

Meeting Minutes
Department of Health and Human Services
Public Health Service
National Diabetes and Digestive and Kidney Diseases
Advisory Council
February 20, 2003

OPEN SESSION
Thursday, February 20, 2003 11:01 a.m. to 12:38 p.m.

This meeting was held by telephone conference, pursuant to notice, due to inclement weather. After a roll call, Dr. Spiegel called the meeting to order.

I. CALL TO ORDER

The NIDDK Director, Dr. Allen M. Spiegel, called to order the 161st National Diabetes and Digestive and Kidney Diseases Advisory Council meeting on February 20, 2003, at 11:01 a.m. in Room 9A22, Building 31C, National Institutes of Health (NIH) campus in Bethesda, MD. He thanked the members for their flexibility in participating in a telephone conference. Dr. Spiegel introduced the five new Council members:

Joining the Kidney, Urologic, and Hematologic Subcommittee:

- < Dr. Robert J. Alpern, Dean and Professor of Medicine, University of Texas, Southwestern Medical Center, Dallas, TX.
- < Dr. E. Darracott Vaughan, Jr., James J. Colt Professor of Urology, Department of Urology, Cornell University Medical College, New York, NY.

Joining the Digestive Diseases and Nutrition Subcommittee:

- < Dr. Raymond N. Dubois, Jr., Director, Gastroenterology, Hepatology and Nutrition, Vanderbilt University Medical Center, Nashville, TN.
- < Dr. Robert H. Eckel, Charles A. Boettcher Professor of Medicine, Department of Medicine, Division of Endocrinology, University of Colorado Health Sciences Center, Denver, CO.

Joining the Diabetes, Endocrinology, and Metabolic Diseases Subcommittee:

- < Dr. Linda A. Sherman, Professor, Department of Immunology, The Scripps Research Institute, La Jolla, CA.

Dr. Spiegel made several other announcements:

- < Dr. Christian Ketchum has joined the Division of Kidney, Urologic and Hematologic Diseases from Johns Hopkins University. He will manage the Division's grant portfolio in fundamental renal biology.
- < Dr. Judith Fradkin, Director, Division of Diabetes, Endocrinology, and Metabolic Diseases received the Nathan Davis Award from the American Medical Association for her outstanding contributions as a public official.

- < Dr. Paul Rushing of the NIDDK Review Branch has been elected a Fellow of the International Behavioral Neuroscience Society.
- < The NIDDK recently published its annual compilation of “Recent Advances and Emerging Opportunities,” which contains patient profiles, vision statements from past Council members, and highlights of findings made possible by NIDDK-funded research.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Robert J. Alpern	Dr. James W. Kikendall (<i>Ex officio</i>)
Dr. Jose Caro	Dr. Earl Harrison (<i>Ex officio</i>)
Ms. Mary E. Clark	Dr. Sum P. Lee
Dr. Raymond N. DuBois	Ms. Nancy J. Norton
Dr. Robert H. Eckel	Dr. Sandra Puczynski
Dr. Richard H. Goodman	Dr. Vicki Ratner
Hon. Levan Gordon	Dr. Linda A. Sherman
Dr. Edward W. Holmes	Dr. E. Darracott Vaughan
Dr. Carolyn Kelly	Dr. W. Allan Walker

Council members absent:
 Mr. David Baldrige
 Dr. Edward J. Benz
 Dr. Daniel Porte (*Ex officio*)

Also present:
 Dr. Allen Spiegel, Director, NIDDK and Chairperson, NDDK Advisory Council
 Dr. Griffin Rodgers, Deputy Director, NIDDK
 Dr. Robert Hammond, Executive Secretary, NDDK Advisory Council

B. NIDDK STAFF AND GUESTS

In addition to Council members, others in attendance included NIDDK staff members, some of whom attended via teleconference from 2 Democracy Plaza, Room 701. Guests were present during the open session of the meeting. Attendees included the following:

Lawrence Agodoa, NIDDK	Jay Hoofnagle, NIDDK	Neal Musto, NIDDK
Sharon Ballard, NIDDK	Donna James, NIDDK	Elizabeth Paterson, NIDDK
Josephine Briggs, NIDDK	Robert Kuczmariski, NIDDK	Judith Podskalny, NIDDK
Francisco Calvo, NIDDK	Stephen James, NIDDK	Sharon Pope, NIDDK
Michelle Cissell, NIDDK	Benjamin Lum, The Blue Sheet	Patricia Robuck, NIDDK
Randy Copeland, NIDDK	Denise Manouelian, NIDDK	Paul Rushing, NIDDK
Jody Evans, NIDDK	Ronald Margolis, NIDDK	Lakshmanan Sankaran, NIDDK
James Everhart, NIDDK	Michael K. May, NIDDK	Salvatore Sechi, NIDDK
Judith Fradkin, NIDDK	Catherine McKeon, NIDDK	Leonard Seef, NIDDK
Lisa Gansheroff, NIDDK	Catherine Meyers, NIDDK	Jose Serrano, NIDDK
Trude Hilliard, NIDDK	Carolyn Miles, CSR	Philip Smith, NIDDK
Gladys Hirschman, NIDDK	David Mineo, NIDDK	Robert Star, NIDDK
Eleanor Hoff, NIDDK	Marva Moxey-Mims, NIDDK	Walter Stewart, NIDDK

Renetta Turner, NIDDK
Dorothy West, NIDDK

Susan Yanovski, NIDDK
Charles Zellers, NIDDK

II. CONSIDERATION OF THE 160TH COUNCIL MEETING MINUTES

A motion was made, and unanimously passed by voice vote, to accept the summary minutes of the 160th Council meeting as submitted.

III. FUTURE COUNCIL DATES

Dr. Spiegel announced the proposed dates for the future Council meetings as follows:

June 11-12, 2003
September 24-25, 2003
February 4-5, 2004
May 26-27, 2004
September 22-23, 2004
February 23-24, 2005
May 19-20, 2005
September 14-15, 2005

IV. ANNOUNCEMENTS: CONFIDENTIALITY AND CONFLICT OF INTEREST **Dr. Hammond**

Dr. Hammond reminded Council members that materials furnished to them are for the purpose of review and discussion only during the closed portion of the meeting, the outcomes of which are privileged. Thus, all communications from applicants or grantees to Council members regarding Council actions on applications must be referred to the Institute. If Council members attempt to handle questions from applicants, a difficult situation could develop for the Council, the Institute, or the investigators.

Members of public advisory committees may not participate in situations in which any violation of conflict-of-interest laws and regulations might occur. It is the responsibility of NIDDK staff to ensure that a Council member does not participate in, or be present at, the review of applications of specific projects in which (to the member's knowledge) any of the following has a financial interest: the member or his/her spouse, minor child, partner, including close professional associates, or any organization with which the member might be connected. To ensure compliance with this directive, a written certification is provided for each member to sign. Because of the need to hold this meeting by telephone conference, the certifications will be mailed to members, who should sign and return them by mail to Dr. Hammond. In closing, Dr. Hammond noted that at meetings at which applications are reviewed in groups without

discussion (for example, *en bloc* actions), all Council members may be present and may participate.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Spiegel

Broad Themes for Council Consideration: Recently, NIDDK staff sought feedback from Council members as to how their talents could most effectively be used during limited meeting time. The consensus was that Council members wish to focus on broad, cross-cutting issues and policies that affect major directions of the NIDDK and NIH. As a result, the NIDDK is establishing an internal process among the Division Directors and program staff to define themes on which Council members' can provide input and advice. Also, Council members are urged to offer (through Dr. Hammond's office) suggestions of themes that they would like to discuss. Once themes are identified, the NIDDK staff will provide relevant background material in advance of the discussion.

A brief discussion ensued on the way in which the NIDDK can more effectively engage the external research community in learning about and applying for funding opportunities. As one approach to this, NIDDK is making its website more user-friendly to investigators. However, this is a passive strategy and the NIDDK is seeking Council's input on more proactive strategies, compatible with NIH procedures and regulations.

