

**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 THIRTY-NINTH MEETING
June 3-4, 2010**

NACCAM Members present

Dr. Lori Alvord, Hanover, NH
Dr. Stephen Barnes, Birmingham, AL
Dr. Timothy Birdsall, Goodyear, AZ
Dr. Gert Bronfort, Bloomington, MN
Dr. Adam Burke, San Francisco, CA
Dr. Lupo Carlota, Memphis, TN
Dr. Sheldon Cohen, Pittsburgh, PA
Dr. Gary Curhan, Boston, MA
Dr. Steven DeKosky, Charlottesville, VA
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Susan Folkman, San Francisco, CA
Dr. Margery Gass, Mayfield Heights, OH
Dr. Janet Kahn, Burlington, VT
Dr. David Kingston, Blacksburg, VA¹
Dr. Sarah Kobrin, Bethesda, MD²
Dr. Shin Lin, Irvine, CA
Dr. Read Montague, Houston, TX²
Dr. Richard Niemtzw, Clinton, MD
Dr. Lynda Powell, Chicago, IL²
Dr. Katherine Shear, New York, NY
Dr. Herman Taylor, Jackson, MS
Dr. Xiaoming Tian, Bethesda, MD

¹ Ad-hoc

² Speaker

NACCAM Members not present

Dr. Boyd Bowden, Columbus, OH
Dr. Francis Collins, Bethesda, MD
Ms. Kathleen Sebelius, Washington, DC

NIH Staff present

Christina Brackena, OD/OAR

David Cabrera, NIH, OD
Paul Coates, ODS, NIH
Nida Corry, NIH/ORWH
Rick Hansen, NEI, NIH
Margarite Klein, ODS, NIH
Isis Mikhail, NCI/OCCAM
Alexandra Price, NCI/OCCAM
Linda Southworth, NCI, NIH

Members of the Public

Aixa Aleman-Diaz
Tyler Cymet
Julia Dollinger
Steven Dentali
Kathi Hanna
Pat Kobor
Pamela Murphy
Georgia Perdue
Michelle Rodrigues
Susan Role
Taylor Walsh

I. Open Session

The first day of the 39th meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) was called to order by Dr Martin Goldrosen. The first session was a workshop dedicated to Gaps and Opportunities in Health Behavior Research. This workshop examined the potential role of CAM in health behavior research. The information garnered in this meeting will be used in the development of NCCAMs third strategic plan.

The workshop was organized into three sessions. In the first session entitled “setting the stage”, Dr Josephine Briggs welcomed guests and provided a “charge” to Council members and invited participants. Dr Emmeline Edwards provided an NIH perspective on behavior change and trans-NIH activities in this area of research. Dr Wendy Weber summarized NCCAMs current investment in behavior change research. In the second session entitled “health behavior research data and methods, Dr Richard Nahin summarized the association between CAM use and healthy behavior based on the most recent data from the National Health Interview Survey. Dr Read Montague followed with a description of neural mechanisms of behavior change. Dr Lynda Powell described behavior change methodology, while Dr Sarah Kobrin summarized current knowledge regarding changing individual behaviors. The third session was a panel discussion on “improving healthy behavior: what is the role of CAM.

II. Closed Session

The second portion of the 39th meeting of the NACCAM started at 8:30 AM on June 4th. This portion of the meeting 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 249 applications were assigned to NCCAM. Of these, 171 were reviewed by NCCAM, and 78 by the Center for Scientific Review. Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 132 applications, requesting \$51,942,380 in total costs.

III. Second Open Session—Call to Order

The second open session of the NACCAM meeting reconvened at 11 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on February 5, 2010, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen explained procedures for public comment and noted that the next Council meeting will be held on September 3, 2010. He introduced Dr. Josephine Briggs, Director of the National Center for Complementary and Alternative Medicine (NCCAM).

Dr. Briggs called Council's attention to one business item: An implementation and oversight contract through NCCAM's Office of Clinical and Regulatory Affairs is in its final stages. The contract, with annual costs of \$300,000 to \$500,000, will be re-competed in 2011.

