



**Department of Health and Human Services
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Advisory Committee to the Director

98th Meeting

June 4, 2009

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EXECUTIVE SUMMARY

The 98th meeting of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH) was held on June 4, 2009, on the NIH campus. NIH Acting Director Raynard Kington, M.D., Ph.D., chaired the meeting. He welcomed new ACD member James Thrall, M.D., Radiologist-in-Chief, Massachusetts General Hospital; Juan M. Taveras Professor of Radiology, Harvard Medical School; and three nominees who were attending as *ad hoc* consultants: David L. DeMets, Ph.D., Chair of the Department of Biostatistics and Medical Informatics, University of Wisconsin–Madison; James S. Jackson, Ph.D., Director of the Institute for Social Research, University of Michigan; and Jeffrey C. Murray, M.D., Vice Chair for Research, College of Medicine, University of Iowa.

Dr. Kington reported that the NIH received \$10.4 billion from the American Recovery and Reinvestment Act (ARRA), and he described the NIH's plans to fund a wide variety of programs under the act. The fiscal year (FY) 2009 appropriation for NIH was passed on March 11. It provided \$30.3 billion in operating funds and will support, in particular, a new trans-NIH initiative in rare and neglected diseases, the National Children's Study, and the NIH Common Fund.

NIH is developing new guidance on human stem cell research in light of the President's March 9 executive order, "Removing Barriers to Responsible Research Involving Human Stem Cells." Draft guidelines were posted for public comment on April 23. The comment period closed on May 26, and the NIH intends to issue final guidelines on July 7.

The NIH also has been seeking public input on issues related to avoiding financial conflict of interest for NIH-funded researchers. The public comment period on the current regulations will be open until July 7, 2009.

Dr. Kington reported that changes to the NIH peer review process are under way. Many changes are in place or are being piloted, and the changes include activities related to the new ARRA programs.

Jeremy Berg, Ph.D., Director, National Institute of General Medical Sciences, reviewed the NIH's current efforts to promote new investigators. More than 450 grants have been awarded under the NIH Pathway to Independence Award (K99/R00) program, which was initiated in 2006 and supports up to 2 years of postdoctoral research followed by up to 3 years of independent research combined with a faculty position. The NIH Director's New Innovator Award, which was launched in February 2007 and targets new investigators who are within 10 years of their terminal degree or end of clinical training, is funding exceptionally innovative research. The program funded 30 awards in 2007 and 31 awards in 2008.

Thomas Kelly, M.D., Ph.D., Director, Sloan-Kettering Institute, described the development and activities of the new NIH Scientific Management Review Board (SMRB), which was created by the NIH Reform Act of 2006 to provide advice for reorganizing the NIH. The SMRB is comprised of non-Federal and Federal members, including at least nine Institute/Center Directors. Its deliberations will strongly feature public input.

Lana Skirboll, Ph.D., Acting Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), provided an update on the new division, which was established by the NIH Reform Act of 2006. DPCPSI activities include identifying, reporting, and funding trans-NIH research related to important areas of emerging science, public health challenges, and knowledge gaps; developing approaches to analyzing the NIH research portfolio; and managing NIH-wide evaluation and performance assessment activities.

Adel Mahmoud, M.D., Ph.D., of Princeton University, and Amy Patterson, M.D., of the NIH Office of the Director, presented the revised recommendations of the ACD Blue Ribbon Panel on risk assessment for the proposed National Emerging Infectious Diseases Laboratory at Boston

University. The recommendations included basic principles and best practices for the project and similar projects in the future.

Beth Furlong, Ph.D., R.N., J.D., reported on activities of the NIH Director's Council of Public Representatives (COPR), which last met on April 16-17, 2009. That meeting included presentations on Science Education Partnership Awards; nanotechnology and the public's health; the Science of Eliminating Health Disparities conference; the Clinical and Translational Science Awards; transparency, access, and public trust; and the NIH communications programs. The COPR members discussed employing a request for information to seek data on the information-seeking behaviors of the public.

Dr. Kington provided further details on programs the NIH planned for the use of the ARRA funding. In particular, the NIH will play a strong advisory role in the use of \$400 million of ARRA funds for comparative effectiveness research. The NIH Office of the Director will oversee a wide range of projects, including both intramural repairs and improvements on the NIH campus and extramural programs (such as the new Challenge Grants and Grand Opportunity Awards, community-based research, summer research experiences for teachers and students, and faculty recruitment in bioethics) to reach out across the Nation.

