

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE**

**NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE
MINUTES OF THE TWENTY-SIXTH MEETING
February 2, 2007**

NACCAM Members present

Dr. Madhulika Agarwal, Washington, DC
*Dr. Stephen Barnes, Birmingham, AL
*Dr. Sheldon Cohen, Pittsburgh, PA
* Dr. Fabio Cominelli, Charlottesville, VA
Dr. Jeanette Ezzo, Baltimore, MD
Dr. Joan Fox, Cleveland, OH
*Dr. Margery Gass, Cincinnati, OH
Dr. David Hillis, Dallas, TX
Dr. Ted Kaptchuk, Boston, MA
*Dr. Shri Mishra, Los Angeles, CA
COL Richard Niemtow, Clinton, MD
Dr. Joel Pickar, Davenport, IA
Dr. Bruce Redman, Ann Arbor, MI
Dr. Danny Shen, Seattle, WA
*Dr. Herman Taylor, Jackson, MS
*Dr. Frank Torti, Winston Salem, NC
Dr. Stefanie N. Vogel, Baltimore, MD
*Dr. David Wilder, Iowa City, IA
*Ad hoc members

NACCAM Members not present

Dr. Carlo Calabrese, Portland, OR
Dr. Silvia Corvera, Worcester, MA
Sec. Michael Leavitt, Washington, DC
Dr. Bala Manyam, Odessa, FL
Dr. Elias Zerhouni, Bethesda, MD

NIH Staff Present

National Center for Complementary and Alternative Medicine

Ms. Adelina Bartels
Ms. Willer Batten
Dr. Josh Berman
Dr. Dale Birkle
Dr. Marc Blackman

Ms. Karla Blaine
Ms. April Bower
Dr. Sheila Caldwell
Mr. Steve Casady
Dr. Margaret Chesney
Dr. Margaret Cole
Ms. Alyssa Cotler
Mr. Edward Culhane
Dr. Laurie Donze
Ms. Linda Engel
Ms. Valery Gheen
Dr. Martin Goldrosen, Executive Secretary
Ms. Anita Greene
Ms. Mary Gregg
Ms. Melinda Haskins
Ms. Deborah Hayes
Ms. Camille Hoover
Ms. Deborah Jennings
Dr. Laura Lee Johnson
Ms. Lekiny Johnson
Mr. Mike Kabatt
Dr. Partap Khalsa
Dr. Jack Killen
Dr. Ruth Kirschstein, Acting Director
Ms. Marguerite Klein
Ms. Robin Klevins
Dr. Peter Kozel
Ms. Catherine Law
Dr. Barbara Moquin
Dr. Richard Nahin
Ms. Ellen O'Donnell
Dr. Nancy Pearson
Ms. Phuong Pham
Dr. Carol Pontzer
Dr. Ranganath Muniyappa, IRP
Ms. Linda Rich
Ms. Jeanie Robinson
Dr. Martina Schmidt
Mr. Ronald Shaw
Ms. Denise Simmonds-Barnes
Dr. Barbara Sorkin
Ms. Kathleen Stephan
Dr. Catherine Stoney
Ms. Chris Thomsen
Mr. George Tucker
Dr. Shan Wong

Ms. Andrea Wongsam-Nollinger

Other NIH Institutes

Dr. Paul Coates, Office of Dietary Supplements

Ms. Andrea Collins, National Cancer Institute

Ms. Betsy Dean, Office of Scientific Policy

Ms. Jody Engel, Office of Dietary Supplements

Mr. Mark Headings, OD/ Budget

Ms. Maggie Pettersen, Clearinghouse

Dr. Marni Silverman, National Institute of Mental Health

Dr. Wendy Smith, National Cancer Institute

Ms. Malaika Staff, National Cancer Institute

Dr. Christine Swanson, Office of Dietary Supplements

Dr. Phil Tonkins, National Cancer Institute

Members of the Public

John Chah

Steven Dentali

Med Diggins

William Duncan

James Fussell

Pamela Gilden

Aviad Haramati

Laura Honesty

Rives Hotra

Erin Loomis

Suzanne Niemeyer

Georgia Persinos

Peter Reinecke

M Richardsen

Michelle Rodrigues

Shawn Stout

I. Closed Session

The first portion of the 26th meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

A total of 207 applications were assigned to NCCAM. Of these, 176 were reviewed by NCCAM, 31 by Center for Scientific Review. Applications that were noncompetitive, unscored, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council did not recommend for consideration on 1 application and concurred on 122 applications requesting \$ 35,195,607 in total costs.

