partnerships with other institutions that meet the criteria.

Funds awarded to establish the Centers of Excellence can be used to train members of health disparity populations as professionals in biomedical and behavioral research. They can also be used to expand and alter existing facilities or to construct new facilities to conduct research on minority and health disparity populations. In addition, funds may be used to establish research endowments at the discretion of the NCMHD Director.

The Centers of Excellence program was launched in the spring of 2001. Four technical assistance workshops have been held thus far, in Morgantown, West Virginia; Dallas, Texas; Birmingham, Alabama; and Seattle, Washington. Three different award mechanisms (R24, P20, and P16) are being used to obtain the broadest possible participation.

The Research Endowment Program is a new initiative whose purpose is to facilitate research on minority and other health disparity populations at institutions with currently funded Programs of Excellence, under section 736 of the PHS Act, in health professions education for underrepresented minority individuals. Eligible institutions are non-research-intensive institutions with endowment investments below the ceiling established in PL 106-525. The idea behind this program is to provide additional endowments to those institutions with small current endowment capacities. This program was launched in FY 2001 with awards made to five institutions.

The Extramural Loan Repayment Program, another new initiative of the NCMHD, was established to build health disparity research capacity by offering loan repayment to individuals with M.D., D.D.S., D.M.D.D.O., D.O., D.C., and Ph.D. degrees. Dr. Ruffin noted that the inclusion of this array of professional health degrees ensures a broader inclusion of individuals conducting research in health disparities. The NCMHD must ensure that at least 50% of individuals participating in this program are members of health disparity populations. Priority is given to individuals conducting biomedical research. Qualifying individuals receive no more than $35,000 annually of the principle and interest of their educational loans. This program provides an incentive for health professionals to engage in basic, clinical, or behavioral research directly relevant to health disparities research. A total of $1.3 million was allocated to the program for 17 awards in FY 2001. The Center made awards in that year in the research areas of psychology, epidemiology, immunology, internal medicine, cardiology, gastroenterology, dermatology, and endocrinology.

In addition, the NCMHD offers a loan repayment program for health professionals from disadvantaged backgrounds to engage in clinical research. A total of $1.8 million was allocated in FY 2001 for 28 awards under this program.

Other new initiatives include programs that focus on promoting partnerships among federal agencies; state, local, tribal, and regional public health agencies; and private entities. Dr. Ruffin briefly described some of the partnerships formed between the NCMHD and other NIH Institutes and Centers. These include, for example, providing partial research funding support for health disparities-related programs of the NCI, the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of General Medical Sciences (NIGMS).

The reporting requirements established under PL 106-525 include an annual report to Congress, a report to be submitted 2 years after the creation of the Center, and a 5-year report submitted by the DHHS assessing the Center's effectiveness. The annual report focuses on health disparities research conducted or supported by NIH, existing and planned Center activities, and a summary and analysis of expenditures in minority health.

Dr. Ruffin briefly outlined the organization and structure of the NCMHD, which comprises four divisional offices: the Office of Extramural Activities, the Division of Scientific Planning and Policy Analysis, the Office of Finance and Administration, and the Division of Research and Training Activities. The latter division is quite large, he said, and encompasses the loan repayment, endowment and Centers of Excellence programs.

Funding for the Center in 2001 was $132 million. In 2002 this amount was increased to $158 million, and $187 million has been provided in the President's FY2003 budget. Future plans include programs on pharmacokinetics, telehealth, and small-business innovation research and initiatives.

*Questions and Answers*

In response to comments from Dr. Bishop on recent reports of health disparities in minority populations, Dr. Ruffin said that all of the various disciplines, fields of study, and health care institutions must work together to address health disparities. He also informed the group that each of the Institutes prepares an annual progress report on its activities in health disparities research to the NCMHD.

Dr. Mala asked about ways in which minority researchers can be encouraged to "get into the pipeline." He said that many small programs and researchers are interested in participating in NIH programs but are intimidated by the seeming complexity of the grant process. Dr. Ruffin referred to the R24 grant mechanism, which is specifically designed to help smaller institutions apply for funding.

