

**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 NINETEENTH MEETING  
January 28, 2005**

*NACCAM Members Present*

Dr. Carlo Calabrese, Portland, OR  
\*Dr. John H. Cardellina II, Frederick, MD  
Dr. Kristina Collins, McLean, VA  
Dr. Deborah J. Cotton, West Roxbury, MA  
Dr. Gerald Cross, Washington, DC  
\*Dr. Roderick H. Dashwood, Corvallis, OR  
Dr. Jonathan Davidson, Durham, NC  
Dr. Jeanette Ezzo, Takoma Park, MD  
Dr. Robert E. Fullilove, New York, NY  
Dr. Murray Goldstein, Washington, DC  
Dr. Leslie Hillis, Dallas, TX  
Dr. Michael Irwin, Los Angeles, CA  
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. Gerald Shulman, New Haven, CT  
\*Dr. Shivendra V. Singh, Pittsburgh, PA  
Dr. Barbara Timmerman, Tucson, AZ  
\*Dr. Stefanie N. Vogel, Baltimore, MD  
Dr. Benjamin Yang, San Francisco, CA

\*Ad hoc members

*NACCAM Members Absent*

Dr. Zang-Hee Cho, Irvine, CA  
Dr. Haile Debas, San Francisco, CA  
Dr. Larry Walker, University, MS

*NIH Staff Present*

*National Center for Complementary and Alternative Medicine*

Ms. Sandra Addae  
Ms. Willer Batten  
Dr. Josh Berman  
Dr. Dale Birkle

Dr. Marc Blackman  
Ms. Shea Buckman  
Ms. Debra Campbell  
Dr. Craig Carlson  
Mr. Steve Casady  
Dr. Margaret Chesney, Deputy Director  
Ms. Alyssa Cotler  
Dr. Laurie Donze  
Ms. Karla Ehrler  
Ms. Linda Engel  
Ms. Carol Fitzpatrick  
Ms. Anne Frost  
Dr. Martin Goldrosen  
Mr. Kevin Green  
Ms. Camille Hoover  
Ms. Jeanette Hosseini  
Dr. Morgan Jackson  
Ms. Deborah Jennings  
Dr. Laura Johnson  
Mr. Roald Keith  
Dr. Jack Killen  
Dr. Jane Kinsel  
Ms. Robin Klevins  
Mr. Peter Kozel

Ms. Catherine Law  
Ms. Irene Liu  
Dr. Qi-Ying Liu  
Dr. Patrick Mansky  
Ms. Genevieve Medley  
Dr. Heather Miller  
Ms. Ilze Mohseni  
Ms. Barbara Moquin  
Dr. Richard Nahin  
Ms. Ellen O'Donnell  
Dr. Nancy Pearson  
Dr. Carol Pontzer  
Ms. Linda Rich  
Ms. Alice Robinson  
Ms. Denise Simmonds-Barnes  
Ms. Kathleen Stephan  
Dr. Catherine Stoney  
Dr. Stephen Straus, Director  
Ms. Jennifer Sutton  
Ms. Chris Thomsen  
Mr. George Tucker  
Ms. Shirley Villone  
Dr. Shan Wong  
Ms. Angie Wongsam-Nollinger

*Other NIH Employees*

Dr. Wendy Smith, National Cancer Institute  
Dr. Christine Swanson, Office of Dietary Supplements

*Members of the Public*

Dr. Stuart Bondurant  
Dr. John Chah  
Dr. Christine Goertz  
Dr. Wayne Jonas  
Ms. Suzanne Niemeyer  
Dr. Georgia Persinos  
Dr. Mary Ann Richardson

**I. Closed Session**

The first portion of the 19th 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 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 248 applications were assigned to NCCAM. Of these, 201 were reviewed by NCCAM, 44 by the Center for Scientific Review, and 3 by another institute. 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 5 applications and concurred on 157 applications requesting \$49,285,156 in total costs.

## **II. Open Session—Call to Order**

The open session of the NACCAM meeting convened at 12:30 p.m. Dr. Stephen E. Straus, Director of the National Center for Complementary and Alternative Medicine (NCCAM), thanked NCCAM staff and Council members for their participation.

Dr. Straus introduced Dr. L. David Hillis, who was joining Council for his first meeting since his appointment as a member. He also introduced and thanked Dr. John H. Cardellina II, Dr. Roderick H. Dashwood, Dr. Gerald Shulman, Dr. Shivendra V. Singh, and Dr. Stefanie N. Vogel, who joined the meeting as ad hoc Council members.

### **III. Sixth Annual State of the Center Report**

Dr. Straus presented the sixth annual State of the Center Report, which focused on NCCAM's appropriations and budget, extramural research portfolio, training and career portfolio, intramural research program, communications and outreach, and future directions.

