

**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-FIFTH MEETING
September 8, 2006**

NACCAM Members present

Dr. Carlo Calabrese, Portland, OR
Dr. Sheldon Cohen, Pittsburgh, PA*
Dr. Fabio Cominelli, Charlottesville, VA*
Dr. Silvia Corvera, Worcester, MA
Dr. Jeanette Ezzo, Baltimore, MD
Dr. Joan Fox, Cleveland, OH
Dr. Ted Kaptchuk, Boston, MA
Dr. Bala Manyam, Odessa, FL
COL Richard Niemtzw, Clinton, MD
Dr. Bruce Redman, Ann Arbor, MI
Dr. Danny Shen, Seattle, WA
Dr. Frank Torti, Winston Salem, NC*
Dr. Stefanie N. Vogel, Baltimore, MD
Dr. Larry Walker, University, MS

*Ad hoc members

NACCAM Members not present

Dr. Gerald Cross, Washington, DC
Dr. Jonathon Davidson, Durham, NC
Dr. David Hillis, Dallas, TX
Dr. Tieraona Low Dog, Tucson, AZ
Dr. Joel Pickar, Davenport, IA

NIH Staff Present

National Center for Complementary and Alternative Medicine

Dr. Julia Arnold
Ms. Adelina Bartels
Ms. Willer Batten
Dr. Josh Berman
Dr. Dale Birkle
Ms. Karla Blaine
Dr. Sheila Caldwell
Ms. Debera Campbell
Mr. Steve Casady
Dr. Margaret Chesney, Acting Director

Dr. Margaret Cole
Ms. Alyssa Cotler
Ms. Linda Engel
Dr. Martin Goldrosen, Executive Secretary
Ms. Anita Greene
Ms. Mary Gregg
Ms. Melinda Haskins
Ms. Camille Hoover
Dr. Jeanette Hosseini
Dr. Morgan Jackson
Ms. Deborah Jennings
Dr. Laura Lee Johnson
Ms. Leikny Johnson
Mr. Roald Keith
Dr. Partap Khalsa
Dr. Jack Killen
Ms. Marguerite Klein
Dr. Peter Kozel
Ms. Catherine Law
Dr. Qi-Ying Liu
Dr. Patrick Mansky
Dr. Heather Miller
Ms. Ilze Mohseni
Dr. Barbara Moquin
Dr. Richard Nahin
Ms. Ellen O'Donnell
Dr. Nancy Pearson
Dr. Carol Pontzer
Ms. Linda Rich
Ms. Jeanie Robinson
Dr. Martina Schmidt
Dr. Barbara Sorkin
Ms. Kathleen Stephan
Dr. Catherine Stoney
Ms. Chris Thomsen
Ms. Jennifer Tisch
Mr. George Tucker
Dr. Shan Wong
Ms. Andrea Wongsam-Nollinger
Ms. Patricia Yu

Other NIH Institutes

Dr. Aftab Ansari, Center for Scientific Review
Dr. Martin Brown, National Cancer Institute
Dr. Daofen Chen, National Institute of Neurological Disorders and Stroke
Ms. Andrea Collins, National Cancer Institute

Ms. Jody Engel, Office of Dietary Supplements
Mr. David Lanier, AHRQ
Ms. Phuong Pham, National Cancer Institute
Dr. Wendy Smith, National Cancer Institute
Dr. Margaret Snyder, Office of Extramural Programs
Ms. Malaika Staff, National Cancer Institute
Dr. Christine Swanson, Office of Dietary Supplements
Mr. Phil Tonkins, National Cancer Institute
Dr. Beth Yetley, Office of Dietary Supplements

Members of the Public

Hannah Bradfal
John Chah
Steven Dentali
Harry L. Gewanter, MD
Michnell Jarver
Rebekah Moar
Suzanne Niemeyer
Tamar Nordenberg
Georgia Persrillos
Maggie Pettersen
Christy Phillips
Rebecca Pille
Michelle Rodrigues

I. Closed Session

The first portion of the 25th 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 268 applications were assigned to NCCAM. Of these, 208 were reviewed by NCCAM, 60 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 agreed with staff recommendations on 1 application for low program priority, 5 applications for high program priority and concurred on 134 applications requesting \$ 52,734,119 in total costs.

II. Open Session—Call to Order

The open session of the NACCAM meeting convened at 1:30 p.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on June 8, 2006, were unanimously approved, with no votes against and no abstentions. Dr. Goldrosen reminded Council members of the next meeting, scheduled for February 2, 2007.

Dr. Goldrosen introduced Dr. Margaret A. Chesney, Acting Director of NCCAM.

III. Director's Remarks—Center Update

Dr. Chesney welcomed Council members and guests, and extended greetings on behalf of Dr. Stephen E. Straus, NCCAM Director. Dr. Chesney introduced three ad hoc Council members: Dr. Sheldon A. Cohen, Dr. Fabio Cominelli, and Dr. Frank M. Torti. She also introduced Dr. Margaret Cole, a new staff member with NCCAM's Office of Policy, Planning, and Evaluation.