Jeffrey Taubenberger, M.D., Ph.D., of the National Institute of Allergy and Infectious Diseases, provided background on influenza outbreaks. He described the H1N1 virus (swine flu), which was first detected in Mexico and, subsequently, has spread around the globe, and placed it within the context of the history of influenza A viruses.

Dr. Kington presented, for the ACD members' consideration, a new list of prescreened bona fide cash awards that NIH employees may receive. The ACD members approved the new awards, adding them to the list of previously approved awards.

WELCOME AND NIH DIRECTOR'S REPORT

The 98th meeting of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH) was held on June 4, 2009, on the NIH campus in Bethesda, Maryland, and Webcast globally. NIH Acting Director Raynard S. Kington, M.D., Ph.D., welcomed the ACD members, invited speakers, and other participants.

New Members

Dr. Kington welcomed one new ACD member, James Thrall, M.D., Radiologist-in-Chief, Massachusetts General Hospital, and Juan M. Taveras Professor of Radiology, Harvard Medical School. ACD member Beatriz Luna was unable to attend the meeting. Dr. Kington also welcomed ACD nominees who were attending the meeting as *ad hoc* consultants:

David L. DeMets, Ph.D., Chair of the Department of Biostatistics and Medical Information, University of Wisconsin–Madison; James S. Jackson, Ph.D., Director of the Institute for Social Research, University of Michigan; and Jeffrey C. Murray, M.D., Vice Chair for Research, College of Medicine, University of Iowa. Elizabeth Furlong, Ph.D., R.N., J.D., the liaison to the ACD from the NIH Director's Council of Public Representatives (COPR), was present.

Agenda

Dr. Kington reviewed the day's agenda, which featured updates on several ongoing NIH efforts, including the initiative for new investigators; the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI); and NIH's implementation of the American Recovery and Reinvestment Act (ARRA). There would be reports on the Scientific Management Review Board (SMRB), the Blue Ribbon Panel on risk assessment for the National Emerging Infectious Diseases Laboratory at Boston University (NEIDL), and the science and origins of influenza.

Personnel Changes and Awards

Dr. Kington reported that on April 29, 2009, Kathleen Sebelius was sworn in as the 21st Secretary of the Department of Health and Human Services (HHS). After 10 years of service at the NIH, Marc Smolonsky stepped down as Associate Director of the Office of Legislative Policy and Analysis, having accepted a position as an advisor within the HHS Office of the Secretary. Rosalind Gray agreed to serve as the Acting Director to the office.

Ira Pastan, M.D., Chief, Laboratory of Molecular Biology, National Cancer Institute (NCI), received the Secretary's Award for Meritorious Service. Two NIH groups received the Hubert H. Humphrey Award for Service to America. Douglas Lowy, M.D., and John Schiller, Ph.D., both of NCI, received the award for their work in human papilloma virus vaccine development. David Chambers, Ph.D.; Jovier Evans, Ph.D.; Amy Goldstein, Ph.D.; Robert Heinssen, Ph.D.; Lauren Hill, Ph.D.; Robert Mays, Ph.D.; Jane Pearson, Ph.D.; Farris Tuma, Sc.D.; Christine Ulbricht; and Philip Wang, M.D., Ph.D., all of the National Institute of Mental Health, received the award for their work on addressing the mental health needs of returning combat veterans.

NIH Budget

Dr. Kington reported that NIH received \$10.4 billion from the American Recovery and Reinvestment Act (ARRA). Of those funds, \$8.2 billion will support scientific research, \$1.5 billion will support construction, \$300 million will support Shared Instrumentation Grants, and \$400 million will be transferred to the Agency for Healthcare Research and Quality (AHRQ) for comparative effectiveness research. The NIH is committed to maximizing the positive impact of these expenditures in the biomedical research community now and in the years to come. Because ARRA funding targets a 2-year window, the NIH has developed novel funding mechanisms, such as Grand Opportunity (GO) Grants and Challenge Grants, to jump-start research in key areas and

to create jobs. Dr. Kington noted that NIH has received approximately 21,000 applications for Challenge Grants.

