

**U.S. 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-FIRST MEETING
September 12, 2008**

NACCAM Members present

Dr. Lori Arviso Alvord, Hanover, NH
Dr. Stephen Barnes, Birmingham, AL
Dr. Timothy Birdsall, Zion, IL
Dr. Gert Bronfort, Bloomington, MN
Dr. Lupo Carlota, Memphis, TN
Dr. Sheldon Cohen, Pittsburgh, PA
Dr. Fabio Cominelli, Charlottesville, VA
Dr. Silvia Corvera, M.D., Worcester, MA
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Joan Fox, Cleveland, OH
Dr. Margery Gass, Cincinnati, OH
*Dr. Richard Hammerschlag, Portland, OR
Dr. Ted Kaptchuk, Boston, MA
Dr. Shin Lin, Irvine, CA
Dr. Richard Niemtzwow, Clinton, MD
Dr. Danny Shen, Seattle, WA
Dr. Herman Taylor, Jackson, MS
Dr. Stefanie Vogel, Baltimore, MD
* Dr. Jon-Kar Zubieta, Ann Arbor, MI

*Ad hoc members

NACCAM Members not present

Dr. Boyd Bowden, Columbus, OH
Dr. Bruce Redman, Ann Arbor, MI
Mr. Michael Leavitt, Washington, DC
Dr. Elias Zerhouni, Bethesda, MD

NIH Staff Present

Daofen Chen, NIH/NINDS
Jody Engel, NIH/ODP/ODS
Ade O'Donnell, NIH/NINDS
Marguerite Klein, NIH/ODP/ODS
Linda Southworth, NIH/NCI

Kati Strong, NIH/CC
Christine Swanson, NIH/ODP/ODS
Dan Xi, NIH/NCI

Members of the Public

Linda Anthony
Virginia Bader
John C. Chah
Sherman L. Cohn
Beth Clay
Tyler Cymet
Steven Dentali
Harry L. Gewanter
Alexis Johnston
Sabina Longes
Lynn Marble
Agnes NgueynPho
Paula J. Oaris
Judith M. Orvos
Georgia Perdue
Margaret Stevenson
Shawn K. Stout
Ann Gill Taylor
Allison Trepod

I. Closed Session

The first portion of the 31st 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 219 applications were assigned to NCCAM. Of these, 180 were reviewed by NCCAM, 39 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 137 applications, requesting \$ 43,938,278 in total costs.

II. Open Session—Call to Order

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

Minutes from the Council meeting on June 6, 2008, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen noted that the next Council meeting is scheduled for Friday, February 6, 2009.

Dr. Goldrosen noted procedures for public comment.

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

III. Report From the Director

Dr. Briggs welcomed participants and outlined the agenda for the meeting.

NACCAM Membership Update

Dr. Briggs thanked two ad hoc Council members, Dr. Jon-Kar Zubieta and Dr. Richard Hammerschlag, for their contributions to the morning's closed session.

NCCAM Organizational Update

Dr. Briggs welcomed three new staff members: Dr. Laura Moen, Program Officer; Felicia Royster, Management Analyst; and Amanda Trayer, Program Analyst. She also noted the departure of Dr. Qi Ying Liu, Program Officer, who has joined the National Institute on Alcohol Abuse and Alcoholism.

Dr. Richard Nahin has been appointed Acting Director, Division of Extramural Research.

Recent recipients of NIH Director's Awards include Marguerite Klein, former NCCAM Program Officer, acknowledged for her development of NCCAM's Product Quality Program; and Dr. Partap Khalsa, Program Officer, NCCAM Division of Extramural Research, acknowledged for his contributions to the NIH Neuroplasticity Workshop Team.

NCCAM Leadership Recruitment

NCCAM expects to name a new Deputy Director by the end of October 2008. The search committee received a large number of applications, and Dr. Briggs is currently conducting interviews.

A search committee has been appointed to fill the position of Director, Division of Extramural Research. The committee chair is Dr. Carole Heilman, National Institute of Allergy and Infectious Diseases. Other members are Dr. Lori Arviso Alvord, NACCAM; Dr. Jack Killen, NCCAM; Dr. Pamela McInnes, National Institute of Dental and Craniofacial Research; Dr. William Meeker, Palmer

College of Chiropractic; and Dr. Jane Steinberg, National Institute of Mental Health.