Ms. Quigley raised the question of whether health professionals of minority backgrounds necessarily want to return to the communities from which they came to serve those populations. Dr. Ruffin agreed that this assumption is not necessarily a valid one, nor is it always true that a person of a particular background will necessarily be sensitive to the needs and concerns of that population.

Mr. Roehr spoke of the fact that persons from minority backgrounds are often enrolled in clinical trials in insufficient numbers to draw valid conclusions about diseases or conditions within those populations as a whole. Dr. Ruffin commented that recommendations from COPR in this regard would be useful and could possibly serve as the impetus for recommendations from the Institutes and Centers.

Dr. Ruffin also described the process by which the ORMH had gone out to communities to learn about their needs and concerns and brought back recommendations to NIH and to various Institutes and Centers. He said that the NCMHD will try to operate in a similar manner to identify local needs concerning NIH programs and

activities.

Dr. Evelyn Bromet asked about what the Center is doing with regard to involving more members of minority populations in nonprofit disease-specific organizations. Dr. Ruffin acknowledged the dearth of participation by minority populations in this regard and said that the Center is reaching out to these organizations to find ways to increase their participation. Dr. Maddox remarked that nonprofit organizations and advocacy groups have the responsibility to find ways to encourage minority participation and that the NIH should be working with them in this regard.

Dr. Bromet also asked about the Center's relationship with the U.S. Department of Justice regarding homicide as the leading cause of death in young black males. Dr. Ruffin replied that, although the Center has not worked directly with the Justice Department in this area, it has worked within NIH in related areas, such as violence and drug abuse.

In closing, Dr. Ruffin said that every one of the NIH Institutes is engaged in minority health activities. These activities add up to a significant amount of funding, and he acknowledged the challenge of disseminating information about these programs through outreach and education.

## COPR COMMENTS AND DISCUSSION

The final portion of the day was devoted to general discussion of issues of interest to COPR members. Dr. Bishop opened this discussion session by raising the question of whether COPR, as a group, could make recommendations concerning the formation of a more coordinated and centralized process to address minority health and health disparities. Dr. Maddox referred to a task force that existed under the Clinton Administration to eliminate racial and ethnic health disparities and a strategic plan developed on behalf of the DHHS and other departments within the federal government. She said that the strategic plan has once again been taken up by the DHHS Director, Claude Allen, who is reassembling agencies within the department, including NIH, to address this issue. She mentioned that Dr. Ruffin, along with representatives of other agencies within the department, testified before the Congressional Black Caucus on the NIH's strategic plan to address health disparities. Dr. Maddox said that Secretary Thompson was also invited to speak at this hearing and that this issue is now regaining some momentum.

Dr. Mala raised the topic of faith-based initiatives. He said that programs such as Alcoholics Anonymous have proved ineffective in reducing alcoholism among Alaskan Native people in his area. However, faith-based initiatives based on a return to traditional healing methods and alternative and complementary medicine have empowered many people to take responsibility for their lives. He expressed interest in hearing what guidelines the Institutes have been given in terms of the definition and application of faith-based initiatives. Dr. Maddox replied that a task force has been assembled very recently and will enter into a dialogue with individual Institutes. She said that many of the Institutes are already supporting community or church based organizations. The DHHS will first survey the Institutes to determine what is being done in this area and will then develop some special initiatives. She pointed out that no special funding was set aside for faith-based initiatives in relation to research and, although there is much excitement about the potential of faith-based community initiatives to promote NIH programs, they will require some extra funding.

Dr. Maddox mentioned a program under the National Institute of Child Health and Human Development (NICHD) to disseminate information about preventing sudden infant death syndrome (SIDS). She said that the risk of SIDS has been reduced through public service messages to educate parents to always lay babies on their backs to sleep. Because it was found that many Native American, African American, and some Puerto Rican communities have not received this message, NICHD has been working with church groups, such as the D.C. Black Church Initiative in Washington, D.C., to help spread this message.

Dr. Maddox and Dr. Kirschstein both emphasized the need to ensure that such messages, as well as those concerning alternative and complementary medicine, remain evidence based, in keeping with the NIH as a research-based institution. Dr. Kirschstein also pointed out the importance of maintaining a distinction, in accordance with Constitutional law, between delivering a health-related message through faith-based or other organizations and providing more specific direction. Dr. Mala said that he would be particularly interested in seeing more data developed on psychoneuroimmunology, and Dr. Kirschstein referred to the last COPR meeting, during which a presentation was given by the Director of the National Center for Complementary and Alternative Medicine about the use of placebos.