The fiscal year (FY) 2009 appropriation for NIH was passed on March 11, 2009. It provided the NIH with \$30.3 billion, an increase of 3.2 percent over the FY 2008 level. The budget supports a new trans-NIH initiative in rare and neglected diseases, the National Children's Study, and the NIH Common Fund. It made permanent NIH's effort to increase public access to research results. The President's FY 2010 budget request was released and asks for \$31 billion for NIH, reflecting an emphasis on cancer and autism research.

Legislative Update

By the end of the 110th Congress, more than a dozen public laws affecting the NIH were enacted. NIH staff members participated in 52 hearings on a wide range of topics. Strong interest in the NIH has continued into the 111th Congress, with 77 new bills containing provisions that target NIH research activities or potentially affect the NIH in various ways. Two public laws have been enacted, targeting research on paralysis and postpartum depression. Bill S. 914, Cures Acceleration Network and National Institutes of Health Reauthorization Act of 2009, if passed, will establish an independent agency to make awards to accelerate the development of cures and treatments, will elevate the National Center on Minority Health and Health Disparities to Institute status, will increase the NIH's authorization appropriations for 2010–2012, and will require conflict-of-interest policies for funding recipients.

Dr. Kington and other NIH Directors testified in a series of House and Senate subcommittee meetings on the use of ARRA funds, the National Children's Study, and the NIH budget. Senator Tom Harkin (D-IA) expressed concern for an ability to provide a "soft landing" when the ARRA funding ends. NIH Directors provided examples of new research activities that would not have been initiated without ARRA funds.

Issues and Actions

The NIH continued to move forward with implementing requirements of the NIH Reform Act, producing the NIH Biennial Report for FY 2006 and FY 2007, and holding the inaugural meeting of the NIH SMRB on April 27–28, 2009.

Dr. Kington reported that funding opportunities have been expanded to include stem cell research in light of President Obama's March 9 executive order, "Removing Barriers to Responsible Research Involving Human Stem Cells." The NIH is developing new guidance on human stem cell research. Draft guidelines were posted for public comment from April 23 to May 26. They limit NIH funding to research using human embryonic stem cells that are derived from embryos created by *in vitro* fertilization for reproductive purposes and are no longer needed for that purpose. Some 48,000 comments were received, and final guidelines will be issued on July 7.

NIH also has been seeking public input on Federal regulations regarding conflicts of interest. It is committed to supporting collaborations that are in the best interests of the American people and has invited comment on all aspects of the current regulations. The comment period is open until July 7, 2009. The NIH has already taken steps to strengthen its existing policies, including training NIH staff to help investigators understand and learn how to manage conflicts.

Dr. Kington reported that changes to the NIH peer review process are under way. Many changes are in place or are being piloted, and they include activities related to the ARRA funding. The new strategies include (1) efforts to engage the best reviewers, involving training and requiring fewer meetings, (2) efforts to improve the quality and transparency of review, including enhancing review criteria and using a nine-point rating scale, (3) efforts to ensure balanced and fair reviews across fields and career stages, including the identification and promotion of new and early-stage investigators, and (4) the establishment of a continuous review of the peer review process.

Discussion

The ACD members commented on the Director's report. Maria Freire, Ph.D., asked about funding to support the program on rare and neglected diseases. Dr. Kington responded that the NIH will use existing resources to support investigators, potentially working with industry, to lower barriers and allow new products to be tested.

Mary-Claire King, Ph.D., asked about potential efforts to provide a soft landing at the end of ARRA funding and to extend funding. Dr. Kington noted that follow-up discussions on that issue are yet to occur. Barbara Wolfe, Ph.D., encouraged NIH to demonstrate the effectiveness of the use of ARRA funds. Dr. Kington noted that tracking activities are under way, but many outcomes of using the ARRA funds (e.g., publications) likely will be realized after the short time frame of the program. He stressed that one part of the program supports laboratory jobs for high school and college students. Dr. Furlong encouraged NIH to publicize the use of ARRA funds by institutions. Colleen Conway-Welch, Ph.D., cited a need to make the story of the use of ARRA funds compelling and understandable to the public. Dr. Kington noted that about \$500 million of NIH's ARRA funds have been distributed so far, with more to be distributed very soon. A floor of \$200 million had been envisioned as support for the Challenge Grants, but more than twice that amount may be disbursed.

