NACCAM Members Present
Dr. Carlo Calabrese, Portland, OR
Dr. Kristina Collins, McLean, VA
**Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Haile Debas, San Francisco, CA
Dr. Jeanette Ezzo, Takoma Park, MD
Dr. Robert E. Fullilove, New York, NY
Dr. Murray Goldstein, Washington, DC
**Dr. Michael Irwin, Los Angeles, CA
Dr. Tierona Low Dog, Albuquerque, NM
Dr. Bala Manyam, Temple, TX
COL Richard Niemtzow, Clinton, MD
Dr. Joel Pickar, Davenport, IA
Dr. Barbara Timmerman, Tucson, AZ
Dr. Larry Walker, University, MS
Dr. Benjamin Yang, San Francisco, CA
** Participated by conference call

NACCAM Members Absent
Dr. Zang-Hee Cho, Irvine, CA
Dr. Jonathan Davidson, Durham, NC
Dr. L. David Hillis, Dallas, TX
Dr. Alan I. Leshner, Washington, DC

Ad hoc member participated by conference call
Dr. Steve Kliewer, Dallas, TX
NIH Staff Present
National Center for Complementary and Alternative Medicine (NCCAM)

Ms. Willer Batten
Dr. Josh Berman
Dr. Dale Birkle
Ms. Michelle Bolek
Ms. April Bower
Mr. Brian Campbell
Ms. Yvette Carter
Mr. Steve Casady
Dr. Margaret Chesney, Deputy Director
Ms. Alyssa Cotler
Ms. Karla Ehrler
Ms. Carol Fitzpatrick
Ms. Anne Frost
Dr. Martin Goldrosen
Mr. Kevin Greene
Ms. Mary Gregg
Ms. Camille Hoover
Dr. Jeanette Hosseini
Dr. Morgan Jackson
Mr. Roald Keith
Dr. Jack Killen
Dr. Jane Kinsel
Ms. Marguerite Klein
Ms. Catherine Law
Dr. Qi-Ying Liu
Dr. Kimberly McFann
Dr. Heather Miller
Ms. Ilze Mohseni
Dr. Richard Nahin
Ms. Ellen O’Donnell
Dr. Nancy Pearson
Dr. Carol Pontzer
Ms. Linda Rich
Dr. Barbara Sorkin
Dr. Stephen Straus, Director
Ms. Jennifer Sutton
Ms. Chris Thomsen
Dr. Shan Wong

Other NIH Employees
Mr. Soaring Bear, National Library of Medicine
Dr. Joyce Hunter, National Institute of Diabetes & Digestive & Kidney Diseases
Dr. Gang Peng, National Institute of Dental and Craniofacial Research
Ms. Hasnaa Shafik, National Cancer Institute
Dr. Christine Swanson, Office of Dietary Supplements
Mr. George Tucker, National Institute of Diabetes & Digestive & Kidney Diseases
Mr. Stephane Philogene, Office of the Director, NIH

Other Government Agencies
Ms. Patricia Barnes, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS)
Dr. Jennifer Madans, CDC, NCHS

Members of the Public
Ms. Pat Anderson
Ms. Carol Brotheron
Dr. Steven Dentali
Mr. Michael Dyer
Ms. Fran Fleming
Ms. Laura Honesty
Mr. Lundstad
Mr. Jun Mao
Mr. Art Miller
Ms. Suzanne Niemeyer
Ms. Martha Nolan
Dr. Georgia Persinos
Ms. Lauren Schwartz
I. Closed Session

The first portion of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) 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 264 applications were assigned to NCCAM. Of these, 171 were reviewed by NCCAM, 65 by the Center for Scientific Review (CSR), and 28 by another NIH institute. The Council did not consider applications that were noncompetitive, unscored, or not recommended for further consideration by the scientific review groups. Council members agreed with staff recommendations on 9 applications, deferred action on 1 application, and concurred on 150 applications requesting $32,877,057 in total costs.