Mr. Roehr proposed that COPR explore what the various Institutes are doing around the subject of pain and possibly make a recommendation to further pursue research in this area. Dr. Kirschstein said that a great deal of research is being done on pain by various Institutes, in terms of pain management and amelioration as well as quality-of-life issues for patients. The National Institute of Dental and Craniofacial Research and the National Institute of Neurological Disorders and Stroke, among others, are two of the Institutes addressing this area. Dr. Kirschstein suggested that the group might want to frame their ideas for further discussion during the next day's working group sessions.

Dr. Mala added that clinicians in his area have been working with the problem of prescription drug abuse by patients with pain. They have been exploring methods such as Chinese medicine, acupuncture, acupressure, and naturopathy in the management of pain. He said that diversion of prescription medications is also a problem in his area. Dr. Mala expressed interest in knowing what non-opioid approaches to pain are being explored by the various Institutes. He also cited the difficulty, as a clinician, of knowing when to appropriately prescribe and when to withhold pain medications because of the potential for abuse. Dr. Kirschstein suggested that Dr. Glen Hanson, Acting Director of the National Institute on Drug Abuse (NIDA), might be pleased to speak to the group on this topic at a future COPR meeting.

Dr. Montoya observed that COPR is moving toward serving in a larger capacity to disseminate health information from NIH to the general public and expressed excitement and enthusiasm for this part of the group's mission. He suggested exploring further ways to do this at the fall meeting of COPR. Dr. Kirschstein supported this idea and suggested that the group develop concrete plans for integrating information from the various Institutes. She described the mission of NIH as being threefold: conducting research, training the next generation of researchers, and communicating scientific findings to the American public.

The group then briefly discussed ways to help new investigators submit grant applications to the NIH. Dr. Montoya described a PowerPoint presentation, "Writing and Receiving Your First NIH Grant," prepared by Ellie Ehrenfeld, Director of the Center for Scientific Review, on how to submit an NIH grant application. Dr. Kirschstein also referred the group to the NIH Web site, where this information can also be found. Dr. Maddox mentioned that many of the Institutes offer similar workshops and programs around the country. She also suggested that it might be useful to send an e-mail to all the Institutes and Centers listing COPR members and their locations, so that a COPR member can be present when these and other workshops and activities take place in their geographic area.

In response to a request from Mr. Sadwin, Anne Thomas repeated some of the information given at the new members' orientation session prior to the beginning of the meeting. She said that NIH receives more than 2 million telephone calls from the public every year. These calls are from patients and their family members as well as healthy people trying to remain so. The questions range from the broad to the specific. Ms. Thomas reported that the NCI's 800 number alone, 1-800-4-CANCER, receives 500,000 calls annually and is staffed by nurses, medical students, and other experts. In addition, six staff people answer e-mail in her office alone, and the individual Institutes receive e-mail from the public as well. The volume of these communications, she said, would seem to indicate that a great many people know about the NIH, although this is belied by the statistics. At a prompting from Dr. Kirschstein, Ms. Thomas also mentioned that the NIH home page is always in the top one or two most-used Web sites in the federal government and is always in the top five health-oriented Web sites.

In this vein of the discussion, Ms. Tetenbaum brought up the division that exists between those members of the general public who do and do not have Internet access. Dr. Kirschstein mentioned that other ways to disseminate health information are also being explored, such as including pamphlets on nutrition on the carts that deliver Meals on Wheels. Ms. Lackritz reiterated the lack of Web access of many sectors of the public and described her efforts to reach young school-aged children to deliver the message about NIH.

As the meeting drew to a close, Ms. Kimberley Hinton praised the efforts of NIH staff and Palladian Partners for coordinating and organizing a flawlessly run meeting. The rest of the group joined her in applauding the meeting staff for their efforts.

Finally, the groups finalized future meeting dates. The next three meetings will be held on October 22-23, 2002; April 14-15, 2003; and October 20-21, 2003.

