

**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 TWENTIETH MEETING
June 3, 2005**

NACCAM Members Present

Dr. Carlo Calabrese, Portland, OR
Dr. Zang-Hee Cho, Irvine, CA
Dr. Kristina Collins, McLean, VA
Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Gerald Cross, Washington, DC
*Dr. Douglas A. Drossman, Chapel Hill, NC
Dr. Jeanette Ezzo, Takoma Park, MD
Dr. Robert E. Fullilove, New York, NY
*Dr. Sankar Ghosh, New Haven, CT
Dr. Murray Goldstein, Washington, DC
Dr. Leslie Hillis, Dallas, TX
Dr. Michael Irwin, Los Angeles, CA
*Dr. George L. King, Boston, MA
*Dr. A. Douglas Kinghorn, Columbia, OH
Dr. Alan I. Leshner, Washington, DC
Dr. Tieraona Low Dog, Albuquerque, NM
Dr. Bala Manyam, Temple, TX
COL Richard Niemtzw, Clinton, MD
*Dr. Bruce Redman, Ann Arbor, MI
*Dr. Jerome Schultz, Riverside, CA
Dr. Barbara Timmerman, Tucson, AZ
Dr. Stefanie N. Vogel, Baltimore, MD
Dr. Larry Walker, University, MS
Dr. Benjamin Yang, San Francisco, CA

*Ad hoc members

NACCAM Members Absent

Dr. Jonathan Davidson, Durham, NC
Dr. Joel Pickar, Davenport, IA

NIH Staff Present

National Center for Complementary and Alternative Medicine

Ms. Willer Batten	Ms. Robin Klevins
Dr. Dale Birkle	Dr. Peter Kozel
Ms. Shea Buckman	Ms. Catherine Law
Ms. Debra Campbell	Dr. Qi-Ying Liu
Mr. Craig Carlson	Dr. Patrick Mansky
Mr. Steve Casady	Ms. Genevieve Medley
Dr. Margaret Chesney, Deputy Director	Dr. Heather Miller
Ms. Alyssa Cotler	Ms. Ilze Mohseni
Mr. Ned Culhane	Ms. Barbara Moquin
Dr. Laurie Donze	Dr. Richard Nahin
Ms. Karla Ehrler	Dr. Robert Nussenblatt
Ms. Linda Engel	Ms. Ellen O'Donnell
Ms. Carol Fitzpatrick	Dr. Nancy Pearson
Ms. Anne Frost	Ms. Martha Pien
Mr. Kevin Green	Dr. Carol Pontzer
Ms. Mary Gregg	Ms. Linda Rich
Ms. Karen Harris	Ms. Alice Robinson
Ms. Camille Hoover	Ms. Denise Simmonds-Barnes
Dr. Jeanette Hosseini	Dr. Catherine Stoney
Dr. Morgan Jackson	Dr. Stephen Straus, Director
Ms. Deborah Jennings	Ms. Jennifer Sutton
Dr. Laura Johnson	Ms. Chris Thomsen
Ms. Emmy Jones	Mr. George Tucker
Mr. Roald Keith	Ms. Shirley Villone
Dr. Jack Killen	Dr. Shan Wong
Ms. Darria King	Ms. Angie Wongsam-Nollinger
Dr. Jane Kinsel	

Other NIH Employees

Dr. Wendy Smith, National Cancer Institute
Dr. Michael Gottesman, Intramural Research, NIH
Dr. Barbara Alving, National Center for Research Resources

Members of the Public

Mr. Gillian Buckley	Ms. Suzanne Niemeyer
Mr. E. M. Den	Dr. Georgia Persinos
Dr. Michael Dyer	Mr. Woo Moon Sun
Ms. Brooke Garner	Mr. Simon Weavers
Mr. Phil Jenkins	Ms. Joan Wilentz
Mr. Chong Lee	

I. Closed Session

The first portion of the 20th 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 306 applications were assigned to NCCAM. Of these, 240 were reviewed by NCCAM, 64 by the Center for Scientific Review, and 1 by another institute. 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 10 applications and concurred on 186 applications requesting \$39,405,456 in total costs.