II. Open Session—Call to Order, Meeting Procedures

The open session of the NACCAM meeting convened at 1:15 p.m. Dr. Jane Kinsel, Executive Secretary, called the meeting to order. Council members voted unanimously to approve the minutes of the previous Council meeting on January 30, 2004. Dr. Kinsel noted the upcoming Council meeting on September 10, 2004, and requested that Council members inform her in advance if they are unable to attend the meeting so that appropriate assignments can be made, particularly for the closed session. She asked those interested in speaking at the public comment session later in the afternoon to sign up at the registration area.

III. Opening Remarks

Council and Staff News

Dr. Stephen E. Straus, Director of the National Center for Complementary and Alternative Medicine (NCCAM), commended Council members on the thoughtful dialog that characterized the morning’s closed session.

Dr. Straus announced that two members, Dr. Haile Debas and Dr. Kristina Collins, had been scheduled to rotate off the Council but had agreed to serve for another 180 days to allow time for the appointment of new members.

In addition, Dr. Straus introduced new members of the Council who had been appointed by the Secretary of Health and Human Services in 2003: Dr. Carlo Calabrese, Dr. Jeanette Ezzo, Dr. L. David Hillis (not present at the meeting), Dr. Bala Manyam, and Dr. Joel Pickar. He thanked Dr. Steven Kliewer who served as an ad hoc member in the morning’s closed session.

Dr. Straus noted that Dr. Robert Fullilove, associate dean for community affairs at the Mailman School of Public Health at Columbia University, has the distinction of being the first African American man to be appointed full professor at that school. Dr. Straus also
congratulated Dr. Benjamin Yang on his appointment as honorary president of the United California Practitioners of Chinese Medicine.

After praising the work of the NCCAM program staff, Dr. Straus welcomed a new program officer, Dr. Catherine Stoney, to the staff.

**Legislative Updates**

Dr. Straus recently briefed the staff of Senator Thad Cochran of Mississippi, who chairs the Senate Committee on Agriculture, Nutrition, and Forestry and is a member of the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education.

Since January, Directors of various Institutes and Centers at the National Institutes of Health (NIH) and NIH Director Dr. Elias Zerhouni have testified before the House and Senate appropriations committees on proposed Fiscal Year (FY) 2005 funding requests. During these hearings, specific questions have arisen on NCCAM-supported activities. In other legislative news, Dr. Straus accompanied the Director of the National Institute on Aging (NIA), Dr. Richard Hodes, to a hearing on Alzheimer’s disease before the Senate Special Committee on Aging. Committee members asked questions about NCCAM’s groundbreaking basic and clinical research on complementary and alternative medicine (CAM) approaches for health problems associated with aging.

**Extramural Activities**

Dr. Straus noted that a program announcement to encourage preliminary studies of CAM at the National Center for Research Resources-supported General Clinical Research Centers was launched on April 6, 2004. Also in April, NCCAM issued the CAM Practitioner Research Education Project Grant Partnership. Through this program, NCCAM plans to build partnerships between CAM institutions and research agencies to increase the quality and quantity of research content in curricula at CAM institutions. The purpose of these partnerships will be to improve CAM practitioners’ understanding of scientific methods.

Dr. Straus stated that guest speakers would later present information to the Council on a major collaboration with the Centers for Disease Control and Prevention (CDC) on CAM use in the United States.

**NCCAM and NIH Roadmap Initiatives**

*Regional Translational Research Centers*

Dr. Straus and Dr. Kinsel are co-leading an NIH initiative to develop and support regional centers that will provide investigators with the resources needed for safe, effective translational research. Dr. Straus’s broader responsibilities related to the NIH Roadmap include developing translational initiatives to bridge between laboratory and clinical research. Next steps include convening a planning meeting to discuss Regional
Translational Research Centers (RTRCs) on July 16, 2004, issuing a request for applications (RFA) for planning grants for RTRCs in FY 2005, and announcing an RFA for development of RTRCs in FY 2006. Dr. Straus discussed that while this initiative is under NCCAM’s mentorship, NIH, not NCCAM, is funding the initiative. He noted that Council members will be asked to offer guidance and to participate in the secondary review of applications.

NIH Public Trust Initiative
Dr. Patricia Grady, Director of the National Institute of Nursing Research, and Dr. Yvonne Maddox, Deputy Director of the National Institute of Child Health and Human Development, are co-chairs of the NIH Public Trust Initiative. The goal of this initiative is to improve public health through promoting public trust in biomedical and behavioral research. Opportunities for Council and public involvement will be announced on the NCCAM Web site.