#### **Appropriations and Budget**

Dr. Straus updated Council on NCCAM's appropriations and budget. He noted that the fiscal year (FY) 2005 Federal budget allocated \$123.1 million for NCCAM, out of a total National Institutes of Health (NIH) budget of \$28.6 billion. After rescissions and other reductions, NCCAM's net budget is \$122.1 million.

Providing an overview of NCCAM's appropriations history, Dr. Straus noted that NCCAM's funding is robust, but that growth is flattening, reflecting an NIH-wide trend. He emphasized that NCCAM's budget offers tremendous opportunities to advance complementary and alternative medicine (CAM) research.

NCCAM has invested its appropriations according to principles articulated in the Center's first strategic plan: to build a CAM infrastructure through the research centers program and to emphasize investigator-initiated research project grants. The centers program was built early in NCCAM's evolution and remains strong. NCCAM has now stabilized funding for the centers based on careful analysis and a thoughtful review of the program; investments in investigator-initiated grants have increased six-fold since 1999.

Dr. Straus placed NCCAM's budgetary trends in the larger context of the NIH environment. NIH funding, which increased 14 to 17 percent annually from 1999 through 2003, will increase 2 to 5 percent annually for the foreseeable future. For almost a decade, NCCAM and its predecessor, the Office of Alternative Medicine, had much higher annual funding percentage increases than did NIH as a whole; the Center and NIH are now experiencing approximately the same growth rates.

#### **Extramural Research Portfolio**

##### *Budgetary Environment*

One way to understand how the budgetary environment affects NCCAM's research is to look at success rates—the percentage of new research grant applications the Center is able to fund each year over the number of grant applications received. NCCAM's success rate decreased as its budget increased because the number of applications grew more than seven-fold from 1999 to 2004. NCCAM has funded an increasing but stabilizing number of new awards.

Diligent management of NCCAM's portfolio increased the success rate from 14 percent in 2002 and 2003 to 17 percent in 2004. Despite this improvement, NCCAM's success rate remains among the lowest of the NIH institutes and centers (ICs).

### *Goals and Priorities*

Dr. Straus outlined how NCCAM has fulfilled many of the research goals set out in its first strategic plan. He noted that, starting essentially from scratch, NCCAM has built the basis for a CAM research enterprise; invested increasingly in rigorous preclinical and clinical studies, particularly in areas of the greatest importance to public health; and actively sought out and acted on lessons learned.

Among the lessons learned was the need to find out who is using CAM, and how, and to use this information to identify research priorities. NCCAM partnered with the Centers for Disease Control and Prevention to ask 31,000 American adults about CAM use as part of the 2002 National Health Interview Survey (NHIS).<sup>1</sup> Results indicated that 62 percent had used CAM in the past year when the definition of CAM included prayer; the top CAM modality when prayer was excluded was natural products, used by 19 percent of respondents. More women than men used CAM, and CAM use was higher among those with higher educations, serious health conditions, and more pain.

Informed by the results of the 2002 NHIS and earlier surveys, NCCAM identified cancer, the neurosciences, musculoskeletal disorders, cardiovascular disease, women's health, and aging as areas for major research investment.

Dr. Straus presented an update on the phase III clinical trials NCCAM is funding. Recruitment is complete for studies of glucosamine/chondroitin for arthritis, *Ginkgo biloba* for dementia, and vitamin E and selenium for prostate cancer prevention. Recruitment is under way for trials of shark cartilage for lung cancer; chelation therapy for coronary artery disease; St. John's wort for minor depression; vitamin E for Down syndrome; phytoestrogens for arteriosclerosis; SAME for depression; and acupuncture for low-back pain. Nearly all major phase III studies are cosponsored with other ICs. Dr. Straus noted the importance of NCCAM's ability to leverage both expertise and funds through such partnerships.

Dr. Straus then commented on the recently released results of an NCCAM-funded phase III trial of acupuncture for osteoarthritis (OA) of the knee. Led by Dr. Brian Berman, the trial is the largest, longest, and most rigorous study of acupuncture to date. It demonstrated that acupuncture significantly reduces pain and improves function in people with knee OA and showed acupuncture to be an effective complement to standard care. Dr. Straus pointed to Dr. Berman's successful approach in initiating his research with early-phase studies and then moving to a phase III clinical trial.

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<sup>1</sup> Barnes P, Powell-Griner E, McFann K, Nahin R. *CDC Advance Data Report #343*. Complementary and Alternative Medicine Use Among Adults: United States, 2002. May 27, 2004.

Looking ahead to FY 2006, Dr. Straus outlined specific research priorities: the phase III trial currently under way of *Ginkgo biloba* for dementia; early-phase studies of milk thistle for liver disease; and development of metrics in order to study alternatives to hormone therapy for women.