II. Open Session—Call to Order

The open session of the NACCAM meeting convened at 1:07 p.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on September 8, 2006, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen reminded Council members of the next meeting, scheduled for Friday, June 1, 2007, and asked that members notify him as soon as possible if they are unable to attend. Dr. Ruth Kirschstein, Acting Director of NCCAM, suggested a future reconsideration of Council meeting dates because of the logistical challenges of traveling on Fridays.-

Dr. Goldrosen introduced three ad hoc Council members: Dr. Shri Mishra, Dr. Herman Taylor, and Dr. David Wilder, along with new ex officio member Dr. Madhulika Agarwal. Dr. Goldrosen also welcomed the following, whose Council appointments are in process: Dr. Lori Arviso Alvord (not in attendance), Dr. Stephen Barnes, Dr. Sheldon Cohen, Dr. Fabio Cominelli, Dr. Margery Gass, and Dr. Frank Torti.

Dr. Goldrosen introduced Dr. Kirschstein, who was named Acting Director of NCCAM in November 2006.

III. Report From the Acting Director—State of the Center

Dr. Kirschstein welcomed Council members and guests and extended greetings on behalf of Dr. Stephen E. Straus, Senior Advisor to the Director of NIH and Founding Director of NCCAM. Dr. Kirschstein lauded Dr. Straus's achievements in establishing NCCAM as part of NIH, and Council responded with a standing ovation of appreciation.

Dr. Kirschstein described her association with both NCCAM and its predecessor, the Office of Alternative Medicine. She recounted her attendance at the first Council meeting and her position on the search committee that selected Dr. Straus.

Search Committee for NCCAM Director

Dr. Kirschstein announced that the Search Committee for the new NCCAM Director has been formed. Committee cochairs are Dr. Patricia Grady, Director of the National Institute of Nursing Research, and Dr. Story Landis, Director of the National Institute of Neurological Disorders and Stroke. Members of the committee are Dr. Nancy Adler of the University of California, San Francisco; Dr. Brian Berman of the University of Maryland; Dr. Stuart Bondurant of Georgetown University; Dr. Marjorie Mau of the University of Hawaii; and Dr. Larry Walker of the University of Mississippi.

NCCAM Organizational Update

Dr. Kirschstein announced three retirements among NCCAM staff: Dr. Morgan Jackson, Director, Office of Special Populations; Dr. Heather Miller, Director, Office of Policy, Planning, and Evaluation; and Ms. Shirley Villone, Program Analyst. She also noted that Dr. Jack Killen has been named Acting Director of the Office of Policy, Planning, and Evaluation.

Dr. Kirschstein noted that last year Dr. Martin Goldrosen was named Acting Director of the recently created Division of Extramural Activities, which includes the Office of Scientific Review and the Office of Grants Management, and oversees committee management functions, including those related to NACCAM.

At the request of the Director of the NIH Clinical Center, the Division of Intramural Research has established an Integrative Medicine Consult Service to support patients and coordinate the resources of the Clinical Center's existing services and departments. A director of the consult service will soon be appointed.

Dr. Kirschstein noted that a new staff member, Deborah Hayes, has joined NCCAM's Office of International Health Research.

National Institutes of Health Reform Act of 2006

Dr. Kirschstein reported that on January 15, 2007, the President signed the NIH Reform Act, following its passage with the unanimous support of Congress. This action affirms the importance of NIH and its vital role in advancing biomedical research to improve the health of the nation.

The legislation authorizes a new process to facilitate trans-NIH research and establishes the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director. DPCPSI will organize a Common Fund for trans-NIH initiatives and a Council of Councils to advise on research proposals to be funded by the Common Fund. A Scientific Management Review Board will conduct periodic organizational reviews of NIH and make recommendations on the use of NIH organizational authorities. The legislation authorizes (but does not appropriate) an increase in NIH funding for each of the next 3 years and requires a public process for reorganizing NIH programs.

An Ad Hoc Working Group, chaired by Dr. Raynard S. Kington, NIH Deputy Director, will analyze the legislation and propose plans for its implementation. Working Group membership includes directors of NIH institutes and centers as well as senior leaders in legislation, policy, management, communications, extramural and intramural activities, budgeting, and general counsel.

NCCAM Budget

Under the current continuing resolution, which expires on February 15, 2007, NCCAM is operating at the fiscal year (FY) 2006 budget authority of \$120.4 million (after the rescission and NIH Roadmap funds have been subtracted). It is projected that NCCAM's FY 2007 budget authority will be slightly more than \$120 million. The President's FY 2008 budget will be released on February 5, 2007.

Dr. Kirschstein reviewed NCCAM's appropriations history through 2007 and discussed the Center's growth compared with that of NIH as a whole. After several years of robust growth, NCCAM's budget is flattening, reflecting an NIH-wide trend.

Extramural Research

Trends in extramural grants were presented, showing the numbers of applications and new awards, as well as success rates, from 1999 to 2006. NCCAM's success rate is currently aligned with that seen throughout NIH.

