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

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

COPR Alumni

CLASS OF 2003

- Luz Claudio (New York)
- Vicki Kalabokes (California)
- Barbara B. Lackritz (Missouri)
- Debra R. Lappin (Colorado)
- Robert Martin
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Barbara B. Lackritz

Term: 1999–2003

Deceased

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

Debra R. Lappin

Term: 1999–2003

Ms. Lappin has brought a public voice to national health and science policy issues for two decades. Appointed to the NIH Council of Public Representatives at the time of its formation in 1999, Ms. Lappin chaired the Council's first working group on Human Research Protections, which presented a comprehensive report to the NIH Director in April 2001. Ms. Lappin has served as a member of ad hoc advisory committees to the NIH Director ad

Term: 1999–2003

Dr. Montoya is the Chief Executive Officer at Affiliated Systems Corporation, a Houston 500 company that is the region's leading think tank and research organization. Dr. Montoya earned his Ph.D. at New Mexico State University and is a behavioral scientist with experience in health services administration and in health services research. He has been principal investigator on several federally funded studies of HIV/AIDS prevention and risk behavior change and on NIH-funded grants that examine the motivational behaviors of drug users and the resulting impact on their health and daily lives.6(t98 He ha)]TJ0.0003 Tc -0.004 Tw [s ser)-7.7(v)2.4149 Ehlt004 Trvic

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DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES

April 24, 2003 Meeting Minutes

NIH PARTICIPANTS:

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

NIH ATTENDEES:

Mary C. Dufour, M.D., M.P.H., Deputy Director, National Institute on Alcohol Abuse and Alcoholism

Ellie Ehrenfeld, Ph.D., Director, Center for Scientific Review

Judith H. Greenberg, Ph.D., Acting Director, National Institute of General Medical Sciences

Gerald T. Keusch, M.D., Director, John E. Fogarty International Center

- T.K. Li, M.D., Director, National Institute on Alcohol Abuse and Alcoholism

Roderic I. Pettigrew, M.D., Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering

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

- Stephen E. Straus, M.D., National Center for Complementary and Alternative Medicine
- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse

Institute and Center Officers of Public Liaison

COPR MEMBERS ATTENDING:

Evelyn Bromet, Ph.D.

Nancye W. Buelow

Ellen E. Grant, Ph.D.

Debra S. Hall, Ph.D.

Kimberley Hinton

Ted Mala, M.D., M.P.H.

Rodrigo A. Muñoz, M.D.

Lawrence B. Sadwin

John Shlofrock

- Leonard J. Tamura, Ph.D.

Zelda Tetenbaum, Ed.D., M.Sc.

Donald E. Tykeson

COPR SPECIAL CONSULTANTS:

James J. Armstrong

Ruth C. Browne, Sc.D., M.P.H.

Barbara D. Butler

Frances J. Dunston, M.D., M.P.H.

Rafael Gonzalez-Amezcua, M.D.

Jim Jensen

William D. Novelli

to determine the need.

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

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

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

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

One member said the agenda did not include some topics raised in previous meetings and suggested that a more abbreviated form be used to hear from I/C Directors. Dr. Muñoz said the AIWG would enumerate subjects the group considers important.

- Another member, who called the previous day's orientation "wonderful though daunting," liked the collaborative meeting format and the opportunity for input after presentations. The member added that two meetings a year may not be enough to accomplish COPR business and that more subcommittees and work groups may be needed.

It was suggested that, rather than meeting more often, COPR meetings could be extended from 2 days to 3. The formal, public meeting could be held on the first day, and the next two days could be used to process new information. Work groups could collaborate to determine the information to present to the full COPR membership. Dr. Kirschstein noted that during its first several meetings, the Council heard from each I/C Director. There was concern that continuing to hear from all I/C Directors would become repetitive for long-time members and generate too much information to adequately process. She E38 66Boz said ctorOPR meetings.0026 Tw 28.2(641.7(T)(64r t481s8(e m68.2(m1(te)8.2(ththapompd[su)-7. M/)-Burklow'0.007)1. that 5.4(f)n)-6.7(c -0.00481.6(om)0714

National Institutes of Health
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October 20, 2003 Meeting Minutes

NIH PARTICIPANTS:

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

COPR MEMBERS ATTENDING:

James J. Armstrong

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Rodrigo A. Muñoz, M.D.

- Nancye W. Buelow

William D. Novelli

Barbara D. Butler

- Lawrence B. Sadwin
- Frances J. Dunston, M.D., M.P.H.

John Shlofrock

Rafael Gonzalez-Amezcua, M.D.

Ellen V. Sigal, Ph.D.

- Ellen E. Grant, Ph.D.

Leonard J. Tamura, Ph.D.

Debra S. Hall, Ph.D.

- Zelda Tetenbaum, M.Sc.
- Kimberley Hinton
- Dawna Torres Mughal, Ph.D., R.D., FADA
- Jim Jensen
- Donald E. Tykeson

NIH Director's Report

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

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

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

Dr. Tamura said that PIPWG saw itself as part of the process of engaging the public in the clinical research enterprise by referencing Dr. Zerhouni's three priorities —trust, bi-directional communication, and education - keeping in mind that even the perception of a lack of transparency can erode public trust. The work group worked with many Institute Officers of Public Liaison (OPLs) to find examples of how public input is obtained, and identified specific practices that effectuate public input in the research priority-setti

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

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

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

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

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

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

Presentation on Enhancing Trust in the Clinical Enterprise

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

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

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

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

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

Education:

Must be in a culturally relevant language and form.

Trust:

Found that the entity most trusted was the government. Most concern was with private enterprise because of a belief that the mission of private enterprise is to benefit shareholders, not the public.

- There is a need for researchers and public communicators who are people of color.

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

The study extended the reach of researchers beyond the building to form partnerships among minorities and majority institutions in the community. The challenge was the time required to forge this partnership. Research outcome is driven by data; community outcome is driven by relationships.

The CDM is generalizable to other sites. The CDM engages the community and researchers/practitioners as co-investigators; i.e., partners in planning, not ancillary reactors to preconceived plans.

The CDM involves three overarching themes illustrated in the JHS study:

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

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

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

On the positive side, gaining knowledge for themselves and their families gives community members an incentive to participate and creates a sharing atmosphere that overcomes differences. The annual follow-up response is greater than 95%.

On the negative side, recruitment is always a problem.

- Obstacles to building trust remain. There is a built-in inequitable power distribution that makes shared control in a CDM difficult. The nature of the scientific enterprise, which is data driven, often gives participants the sense that "all you want is our data." In addition, the difficulty of changing researchers' methods of inquiry, timetables, and resource allocation can preclude investment in community building. Finally, although building trust is on-going, trust remains fragile. Once established, trust can never be taken for granted and requires constant vigilance. Conflicts over meaning, language, values and beliefs, assumptions, and promises are inevitable, necessitating the on-going joint development of operational norms.

Community-driven possibilities for engendering trusting research communities:

Develop models for community-driven research and multi-method evaluations.

Fund studies that attend to how researchers build their research communities.

Provide training for investigators and NIH staffand reviewers to facilitate broad-based, multiethnic studies.

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

Presentation on Introducing Research into Communities

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

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

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