

**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 FIFTEENTH MEETING
September 8, 2003**

NACCAM Members Present

*Dr. Edwin Blalock, Birmingham, AL
Dr. Kristina Collins, McLean, VA
**Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Jonathan Davidson, Durham, NC
Dr. Haile T. Debas, San Francisco, CA
Dr. Murray Goldstein, Washington, DC
Dr. Michael Irwin, Los Angeles, CA
Dr. Janet Kahn, Burlington, VT
Dr. Konrad Kail, Phoenix, AZ
Dr. Ted Kaptchuk, Boston, MA
Dr. Alan I. Leshner, Washington, DC
Dr. Tieraona Low Dog, Albuquerque, NM
Dr. William Meeker, Davenport, IA
*Dr. Shri Mishra, Los Angeles, CA
***COL Richard Niemtow, Clinton, MD
*Dr. Robert Russell, Boston, MA
*Dr. James Sowers, Brooklyn, NY
Dr. Barbara Timmerman, Tucson, AZ
Dr. Larry Walker, University, MS
Col. James Williams (Ret), Camp Hill, PA
Dr. Benjamin Yang, San Francisco, CA

* Ad hoc members

** Participated by conference call

*** Ex Officio Member

NACCAM Members Absent

Dr. Zang-hee Cho, Irvine, CA

NIH Staff Present

National Center for Complementary and Alternative Medicine (NCCAM)

Ms. Willer Batten	Ms. April Bower
Dr. Josh Berman	Mr. Brian Campbell
Dr. Dale Birkle	Ms. Cheryl Caponiti
Dr. Marc Blackman	Ms. Victoria Carper
Ms. Michelle Bolek	Mr. Steve Casady

Dr. John Chah
Dr. Margaret Chesney, Deputy Director
Ms. Linda Engel
Ms. Carol Fitzpatrick
Dr. Martin Goldrosen
Ms. Anita Greene
Ms. Melinda Haskins
Ms. Mary Jo Hoeksema
Ms. Camille Hoover
Dr. Morgan Jackson
Mr. Mike Kabatt
Dr. William Kachadorian
Dr. Jane Kinsel
Ms. Marguerite Klein
Ms. Robin Klevins
Ms. Karen Kun
Ms. Catherine Law
Ms. Janet Lee
Mr. Patrick Mansky

Dr. Kimberly McFann
Dr. Heather Miller
Dr. Richard Nahin
Ms. Ellen O'Donnell
Ms. Donna Osborne
Dr. Nancy Pearson
Dr. Carol Pontzer
Ms. Linda Rich
Ms. Denise Simmonds-Barnes
Dr. Barbara Sorkin
Mr. Carlton Smith
Dr. Stephen Straus, Director
Ms. Jennifer Sutton
Ms. Chris Thomsen
Ms. Jennifer Tisch
Ms. Shirley Villone
Ms. Allison Wise
Dr. Shan Wong

Other NIH Employees

Ms. Naresh Chand, National Institute of Drug Abuse
Dr. Paul Coates, Office of Dietary Supplements
Dr. Jack Killen, National Institute of Allergy and Infectious Diseases (NIAID)
Mr. Dave Mineo, National Institute of Diabetes & Digestive & Kidney Diseases
Dr. Christine Swanson, Office of Dietary Supplements
Dr. Ed Tramont, NIAID

Members of the Public

Ms. Rupert Aubrose
Ms. Bridget Behling
Ms. Meryl Bloomrosen
Ms. Jane Choy
Ms. Kysa Christie
Dr. Steven Dentali
Dr. Fredi Kronenberg
Ms. Melanie Le Taurmeau
Ms. Lisa Muney-Dietrzak
Ms. Suzanne Niemeyer
Dr. Georgia Persinos
Ms. Chris Peterson
Ms. Elizabeth Sheley
Ms. Pattie Yu
Dr. Haidi Zhang

The National Advisory Council For Complementary and Alternative Medicine (NACCAM) began the closed session at 9:35 a.m. on September 8, 2003 at the NIH Neuroscience Conference Center in Rockville, Maryland. Dr. Jane Kinsel, Executive Secretary, called the meeting to order.

I. Closed Session

The first portion of the meeting was closed to the public in accordance with the provisions set forth in Section 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 299 applications were assigned to NCCAM. Of these, 204 were reviewed by NCCAM, 73 by the Center for Scientific Review, and 22 by other institutes. Applications that were noncompetitive, unscored, or were not recommended for further consideration by the scientific review groups were not considered by Council. Council concurred with 195 applications requesting \$37,273,887 in total costs.