Council members' suggestions included:

- < Increased liaison with other NIH Institutes and Centers in areas such as nutrition, obesity, cardiovascular disease, and co-morbidities. Interactions with multiple Institutes might shed light on research issues such as how chronic inflammatory disease can sometimes progress to cancer, and also, the relationship between inflammation, diabetes and heart disease. (The NIDDK already has several venues to promote such information-sharing and collaborations, including statutory disease-oriented interagency coordinating committees, with broad representation from NIH and other federal agencies);
- < Communication with non-profit and professional organizations, especially their public policy committees and representatives, so that they can communicate to their membership information about NIH meetings, research solicitations and other items of interest. One Council member suggested that the NIDDK could serve as a clearinghouse for information useful to professional societies and their members. (Dr. Spiegel mentioned that NIDDK had engaged its constituency groups to help bring the recently established NIH Extramural Loan Repayment Programs for pediatric and clinical research to the attention of their members);
- < Communication with chairs of academic institutions via a short email that provides links, which they can access at their discretion, to more detailed information on specific topics that are relevant to them;
- < Specific targeting of information to new investigators to help maintain their commitment to research careers. (The NIDDK already orchestrated a series of meeting with K23 grant holders and several discipline-specific sessions);
- < Use of "list-servs" to disseminate funding opportunities to relevant audiences (however, messages must be short or they will not be read); and

- < More personal communications with Principal Investigators, such as short, friendly emails that point to the posting of new or updated information of relevance on the NIDDK website or elsewhere.

Dr. Spiegel thanked the Council members for their helpful suggestions and asked Dr. Hammond to follow-up to determine whether there are NIH procedures that govern how proactive an Institute can be in contacting its grantees, constituency groups, and others in order to share information about funding opportunities, meetings, etc.

Several other Council members suggested broad topics for future discussion, including:

- < How to evaluate the success of different funding mechanisms;
- < Paradigms for interacting with professional societies, not only about scientific issues, but also about social, political and even legal issues. (Dr. Spiegel noted that there are procedures governing the process by which NIDDK may comment on pending legislation);
- < How to avoid redundancy of funding between the NIH and non-profit/professional organizations that direct their resources to research;
- < Making workshops available to wider audiences through the use of telecommunication technologies; and
- < Taking an aggressive approach to increasing the numbers of minority investigators. Dr. Spiegel noted that Dr. Lawrence Agodoa, the Director of the NIDDK Office of Minority Health Research Coordination, has taken an active role, including the establishment of an NIDDK Network of Minority Research Investigators. The goal of this organization is to link new investigators with information about NIDDK in order to foster mentoring and grantsmanship. Dr. Spiegel noted that he had visited the Meyerhoff program at the University of Maryland, Baltimore county, part of the State University of Maryland system, which has had great success in encouraging undergraduate minority students to enter Ph.D. programs in science.

A Council member proposed having an extended discussion at an upcoming meeting so that members can gain a better working knowledge of current issues and research dynamics at the NIDDK and within the NIH, and thus have a better sense of how they can further research goals.

NIH Roadmap Initiative: The presentation to the Council by the Director, NIH, Dr. Elias Zerhouni, has been deferred to the next meeting. In the interim, a poll of Council members identified two specific topics of interest: (1) NIH-wide obesity research; and (2) training the next generation of clinical investigators. Of particular interest to Dr. Zerhouni is a “Roadmap” process which he began last summer to address challenges and opportunities that transcend the scope of any single Institute or Center (and which are not disease-specific). In August 2002, a series of focus meetings were held, with the participation of NIH Institute leadership and representatives, along with some members of the external community, including a number of investigators supported by the NIDDK. Further refinement of Roadmap topics occurred at the NIH Director’s Leadership Retreat with NIH Institutes and Centers Directors in September 2002. The present list of topics (which was sent to Council members and appears again at the end of these minutes) includes many of interest to the NIDDK, such as: “Biological Pathways and Networks,” “Regenerative Medicine” (which includes research on stem cells and tissue

engineering), “Molecular Libraries,” “High-Risk Research,” and “Public-Private Partnerships.” A major Roadmap category, “Re-engineering the Clinical Research Enterprise,” was recently explored in a summit meeting convened and moderated by Dr. Zerhouni. Dr. Robert Star of the NIDDK staff has been extensively involved in assisting the NIH science policy staff with respect to this topic and can be contacted by Council members directly for more detailed information. The Roadmap process does have fiscal implications, as reflected in the \$35 million placeholder for Roadmap-related activities included in the President’s budget request for the NIH for FY 2004.

