

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-NINTH MEETING  
February 1, 2008

***NACCAM Members present***

Dr. Lori Arviso Alvord, Hanover, NH  
Dr. Stephen Barnes, Birmingham, AL  
Dr. Timothy Birdsall, Zion, IL  
Dr. Bowden Boyd, 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. Joan Fox, Cleveland, OH  
Dr. Margery Gass, Cincinnati, OH  
\*Dr. Scott Haldeman, Santa Ana, CA  
Dr. Ted Kaptchuk, Boston, MA  
Dr. Shin Lin, Irvine, CA  
Dr. Richard Niemtow, Clinton, MD  
Dr. Danny Shen, Seattle, WA  
Dr. Herman Taylor, Jackson, MS  
Dr. Frank Torti, Winston Salem, NC  
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. Bruce Redman, Ann Arbor, MI  
Dr. Elias Zerhouni, Bethesda, MD

***NIH Staff Present***

C Paul Coates, ODS/OD  
Debra Dabney, NIMH  
Linda Duffy, NCRR  
Judy Dulovich, OHR/CSD  
Jody Eroel, ODS  
Elan Ey, OHR/CSD  
Rachel Fisher, NIDDK  
Clarie Harris, NCI  
Judith O'Connor, NIH, OD  
Oluwadanulsa Olak, NCI/OCCAM  
Linda Southworth, NCI

Christine Swarson, NIH/ODP/ODS  
Tracy Waldeck, NIMH  
Kate Whelan, NIMH  
Kate Whilan, NIMH  
Jeffrey D. White, NCI  
Dan Xi, NCI

***Members of the Public***

Virginia Bader  
Beth Clay  
Steven Dentali  
William A. Duncan  
Harry L. Gewanter  
Ariad Haramati  
Thomas Hoffman  
Laura Honesty  
Alexis Johnston  
Folajomi Lofinmakin  
Erin Loomis  
R. I. Martinee  
Suzanne Niemeyor  
Lauren Nusiol  
George Perdue  
Sonya Serra  
Shawn K. Stout  
Sharon Strut  
Ana Tavakoli

**I. Closed Session**

The first portion of the 29th 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 193 applications were assigned to NCCAM. Of these, 176 were reviewed by NCCAM, 17 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 123 applications - requesting \$32,568,446 in total costs.

**II. Open Session—Call to Order**

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

Minutes from the Council meeting on September 5, 2007, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen noted that the next Council meeting is scheduled for Friday, June 6, 2008.

Dr. Goldrosen reviewed the afternoon's meeting agenda and noted procedures for public comment.

Dr. Goldrosen introduced Dr. Ruth Kirschstein, Acting Director of NCCAM.

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

Dr. Kirschstein welcomed participants and visitors to the meeting.

#### **NACCAM Membership Update**

Dr. Kirschstein welcomed six new Council members: Dr. Timothy C. Birdsall, Dr. Boyd W. Bowden II, Dr. Gert Bronfort, Dr. Lupo T. Carlota, Dr. Shin Lin, and Dr. Herman A. Taylor, Jr. Dr. Kirschstein also welcomed Dr. Stephen Ezeji-Okoye, ex officio member, and Dr. Scott Haldeman, ad hoc member.

#### **NCCAM Organizational Update**

Dr. Kirschstein noted the departure of Dr. Margaret A. Chesney, former Director of the NCCAM Division of Extramural Research and Training and NCCAM Deputy Director; the retirement of Dr. Nancy J. Pearson, Program Officer, Division of Extramural Research and Training; and the departure of Ms. Marguerite Klein, Program Officer, Division of Extramural Research and Training.

Dr. Kirschstein also noted the following staff transfers within NCCAM: Dr. Sheila Caldwell is now Program Officer for the Office of Special Populations, and Dr. Peter Kozel is Review Officer in the Division of Extramural Activities.

#### **Budget Update**

Dr. Kirschstein discussed NCCAM budgets for FY 2008 and FY 2009. The NCCAM budget authority for FY 2008 (ending September 30, 2008) is \$121,577,000, which reflects a rescission of \$2,162,000. For FY 2009, the President's budget request places NCCAM's net budget at \$121,695,000, essentially the same as the FY 2008 appropriation and in line with NIH as a whole.

Dr. Kirschstein discussed NCCAM's funding strategy for FY 2008. The anticipated R01 payline will fund grants that have priority scores below 175 and that are below the 15th percentile; they will be funded at recommended levels. The anticipated R21 payline will fund grants with priority scores below 155. Inflation for noncompeting awards is limited to 1 percent over FY 2007 levels.