Communications Update
Dr. Straus noted recent achievements of the Office of Communications and Public Liaison under Chris Thomsen’s leadership. In April 2004, NCCAM received 4 of the roughly 50 awards given by the NIH Director across NIH for plain language. Appreciating the advantages of communicating clearly to the public about CAM research, NCCAM has made it a priority to use plain language. NCCAM also recently received several Blue Pencil Awards from the National Association of Government Communicators. In addition, NCCAM was recognized in a report entitled “Enhancing Public Input and Transparency in the National Institutes of Health Research Priority-Setting Process,” produced by the NIH Council of Public Representatives (COPR), a Federal advisory committee comprising members of the public. NCCAM also received two of the four awards that COPR presented to NIH Directors last week for activities that represented exemplary ways of interacting with the public. Dr. Straus noted that these awards recognize the strong outreach NCCAM is making to seek input regarding its strategic goals.

NCCAM’s Second 5-Year Strategic Plan
Dr. Straus briefed the Council on progress in its strategic planning efforts. NCCAM plans to maintain its current overall vision and strategies but will revise plans based on a review of its progress to date. NCCAM can now prioritize investments with far greater specificity to achieve maximum success and impact.

Strategic planning activities included a staff retreat on February 11, 2004, followed by a meeting with an expert group of consultants. Two national stakeholder forums were held—one in Bethesda, Maryland, on March 22, 2004, and another in Seattle, Washington, on April 19, 2004. A 2-day retreat was held on May 23-25, 2004, in Hunt Valley, Maryland, to develop plan specifics. NCCAM intends to complete a first draft of its strategic plan by September 10, 2004, Council meeting and to incorporate public comments on the plan in time for the January 28, 2005, Council meeting.
In response to a question on how NCCAM is addressing budget challenges in the strategic plan while maintaining its key goals, Dr. Straus stated that this year’s budget is approximately $117 million. The strategic plan does not allocate budget dollars, but rather addresses the priorities in which NCCAM will invest. NCCAM may need to fund some initiatives at a lower level and may explore additional funding sources. Dr. Straus noted that this is a very time-consuming and complex process. He emphasized that despite this challenge, NCCAM’s leadership will do its best to steward the Center’s resources and will ask Council for help in setting priorities.

Dr. Straus announced to Council members that their annual photographs would be taken during the break.

IV. Update on Co-Sponsorship of Program Announcements

Dr. Margaret Chesney briefed the Council on several grants that other groups in NIH have initiated and that NCCAM has agreed to support.

Trans-NIH Obesity Initiatives
In all trans-NIH obesity initiatives, NCCAM is interested in CAM approaches to weight maintenance and the prevention and treatment of overweight or obesity. Initiatives noted are as follows.

- The Prevention and Treatment of Pediatric Obesity in Primary Care Settings initiative supports development of methods to prevent or treat childhood obesity, including CAM approaches to this research area.

- The Neurologic Basis of Human Obesity initiative supports multidisciplinary programs focusing on understanding the biological basis of eating behavior. Dr. Chesney noted that NCCAM is interested in supporting research on CAM-related mind-body studies on stress and its possible impact on eating behaviors.

- Ancillary Studies to Obesity-Related Clinical Trials (R01) will include CAM-related research questions that can be added to ongoing trials sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases and NIA.

Trans-NIH Mind-Body Initiatives
NCCAM has been involved in three trans-NIH mind-body initiatives. Approximately 18 months ago, the Office of Behavioral and Social Sciences Research (OBSSR) assembled program officers from throughout NIH and developed the following research initiatives.

- The Exploratory/Developmental Research Program (R21), funded by OBSSR, supports the infrastructure and exploratory and developmental programs at institutions that have high potential for advancing mind-body and health research but that lack the resources needed to qualify for larger awards.
The Research on Mind-Body Interactions and Health (R01) initiative encourages interdisciplinary collaboration and innovation toward understanding the processes underlying mind-body interactions and health and collaborations to apply such basic knowledge to interventions and clinical practice. This initiative will involve NCCAM funding.

