

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 THIRTIETH MEETING  
June 6, 2008

***NACCAM Members present***

Dr. Lori Arviso Alvord, Hanover, NH  
Dr. Stephen Barnes, Birmingham, AL  
Dr. Timothy Birdsall, Zion, IL  
Dr. Boyd Bowden, Columbus, OH  
Dr. Gert Bronfort, Bloomington, MN  
Dr. Lupo Carlota, Memphis, TN  
Dr. Sheldon Cohen, Pittsburgh, PA  
Dr. Fabio Cominelli, Charlottesville, VA  
Dr. Stephen Ezeji-Okoye, Palo Alto, CA  
\*Dr. Glenna Dowling, San Francisco, CA  
Dr. Joan Fox, Cleveland, OH  
Dr. Margery Gass, Cincinnati, OH  
\*Dr. Steven Hersch, Charlestown, MA  
Dr. Ted Kaptchuk, Boston, MA  
Dr. Shin Lin, Irvine, CA  
Dr. Richard Niemtzw, Clinton, MD  
Dr. Bruce Redman, Ann Arbor, MI  
Dr. Danny Shen, Seattle, WA  
Dr. Herman Taylor, Jackson, MS  
Dr. Stefanie Vogel, Baltimore, MD

\*Ad hoc members

***NACCAM Members not present***

Dr. Silvia Corvera, M.D., Worcester, MA  
Mr. Michael Leavitt, Washington, DC  
Dr. Elias Zerhouni, Bethesda, MD

***NIH Staff Present***

Linda Southworth, NCI  
Christine Swanson, NIH/ODP/ODS  
Andrea Collins, NCI/NCCAM  
Jody Engel, ODS  
Dan Xi, NCI  
Marguerite Klein, ODS  
Claire Harris, NCI  
Kati Strong, NIH/CC  
Joan Wilentz, NIH

### ***Members of the Public***

Suzanne Niemeyer  
Steven Dentali  
Nora Cook  
Pattie Yu, GYMR  
Christy Hoang  
Cynthia Jardue  
Prachi Patel  
Hope Killman  
Susan Eads Role  
Syed Ali Rizvi  
Kam Lam  
Harry L. Gewanter  
Nancy Biery  
Lauren Musiol  
Georgia Persiros

### **I. Closed Session**

The first portion of the 30th 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 302 applications were assigned to NCCAM. Of these, 247 were reviewed by NCCAM, 55 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 159 applications - requesting \$38,490,618 in total costs.

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

The open session of the NACCAM meeting convened at 11:00 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on February 1, 2008, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen noted procedures for public comment.

Dr. Goldrosen introduced Dr. Josephine Briggs, Director of NCCAM.

### **III. Report From the Director**

Dr. Briggs thanked Council and staff for their preparatory work and outlined the process and agenda for the meeting.

## **NACCAM Membership Update**

Dr. Briggs noted two departing Council members: Dr. Stephanie Vogel and Dr. Frank Torti. This meeting ends Dr. Vogel's official 4-year term, but her participation will extend through September. Dr. Torti recently was appointed Principal Deputy Commissioner and Chief Scientist, Food and Drug Administration.

## **NCCAM Organizational Update**

Dr. Briggs noted the appointment of Dr. Martin Goldrosen as Director, Division of Extramural Activities. Dr. Briggs also welcomed two new staff members: Dr. Linda Duffy, Program Officer for Probiotics, Pediatrics, Nutrition, and Gastrointestinal Health, Division of Extramural Research; and Lori Thompson, Deputy Executive Officer.

## **Deputy Director Search Committee**

A search committee is seeking to fill the position of NCCAM Deputy Director by the end of October 2008. Dr. Briggs outlined the search criteria and noted that the process is expected to be very competitive. Committee chair is Dr. Stephen Katz, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases. Other members are Dr. Aviad Haramati, Professor, Georgetown University School of Medicine; Camille Hoover, Executive Officer, NCCAM; Dr. Janet Kahn, Executive Director, Integrated Healthcare Policy Consortium; Dr. Richard Nakamura, Deputy Director, National Institute of Mental Health; and Dr. Brent Stanfield, Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases.

## **Intramural Program Strategic Review**

An ad hoc committee of the Council, led by Dr. Stephen Barnes, will review the state of CAM research in NIH intramural programs and identify priorities for NCCAM's own intramural research. The committee will convene in early fall 2008; a report is expected in January 2009.