Dr. Kirschstein thanked the group and adjourned the meeting at 4:15 p.m.

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DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

# October 22, 2002 Meeting Minutes

## NIH PARTICIPANTS:

- Elias A. Zerhouni, M.D., NIH Director
- Ruth Kirschstein, M.D., NIH Deputy Director
- Edward O'Neil, Ph.D., COPR Facilitator
- Jennifer Gorman Vetter, M.P.A., COPR Executive Secretary, NIH Public Liaison Officer, Office of Communications and Public Liaison
- John Burklow, Acting Associate Director for Communications, NIH, Acting Director, Office of Communications and Public Liaison

## NIH ATTENDEES:

- Institute and Center Officers of Public Liaison (OPLs)

## COPR MEMBERS ATTENDING:

- Evelyn Bromet, Ph.D.
- Nancye Buelow
- Luz Claudio, Ph.D.
- Ellen Grant Bishop, Ph.D.
- Debra S. Hall, Ph.D.
- Kimberley Hinton
- Vicki Kalabokes
- Barbara Lackritz
- Debra Lappin, J.D.
- Ted Mala, M.D.
- Isaac Montoya, Ph.D.
- Rod Muñoz, M.D.
- Rosemary Quigley, J.D., M.P.H.
- Bob Roehr
- Lawrence Sadwin
- Len Tamura, Ph.D.
- Zelda Tetenbaum
- Don Tykeson
- Doug Yee

## NIH Director's Report: NIH Update

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

Dr. Zerhouni welcomed everyone to the Council of Public Representatives (COPR) meeting, noting the impressive diversity of those assembled. He cited the importance of collecting the public's perspective on recent work at the National Institutes of Health (NIH) and on the implications of recent advances in biomedical research.

Dr. Zerhouni said the presence of the Council's eight founding members increased the significance of this meeting, since they will be rotating off the Council next year. He introduced officials from the NIH, Office of the Director: Mr. John Burklow, Acting Associate Director for Communications, and Mrs. Jennifer Gorman Vetter, COPR Executive Secretary and NIH Public Liaison Officer, both from the Office of Communications and Public Liaison.

Dr. Zerhouni reported on his first five months as the NIH Director. He said, at the outset, it was obvious that the learning curve would be steep and rapid due to the current phase of remarkable growth. The President and Congress have questioned the NIH's use of resources, its plans for using the resources provided by the doubling of the NIH budget, and the NIH strategic plan. Dr. Zerhouni has met with Members of the NIH Advisory Council to the Director (ACD), as well as the Scientific Directors of all the Institutes and Centers (ICs). He has made himself available to a broad range of constituencies. He has testified twice before Congress. On one occasion, he testified in response to inquiries from Sen. Arlen Specter, (R-PA), about the availability of stem cell lines for researchers. Soon after becoming Director, Dr. Zerhouni created a task force on stem cell research. The task force has taken a proactive role examining issues such as training requirements.

Dr. Zerhouni said that his top priority as the NIH Director was "to attract researchers to do the work" and fill positions in the NIH leadership. He gave a progress report on his goal. He cited the appointment of new directors to the National Institute of Mental Health (Thomas R. Insel, M.D.), the National Institute on Alcohol Abuse and Alcoholism (Ting-Kai Li, M.D.), and the recently established National Institute of Biomedical Imaging and Bioengineering (Roderic I. Pettigrew, M.D., Ph.D.). Dr. Zerhouni said that he is working diligently to fill other vacant positions. He sees an urgent need to ensure strong NIH leadership and to maintain a global view of the organization's role, focusing on the translation of scientific findings into real-world benefits.

In Congressional briefings, Dr. Zerhouni is asked on occasion to pinpoint what the NIH has done of value for the American public. He pointed out that, recently, a part of the answer can include the NIH connections to all three of the recently awarded Nobel Prizes for Science, not only in Medicine and Chemistry, but in Economics as well.

Dr. Zerhouni spoke of the important contributions made by the COPR founding members who are rotating off the Council: Dr. Luz Claudio, Ms. Vicki Kalabokes, Ms. Barbara Lackritz, Ms. Rosemary Quigley, Mr. Bob Roehr, and Mr. Doug Yee. Dr. Zerhouni was photographed with each and awarded them certificates.

