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 2009

- Christina Clark (Michigan)
- Valda Boyd Ford (Nebraska)
- Nicole Johnson (Florida)
- Cynthia A. Lindquist (North Dakota)
- Marjorie K. Mau (Hawaii)
- James H. Wendorf (New Jersey)

Christina Clark

Term: 2005–2009

Ms. Christina Clark, whose son was diagnosed with ALS (Lou Gehrig's disease) in 1997, left her career in local politics and community service to establish the Foundation for Interdisciplinary Motor Neuron Medicine (The ALS BioTeam). The foundation has been the catalyst for using interdisciplinary strategies in several ALS research studies relating to drug screening and stem cell research. The ALS BioTeam focuses on accelerating therapeutic opportunities by acting as a voluntary facilitator for inter-academic and industry collaborations.

Ms. Clark is a trustee of the ALS Association (ALSA) and serves on ALSA's Research and Advocacy Committees, and she often serves as ALSA's board liaison at scientific meetings. She is a member of the National Institutes of Health/National Institute of Neurological Disorders and Stroke oversight committee for a clinical trial. In 1996, she was appointed a commissioner for the State of Michigan Commission on Services to the Aging by Governor John Engler. From 1992 to 2002, Ms. Clark was a member of the Board of Directors of the Greater Michigan Chapter of the Alzheimer's Association, and she was the chapter's Public Policy Chair from 1996 to 2002.

Ms. Clark has held positions as Vice President of Geonomics, Inc., and as a consultant and Director of Legislative Affairs for the Mutual Insurance Corporation of America and for American Physicians Assurance. She was elected a County Commissioner from Lapeer County, Michigan, and was named Citizen of the Year in 1997. She is the founder and President of Metamora Concerned Citizens Association, which provides a grass-roots base for community advocacy on Superfund, 911 emergency, and other local issues.

Ms. Clark received a bachelor's degree from Cornell University, a master's degree from Harvard University, and an M.B.A. from Michigan State University. She resides with her husband on their farm in Metamora, Michigan.

Valda Boyd Ford

Term: 2005–2009

Ms. Valda Boyd Ford is a well-known presenter on leadership, public health, and cultural competency. She is President and Chief Executive Officer of the Center for Human Diversity, Inc., one of the nation's leading training institutes on cultural competency since 1998. Her particular interest is in creating environments that allow for all people to be respected regardless of race, religion, national origin, or other perceived differences. She served as Director of Community and Multicultural Affairs at the University of Nebraska Medical Center for almost six years and, since 2005, has served as the Director of Refugee Initiatives for Unite for Sight, an international agency dedicated to eradicating preventable blindness. She is the host and executive producer of *Valda's Place,* a weekly cable television talk show, and a member of the National Speakers Association.

Ms. Ford has developed support groups, provided small and large group training, and presented or consulted in Saudi Arabia, United States Virgin Islands, China, the Netherlands, Poland, Ghana, Saudi Arabia, Denmark, Sierra Leone, Sri Lanka, Wales, Afghanistan, Australia, and 25 U.S. states. In conjunction with the National Heart, Lung, and Blood Institute's The Heart Truth™ campaign, she founded the annual Heart and Soul Red Dress Event to raise awareness of heart disease among underserved women.

Ms. Ford has worked with Unite for Sight in refugee clinics in Africa and Asia. She developed partnerships with eye doctors and surgeons to provide free sight-restoring cataract surgery as well as thousands of pairs of eyeglasses to refugees living in camps. Ms. Ford was recognized as Unite for Sight's Humanitarian of the Year in 2005 and its Volunteer of the Year in 2006.

Ms. Ford created a series of DVDs on cultural competency, intercultural communication, and her work with refugees from Liberia. She has an M.P.H. from the University of North Carolina at Chapel Hill, a master's degree in nursing administration from Creighton University, and a B.S. from Winston-Salem State University.

Nicole Johnson

Term: 2005–2009

Ms. Nicole Johnson is an international diabetes advocate. She travels extensively, promoting awareness, prevention, and early detection of this condition, which she shares. She is also a corporate and government affairs advisor for patient groups and biotechnology companies. In the last nine years, Ms. Johnson has helped raise nearly $20 million for diabetes research and programs. She is the president of the Nicole Johnson Foundation, which supports diabetes education programs across the country.

Ms. Johnson hosts the weekly CNBC diabetes talk show *dLife* and writes monthly columns and articles for various publications and Web sites. She has published four books, including three diabetes cookbooks coauthored with renowned chef Mr. Food. Her autobiography, *Living with Diabetes,* in part chronicles her experiences as Miss America 1999.

Ms. Johnson serves on numerous advisory boards, including the Tampa Bay chapter of the Juvenile Diabetes Research Foundation and the Education for Children with Diabetes Foundation. She is a past national board member of the American Diabetes Association. Ms. Johnson has received numerous awards for her advocacy work.

She holds an M.A. in journalism from Regent University and an M.P.H. from the University of Pittsburgh. Ms. Johnson lives in Tampa, Florida, with her daughter, Ava Grace, who was born in early 2006.

Cynthia A. Lindquist

Term: 2005–2009

Dr. Cynthia Lindquist, also known as Ta'sunka Wicahpi Win (Star Horse Woman), is a member of the Spirit Lake Dakota Nation and President of Cankdeska Cikana (Little Hoop) Community College, one of 37 tribal colleges and universities in the United States.