Ralph Horwitz, M.D., wondered about possible strategies within the new cures network. Dr. Kington replied that this complex issue likely will be a focus for the next NIH Director. It might benefit from creative ideas in the rare diseases initiative. Dr. Horwitz also cited a need to consider areas outside the NIH's work that relate to opportunities for advances in community health. Health advocacy groups are playing a role.

UPDATE ON NEW INVESTIGATORS

Jeremy Berg, Ph.D., Director, National Institute of General Medical Sciences, reviewed the NIH's current efforts to promote new investigators. He described past analyses of the challenge, showing the strong trend toward older average ages of NIH-funded principal investigators (PIs). In 2006, NIH initiated the Pathway to Independence Award (K99/R00) program, which encourages new investigators by supporting up to 2 years of postdoctoral research followed by up to 3 years of independent research combined with a faculty position. It made 183 awards in 2007 and 180 awards in 2008. In all, 453 grants have been awarded. Dr. Berg noted that about 20 percent of the awards are for human subjects research. Almost all awardees have remained at the institution where they conducted their postdoctoral training for their K99 work. So far, 120 K99 grantees have transitioned to the R00, including six from intramural NIH. Only 20 K99s have ended without a transition to the R00.

Dr. Berg reviewed progress for the NIH Director's New Innovator Award, which was launched in February 2007 and targets new investigators who are within 10 years of their terminal degree or end of clinical training. The goal is to fund exceptionally innovative research. The program funded 30 awards in 2007 and 31 awards in 2008 and has helped increase the total number of new R01 investigators. Dr. Berg reviewed the NIH policy for funding new and early-stage investigators. Its goals are to raise the success rate of new investigators to that of established investigators submitting new applications and to increase the percentage of early-stage investigators in the pool of new investigators from 55 percent to about 75 percent. Dr. Berg noted that ARRA funds will support P30 grants for new faculty recruitment to enhance research resources through biomedical research core centers.

Discussion

Thomas J. Kelly, M.D., Ph.D., encouraged NIH to model the distribution of investigators 20 years from now, based on the current initiatives. He wondered whether some factors that make it

difficult to bring young investigators into the NIH portfolio are external to the NIH (e.g., extended residencies). Dr. Murray encouraged the NIH to track the K99/R00 investigators to gauge success of the program and to track the effects of multiple-PI mechanisms.

Dr. King asked the NIH to consider the need to train young investigators to write successful applications. Dr. Thrall proposed the creation of incentives to reduce the length of the postdoctoral period. Dr. Berg noted that the NIH has been reluctant to use the strategy of start-up packages, preferring that investigators seek initial R01s. Catherine DeAngelis, M.D., M.P.H., cited a need to increase the number of physician investigators. Perhaps partnerships could be used to shift research toward, for example, human subjects research. The Clinical and Translational Science Awards (CTSAs) encourage that, to some extent. Dr. DeMets cited a lack of quantitative scientists—more R01 awards and training are needed in that area. Dr. Jackson noted that the older average age of PIs is not all bad. The upcoming National Research Service Award Report will provide information about this and many of the issues being discussed. Dr. Kington stated that the report will be distributed to the ACD members at the next meeting. Keith Yamamoto, Ph.D., wondered whether the NIH might play a role in defining the academic mission for training graduate students. A serious consideration could affect the time involved. Dr. Kington called for analysis of the situation.

NIH SCIENTIFIC MANAGEMENT REVIEW BOARD (SMRB): AN OVERVIEW

Dr. Kelly, a member of both the Advisory Committee to the Director (ACD) and the Scientific Management Review Board (SMRB), described the development and activities of the SMRB, which was created by the NIH Reform Act of 2006 to provide advice for reorganizing the NIH. Dr. Kelly reviewed the organizational evolution of NIH, which has been characterized by growth through addition rather than reorganization. Today the NIH includes 27 Institutes and Centers (ICs) and a series of special offices within the Office of the Director. In 2001, Congress expressed concern about the need for coordination within NIH. An Institute of Medicine (IOM)

report in 2003 recommended that the NIH Director initiate a public process to evaluate scientific needs, opportunities, and consequences relevant to any proposed changes in the number of ICs.

