

**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-THIRD MEETING
February 3, 2006**

NACCAM Members Present

Dr. Carlo Calabrese, Portland, OR
*Dr. Yung-chi Cheng, New Haven, CT
*Dr. Fabio Cominelli, Charlottesville, VA
*Dr. Silvia Corvera, Worcester, MA
Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Gerald Cross, Washington, DC
Dr. Jonathan Davidson, Durham, NC
*Dr. Jules Dienstag, Boston, MA
Dr. Jeanette Ezzo, Takoma Park, MD
Dr. Joan Fox, Cleveland, OH
Dr. Robert E. Fullilove, New York, NY
Dr. Ted Kaptchuk, Boston, MA
Dr. Alan I. Leshner, Washington, DC
Dr. Tieraona Low Dog, Albuquerque, NM
Dr. Bala Manyam, Temple, TX
COL Richard Niemtzw, Clinton, MD
Dr. Joel Pickar, Davenport, IA
*Dr. Frank Torti, Winston-Salem, NC
Dr. Stefanie N. Vogel, Baltimore, MD
Dr. Larry Walker, University, MS

*Ad hoc members

NACCAM Members Absent

Dr. Leslie Hillis, Dallas, TX

NIH Staff Present

National Center for Complementary and Alternative Medicine

Dr. Julia Arnold
Ms. Willer Batten
Dr. Josh Berman
Dr. Dale Birkle
Mr. Yancy Bodenstein
Ms. April Bower
Dr. Sheila Caldwell

Ms. Debra Campbell
Mr. Craig Carlson
Mr. Steve Casady
Dr. Margaret Chesney, Deputy Director
Ms. Mary Clements-Krob
Ms. Alyssa Cotler
Ms. Margarite Curtis-Farrell
Dr. Laurie Donze
Ms. Linda Engel
Ms. Carol Fitzpatrick
Ms. Valery Gheen
Ms. Mary Gregg
Ms. Camille Hoover
Dr. Jeanette Hosseini
Dr. Morgan Jackson
Ms. Deborah Jennings
Dr. Laura Johnson
Ms. Lekiny Johnson
Mr. Mike Kabatt
Dr. Partap Khalsa
Dr. Jack Killen
Ms. Marguerite Klein
Dr. Peter Kozel
Ms. Catherine Law
Dr. Qi-Ying Liu
Dr. Patrick Mansky
Dr. Heather Miller
Ms. Ilze Mohseni
Dr. Richard Nahin
Ms. Ellen O'Donnell
Dr. Nancy Pearson
Dr. Carol Pontzer
Ms. Linda Rich
Ms. Jeanie Robinson
Mr. Tim Sannes
Dr. Martina Schmidt
Ms. Denise Simmonds-Barnes
Dr. Barbara Sorkin
Ms. Stephan Kathleen
Dr. Catherine Stoney
Dr. Stephen Straus, Director
Ms. Jennifer Sutton
Ms. Chris Thomsen
Mr. Jon Tilburt
Ms. Jennifer Tisch
Mr. George Tucker

Ms. Shirley Villone
Dr. Shan Wong
Ms. Angie Wongsam-Nollinger

Other NIH Employees

Mr. Mark Headings, Office of the Director
Dr. Leonard Seeff, National Institute of Diabetes and Digestive and Kidney Diseases
Dr. Wendy Smith, National Cancer Institute
Dr. Christine Swanson, Office of Dietary Supplements
Mr. Phil Tonkins, National Cancer Institute
Dr. Dan XI, National Cancer Institute

Members of the Public

Dr. Brian Berman
Dr. John Chah
Ms. Janet Choy
Dr. Steven Dentali (speaker)
Dr. Aviad Haramati
Ms. Laura Honesty
Mr. Rives Hotra
Ms. Martha Lappin
Ms. Joan Leach
Ms. Erin Loomis
Ms. Corey Mackison
Mr. Steven Mister
Ms. Suzanne Niemeyer
Ms. Georgia Persinos
Mr. Andrew Shaw
Ms. Barbarba Silverman
Mr. Bill Silverman
Ms. Marni Silverman
Mr. Shawn Stout
Ms. Joan Wilentz

I. Closed Session

The first portion of the 23rd 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 285 applications were assigned to NCCAM. Of these, 230 were reviewed by NCCAM, 53 by NIH 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 9 applications and concurred on 172 applications requesting \$39,664,117 in total costs.