Post-meeting note: A conference call of the Advisory Council was held on November 3, 2003 to consider applications that were responsive to RFA AT03-004 Cranberry: Urinary Tract Infections and Other Conditions. A total of 46 applications were reviewed by NCCAM. Applications that were noncompetitive, unscored, or were not recommended for further consideration by the scientific review group were not considered by Council. Council recommended one (1) application for Low Program Priority, and concurred with 35 applications requesting \$10,043,152 in total costs.

II. Open Session – Call to Order, Meeting Procedures

The open session of the NCCAM meeting convened at 1 p.m. Dr. Jane Kinsel, Executive Secretary, called the meeting to order. The members voted unanimously to approve the minutes of the previous Council meeting, which took place on June 2, 2003. Dr. Kinsel also made note of the dates of future council meetings, and announced that a public comment session was scheduled for later in the afternoon.

III. Director's Remarks

Introduction of New and Ad Hoc Council Members

Dr. Stephen Straus announced that the Secretary of Health and Human Services (HHS) appointed new members to the NCCAM Advisory Council: Dr. Deborah Cotton, Dr. Jonathon Davidson, Dr. Alan Leshner, Dr. Tieraona Low Dog, and Dr. Larry Walker. He introduced the ad hoc members attending this Council meeting: Dr. Edwin Blalock, Dr. Shri Mishra, Dr. Robert Russell, and Dr. James Sowers. In addition, Col. Richard Niemtzwow was present as an ex officio member.

Update on Fiscal Year 2004 Appropriations

Dr. Straus updated the Council on the status of the Fiscal Year (FY) 2004 appropriations process. On July 10, the House of Representatives passed its version of the FY 2004 Labor, Health and Human Services and Education appropriations bill providing \$116.2 million for NCCAM. On June 26, the Senate Appropriations Committee passed its version of the same bill, which includes \$117.9 million for NCCAM. The full Senate is expected to begin debating its version of the FY 2004 Labor, Health and Human Services, and Education appropriations bill on September 2. After the full Senate passes this bill, a conference committee, comprised of members of the House and Senate, will meet to reconcile a final version of the FY 2004 Labor, Health and Human Services, and Education appropriations bill. A final funding figure for NCCAM will be negotiated as part of this process.

NIH Roadmap

Dr. Straus briefed Council on the progress the National Institutes of Health (NIH) is making to implement Dr. Zerhouni's NIH Roadmap initiative. In June, the directors of the NIH institutes and centers met to review and prioritize all of the NIH Roadmap working groups. The highest-ranking recommendations were then reorganized under three major headings: New Pathways to Discovery, Research Teams of the Future, and Re-engineering the Clinical Research Enterprise. Initiatives captured under these headings will be funded in FY 2004 with money from the NIH Director's one percent transfer authority and the NIH Director's Discretionary Fund. The original 15 Roadmap working groups have been reorganized into 9 implementation groups and charged with devising plans for executing the various initiatives.

Institute of Medicine Studies

In July, the National Academy of Sciences' Institute of Medicine (IOM) released its study on NIH restructuring. None of the recommendations applied specifically to NCCAM. A new member of Council, Dr. Alan Leshner, was a member of the IOM panel that drafted this report and agreed to brief Council on the report's recommendations later in the day.

The IOM study on complementary and alternative medicine (CAM) is ongoing. The objective of this study is to use existing data to clarify the scope of CAM use by Americans, assess the public health impact of CAM, and clarify the scientific and policy issues that inform research decisions. Dr. Straus announced that several experts had been added to the IOM panel. He also listed the panel's future meeting schedule.

NCCAM Director Appointments

Dr. Zerhouni appointed Dr. Straus as the NIH representative to the IOM Clinical Research Roundtable. The Roundtable, which is made up of representatives from academia, private sector, advocacy community, and government, was established to focus on issues related to translation of clinical research into clinical practice. In the future, the Roundtable will explore mechanisms to encourage enhanced collaborations in clinical research. Dr. Zerhouni also asked Dr. Straus to join the NIH Director's Steering

Committee. The steering committee is an effort to centralize and share NIH management, and gives NCCAM a place at the management table.

General Announcements

At the end of the meeting, Dr. Straus made several general announcements. First, he congratulated the Division of Intramural Research for receiving several recent awards. Second, he listed the programs announcements NCCAM has released since May 2003: Biobehavioral Pain Research and Exploratory/Developmental Grants for Clinical Studies. Additionally, he reported that NCCAM has made six awards in FY 2003 under the auspices of the NIH Loan Repayment Program. Finally, he announced that NCCAM has appointed Dr. John Killen to direct the Office of International Health Research.