NCCAM Budget

Dr. Chesney estimated that NCCAM's fiscal year (FY) 2007 budget authority will be approximately \$118 million after contributions, rescissions, and transfers. This would be \$2 million less than NCCAM's FY 2006 budget authority. Dr. Chesney projected that NCCAM will receive its appropriation early in the calendar year, 2007 and, along with the other Institutes and Centers at the National Institutes of Health, will operate under a continuing budget resolution until that time.

Loan Repayment Program

Dr. Chesney updated Council on NCCAM's participation in the National Institutes of Health (NIH) Loan Repayment Program. Through the program, NIH repays qualified educational loans for professionals in selected fields in exchange for 2 or 3 years of commitment to research. NCCAM has funded 9 of the 30 applications it has received; 4 of the funded applicants hold complementary and alternative medicine (CAM) degrees.

Product Quality Working Group

Dr. Chesney discussed NCCAM's Product Quality Working Group (PQWG), which assesses the quality of natural products proposed for investigation. The working group will be evaluated with input from principal investigators, PQWG members, and NCCAM program officers. The evaluation will consider the clarity, comprehensiveness, and fairness of PQWG policy and process; results will be reported at an upcoming Council meeting. This was also presented during the closed session by Marguerite Klein.

North American Research Conference on Complementary and Integrative Medicine

Dr. Chesney described NCCAM's participation in the recent North American Research Conference on Complementary and Integrative Medicine in Edmonton, Alberta, Canada. The conference had more than 600 participants from 22 countries, and it offered more than 200 poster presentations, as well as many panels and symposia. Office of Communications and Public Liaison personnel staffed the NCCAM exhibit booth, and program officers were available to answer questions from current and potential grantees. NCCAM program staff participated in workshops on Federal and nonprofit research

support for CAM, scientific and methodological issues in CAM research, electronic grant submission procedures, and grant support of CAM research training.

Recent Reports on Soy

Dr. Chesney discussed recent findings on soy:

- A National Institute of Environmental Health Sciences workshop on soy reported uncontrolled and widely varying isoflavone content in animal chow and unlabeled isoflavone content in foods prepared for human consumption.
- A systematic review on soy by the Agency for Healthcare Research and Quality (AHRQ) found that evidence from clinical trials is equivocal. A wide variety of soy products have been studied and considerable variability exists in the quality of the soy used in the studies.

Dr. Chesney explained that variability in soy content, quality, and labeling in both animal chow and human food may explain why data on soy and its health effects are inconsistent. NCCAM does not have enough confidence in the available data to develop a research agenda on soy. To address this issue, NCCAM is working with the NIH Office of Dietary Supplements to convene a workshop with other components of NIH, the U.S. Department of Health and Human Services, and the U.S. Department of Agriculture to discuss next steps. The workshop will help NCCAM develop a strategy to build a more solid base for soy research, produce guidance for the research community, and eventually lead to steps toward lifting NCCAM's "pause" on funding soy research.

Scientific Advances: Prevention of Rheumatoid Arthritis and Mind-Body Medicine

Dr. Chesney noted that NCCAM-funded research produces a continuous stream of scientific findings on CAM. She highlighted the results of two recent research studies—both reported in peer-reviewed scientific journals—as examples of scientific advances accomplished through NCCAM funding.

The first study found that an extract from the spice turmeric—which contained three major curcuminoids—prevented joint inflammation in rats with rheumatoid arthritis when treatment was begun before the onset of inflammation.

The second study, which compared treatments for chronic low-back pain, found that participants in a yoga group showed significantly greater improvement in physical functioning than those using a self-help book. The investigators recently secured R01 funding for a larger clinical trial of yoga for low-back pain.

Discussion

Council discussed NCCAM's funding. Dr. Chesney stated that NCCAM is proposing initiatives that take into account the projected budget. For example, one proposal for FY 2007 focuses on performing secondary analyses of existing clinical samples; another proposes working with practice-based research networks that have existing data sets. Dr. Chesney noted that NCCAM will need to be

strategic with its funding, and that this underscores the importance of Council’s advice in determining research priorities.

IV. Presentations of New Initiatives

Concept: Health Services Research Using Existing Primary Care Research Networks

Project Concept Review

Dr. Morgan Jackson, Director of NCCAM’s Office of Special Populations, Division of Extramural Research and Training, proposed a project that aims to increase scientific knowledge about CAM use as practiced in community health care settings—including cost effectiveness and efficacy—using both patient-centered and clinical outcomes. Projects would be funded for 3 years through the R21 mechanism and would leverage previous Federal investments by using existing data sets and taking advantage of the assets of existing federally funded primary care research networks (e.g., large patient populations, diverse settings, and integrated electronic data systems).

Discussion

Council discussed potential projects that could be funded under this initiative. Dr. Martin Brown, Program Officer of the Cancer Research Network, joined this discussion, described the network and the breadth of practices and health plans that comprise the network, and the extensive database that the network has created.