The *Ginkgo biloba* trial seeks to determine whether using the herb decreases the incidence of dementia, especially Alzheimer's disease. More than 3,000 people are taking part in the study. Cosponsoring the study with NCCAM are the National Institute on Aging (NIA); the National Heart, Lung, and Blood Institute; and the National Institute of Neurological Disorders and Stroke. Dr. Straus noted that, no matter what the findings about *Ginkgo*, the trial will make important contributions to our understanding of the natural history of Alzheimer's disease through its use of neuropsychological imaging and analysis of risk factors.

Milk thistle is widely used for liver diseases, including hepatitis C, cirrhosis, and nonalcoholic hepatosteatosis. In partnership with the National Institute of Diabetes and Digestive and Kidney Diseases, NCCAM crafted a phased approach to milk thistle research. A Small Business Innovation Research (SBIR) grant was used to support the development of a standardized product for clinical trials. The next steps include studying basic mechanisms and conducting early-phase trials. Results from these trials will determine whether research should proceed to phase III studies.

NCCAM supports various research on CAM therapies for hot flashes and other menopausal symptoms. In January 2004, the Center convened a workshop to assess existing tools for measuring hot flashes. Then, in conjunction with NIA, the National Institute of Biomedical Imaging and Engineering, and the Office for Research on Women's Health, NCCAM issued an RFA for SBIR funding to improve objective measures of hot flashes. In addition, the Center and NIA are cosponsoring a March 2005 state-of-the-science conference on managing the menopausal transition. With this groundwork in place, NCCAM will be in a position to consider sponsoring clinical trials in the coming years.

NCCAM is also active in major trans-NIH initiatives that address crosscutting public health concerns and research issues. These include OA and obesity initiatives, the Neuroscience Blueprint, and the NIH Roadmap for Medical Research. Dr. Straus noted that NCCAM stands to benefit substantially from the Roadmap's focus on advancing interdisciplinary research.

Dr. Straus concluded his comments on extramural research by noting the lessons NCCAM has learned about the challenges of CAM research in its first 6 years. These include the need to address complex methodological issues. For example, some NCCAM research began based on what Dr. Straus termed "assumptions" about product quality and optimal dosages and delivery practices. The risk this carries, he explained, is that therapies may be prematurely declared unsafe or ineffective if such issues are not addressed before conducting large-scale research into safety and efficacy. Another lesson

learned is that funding mechanisms must be commensurate with the emerging state of the CAM research community.

### **Training and Career Portfolio**

Dr. Straus reported that NCCAM has steadily increased funding for both research training and career development. He explained that the growth of NCCAM's investment has been predicated on lessons learned about CAM research training and career development. Challenges identified over the past 6 years include the limited number of qualified CAM researchers and seasoned research mentors and a lack of research infrastructure and culture at CAM institutions.

One way NCCAM assists new CAM researchers is by participating in the NIH Loan Repayment Program, which repays past educational debt, allowing interested individuals to continue to pursue research training and careers in research. Dr. Straus noted that both CAM- and conventionally trained investigators are participating in the program.

To help strengthen its training and career programs, NCCAM convened an expert panel to evaluate them. Dr. Straus noted that the panel's report would be presented later in the day and that NCCAM has already embarked on course corrections. Based on the panel's recommendations, NCCAM has crafted concepts for two new initiatives—a research training award targeted for CAM practitioners and a postdoctoral career development award—also to be presented later.

### **Intramural Research Program**

Dr. Straus spoke about NCCAM's Division of Intramural Research, which grew rapidly during the first few years, although its funding was less than 4 percent of the entire research budget. Its growth then plateaued for a variety of reasons as NCCAM examined lessons learned and sought guidance in addressing them. The current major areas of emphasis for intramural research are endocrine/metabolic conditions, cancer, and pain.

Dr. Marc Blackman stepped down as the Division's director several months ago to concentrate on his own research. Dr. Robert Nussenblatt from the National Eye Institute has been appointed Acting Scientific Director of the Division, pending the initiation of a national search for a new Scientific-Clinical Director to lead major efforts in the CAM-related neurosciences, including neuropharmacology, neuroimmunology, imaging, and mind-body medicine. Dr. Straus noted that the acquisition of major new space in the last 6 months has made this programmatic growth feasible.

### **Communications and Outreach**

Dr. Straus provided a snapshot of the achievements of NCCAM's Office of Communications and Public Liaison (OCPL). During FY 2004, 1.3 million individual users accessed NCCAM's Web site. The Center's clearinghouse responded to 15,000 public inquiries, and OCPL fielded nearly 600 media inquiries. The Office expanded its

quarterly newsletter from four pages to eight. It also organized two national stakeholder forums, two live Web chats with the cancer community, a teleconference, and exhibits at more than 20 professional meetings.