#### **CAM Health Education Curriculum Grants**

Dr. Kirschstein noted Dr. Pearson's leadership in creating NCCAM grants to develop CAM curricula in conventional health professions schools. Nine related articles were published in the October 2007 issue of *Academic Medicine*.

#### **Interdisciplinary Workshop on Complexity Science**

NCCAM held an interdisciplinary workshop in collaboration with Georgetown University on October 8-10, 2007. The purpose of the workshop was to explore the potential applications of complexity science to research on the efficacy and mechanisms of action of complicated, multimodal and/or individualized interventions. This was the first in a series of explorations into research methodology addressing issues related to whole medical systems.

### **Grantsmanship Workshop**

On June 3–5, 2008, NCCAM will sponsor a workshop on grantsmanship, especially targeted to those who have had little or no experience in submitting grant applications. The workshop will offer researchers, fellows, and graduate students an in-depth understanding of NIH grants, the grant review process, and Federal regulations and policies.

### **IV. New Director's Remarks**

Dr. Kirschstein expressed her appreciation for the opportunity to serve as NCCAM's Acting Director. She then introduced Dr. Josephine P. Briggs, NCCAM's new Director, who discussed her values as a physician and a scientist, her personal and professional experiences, and her hopes for the future of NCCAM.

From 1997 to 2006, Dr. Briggs directed the Division of Kidney, Urologic, and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Working in nephrology exposed her to patients who were very sick and perhaps felt depersonalized by their technology-intensive care. She realized that patients' personal, spiritual, and emotional supports are critical to their ability to live with kidney disease. Dr. Briggs shared her belief in respecting patients' diverse cultural beliefs, treating the whole person, and strengthening communication with patients.

Dr. Briggs described her respect for scientific rigor and the scientific method, balanced with healthy skepticism of dogma—even scientific dogma. Conventional medicine sometimes is in error, and critical thinking is important in biomedical science. Dr. Briggs noted that breakthroughs sometimes come from outside the scientific mainstream, and acknowledged “the wisdom of grandmothers and of tradition.”

While co-chairing a conference with NCCAM's former Director, Dr. Stephen Straus, on the science of the placebo, Dr. Briggs developed her interest in CAM research. Subsequently, she and Dr. Straus co-chaired an NIH Roadmap working group on translational medicine. Dr. Briggs also worked with Dr. Straus and NCCAM staff on clinical trials cofunded by NCCAM and NIDDK. She is enthusiastic about the many ways in which modern science can benefit CAM research.

Dr. Briggs expressed her strong support of NIH. She believes that NIH offers its employees a sense of public service in addition to stimulating interaction with scientific colleagues. NIH also reflects the Federal Government's dedication to the sponsorship and thoughtful oversight of the very best biomedical research.

In upcoming months, Dr. Briggs plans to spend much of her time listening—to Council members, NCCAM staff, NIH colleagues, and others. She will contact Council members for their advice about how NCCAM should move forward, especially with regard to setting priorities, recognizing areas of scientific promise, and obtaining input from other stakeholders in the field. Dr. Briggs will provide updates at subsequent meetings.

## **Discussion**

Responding to a question from Council about her research on antioxidants and kidney disease, Dr. Briggs noted that results of animal studies have been impressive and the fundamental antioxidant hypothesis is promising, but determining how antioxidants might affect disease in humans has been difficult. Advances in modern science may help explain the mechanisms involved.

### **V. Acknowledgment of Dr. Ruth Kirschstein's Leadership**

Dr. Jack Killen, NCCAM Acting Deputy Director and Acting Director of the Division of Extramural Research and Training, expressed gratitude on behalf of NCCAM staff and Council to Dr. Kirschstein for her leadership and accomplishments during her tenure as NCCAM Acting Director. Participants honored her with a standing ovation.

### **VI. Local Research—Global Relevance: The Jackson Heart Study**

Dr. Briggs introduced Council member Herman Taylor, M.D., professor of medicine at the University of Mississippi Medical Center and principal investigator for the Jackson Heart Study (JHS). Funded by the National Heart, Lung, and Blood Institute and the National Center for Minority Health and Health Disparities, JHS is a longitudinal study investigating the causes of cardiovascular disease (CVD) among more than 5,000 African American residents of the Jackson, Mississippi, metro area. It is the largest study of its kind to date. In addition to exploring biological variables, JHS is focusing on the role of sociocultural and psychosocial factors such as stress, racial discrimination, and coping strategies.

Dr. Taylor presented background information on CVD, the groundbreaking Framingham Heart Study, and the high rates of CVD-related deaths among African American men and women. He then described the JHS study objectives and design and reviewed some early findings.