Intramural Research Program Reviews

The Blue Ribbon Intramural Research Program Strategic Review is examining the state of CAM research in NIH intramural programs and will identify priority areas for developing NCCAM's intramural research. The review is being conducted by an ad hoc committee of Council, with Dr. Stephen Barnes serving as a member of the panel and the Council liaison. A report is expected in March 2009.

The Intramural Board of Scientific Counselors will evaluate NCCAM's current intramural research programs. The board chair is Dr. Brian Issell, Scripps Health. Other charter members are Dr. Tieraona Low Dog, University of Arizona, and Dr. David Kingston, Virginia Tech. Ad hoc members are Dr. William Garvey, University of Alabama at Birmingham, and Dr. Jianping Ye, Pennington Biomedical Research Center.

Budget Update

Dr. Briggs discussed the NCCAM budget for fiscal year (FY) 2009. The President's budget request is \$121,695,000, essentially the same as the FY 2008 appropriation. The U.S. House of Representatives allowance for FY 2009 is \$125,878,000; the U.S. Senate allowance is \$125,082,000. Because of the Presidential election, enactment of the FY 2009 budget may be delayed; in that case, NIH will operate under a continuing resolution.

Current Events

Eligibility requirements for Osher/NCCAM K01 career development fellowships have been expanded to include individuals with doctorates in non-CAM fields who are also licensed CAM practitioners. (Previously, only CAM practitioners with doctorates from CAM institutions were eligible.)

On June 16, 2008, U.S. Department of Health and Human Services Secretary Michael Leavitt signed a memorandum of understanding with the Chinese Vice Minister of Health to foster scientific research on traditional Chinese medicine (TCM). The signing marked the opening of a 2-day TCM research roundtable at NIH.

NCCAM's first grantsmanship workshop, held June 3-5, 2008, was well received. A videocast of the workshop is available on the NCCAM Web site.

NIH Update

Dr. Francis Collins has stepped down as Director of the National Human Genome Research Institute. Dr. Alan Guttmacher is Acting Director.

The aging of the R01 workforce is an issue of concern at NIH. The average age of an R01 first grant holder is 42, and 55 is the expected mean age for grant holders by 2012. The current practice of targeting “new investigators” does not always have the intended effect of favoring researchers in the early stages of their career. A new definition of an early stage investigator is under consideration: an individual who receives an R01, has not held a significant NIH grant in the past, and is within 10 years of completing a doctoral degree or clinical residency training. Dr. Briggs noted that NCCAM differs from the rest of NIH in that NCCAM budgets relatively less for R01 grants and relatively more for R21 grants. She pointed out that NCCAM’s recent R01 and R21 grants have had comparable success rates, but there are concerns that R21s don’t have the same career-building impact as R01s. The optimum role of both types of grants NCCAM’s will be a matter for future Council consideration.

The NIH peer review process is currently under evaluation. Dr. Briggs outlined some changes likely to arise from the evaluation. One such possible change is to limit grant resubmissions to one cycle. It appears that two submission cycles improve science, but a third cycle causes too much delay.

Council members discussed issues related to research funding at NIH and NCCAM and the possible reduction in submission cycles.

2007 Publication Summary

A list of scientific publications from 2007 citing NCCAM support was distributed. There were 448 such publications, citing 249 grants; 70 papers were published in “high-impact” journals.

Dr. Briggs also highlighted two examples of NCCAM-funded studies: a review of botanical therapeutics, published in the July 2007 issue of *Nature Chemical Biology*; and a study of toxic metals in Ayurvedic medicines sold on the Internet, published in an August 2008 issue of the *Journal of the American Medical Association*.

Summer Scientific Retreat

Dr. Briggs briefly summarized highlights from a retreat at which NCCAM scientific staff reviewed the status and future directions of the biologicals research portfolio in five areas (probiotics, soy, ginseng, echinacea, and glucosamine) and discussed research directions for conditions that show promise for CAM interventions (depression, irritable bowel syndrome, and chronic back pain).