Prior to serving as President of Cankdeska Cikana Community College, Dr. Lindquist worked in health care administration, starting as the Spirit Lake tribe's health director/planner in the early 1980s. She wrote and developed the Northern Plains Healthy Start initiative and is an adjunct faculty member at the University of North Dakota School of Medicine and Health Sciences. Dr. Lindquist served as Executive Director, North Dakota Indian Affairs Commission, and as Senior Advisor to the Director, Indian Health Service, U.S. Department of Health and Human Services.

In 2004, Dr. Lindquist was appointed by President Bush to serve as a member of the National Advisory Council on Indian Education. She is also a member of the Barbara Jordan Health Policy Scholars advisory committee for the Kaiser Family Foundation and a founding member of the National Indian Women's Health Resource Center. Dr. Lindquist serves as secretary for the American Indian Higher Education Consortium, an advocacy organization for tribal colleges and universities. She also serves on the American Indian College Fund Board of Trustees.

Dr. Lindquist earned a master's degree in public administration from the University of South Dakota and a doctorate in educational leadership from the University of North Dakota.

Marjorie K. Mau

Term: 2005–2009

Dr. Marjorie Mau is Professor and Chair of the Department of Native Hawaiian Health at the John A. Burns School of Medicine of the University of Hawai'i. Dr. Mau, a Native Hawaiian, was born and raised in Honolulu and has spent more than 12 years working with Native Hawaiian communities to improve their health status and eliminate health disparities. The Department of Native Hawaiian Health is the first of its kind in an accredited U.S. medical school. The department's role is to highlight the unique contributions the indigenous people of Hawai'i bring to the state, the United States, and the international community and to improve access to health care in underserved communities of Native Hawaiians and Pacific Peoples throughout Hawai'i. As a physician, Dr. Mau provides diabetes and endocrinology subspecialty services to patients on the island of Molokai, where approximately 60% of the residents are of Native Hawaiian ancestry.

Dr. Mau has gained a reputation for building and fostering relationships for the betterment of health and for the elimination of health care disparities, especially among Native Hawaiians. A major focus of Dr. Mau's career continues to be the prevention and control of diabetes mellitus in Native Hawaiians and other ethnic populations. Her work has led to the development and implementation of the Kulia Ola Kino Maika'i Program (Strive for Good Health), a peer educator-led program that has been shown to improve diet and exercise behaviors in Native Hawaiians with or at risk for diabetes.

Dr. Mau is also a strong advocate for increasing the number of Native Hawaiians and other underrepresented ethnic minority students in higher education. In the Department of Native Hawaiian Health, two programs—the Imi Ho'ola (Those Who Seek to Heal) Program and the Native Hawaiian Center of Excellence—are aimed at recruiting and supporting medical students and faculty of Native Hawaiian or other Pacific Island ancestry to pursue careers in health and medicine.

Dr. Mau is an active member of the Ahahui O Na Kauka (the Association of Native Hawaiian Physicians), the American Diabetes Association, and the Endocrine Society, and she is a Fellow of the American College of Physicians and the American Society of Internal Medicine.

She received her undergraduate and medical degrees from Creighton University and her M.S. from Harvard School of Public Health. Dr. Mau enjoys body surfing, hiking, and bicycling and is a member of Pa Ku'i A Lua, a Native Hawaiian martial arts group.

James H. Wendorf

Term: 2006–2009

Mr. James Wendorf is Executive Director of the National Center for Learning Disabilities (NCLD), which seeks to ensure that the nation's 15 million children, adolescents, and adults with learning disabilities have every opportunity to succeed in school, work, and life. He directs NCLD's efforts to provide essential information to parents, professionals, and individuals with learning disabilities; to promote research and programs that foster effective learning; and to advocate for policies that protect and strengthen educational rights and opportunities. Get Ready to Read!, a national initiative to screen four-year-olds for skills critical to success in reading, is the largest program in this effort.

For the past 20 years, Mr. Wendorf has worked in the not-for-profit sector to build national and international partnerships supporting learning and literacy programs. These programs have won support from a wide range of foundation and corporate partners, including the W.K. Kellogg Foundation, the Cisco Systems Foundation, Ford Motor Company Fund, Visa USA, the Goizueta Foundation, the Emily Hall Tremaine Foundation, and the John D. and Catherine T. MacArthur Foundation. Prior to joining NCLD in 1999, Mr. Wendorf served as Vice President and Chief Operating Officer of Reading Is Fundamental, Inc., the nation's largest nonprofit children's literacy organization, based in Washington, DC.

Mr. Wendorf serves on the advisory boards of the National Association for the Education of African American Children with Learning Disabilities and the Home School Institute. He is frequently called upon by the news media to comment on policies and programs affecting individuals with learning disabilities; recent appearances include C-SPAN, *The New York Times,* the Associated Press, and *Christian Science Monitor.*

Mr. Wendorf earned a B.A. *cum laude* from Yale College and master's degrees in English language and literature from the University of Cambridge and Cornell University.