In discussion of the Roadmap Initiative, one Council member commented that an important cross-cutting topic is the degree to which *in utero* metabolic events can influence expression of disease states in adulthood. Opportunities exist for the development of early markers that could potentially be used to prevent adult disease. This concept is particularly relevant to obesity and diabetes (type 1 and 2). Of note, the NIDDK is supporting a consortium to identify potential environmental triggers for type 1 diabetes. Another Council member commented that with respect to clinical infrastructure and resources, high-end instrumentation is needed to further our understanding of human disease.

Obesity Research: Dr. Zerhouni has identified obesity research as an important NIH priority, with involvement of multiple NIH Institutes and Centers. The NIDDK is the lead Institute for this research, which spans the Division of Digestive Diseases and Nutrition, and the Division of Diabetes, Endocrinology and Metabolic Diseases. To provide an overview of the magnitude of the health problems and related NIDDK research efforts on obesity, Dr. Spiegel called upon Dr. Susan Yanovski and Dr. Philip Smith, the co-directors of the newly established NIDDK Office of Obesity Research and the trans-NIDDK staff working group.

Dr. Susan Yanovski described the epidemic proportion of obesity in the U.S. From 1976 to 2000, the percentage of obese American adults doubled, from 15 percent to 31 percent. In children, the situation is even worse over the same time period, with an apparent tripling of the percentage of children who are obese. The NIDDK has taken these statistics very seriously. A decade ago, there was only a single NIDDK program with the word “obesity” in its title, today there are 11 such NIDDK programs that have a substantial proportion of research projects related to obesity.

Dr. Philip Smith explained that major discoveries in the pathophysiology of obesity have led to unparalleled opportunities in a number of areas, including the neuroendocrinology of obesity, cellular metabolism, and human genetics. Vigorous research, on the part of NIH, academia, and industry, is aimed at identifying signaling pathways critical to the onset and maintenance of obesity, and at developing ways to target specific steps for intervening in these pathways. It will be essential to build a consensus, both within and outside the NIH, with respect to how budget resources can best be focused so as to remove barriers to progress. The intent is not to dictate to the scientific community, but rather, to ensure broad input in defining barriers, challenges and intermediate goals. Particular intractable problems will be dealt with by convening workshops of scientific leaders from multiple disciplines. However, the greatest challenge is to prevent obesity in the first place by using new tools to define the roles of genetics, genomics and environmental

triggers, from conception to maturity. Another topic of interest is the application of successful models of behavioral change to achieve long-term improvements in both physical activity and eating behavior.

Dr. Spiegel commented that under Dr. Zerhouni's leadership, the NIH as a whole is taking new steps to strengthen its efforts to combat the obesity epidemic. One Council member suggested that the word "obesity" might be added to the title of NIDDK, but Dr. Spiegel noted that neither he nor Dr. Zerhouni has the authority to make that kind of change because it would require congressional legislation. Moreover, obesity is an integral part of the research missions of many NIH components; therefore, it can probably be addressed most effectively through heightened NIH coordination. Dr. Spiegel noted that the February 7, 2003 issue of *Science* has some excellent material on obesity.

VI. REPORT FROM THE NIDDK DEPUTY DIRECTOR

Dr. Rodgers

Dr. Rodgers said that following eight continuing resolutions, the House and Senate had agreed upon a \$27.2 billion omnibus appropriation bill for the NIH for FY 2003, which was expected to become law very shortly. The Council members were provided with an article from *The Washington Fax*, which reported that a significant part of NIH's 2003 budget will be allocated to the emerging national challenges of biodefense. The increase for the NIDDK budget was not precisely known, but was estimated to be on the order of 10 percent. At that level of increase, NIDDK staff would be able to implement the full set of planned initiatives previously discussed with the Council. The final projected paylines would be to the 22nd percentile for new competing grants and to the 24th percentile for competing renewal grants, consistent with the values in fiscal year 2002. However, the NIDDK may delay the start of a few initiatives, in order to consolidate the funding of unmet needs in some NIDDK clinical trials and multi-site studies.