Dr. Straus also remarked on the awards that OCPL won in the past year, including NIH communication awards, Blue Pencil awards from the National Association of Government Communicators, and a “Best of the Web” citation from *Prevention* magazine. Initiatives for 2005 include an “Herbs at a Glance” fact sheet series that provides concise information on herbal supplements, as well as a Web-based CAM continuing education center.

### **Future Directions**

To chart its future directions, NCCAM embarked on developing a second strategic plan 17 months ago. Dr. Straus delineated the principles that guided the plan’s development: NCCAM would maintain its current strategic areas; continue to review and critique progress to date; revise directions according to lessons learned; craft a plan that outlined more specific goals and objectives than did the first plan; and prioritize investments by targeting opportunities that offer the greatest success and public health impact.

Steps in the process included reviewing NCCAM’s history and portfolio; engaging NCCAM staff, NIH colleagues, Council members, grantees, and professional and lay stakeholders in retreats, think tanks, and public forums; and releasing drafts of the plan for staff, Council, and public comment.

Dr. Straus announced that the final version of NCCAM’s second 5-year strategic plan, *Expanding Horizons of Health Care: Strategic Plan 2005–2009*, was released on the day of the Council meeting. The new plan prioritizes investments and sets master health goals that include enhancing health and wellness, managing pain and other symptoms and disabilities, impacting the treatment and prevention of important public health conditions, and reducing health problems among specific populations. It also calls for NCCAM to increase basic research and to continue to leverage opportunities to partner and collaborate.

The plan outlines four strategic areas:

1. *Investing in Research* encompasses mind-body medicine; biologically based practices; manipulative and body-based practices; energy medicine; whole medical systems; international health research; health services research; and the ethical, legal, and social implications of CAM research and integrated medicine.
2. *Training CAM Investigators* involves tailoring NCCAM’s programs to reflect evolving needs, fostering a culture of research, and providing resources to build careers in CAM research.

3. *Expanding Outreach* entails translating the fruits of CAM research for the public and for health care professionals, so that they can make informed decisions about CAM, as well as enriching the pool of CAM researchers.
4. *Advancing Our Organization* includes promoting organizational growth, encouraging and empowering staff, and providing effective management.

Dr. Straus pointed to parallels between NCCAM's new strategic plan and the recently released recommendations of the Institute of Medicine (IOM) report, *Complementary and Alternative Medicine in the United States*, to be presented later in the meeting.

In conclusion, Dr. Straus reiterated that NCCAM's vision for the future is to further the scientific investigation of CAM, enhance the credibility of CAM research, and ultimately improve public health.

#### **IV. Report of the Institute of Medicine**

Dr. Margaret Chesney, Deputy Director, NCCAM, introduced Dr. Stuart Bondurant, chair of the committee that produced *Complementary and Alternative Medicine in the United States*. Released on January 12, 2005, this IOM report was commissioned by NCCAM, 16 other NIH ICs, and the Agency for Healthcare Research and Quality to address a wide range of CAM science, policy, and practice issues.

Dr. Bondurant commended IOM staff for their efforts on the report and noted that his presentation would largely be a reprise of Dr. Straus's earlier remarks on NCCAM's research priorities and directions. He provided an overview of the report's development, which included a survey of the scientific literature, a series of public meetings, and the creation of a liaison group of approximately 30 leaders in the CAM community who met with the IOM committee.

Dr. Bondurant then outlined the report's objectives:

- To describe the use of CAM therapies by the American public and to provide a comprehensive overview of the therapies in use, the populations using them, and how these therapies are provided;
- To identify major scientific, policy, and practice issues on CAM research and the translation of validated therapies into conventional medical practice; and
- To develop conceptual models or frameworks to guide public- and private-sector decisionmaking as research and practice communities confront the challenges of conducting CAM research, translating research findings into practice, and addressing distinct policy and practice barriers inherent in that translation.

Patients, health professionals, and public officials need evidence of efficacy, safety, and cost-effectiveness to make informed decisions about all health care inventions, including CAM. Dr. Bondurant commented that the report's most fundamental recommendation is that consistent principles and standards be used to evaluate all medical treatments,

whether conventional or CAM. He noted that implementing this recommendation requires that investigators develop and use common methods, measures, and standards to generate and interpret the evidence needed for patients and practitioners to make informed decisions about the use of CAM and conventional therapies.

### **Dietary Supplements**

The use of dietary supplements is widespread and increasing, and research requires the availability of consistent, standardized, and safe products. Because the current regulatory framework does not result in consistent and standardized products, however, it is not possible to assess benefit or harm. The IOM committee recommended that Congress amend the Dietary Supplement Health and Education Act and the current regulatory framework to strengthen quality-control measures, ensure accuracy and comprehensiveness in labeling and other disclosures, aid enforcement against inaccurate and misleading claims, conduct research in consumers' use of supplements and product efficacy, and augment consumer protections.