During his update on communications activities, Dr. Straus stated that Dr. Norman Farnsworth of the University of Illinois will give the next lecture in the Distinguished Lecturers in the Science of CAM Series. NCCAM partnered with the Dallas County Community College District to develop distance learning curricula for community colleges and is working with Cancer Care, Inc. and the American Society of Clinical Oncology to sponsor a live webchat regarding cancer and CAM.

Dr. Straus ended his formal opening remarks and introduced Dr. Bernard Goldstein who presented the results of the Botanical Centers Review.

IV. Report of Expert Panel on Botanical Research Centers Program

Dr. Bernard Goldstein, dean of the University of Pittsburgh Graduate School of Public Health, presented the results of an expert panel review of the NIH Botanical Research Centers Program (BRCP), which is jointly supported and administered by NCCAM, the NIH Office of Dietary Supplements (ODS), and the National Institute of Environmental Health Sciences (NIEHS). In reviewing the BRCP, the expert panel was charged with considering issues such as the range of current botanical research center activities, the role of clinical research in the centers, the value of organizing centers around specific research themes, and the most suitable funding mechanisms for botanical research centers.

In the course of its 1-day meeting in February 2003, the expert panel concluded that the BRCP has contributed to the growth and development of the field, drawn new investigators into botanical research, and made noteworthy efforts to study the use of botanicals in special populations, such as women and the elderly. At the same time, however, the panel found that the research centers have produced a less impressive research record than might have been expected. Furthermore, panel members noted a number of organizational issues that have posed challenges for NIH staff in managing the BCRP:

- Shared funding and oversight between the three NIH sponsors

- Use of different funding mechanisms for research centers in the program (both P50 and P01 awards)
- Variability in research center performance

In light of these findings, the panel recommended that NIH take steps to foster higher standards of research productivity throughout the BRCP, and consider funding mechanisms that would more readily allow for NIH staff involvement and oversight. At the same time, the panel members recognized that the choice of funding mechanism is less important than selecting program requirements to be included in the RFA for the next generation of research centers and adopting clear operating guidelines for the program.

The expert panel also called for steps to enhance the efficiency of the centers' research activities in the future. To achieve greater economies of scale, panel members suggested that future centers seek further collaborations with the Food and Drug Administration and other NIH-funded scientists conducting botanical research. In addition, when selecting an organizing theme, panelists recommended that future centers be encouraged to consider botanicals already under study (or slated for study) by the National Toxicology Program of the NIEHS. To further enhance the centers' efficiency, panelists urged that some research-related activities, such as research training and public outreach, be reevaluated or eliminated in the future.

In the end, the expert panel recommended that future centers be encouraged to select high impact themes and increasingly focus their studies on the safety and efficacy of botanicals in humans. The panelists also called for the centers themselves to place further emphasis on quality assurance and quality control – and the NIH to take steps wherever possible to help address these obstacles and enhance the efficiency of all of the botanical research it supports.

V. Concept Clearance – Botanical Research Centers Program (BRCP)

Following the report from the expert panel that reviewed the current BRCP, Dr. Christine Swanson, ODS, presented a concept proposal to extend the program after the initial centers expire in FY 2005. Dr. Swanson noted that the BRCP was established in response to a 1999 Congressional mandate to “establish a botanical research initiative,” and that the NIH currently supports six such centers.

Under the concept proposal Dr. Swanson presented, the next round of research centers will be expected to pursue the interdisciplinary study of botanicals and research likely to be translated into practical health benefits, particularly in the areas of botanical safety and efficacy. The research centers are expected to advance botanical research by defining the chemical and biological characteristics of selected botanicals through preclinical studies that will provide a strong science base and rationale for clinical trials. The centers should also cultivate the use of contemporary technologies and innovative approaches in botanical research and support research training and career development through mentored research activities.

To unify the BCRP, NIH will employ a single award mechanism for future centers: the P50 specialized center award, consisting of several R01-like individual research projects and resource cores that will contribute to each center's overall research objective. The interrelationships among the research projects and resource cores should result in a greater contribution to botanical research than if each project were pursued individually.

Following Dr. Swanson's presentation, Dr. Straus noted that NCCAM currently funds about half of the research center program's budget, which will continue, as the NIH sponsors have chosen to maintain the number of centers in the program at current levels.

In the discussion that followed, several Council members expressed interest in the sharing of expertise and resources among botanical research centers. Others emphasized the importance of establishing a clear research focus and the advantages of stability in research center funding. There was also discussion of the question of whether applications from potential new center sites could successfully compete against those from established botanical research centers, with one Council member suggesting that the RFA include specific review criteria for judging proposed new center sites. At the conclusion of their discussion, Council members approved the concept as proposed.