NATIONAL INSTITUTES OF HEALTH

DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES (COPR)

MEETING MINUTES

April 17, 2009

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

Spring 2009 Meeting
Building 31, C-Wing, Conference Room 6, NIH Campus
Bethesda, Maryland

April 17, 2009

NIH Participants

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

COPR Members Attending

Stephanie Aaronson*
Syed M. Ahmed, M.D., Dr.P.H., M.P.H.
Micah Berman, J.D.
Lora M. Church
Naomi Cottoms, M.S.
Elmer R. Freeman, M.S.W.
Elizabeth Furlong, Ph.D., J.D., R.N.
Brent Jaquet
Amye Leong, M.B.A.*
Jordan P. Lewis, M.S.W.*
Matthew Margo, LL.M.
Linda Crew McNamara, M.B.A., R.N.
Eileen Naughton, J.D.
Gregory R. Nycz*
Lynn M. Olson, Ph.D.*
Ann-Gel S. Palermo, M.P.H.
Carlos Pavão, M.P.A.
John Walsh
James H. Wendorf, M.A.
Leo Wilton, Ph.D.*
James Wong, Ph.D.

*COPR Conditional Appointee

COPR Members Not Present
Anne Muñoz-Furlong

ACD Liaison
John C. Nelson, M.D., M.P.H.

Additional Speakers
L. Tony Beck, Ph.D., Program Officer, Division for Clinical Research Resources, National Center for Research Resources, NIH
Joyce A. Hunter, Ph.D., Deputy Director, National Center on Minority Health and Health Disparities, NIH
Roderic Pettigrew, M.D., Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering, NIH

CONTENTS

EXECUTIVE SUMMARY

The 21st meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) took place on April 17, 2009.

Lawrence A. Tabak, D.D.S., Ph.D., Acting Deputy Director, NIH, introduced and welcomed the new COPR conditional appointees: Stephanie Aaronson; Amye Leong, M.B.A.; Jordan P. Lewis, M.S.W.; Gregory R. Nycz; Lynn M. Olson, Ph.D.; and Leo Wilton, Ph.D.

Opening his remarks, Dr. Tabak announced that NIH had released its first *Biennial Report of the Director* in January 2009. He also reported that President Obama had issued an executive order removing limits on federally supported research on human embryonic stem cells and directing NIH to expand its support for human stem cell research.

Noting NIH's gratitude to the president and Congress, Dr. Tabak provided an update on the impact of the American Recovery and Reinvestment Act (ARRA) on NIH. ARRA appropriated $10 billion directly to NIH. This funding included support for extramural scientific research; facilities repair, improvements, and construction at extramural institutions funded by NIH; repair, improvements, and construction of NIH facilities; and scientific equipment in the extramural research community.

John Bartrum reported that Congress had passed the fiscal year (FY) 2009 federal budget on March 11. This budget provided NIH with a 3.2% increase over the FY 2008 budget.

Marc Smolonsky highlighted two bills. One would reauthorize the National Cancer Act, and the other would tighten NIH oversight of conflicts of interest among agency grantees.

L. Tony Beck, Ph.D., described NIH's Science Education Partnership Award (SEPA) program within the National Center for Research Resources. He explained that SEPA encouraged and supported partnerships to increase the participation of a diverse population of young people in clinical and basic research careers. It offered programs in science, technology, engineering, and

mathematics at 44 project sites for K–12 students, parents, and teachers. SEPA also supported informal science education at 24 science centers and museums.

Roderic Pettigrew, M.D., Ph.D., described some recent advances in nanomedicine research. He explained that the advances allowed scientists to use nanotechnology to investigate the fundamental mechanisms of disease, improve medical diagnostics, and deliver drugs and gene therapy.

Raynard S. Kington, M.D., Ph.D., Acting NIH Director, announced via teleconference that NIH had just issued draft guidelines that would allow funding for research using human embryonic stem cells derived from embryos created by *in vitro* fertilization for reproductive purposes. Dr. Kington said research using human embryonic stem cells held great promise for helping scientists understand the human body and develop interventions to improve human health.

Joyce A. Hunter, Ph.D., reported on the first NIH research summit on "The Science of Eliminating Health Disparities." The summit focused on the integration of science, practice, and policy. More than 4,400 scientists, clinicians, policymakers, and health advocates participated.

Elmer R. Freeman, M.S.W., and Linda Crew McNamara, M.B.A., R.N., reported that the COPR's Agenda Work Group had discussed how the COPR should introduce itself to the new NIH Director after his or her appointment. The work group planned to describe the COPR's history, values, processes, and outcomes to the new Director. The COPR would also offer recommendations for future opportunities and ways to support the new Director's goals for the COPR.

Brent Jaquet reported that the Communications Work Group had developed a request for information (RFI) targeted to individual consumers, health care providers, and organizations to determine the kinds of health information they sought and how they obtained that information. The RFI complemented a study done by the NIH Office of Communications and Public Liaison to refine efforts to enhance awareness of NIH health information.

COPR members reviewed written public comments from Mira Geffner from the American Porphyria Foundation; Michael Spreadbury of Hamilton, MT; and Diane Gioia-Bargonetti of New York.

John C. Nelson, M.D., M.P.H., presented the Advisory Committee to the Director Liaison Report. Presentations at the December 2008 meeting of the Advisory Committee to the Director included an update on risk assessment for the Boston University National Emerging Infectious Diseases Laboratories and a report on research on the genetics of dog morphology.

Dr. Kington closed the meeting by thanking the COPR members for their continued extensive contributions to the Council and NIH programs.

WELCOME
Elmer R. Freeman, M.S.W., and Linda Crew McNamara, M.B.A., R.N.

Elmer R. Freeman, M.S.W., Agenda Co-chair, welcomed members of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) to the meeting. He reported that Raynard S. Kington, M.D., Ph.D., Acting Director of NIH, had been delayed and would be joining the meeting later in the day. Lawrence A. Tabak, D.D.S., Ph.D., Acting Deputy Director of NIH, would present the NIH Director's Update.