## **Current Events**

NCCAM's first grantsmanship workshop took place June 3-5, 2008; interest in the workshop was strong (200 applicants, 75 participants), and preliminary feedback has been positive. A meditation workshop is planned for July 2008. A meeting of curriculum development (R25) grantees is also planned for July.

The Botanical Research Centers program, cosponsored by NCCAM and the NIH Office of Dietary Supplements, is up for renewal. NCCAM and ODS plan to renew this initiative and expect intense competition.

Results of the latest National Health Interview Survey, which includes a CAM component and new data on pediatric use of CAM, are expected later this summer, as are results from two important NCCAM clinical trials: the Ginkgo Evaluation of Memory (GEM) study and the Glucosamine/Chondroitin Arthritis Intervention (GAIT II) ancillary study.

## **NIH Update**

NIH is under legislative mandate to ensure public access to published results of all NIH-funded research via one database, PubMed Central. The process of uploading results to the database is moving forward.

An extensive effort has been under way to evaluate NIH's peer review process, with the goal of optimizing its efficiency and effectiveness. Dr. Briggs outlined some changes that are likely to result from this effort.

## **Budget Update**

Dr. Briggs discussed NCCAM budgets for fiscal years (FY) 2008 and FY 2009. The appropriation for FY 2008 (which ends September 30, 2008) is \$121,577,000. For FY 2009, the President's budget request is \$121,695,000, essentially the same as the FY 2008 appropriation. NCCAM is 4 percent of the overall NIH budget.

Dr. Briggs compared NCCAM's budget mechanism (number and dollar amount of grants/awards by type) with that for NIH as a whole. She also reviewed NCCAM's appropriations history, noted funding allocations and trends by research category, and summarized recent funding for CAM institution capacity building.

## **IV. CAM Research Capacity-Building Working Group Committee Report**

Dr. Barbara Sorkin, Program Officer, NCCAM Division of Extramural Research, presented recommendations from the CAM Research Capacity-Building Working Group. The Working Group developed a concept for optimizing NCCAM's future funding of research capacity-building efforts at CAM institutions. The concept takes into account that CAM institutions tend to be relatively small and focused more on training practitioners than on conducting research. Compared with NCCAM's former Developmental Centers for Research on CAM (DCRC) program, the new concept takes a more flexible, long-term approach and places greater emphasis on the collaboration/mentoring role of research-experienced institutions. The concept's three parts are the Centers for CAM Research Capacity Building (C3B, the "next generation" of DCRC), CAM research faculty development support, and augmenting research resources (such as laboratory facilities and equipment) at CAM institutions.

## **Discussion**

Council members commented on the Working Group's concept, noted that NCCAM should support institutions as well as individual researchers, and suggested that NCCAM focus its support on CAM institutions that have (1) some history of research involvement and (2) a commitment to science. Dr. Briggs explained that the Working Group's concept represents a "tweaking" of the existing process, and that we do not anticipate a change in the allocation of funding to this area.

Council unanimously passed a motion to approve the Working Group's broad concept.

## **V. Office of Portfolio Analysis and Strategic Initiatives**

Dr. Alan Krensky, Director, NIH Office of Portfolio Analysis and Strategic Initiatives (OPASI), described OPASI's mission, structure, and functions. OPASI supports trans-NIH research through portfolio analysis, strategic coordination, and evaluation activities. Its Roadmap for Medical Research provides "incubator space" to test new programs, funding mechanisms, and approaches to problems. Dr. Krensky explained how new initiatives are chosen for the Roadmap and noted some current initiatives and topics under development. Interdisciplinary research is a fundamental Roadmap initiative; important new topics include epigenomics and the microbiome. Areas of trans-NIH coordination outside the Roadmap include obesity research, neuroscience, regenerative medicine, informatics, pharmacogenomics, health disparities, and children's health. OPASI emphasizes placing "science first," using evidence-based planning, maintaining transparency, communicating plans, and managing change. Ultimately, OPASI's success will be measured by its ability to fill gaps at NIH, alleviate redundancies, and add value to NIH's strategic planning and research portfolio.

### **Discussion**

Dr. Briggs noted ways in which NCCAM benefits from participating in OPASI, citing as examples the PROMIS and microbiome initiatives. Council members discussed the importance of informatics in light of the massive volume of data at NIH.