The Research Infrastructure Program (R24) supports infrastructure development and fosters innovative studies designed to enhance the quality and quantity of mind-body and health research and to develop new research capabilities to advance this area of research. This program aims to facilitate interdisciplinary collaboration. These grants will be fully funded by OBSSR.

Initiatives with the National Cancer Institute
NCCAM often partners with the National Cancer Institute (NCI) on CAM. Dr. Chesney briefly noted several collaborative initiatives for which NCI is the lead agency, as follows.

- The Developmental Projects in Complementary Approaches to Cancer Care (R21) initiative supports research on the safety, efficacy, and mechanisms of action of CAM approaches to preventing and treating cancer, its symptoms, and the side effects of conventional therapies.

- NCI invited NCCAM to participate in its Clinical Cancer Therapy and Prevention Research (R01) initiative, which supports innovative clinical trials and related laboratory studies intended to develop insights into cancer biology and new approaches to preventing and treating cancer.

- The Pathogenesis and Treatment of Lymphedema and Lymphatic Diseases (R01) program supports research on CAM treatments for primary and secondary lymphedema.

Dr. Chesney noted that these trans-NIH initiatives increase NCCAM’s visibility, provide opportunities for the Center’s researchers to collaborate with other NIH investigators, and help integrate NCCAM into NIH initiatives.

V. Overview of National Center for Health Statistics
Dr. Straus introduced Dr. Jennifer Madans, Associate Director for Science at CDC’s National Center for Health Statistics (NCHS), and noted that NCCAM’s collaboration with CDC is trans-agency collaboration at its best. The Council approved this collaboration 3 years ago.

Dr. Madans provided an overview of NCHS. The NCHS mission is to provide statistical information that will guide actions and policies to improve the health of people in the United States. NCHS monitors trends and disparities in health status, health care utilization, health behaviors, and risk factors. It also pioneers development of new
methodologies for collecting and analyzing data, evaluating data quality, and disseminating information. The data are used to make comparisons across populations, providers, and geographic areas; identify health problems, risk factors, and disease patterns; and plan or assess public health programs.

In addition, Dr. Madans described the major data programs—Vital Statistics; Population Health, which includes the National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey; and Health Care Systems, which includes the National Health Care Survey—and their data sources, sampling techniques, and data applications. The sample and content design of the NHIS, a very large population-based survey, is generally constant; however, supplemental modules on various topics can be added for one or two years of data collection. An advantage of supplemental modules is that they can be used to analyze specific health status issues, such as chronic disease rates, utilization of health care services, health insurance and access to care, health behaviors and risk factors, and sociodemographic and socioeconomic variables.

Dr. Madans also discussed some of the challenges and opportunities for NCHS data-collection systems, such as the need for rapid, high-quality vital statistics with updated content; a robust NHIS redesigned to better reflect population shifts; expanded coverage of emerging health care providers; and more regular collection of data on health care delivery systems. NCHS is in the midst of a reengineering campaign to update all of its data-collection and date-dissemination systems. In discussing data dissemination, Dr. Madans noted that NCHS releases as much data as possible for public use through its Web site and other media. Further, the NCHS Research Data Center provides a mechanism for researchers to access data not usually released to the public because of confidentiality. Specialized resources on the NCHS Web site include “Data Warehouse on Trends in Health and Aging” and “Healthy Women: State Trends in Health and Mortality.”

Dr. Straus thanked Dr. Madans and asked for questions, if any, on the NHIS. Members asked about collecting data on specific neighborhoods and on special populations, such as institutionalized people, migrant workers, and illegal immigrants. Dr. Madans noted that although NCHS usually surveys households, some surveys include nursing home residents. She noted difficulties in finding illegal immigrants and homeless people.