NIH DIRECTOR'S UPDATE
Lawrence A. Tabak, D.D.S., Ph.D.
Acting Deputy Director, NIH

Lawrence A. Tabak, D.D.S., Ph.D., officially welcomed the COPR members and conditional appointees to the COPR's 21st meeting.

Dr. Tabak welcomed and introduced the new COPR appointees: Stephanie Aaronson; Amye Leong, M.B.A.; Jordan P. Lewis, M.S.W.; Gregory R. Nycz; Lynn M. Olson, Ph.D.; and Leo Wilton, Ph.D. The appointees were selected through an extremely competitive application process. Dr. Tabak hoped that the appointees would find their service to the Council to be rewarding and meaningful.

Biennial Report

Dr. Tabak reported that NIH had released its first *Biennial Report of the Director* in January 2009. Congress had mandated the report as part of the NIH Reform Act of 2006, which condensed approximately 30 reports into a single document. The new report assessed the state of biomedical and behavioral research and provided details on the research, priorities, and plans of the NIH Institutes and Centers (ICs). The report is available online at http://report.nih.gov/biennialreport.

Stem Cells

On March 9, 2009, President Obama issued an executive order removing limits on federally supported research on human embryonic stem cells and directing NIH to expand its support for human stem cell research. The order allows NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." At the time of the COPR meeting, NIH was developing draft guidelines to govern its funding of stem cell research and was planning to establish a formal process to gather public input on the draft guidelines. NIH expected to release the guidelines within the 120-day time frame called for in the executive order. COPR members were encouraged to participate in the public input opportunity and share it widely among their constituencies.

Dr. Tabak provided an update on the impact of the American Recovery and Reinvestment Act (ARRA) on NIH. This funding was designed to stimulate the economy, create and preserve jobs, and advance biomedical research. Dr. Tabak expressed the agency's gratitude to President Obama and Congress for NIH's opportunity to play a role in improving the nation's health and economy.

ARRA appropriated $10 billion directly to NIH. This funding included:

- $8.2 billion for extramural scientific research.
- $1 billion for facilities repair, renovations, and construction at extramural institutions funded by NIH.
- $500 million for repair, improvements, and construction of NIH facilities.
- $300 million for scientific equipment in the extramural research community.

The Agency for Healthcare Research and Quality (AHRQ) would receive an additional $400 million of ARRA funds for comparative effectiveness research.

NIH planned to use some of the funds to stimulate and accelerate biomedical research through existing mechanisms. Specifically, the agency would fund meritorious R01, R21, and R03 grant applications that had been peer reviewed and approved for funding by National Advisory

Councils of the ICs but were not funded because of insufficient resources. The ICs also would award administrative supplements to accelerate ongoing research.

NIH planned to use other ARRA funds to expand science with new programs through revisions to extant programs (formerly called "competitive supplements"), new NIH-wide programs, and new IC-specific programs. New NIH-wide programs would include the following:

- Challenge Grants funding up to $500,000 per year for up to 2 years to address gaps in existing knowledge identified by the ICs.
- Grand Opportunities (GO) grants to support high-impact, well-defined, and large-scale projects.
- Signature Initiatives, or exceptionally creative projects, to address major challenges in biomedical research in such areas as nanotechnology, genome-wide association studies, Alzheimer's disease, large-scale sequencing projects using oral fluids as biomarkers, and community-based research.

Another ARRA-supported program would support summer research jobs for students and summer internships for science teachers at NIH-funded laboratories. These programs would engage students and educators in research and encourage students to pursue science careers. In addition, NIH planned to enhance research capacity in U.S. academic institutions by supporting newly trained scientists, pilot research projects, and bioethicist recruitment. Dr. Tabak encouraged COPR members to promote the opportunity through their constituencies, noting the impact this program could have to enhance the research pipeline by increasing the number of young people who became fascinated and excited by science. The program also would provide opportunities for teachers to make their resources and lessons more exciting and innovative.

A new program to support faculty recruitment was funded under ARRA as well. Core Centers for Enhancing Research Capacity in U.S. Academic Institutions were designed to help institutions recruit new faculty through startup packages and pilot research projects. Particular emphasis was placed on recruitment of bioethicists. One example of an IC-specific program was the research addressing the heterogeneity in Autism Spectrum Disorders through the National Institute of Mental Health.

NIH planned to use the ARRA funds for the NIH Common Fund to stimulate and accelerate biomedical research with existing mechanisms, including support for additional New Innovator Grants and administrative supplements to accelerate ongoing research. The funds would also support Challenge Grants addressing current Common Fund emphasis areas and GO grants addressing a broad spectrum of trans-NIH topics.

Budget Update

John Bartrum, Associate Director for Budget in the NIH Office of the Director (OD), reported that Congress had passed the fiscal year (FY) 2009 federal budget on March 11. This budget provided NIH with a 3.2% increase over the FY 2008 budget. The legislation also provided funding to support a rare and neglected disease initiative, continue the National Children's Study, and increase the NIH Common Fund.

The President was expected to release his FY 2010 budget in May. The budget was expected to propose investing more than $6 billion in cancer research across NIH as part of a multiyear strategy to double federal cancer research funding. It would also include funding for autism research.