Council proposed involving stakeholders and advisory groups to guide the initiative and suggested seeking grant review assistance from public health experts and AHRQ.

Council passed a motion to approve the project concept.

Concept: Genomic and Expression Influences on CAM Variability—Secondary Analysis of CAM Clinical Trials

Project Concept Review

Dr. Carol Pontzer, NCCAM Program Officer, Division of Extramural Research and Training, proposed an initiative to examine genomic differences that may be responsible for variations in individual responses to CAM interventions. Researchers would perform secondary analyses on existing samples from ongoing and completed CAM clinical trials. Projects would be funded for 3 years through the R21 mechanism.

Discussion

Council indicated general support, but asked that several issues be addressed before implementation of the concept. NCCAM will review the proposed grant mechanism, projected costs, necessary sample sizes, and scope of biological material to be tested. Dr. Pontzer stated that she would address these issues and present a revised project concept description to Council at a future meeting.

Small Business Innovative Research (SBIR) Concepts

Dr. Catherine Stoney, NCCAM Program Officer, Division of Extramural Research and Training, outlined the three phases of the SBIR program, from establishment of technical merit and feasibility in phase I through commercialization in phase III. (Dr. Stoney noted that NCCAM does not fund phase III SBIR projects.)

Three project concepts for the SBIR grant program were presented.

Concept: Phase II—Tools and Technology to Measure Patient Adherence in CAM Research

Dr. Stoney noted that studies of patient behavior indicate that only about one-half of patients leaving a physician's office follow the treatment instructions given. This phase II initiative aims to broaden and improve measures of adherence to treatment regimens by stimulating the development of innovative tools for monitoring objective measures of patient adherence with CAM study protocols (e.g., assays for detection of biologically active CAM agents or metabolites as well as tools and technologies to assess adherence with study protocols for mind-body modalities such as meditation). Funding will be restricted to phase I SBIR grantees.

Council passed a motion to approve the project concept.

Concept: Phase I—New Technologies for Assessing Manual Therapies

Dr. Partap S. Khalsa, NCCAM Program Officer, Division of Extramural Research and Training, proposed a phase I SBIR initiative. Funded projects would seek to develop new technology, research tools, instruments, and devices, or new applications of existing technology in order to illuminate the biological effects of manual therapies. The initiative would also fund projects to develop new and innovative approaches to diagnosing, managing, treating, and preventing a wide variety of neuromusculoskeletal conditions that are treated by manual therapies.

Council passed a motion to approve the project concept.

Concept: Phase I—Microarrays for Detection of Probiotic Outcomes

Dr. Pontzer proposed an initiative to design and construct a custom microarray to study microflora composition in the human gastrointestinal tract. The array could ultimately be used to examine the effects of probiotic interventions for illnesses such as inflammatory bowel disease and colon cancer.

Discussion

Council discussed the limitations of previous research, the complexities of the gut microflora, and the potential difficulty in applying this information to probiotic interventions and disease outcomes. NCCAM tabled the current version of the concept. Dr. Pontzer will work with Dr. Cominelli and others to modify the proposed concept. A revised project concept will be presented to Council at the future meeting.

V. Announcement of Grant-Writing Workshop

Dr. Wendy Smith, Program Director of NCI's Office of Cancer Complementary and Alternative Medicine (OCCAM), announced an NCI grant-writing workshop to be held November 8, 2006, in collaboration with the annual meeting of the Society for Integrative Oncology in Boston. The workshop will offer solutions to the most common problems reviewers have found in past grant applications. Further information about the workshop can be found on the OCCAM page of the NCI Web site.

VI. Public Comment Session

Dr. Goldrosen opened the floor for public comment.

Dr. Harry Gewanter, a pediatric rheumatologist in Richmond, Virginia, addressed Council as a representative of the American Academy of Pediatrics (AAP). He reported that AAP has established the Provisional Section on Complementary, Holistic, and Integrative Medicine to address issues surrounding the use of CAM in pediatrics. Dr. Gewanter highlighted the results of a 2001 survey of AAP member pediatricians, in which 87 percent of respondents reported that a patient or parent had asked them about CAM. Dr. Gewanter stated that although substantial numbers of children are using CAM, few data exist on CAM's effects in children. He asked that NCCAM and Council consider issues related to pediatrics in deliberations about research, policies, programs, and funding.

Dr. Chesney noted that NCCAM will be cooperating in a future National Health Interview Survey that will include questions on pediatric CAM use. Council suggested that pediatricians and their physician groups invite CAM practitioners to grand rounds and national meetings. Dr. Gewanter indicated that such activities have taken place in his practice community and that CAM sessions are planned for the AAP national meeting in October 2006 and the Pediatric Academic Societies' meeting in 2007.

Dr. Goldrosen adjourned the meeting at 3:35 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

Margaret A. Chesney, Ph.D.
Acting Director,
National Advisory Council for
Complementary and Alternative Medicine