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 FOURTEENTH MEETING

June 2, 2003

NACCAM Members Present
*Dr. Yung-Chi Cheng, New Haven, CT
Dr. Zang-Hee Cho, Irvine, CA
Dr. Kristina Collins, McLean, VA
*Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Haile T. Debas, San Francisco, CA
*Dr. Steven T. DeKosky, Pittsburgh, PA
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. William Meeker, Davenport, IA
*Dr. Alan R. Shuldiner, Baltimore, MD
Dr. Barbara Timmerman, Tucson, AZ
*Dr. Stefanie N. Vogel, Baltimore, MD
*Dr. Larry Walker, University, MS
Col. James Williams (Ret), Camp Hill, PA
Dr. Benjamin Yang, San Francisco, CA
*Ad hoc members

NACCAM Members Absent
None

NIH Staff Present
National Center for Complementary and Alternative Medicine (NCCAM)
Ms. Julia Arnold
Mr. Howard Baldwin
Ms. Willer Batten
Dr. Josh Berman
Dr. Marc Blackman
Mr. Brian Campbell
Ms. Cheryl Caponiti
Ms. Victoria Carper
Mr. Steve Casady

Dr. John Chah
Dr. Margaret Chesney, Deputy Director
Ms. Mimi Choi
Ms. Alyssa Cotler
Mr. Jimmy Do
Ms. Linda Engel
Ms. Carol Fitzpatrick-Mulligan
Dr. Martin Goldrosen
Ms. Anita Greene
Ms. Carolyn Hodgkins
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. Irini Manoli
Dr. Heather Miller
Ms. Ilze Mohseni
Ms. Barbara Moquin
Dr. Richard Nahin
Dr. Nancy Pearson
Mr. Marc Pitts
Dr. Carol Pontzer
Ms. Linda Rich
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
Dr. Paul Coates, Office of Dietary Supplements
Ms. Cherly Caponiti, National Institute of Aging
Ms. Melinda Haskins, National Institute of Allergy and Infectious Diseases
Ms. Colleen Lee, National Cancer Institute
Officer Michael McGraw, Office of Research Services
Dr. Margaret Snyder, Office of the Director

Dr. Christine Swanson, Office of Dietary Supplements
Dr. Anne Washburn, National Cancer Institute

Other Federal Employees
Dr. Mark McClellan, Commissioner, Food and Drug Administration

Members of the Public
Ms. Alian Aguila
Mr. Victor Aramayo
Ms. Denise Beasley
Ms. Justin Beasley
Mr. Jim Bernstein
Ms. Linda Boone
Ms. Kysa Christie
Dr. Steven Dentali
Dr. Christine Goertz
Ms. Laura Honesty
Dr. Kurt Hegetschweiler
Ms. Penelope Johnson
Dr. Fredi Kronenberg
Ms. Melanie Le Taurmeau
Dr. Georgia Persinos
Ms. Elizabeth Sheley
Ms. Lauren Shepherd
Mr. Dennis Smith
Mr. Kain Vaak
Mr. Christoper Walker

The National Advisory Council For Complementary and Alternative Medicine (NACCAM) convened at 8:30 a.m. on June 2, 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 244 applications were assigned to NCCAM. Of these, 185 were reviewed by NCCAM, 56 by the Center for Scientific Review, and 3 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 recommended 4 applications for high program priority, 2 applications for low program priority and concurred with 160 applications requesting $21,150,638 in total costs.

II. Open Session/Approval of Prior Meeting Minutes

The open session of the NACCAM convened at 12:30 p.m. Dr. Jane Kinsel, Executive Secretary, called this portion of the meeting to order and reviewed the agenda for the open session. The members voted unanimously to approve the minutes of two previous meetings, January 27, 2003 and March 17, 2003.

III. Opening Remarks

Introduction of Retiring Members and Ad Hoc Members. Dr. Stephen Straus, Director of the National Center for Complementary and Alternative Medicine (NCCAM), welcomed those present. He noted that five Council members would soon come to the end of their terms: Dr. Janet Kahn, Dr. Konrad Kail, Dr. Ted Kaptchuk, Dr. William Meeker, and Col. James Williams (Ret.). Dr. Straus thanked them for their service and presented each with a certificate. NCCAM is still awaiting approval of incoming council members. He welcomed seven participating ad hoc members: Drs. Yung-Chi Cheng, Deborah Cotton, Steven DeKosky, Alan Leshner, Alan Shuldiner, Stefanie Vogel, and Larry Walker.