Biologicals Research Pipeline

Dr. Briggs noted that “pain and plants” are focus areas for NCCAM research. She briefly reviewed the four-part research paradigm that is the context for assessing NCCAM’s research portfolio, noting that translational tools are needed to provide the methodological building blocks for efficacy and effectiveness research.

IV. Concept Clearance: Program for Translational Tools for CAM Clinical Research

Dr. Catherine Stoney, Program Officer, NCCAM Division of Extramural Research, outlined a proposed initiative to develop and validate translational tools that will improve comparability and generalizability of clinical studies on CAM interventions. These tools will facilitate rigorous study of CAM practices widely used by the public, by improving the conduct and reporting of clinical studies, patient-reported outcome measures, and biological and physiological outcome measures. The initial focus will be on mind-body medicine interventions, manual therapies, and acupuncture.

Discussion

Council members commented on the proposed initiative and pointed out some of the methodological issues in CAM research, such as the need to refine modality definitions, the potential risk of “overdefining” modalities, the question of whether some benefits of therapy might be lost in a rigid research setting, the need to address quality of reporting, and differences between efficacy and effectiveness research. Dr. Briggs noted the importance of including the CAM community, especially CAM practitioners, in developing these methods .

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

V. Botanicals—Their Past, Present, and Future

Following a 1-hour break for lunch, Dr. Briggs reconvened the meeting at 1 p.m. and introduced Council member Stephen Barnes, Ph.D., Professor of Pharmacology and Toxicology, University of Alabama at Birmingham, and

Associate Director, Purdue-UAB Botanicals Research Center for Age-Related Diseases. Dr. Barnes presented a “big picture” overview of botanicals, including their history and role in society, use as a source of medicines, and current research trends and challenges.

Humans have a long history of exposure to plant-derived phytochemicals. Dr. Barnes traced milestones in this history and highlighted lessons to be learned. Dr. Barnes also outlined the history of pharmacology, noting how its development in the 19th century arose from advances in physiology. Plants were used systematically in the practice of medicine during the 19th and early 20th centuries. Then, with the arrival of synthetic organic chemistry and modern pharmacology, bioactives could be made in the chemistry lab. Expansion of the modern pharmaceutical industry was driven by Federal legislation and based on the synthesis and manufacture of specific compounds, which were subject to Government oversight for consumer protection.

Drug discovery has built on developments in the field of physiology, and infective illness has receded during the past 60 to 70 years. However, despite advances, AIDS, new flu strains, and drug resistance persist. The combinatorial chemistry approach to drug discovery, which began around 1990, now involves the use of robots to synthesize and test huge numbers of compounds. Dr. Barnes suggested that a better approach is to look more closely at life itself. Life is combinatorial chemistry, and botanicals are life—representing a unique window into biological and chemical space.

Botanicals research presents unique challenges. It is essential to appreciate the critical importance of absorption, distribution, metabolism, and excretion (ADME). Complications include factors that make it difficult to know precisely what is in the substance being studied, questions about the role of formulation, and problems in controlling study subjects’ intake of phytochemicals. Dr. Barnes illustrated these challenges with examples from recent research.

Finally, education is a serious issue in the advancement of botanicals. Dr. Barnes recommended greater emphasis on teaching medical students about alternative medical traditions. He also pointed out that knowledge is all around us, but we must train people to recognize it or it will be lost.

Discussion

Council members discussed issues in botanicals research, including approaches to personalized medicine, looking for patterns in the existing knowledge base to determine what compounds are safe, looking to other societies for information that will help us understand botanicals, the utility of animal research, the decline in pharmacognosy education, and the importance of carrying knowledge from one generation to the next.

VI. Preconcept Discussion: Biological Pipeline

Dr. Briggs and the Council discussed issues in positioning NCCAM's botanicals research portfolio. An underlying question is the extent to which NCCAM should steer the botanical research portfolio by prioritizing agents and research question of particular urgency. The alternative approach is to rely on investigator-initiated proposals from the research community and the peer review for priority setting, which currently results in a very interesting and diverse portfolio, but one that does not consistently building the data needed for translational research on specific agents. One lesson learned from large clinical trials of herbals to date is that the more that is known about ADME of any compound being given to people, the better for future trials. Other points included the importance of understanding biological mechanism as well as chemical properties, and optimizing the outcome measures, the specific conditions and characterizing appropriate target populations for clinical studies .