By statute, the SMRB comprises non-Federal and Federal members, including at least nine IC Directors. The current SMRB Chair is Norman Augustine, of Lockheed Martin. The SMRB is charged with determining, at least once every 7 years, the extent to which organizational authority should be used. In that time, it also must issue a full report with recommendations. Its deliberations must afford ample opportunity for public input. Dr. Kelly reported that the first meeting of the Board occurred April 27-28, 2009. The members received a series of briefings and formed the following workgroups:

- *Deliberating Organizational Change (DOC):*
 - The DOC Working Group will consider principles for optimal design of biomedical research enterprises and will develop principles, criteria and strategies for contemplating changes in the NIH organization.

- *Substance Use, Abuse, and Addiction (SUAA):*
 - The SUAA Working Group will analyze the state of the science of substance use, abuse, and addiction; will consider public health needs to determine whether organizational or management changes are needed; and, if so, will consider options and strategies for reorganizations.

- *Clinical Center/Intramural Research Program (CCIRP):*
 - The CCIRP Working Group will analyze current scientific opportunities and public health needs to determine whether organizational or management changes are needed, and, if so, will consider options and strategies for such.

Discussion

Dr. Wolfe noted that the NIH organization chart placed the Office of Behavioral and Social Sciences Research (OBSSR) within DPCPSI. Dr. Kington stated that DPCPSI includes agencies with cross-cutting content. Congress shifted OBSSR's placement in the NIH structure with no change in its budget. John Nelson, M.D., M.P.H., encouraged the SMRB to liaise with associations within the clinical community. Karen Holbrook, Ph.D., wondered whether the SMRB intends to "tinker" with the NIH structure or propose large, bold reorganization.

Dr. Kelly noted that the IOM report laid out broad principles, so the Board can move forward to consider some specifics. Dr. Yamamoto urged the SMRB to consider large-scale organizational change and not only specific revisions within the structure. Dr. Kelly stated that the SMRB's reports will be distributed to Congress and elsewhere, including to the NIH Director.

Dr. Kington agreed with the other ACD members that the SMRB should obtain input from the ACD. Michael Gottesman, M.D., Deputy Director for Intramural Research, noted that the NIH Clinical Center (and its linked activities, such as the CTSAs) would benefit from a business model. Perhaps the SMRB could help develop one. Alan Leshner, Ph.D., urged the SMRB to avoid duplicating previous reports about the NIH's organization, such as reports on the intramural/extramural relationship.

DIRECTOR'S REPORT: DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI)

Lana Skirboll, Ph.D., Acting Director of DPCPSI, reviewed the progress of the new division, which was established by the NIH Reform Act of 2006. DPCPSI's activities include:

- Identifying, reporting, and funding trans-NIH research related to important areas of emerging science, public health challenges, and knowledge gaps.
- Developing new approaches to analyzing the NIH research portfolio.

- Managing NIH-wide evaluation and performance assessment activities.
- Coordinating activities related to research on AIDS, behavioral and social sciences, women's health, disease prevention, rare diseases, and dietary supplements.

DPCPSI oversees management of the Common Fund, which currently is 1.8 percent of the NIH budget. In FY 2008, the fund provided 1,076 new awards. It supports programs within the NIH Roadmap for Medical Research, which seeks to transform the way research is conducted and targets research programs that do not fall within the mission of a single IC. About 30 percent of the Common Fund budget provides funding for high-risk, high-reward projects. The projects emphasize human biology, clinical research, and translation of research to improve health. Some initiatives focus on the development of tools, methodologies, or technologies. Dr. Skirboll described the Pioneer Award Program, the New Innovator Award Program, and the TR01 Program, which encourage innovation using Common Fund monies. She reviewed the planned uses of ARRA funds within the Common Fund program, including Challenge Grants, GO Grants, and supplements.

Discussion

Dr. Freire encouraged NIH to measure the economic impact of the use of ARRA funds and to publicize the results. Dr. Wolfe added that the science of cost/benefit analysis related to the NIH efforts needs to improve. Dr. Kington noted that NIH is developing a new blueprint initiative to provide investments in behavioral research across the NIH research portfolio.