## **VI. Transforming the Neural Circuitry of Emotion and Attention Through Meditation**

Following a 1-hour break for lunch and Council photo session, Dr. Briggs reconvened the meeting at 1:05 p.m. and opened the afternoon's mini-symposium on meditation. Dr. Briggs commented on the timeliness of the topic and introduced the keynote speaker, Dr. Richard Davidson, Vilas Professor of Psychology and Psychiatry, University of Wisconsin-Madison.

Dr. Davidson presented an overview of research on the effects of meditation on emotion and attention. This research reflects two basic ideas: (1) People differ in trait levels of happiness, loving kindness, compassion, and clarity of attention, and these differences are associated with different underlying biological characteristics. (2) These traits are the product of skills that can be enhanced through mental training, which induces changes in the brain and in other parts of the body. Meditation is a vehicle for such training.

Studies have found, for example, that marriage and wealth are not correlated with happiness, but spending money on others is correlated with happiness. Such findings raise the question of whether and how happiness and other positive traits can be enhanced, and how these traits can be measured. Evidence on neuroplasticity (the ability of the brain to change) has shown that the human brain does change in response to training in music and motor skills; animal studies have shown that maternal behavior causes gene-level neural changes in offspring, and that neurogenesis (the growth of neurons) is affected negatively by stress and positively by exercise. Meditation may be regarded as a form of mental exercise.

Dr. Davidson discussed several studies conducted by the Waisman Laboratory for Brain Imaging and Behavior and its associated facilities (Center for Creating a Healthy Mind,

Laboratory for Affective Neuroscience, Waisman Center, and University of Wisconsin-Madison Departments of Psychology and Psychiatry). Studies used fMRI to study brain activity under various circumstances. Among the findings is that meditation can improve attention.

These studies provide scientific underpinning for the contemplative practices of many classical traditions and the insights they yield may help researchers better understand how to harness the power of the mind to improve health.

## **Discussion**

Council members and Dr. Davidson discussed aspects of meditation research, including the relationship between duration of training/practice and continuation of effects; possible comparisons with other disciplines (e.g., music); the importance of not assuming that all forms of meditation have the same effects on the brain; the possibility of a “dose effect”; difficulties “disentangling” other health behavior changes in which meditators might engage (e.g., diet); and the possible effect of meditation in reducing the extent to which social comparison affects self-perception of happiness, with implications for competitiveness.

## **VII. AHRQ Report on Meditation**

Dr. Briggs noted that NCCAM's decisions about its research portfolio should be guided by the need to develop an evidence base that will be useful to policymakers, health professionals, and the general public in evaluating CAM modalities. Structured reviews of scientific evidence, such as the reports produced by the Agency for Healthcare Research and Quality (AHRQ) in partnership with NCCAM, provide one tool to assess whether the research base will meet these goals. Dr. Briggs introduced Dr. Richard Nahin, NCCAM Senior Advisor for Scientific Coordination, who spoke about the AHRQ report on meditation, published in June 2007. Dr. Nahin spearheaded NCCAM's collaboration with AHRQ to produce the report.

The qualitative objective of the AHRQ report on meditation was to describe the main components of meditation practices, the role of spirituality, training requirements, and criteria for success. Its quantitative objective was a meta-analysis of the research literature on therapeutic use of meditation in health care, therapeutic efficacy and effectiveness, the role of effect modifiers, and effects of meditation on physiological and neuropsychological outcomes.

The report's meta-analysis produced a wealth of data (including 60 figures and 18 tables), making it possible to both test hypotheses and generate them. Dr. Nahin used findings on hypertension to illustrate how meta-analysis results are reported. He closed with a summary of the report's strengths and limitations. The report is unique in its depth and breadth. One limitation is that it did not address the appropriateness of controls—a problem in designing meditation research; however, its comprehensive categorization should help researchers address this issue.

## **Discussion**

Dr. Briggs noted that NCCAM's participation in the AHRQ process is intended to help establish research priorities, not to lead health care decisions regarding therapies.

## **VIII. Update on Meditation Workshop**

Dr. Catherine Stoney, Program Officer, NCCAM Division of Extramural Research, reviewed NCCAM's involvement in meditation research and presented an overview of an upcoming workshop on meditation. Dr. Stoney is leading NCCAM's meditation research planning activity.