### **Research Challenges**

Dr. Bondurant reviewed CAM research challenges, specifically a lack of basic science research, research on treatment costs and cost-effectiveness, practice-based research, and systems to reconcile CAM and conventional diagnoses. He also noted the lack of experienced CAM scientists and junior researchers. The IOM committee recommended that NIH and other public agencies develop and implement a sentinel surveillance system, practice-based research networks, and CAM research centers, such as those that NCCAM already has in place. Questions relevant to CAM should be included on federally funded health care surveys. In addition, periodic comprehensive national surveys should be carried out to assess changes in patterns, perceptions, costs, and prevalence of CAM and conventional therapies, with oversampling of ethnic minorities. Understanding exactly how the American public is using CAM therapies will facilitate finding better ways to test these therapies.

### **Gaps in Knowledge About CAM Use**

Too little is known about how CAM use is initiated, motivations for use, how the public obtains CAM information, and whether CAM use triggers positive changes in health behaviors. The committee recommended that NIH and other public agencies conduct quantitative and qualitative research on the social and cultural dimensions of the illness experience, patients' and practitioners' adherence to treatment guidelines, practitioner-patient interactions, CAM's effects on health and wellness, and adverse events associated with CAM use. Concerned about the quality of CAM information available to the public, the IOM committee also recommended research on how the public accesses and evaluates CAM information and suggested that the National Library of Medicine and other Federal entities develop criteria to assess the quality and reliability of such information. Dr. Bondurant noted that NCCAM has already taken steps in this direction.

## **Comprehensive Integrated Health Care**

The IOM committee determined that comprehensive health care should include access to both conventional care and CAM. Several recommendations focused on the need for research to compare costs and outcomes in integrated models of health care delivery, especially by Federal agencies such as the Department of Health and Human Services and the Department of Veterans Affairs. Information on CAM should be integrated into the curricula of health professional schools at all levels, so that licensed professionals can competently advise their patients about CAM. Models of research training for CAM practitioners should be created. In addition, training standards and practice guidelines should be available in all CAM disciplines, with licensing boards and certifying agencies articulating competency standards on the use of conventional medicine and CAM, consistent with practitioners' scope of practice.

### **Summary**

Dr. Bondurant summarized his remarks by noting the American public's widespread use of CAM. He reiterated that the same rules should apply for testing a therapy's effectiveness and safety, whether it is a CAM or a conventional therapy, and concluded that the ultimate goal should be the creation of a health care delivery system that is comprehensive, patient centered, evidence based, and cost effective.

### **V. Discussion of the IOM Report on CAM Use**

Dr. Chesney and Dr. Straus thanked Dr. Bondurant for sharing his expertise and time, and Dr. Straus opened the floor to questions from Council.

In response to a comment about building an infrastructure to provide CAM research training, Dr. Bondurant noted that the need for infrastructure in CAM institutions is especially great. Dr. Brian Berman, who also served on the IOM committee, added that establishing collaborations and partnerships between academic health centers and CAM institutions is particularly important.

One Council member commented that the review process for funding research remains focused on a medical-pharmaceutical model, which could adversely affect CAM-based research proposals. Dr. Bondurant noted that the IOM committee recommended that committees reviewing such proposals include CAM-competent reviewers.

Council also discussed the implications of an integrated model incorporating CAM and conventional practices, including concerns that a CAM practice could adversely affect conventional medical therapy. For example, megavitamin therapy could interfere with chemotherapy. The need for health care practitioners to have easy access to information about the potential complications of combining conventional and CAM therapies was discussed. Dr. Berman noted that the IOM report provides a vision of integrative health care that is focused on principles of compassionate and patient-centered care.

## **VI. Acupuncture as Adjunctive Therapy for Osteoarthritis of the Knee**

Dr. Straus introduced Dr. Brian Berman, principal investigator for an NCCAM-funded study on acupuncture for OA of the knee. Dr. Berman presented an overview of treatments for knee OA, earlier studies of acupuncture as an intervention, and the results of his recent multicenter, randomized, phase III clinical trial. Dr. Berman explained his phased approach to studying acupuncture for knee OA. He began with a phase I pilot study and then moved to a phase II randomized trial before progressing to a phase III trial. The phase III clinical trial sought to determine whether traditional Chinese acupuncture provided greater pain relief and improvement in function than does sham acupuncture or education in patients with OA of the knee.