Budget Update. Dr. Straus gave an update on NCCAM's Fiscal Year 2003 appropriation. In 2002, NCCAM received $104.6 million. The appropriation for 2003 came to $114.1 million. However, the final bill that President Bush signed into law authorized an immediate 0.65% across-the-board reduction to offset additional funds provided to other agencies in the bill. As a result, NCCAM's final FY 2003 funding level is $113.4 million. For FY 2004, the President has requested $ $116.2 million. The House and Senate Appropriations Committees' Subcommittees on Labor, Health and Human Services, and Education have not announced when they will report their recommended FY 2004 funding levels.

For FY 2003, NCCAM has projected how the research funding will be allocated. Specifically, 54 percent of the funding will be devoted to support of research project grants, 18 percent will be allocated to centers, 11 percent will be directed towards education and careers awards, 8 percent will be allocated for research contracts, and 4 percent will support training awards. Finally, 5 percent of the funding will go to the intramural research program.

Congressional Update. In April, Dr. Straus accompanied Dr. Zerhouni to the House and Senate appropriations hearings. Members of both the House and Senate Committees expressed overarching and nonpartisan support for the National Institutes of Health (NIH). In addition to attending these hearings, Dr. Straus met with the staff of Senator Don Nickles (R-OK), Chairman of the Senate Budget Committee, to discuss the Center's research priorities and interests.

Ephedra Working Group. On March 17, the Council received the report of the Ephedra Working Group, which was convened to 1) discuss clinical and methodological issues related to ephedra research; 2) identify scientific research gaps; and 3) suggest options for

future research directions. The working group concluded that the current data on the safety of ephedra are inconclusive. The working group suggested that research to evaluate the safety of ephedra should be the highest priority, and urged the NIH to sponsor a case control study to determine if ephedra is causally related to serious but rare adverse events in adolescents who report using ephedra for any reason. The Council concurred with this assessment. Plans are now underway to develop an initiative. NCCAM is awaiting input from the Department of Health and Human Services (HHS) on policy developments that might affect the future of the initiative.

NIH Roadmap. In the summer of 2002, NIH Director Dr. Zerhouni established 15 roadmap groups, co-chaired by IC Directors, to identify roadblocks to scientific progress and actions to overcome them. Dr. Straus is co-chairing the translational research group, and the high-risk research group. On June 20, the IC Directors will attend a budget retreat to review and rank all of the roadmap groups' recommendations. These recommendations will be used as the basis for developing trans-NIH initiatives and possible modifications to existing policies.

Recent Award Solicitations. Dr. Straus presented information on several recent award solicitations. In February, NCCAM issued an RFA to solicit research applications on the role of cranberry in the prevention and treatment of urinary tract infections. A program announcement is out to invite applications from investigators regarding secondary analysis of complementary and alternative medicine (CAM) use in minority populations. Through its support of the Preclinical Antiviral Testing Program for CAM, NCCAM is seeking to assess CAM products for their ability to combat pathogens, including those linked to infectious diseases, such as Severe Acute Respiratory Syndrome (SARS). To date, the Center has passed 13 inquiries to the National Institute for Allergy and Infectious Diseases for in vitro evaluation. Finally, last June, NCCAM reviewed its research centers programs. This effort led to three separate center initiatives. The applications generated by these initiatives will be reviewed later this summer with the goal of bringing them to the September Council for second final review and approval.

Significant Staff Changes. Dr. Straus imparted news regarding significant changes in the extramural research program staff. Foremost, the NCCAM Office of Clinical and Regulatory Affairs is fully staffed, having hired a biostatistician and three health program specialists. Dr. Christine Goertz, Dr. Mary Ann Richardson, and Capt. Nancy Hazelton from the NCCAM Division of Extramural Research and Training have left, and the Center is advertising for new program officers.

Communications Update. With respect to the Center's communications program, it was announced that a staff bibliography is now posted on the NCCAM website. In addition, the Center co-sponsored a six-week lecture series with the Smithsonian Institution, and sponsored the fourth lecture in Distinguished Lectures in the Science of CAM.

A member of Council suggested that after examining NIH priorities, NCCAM might want to bring together experts in CAM to determine how the Center can align its priorities with those of the larger NIH. Dr. Straus explained that the NCCAM scientific

staff will participate in a planning retreat to discuss the Center's proposed research initiatives and general direction. At that time, NCCAM scientific staff and senior leadership will discuss how to integrate NCCAM and NIH's scientific interests and goals. A major activity over the next 18 months will be to draft the next version of NCCAM's strategic plan, aligning it with the NIH roadmap activities.

IV. Concept Clearance

Dr. Nancy Pearson, NCCAM, presented a project concept for an Exploratory/Developmental Grant (R21) for Clinical Studies. Recently, a trans-NIH Exploratory/Developmental Grant (R21) initiative was launched to emphasize novel ideas that are outside mainstream thinking and that bear considerable risk of failure. The proposed NCCAM announcement is more targeted and would solicit R21 grants for exploratory/developmental research grants for pilot and feasibility CAM research. These grants would provide investigators with preliminary data leading to larger projects.