II. Open Session—Call to Order

The open session of the NACCAM meeting convened at 1:20 p.m. Dr. Stephen E. Straus, Director of the National Center for Complementary and Alternative Medicine (NCCAM), called the meeting to order. He thanked Council members and NCCAM staff for their participation.

Dr. Straus introduced and thanked the ad hoc members of Council: Dr. Douglas Drossman, Dr. Sankar Ghosh, Dr. George King, Dr. A. Douglas Kinghorn, Dr. Bruce Redman, and Dr. Jerome Schultz. Dr. Straus reported that Dr. Stephanie Vogel's appointment to Council has been made official.

Dr. Straus thanked the departing members of Council: Dr. Zang-Hee Cho, Dr. Kristina Collins, Dr. Murray Goldstein, Dr. Michael Irwin, Dr. Barbara Timmerman, and Dr. Benjamin Yang. Dr. Straus presented the departing Council members with certificates of appreciation from NCCAM and from the Secretary of the U.S. Department of Health and Human Services (HHS).

III. Director's Remarks

Dr. Straus updated Council on NCCAM's appropriations and budget. He noted that the fiscal year (FY) 2005 Federal budget allocated \$123.1 million for NCCAM, out of a total National Institutes of Health (NIH) budget of \$28.6 billion. After rescissions and other reductions, NCCAM's net budget is \$122.1 million. The President's FY 2006 Budget Request includes \$122.7 million for NCCAM; Congress will determine actual appropriations.

Dr. Straus placed NCCAM's budgetary trends in the larger context of the NIH environment. NCCAM's funding is robust, but growth is flattening, reflecting an NIH-wide trend.

Dr. Straus discussed an interagency agreement with the U.S. Department of Agriculture's Agricultural Research Service to screen 50 dietary supplements for *in vitro* activity against six oxidants; determine if specific "antioxidants" exhibit broad activity or protect against only one or a few oxidants; and propose best antioxidants to test in *in vivo* models.

Dr. Straus highlighted several recent and upcoming events sponsored or cosponsored by NCCAM:

- State-of-the-Science Conference on the Management of Menopause-Related Symptoms
- Distinguished Lecture by Dr. Ralph Snyderman on Integrative Medicine
- Conference on the Biology of Manual Therapies
- Integrating Psychology, Neuroscience and Physiological Mechanisms: A New Framework Applied to Asthma and Atherosclerosis

Dr. Straus provided an overview of the NCCAM Director's Fellowship, funded by the Prince of Wales Foundation. This intramural fellowship will focus on clinical, translational, or basic CAM research working with another NIH institute or center (IC). The partnering IC will provide partial matching support. Research will be conducted as part of the cosponsoring IC's intramural program and the fellow will serve as a liaison between NCCAM and this IC. Dr. Straus also discussed the 3-year CAM Oncology Fellowship, cosponsored by NCCAM, the National Cancer Institute (NCI), and the U.S. Food and Drug Administration.

Dr. Straus mentioned that NCCAM's Office of Communications and Public Liaison had received a silver medal from the World Wide Web Health Awards. The Office has implemented a Live Help response service and a continuing education series on the NCCAM Web site. Other communications news included outreach to Alaska natives and publication of *Thinking About Complementary and Alternative Medicine: A Guide for People with Cancer*, a booklet coproduced with NCI.

Dr. Jane F. Kinsel, NACCAM Executive Secretary, announced the public comment session to be held at the conclusion of the open session, and invited those who were interested in speaking to sign up. Minutes from the Council meeting on January 28, 2005, and the Council conference call on April 4, 2005, were approved.

IV. New NIH Conflict of Interest Regulations

Dr. Straus introduced Dr. Michael Gottesman, NIH Deputy Director for Intramural Research. Dr. Gottesman presented an overview of the interim NIH final regulations on

conflict of interest, focusing on the history of NIH conflict of interest regulation, the interim final regulations, and what the future may hold in this area. Dr. Gottesman described how the interim regulations apply to senior scientists and to NIH staff as a whole. He emphasized that the interim regulations are part of an evolving process and that NIH is committed to recruiting and retaining top scientists.

Responding to questions from Council, Dr. Gottesman discussed potential timeframes for next steps and explained that interim regulations focus on NIH scientists' current research rather than their past research or employment.