II. Open Session: Call to Order

The open session of the NACCAM meeting convened at 2:05 p.m., February 3, 2006. Dr. Richard L. Nahin, Acting NACCAM Executive Secretary, called the meeting to order.

Minutes of the September 9, 2005, Council meeting and the December 29, 2005, Council conference call were unanimously approved. Council operating procedures also were approved unanimously.

Dr. Nahin announced that the next Council meeting date has been changed to Thursday, June 8, 2006.

Dr. Nahin introduced Dr. Stephen E. Straus, NCCAM Director.

III. Director's Remarks: State of the Center

Dr. Straus presented the seventh annual State of the Center Report, which focused on NCCAM organizational activities, extramural research and training, intramural research and training, and outreach.

Organizational Activities

Advisory Council

Dr. Straus welcomed the new NACCAM members: Dr. Joan Fox, and returning member Dr. Ted Kaptchuk. He announced that Dr. Corvera, who has been nominated to the Council, will serve as an ad hoc member at the February 3rd meeting. Other ad hoc Council members in attendance were: Dr. Yung-chi "Tommy" Cheng, Dr. Fabio Cominelli, Dr. Jules Dienstag, and Dr. Frank Torti. Dr. Straus expressed his thanks to Dr. Nahin for serving as the Council's Acting Executive Secretary.

NCCAM Staff Update

NCCAM staff updates include:

- Ms. Jennifer Sutton serving as Acting Director in the Office of Science Policy and Operations.
- Dr. Martina Schmidt becoming Scientific Review Administrator for the Office of Scientific Review.
- Dr. Robert Nussenblatt joining the Division of Intramural Research as Acting Scientific and Clinical Director.

- Dr. Partap Khalsa becoming Program Officer for the Division of Extramural Research and Training.
- Ms. Carol Fitzpatrick, Committee Management Officer, is leaving NCCAM to join the National Institute of Biomedical Imaging and Bioengineering. Council members expressed thanks to Ms. Fitzpatrick for her hard work at NCCAM and with the Council.
- Dr. Jane Kinsel, Associate Director of NCCAM and Director, Office of Science Policy and Operations has, left for a position at Boston University.

Appropriations and Budget

Dr. Straus updated Council on NCCAM's appropriations and budget. He noted that NCCAM's budget is robust but growth is flattening, reflecting a trend seen throughout the National Institutes of Health (NIH).

In fiscal year (FY) 2006, the Federal budget allocates \$122.7 million for NCCAM, out of a total NIH budget of \$28.6 billion. After rescissions and contributions to the NIH Roadmap, NCCAM's budget authority for FY 2006 is nearly \$120.4 million. Dr. Straus stated that the growth in NCCAM's appropriation levels—often substantial in the Center's early years—now mirrors that of NIH as a whole.

Extramural Research and Training

Trends

Dr. Straus discussed the trends in extramural research since 1999, including a 30-fold increase in the number of funding applications and a nearly 8-fold increase in the number of new awards. Dr. Straus noted that the number and quality of research funding applications and awards demonstrates that a complementary and alternative medicine (CAM) research enterprise is thriving in the United States.

NCCAM's highest priorities are research project grants and research training, and the Center has been resourceful to maintain its investments in those areas. Dr. Straus pointed out that, in anticipation of a flattening budget, NCCAM strategically shifted money to maintain as high a success rate as possible among applicants for research funding. NCCAM's success rate has remained relatively stable in last few years, while the success rate across NIH has dropped and is projected to continue decreasing.