VI. Concept Clearance – CAM Practitioner Research Education Grant

Dr. Nancy Pearson introduced a concept for an initiative to fund CAM practitioner research education, starting in 2005. This initiative would increase the quality and quantity of research content in the curricula at CAM professional schools. In partnership with research-intensive institutions, CAM professional schools would use the grants to enhance CAM practitioners' exposure to, understanding of, and appreciation of the evidence-based biomedical research literature and approaches to advancing scientific knowledge.

CAM practitioner training is well established in modalities such as naturopathy, chiropractic, and Oriental medicine. However, inclusion of biomedical research information is seldom prominent in their curricula. Increasing the research content of CAM practitioner training curricula would better enable CAM practitioners to critically evaluate biomedical literature, participate in clinical research, and seek advance research training and career development. This initiative proposes the use of an Education Project Grant (R25), which would support development and enhancement of lecture and methods courses in biomedical research. The grant would also support short-term faculty and student research projects, strengthen faculty research skills, and promote incorporation of research training components into the CAM training program. This would all be done in partnership with a research-intensive institution, which would provide experienced mentors and teachers to support curriculum development, teaching, and other training activities.

Research content in CAM practitioner curricula varies widely from school to school. The initiative would help introduce research-based information into a curriculum and expand existing research training at CAM professional schools. The result would be CAM schools with a stronger research component and with a relationship with a research institution.

Council members commented that it is important to develop CAM practitioners who are more comfortable with research, even if they do not do it themselves. CAM trainees need models and qualified teachers who can critically evaluate their research. One Council member noted that the initiative had both short- and long-term benefits, for medicine and CAM integration, by helping to change the culture.

Council unanimously approved the concept.

VII. AIDS Programs at the National Institute of Allergy and Infectious Diseases

Dr. Edmond Tamont, Director of the Division of AIDS (DAIDS), at the National Institute of Allergy and Infectious Diseases (NIAID), provided an overview of CAM use among AIDS patients and related research needs.

Dr. Tramont described the case history of an HIV patient who appeared to be compliant in taking antiretroviral therapy, but was having problems with an unexpectedly high viral load. After taking a more extensive medical history, it was found that she had begun taking St. Johns wort for depression, and it was interfering with maintaining appropriate plasma levels of her medication. Studies have shown that HIV patients often turn to CAM. It is therefore an important interplay that warrants monitoring and investigation.

An estimated 50 percent of HIV patients in the U.S. use at least one CAM approach, usually vitamins and herbal medicines. Up to 95 percent of HIV patients in other countries are using CAM. The issue of the impact of CAM used in conjunction with conventional medicine is important and warrants collaboration between DAIDS, NIAID and NCCAM.

VIII. Concept Clearance – Use of CAM in the Management of HIV/AIDS

Dr. Morgan Jackson, NCCAM, presented a concept to further the collaboration mentioned by Dr. Tramont. The purpose of the initiative is to stimulate research that would elucidate the risks, mechanisms, and benefits of using CAM in the management of HIV/AIDS. While highly active anti-retroviral therapy (HAART) and other methods have prolonged life and increased the quality of life for HIV/AIDS patients, physical and emotional consequences of the disease and its treatments remain, prompting the majority of patients to seek relief in CAM treatments. Some CAM approaches are beneficial, but there is a risk that they might displace or interfere with proven treatments, in addition to causing side effects of their own. Few of the studies of CAM approaches to HIV/AIDS have as yet yielded results warranting larger scale prospective trials. NCCAM has, in the

past, released RFAs aimed at promoting studies of CAM approaches in HIV/AIDS and of botanical/anti-retroviral drug interactions. However, few of the investigators researching in this area have been from institutions with sizable HIV/AIDS patient populations, and with the research facilities and infrastructure necessary to move this field forward.

NCCAM proposes to fund experienced and well-prepared investigators in institutions with a substantial history of HIV/AIDS research to undertake basic, translational, or early phase clinical trials to investigate a variety of CAM approaches in HIV/AIDS and its complications. Eligible institutions will have an AIDS-funded research base from NIH that exceeds a high dollar amount to be specified in the RFA. This research base cannot include sources other than NIH.

The objectives of the initiative, using the R21 funding mechanism, include the following:

- § Identify potential roles for CAM treatments in managing HIV/AIDS and/or its complications prior to initiation of HAART, in association with HAART, or to ameliorate HAART side effects.
- § Understand mechanisms of action of CAM interventions that have potential for contributing to, or interfering with, standard treatments.
- § Stimulate CAM research at leading HIV/AIDS research institutions.

