

**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-EIGHTH MEETING  
February 5, 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. Sheldon Cohen, Pittsburgh, PA  
Dr. Gary Curhan, Boston, MA  
\*Dr. Steven DeKosky, Charlottesville, VA  
Dr. Susan Folkman, San Francisco, CA  
Dr. Margery Gass, Mayfield Heights, OH  
Dr. Janet Kahn, Burlington, VT  
Dr. Shin Lin, Irvine, CA  
\*Dr. Katherine Shear, New York, NY  
\*Dr. Herman Taylor, Jackson, MS  
Dr. Xiaoming Tian, Bethesda, MD

\*Teleconference

**NACCAM Members not present**

Dr. Boyd Bowden, Columbus, OH  
Dr. Lupo Carlota, Memphis, TN  
Dr. Francis Collins, Bethesda, MD  
Dr. Stephen Ezeji-Okoye, Palo Alto, CA  
Dr. Richard Niemtow, Clinton, MD  
Ms. Kathleen Sebelius, Washington, DC

**NIH Staff present**

Sally Amero, OER, OD, NIH  
Rick Hansen, NEI, NIH  
Karin Lohman, OER, OD, NIH  
Emilee Pressman, OER, OD, NIH  
Linda Southworth, NCI, NIH  
Dan Xi, NCI, NIH

## **Members of the Public**

Pamela Murphy  
Andrea Weiss  
Alison Shaffer

### **I. Closed Session**

The first portion of the 38th 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 263 applications were assigned to NCCAM. Of these, 164 were reviewed by NCCAM, 99 by 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 126 applications, requesting \$36,196,377 in total costs.

### **II. Open Session—Call to Order**

The open session of the NACCAM meeting convened at 10 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on September 11, 2009, 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 June 4, 2010. He also noted that today's open session will be truncated, because of the major snowstorm forecast for the region. He then introduced Dr. Josephine Briggs, Director of NCCAM.

Dr. Briggs welcomed five new Council members: Dr. Adam Burke, Dr. Gary Curhan, Dr. Steven DeKosky, Dr. Susan Folkman, and Dr. Janet Kahn. Dr. Briggs also noted three recent NCCAM staff appointments: Dr. Emmeline Edwards, Director, Division of Extramural Research; Eric Gallagher, Chief Information Officer; and Dr. Karin Lohman, Director, Office of Policy, Planning, and Evaluation.

### **III. Initiative Discussion and Concept Clearance**

As background for discussions of two proposed initiatives, Dr. Briggs described a three-part research "funnel," in which results from mechanistic studies and early phase clinical studies inform the selection and design of larger (and more expensive) randomized clinical trials (RCTs).

#### **Mechanistic Research on Natural Products**

Dr. Carol Pontzer, Program Officer, NCCAM Division of Extramural Research, outlined a proposed initiative to support mechanistic research on natural products. This initiative

would stimulate research to provide information needed for more definitive RCTs, such as data on active components and mechanisms of action. Currently, such information is lacking for many natural products of interest. Dr. Pontzer summarized the purpose and scope of the initiative, criteria to be used in reviewing applications, and examples of potential research objectives and responsive projects.

**Discussion.** Council members and Dr. Briggs commented on the proposed initiative and discussed related issues, such as why information on biological signatures is important in complementary and alternative medicine (CAM) research, and the complexities of addressing mechanistic questions (e.g., the possibility that modern products may eliminate important components present in traditional botanicals). Dr. Briggs noted that the NCCAM Web site will list priority products for this initiative, but that investigators may propose others.

Council unanimously passed a motion to approve the concept for this initiative.

### **Targeted CAM Clinical Studies: Early Phase Research and Development**

Dr. Wendy Weber, Program Officer, NCCAM Division of Extramural Research, outlined a proposed initiative to support early-phase clinical studies in targeted, high-priority areas. This initiative would focus on CAM interventions that have shown promise, and would seek to fill knowledge gaps related to RCT design issues such as safety, dosing, controls, and outcome measures. Research results will help NCCAM determine whether a project is worthy of major investment in larger studies. Dr. Weber summarized the purpose and scope of the initiative, criteria for identifying target areas, and examples of potential targets.

**Discussion.** Council members and Dr. Briggs commented on the proposed initiative and discussed related issues, such as the need to make clear that funding under this initiative does not guarantee funding of a subsequent RCT, and that the targeted studies will not be large enough to definitively answer efficacy questions. Dr. Briggs noted that investigators will need permission to submit applications.