Progress and Priorities

Dr. Straus acknowledged that NCCAM receives applications covering every disease and condition. In its strategic planning for the years 2005-2009, NCCAM solicited advice on the conditions for which people are most likely to use CAM and for which there may be the most scientific and clinical opportunities. NCCAM has used this information to refine its research priorities and focus on:

- Anxiety and depression
- Cardiovascular diseases
- Ethno medicine
- HIV/AIDS
- Immunity
- Inflammatory bowel diseases
- Insomnia
- Chronic liver diseases
- Obesity/metabolic syndrome/diabetes
- Respiratory diseases

In its first few years, NCCAM learned some lessons about evaluating natural products. These products may not be adequately standardized or characterized, and, at present, optimal dosages are unknown. In response, NCCAM has established several measures to enhance the quality of studies involving natural products. These measures include the establishment of:

- A policy and guidance on the use of biologically active agents in NCCAM-funded research;
- A Phase I Resource Center to consolidate botanical-drug interaction, dose ranging, and pharmacokinetic/pharmacodynamic studies for priority products;
- A Virtual Analytic Resource Center to randomly assess products in 10 percent of clinical trials to ensure their stability and verify that they meet the manufacturer's specifications;
- A Product Quality Working Group of Council to evaluate funding requests that involve the use of biologically active agents.

Dr. Straus discussed a shift in NCCAM's approach to research, with emphasis moving away from large multi-center phase III clinical trials and toward both smaller phase I and II trials as well as basic studies to improve understanding of the mechanism of action of different CAM modalities.

Dr. Straus addressed the concept of putting certain research areas on "pause." These are areas in which NCCAM has already invested substantial resources; putting them on "pause" announces to the research community that conducting new studies is not a high priority. Research areas currently on "pause" include:

- *Ginkgo biloba* for neurodegenerative diseases
- Saw palmetto and African plum for benign prostatic hyperplasia
- Soy protein
- Manipulative therapies for low-back pain
- Low-carbohydrate diets for weight loss

The goal of a "pause" is to realize the results of the currently funded research before deciding whether additional research on these topics would be beneficial.

Centers

Following a major external assessment of the program three years ago, NCCAM revised its approach to Centers and added International Centers, Centers of Excellence, and centers focusing on an array of specific disciplines. NCCAM continues to collaborate with the Office of Dietary Supplements to fund Botanical Centers. Dr. Straus noted that NCCAM's investment in centers remains substantial, though overall spending on the program is down.

Research Advances

Dr. Straus discussed highlights of extramural research results released in FY 2005, including:

- A trial of *Echinacea angustifolia* to treat and/or prevent the common cold (published in *The New England Journal of Medicine*);
- A study using positron emission tomography, which demonstrated that the areas of the brain activated when people experience analgesic relief from pain were also activated when the patients were given placebo analgesics (published in the journal *Neuroscience*);
- A study of a traditional Chinese medicine herbal mixture, which may be effective as an alternative to systemic steroids for persistent asthma (published in the *Journal of Allergy and Clinical Immunology*).

In addition, the results of the Glucosamine/Chondroitin Arthritis Intervention Trial were presented at the American College of Rheumatology Annual Meeting in November 2005. As reported in the meeting abstract, the combination of glucosamine and chondroitin sulfate was not effective in all arthritis patients, but it was effective in those with moderate-to-severe knee pain due to osteoarthritis. The study was subsequently published in the *New England Journal of Medicine*.

E-grants

Dr. Straus noted that grant applications for all Federal agencies, including NIH, are being transitioned to an electronic platform. In a phased rollout through 2007, grant applicants will be required to submit their applications electronically, using the SF 424 R&R form. Grantees are being notified, and information is available on the NIH Office of Extramural Research Web site.

Training

Training investigators is a major focus at NCCAM, with NCCAM proportionally being among the top investors at NIH in this area. NCCAM is joining a new trans-NIH initiative, the NIH Pathway to Independence Award, to assist postdoctoral fellows in

transitioning into R01 awards. These awards will fund individuals for 1 to 2 years to finish postdoctoral research and will then provide a guaranteed commitment of start-up money to a university for three years for the individual to do R01-level research.