The founding COPR members presented a plaque to Dr. Ruth Kirschstein in appreciation of her guidance of the COPR in its first years while she was the NIH Acting Director.

## Report on the NIH Road Map Initiative

**Dr. Zerhouni**

Dr. Zerhouni gave a presentation entitled "A Vision for Medical Discovery in the 21st Century." He emphasized the importance of seeking public input for the NIH strategic vision. He reviewed the evolution of the NIH budget, which is expected to grow over the next two decades. He emphasized the need to accompany growth with wisely applied resources, to meet the challenges ahead. The increased budget, said Dr. Zerhouni, stems from the recognition that changes in biomedical research have increased in both cost and complexity. For example, a single bioimaging array experiment can cost $3,000 - $4,000. However, technological advances have reduced the time required for gene identification from years, just a decade ago, to a period of 20 minutes.

Biomedical research is a priority for the entire United States, not just for the NIH. According to projections, investment in research facilities and faculty at U.S. medical schools will triple within the next 5 years, compared to 1990 levels. An increased capacity to conduct research, to prevent, treat and cure disease, will determine the success of the U.S. research enterprise.

Increased investments lead to more applications submitted for review and more grants awarded, and they stimulate non-federal investment in research. Over the past 30 years, in the Pharmaceutical Research and Manufacturers (PhRMA), the companies have tripled their research and development expenditures, creating more than 200,000 new jobs and 1,300 new, enduring biotechnology companies. Until 1991, the NIH spent more on biomedical research than the entire pharmaceutical industry. In that year, private industry funding exceeded federal spending. Today, private industry is developing an ever-increasing number of drug targets and mechanisms, as reflected by the many new medications on the market. Private biomedical investment has reduced Federal biomedical spending to a secondary source of funding.

The unusual convergence of many of the life science areas leads explorations in new directions, said Dr. Zerhouni. Existing ideas are being redirected with new tools, technologies, and observations - sparked by the development of new approaches, such as, high-throughput screening for selection, transgenic animals and mutational analysis, and progress in structural biology. The fields of genetics and genomics are driving these discoveries. They now allow us to understand the evolutionary forces that influence gene patterns and expression. The past 10 years have produced tremendous changes in biomedical research. For the first time in human history, we have the "parts list" of nature. To master our destiny, we must continue to combat the burden of disease and accelerate the pace of discovery. The NIH is the vanguard of this effort.

The complexity of biological systems is a major barrier to questions facing biomedical science. Reductionist approaches may be unable to solve that complexity. Technical limitations hinder dynamic visualization at the subcellular level. Challenges remain in the exploration of cell trafficking, signaling, and other complex molecular systems and their controls. The "signal-to-noise" ratio limits the computational analyses of these systems. The complexity of these and other molecular systems requires us to come up with better techniques to understand them.

The NIH's Road Map Initiative outlines a vision for NIH research that identifies the scientific challenges and roadblocks to progress and indicates future directions for research. The NIH as a whole must take responsibility, because any single Institute cannot undertake this enterprise. In defining a vision for NIH research strategies, three broad priorities have emerged:

> First, the NIH must explore **new pathways to discovery** and **develop revolutionary methods of research**. It must accelerate and expand existing technologies and resources, particularly proteomics and large-scale array technologies for the genomic era. We must increase the number of, and access to, molecular research libraries and press forward with methods for the structural study of complex molecules. Mathematical modeling and computer simulation of complex systems must also expand. Developing revolutionary methods of research will also include integrative approaches to systems biology, quantitative analyses of dynamic, genome-wide patterns of expression, epigenetics, differential gene expression, comprehensive analyses of complex molecular networks, and regenerative medicine.

Second, the NIH must **promote the research teams of the future**, by overcoming structural and cultural barriers to "team science." Aiding this effort will be the establishment of interdisciplinary undergraduate and graduate programs and the creation of better mechanisms for funding of multidisciplinary teams without compromising investigator "R01" research. Better support is needed for high-risk/high-impact research. The NIH should actively explore ways to leverage private-sector partnerships, to optimize resources. The system's key is still the creative individual.