BLUE RIBBON PANEL TO ADVISE ON THE RISK ASSESSMENT OF THE NATIONAL EMERGING INFECTIOUS DISEASES LABORATORY

Adel Mahmoud, M.D., Ph.D., of Princeton University, presented the revised recommendations of the ACD Blue Ribbon Panel on the risk assessment for the proposed high- and maximum-containment research laboratory (the National Emerging Infectious Diseases Laboratory (NEIDL)) at Boston University. Amy Patterson, M.D., of the NIH Office of the Director, reviewed the background of the project, beginning with a grant awarded by the National Institute of Allergy and Infectious Diseases (NIAID) to Boston University Medical Center to build the laboratory and including the work of the Blue Ribbon Panel, which was established to guide the NIH in responding to judicial requests and public concerns regarding potential public health risks. The Panel's charge is to provide advice and recommendations regarding the development of strategies to assess and mitigate any potential health risks and to enhance local community engagement and communications. To inform the Panel's analysis, the NIH commissioned a National Research Council committee to evaluate a previous risk assessment. The Panel has conducted eight public presentations on the project.

Dr. Mahmoud reviewed the final recommendations of the Blue Ribbon Panel regarding the design of a supplementary risk assessment including the proposed agents for study, scenarios, and methodologies. The Panel also made recommendations for community engagement and communication, based on a series of public meetings attended by members of Boston communities. Dr. Mahmoud had presented the Panel's draft principles and recommendations for community engagement at the December 2008 ACD meeting. The ACD members' comments were incorporated to produce the following principles:

- Rigorous, balanced, and transparent local biosafety review of proposed research.
- Transparency regarding laboratory operations, research, and oversight.
- Appropriate scientific and technical expertise.

- Community engagement.
- Engagement of local public health authorities.
- Ongoing operations oversight.

Dr. Mahmoud presented details for the following recommended best practices:

- Transparent biosafety assessment of biocontainment research by an expert committee.
- Communications about phase-in of high- and maximum-containment research operations.
- Communications about the body of scientific and technical expertise applied to the operations of high- and maximum-containment laboratories.
- Engagement of local public health authorities.
- Ongoing community liaison activities.

Discussion

Dr. Nelson proposed that the principle of community engagement be moved up to the first position in the list of six principles. He proposed raising the fifth principle to the second position. The final principle, oversight, should include oversight at the local level. Dr. Patterson noted that the building in Boston is complete and is awaiting local permits. It will serve as a training facility for public health responders. Three lawsuits challenging the proposed biocontainment-facility component continue to make their way through the court systems.

Dr. Mahmoud stressed that the plan is to have public health officials play an ongoing role in the

functioning of the facility. The ACD members voted unanimously to approve the recommendations with the changes suggested by Dr. Nelson.

NIH DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES (COPR) LIAISON REPORT

Dr. Furlong reported on activities of the COPR, which met on April 16-17, 2009. That meeting featured presentations by Anthony Beck, Ph.D., on Science Education Partnership Awards; Roderic Pettigrew, M.D., Ph.D., on nanotechnology and the public's health; Joyce Hunter, Ph.D., on the Science of Eliminating Health Disparities Conference; Karen Peterson, Ph.D., on nanomedicine at the NIH; Timothy Hays, Ph.D., on transparency, access, and public trust; Donna Jo McCloskey, Ph.D., R.N., on the CTSA's; and John Burklow on NIH communications programs.

At the April meeting, the COPR welcomed six new members: Stephanie Aaronson; Amye Leong, M.B.A.; Jordan Lewis, M.S.W.; Gregory Nycz; Lynn Olson, Ph.D.; and Leo Wilton, Ph.D. The COPR's Communications Work Group reported on activities for promoting public awareness of the NIH. In particular, it supported the idea of developing and applying a request for information (RFI) to seek data on the information-seeking behaviors of the public. This strategy has the potential to reach a wide and diverse group of health consumers, providers, and organizations. The work group recommended that the NIH base the RFI questions on content from the NIH Communications Directors' Workshop in September and employ COPR alumni to enhance participation. People should be able to use the NIH Web site, e-mail, and regular mail to respond to the RFI. The COPR made a series of recommendations for alerting constituencies and organizations about the RFI and for developing outreach to individuals, populations, online social networks, CTSA participants, advocacy groups, and non-English speakers. Incentives for RFI responders could include tours of the NIH campus. Dr. Furlong stated that the COPR will conduct analysis of the RFI data and examine the usefulness of the RFI process.