Intramural Research and Training

The focus of the NCCAM Division of Intramural Research, currently under the leadership of Dr. Robert Nussenblatt, is on clinically oriented research: from bench-to-bedside and from bedside-to-bench. The potential for NCCAM to leverage the resources of the NIH Clinical Center to advance CAM research makes this research possible. Dr. Straus explained that NCCAM intramural research emphasizes studies of age-related diseases, including cancer, musculoskeletal pain, arthritis, diabetes, and obesity.

Intramural Research Highlights

Dr. Straus described several recent intramural research projects, including:

- A study that validated a quantitative insulin sensitivity check index (QUICKI) as an accurate and sensitive surrogate index for insulin sensitivity in humans (published in *Diabetes*);
- A study of dehydroepiandrosterone (DHEA) that found it stimulates the proliferation of and gene expression in human prostate cancer cell lines (published in the *American Journal of Physiology—Endocrinology and Metabolism*).

NCCAM Director's Fellowships

The first NCCAM Director's Fellowships in CAM Research, which was partly supported by the Prince of Wales Foundation, have been awarded to Marni N. Silverman, Ph.D. and Patrick P. McCue, Ph.D. One goal of this program is to match new doctorate recipients with NIH intramural mentors in an area of mutual interest.

The first Bioethics Fellowship has been awarded to Jon Tilburt, M.D., M.P.H., to work with Dr. Ezekiel Emanuel and Dr. Frank Miller at the NIH Clinical Center.

Recruitment is under way for the first CAM/Oncology Fellowship, which is a collaborative activity with NCI's Office of Cancer Complementary and Alternative Medicine.

Intramural Program Growth

Dr. Straus discussed several developments in the growth of the NCCAM intramural program. Because space is at a premium, NIH is building a new satellite campus in the Twinbrook area of Rockville to house intramural research, laboratory facilities, shared conference facilities, and other resources. NCCAM's intramural laboratories will move

to this campus. Dr. Straus announced that recruitment has started for both a Scientific Director/Clinical Director to build the clinical research portfolio and attract new investigators.

Outreach

Dr. Straus noted that expanding outreach is a major priority as NCCAM aims to:

- Increase awareness of the Center and its mission.
- Provide credible information to the public.
- Help educate the public and professionals about the research evidence on CAM.

Information Dissemination

The NCCAM Web site received 1.9 million visitors in 2005 and was voted *Prevention* magazine's "Best Alternative Medicine" Web site. The site's new features include the "Herbs at a Glance" publication series, a Live Help inquiry-response service, and expanded content.

The NCCAM Clearinghouse responded to nearly 14,000 public inquiries in FY 2005 and distributed 127,000 publications, including 3,800 copies of NCCAM's new strategic plan. The NCCAM exhibit traveled to 18 professional and scientific meetings.

The public can stay informed about NCCAM activities through the *CAM at the NIH* newsletter, which has 6,500 print subscribers and 8,600 online subscribers. NCCAM also distributes a monthly eBulletin, *NCCAM Update*, to 5,400 e-mail subscribers.

Speakers in the 2005 Distinguished Lecture Series included Dr. Ralph Snyderman of Duke University ("Integrative Medicine: A Foundation for Prospective Health Care") and Dr. Anne Harrington of Harvard University ("Is Spirituality Good for Your Health?"). Dr. Bruce Rosen of Harvard University and Dr. Ram Sasisekharan of the Massachusetts Institute of Technology will present upcoming lectures.

Educational Resources

The new NCCAM Online Continuing Education Series, which includes video lectures by distinguished scientists and a continuing education program for physicians and nurses, has 4,800 registered users.

IV. Concept: Administrative Supplements for CAM Practitioner Research Trainees

Dr. Nahin introduced Dr. Nancy Pearson, NCCAM Program Officer, Division of Extramural Research and Training. Dr. Pearson presented a concept for administrative supplements to support CAM practitioner research trainees.