Third, the NIH must **re-engineer the clinical research enterprise**. Innovative methods in clinical research need to be developed. Clinical research procedures and policies need to be standardized. Dr. Zerhouni proposed the establishment of a national clinical research data resource, national standards for clinical research data, and a national computational infrastructure. We need to find ways to facilitate access to data, such as molecular libraries for testing.

Dr. Zerhouni ended his presentation and asked for comments.

*Comments and Discussion*

Dr. Zerhouni responded to a comment noting the absence of the behavioral sciences from his list of areas in need of expansion and improvement. He assured the listener that the Institute budgets and needs are under careful review.

Dr. Mala asked for ideas on how busy clinicians might become involved in clinical research. Citing the large decrease in cancer hospitalizations, Dr. Zerhouni noted the movement of clinical care away from hospitals and into the community. However, the information infrastructure to monitor this trend is missing. Some Institutes are working on ways to involve community physicians, but we need the ability to standardize information gathering. These difficulties exist in the academic health centers and throughout the community. Mr. Roehr raised the possibility of using large public and private institutions—such as the Veterans Administration and Kaiser Permanente—to mine data.

Dr. Zerhouni said that the NIH wants to stimulate multidisciplinary education, not just in top-flight universities, but in 4-year colleges, focusing on general science rather than microbiology. New multidisciplinary pathways to training need to be developed in behavioral science, social science, and psychology, as well as the biological sciences. Professional schools must be encouraged to train people in ways that are less categorical.

Dr. Zerhouni responded to comments made by Ms. Lappin concerning the access to data and materials. He cited the importance of protecting intellectual property, adding that the issue is seen differently by different government agencies, e.g., the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). However, once protections are in place, data sharing should be encouraged.

## Update on the NIH Response to the Report of the COPR Working Group on Human Research Protections

**Wendy Baldwin, Ph.D., Deputy Director for Extramural Research, NIH; Lana Skirboll, Ph.D., Associate Director for Science Policy, NIH**

Drs. Baldwin and Skirboll reported on the NIH response to COPR's report on Human Research Protections (HRP). The report identified many of the stresses on the current system of protections. NIH is taking steps to strengthen the system. This will create burdens for researchers and require increased education.

Chief among these steps is the creation of the Human Subjects Research Enhancement Program, which designates money for improving the HRP system in many areas targeted by the COPR report. So far, the NIH has spent $25 Million on the program and made 142 awards.

Dr. Baldwin was encouraged by the Institutes' response. For example, interest is growing for awards in the behavioral sciences, for improving the informed consent process, and for ethics training. The applications process is getting underway.

The NIH is developing tools for research participants, researchers and administrators, including an "online chat room" where users can post questions. Dr. Baldwin cited increasing support for research on ethical issues, informed consent, and behavioral interactions in the research process. The growing interest, she said, reflects a recognition that the power of research has yet to be focused on the understanding of research itself. A recent announcement for a short-term ethics-training program has received a slow response, said Dr. Baldwin, but interest has been increasing. The program helps investigators understand bioethics.

Various stakeholders have met on the issue of conflicts of interest and stimulated the sharing of community insights, discussing ways in which these issues have been addressed within other institutions. A report from that meeting is forthcoming.

*Comments and Discussion*

Responding to a question about the extent to which the NIH has contemplated public access to research results, Dr. Baldwin said the NIH has not considered access to data during a clinical trial, because this would disrupt the research process. She acknowledged that providing this access could be important to informed consent. Ms. Buelow reiterated that the public is very interested in data sharing and wants to take part in the research process.

COPR Members expressed the need for improved dissemination of the HRP report, possibly through its publication in a peer-reviewed journal. Dr. Baldwin promised to give the matter thought and make further suggestions.

*Role of the NIH in Implementing the Privacy Rule*

Dr. Skirboll informed the group of the NIH's efforts to reach out to the research community with information and resources for implementing the Health Insurance Portability and Accountability Act (HIPAA). These efforts encompass a research-oriented website, brochures for general and specific audiences, speaking engagements, and trained NIH staff. The Office for Civil Rights—the Agency responsible for oversight and enforcement of HIPAA—has asked the Department of Health and Human Services (DHHS) to develop educational materials for researchers. The NIH, along with the FDA, the CDC, the Agency for Healthcare Research and Quality, and the Office of Human Research Protections is leading a cooperative effort to develop this material. DHHS committees and NIH working groups

assist in the coordination effort.