The program announcement would be issued for three years. The research objective is to encourage submission of high-quality preliminary studies that will provide a basis for larger clinical studies that will test the efficacy of CAM therapies in all five CAM research domains, as defined by NCCAM: alternative medical systems, biologically based therapies, energy medicine, manipulative and body-based therapies, and mind-body medicine.

The maximum duration of the R21 grants would be three years to allow completion of well-designed studies. Awards would allow $400,000 over three years, in modular budget format of $25,000, not to exceed $250,000 in a single year.

The program announcement will encourage potential applicants to contact the DERT program officers. NCCAM now has better experience judging the kind of research that fits the R21 format, and can provide guidance to the applicants. This process will also help screen out over-ambitious proposals and steer them to R01 awards.

Council members urged that NCCAM develop this initiative and work to accelerate if possible the process for R21s. Dr. Straus added that the intent is not to provide more money and more time, but rather to improve the likelihood that the research will succeed. Grantees will not always need the third year, and the Council will need to help by making recommendations on duration.

The Council voted unanimously to approve the concept.

Dr. Pearson briefly described several NIH initiatives led by the Office of Behavioral and Social Science Research. NCCAM is participating in these mind-body initiatives. Dr. Straus added that there will be a growing NIH investment in neurobiology and mind-body approaches.

V. Working Group on Cancer

Dr. Kinsel presented a proposal to form a working group on cancer that would be charged to explore and review opportunities arising from the National Cancer Institute (NCI) best case series. The working group would evaluate and suggest to Council those cases that merit further review and study.

The Cancer Advisory Panel on Complementary and Alternative Medicine (CAPCAM) was created in 1999 as a collaboration between NCI and NCCAM to make recommendations for research on CAM interventions in cancer. Last year, NIH was asked to reduce the number of chartered committees, and CAPCAM was disbanded. The current proposal is for a Council working group that would continue to review the best case series. The group would meet annually, or as needed, over the next three years. After this time, NCCAM would evaluate and assess whether this model is working. Membership would include several Council members, basic and clinical investigators, clinicians, practitioners, and a patient advocate.

Ms. Colleen Lee, Practice Assessment Program Manager, briefly summarized NCI's efforts to bring the best-case series forward. They determine if the information they get is scientific, credible, valuable, and actionable.

Dr. Straus said that there has been great difficulty in assessing the validity of anecdotes regarding claims. The NCI Office of CAM Research has worked hard, but few cases have met the threshold of showing that patients respond. In many cases, practitioners and patients lack the necessary documentation. The goal is to find patients who respond to alternative treatment.

Dr. Kail, who had been a member of CAPCAM, said the Panel had discussed the best-case series program. There had not been much success in obtaining reliable records and documentation. Dr. Straus noted that in some cases documentation did not exist to show the basis for the cancer diagnoses, and in others documentation did not exist regarding claimed improvements. The intent is not to restrict the work to the United States, and NCCAM would welcome information from other countries. Dr. Straus also suggested that patient groups could play a role in assembling information to submit.

At the suggestion that the best case series should be expanded beyond cancer, Dr. Straus explained that, given the challenges and difficulties in making the best case series work, he wanted to first build a successful model for cancer before expanding into other areas.

Several Council members urged moving forward with the proposed working group. Cancer patients disproportionately use CAM approaches, so this is a high-yield activity in terms of responding to the public. The public expects an active approach, and the scientific community should respond by assuming this responsibility.

The Council unanimously supported the proposal to establish a working group on cancer.

VI. Overview of Activities at the Food and Drug Administration (FDA)

Dr. Straus introduced Dr. Mark McClellan, Commissioner of the Food and Drug Administration (FDA). Dr. McClellan said that there are many opportunities for NIH to work with the FDA on approaches that improve public health. Regarding dietary supplements, the FDA, under the Dietary Supplement Health and Education Act of 1994, is charged with ensuring a balance between access to dietary supplement products and verification that those products are safe and properly labeled.

The safety of several dietary supplements has been in the news recently; one example is ephedra. The FDA solicited public comments on a proposed rule for ephedra-containing products. The risk definitions used by the FDA in the past may need to be changed. Sentinel adverse events could be indicative of a larger problem and need to be carefully evaluated. The FDA is in the process of determining whether ephedra, as currently marketed, poses an unreasonable risk.