Dr. Kirschstein described NCCAM's staged approach to research, which begins with mechanistic studies, followed by phase I and II trials, which may then lead to phase III trials. NCCAM continues working to raise the bar on the quality of research through its policy and guidance regarding biologically active agents used in CAM and placebo materials.

Dr. Kirschstein updated Council on the status of the phase III study of chelation therapy for coronary artery disease, which is cosponsored by NCCAM and the National Heart, Lung, and Blood Institute (NHLBI). Approximately 1,160 participants have been randomized to date at 110 clinical sites in the United States; 21 sites in Canada are being added. Dr. Kirschstein explained that because heart disease is a key focus at NHLBI, the grant will be transferred to NHLBI after the review by the data and safety monitoring board on February 23, 2007. NCCAM will continue to be represented on the steering committee.

Training and Career Development

Dr. Kirschstein presented trends in NCCAM spending on training and careers from FY 1999 to 2006. After several years of substantial increases in expenditures for both training and career development, spending began to flatten in FY 2005 and 2006, respectively.

Outreach and Education

Dr. Kirschstein presented data about recent NCCAM outreach and education activities, which provide credible information and education to the public and professionals.

Information Dissemination

The NCCAM Web site has seen an increase of one-half million users in the past year.

The information clearinghouse keeps subscribers up to date with health information products such as the quarterly newsletter, *CAM at the NIH*, which has 18,000 subscribers. NCCAM also distributes a monthly eBulletin, *NCCAM Update*, to 7,000 e-mail subscribers.

NCCAM supports health education and promotion programs, such as a partnership with AARP on a survey of older Americans' use of CAM, as well as the PBS television special "New Medicine."

Speakers in the 2006 Distinguished Lecture Series included Dr. Ram Sasisekharan of the Massachusetts Institute of Technology ("Natural Products: Challenges and Opportunities") and Dr. Bruce Rosen of Harvard Medical School ("Neurobiological Correlates of Acupuncture").

Educational Resources

A series of eight continuing education courses on CAM subjects is available online. To date, more than 8,000 users have registered for courses in this series.

CAM on PubMed, a database developed jointly by NCCAM and the National Library of Medicine, now contains about one-half million items.

IV. Concept: Omics and Variable Responses to CAM: Secondary Analysis of CAM Clinical Trials

Dr. Margaret A. Chesney, NCCAM Deputy Director, introduced Dr. Carol Pontzer, NCCAM Program Officer, Division of Extramural Research and Training.

Dr. Pontzer and Dr. Laura Lee Johnson, a statistician with NCCAM's Office of Clinical and Regulatory Affairs, presented a concept for an initiative to examine the role of omics (including genomics, proteomics, and metabolomics) in variable responses to CAM interventions.

Dr. Pontzer had originally proposed the concept at the September 8, 2006, NACCAM meeting. At that time, Council expressed general support but asked for additional input on feasibility, specifically as related to sample size and cost.

Project Concept Review

Dr. Pontzer stated that the initiative aims to produce value-added science by leveraging NCCAM's investments in clinical trials to explore potential associations between omics

and variable responses to CAM. It is also intended to stimulate the CAM community to initiate omics investigations.

Dr. Pontzer explained that since the September meeting, she had solicited additional input regarding feasibility from internationally known geneticists and statisticians from various NIH intramural and extramural programs.

Dr. Pontzer pointed out the revised concept's broadened focus, reflected in a change in the title from "Genomics" to "Omics." Although NCCAM anticipates that most proposed work will deal with SNP analysis and gene expression arrays, it is also open to proteomic and metabolomic approaches. Dr. Pontzer noted that literature is burgeoning on the analysis of gene expression profiles and their relationship to clinical outcomes. She also noted that the high patient variability observed in the treatment arm of many CAM and conventional clinical studies could be the result of omic differences. Dr. Pontzer provided examples of omics uses in CAM, such as the identification of differences in the metabolism of hyperforin in studies on St. John's wort.

Dr. Johnson then discussed the feasibility of the revised concept. She noted that any studies funded under this mechanism would need to have clear objectives and a credible hypothesis for expectation of a genetic basis for the observed differences in the CAM effect. She addressed issues of sample size, tissue relevancy, storage, consent/reconsent, confounding data, and costs, concluding that the concept is feasible.

Discussion

Council indicated that the revised proposal addressed most of the issues raised earlier. Council discussed the challenges of determining sample size, ensuring statistical power, and storing samples. Also discussed was the importance of planning for retrospective omics research when conducting studies (e.g., ensuring that adequate sample information is collected prospectively).

Council passed a motion to approve the project concept.

V. Biennial NCCAM Advisory Council Report Certifying Compliance With Inclusion Guidelines

Dr. Kirschstein introduced Dr. Jonathan Berman, Director, NCCAM's Office of Clinical and Regulatory Affairs. Dr. Berman presented the *2007 Report Certifying Compliance with Population Inclusion Guidelines*.