*Development of a National Database for Clinical Research Using Gene Transfer*

Dr. Skirboll reported on the development of the Genetic Modification Clinical Research Information System (GeMCRIS), a national database for clinical research on gene transfer. GeMCRIS will serve as an analytical tool for a diverse group of users, including Federal Agencies, National Advisory Committees, investigators, policy makers, patients, and the public. A Data Safety Monitoring Review Board will be formed, to review cross-trial reports of adverse events.

GeMCRIS will allow for systematic analysis of data across clinical trials and will enhance the application of knowledge acquired from research. The database is being developed in phases, under the purview of a steering committee that is composed of representatives from the NIH Office of Biotechnology Activities and ICs with gene transfer portfolios, and in collaboration with the FDA.

GeMCRIS will facilitate the analysis of safety information from all gene transfer clinical trials for the NIH and the FDA. It will provide reports that will inform diverse user groups, including IRBs, local data safety monitoring boards, investigators, and research participants and their families. GeMCRIS will also be useful for other areas of clinical research, and for the National Library of Medicine, General Clinical Research Centers, National Gene Vector Laboratories, and the CDC, all of which have shown interest in using the database. GeMCRIS may represent the beginning of a core format for reporting adverse events for all Federal agencies and others engaged in clinical research.

Dr. Skirboll noted that privacy protections are important, citing the example of Jesse Gelsinger's father, who completely lost his privacy in the wake of the teenager's death during a gene transfer experiment. Because information submitted to the NIH database is available through the Freedom of Information Act. Dr. Skirboll anticipates that the database will receive reports that have been stripped of patient identifiers to the extent that this is possible.

*Comments and Discussion*

Dr. Skirboll was asked whether the FDA would subject private research to the same requirements imposed upon federally funded studies. Dr. Skirboll expects FDA to make these decisions.

## Report and Discussion on COPR Planning Session

**Dr. Zerhouni, Dr. O'Neil, and COPR Members**

Edward O'Neil, Ph.D., a professor of family and community medicine and dental public health, and director of the Center for the Health Professions at the University of California, San Francisco, facilitated the COPR Planning Session, and reviewed the outcomes of pre-meeting discussions with COPR members. In confidential interviews, he explored the opinions of the COPR members about COPR's role within the NIH. He asked COPR members some key questions:

- What do you see as COPR's role at the NIH and for the country?
- What issues are of particular importance to you?
- What ways does COPR work best?
- Where could it be improved?

From the interviews, he said, "no particular stain of advocacy" had emerged. Dr. O'Neil summarized the interviews and the pre-meeting discussions. He found that members view COPR's role as having three main elements.

First, COPR is **to provide a voice for public input to the NIH and its Director**. All but two members see this as a central role. All members recognize the need to incorporate public concerns into NIH strategies, but they are uncertain how it should be done. Members have different opinions on the proper role of COPR. They contemplate a role that is primarily advisory in nature, as well as one that takes an activist stance. On the whole, members are concerned about duplicating the work of the NIH Offices of Public Liaison (OPLs). They have concerns about the public's attitude toward the policy process in science. All see the important relationship between the needs of the public and the NIH agenda.

Second, COPR is to **carry the NIH message to the various public groups represented by the Council**. Some members do not consider this role important, and COPR members have uneven interests and abilities to serve this networking function. Those carrying the NIH message would like more guidance. Members recognize that they must integrate their roles as a public voice with their outreach responsibilities. They seek adequate management and support that is accounted for systematically - with real evidence.

Third, COPR members must **participate in focused work that addresses the goals and concerns of the NIH and COPR**. Members agree: the best work to date is the report produced by the COPR HRP workgroup. To be successful, such work requires an extraordinary commitment, adequate resources and encouragement from the NIH.