Dr. Straus thanked Dr. Gottesman for his work on behalf of NIH scientists and his presentation to Council.

V. NIH Roadmap: A New Vision for Translational Research

Dr. Straus introduced Dr. Barbara Alving, Acting Director of NIH's National Center for Research Resources (NCRR), who is leading an NIH effort to promote translational research. Translational research is a core focus of Re-engineering the Clinical Research Enterprise, one of the three NIH Roadmap for Medical Research themes. Dr. Straus noted that the Roadmap's major emphasis on the clinical research enterprise is of particular interest to NCCAM, as NCCAM funds a higher percentage of clinically oriented grants than most other NIH components or ICs.

Dr. Alving presented a new vision for translational research, which draws upon many of the ideas from the Roadmap and is trans-NIH in nature. This large, transformative effort to address NIH's translational research activities replaces a smaller-scale effort to develop Regional Translational Research Centers (RFA-RM-05-008, Regional Translational Research Center Planning Grants).

Dr. Alving thanked Dr. Straus and Dr. Stephen Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, for their leadership on Roadmap activities involving clinical and translational research. She provided a history of the initiative to promote translational research and discussed the challenges involved, as well as potential approaches to forming an academic home for clinical and translational sciences. She noted that it is more efficient to capitalize on existing infrastructures at academic health centers than to reinvent develop translational research centers.

Dr. Alving explained that while NIH has many resources in place to advance translational research, the resources must be coordinated efficiently and gaps must be filled. Issues to be addressed and gaps to be filled are:

- Research design, statistics, regulatory affairs
- Biomedical informatics
- Career development program
- Inpatient, outpatient, and community accrual sites for clinical trial participants
- Pilot project program

- Governance core

In response to a question from Council, Dr. Alving stated that the initiative would provide a corps of well-trained translational investigators by helping academic health centers manage regulatory burdens and by eliminating inefficiencies.

Dr. Straus reported that the initiative was intended to leverage existing resources and fill in gaps for areas not covered by existing mechanisms. Council and Dr. Alving discussed the resources available for the initiative.

Dr. Alving addressed a question from Council by noting that the initiative will provide a means of linking academic and clinical practice. Dr. Straus stated that NCCAM was interested in helping to develop the initiative in order to enhance the discipline of clinical and translational science in settings such as chiropractic and naturopathic colleges as well as in schools of conventional medicine and dentistry, nursing, Osteopathy and pharmacy.

Dr. Straus thanked Dr. Alving for her leadership and her presentation to Council.

VI. Biologically Active Components Used in CAM

Dr. Straus introduced Ms. Marguerite Klein, Program Officer at NCCAM. Ms. Klein reviewed two guideline documents that have been posted in the *NIH Guide*:

- *NCCAM Interim Policy: Biologically Active Agents Used in Complementary and Alternative Medicine (CAM) and Placebo Materials* and
- *NCCAM Interim Applicant Guidance: Product Quality: Biologically Active Agents Used in Complementary and Alternative Medicine (CAM) and Placebo Materials*.

The policy and guidance apply to research funding requests that involve use of botanicals, probiotics, placebos, products derived from animals, and other biological agents, excluding homeopathic medicines. The guidance to applicants lists product information to be included in initial research and training grant applications. It also addresses “just-in-time” information, which is detail about product quality that best-scoring applicants must submit to NCCAM following peer review.

Effective June 1, 2005, the policy stipulates that NCCAM will notify the best-scoring applicants following peer review. These applicants will submit “just-in-time” information as requested. A working group of Council will evaluate the information and inform the applicant and Council of the results. Based on the evaluation result, Council will make recommendations to NCCAM to make the final funding decision.

Ms. Klein noted that information on the policy is being disseminated via the *NIH Guide*, the NCCAM Web site, NCCAM’s newsletter, exhibits at scientific meetings, and e-mail and listserv messages.

Ms. Klein introduced Dr. Kinsel, who proposed a plan to establish a working group of Council for a 1-year interim period to review and evaluate “just-in-time” product information provided by applicants.

The working group would:

- Evaluate product information provided by applicants;
- Determine whether such information should continue to be required of applicants;
- Include subject-matter experts in pharmacognosy, natural products chemistry, and characterization/standardization of natural products; and
- Meet each Council cycle for 1 year (i.e., three times in 2006), beginning with the January 2006 Council meeting.