The report includes NCCAM clinical trial data from FY 2004 and 2005, which were tabulated and analyzed in the FY 2005 and 2006 reporting years, respectively. The data are broken into two categories: all clinical research and phase III clinical research.

FY 2005 reporting year: In all NCCAM clinical trials, 59 percent of participants were women, and 36 percent were minorities. In phase III studies, 42 percent were women and 15 percent were minorities.

FY 2006 reporting year: In all NCCAM clinical trials, 56 percent of participants were women, and 22 percent were minorities. In phase III studies, 47 percent were women and 10 percent were minorities.

Discussion

Council discussed limitations to definitions and data on subpopulations within the minority category, recognizing that NCCAM is collecting data to the best of its abilities within the confines of the reporting structure. It was remarked that refining the category definition would yield better information on how U.S. minorities use CAM.

Council voted unanimously to approve the report.

VI. Office of Behavioral and Social Sciences Research, NCCAM, and Mind-Body Research

Dr. Kirschstein introduced Dr. David B. Abrams, Director, NIH Office of Behavioral and Social Sciences Research (OBSSR). Dr. Abrams described the role of his office within NIH and how it relates to NCCAM and mind-body research.

Dr. Abrams stated that Congress established OBSSR within the NIH Office of the Director in 1993 to enhance behavioral and social sciences research and training, integrate a biobehavioral interdisciplinary perspective into all NIH research areas, and improve communication among behavioral and social scientists, and with the public. Although OBSSR does not directly fund grants, it looks for common areas of interest among the 27 NIH institutes and centers and develops interdisciplinary partnerships to create grant programs that accomplish what a single IC could not.

OBSSR promotes systems integration to capitalize on new discoveries and new tools such as informatics, computer technology, and gene-environment interaction. The office aims to stimulate research that integrates multiple levels of analysis—from cells to behavior to society—that are required to understand the ways individual and contextual factors interact to determine health status.

New goals for the office include promoting the integration of biomedical causes (such as genes, molecules, proteins) with socioecological “causes of causes” (such as behavioral and social factors). Three current NCCAM/OBSSR grant programs in mind-body medicine support research into socioecological arenas:

- Research on Mind-Body Interactions and Health (R01)
- Mind-Body Interactions and Health: Exploratory/Developmental Research Program (R21)

- Mind-Body Interactions and Health: Research Infrastructure Program (R24).

Under these programs, investigators are studying such topics as integrative healing in irritable bowel syndrome, nitric oxide generation and release in responses to acupuncture, neuroendocrine mechanisms in yoga treatment of insomnia, mind/brain/body interactions in stress-related disorders, and the impact of stress on wound healing.

Dr. Abrams noted that integrative and transdisciplinary research is being formalized within NIH on a large scale through the new Office of Portfolio Analysis and Strategic Initiatives, which is housed in NIH's Office of the Director. Systems strategies are also being supported through NIH Director Elias Zerhouni's NIH Roadmap for Medical Research and the NIH Blueprint for Neuroscience Research.

Discussion

Council discussed potential opportunities for behavioral and CAM research under the NIH Roadmap, Office of Portfolio Analysis and Strategic Initiatives, and Institutional Clinical and Translational Science Awards programs. Council also discussed the reduced number of behavioral proposals submitted for the second Roadmap compared with the first, the relative lack of qualitative studies, and the need to increase the quality of behavioral medicine proposals submitted to NIH.

Dr. Chesney noted that NCCAM's funding priorities for research include qualitative studies. In addition, she assured Council that NCCAM will continue to enlist grant reviewers who are knowledgeable about qualitative research.

Dr. Abrams noted that in addition to responding to NIH grant initiatives, investigators are free to contact his office to discuss research ideas and mechanisms.

VII. Public Comment Session

Dr. Goldrosen opened the floor for public comment.

Mr. Peter Reineke, former legislative director for U.S. Senator Tom Harkin, stated that NCCAM has had a positive impact both on the published research and research infrastructure in the United States. He said that Americans' widespread use of untested CAM therapies was a fundamental impetus behind the legislation creating NCCAM, and he entreated Council to consider this when reviewing research proposals. He also urged NCCAM to increase its coordination with FDA and consider FDA's criteria for adequate research quality when evaluating study proposals.

Dr. William Duncan, a former staff member to U.S. Representative Ernest Istook who worked on the legislation that created NCCAM, thanked NCCAM and Council for their accomplishments since the Center's creation. Dr. Duncan challenged NCCAM to continue research into potential treatments for major chronic diseases.

Dr. Goldrosen adjourned the meeting at 3:58 p.m.

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

Martin Goldrosen, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Alternative
Medicine

Ruth L. Kirschstein, M.D.
Chairperson
National Advisory Council for
Complementary and Alternative
Medicine