NCCAM is interested in meditation because (1) meditation is widely practiced by the public; (2) it is part of the mind-body research component of the NCCAM Strategic Plan for 2005-2009; and (3) although many studies have been done, much remains to be learned. Other NIH institutes and centers have expressed interest in meditation research. NCCAM's external steering committee has been helpful in the planning process.

The purpose of the upcoming workshop is to identify research gaps and opportunities; identify next steps for research; bring together experts in meditation and other fields who can inform the direction of research; and address specific research questions and develop recommendations. Participants' areas of expertise include evidence-based medicine, design methodologies, biostatistics, systems science, central-peripheral interactions, epidemiology, scholar-practitioners, and primary disease groups.

The workshop will emphasize in depth discussions with broad input and will use the AHRQ report as a backdrop. Its four panels will address meditation practices (including why people meditate, key features of the various practices, and a common vocabulary); research design approaches; physiological mechanisms and outcomes; and psychological processes and outcomes.

### **Discussion**

Dr. Briggs discussed the usefulness of workshops to help define the research agenda and to stimulate applications and noted that the workshop's report is expected in September 2008.

## **IX. Future Directions**

### **Listening Tour**

Dr. Briggs summarized her "listening tour" activities during her first 4 months as NCCAM Director, including a stakeholders' meeting with leaders of professional organizations; visits to grantees; conversations with individual Council members, grantees, advocates and critics, practitioners, and leaders of other NIH institutes and centers; international meetings; and trips to Australia and China. Dr. Briggs was part of a delegation that accompanied U.S. Health and Human Services Secretary Michael Leavitt to China, where they met with Chinese officials to discuss U.S.-Chinese collaboration on traditional Chinese medicine research.

### **Research Paradigm**

Dr. Briggs noted her strengthened conviction regarding the importance of NCCAM's mission and her increased awareness of the importance of CAM practices to many

Americans. She also acknowledged the challenges of developing a research agenda that is relevant and rigorous and noted that existing research paradigms are not ideally configured to answer some of the practical questions that are important to the health of Americans.

Dr. Briggs explained a four-part research paradigm that provides context for shaping NCCAM's research portfolio:

- Basic science—How might it work?
- Translational research—Can it be studied in people? What tools are needed?
- Efficacy studies—What are the specific effects?
- Effectiveness research—How is it used in the real world? Is it a better treatment?

### **CAM Biological “Pipeline”**

Unlike the drug development pipeline, which begins in the laboratory, the CAM pipeline for biologicals begins in the real world. With that in mind, questions to guide thinking about NCCAM's research portfolio include: How can NCCAM more effectively focus the study of herbals and other biologicals? Which interventions are most promising? What are the needed resources? How should NCCAM approach priority setting? NCCAM staff will hold a retreat this summer to address these questions.

Dr. Briggs and Council discussed related issues, including emphasis on animal versus human research; discovery research; interspecies questions with regard to biomechanism data; biomarker research; aspects of the pipeline concept (e.g., whether a reductionist approach might miss key drivers of effectiveness); and possible design issues in some recent clinical trials.

### **CAM “Real World” Effectiveness**

Dr. Briggs gave examples of efficacy and effectiveness research and noted the emphasis on the former at NCCAM and throughout NIH. Both types of studies address questions that are key for an evidence base, and NCCAM needs to find ways to incorporate rigorous effectiveness studies in its research portfolio. Related questions are: How can NCCAM build a portfolio of research that tests CAM effectiveness in the real world? Which conditions and which CAM modalities are ready for this type of study? What methods are best?

Dr. Briggs and Council discussed related issues, including population-based observational studies and the managed care industry as possible sources of data for effectiveness research; taking into account people's opinions and beliefs and practitioners' competency and training; and improving classifications of patients to facilitate individualized treatment choices.

### **Outreach: “Time to Talk” Campaign**

Dr. Briggs discussed NCCAM's “Time to Talk” campaign, which was formally launched at the meeting. The campaign encourages patient-provider discussions about CAM use and provides a variety of related materials. AARP partnered with NCCAM on the



formative research for the campaign, and NCCAM is interested in finding additional outlets for the materials.

**X. Public Comment Session and Closing**

Dr. Briggs opened the floor for public comment. Dr. Harry Gewanter, representing the American Academy of Pediatrics' Section on Complementary, Holistic, and Integrative Medicine, reviewed the section's activities and spoke in support of CAM research that focuses on children.

After thanking Council and the speakers for their participation, Dr. Briggs adjourned the meeting at 4 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