

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING MINUTES

June 5, 2007

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I. CALL TO ORDER AND OPENING REMARKS - Dr. Elizabeth G. Nabel

Dr. Elizabeth G. Nabel, Director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed members to the 226th meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Member Updates:

Dr. Nabel introduced the new Council members:

- Joe Garcia, M.D., Professor and Chair, Department of Medicine, University of Chicago
- Rao Musunuru, M.D., President of Bayonet Point/Hudson Cardiology Associates, Hudson, Florida
- Jeanine Arden Ornt, J.D., Vice President and General Counsel, Case Western Reserve University
- Paula Polite, Manager of Quality Programs for the City of Memphis, Tennessee; and Founder and Past President of the Sarcoidosis Research Institute
- Steven Shapiro, M.D., Jack D. Myers Professor and Chair, Department of Medicine, University of Pittsburgh
- Shaun Coughlin, M.D., Ph.D., Director, Cardiovascular Research Institute, University of California, San Francisco (not in attendance)

New Staff:

Dr. Nabel welcomed Dr. Michael S. Lauer, who has accepted the position of Director of the Institute's Division of Prevention and Population Sciences (DPPS), effective July 1, 2007. Dr. Lauer is currently Director of the Cleveland Clinic Foundation Exercise Laboratory; Vice-Chair of the Clinic's Institutional Review Board; Professor of Medicine, Epidemiology, and Biostatistics at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University; and a Contributing Editor of the Journal of the American Medical Association. A leader in the cardiovascular community, Dr. Lauer has an exceptionally strong background in cardiovascular epidemiology and medical research.

Dr. Nabel announced several other changes in personnel:

- Dr. Diane Bild has accepted the position of Deputy Director of DPPS. (She is currently the Acting Deputy Director.) In addition to her new duties, Dr. Bild will continue to manage the Multi-Ethnic Study of Atherosclerosis (MESA).
- Dr. Denise Simons-Morton has accepted the position of Senior Scientific Advisor to the Director of DPPS. (She is currently Chief of the Clinical Applications and Prevention Branch in DPPS.) In her new position, Dr. Simons-Morton will focus on the development of clinical trials to identify practical, effective disease prevention methods; cross-cutting obesity research issues; and the translation of research results into practice.

- Dr. Peter Savage, currently Acting Director of DPPS, will join the Office of the Director, NHLBI, as the Special Assistant for Clinical Research. Dr. Savage will work with the Institute's leadership to strengthen oversight and support of the Institute's clinical research program.

Dr. Nabel also announced two departures from the Institute:

- Dr. Charles Friedman, who established the Institute's Center for Research Informatics and Information Technology, has joined the Office of the Secretary, DHHS. Mr. Ralph Van Wey is currently serving as Acting Director of the Center.
- Dr. Carol Vreim, Deputy Director of the Division of Lung Diseases since 1995, will be retiring in August. Dr. Vreim has been an outstanding role model of scientific and administrative excellence since joining the Institute in 1976.

Invited Guests:

Dr. Nabel introduced Mr. Marc Smolonsky, Associate Director for Legislative Policy and Analysis, NIH

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II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST - Dr. Elizabeth G. Nabel

The Council was reminded that according to Public Law 92-463, the Federal Advisory Committee Act, the meeting of the NHLBAC would be open to the public except during consideration of grant applications. A notice of this meeting was published in the *Federal Register* indicating that it would start at 8:30 a.m. and remain open until approximately 12:00 p.m. Dr. Nabel also reminded the Council members that they are Special Government Employees and are subject to Departmental conduct regulations.

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III. REPORT OF THE DIRECTOR - Dr. Elizabeth G. Nabel

Budget Report:

Dr. Nabel reviewed the Institute's budget. The FY 2008 President's Budget is \$2,925,413,000, an increase of only \$6,605,000 (0.23 percent) over the FY 2007 Continuing Resolution (upon which the FY 2008 President's Budget was built). The extramural portion of the Institute's FY 2008 President's Budget comprises: research project grants (74.8 percent); contracts (11.2 percent); centers (5.4 percent); career grants (2.9 percent); training grants (3.4 percent); other (2.2 percent).