VII. Complementary and Alternative Medicine Use Among Adults and Children, United States, 2007

Dr. Richard Nahin, Acting Director, NCCAM Division of Extramural Research, reported on the CAM supplement to the 2007 National Health Interview Survey (NHIS). Dr. Nahin, who leads the CAM survey effort, presented background information on NHIS and the CAM sample and highlighted selected 2007 findings and comparisons with 2002.

Research questions addressed by the 2007 CAM survey concern who uses CAM and for what medical conditions, use of CAM for wellness and prevention, changes in CAM use over the last 5 years, use of CAM in relation to conventional treatments, reasons people use and stop using CAM, and expenditures on CAM. The 2007 survey was the first to ask about CAM use among children. It also added 8 more diseases/conditions, 9 more CAM therapies (including sections on traditional healers and movement therapies), and 10 more dietary supplements to the questionnaire.

The survey found that 38.3 percent of adults used some form of CAM, compared with 36 percent in 2002. Dietary supplements were by far the most prevalent CAM modality and back pain the most prevalent condition for which CAM was used. Most CAM use was to treat some kind of pain. Compared with 2002, usage increased significantly for meditation, massage, and yoga; fewer people used CAM for head colds and stomach problems; and more used CAM for cholesterol control. CAM use was greater among people with multiple medical conditions and people with more education. Racial/ethnic differences were reported in CAM use. People who delayed or did not receive conventional care because of cost were more likely to use CAM.

The survey found that 11.8 percent of children used CAM. Use was greater among children whose parents use CAM. Dietary supplements were the most prevalent modality for children. Usage rates for homeopathy, traditional healers, naturopathy, and biofeedback were higher for children than adults. Back pain and colds were the top conditions for which children used CAM.

Many analyses of the 2007 NHIS data are under way. The next survey will be in 2012.

Discussion

Council members commented on the NHIS findings, interpretation, methodology, and future analyses. Dr. Briggs requested Council's input on analyses of 2007 data and content for the 2012 questionnaire.

VIII. Concept Clearance: Complementary and Alternative Medicine for Treatment of Chronic Pain

Dr. Partap Khalsa outlined a proposed initiative to rigorously examine the contribution of CAM interventions, as used in "real-world" practice settings, to the treatment of chronic pain. Studies of highly promising interventions with a reasonable evidence base of efficacy will be encouraged. Studies should include conventional clinical endpoints for assessing pain therapies, as well as other effectiveness measures that are meaningful to patients and/or result in improved health or well-being. The initial focus will be on manual therapies for chronic back pain.

Discussion

Council members commented on the proposed initiative and discussed related issues, such as limitations of back pain trials to date, this initiative's emphasis on health care questions, the importance of studying different kinds of back pain, reduction in use of conventional pharmaceuticals as a potential outcome measure, cost considerations, the need for practitioners' input, and inclusion of mindfulness therapy in this initiative.

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

IX. Director's Wrap-Up

Dr. Briggs noted that the initiatives discussed today are broad, but that NCCAM is also interested in other, narrower initiatives. She encouraged an ongoing dialogue on research directions at NCCAM. The next Council meeting will address the issue of how well NCCAM's R21 research portfolio is being used.

X. Public Comment Session and Closing

Dr. Briggs opened the floor for public comment. Dr. Tyler Cymet, American Association of Colleges of Osteopathic Medicine, noted problems associated with differences in CAM terminology and recommended development of a glossary or thesaurus. Dr. Harry Gewanter, representing the American Academy of Pediatrics' Section on Complementary, Holistic, and Integrative Medicine, reviewed the section's activities and expressed support for the inclusion of children in the 2007 NHIS survey.

After thanking Council and the speakers for their participation, Dr. Briggs adjourned the meeting at 3:55 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