Council unanimously passed a motion to approve the concept for this initiative.

## **V. Report from the Director**

### **NIH News**

Recent NIH appointments include Dr. Eric Green, Director, National Human Genome Research Institute; Dr. Alan Guttmacher, Acting Director, National Institute of Child Health and Human Development; Dr. Deborah Olster, Acting Director, Office of Behavioral and Social Sciences Research; and Dr. Susan Shurin, Acting Director, National Heart, Blood, and Lung Institute.

### **Budget Update**

Dr. Briggs presented NCCAM budget information for fiscal year (FY) 2010, including total appropriations, budget mechanism details, and comparisons to FY 2009. The total appropriation (conference mark) for FY 2010 is \$128.8 million, an increase of 2.7 percent from FY 2009; however, funds available for competing awards have declined.

Dr. Briggs also summarized NCCAM's American Recovery and Reinvestment Act allocation and FY 2009 commitments.

Dr. Briggs outlined five NIH priority areas established by the Director, Dr. Francis Collins, and noted NCCAM's potential contributions to these priorities. She summarized the President's FY 2011 budget request for NIH (\$32 billion, an increase of 3.2 percent from FY 2010), and explained that increases for individual institutes and centers are being calculated on the basis of their contributions to the priority areas, as reflected in data from the new Research, Condition, and Disease Categorization (RCDC) coding system.

### **Recent Events**

NCCAM held a research symposium on December 8, 2009. A portrait honoring Dr. Stephen E. Straus, NCCAM's founding Director, was unveiled at NCCAM's office suite in building 31 also on December 8, 2009.

### **Research Highlights**

Dr. Briggs highlighted several examples of recent NCCAM-funded research, including Ginkgo Evaluation of Memory (GEM) study results on dementia and cognitive decline. Dr. DeKosky noted publication of GEM results on cardiovascular outcomes. Dr DeKosky also noted that the GEM data will be used to generate a number of additional studies. Dr. Briggs called attention to dietary supplement sales statistics indicating that NIH research results appear to be influencing consumer behavior in this area. Dr. Briggs also mentioned an analysis of CAM costs as reported in the 2007 National Health Interview Survey, and CAM use studies drawing on data from insurance claims and a practice-based research network.

### **Strategic Planning Midpoint Review**

Dr. Briggs reported on the status of the strategic planning process. Next steps include workshops on natural product mechanistic issues (scheduled for March 26), controls in studies of mind-body therapies (April 26-27), back pain (May 10-11), NCCAM's role in behavioral research (June Council meeting), and omega-3 fatty acids (date to be announced). The draft plan is due in late summer.

There have been more than 400 comments from about 300 individuals and organizations in response to planning documents posted on NCCAM's Web site. Dr. Briggs noted concerns expressed by critics of NCCAM and by CAM practitioners, as well as a consensus of support for focusing on product integrity, symptom management, healthy behaviors and wellness promotion, basic/translational studies, and real-world outcomes. In light of the comments received, Dr. Briggs emphasized the importance of objectivity and neutrality in NCCAM-supported research, and noted the appropriateness of focusing research by basing priorities on science, potential impact, use, and promise. She also summarized lessons learned from research to date.

**Discussion.** Council members commented on a wide range of issues related to CAM research directions and the public's response to NCCAM's strategic planning efforts, such as consideration of underlying processes as well as symptom management, effects of patient-practitioner interactions, and the need to address prevention. The importance of flexibility in defining "complementary" and "alternative" was noted. One theme of the

discussion was the notion of “a fundamental human tension between exuberant belief and rational skepticism,” as expressed by Dr. Ted Kaptchuk, a former Council member, in a recent article.

**V. Council Operating Procedures**

Dr. Goldrosen reviewed the Council’s operating procedures, including processes for NCCAM reports to Council, secondary review of grant applications, approval of concepts for research initiatives, and handling of appeals from applicants. Council unanimously passed a motion approving the operating procedures as presented.

**VI. Public Comment Session and Closing**

Ms. Alison Teitelbaum, speaking on behalf of the Interstitial Cystitis Association, summarized information on interstitial cystitis and urged NCCAM to support related research.

Dr. Briggs adjourned the meeting at 12 p.m.

We hereby certify that, to be 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