The FY 2007 Joint Resolution (the amount the NHLBI actually received) is \$2,919,980,000 — \$1,172,000 more than the Continuing Resolution. In addition, the NHLBI had another \$35 million to work with since it was no longer required to contribute to the Common Fund (i.e., NIH Roadmap activities) from its own appropriation. (The overall FY 2007 Joint Resolution provided funds specifically for the support of the Common Fund so that individual Institutes/Centers were no longer required to contribute from their own appropriations.)

Dr. Nabel assured the Council that the Institute intends to maintain its commitment to investigator-initiated research and to its training programs during these tight budgetary times, and will continue to seek the advice of Council on such matters.

Updates:

Dr. Nabel updated the Council on two programs:

- The NHLBI is establishing a Registry of Angioplasty Registries (ROAR) to increase understanding about the rate of subacute thrombosis for both drug-eluting and bare metal stents, the predisposing factors for the thrombotic events, and ways to reduce the risks of them. The program has been announced in the Federal Business Opportunities, and the Request for Proposals (RFP) is expected to be released soon.
- The NHLBI is planning to co-sponsor, with the National Cancer Institute, part of the NIH Genes, Environment, and Health Initiative that was announced in February 2006.

NHLBI Strategic Plan:

The [NHLBI Strategic Plan](#) — a version for scientific audiences, as well as a summary brochure for public audiences — is being printed. The plan will be distributed widely to scientific groups, professional organizations, public interest groups, and the Congress.

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IV. NIH REAUTHORIZATION - Mr. Mark Smolonsky

Mr. Marc Smolonsky, Associate Director for Legislative Policy and Analysis, NIH, discussed the [NIH Reform Act of 2006](#) that reauthorized the NIH. The Act includes several provisions to enhance management of the NIH, including establishment of a new Division of Program Coordination, Planning, and Strategic Initiatives within the NIH Office of the Director to identify and report on areas that would benefit from trans-NIH research. It also establishes a Common Fund to pay for such research. The Act requires establishing "... an electronic system to uniformly code research grants and activities ..." (The NIH Research, Condition, and Disease Categorization system, described below, responds to this requirement.) The Act also establishes a scientific process for recommending and making future organizational changes at the NIH.

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V. NIH RESEARCH, CONDITION, AND DISEASE CATEGORIZATION (RCDC) - Dr. Carl Roth

Dr. Carl Roth, Director of the Office of Science Technology, NHLBI, described the NIH RCDC initiative, an NIH-wide effort to improve access to, and reporting on, the NIH research portfolio. Each year the NIH reports to the Congress and the public on how much it spends in approximately 360 research and disease areas. The NIH reports are obtained by aggregating the reports of the individual Institutes/Centers (ICs), even though the ICs currently use inconsistent reporting methodologies.

In the RCDC system, an area to be reported on is summarized in a category "fingerprint" - a list of relevant concepts (with weights to reflect their relative importance) that have been selected by NIH scientific experts to define a research category. Similarly constructed project fingerprints are compared (using an algorithm) with the category fingerprints to determine which individual projects are reported within a category.

The RCDC system is expected to provide consistency, transparency, and efficiency to the NIH reporting process. Recognizing that there is no such thing as "100 percent accuracy," the system represents a significant improvement over the status quo. Reports using the RCDC system will begin in FY 2008 and will almost certainly produce different total dollar amounts for categories than previously reported by the NIH.

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VI. MEETING OF THE BOARD OF EXTERNAL EXPERTS - Dr. Elizabeth G. Nabel

The Board of External Experts (BEE) is a newly constituted advisory working group to the NHLBI Council. It is charged with implementing the NHLBI Strategic Plan, discussing and prioritizing program ideas and potential initiatives, serving as an incubator for new ideas and recommendations, recommending improvements in the Institute's business operations, and providing advice on a program's effectiveness.

The BEE met on June 1, 2007 and discussed implementation of the NHLBI Strategic Plan. Dr. Nabel summarized the BEE's recommendations and Council members offered additional ideas.

The BEE also discussed the future of the Institute's Specialized Centers of Clinically Oriented Research (SCCORs) and Clinical Research Networks (CRNs). Noting opportunities for synergy, the BEE suggested redesigning SCCORs to support early translational research that could feed into CRNs. Dr. Nabel noted that the Institute plans to further discuss this along with other related ideas with the Council.