Regarding the general issue of safety, additional research is needed to identify components, including contaminants, of dietary supplements. More and better data will help set standards. Through the sequential testing used in the drug approval process, potential safety issues can be identified early. Likewise, safety profiles of ingredients in dietary supplements will be very useful. Many people view dietary supplements as largely safe. The public is making more decisions that affect their own health, and they should have safety and efficacy information about the products they are taking.

Another issue concerns claims of health benefits by dietary supplements. The FDA wants to help product developers explain their products accurately. The FDA is also taking more aggressive enforcement against untruthful claims. The better the evidence base, the easier this is to do. An interactive dialogue with industry is important.

The Orphan Drug Act can cover dietary supplement products, but most companies do not choose to pursue that route. There are a number of criteria for converting a dietary supplement into drug product, such as demonstration of safety, efficacy, and material consistency, including purity. An understanding of the mechanism of action helps to support claims.

One Council member expressed concern regarding whether practitioners of traditional Chinese medicine might still be able to prescribe ephedra, which has a long history of use. Dr. McClellan noted that the recent discussions have focused on using the supplement for sports performance enhancement and weight loss.

Dr. Straus commented that these issues resonate strongly with NCCAM. Studying safety is a high priority. NCCAM's research portfolio includes large clinical trials, as well as a growing number of Phase I/II studies to evaluate doses and safety. He has appreciated FDA guidance regarding dietary supplements, as it helps in testing products in the research pipeline.

VII. Cancer patients and CAM: Exploring Information Needs

Ms. Chris Thomsen, Director of NCCAM's Office of Communications and Public Liaison, spoke about a focus group project conducted by NCCAM and NCI. The focus group was done to understand the CAM information needs of cancer patients and where/how they get information on CAM so that NCCAM and NCI can provide evidence-based information on CAM to patients and families. Cancer is the subject of 49 percent of inquiries from the public to the NCCAM Clearinghouse.

The project involved six 90-minute focus groups conducted by telephone; there were four groups of survivors, and two of caregivers. All had used both CAM and conventional treatment. There were also six in-depth interviews with patients who used only CAM. This was a diverse population, with an equal number of men and women, 22 types of cancer, and 23 states represented. Participants said they sought CAM to relieve symptoms and improve prognosis, improve quality of life, boost the immune system, back up conventional medicine, cure the disease, and ease side effects. The dominant reason given for using CAM was that the patients did not like what conventional medicine offered. They wanted some control over the disease, and something they could do for themselves.

The patients sought CAM throughout the disease process, from diagnosis through end of treatment. They found information starting with the Internet, which involved extensive searching that was unsystematic and inefficient. Most started with no plan or method, felt overwhelmed and frustrated, and felt a great and urgent need for information. They were frustrated by the volume of written materials. None mentioned NIH or NCCAM as a source for CAM information. They did rely heavily on word of mouth. Support groups were important, because they wanted to hear about CAM from other patients. Most wanted to hear about CAM from their doctors and wanted to know the doctor was open to CAM and could direct them to a source for CAM. Most did not disclose their CAM use to their doctors, however, for they assumed the physicians would oppose it. Those physicians who were open to CAM had a stronger relationship with their patients than those who were not.

Dr. Cheng commented that this is important and significant work. The difficulty is that NCCAM has little to offer because the evidence is not there yet. Ms. Thomsen said that information produced by the federal government is on the NCCAM website. NCCAM can focus on consumer education – how to get coverage, find a practitioner, etc. Dr. Cheng said that he has been looking for evidence-based information, but most of those trials conducted thus far have problems associated with them. He finds it hard to advise patients because of the dearth of information. This will improve with time. Dr. Goldstein said that the approach his group takes is not to advise about efficacy. They do provide information about what is and is not known, then allow the patient to make his or her own decision. They inform, rather than advise.

Dr. Straus observed that not everything is safe, and there are known interactions to be avoided. Dr. Kail pointed out that patients are not comfortable talking to their doctors.

However, the courts hold that doctors should initiate the conversation in order to avoid bad interactions. His concern is that they will therefore advise against CAM.

Dr. Chesney observed that patients are easily overwhelmed by too much information. There needs to be a way to help people navigate well through the information. There should be more effective outreach to the community. Dr. Collins said that it is important to understand that patients are not looking for specific research. They are overwhelmed with the whole world of CAM. Dr. Cheng added that he is working on forming a consortium of top research institutes in Asia. He hopes they can share their platforms of quality control, bioinformatics, and clinical information. Dr. Goldstein wondered if, to work around public distrust of government, NCCAM would be better off working with outside organizations like the cancer society or heart association. Other branches of NIH have experience in this area. Ms. Thomsen noted that NCCAM should take every opportunity to work with these groups.

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 4:35 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Jane F. Kinsel, 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