Discussion

Dr. Nelson, who is the ACD liaison to the COPR, applauded its efforts and suggested holding a joint ACD-COPR meeting. He stated that COPR members have the capacity to serve as ambassadors for the NIH.

UPDATE ON NIH IMPLEMENTATION OF THE AMERICAN RECOVERY AND REINVESTMENT ACT (ARRA)

Dr. Kington provided a broad view on NIH's approach to ARRA funding, explaining the streams of funding and the status of current initiatives. With receipt of \$400 million of ARRA funds, the NIH will be involved in numerous decisions related to comparative effectiveness research (CER). Elizabeth Nabel, M.D., Director, National Heart, Lung, and Blood Institute, serves as the NIH representative on a Federal Coordinating Committee and participated in a March 2009 stakeholder meeting of the IOM CER Priority Setting Committee. Prior to ARRA, the NIH created an internal CER Coordinating Committee, chaired by Dr. Nabel and Richard Hodes, M.D., Director, National Institute on Aging, to help position the agency within the larger discussion regarding CER.

The NIH Office of the Director will oversee the use of \$500 million for on-campus repairs, improvements, and new construction. The Office also received \$800 million for extramural programs and has used these funds to support activities that will fill gaps across topics, areas, and mechanisms that are not being filled by Institute and Center efforts. As examples, \$200 million will support Challenge Grants, \$30 million will support community-based research, \$26.4 million will support summer training for teachers and students, and \$10 million will support faculty recruitment in bioethics. Dr. Kington presented the list of broad challenge areas for the Challenge Grant funding, led by the topics of enabling technologies and translational research. He described the application review process.

Dr. Kington stressed that the extraordinary number of applications for Challenge Grants indicates that the biomedical research community has enormous untapped capacity. The short-term effects of the Challenge Grant program align with the goals of ARRA. The long-term effects of the program will lead to scientific advances.

The summer program for students and teachers will serve participants in all 50 states, supporting about 3,900 positions in FY 2009 and FY 2010. ARRA will use two existing programs to fund shared instrumentation, targeting both expensive and less expensive equipment. Dr. Kington reported that the NIH has received about 2,600 applications for the Grand Opportunities Grants and briefly cited a long list of additional award solicitations. Two solicitations, the NIH Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies Pilot Program and the NIH Small Business Catalyst Awards for Accelerating Innovative Research, target small businesses. The NIH administration has begun to develop strategies for tracking the use of the ARRA funds and the outcomes.

Discussion

Dr. King expressed concern about the burden of new reporting requirements for extramural research. She encouraged the NIH to beta-test and streamline the new reporting strategies. Sally Rockey, Ph.D., Acting NIH Deputy Director for Extramural Research, noted that for each ARRA award, the numbers of jobs created and expenditures will be reported directly to a Web site created by the Office of Management and Budget—not to the NIH, although the NIH can provide guidance to awardees. The first reports will be required in late summer or early fall 2009, and reporting will be quarterly. Dr. Kington welcomed the idea that reporting for the ARRA initiatives will stimulate a discussion, with long-term implications, of how the Federal Government tracks its impact on science in general. Dr. Holbrook added that the responsibilities for reporting will lie more with the offices of sponsored research than with the individual investigators.

Dr. Yamamoto wondered about the numbers of grant applications that might occur in 2011, after the ARRA funding has stopped. Will the NIH be able to offer a good number of R01s then? Antonio Scarpa, M.D., Ph.D., Director, Center for Scientific Review (CSR), predicted that the CSR will be prepared for applications. The key concern is the availability of reviewers.

SCIENTIFIC PRESENTATION: INFLUENZA—THE ONCE AND FUTURE VIRUS

Jeffrey Taubenberger, M.D., Ph.D., NIAID, presented a history of influenza outbreaks. He described the recent history of the H1N1 virus (swine flu), which was first detected in Mexico and, subsequently, has spread around the globe. As of June 4, there were 11,054 identified cases in the United States and 17 deaths. In Mexico, there were fewer cases but many more deaths. Dr. Taubenberger suggested that the identified cases might be the tip of the iceberg. Retrospective serosurveys will be needed to determine the real attack rate of the virus.