Looking back on the FY2002 appropriation, the NIDDK funded a total of nearly 3,000 research project grants, an increase of about 50 from FY2001. Program highlights include:

- < Collaboration with the Office of Research on Women's Health in partially supporting three centers: one on urinary tract infections, one on urinary incontinence, and one on addressing both interstitial cystitis and irritable bowel syndrome;
- < Launch of Diabetes Prevention and Control Projects, to spur the translation of the results of the Diabetes Prevention Program (DPP) clinical trial to patients and practicing physicians;
- < Contributing approximately \$1 million to the Minority Organ and Tissue Transplantation Educational Program (MOTTEP), which seeks to increase organ donation among minority populations; and
- < Support for a unique Diabetes Based Science Education in Tribal Schools Program

With respect to research manpower, the National Research Service Award (NRSA) trainees received a ten percent stipend increase in FY2002 (and they are scheduled for a four percent increase in FY2003, in a continuing process to raise NRSA stipend levels toward those recommended by a specially appointed committee of the National Academy of Sciences). In

FY2002, the NIDDK expended slightly over \$2 million on 38 contracts under the Loan Repayment Program (and the NIH intends to double the size of the program for FY2003).

Looking ahead to FY2004, the overall President's budget for the NIH represents about a two percent increase over the previous fiscal year. However, when it is adjusted for one-time FY2003 facilities costs, the total available for NIH non-biodefense research represents an increase of approximately four percent. The five-year doubling of the NIH budget from FY1999 through FY2003 enabled the NIDDK to undertake many significant initiatives, including the establishment of several different consortia and resources to support bioinformatics, genetic linkage analysis, new animal models of disease, and clinical practice databases. The new NIDDK Central Repositories will greatly facilitate storage of, and access to, data and tissue samples from NIDDK's clinical trials, thereby leveraging the Institute's clinical research efforts. In addition to regularly appropriated funds, of particular note for NIH-wide diabetes research is the recent legislative extension and funding augmentation of the Special Statutory Funding Program for Type 1 Diabetes Research. Funding will now extend from FY2004 through FY 2008 at \$150 million annually for this program, for which the NIDDK leads the planning, implementation and evaluation process on behalf of the Secretary, DHHS.

VII. ANNUAL APPROVAL OF COUNCIL OPERATING PROCEDURES
Dr. Hammond

Consistent with annual requirements, Dr. Hammond asked for and received unanimous Council approval of its operating procedures, including updates on three items: (1) allowing MERIT awardees to apply for extensions of up to 5 years, as opposed to the previous three year limitation; (2) continuation and expansion of the *en bloc* concurrence to all grant and cooperative agreement mechanisms, not only R01s and R03s; and (3) continuation of the delegation to staff the authority for consideration of administrative supplements, provide bridging funds pending consideration of award, and restorations. All actions will then be reported back to the Council by the NIDDK staff.

At 12:38 p.m., Dr. Spiegel adjourned the open session and the Council proceeded to other business in closed session.

VIII. REPORTS OF SUBCOMMITTEES: CONSIDERATION OF APPLICATIONS
(CLOSED SESSION)

IX. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1158 grant applications, requesting support of \$245,832,011 were reviewed for consideration at the February 19-20, 2003 meeting. Funding for those 1158 applications was recommended at a level of \$240,182,036.

X. ADJOURNMENT

Dr. Spiegel thanked the Council members for their attendance and advice. There being no other business, Dr. Spiegel adjourned the 161st meeting of the NDDK National Advisory Council on February 20, 2003 at approximately 12:48 p.m.

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

A handwritten signature in cursive script, appearing to read "Allen Spiegel".

*Allen M. Spiegel, M.D.
Director, National Institute of Diabetes and Digestive and Kidney Diseases
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council*

Attachment: NIH Roadmap Topics

- I. New Pathways to Discovery
 - A. Approaches
 - 1. A comprehensive set of building blocks for biology
 - 2. Biological pathways and networks
 - 3. Regenerative medicine
 - B. Technologies
 - 1. Structural biology
 - 2. Bioinformatics/computational biology
 - 3. Molecular libraries
 - 4. Nanotechnology
 - 5. Molecular imaging
- II. Research Teams of the Future
 - A. Multi-disciplinary research teams
 - B. Public/private partnerships
 - C. High-risk research
- III. Re-engineering the Clinical Research Enterprise
 - A. Translational research, innovations, infrastructure/resources
 - B. A nationally integrated clinical research system
 - C. Workforce training
 - D. Clinical research informatics
 - E. Public trust