Legislative Update

Marc Smolonsky, Associate Director for Legislative Policy and Analysis, explained that NIH was one of many federal programs considered for inclusion in ARRA. Therefore, NIH's inclusion in the bill was an extraordinary affirmation of Congress's confidence in NIH and boded well for the agency's future. Congress's continued interest in NIH was demonstrated by the fact that in its first few months, the new Congress considered almost 50 bills related to NIH.

Two bills of particular importance included an effort led by Senator Edward Kennedy (D-MA) to reauthorize the National Cancer Act and a proposal led by Senator Charles Grassley (R-IA) to tighten NIH oversight of conflicts of interest among agency grantees.

Discussion (COPR Members)

Amye Leong, M.B.A., requested regular updates on legislation that could affect NIH. Mr. Smolonsky said that his office could provide the COPR with regular updates. In addition, the Office of Legislative Policy and Analysis posts information on legislation relevant to NIH on its Web site at http://olpa.od.nih.gov. Kelli L. Carrington, M.A., added that the Office of Communications and Public Liaison (OCPL), OD, provided COPR members with frequent updates on legislative activities and the new conditional appointees would begin to receive this information.

Matthew Margo, LL.M., asked whether NIH had developed plans for the increased cancer research funding that would start in FY 2010. He also asked whether NIH's plans included increased research on chronic obstructive pulmonary disease (COPD). Mr. Bartrum explained that much of the information on the FY 2010 budget was not yet publicly available but would be for the start of the fiscal year. Mr. Smolonsky added that Congressional mandates to conduct disease-specific research could be disruptive to the goal of funding sound science and sometimes undermined the peer review process.

John Walsh asked how NIH would use its comparative effectiveness funds, noting that it seemed AHRQ planned to use its comparative effectiveness funds to study cost-effectiveness. He also stressed a need for interaction among the agencies for an effective approach to comparison. Dr. Tabak replied that, as provided in the context of the Challenge Grant topics, NIH planned to define the concept broadly.

John C. Nelson, M.D., M.P.H., suggested that NIH develop a "stem cell 101" video to explain stem cell research to the public. Dr. Tabak said that NIH had some education materials on stem cell research but a basic video was a good idea. He added that a well-informed public was the agency's best ally.

Syed M. Ahmed, M.D., Dr.P.H., M.P.H., commented that most biomedical research took longer than 2 years and asked if there was an option for institutions to use the funds for longer-term research projects. Dr. Tabak explained that NIH had to balance the need to spend the ARRA funds to stimulate the economy with the time required to conduct high-quality research. For this reason, NIH was not using a formulaic approach in its ARRA plans. Program staff members were reviewing each application carefully and methodically to ensure that the research could produce results in 2 years. NIH was mindful of the need to establish reasonable criteria for what investigators could accomplish in 2 years.

Gregory R. Nycz asked about NIH's role in comparative effectiveness research given that although most research of this type was focused on populations, in recent years there had been an increased focus on personalized medicine by NIH and others. Dr. Tabak replied that NIH had a long history of supporting this type of research, which had been referred to by other terms. For example, NIH had funded research on the features that make a therapy effective for one person and not another and ways to determine whether patients have these features in advance. Dr. Tabak said that there was a tremendous role for NIH in comparative effectiveness research, and NIH planned to continue and probably expand this type of research.

Ms. Leong asked about NIH's plans after the ARRA funding ended. Dr. Tabak said that a rapid infusion of substantial resources into the system would increase future demand for NIH's resources. This demand would be positive because it would drive scientific advances. The funds would get young people excited about science as a career path. The ARRA-supported programs were one-time opportunities and would not be renewable. They were likely to generate many ideas that would be the focus of applications for renewable mechanisms. In addition, the ARRA funds would support infrastructure that would persist when the funding ended and would support the science of the future. The funding had many attributes, including and importantly sparking and supporting interests of young people in science.

Naomi Cottoms, M.S., asked whether the new summer job opportunities would include positions in rural areas. Dr. Tabak said that any institution that received NIH funding could offer training to students and science teachers. He noted that an NIH Web site

(http://grants.nih.gov/recovery/summer_opps_contacts.html) listed institutions around the country that offer summer educational programs supported by ARRA funds.

Mr. Freeman requested clarification on NIH's signature initiative on community-based research. Dr. Tabak said that the NIH OD would administer this initiative, which was in its formative stages. NIH would use these funds to create an infrastructure that could support community-based research after the ARRA funding ended. NIH might also engage with local and national foundations to ensure that the infrastructure would be used in the future. Dr. Tabak predicted that the initiative would probably start in FY 2010 to provide NIH and prospective applicants with sufficient time to prepare.

In response to comments by Stephanie Aaronson about including mechanisms for outreach and recruitment of teachers and curriculum models to connect students to science, Dr. Tabak explained that NIH supported the development of science curricula from elementary through high school and that these curricula were freely available to teachers across the country.

SCIENCE EDUCATION PARTNERSHIP AWARD PROGRAM
L. Tony Beck, Ph.D.
Program Officer, Division for Clinical Research Resources, National Center for Research Resources (NCRR), NIH

L. Tony Beck, Ph.D., reported that almost half of American adults, or 90 million people, had difficulty understanding and using health information and that only 17% of Americans considered themselves well informed about science, and most had not heard of NIH. Furthermore, he said, U.S. students performed poorly on international tests of math, science, and problem-solving skills compared to students in other countries.