JHS has found high rates of metabolic syndrome and low levels of diabetes control among participants. Obesity is common. Religious involvement is associated with lower blood pressure and cortisol levels. Social support is weaker among women than men and declines with age. Many participants use vitamins (especially multivitamins, and vitamins E and C) and about one-quarter use alternative medicines such as garlic.

An important element of JHS has been the involvement of Jackson's African American community in planning and conducting the study, which has helped researchers gain the trust of the study population. JHS is fostering collaboration among minority researchers and has numerous institutional partners, including historically black colleges. Its training programs for high school and college students are successfully encouraging minority youth to pursue careers in public health and epidemiology. Participants in the JHS Scholars program hold summer internships around the world.

Dr. Taylor emphasized that JHS transcends geography and ethnicity to provide new insights with global relevance. He noted the high CVD mortality rates worldwide, ways in which racism might be a factor in poor health, examples of ethnicity-based social inequities in other countries, and JHS's international partnerships in genetic research.

In closing, Dr. Taylor summarized the pros and cons of population-based epidemiological studies like JHS. Although such studies are expensive and lengthy, they offer many benefits:

- Identifying modifiable risk factors that can lead to prevention
- Producing findings that are understandable to the public and media—and actionable
- Learning about clinical practice and self-care patterns in “the real world”
- Creating a platform for further discovery

Information about JHS is available at [www.isums.edu/~jhs](http://www.isums.edu/~jhs).

## **Discussion**

Dr. Taylor responded to questions about culture shock experienced by immigrant refugees; the study population’s demographics, risk factors, and CVD rates; the potential for developing the observational study into an intervention study; and urban-rural comparisons.

### **VII. Product Integrity Policy: Future Directions**

Marguerite Klein, NCCAM Program Officer, Division of Extramural Research and Training, discussed NCCAM’s product integrity policy, including its history, challenges, and proposed revisions. (The policy originally referred to “product quality”; that was changed to “product integrity,” to avoid regulatory connotations.)

The policy requires investigators who are likely to receive NCCAM grants to provide convincing evidence that biologically active test agents and placebos are of sufficient quality to ensure that results of the investigations can be replicated. An ad hoc external working group evaluates the information provided. Grants are awarded only if the information is deemed satisfactory.

From January 2006 to November 2007, 128 sets of product information were evaluated. Of these, 90 percent achieved a satisfactory rating within 2 months of the initial evaluation. Most of the products evaluated were plant derived. During this period, the percentage of NCCAM-funded studies undergoing product integrity evaluation increased, and the percentage of evaluated studies involving human subjects decreased.

The policy is working, in that NCCAM now knows “what is in the bottle.” However, the current process is unsustainable. It is burdensome for investigators; submissions sometimes include too much information; evaluations are resource intensive and time consuming; and there are challenges with “mission creep,” committee management issues, and delays in awarding grants.

Under the proposed plan, the policy statement will remain essentially unchanged, but the implementation process will be revised to make it less burdensome while maintaining rigorous evaluation. Planned process changes include:

- Evaluating product information in-house, with external consultation as needed
- Giving investigators a clearer idea of the quantity of information required
- Emphasizing product specifications and characteristics, not manufacturing processes
- Requiring less information from studies that have IND (investigational new drug) FDA status.

Ms. Klein reviewed the types of information requested for test agents and placebos, showed an information response template, summarized what does and does not change under the proposed plan, and noted the proposal's advantages and potential disadvantages.

### **Discussion**

Dr. Briggs acknowledged Ms. Klein's contribution to the development of NCCAM's product integrity process. Ms. Klein responded to questions about access to information on products that have cleared the evaluation process, transition from external to internal reviews, and a Web format for evaluation.

### **VIII. Public Comment Session**

Dr. Goldrosen opened the floor for public comment.

Dr. Harry Gewanter, representing the American Academy of Pediatrics' Provisional Section on Complementary, Holistic, and Integrative Medicine, spoke in support of increased research on the efficacy and safety of CAM interventions for children.

Ms. Beth Clay, representing the Wisneski Institute, spoke about CAM-related research at NIH and offered her organization as a resource to NCCAM.

Dr. Bill Duncan, representing the American Association for Health Freedom, reflected on NCCAM's history, commented on developments in CAM treatments, and offered his organization as a resource to NCCAM.

Dr. Briggs thanked Council and the speakers for their participation.

Dr. Goldrosen adjourned the meeting at 3:44 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

Ruth L. Kirschstein, M.D.  
Chairperson  
National Advisory Council for  
Complementary and Alternative  
Medicine