Project Concept Review

Dr. Pearson explained that the goal of the proposed concept is to encourage more CAM practitioners to contribute their expertise in specific therapies to CAM research. Attracting these professionals to CAM research has been a challenge because they may lack the educational qualifications or research experience to be competitive for fellowship or career awards or have questions about committing to a research career.

The proposed initiative would provide supplemental administrative funds to a current NCCAM grantee to support a CAM practitioner as a research assistant or in another appropriate position. The CAM practitioner would receive hands-on research experience and support for coursework and other training activities. NCCAM plans to contact R01, P01, U19, and P50 grantees and request their permission to be listed as potential mentors on the NCCAM Web site.

The intent of the proposed administrative supplement is to give CAM practitioners exposure to research under experienced mentors. Award recipients who then choose to pursue research careers will be more competitive for research training, career development, or research grant awards.

Discussion

Council discussed the distinctions between the proposed administrative supplement, the new NIH Pathway to Independence Award, and existing career development awards. Council voted unanimously to approve the concept for administrative supplements.

V. Product Quality Working Group Update

Dr. Straus introduced Dr. Steven Dentali, Vice President, Scientific and Technical Affairs, American Herbal Products Association, who chairs the Council Product Quality Working Group.

Dr. Dentali noted that the Council approved the concept for the Product Quality Working Group last year and then discussed the Working Group's history, activities, and next steps.

The Product Quality Working Group was formed to ensure that biologically active agents used in NCCAM research are adequately standardized and characterized. The Working Group evaluates information related to the quality of biologically active and placebo agents proposed for use in studies being considered for support by NCCAM. Its findings are provided to Council. The goals of this effort are to:

- Provide focused evaluation of product quality;
- Better integrate product quality considerations into NCCAM's deliberations;

- Streamline the Council's review of grant applications;
- Allow the Council to draw upon specialized expertise.

On January 19, 2006, the Working Group convened a teleconference to review 15 applications using biologically active agents. Using a "just-in-time" process to request information only from those applicants likely to be funded, investigators were required to provide information on:

- Identification and description of the raw material;
- Source of raw material;
- Cleanliness and quality standards;
- Extraction procedures and formulation of extracts;
- Stability and storage information.

While providing this information may seem burdensome to applicants, Dr. Dentali felt that it was essential to ensure the quality of the research and should be included in subsequent publications on the research. He hoped that NCCAM's interim guidance and the Working Group prove to be valuable training tools for researchers proposing to study biologically active agents.

In the future, NCCAM program staff and the Working Group will address issues related to reserving and analyzing products, the plan for which has particularly challenged applicants.

Discussion

Dr. Dentali responded to questions from the Council about methodology and quality control. It was noted that chemical fingerprinting is sometimes not sufficient for identification. Factors such as agricultural practices, harvesting, collection, and processing may affect the components identified through chemical analysis.

Dr. Straus thanked Dr. Dentali and the Working Group for articulating and implementing reasonable expectations for product quality in research.

Dr. Nahin acknowledged Ms. Marguerite Klein, for developing the Working Group's guidelines and for her role as its Executive Secretary to the Group.

VI. Public Comments

Dr. Margaret Chesney, Deputy Director of NCCAM, shared a statement by Dr. Aviad Haramati of Georgetown University School of Medicine, who wanted to express his thanks to Council members for their support of the R13 grant that has helped to fund the North American Research Conference on Complementary and Integrative Medicine to be held in Edmonton, Alberta, Canada, May 24-26, 2006.

VII. Closing Comments and Adjournment

Dr. Chesney extended her thanks to the Council for its assistance in building CAM research, not just at NIH, but also setting a standard for the field as a whole.

Dr. Nahin and Dr. Chesney thanked everyone for attending the 23rd Council meeting. The meeting adjourned at 4:20 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

Stephen E. Straus, M.D.
Chair
National Advisory Council for
Complementary and Alternative
Medicine