VI. Introduction to the CAM Supplement of the 2002 National Health Interview Survey

Dr. Morgan Jackson, Chief of NCCAM’s Office of Special Populations, discussed the CAM supplement of the 2002 NHIS. He noted that prior to that year’s survey, limited information was available on CAM use in racial and ethnic minority populations. To address this knowledge gap, the Council approved an RFA, and NCCAM and NCHS developed the supplemental CAM module administered with the 2002 NHIS. Dr. Jackson noted that characteristics of the NHIS offered NCCAM several advantages in its use. For example, the NHIS involves a national probability sample of households and oversamples Hispanic-American and African-American households.
Dr. Jackson briefly outlined the process of developing the CAM supplement. Working within an accelerated timeline, NCCAM convened two panels—a design panel of survey researchers, CAM survey experts, and Federal representatives and a validation panel of consultants with CAM knowledge and survey experience in target communities to address face validity and cultural sensitivity. Both panels reviewed the draft survey, which then went through cognitive testing at the NCHS laboratory and was submitted to the Office of Management and Budget and to an Institutional Review Board for clearances.

Further, Dr. Jackson noted that the survey has provided a wealth of information and recently was discussed on the front page of the *Washington Post*. He also stated that through its initiative, PAR-03-102: Secondary Analysis of Data on CAM Use in Minority Populations, which solicits research projects to analyze existing data sets, NCCAM has funded four projects to analyze data from the NHIS and anticipates funding additional analyses of CAM data from the NHIS supplement.

VII. Summary of CDC Advanced Data Report: CAM Module

Ms. Patricia Barnes, statistician at the NCHS, provided a summary of the 2002 NHIS report, noting that the survey collected CAM information on a subset of 31,044 people representing the civilian, noninstitutionalized U.S. adult population. The report provides descriptive statistics for 27 CAM therapies, including categories such as “ever used” and “used in the past 12 months,” most frequently used natural products, health problems or conditions treated with CAM, use of CAM by selected groups, and reasons for CAM use. Results showed that approximately 75 percent of adults in the United States have “ever used” CAM if prayer were included in the statistics; if prayer were excluded, the percentage dropped to approximately 50 percent of those surveyed.

Ms. Barnes noted the most commonly used CAM therapies (prayer, followed by use of natural products), the most commonly used natural products (echinacea), and the health problems or conditions most commonly treated with CAM (back pain). Other significant findings about CAM use:

- Women were more likely than men to use CAM.
- When prayer was included in the definition of CAM, older adults were more likely to use CAM than younger adults.
- When prayer was included in the definition of CAM, African-American adults (71 percent) were more likely than Asian-American adults (62 percent) or White adults (60 percent) to use CAM; when prayer was excluded, CAM use was more likely among Asian-American adults (43 percent) than White adults (36 percent) or African-American adults (26 percent).
- When prayer was excluded from the definition, non-Hispanic adults were more likely than Hispanic adults to use CAM; no difference emerged when prayer was included.
- CAM use increased with education level and income level when prayer was excluded from the definition.
Regional differences emerged when prayer was *included* in the definition of CAM, with use highest in the South (65 percent) and lowest in the Northeast (58 percent).

When prayer was *excluded*, CAM use was highest in the West (42 percent) and lowest in the South (30 percent).

Former adult smokers were more likely to use CAM than current adult smokers or adults who had never smoked.

Ms. Barnes also discussed reasons survey participants cited for using CAM and some survey limitations and strengths. She noted that adding a CAM supplement to the NHIS would enable researchers to track trends of CAM use.

Dr. Straus thanked Ms. Barnes for her presentation and invited questions from Council members.

**VIII. Discussion**

Dr. Straus clarified the issue of prayer inclusion/exclusion by noting that there are many cultures in which CAM includes prayer. The idea was not to specifically label prayer as CAM, although there are CAM prayer approaches. For example, NCCAM currently supports research to examine health outcomes for people who have been prayed for by others. Dr. Murray Goldstein commented on the overwhelming potential impact of spirituality as demonstrated in the data. He remarked that although spirituality tends to be dismissed in the field of biomedicine, its study should fall within NCCAM’s mission.

Dr. Chesney added that spirituality is widely practiced and thus requires scientific scrutiny. She noted that behavioral scientists are already asking questions that go beyond denominational issues to address the belief in a higher power or a higher purpose in life. Studies are beginning to show that spirituality is associated with very important biological outcomes. In its strategic planning, NCCAM is considering spirituality as part of the mind-body connection and its importance to the public. Dr. Chesney cited examples in which scientists are studying ways of measuring spirituality, including measures that describe disease progression. She noted that this research will yield data on spirituality and the progression of HIV/AIDS.