III. Stress and Health

Dr. Briggs introduced Dr. Sheldon Cohen, of Carnegie-Mellon University and the University Of Pittsburgh School Of Medicine, whose presentation was titled "The Psychology of Stress and Health."

Dr. Cohen opened his talk with epidemiological, psychological, and biological definitions of stress and addressed how they can be integrated. Stress can be viewed as a process: a person's exposure to a potential stressor leads to an appraisal of whether it is stressful, in light of his or her ability to cope. If he or she cannot cope, a negative emotional response follows, which can result in poor health practices. This, in turn, can increase the risk of physical and psychological disease.

Measurement of stress may involve specific events such as divorce, natural disasters, or job loss—or nonspecific measures. Surveys may be used to assess degrees of stress—for example, life event interviews and the Perceived Stress Scale. Stress may be acute or chronic, but there is no agreed-upon interval upon which acute stress

becomes chronic. It is thought that 1) acute stress can trigger an underlying condition (e.g., asthma, cardiovascular disease), 2) chronic stress is related to disease development, and 3) acute stress can trigger an event in the presence of chronic stress.

The most sophisticated work regarding stress has been done in the area of depression. Data show that 50 to 80 percent of depressive episodes are preceded 3 to 6 months by a major life event (death of a spouse, partner, or child; separation or divorce; work or school problem). Other stress–disease connections include upper respiratory infections, HIV/AIDS, and coronary heart disease. Long-term cardiovascular risk increases among those who have experienced traumatic events (such as the loss of a child) and emotional, physical, or sexual abuse. The evidence is increasing that acute stress (earthquakes, anger, missile attacks) can trigger cardiovascular events. Stressful life events have been associated with disease progression and decreased survival in HIV-positive individuals.

But not everyone succumbs to stress. Factors identified as potential buffers against stress are social support networks; an individual's overall health and stamina; tangible resources such as money; psychological resources such as feelings of self-efficacy, control, and esteem; and resources offered by institutional, cultural, and political entities such as agencies and social groups.

IV. Report From the Director

Following a break for lunch, Dr. Briggs reconvened the meeting at 1:30 p.m.

NACCAM Update

Five members will end their terms on July 31, 2010. Four members will be present for the September 2010 NACCAM meeting: Drs. Lori Arviso Alvord, Stephen Barnes, Boyd Bowden, Sheldon Cohen, and Xiaoming Tian. Dr. Marjorie Gass completed her service on Council and Dr. Briggs thanked her. Dr. Briggs then introduced ad hoc member Dr. David Kingston, Virginia Polytechnic Institute and State University.

National Institutes of Health (NIH) News

A tribute to Ruth Kirschstein, M.D., took place on May 17. She was Director of the National Institute of General Medical Sciences from 1974 to 1993 and the first woman institute director at NIH. She also served as Acting Director of NIH twice in 1993 and from 2000 to 2002. In addition she also served as Acting Director of NCCAM from November 2006 to January 2008.

Dr. Raynard Kington resigned his post as Deputy Director of NIH, effective at the end of July. He will become President of Grinnell College.

Dr. Harold Varmus will return to NIH as Director of the National Cancer Institute.

Search committees have been formed to find suitable candidates for the posts of Director of the National Institute of Child Health and Human Development and Director of the National Heart, Lung, and Blood Institute.

Staff Update

Dr. Briggs introduced new NCCAM staff members and noted the departure of Laurie Donze, Ph.D., Scientific Review Officer.

Research Highlights and 2009 Publication Summary

Dr. Briggs highlighted guidelines published in the June 10, 2010, issue of the *Journal of Nutrition*, "Guidance from an NIH Workshop on Designing, Implementing, and Reporting Clinical Studies of Soy Interventions."

A 2009 bibliography of scientific publications citing NCCAM support was distributed to Council members. To date, NCCAM has supported research that has led to more than 3,800 peer-reviewed journal articles and other publications.

Budget Update

Dr. Briggs presented NCCAM budget information, including appropriations for fiscal year (FY) 2010, the President's request for FY 2011, and American Recovery and Reinvestment Act (ARRA) operating allowances for FY 2009 and 2010. NCCAM's budget for FY 2010 is almost \$129 million, and the NIH budget is \$31 billion. The President's request for FY 2011 is \$32 billion for NIH overall and includes \$132 million for NCCAM. Dr. Briggs also noted that ARRA funds for NIH were \$10.4 billion, of which \$31.7 million was apportioned to NCCAM.