Dr. Beck explained that NIH had created the Science Education Partnership Award (SEPA) program in 1991 to develop a diverse pipeline of future scientists and clinicians. SEPA encouraged and supported partnerships between scientists or clinicians and educators, community organizations, and science centers to increase the participation of a diverse population of young people in clinical and basic research careers. The program's informal

purpose was to improve understanding and support of NIH-funded medical research among K–12 students and adults.

SEPA offered programs in science, technology, engineering, and mathematics (STEM) at 44 project sites for K–12 students, parents, and teachers. It also supported informal science education at 24 science centers and museums. These programs targeted students from minority populations living in inner cities, rural areas, and tribal communities. SEPA projects advanced science and health education through such mechanisms as interactive traveling exhibits, three-dimensional animated lessons, virtual and mobile laboratories, and online teaching curricula.

SEPA had several mobile laboratories that traveled to different communities and offered students, teachers, and the lay press the opportunity to conduct hands-on experiments. SEPA also had developed a Web site (http://www.ncrrsepa.org) offering educational resources (including lists of workshops, museum exhibits, and Web sites) for K–12 and college students. The site provided free downloadable classroom curricula for teachers and information on current and past SEPA projects. All SEPA projects were required to make clear that they were funded by NIH.

Dr. Beck listed many topics of interest to the COPR that SEPA projects had addressed, including infectious disease control and prevention, health literacy, and health disparities. Dr. Beck said he would like to identify resources and networking opportunities through SEPA to support COPR member activities.

Discussion (COPR Members)

Dr. Ahmed warned against underestimating the extent of health illiteracy in the United States. Dr. Beck said that one of SEPA's goals was to teach the public about the connections between lifestyle and health.

Mr. Walsh asked about SEPA evaluations. Dr. Beck said that SEPA had always included an evaluation component and had increased the rigor required for SEPA evaluation plans in response to Department of Health and Human Services requests.

Brent Jaquet asked about the role of other ICs in supporting SEPA and whether the program would receive any stimulus funding. Dr. Beck explained that several ICs were co-funding SEPA projects and the stimulus funding offered several opportunities for SEPA. For example, the ARRA supplement opportunity, Summer Research Experiences for Students and Science Educators, was very well suited for SEPA because many of the SEPA projects included this type of internship opportunity.

Ann-Gel S. Palermo, M.P.H., pointed out the limited number of minority males pursuing science careers. Dr. Beck said that the students served by SEPA were of both sexes and many different ethnic backgrounds. Many SEPA projects used the Near-Peer Mentor model, in which college students encouraged younger students to pursue science. These mentors included males and females from different ethnic backgrounds.

Ms. Palermo asked whether NCRR could use its evaluation results to support policy changes that could make medical, dental, and pharmacy school affordable. Dr. Beck replied that some SEPA programs had arrangements with local universities to cover the costs of a college education for qualified students. Dr. Beck was working with other SEPA programs to help underserved students succeed in graduate school.

Carlos Pavão, M.P.A., praised the informal nature of the SEPA programs, which taught students that science is fun. He added that the Health Resources and Services Administration (HRSA) supported a program encouraging youth of color to enter the health care field and suggested that perhaps SEPA could collaborate with HRSA.

NANOTECHNOLOGY AND THE PUBLIC'S HEALTH
Roderic Pettigrew, M.D., Ph.D.
Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH

Roderic Pettigrew, M.D., Ph.D., explained that a nanometer (nm) was 1 billionth of a meter. HE said that the advantages of small size included:

- Nanotechnology operates at the scale of biologic intracellular and transcellular activity.
- Nanoscale objects have greater surface area relative to volume than large objects (for example, 4 g of carbon nanotubes, which weigh slightly less than a teaspoon of water, have the same surface size as a football field).
- Nanoscale objects have greater response to biophysical (electrochemical) forces.

Dr. Pettigrew said that scientists could use nanotechnology to investigate the fundamental mechanisms of disease. Specifically, they could use cellular and molecular imaging of nanoscale particles to understand clinically important problems. For example, investigators were using this technology to identify Alzheimer's disease in patients before they exhibited memory loss.

Nanotechnology was used to improve medical diagnostics in the early stages of disease and at the initial point of contact with the health care provider. For example, a nanotechnology-based small handheld device under development could detect the presence of chlamydia, a common sexually transmitted disease. Another technology was designed to detect circulating tumor cells in a sample of blood at a concentration of one tumor cell per billion normal cells; this technology could be useful for preventing cancer metastases by identifying the need for therapeutic intervention before a metastatic tumor had formed.

Scientists also were using nanotechnology for targeted drug and gene delivery. The ultimate goal was to take advantage of the unique properties of nanotechnology to combine diagnostics and therapeutics. For example, researchers had developed a nanoparticle to help visualize cancer in the brain. This nanoparticle could also carry an agent that provided therapy when stimulated by light.

Discussion (COPR Members)

Ms. Leong asked about the potential adverse effects of nanomedicine. Dr. Pettigrew replied that the ability of nanotechnology to deliver drugs only to the intended site held the promise of reducing side effects, although it might not eliminate them. However, he said, nanotechnology

was associated with some concerns, such as the need to understand the unique biosafety profiles of small particles.

Ms. Leong asked how NIH prioritized funding for its nanotechnology research. Dr. Pettigrew explained that NIH funded projects suggested by investigators and tried to stimulate research in areas that it identified as having high priority or potential.

Mr. Margo asked about NIH's budget for nanotechnology research. Karen Peterson, Ph.D., of NIBIB, replied that the total funding for nanotechnology across NIH was $304 million. The primary NIH sponsors of nanotechnology research were the National Cancer Institute, NIBIB, the National Institute of General Medical Sciences, and the National Heart, Lung, and Blood Institute.