A total of 570 participants, 50 years of age or older, received a 26-week course of therapy. Participants were assigned to one of three interventions: acupuncture, sham acupuncture, or a combination of educational materials and teaching. Participants in the study had moderate knee pain, were permitted to continue using nonsteroidal anti-inflammatory medications (NSAIDs), and had no prior experience of acupuncture. They could continue to take NSAIDs as needed during the study.

Primary outcome measures were changes from baseline in pain and function scores on the Western Ontario and McMaster Universities (WOMAC) OA index. Secondary outcomes included results of a patient global assessment, 6-minute walk distance, physical health scores on the 36-item Short-Form Health Survey (SF-36), and adverse effects. WOMAC pain and function scores improved significantly in the true acupuncture group, compared with the sham acupuncture and education groups. Participants receiving acupuncture also showed significantly greater improvement in patient global assessment scores than did participants receiving the sham treatment.

The study's strengths included a large sample size with adequate statistical power; use of valid, reliable, and quantifiable outcome measures; inclusion of a sham control group; blinding of assessors; and multiple analyses of data. Study limitations included the high attrition rate in the education control group and the possible unmasking of assignments to sham and acupuncture study arms.

Dr. Berman and colleagues concluded that traditional Chinese acupuncture is safe, well tolerated, and effective as a complement to standard therapy in reducing pain and improving physical function in patients with symptomatic knee OA that causes moderate or greater pain. The clinical implication is that acupuncture may have an important role as an adjunct therapy in an integrated approach to OA of the knee.

Through tracking study participants, Dr. Berman and team will examine 3-year data to evaluate long-term effects and perform a cost-benefit analysis. Also planned is a systematic review of acupuncture for knee OA and safety and efficacy studies of an herbal formula that might eventually be tested in conjunction with acupuncture.

Dr. Berman described details of the study design and methodology, including differences in how the true and sham acupuncture treatments were administered. He remarked that the need for methodological rigor precluded the study's acupuncturists from providing the individualized treatment typical of clinical practice.

Dr. Berman discussed potential biological mechanisms that could account for the effects of acupuncture on OA, including the possible role of neurochemicals. He noted that little evidence now exists that acupuncture has anti-inflammatory or disease-modifying effects.

A Council member pointed to potential difficulties with the use of acupuncture as a treatment, including the time commitment required and quality-control issues related to integration with conventional care. Dr. Berman observed that these represent challenges of translating research results into practice. Dr. Straus commented that metrics and standards for quality control and referral practices are crucial to successful integration of CAM and conventional therapies.

## **VII. Report of Expert Panel on Research Training**

Dr. Chesney introduced Dr. Charles Flexner, who presented the recommendations of the expert panel convened to evaluate NCCAM's research training programs. Dr. Flexner acknowledged the leadership of Dr. Donald Wilson, who chaired the expert panel but was unable to attend the Council meeting because of illness.

Dr. Flexner noted that the panel was asked to consider the following questions: (1) how can NCCAM best target its research resources; (2) how should NCCAM allocate its funds among different training levels (i.e., predoctoral, postdoctoral, junior faculty); and (3) what approaches are best for preparing specific groups of investigators for CAM research, such as clinical investigators, underrepresented minorities, and CAM practitioners. The panel considered comments and information from NCCAM-funded training program directors, NIH research training experts, site visit reports, and data on current NCCAM-funded investigators and programs.

Among NIH ICs, NCCAM ranks sixth in the percentage of funds that it devotes to research training and second in the percentage of funds it commits to career development. Among the Center's currently funded investigators, 44 percent hold Ph.D. degrees, 36 percent have M.D. degrees, 12 percent are M.D./Ph.D.s, and 4 percent have CAM or CAM/Ph.D. degrees. The leading fields of training for investigators with Ph.D.s are pharmacology and the pharmaceutical sciences, psychology, and physiology, which is consistent with NCCAM's research priorities.

The expert panel found that the major challenge to NCCAM's research training programs is the absence of an established CAM research infrastructure and culture.

## **Recommendations**

Dr. Flexner noted that, given the current lack of a CAM research infrastructure and culture, the panel believed that conventional academic biomedical institutions may be the best settings for most CAM research training, largely because of their existing research capabilities. But even established CAM research training programs should maximize their infrastructure and resources to be most effective.

The panel also urged that NCCAM continue to train researchers from both CAM and conventional biomedical backgrounds. The Center should maintain its current distribution of research training support, continuing to place a greater emphasis on postdoctoral training and career development for junior faculty.

Panel members suggested that NCCAM continue to split its research training resources between fields that other NIH ICs and centers are unlikely to address (e.g., pharmacognosy) and more conventional fields of biomedical research that are vital to CAM research (e.g., pharmacology). NCCAM should consider targeted awards for CAM practitioners, career transition awards for promising postdoctoral trainees, new approaches to attract minorities to CAM research, and increased support for research training and resource development.