Dr. Taubenberger described the biology and history of influenza A viruses, which include H1N1. The viruses are diverse and evolve rapidly. The host range is extensive, involving birds and mammals. In the United States, more than 36,000 deaths are attributed to influenza A viruses each year. Pandemics are believed to result from animal flu strains. The current H1N1 viruses are 100 percent resistant to oseltamivir. Dr. Taubenberger reviewed the influenza A pandemics of the 20th century and described the pathogen's ability to undergo host-switching. The influenza A viruses of today are descendents of the virus responsible for the 1918 pandemic ("Spanish Flu"). Dr. Taubenberger has studied the 1918 flu virus to determine reasons for its pathogenicity, its origins, and its relevance for future pandemics. He seeks to determine whether the lethal aspect resulted from a unique mutation in a single gene or a combination of genes. At the time, most fatalities were the result of secondary bacterial pneumonias. It is very difficult to determine the origin of such pandemics, because the early cases are small in number and undetected.

The investigators seek answers to a number of epidemiological questions about the 2009 virus, such as: Where and when did the reassortment virus emerge? How transmissible is it in

humans? What partial immunity exists? Will it continue to spread in humans? In particular, they wish to determine the mutations that allow the latest H1N1 virus to spread from human to human.

Discussion

Dr. Taubenberger noted that contracts to develop a vaccine have been made and a vaccine might be ready by fall 2009. Issues such as the timing of application of the vaccine have yet to be addressed. Dr. Taubenberger expressed doubts about the reported cases in Mexico, wondering whether the denominator used in the rate estimations might have been high. There might have been underdiagnosis. The age distributions of patients in Mexico and the United States have appeared to differ. Dr. Wolfe suggested that epidemiologists study United States data based on localities rather than states.

REVIEW OF OUTSIDE AWARDS FOR ACD APPROVAL

Dr. Kington presented, for the ACD members' consideration, a new list of prescreened bona fide cash awards that NIH employees may receive. The awards were screened by the NIH legal staff and by Drs. Wolfe and Holbrook. They will be added to the list of awards previously approved. Dr. Conway-Welch noted that various nursing associations provide awards. The NIH staff will contact the National Institute of Nursing Research to obtain a list of potential awards to add to the list of prescreened awards. The ACD members voted to approve the current list.

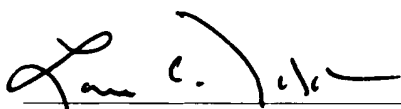
ADJOURNMENT

Dr. Kington thanked the ACD members, invited speakers, and guests and adjourned the meeting.

SUMMARY AND CONCLUSIONS

The Advisory Committee to the Director of the National Institutes of Health convened on June 4, 2009, in Bethesda, Maryland, to receive updates on the NIH budgetary process, including the disposition of ARRA funds; to receive a report from the Blue Ribbon Panel on the initiative to create a biocontainment laboratory in Boston; to discuss the structures and progress of the NIH Scientific Management Review Board and the Division of Program Coordination, Planning, and Strategic Initiatives; and to receive an update on NIH's programs to promote new investigators. A representative from the National Institute of Allergy and Infectious Diseases provided background on pandemic viruses and the recent outbreak of the H1N1 virus. The ACD members received a report from the NIH Director's Council of Public Representatives and accepted a new list of bona fide awards that NIH employees may receive.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.



AUG 14 2009

Lawrence A. Tabak, D.D.S., Ph.D.
Executive Director, Advisory Committee to the Director
Acting Deputy Director, NIH



AUG 14 2009

Raynard S. Kington, M.D., Ph.D.
Chairman, Advisory Committee to the Director
Acting Director, NIH

ABBREVIATIONS AND ACRONYMS

ACD	Advisory Committee to the Director
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
CCIRP	Clinical Center/Intramural Research Program (SMRB workgroup)
CER	Comparative effectiveness research
COPR	NIH Director's Council of Public Representatives
CSR	Center for Scientific Review
CTSA	Clinical and Translational Science Award
DOC	Deliberating Organizational Change (SMRB workgroup)
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
FY	Fiscal year
GO	Grand Opportunity
HHS	U.S. Department of Health and Human Services
IOM	Institute of Medicine
NCI	National Cancer Institute
NEIDL	National Emerging Infectious Diseases Laboratory
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OBSSR	Office of Behavioral and Social Sciences Research
PI	Principal investigator
RFI	Request for information
SMRB	NIH Scientific Management Review Board
SUAA	Substance Use, Abuse, and Addiction (SMRB workgroup)