Mr. Margo asked Dr. Pettigrew whether he predicted positive developments in Alzheimer's disease. Dr. Pettigrew said that research had made steady progress in this field and there was no reason to believe that this progress would not continue. Although scientists understood a great deal about the disease's pathophysiology, he said, no effective medicines were currently available. A tool that could identify the disease in patients before they developed symptoms would be promising for the day when an effective intervention became available.

DRAFT NIH GUIDELINES FOR HUMAN STEM CELL RESEARCH

The COPR listened to a teleconference in which Dr. Kington announced that NIH had just issued draft guidelines for human stem cell research. These draft guidelines would allow funding for research using human embryonic stem cells that were derived from embryos created by *in vitro* fertilization (IVF) for reproductive purposes and were no longer needed for that purpose. The draft guidelines are available in the *Federal Register* at http://edocket.access.gpo.gov/2009/E9-9313.htm.

To comply with Federal Advisory Committee Act Regulations, COPR members did not discuss the draft guidelines during this meeting.

THE SCIENCE OF ELIMINATING HEALTH DISPARITIES CONFERENCE

Joyce A. Hunter, Ph.D.
Deputy Director, National Center on Minority Health and Health Disparities (NCMHD), NIH

Joyce A. Hunter, Ph.D., reported that NCMHD coordinated the first NIH research summit on "The Science of Eliminating Health Disparities" on December 16–18, 2008. The summit focused on the integration of science, practice, and policy. More than 4,400 scientists, clinicians, policymakers, and health advocates participated.

Additionally, approximately 1,400 young investigators attended a pre-summit workshop focused on the NIH grant process. The workshop included sessions on funding mechanisms, an overview of the agency's peer review process, a CD of a mock study session, and two presentations (fundamentals and advanced) on writing a fundable application. The 3-day summit activities began with an opening session featuring Dr. Maya Angelou. During the opening ceremony, Dr. Kington announced the development of an NCMHD Intramural Program. Plenary presentations, scientific breakout sessions, and poster and exhibitor displays were held each day. An awards banquet recognized several individuals who had made extraordinary contributions to improving minority health or eliminating health disparities. A town hall meeting provided an opportunity for participants to offer recommendations for health reform to be sent to the White House.

Dr. Hunter said that NCMHD planned to issue a report with the recommendations from the summit later in the year. The Center also had commissioned a supplement in the *American Journal of Public Health* focused on scientific presentations from the breakout sessions that would be published in the winter of 2010.

Discussion (COPR Members)

Mr. Pavão attended the summit and commended the organizers for defining "disparities" broadly to include disabilities, socioeconomic factors, and sexual orientation and for engaging community members.

Ms. Cottoms also attended the summit. She commented that participants defined "cultural competence" in different ways and asked NCMHD to take the lead in developing a common concept for this notion.

Ms. Leong asked about the role of the community in working with NCMHD and NIH to implement some of the recommendations from the summit. Dr. Hunter explained that NCMHD coordinated NIH's health disparities strategic plan and the next version of the plan would probably include some of the summit recommendations. This document would provide guidance on future directions for NCMHD, NIH, and partners.

Mr. Jaquet asked whether the video of a mock study section was available on the Internet. Dr. Hunter replied that the video was available but it had been based on an earlier set of review criteria. The Center for Scientific Review was revising the video to reflect the current review criteria.

Micah Berman, J.D., pointed out that a common theme from the summit recommendations was the recognition that health is about much more than medicine. He said that this theme needed to be recognized throughout NIH.

Mr. Pavão commented that the summit included speakers from many federal agencies. Dr. Hunter explained that NCMHD had always collaborated with other federal partners. A priority for the summit was the inclusion of representatives of underserved populations.

COPR WORK GROUP PRESENTATIONS

Agenda Work Group Presentation
Elmer R. Freeman, M.S.W., and Linda Crew McNamara, M.B.A., R.N.

Linda Crew McNamara, M.B.A., R.N., reported that the COPR's Agenda Work Group had met on the previous day to discuss how the COPR should introduce itself to the new NIH Director upon his or her appointment. The work group decided that it would present the COPR's history, values, processes, and outcomes. The COPR would also offer recommendations for future opportunities for the Council and discuss ways to support the new Director's goals for the COPR. Ms. Crew McNamara reported the contributions of the COPR members to NIH programs and outreach activities since October 2008. She noted that activities were listed on the COPR Web site at http://copr.nih.gov/activities.asp.

COPR members viewed some colonoscopy public service announcements produced by Mr. Margo. These announcements referred viewers to the CBS Cares Web site, which featured a link to the National Cancer Institute's colon and rectal cancer home page.

Communications Work Group Presentation
Brent Jaquet

Mr. Jaquet reported that the Communications Work Group had developed a request for information (RFI) targeted to individual consumers, health care providers, and organizations to determine the kinds of health information they sought and how they obtained that information. The RFI complemented the NIH OCPL study designed to refine efforts to enhance awareness of NIH health information. Respondents would be able to submit their input through an NIH Web site, by e-mail, or by regular mail. The COPR recommended that the RFI be open for 180 days. The COPR planned to evaluate the success of this effort for future activities in which it would seek public input.