Dr. Flexner concluded by noting that NCCAM's approach to training and career development is well suited to the field of CAM. In the years ahead, NCCAM should ensure that research training occurs in settings with active research programs and adequate resources and should continue to build a CAM research infrastructure and culture at both conventional and CAM institutions.

## **Discussion**

Dr. Chesney thanked Dr. Flexner for his presentation. She also thanked Ms. Jennifer Sutton, who leads NCCAM's evaluation program, and Dr. Nancy Pearson, who oversees the Center's research training and career development portfolio.

Council members made suggestions for increasing NCCAM's involvement in predoctoral-level research training. For example, they remarked that students' early participation in conventional or CAM fields could help increase the pool of future researchers and foster positive attitudes toward CAM research.

Dr. Straus observed that predoctoral students are among those NCCAM reaches through the funding it provides to 15 medical and nursing schools to develop model CAM curricula. Dr. Flexner noted that the NIH Office of the Director has issued an RFA for T32 funding for predoctoral clinical research training as part of its NIH Roadmap initiatives. Dr. Straus commented that Roadmap funding mechanisms for training are open to CAM researchers.

Dr. Chesney emphasized the need to be creative and flexible in reaching predoctoral students in a time of budget-tightening. She suggested looking for ways to leverage NCCAM's existing resources, noting that the Center could consider, for example, challenging its Centers of Excellence for Research on CAM to create opportunities for medical students to become involved.

### **VIII. Concepts for Research Training Initiatives**

Dr. Chesney introduced Dr. Nancy Pearson, NCCAM program officer, Division of Extramural Research and Training. Dr. Pearson remarked that some of the recommendations Dr. Flexner described could be implemented by strengthening NCCAM's existing programs, such as institutional training grants, which help build infrastructure for CAM research. The Center conducts an annual meeting with principal investigators on curriculum development grants and plans to publish guidelines for CAM curriculum development in professional schools based on these meetings. Dr. Pearson mentioned that NCCAM has established a new CAM curriculum development partnership grant to increase or improve the infrastructure of research training in schools training CAM practitioners.

Dr. Pearson then presented concepts for two initiatives for Council's consideration: targeted awards for CAM practitioners and career development awards for postdoctoral fellows. Both are designed to address gaps identified by the research training panel.

#### **CAM Practitioner Research Career Development Award**

Dr. Pearson explained that part of NCCAM's mission is to train CAM practitioners interested in pursuing a research career. However, CAM practitioners often have less opportunity than conventional medical practitioners to be involved in research during their clinical training. As a result, they are often less competitive for career development awards and other funding for postdoctoral trainees and newly independent research investigators.

The CAM Practitioner Research Career Development Award would provide up to 5 years of support for a CAM practitioner with a clinical doctorate who has never been a principal investigator on an NIH research, career, or fellowship grant. Funding would be through a mentored career development award mechanism (K01) and would provide salary, fringe benefits, and a research development fund. The award would provide the candidate with time to focus on broad research training under the guidance of a mentor at a conventional research-intensive institution who has experience training postdoctoral investigators and an interest in CAM research.

Because this award mechanism would be limited to CAM practitioners, it would give them a special opportunity to enter a biomedical research career-training track at the postdoctoral level by competing for a career development award by themselves. The goal is to equip trainees with the skills and knowledge needed to compete successfully for

grants with researchers trained in conventional medical settings. Dr. Pearson expects that fewer than five awards would be made per year.

### **NCCAM Career Transition Award**

Dr. Pearson noted that one of the most challenging transitions in any research career is that from postdoctoral trainee to independent scientist. For postdoctoral trainees conducting CAM research, this transition has added challenges because relatively few research institutions have CAM departments where they might seek positions.

The NCCAM Career Transition Award, using the K22 mechanism, would provide up to 3 years of support to an outstanding advanced trainee who has been conducting CAM research for at least 2 years at the postdoctoral level. The award would provide a salary, fringe benefits, and a research development fund during the first 3 years that the awardee is an independent investigator.

Dr. Pearson noted that the NCCAM Career Transition Award represents a transferable grant that can be activated immediately upon obtaining an independent position, such as assistant professor, at a research institution. The hope is that this would improve awardees' chances of competing for independent positions at highly rated research institutions. A related goal for NCCAM is to increase the probability that the very best new CAM researchers would obtain positions at research-intensive institutions and start high-quality CAM research at these sites. Dr. Pearson estimated there would be up to three awards each year.

### **Discussion**

Council asked how much money NCCAM would invest in the Career Transition Award. Dr. Pearson stated that the award is complex and details are still being worked out, including surveying other ICs that offer K22 awards about the amount of funding they provide to awardees.