Legislative Update

The Patient Protection and Affordable Care Act (PPACA), signed on March 23, 2010, established the Cures Acceleration Network, which creates but does not appropriate a network to bridge the gap between laboratory studies and life-saving therapies. The bill contains language about pain research—it allows the NIH Pain Consortium to make recommendations about pain research initiatives to be paid for by the common fund. It also establishes a nonprofit institute outside NIH called the Patient-Centered Outcomes Research Institute.

Dr. Briggs reported on a hearing held May 26, 2010, that was precipitated by a U.S. Government Accountability Office (GAO) report on the marketing of herbal dietary supplements. The report addressed deceptive or questionable marketing practices that led to excessive product health claims and that disseminated misinformation.

Dr. Briggs informed Council of NIH's Notice of Proposed Rulemaking on Conflicts of Interest, as published in the *Federal Register* on May 21.

Dr. Briggs advised Council about the Institute of Medicine report, "Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease."

Dr. Briggs reported on "The Big Think" meeting held at NIH on May 7, 2010. The meeting was designed to generate trans-NIH ideas that are bold, transformative, crosscutting, specific enough to allow development of RFAs or RFPs, and affordable.

Outreach Update

Dr. Briggs reported on her recent visits and talks with stakeholders. She informed Council of the next Stephen E. Straus Distinguished Lecture, which will be on December 15, 2010. Dr. Vikas Sukhatme, of Harvard Medical School, will speak about the development of innovative new therapies from yesterday's medicines.

V. Strategic Planning Update

Dr. Jack Killen, NCCAM's Deputy Director, provided a status report on the Center's strategic plan to address research priorities and scientific directions, build research capacity and collaboration, disseminate information about NCCAM research to achieve maximum impact, and ensure responsible stewardship of the public trust. A document will be drafted in late summer and publication is planned for February 2011.

Dr. Killen identified three long-range goals for NCCAM: 1) enable evidence-based decision making regarding the use and integration of CAM practices into health care and health promotion, 2) identify improved approaches for managing difficult symptoms and chronic health problems, and 3) identify practical and personalized strategies for promoting health and well-being.

Natural Products Think Tank

Craig Hopp, Ph.D., Program Officer, NCCAM Division of Extramural Research, presented an overview of this March 26 workshop. The attendees represented academia, trade and industry members, NIH, and the Food and Drug Administration. These diverse participants met to discuss natural products "principles" and to develop a dialogue regarding the future directions for CAM natural products research and development.

Workshop on Control/Comparison Groups for Trials of Nonpharmacologic Interventions (NPIs)

Richard Nahin, Ph.D., M.P.H., NCCAM's Senior Advisor for Scientific Coordination and Outreach, provided an overview of the April 26 to 27 workshop: 1) to review the comparative strengths and weaknesses of various control groups and arrive at a consensus as to which control group would be most appropriate for a particular research question; and 2) to provide guidance to NIH and the scientific community on the most appropriate control/comparison groups for various research questions testing the efficacy of NPIs.

Workshop on Deconstructing Back Pain

Partap Khalsa, Ph.D., D.C., Program Officer in NCCAM's Division of Extramural Research, noted that the May 10 to 11, 2010, meeting was a followup to a 2009 workshop. Attendees discussed the need for studies to better understand chronic back pain (including looking outside the back—i.e., at the brain and the central nervous system), to assess new interventions and management strategies for back pain (particularly as a chronic condition), to evaluate the utility of existing datasets and ongoing cohort studies for future studies of chronic back pain, and to determine what study designs should be used.

VI. Public Comment Session and Closing

Ms. Aixa Aleman-Diaz, M.A., commented on the role of CAM practitioners.

Dr. Briggs thanked Council members and adjourned the meeting at 3:25 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

Josephine Briggs, M.D.
Chairperson
National Advisory Council for
Complementary and Alternative
Medicine