In response to a question on deciding to exclude traditional Chinese medicine (TCM) as a CAM category, Dr. Richard Nahin, NCCAM’s Senior Advisor for Scientific Coordination and Outreach, noted that the initial draft of the supplement was based on a compilation of already published surveys. Because the survey had to be administered in 10 minutes, the questions used were those that did not require lengthy explanations. Dr. Jackson added that the survey included acupuncture as an example of a TCM component.

Dr. Tieraona Low Dog suggested that ragweed and chamomile be listed as two separate plants, not together, under natural products. Dr. Chesney replied that NCCAM would look into the issue more closely.
Dr. Straus discussed the potential value of longitudinal surveys and whether it would be appropriate to refine the survey and conduct it in 5-year intervals. This will be discussed in deliberations for the FY 2006 budget. He also mentioned that these surveys are very expensive and that rapid fluxes in the use of CAM therapies mean that results do not always reflect current usage. As an example, Dr. Straus noted the media’s response to NCCAM’s press releases about the survey, in which media members noted their surprise that despite the current popularity of the Atkins diet, the 2002 survey found only 4 percent of those surveyed reported use of such diets.

Dr. Nahin responded to questions on which conditions triggered participants’ use of specific CAM therapies and the length of that use. He noted that the survey asked participants whether they continued to use the CAM therapies past the first year, a question that helps determine if they are continuing to use the therapies. For each type of therapy, people were asked about three primary conditions for which they used the therapy and whether the therapy was effective in treating the condition. Dr. Nahin agreed that it would be useful to add more time variables to the survey.

Responding to a question on collecting information on adverse reactions, Dr. Jackson commented that people have different perceptions of what constitutes an adverse event based on whether an event is the result of a conventional therapy or a CAM therapy. For example, people might consider a rash or nausea to be an adverse event if they are using CAM, whereas they tend to consider only more serious side effects as adverse events when using conventional medicine.

The Council expressed appreciation for having an opportunity to hear the survey results.

IX. General Discussion

On the issue of CAM grant applications and the level of CAM expertise of the reviewers in study sections convened by CSR, Dr. Straus remarked that although CAM is a new discipline, NCCAM has gone to great lengths to seek out individuals with CAM expertise. Dr. Martin Goldrosen, Chief of NCCAM’s Office of Scientific Review (OSR), elaborated on the approach that NCCAM has taken to ensure CAM expertise on review panels. He mentioned a database used by Scientific Review Administrators (SRAs) that includes a component identifying a reviewer’s expertise. Dr. Goldrosen noted that in the past 3 years, NCCAM has identified at least 250 individuals with expertise in the various areas of CAM research. NCCAM program staff members also interact with the SRAs to share information and expertise on their specialty areas. The overall success rate of the R01s reviewed by CSR is essentially the same as that of grants reviewed by NCCAM’s OSR. Regarding natural products, Dr. Straus mentioned that NCCAM has provided CSR with written guidelines for evaluating natural product research proposals.

Some R01 grants may rank low on raw score but high on percentile. Dr. Straus commented that NCCAM uses percentile information to help identify those grants that bring high-quality research approaches to the study of CAM. In the past year, one of the
factors for considering a grant beyond the payline for funding was the percentile information.

Council members discussed descriptive observational studies, looking at questions such as: What do naturopaths do? What do herbalists do? What kinds of CAM are they prescribing? What mix of activities do chiropractors have in their practices? What else do massage therapists do besides massage therapy? Dr. Straus noted that NCCAM’s strategic planning retreat in May 2004 included a workshop on health services research that addressed this issue. After discussion on the mix of basic biomedical research versus descriptive observational and clinical research, there was general consensus that a prioritized balance of basic research and observational/clinical studies is needed.

X. Public Comment Session

Mr. Lundstad commented that insurance companies could support people in dealing with their feelings about being diagnosed with a chronic or terminal illness. He suggested that front-end counseling should be provided as a standard part of delivering a diagnosis. Dr. Straus thanked Mr. Lundstad for his cogent and sensitive comments.

Dr. Straus adjourned the meeting at 3:40 p.m.