Council discussion focused on the need to make the application process more accessible. One Council member noted that new investigators are confused about the awards available and suggested a simplified method of application, such as one form to be used in applying for all award mechanisms. Agreeing that the application process is complex, Dr. Pearson said she is available to consult with potential applicants about funding opportunities and to provide guidance in navigating the NIH grants arena. She and Dr. Kozel will present a poster at the National Postdoctoral Association's annual meeting in March, aimed at educating potential applicants about various funding mechanisms.

To make information about funding opportunities more accessible to the research community, Dr. Chesney is working with Irene Liu of the Center's Office of Communications and Public Liaison to reorganize the research section of NCCAM's Web site. Research initiatives will be organized by topic rather than by mechanism. Council voted unanimously to approve both concepts.

## **IX. NCCAM Report on Inclusion of Women and Minorities**

Dr. Straus introduced Dr. Josh Berman, Director, NCCAM's Office of Clinical and Regulatory Affairs, who reported on the Center's inclusion of women and minorities in clinical trials. After introducing Dr. Laura Lee Johnson, a new biostatistician at NCCAM, Dr. Berman then discussed the findings of the 2005 Biennial Report Certifying Compliance with Racial and Ethnic Guidelines. The report includes NCCAM clinical trial data from FY 2002 and 2003, which were tabulated and analyzed in the FY 2003 and 2004 reporting years, respectively. The data are reported in two categories: all clinical research and phase III clinical research.

*FY 2003 reporting year:* In all NCCAM clinical trials, 52 percent of participants were women, 13 percent were African American, and 8 percent were Hispanic. In phase III studies, 42 percent were women, 8 percent were African American, and 8 percent were Hispanic.

*FY 2004 reporting year:* In all clinical trials, 49 percent of participants were women, 13 percent were African American, and 7 percent were Hispanic. In phase III studies, 42 percent were women, 8 percent were African American, and 9 percent were Hispanic.

A discussion ensued about how racial and ethnic participation varies by gender and about how demographics for CAM use correspond to those for NCCAM clinical trial participants. Dr. Straus concluded by emphasizing the need to track data on the inclusion of women and minorities to identify trends.

Council voted unanimously to approve the report.

## **X. Concept: Database of Dietary Supplement Labels**

Dr. Jane F. Kinsel, NACCAM Executive Secretary, introduced Dr. Christine Swanson, Program Director for the Botanical Research Centers at NIH's Office of Dietary Supplements (ODS). Dr. Kinsel explained that as an NIH office, ODS does not have a separate advisory council, and therefore NCCAM was partnering with ODS to bring a concept before NACCAM for review.

Dr. Swanson presented a concept for an initiative to develop and maintain a database of information from the labels of all dietary supplements sold in the United States. She explained that the initiative is in response to a Congressional directive and that ODS would fund a contract for database development.

Noting that a comprehensive database of information from dietary supplement labels does not currently exist, Dr. Swanson explained that a database containing information on the name and amount of each ingredient declared on the label of these products would be useful for research purposes and for consumer information. Research to assess total intakes of essential nutrients and other bioactive constituents from foods and supplements requires such a database. Dr. Swanson noted that approximately 50 percent of all adults

in the United States regularly use dietary supplements and would benefit from having access to a single source of information about them.

Dr. Straus asked Dr. Swanson if there is any precedent for NIH serving a comparable function on behalf of an industry sector. Replying that there is not one to her knowledge, Dr. Swanson said that ODS will seek the guidance of the NIH Contracts Office.

Council asked about the reliability and specificity of labels currently used in the marketplace. Dr. Swanson responded that the U.S. Food and Drug Administration (FDA) requires that labels list all ingredients by amount in a dietary supplement.

Council inquired about project costs. Dr. Swanson estimated project costs to ODS to be \$1 million, noting that there would be no costs to NCCAM. She added that the effort required to develop databases often exceeds preliminary estimates.

Queries were raised about the logistics of gathering and maintaining information on the dietary supplement labels. Dr. Swanson noted that dietary supplement manufacturers would be the best source of information. Council asked whether manufacturers had an incentive to cooperate, and Dr. Swanson suggested that complying with the Congressional request would be an incentive. She added that ODS met with several top dietary supplement manufacturers 3 years ago, and they were amenable to contributing to such a database.

Council voted unanimously to approve the concept.

## **XI. Council Operating Procedures**

Dr. Kinsel thanked Council members and participants and addressed several items of business. The members voted unanimously to approve the following:

- Minutes of the previous Council meeting, held on September 10, 2004; and
- Operating procedures for Council's role in the closed session's second-level of grants review and the open session's advice on policies and initiatives.

## **XII. Public Comment Session**

There were no comments from the public.

Dr. Kinsel adjourned the meeting at 4:30 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