Mr. Jaquet explained that the OCPL would disseminate the RFI to NIH constituency groups through the Office of the Director and the ICs. All COPR members and COPR alumni would be asked to have at least five external contacts submit responses. The work group emphasized the importance of reaching out to a broad range of consumers through online social networks, blogging communities, and CTSA grantees and their community partners.

As an incentive to respond to the RFI, COPR members suggested NIH might offer all respondents the opportunity to tour the NIH campus and meet with NIH staff to discuss issues relevant to the RFI.

Mr. Jaquet noted that once the responses were received, they would need to be analyzed, and Leo Wilton, Ph.D., had offered to assist OCPL with this task. OCPL planned to use the results for planning purposes.

NIH DIRECTOR'S REMARKS
Raynard S. Kington, M.D., Ph.D.
Acting Director, NIH

Raynard S. Kington, M.D., Ph.D., joined the COPR for the remainder of the meeting (after the Stem Cell Teleconference). He thanked the work groups for their recommendations and said that NIH was likely to act on the results of the Communications Work Group's RFI.

Dr. Kington said that he was delighted to develop draft guidelines to expand opportunities in research and opportunities using human embryonic stem cells. He said that NIH believed that these areas of research held great promise for helping scientists understand the human body and develop interventions to improve human health. NIH would rely on the COPR members as spokespersons to help the public understand the agency's activities in these areas and to encourage their communities to comment on the draft guidelines.

PUBLIC COMMENT

Mr. Freeman announced that COPR had received three written public comments:

- Mira Geffner, Development Director of the American Porphyria Foundation, commented on the importance of porphyria research.
- Michael Spreadbury of Hamilton, MT, expressed concern about the safety of the NIH Rocky Mountain Laboratories.
- Diane Gioia-Bargonetti of New York discussed the need to build bridges between the medical and alternative communities.

ADVISORY COMMITTEE TO THE DIRECTOR (ACD) LIAISON REPORT
John C. Nelson, M.D., M.P.H.

Dr. Nelson reported that at the ACD's last meeting, the committee had heard a presentation on the NIH Blue Ribbon Panel to Advise on Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories (BU Panel). Pending the outcome of court decisions, the facility would have no biosafety lab level 3 or 4 operations. A set of principles and best practices was being developed that could be used for similar events in the future. The BU Panel would provide an update to the ACD at its June 4 meeting.

Other presentations at the meeting included:

- An update from Dr. Tabak on NIH's efforts to enhance its peer review process.
- A discussion by Sally Rockey, Ph.D., on NIH's procedures for ensuring objectivity in research through its financial conflict-of-interest regulations.
- Information from Elaine Ostrander, Ph.D., of the National Human Genome Research Institute on recent research on the genetics of dog morphology, which could be informative for scientists studying the human genome.
- A report by Josephine Briggs, M.D., Director of the National Center on Complementary and Alternative Medicine (NCCAM), on NIH's research on complementary and alternative medicine (CAM).

Discussion (COPR Members)

Mr. Margo asked about the lessons learned from dog genetics for human health. Dr. Nelson explained that like humans, dogs shared the same genome but were fundamentally different, so the same types of analysis used in these studies could be applied to human genome studies to better understand the reasons for the differences in human health and disease. Using the same kind of analyses performed in the dog studies could help elucidate the reasons for the health differences in humans. Dr. Kington added that this study was reported in a cover article in *Science*. An interesting conclusion in the study was that relatively small differences of the genome control enormous differences between dogs. This finding might provide clues to causal pathways and treatments for human disease. Dr. Kington said his office would send the COPR copies of the article, along with a lay summary and a press release.

Ms. Leong asked about research on CAM at NIH. Dr. Kington replied that NIH believed in using the scientific method as an approach to building evidence for public policy and clinical practice. The public, he said, paid attention to NCCAM's research. For example, when some NCCAM-sponsored trials showed no demonstrable benefit from St. John's wort for depression or echinacea for colds, sales of these products declined considerably. Dr. Kington said that this research was a reasonable investment for the American people because large numbers of Americans used these products. NIH, he said, had an obligation to conduct the research to understand whether the agents and techniques were effective, under what circumstances, and what could be learned from them.

Ms. Leong asked whether NIH was taking a global lead in CAM research. Dr. Kington explained that NIH was the largest research funding agency in the world. He said that NIH-funded research had an impact well beyond the U.S. borders.

CLOSING REMARKS

Dr. Kington closed the meeting by noting that the COPR was an extraordinary committee that provided advice that NIH could not obtain from other sources. He thanked the COPR members for taking the time to serve on the Council and said that NIH and the American people appreciated their service because it helped NIH be a better agency.

Dr. Kington announced that the next COPR meeting would take place on October 30, 2009.

ADJOURNMENT

Dr. Kington adjourned the meeting.

ABBREVIATIONS AND ACRONYMS

ACD	Advisory Committee to the Director
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
CAM	complementary and alternative medicine
COPD	chronic obstructive pulmonary disease
COPR	Council of Public Representatives
CTSA	Clinical and Translational Science Award
FY	fiscal year
GO	Grand Opportunities
HRSA	Health Resources and Services Administration
ICs	Institutes and Centers
IVF	*in vitro* fertilization
NCCAM	National Center on Complementary and Alternative Medicine
NCMHD	National Center on Minority Health and Health Disparities
NCRR	National Center for Research Resources
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIH	National Institutes of Health
nm	nanometer
OCPL	Office of Communications and Public Liaison
OD	Office of the Director
RFI	request for information
SEPA	Science Education Partnership Award