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VII. PRESENTATION OF INITIATIVES - Dr. Elizabeth G. Nabel

NHLBI staff presented 13 new initiatives, which were reviewed and ranked by the BEE. The Council was supportive of the initiatives, but made a number of specific recommendations for consideration prior to their release. Dr. Nabel will consider the recommendations of the BEE and the Council and other budgetary and programmatic issues in determining which of the proposed initiatives, if any, to implement.

Deep Vein Thrombosis and Venous Disease , RFA

To support basic and clinical research on venous thrombotic diseases, with emphasis on sharing resources to improve diagnosis, therapy, and prevention; and to collaborate with the Center for Disease Control and Prevention (CDC) and its ongoing Thrombosis and Hemostasis Program.

Council recommended this initiative.

Mechanisms and Management of Cardiovascular and Metabolic Complications of HIV/AIDS , RFA

To elucidate the underlying mechanisms of, and to identify treatment strategies and interventional approaches for, cardiovascular risk in individuals with HIV infection who are on Highly Active Antiretroviral Therapy (HAART).

Council recommended this initiative.

Metabolomics of the Respiratory System in Health and Disease , RFA

To apply metabolomics approaches to the study of the respiratory system.

Council considered this area of research to be very important, but suggested considering combining with the Molecular Phenotypes for Lung Diseases initiative.

Molecular Phenotypes for Lung Diseases , RFA

To re-define major categories of lung diseases using molecular phenotypes, a critical step toward the development of personalized and pre-emptive approaches to Pulmonary medicine.

Council recommended this initiative.

Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG) Follow-Up Study , RFP

To provide structured follow-up of the participants in the original BABY HUG treatment study, in order to characterize the long-term benefits and toxicities associated with initiation of hydroxyurea treatment at an early age.

Council recommended this initiative.

Pilot and Pre-Test of Acute Coronary Syndrome Module for the National Hospital Discharge Survey (Interagency Agreement) ,RFA

To obtain improved national estimates of the annual incidence and in-hospital care patterns of acute coronary syndrome.

Council recommended this initiative.

Prevention of Atherosclerotic Cardiovascular Events Trial , RFP

To conduct a randomized clinical trial in older patients to assess the clinical benefit of enhanced low density lipoprotein cholesterol (LDL-C) lowering compared to current guideline-based therapy.

Council recommended this initiative.

Systolic Blood Pressure Intervention Trial (SPRINT) , RFP

To conduct a multicenter randomized trial to determine whether treating systolic blood pressure to a lower goal than currently recommended will reduce cardiovascular disease.

Council recommended this initiative and recommended a partnership with PhRMA.

Targeted Approaches to Weight Control for Young Adults , RFA

To support 4 to 5 studies to develop and test promising, innovative intervention approaches for weight loss and/or prevention of further weight gain in young adults.

Council recommended this initiative.

Biorepository and Limited Access Data Set Information Coordinating Center , RFP

To establish an Information Coordinating Center that will develop and maintain an administrative and data management infrastructure to facilitate access to two valuable NHLBI scientific resources, the Biological Specimen Repository and the Limited Access Data Set programs.

Council recommended this initiative.

Cardiovascular Health Study (CHS) - Transition Phase Renewal , RFP

To maintain the CHS infrastructure for continued access to study resources (including DNA) and expertise, and to support scientific collaborations and mentorship of early-career investigators.

Council recommended this initiative.

Coronary Artery Risk Development in Young Adults (CARDIA) Study - Renewal , RFP

CARDIA will capitalize upon two decades of study by conducting an examination of data and stored specimens collected throughout young adulthood to study the impact of traditional and novel risk factors on the development of subclinical abnormalities in mid-life.

Council recommended this initiative.

Multi-Ethnic Study of Atherosclerosis (MESA) - Renewal , RFP

To continue to study the MESA cohort to capitalize and expand upon the resources of data, samples, and infrastructure that have been developed over 10 years.

Council recommended this initiative.

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

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VIII. REVIEW OF APPLICATION

The Council considered 1,143 applications requesting \$1,512,657,417 in total direct costs. The Council recommended 1,141 applications with total direct costs of \$1,498,891,712. A summary of applications by activity code may be found in Attachment B.

ADJOURNMENT

The meeting was adjourned at 3:30 p.m. on June 5, 2007.