







## DIRECTOR'S COUNCIL

### 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



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

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 me

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





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 formin

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 inform



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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.

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**

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

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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This page last reviewed on November 28, 2011

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