Other important issues that emerged from the members' discussions on the previous day:

- Safety of human research subjects
- Health disparities
- Public understanding of the role and value of biomedical research
- Public input into new research directions

Informal discussions have worked well in the past, particularly where work focused on a single issue and individual members worked directly with the NIH. The

Council's diverse membership is an asset. Other strengths include COPR's access and relationships, the agenda-setting process, and the ability to bring the NIH to local communities.

The Council cited areas in need of improvement. Members should reach a consensus about COPR's role and expectations of its work. Members would like the Director to incorporate his expectations for COPR into his broader strategic vision for the NIH. Members also want to understand COPR's distinctive role as the "capstone" in the system of public input. If public input is valued, then the agenda-setting and decision-making processes must be clarified and tied to the Director's agenda.

Members would also like clarification on how to use NIH resources to carry out the Council's work. COPR seeks clarification on how its work is disseminated and used within the NIH, and what its relationship is to other NIH public advisory bodies. Once COPR's role and agenda have been clarified, the need for meetings can be assessed (i.e., how many per year and appropriate timing). Adequate staff support is necessary, and accountability between COPR and staff needs to be defined.

Next, Dr. O'Neil presented the "COPR Action Agenda:"

- Develop testimony for the IOM Committee's Review of the NIH Structure and submit to the NIH Director, who will forward to the IOM Committee
- Continue setting COPR's priorities, in cooperation with the Agenda Work Group, whose co-chairs will also serve on the Executive Issues Work Group and COPR liaison
- Enhance communication with the members of other public groups and councils, in an effort to look at public participation practices within the NIH and to do so by:
    - Sending a COPR representative to the ACD Meeting on December 5, 2002
    - Drafting a report examining other public participation practices
    - Exploring the possibility of a summit on public input across the NIH

*COPR Member Comments and Discussion*

Ms. Kalabokes and Dr. Mala reported that the COPR Working Group on Health Disparities has received valuable assistance from the various OPLs.

Dr. Muñoz raised the issue of retaining public trust in the research enterprise. The members made various suggestions for enhancing the NIH's public image. Dr. Mala suggested posting "one-liner" advertisements in public places, such as on public transportation. The ads could highlight some NIH achievements and research activities. (e.g., "9,864 research grants this year alone. NIH: Protecting Your Health") Ms. Hinton agreed that the NIH needs to tout its own accomplishments. She envisioned a booklet providing the history of the Institutes, with a timeline of achievements. (e.g., "NIH: The First 50 Years"). Dr. Kirschstein noted that something similar was developed in 1987 when the NIH celebrated its centennial. The 1987 publication of the NIH history and the NIH Almanac would be wonderful resources for this type of information. They are available for any COPR member who requests them.

It was suggested that a speaker could be invited to a COPR meeting to talk about the history of medicine and the history of the NIH. Mr. Burklow mentioned that Dr. Victoria Harden, NIH Historian and Director of the Dewitt Stetten, Jr. Museum of Medical Research, might be good choice for such a talk. The COPR Agenda Working Group will consider inviting Dr. Harden to speak.

Concerning the issue of public trust, Ms. Lappin said that the *Conflict of Interest* conference, mentioned earlier by Dr. Skirboll, was a great success. An overarching theme was retention of the public trust, and the conference addressed many issues from the COPR Human Research Protections (HRP) Report.

Mr. Yee expressed concerns about reaching a diverse audience with NIH messages and activities. Many of the people he deals with are not college graduates, and it is important that messages be targeted to them.

Ms. Quigley agreed that surveys show the public has difficulty in trusting biomedical researchers, but that those who are sick still invest a great deal of hope and remain willing to participate in clinical research.

Dr. Skirboll said that in order to retain public trust, the goal must be to ensure the trust of the community. Most surveys, she said, show support for scientists relative to other professions. Dr. Kirschstein concurred with these remarks, saying that Gallup polls have shown that many Americans think the best hope and benefit for their health lies in biomedical research.

## Wrap-Up and Scheduling of Upcoming COPR Meetings

*The following future meeting dates were set:*

**2003:**

- April 24-25
- October 20-21

**2004:**

- April 26-27
- October 18-19

Dr. Zerhouni thanked all those present for their interest and participation. The meeting was adjourned at 4:30 p.m. on Tuesday, October 22, 2002.

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