Dr. Kinsel stated that the proposed working group would provide focused evaluation of product quality; better integrate product quality considerations into NACCAM deliberations; streamline NACCAM review of grant applications that propose to study biologically active products; and allow NACCAM to draw upon specialized expertise in product characterization, standardization, and quality.

In response to questions from Council, Dr. Kinsel clarified that the working group could consist largely or entirely of non-Council members, but that it would report to Council.

In response to a question from Council, Ms. Klein stated that a working group as proposed would provide the expert advice needed to review technical information about product quality. Dr. Straus noted that a working group of this type would help ensure a more even playing field for applicants.

Following additional discussion, Council voted and approved the motion with no votes opposed or abstentions.

VII. Concept Proposals for Health Disparities Research

Dr. Chesney introduced Dr. Morgan Jackson, director of NCCAM’s Office of Special Populations. Dr. Jackson presented two concept proposals for Council’s consideration:

- Exploratory/Developmental CAM Projects
- Planning Grants for Applications for Academic Partnerships Between Minority Institutions and Experienced CAM Research Institutions

Dr. Jackson provided an overview of recent NCCAM activities in the study of CAM use in minority populations, including participation in an HHS/NIH initiative regarding racial and ethnic health disparities, which targeted cancer, cardiovascular disease, diabetes, HIV/AIDS, adult and child immunizations, and infant mortality; NCCAM’s collaboration with the National Center for Health Statistics of the Centers for Disease Control and Prevention in the largest compilation to date of data on CAM use in minority populations;

and NCCAM's initiative Secondary Analysis of Data on CAM Use in Minority Populations. The concept proposals Dr. Jackson presented to Council would build on these efforts.

Exploratory/Developmental CAM Projects

Dr. Jackson reported that this solicitation would support exploratory/developmental research projects at institutions that have NIH or Agency for Healthcare Research and Quality awards for centers on minority health or health disparities research. Dr. Jackson reported that the goals of the announcement are to:

- Stimulate the submission of high-quality, preliminary studies of CAM at institutions with infrastructure and activities focusing on minority health research or health disparities relating to racial and ethnic minority populations;
- Attract investigators experienced in minority health research and health disparities research to the field of CAM;
- Provide a stable scientific environment where CAM practitioners can participate actively in rigorous research; and
- Increase the knowledge base of information regarding CAM and health disparities.

The program announcement would be funded through NCCAM's preclinical and clinical R21 research project grant mechanisms.

Council discussed the meaning of the term "minority." Dr. Fullilove noted that the use of the term relates back to the disparities discussed in an Institute of Medicine report, and that identifiable disparities qualify for federal funding research. Dr. Fullilove also noted that this initiative provides an opportunity to perform quality, pioneering research.

Council unanimously approved the concept proposal.

Planning Grants for Applications for Academic Partnerships Between Minority Institutions and Experienced CAM Research Institutions

Dr. Jackson reported that this initiative would provide funds to investigators at minority institutions to facilitate planning CAM research projects in association with institutions or investigators experienced in CAM-related research. The initiative would fund planning grants to facilitate collaborative interactions between investigators at minority institutions and investigators at institutions experienced in CAM research.

Dr. Jackson reported that the goals of this solicitation are to:

- Stimulate research on CAM and health disparities;
- Establish productive research collaborations between minority institutions and CAM researchers or research institutions;
- Increase the CAM research capacity at minority institutions; and

- Assist investigators at minority institutions in preparing CAM research project grant applications.

This program will use the NIH R03 grant mechanism, which provides up to \$50,000 per year for up to 2 years of funding.

In response to a question from Council, Dr. Chesney stated that the term “CAM-experienced” might be further defined and clarified as the initiative is finalized. Dr. Jackson noted two points from Council addressing implementation of relationships between NCCAM and researchers.

Council unanimously approved the concept proposal.

VIII. Public Comments

No questions or comments were received from the public. Dr. Straus thanked the participants and adjourned the meeting at 3:50 p.m.

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

Jane F. Kinsel, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Alternative
Medicine

Stephen E. Straus, M.D.
Chair
National Advisory Council for
Complementary and Alternative
Medicine