A question was raised about the RFA addressing CAM approaches as an alternative to, as well as to complement, antiviral therapy. Dr. Jackson commented that there have been recent changes in the use of antivirals – they are being used much later now. Dr. Tramont added that many patients do not want to start antivirals right away, and their physicians are delaying the start of antivirals. Patients who have made that decision might opt to participate in a CAM study. Particularly with the burden of disease affecting under-resourced countries, CAM modalities that can work may be helpful. In India, for example, it is estimated that 90 percent of those affected cannot afford conventional medicine and therefore go to Ayurvedic practitioners.

Dr. Jackson noted that, in looking at the portfolio, the last two RFAs issued by NCCAM in this area have not accomplished the intended results. This RFA will solicit the best research across several domains in which potential exists. Dr. Low Dog suggested that this also be considered as a focus for one of the botanical centers. Dr. Straus added that this proposed collaboration with DAIDS, NIAID is a new strategy to build NCCAM's HIV portfolio. In response to a request for clarification on the issue of non-NIH funding, Dr. Straus replied that the grantee must be from an institution with a track record of funding.

The concept was approved.

IX. Highlights of the Institute of Medicine Report

Dr. Leshner, who participated as a member of the Congressionally mandated IOM Panel, discussed the report, *Enhancing the Vitality of the NIH: Organizational Change to Meet*

New Challenges. The Panel's task was to examine the NIH organization, recommend whether restructuring might be necessary, and how any restructuring might best be accomplished. Dr. Leshner noted that public representatives were added to the IOM committee to ensure diversity of input.

The general conclusion was that NIH is an outstanding organization already. No massive reorganization or consolidation is warranted. The issue is how to enhance the strength of NIH. Some of the recommendations apply specifically to NCCAM. These include:

1. Assure that centralization of management functions will not undermine NIH's abilities regarding research.
2. Create a public process for considering any proposed changes in the number of NIH institutes and centers (IC). Related to that, the panel suggested two potential mergers: National Human Genome Research Institute and National Institute of General Medical Sciences; and the National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism.
3. Strengthen the overall NIH clinical research effort through consolidation of programs and creation of a new leadership position. Dr. Leshner noted that this recommendation seems to be consistent with the NIH Roadmap exercise, although they were unaware of the status of the NIH Roadmap at the time. There should be some standardization among the various institutes in terms of how they operate. This might warrant creation of a National Center for Clinical Research and Research Resources, and a deputy director to accomplish this.
4. Enhance and increase trans-NIH funding and planning. Initially, 5 percent of IC budgets should go for trans-NIH initiatives. The funds should be in escrow. This requires conversation across NIH.
5. Strengthen the office of the NIH director in order to enhance planning.
6. Establish a process for creating new offices and programs within the Office of the Director.
7. Create a Director's special projects program for high-risk, high-potential-payoff research, modeled on DARPA and with an initial budget of \$100 million. Peer review favors low-risk research, especially when money is tight.
8. Promote innovations and risk-taking in intramural research.
9. Improve and standardize level-of-investment data and information management systems.
10. Set terms (with a maximum of two 5-year terms) and conditions for IC director appointments, and improve the IC director review process. The purpose of this recommendation is to gain an infusion of new ideas.
11. Set terms (possibly 6 years, possibly renewable) and conditions for the NIH director.
12. Reconsider the special status of the National Cancer Institute (NCI). Currently the NCI director is appointed by the President, and the NCI budget is determined separately from the rest of the NIH budget.
13. Retain integrity in appointments to advisory councils and reform advisory council activity and membership criteria. Each NIH advisory council functions

differently. Some are rubber stamps, while others are more actively involved. There is a need for more credibility in the process.

14. Increase funding for research management and support.

In an organization dedicated to science, there is a need to constantly reconsider where the organization is and map to the future. In the growth to 27 institutes and centers, coordination has become more of an issue. Dr. Straus noted that setting aside a percentage of the budget for a coordinating activity is under consideration.

Some NIH Roadmap initiatives are more targeted than would apply to NCCAM. However, NCCAM recognizes its responsibility to support a broader evolution of biomedical research. Dr. Straus added that the NIH Roadmap has involved hundreds of members of the public. NIH must determine how to efficiently and effectively translate the promising findings of biomedical research from the laboratory to the clinic.

VIII. Public Comment Session

No members of the public came forward to speak when the session was announced.

IX. Adjournment

Dr. Straus adjourned the meeting at 4:20 p.m.