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 FORTY-EIGHTH MEETING
February 1, 2013

NACCAM Members Present

Dr. Brian Berman, Baltimore, MD
Dr. David Borsook, Waltham, MA[1]
Dr. Daniel Cherkin, Seattle, WA
Dr. Gary Curhan, Boston, MA
Dr. Steven DeKosky, Charlottesville, VA
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Susan Folkman, San Francisco, CA
Dr. Jane Guiltinan, Seattle, WA
Dr. Scott Haldeman, Santa Ana, CA
Dr. Frances Henderson, Jackson, MS
Dr. David Kingston, Blacksburg, VA
Dr. John Licciardone, Fort Worth, TX
Dr. Philippa Marrack, Denver, CO
Dr. Lloyd Michener, Durham, NC
Dr. Deborah Powell, Minneapolis, MN[1]
Dr. Lynda Powell, Chicago, IL
Dr. Chenchen Wang, Boston, MA[1]

[1] Ad-hoc

SPEAKERS

Dr. Paul Coates, Bethesda, MD
Dr. Joe Selby, Washington, DC
Dr. Kaycee Michelle Sink, Winston-Salem, NC
Dr. Beth Snitz, Pittsburgh, PA
Dr. John Williamson, Bethesda, MD

NACCAM Members Not Present

Dr. Richard Niemtzow, Clinton, MD

NIH Staff Present

Diane Hannemann, OSP, OD, NIH
Tom Zhe Liang, NIMH, NIH
Yuan Luo, CSR, NIH
Kathy Salaita, CSR, NIH
Kanesha Simmons, NIMH, NIH
Wendy Smith, OSP, OD, NIH
Barbara Sorkin, ODS, NIH
Sharon Williams, OSP, OD, NIH

Members of the Public

Marguerite Clarkson
Steven Dentali
Cathleen Kearns
Amita Shukla

I. Closed Session

The first portion of the forty-eighth meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

A total of 119 applications were assigned to NCCAM. Of these, 29 were reviewed by NCCAM, 90 by Center for Scientific Review. Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 53 applications, requesting $15,305,288 in total costs.

II. Open Session—Call to Order

The open session convened at 10:15 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

The minutes of the October 12, 2012, NACCAM meeting were approved unanimously.

III. NCCAM Director's Welcome and Overview of Meeting

NCCAM Director Dr. Josephine Briggs welcomed Council members and guests, briefly summarized the agenda items, and introduced Dr. M. Catherine Bushnell, Scientific Director of NCCAM's Division of Intramural Research.

IV. Introduction to the NCCAM Intramural Research Program

Dr. Bushnell explained that NCCAM's new intramural research program will focus on the study of pain and its central modulation. Both animal and human studies will be conducted, and human research will include both pain patients and normal volunteers.

The neural basis of pain perception can be evaluated by combining imaging with more traditional methods of studying pain. For example, in a study of the effect of distraction on the perception of pain, participants might complete questionnaires about the intensity of their pain with and without distraction, and they might also undergo brain imaging while they are distracted and while they are not. The self-reports and imaging results would then be analyzed together to evaluate the relationship between the subjective perception of pain and changes in the brain.

Previous research has shown that some mind and body practices that people use to help control pain have a profound effect on pain perception. For example, one study showed that people who practice yoga regularly have a higher tolerance to pain than those who do not.

Both pain and certain mind and body practices may change brain structures. Previous research has shown that chronic pain, such as that associated with fibromyalgia or arthritis, accelerates the age-related loss of gray matter. Practicing yoga, on the other hand, is associated with greater retention of gray matter.

The intramural research program will examine the mechanisms of placebo analgesia, which may involve reward anticipation pathways in the brain and changes in levels of the neurotransmitter dopamine. The extent of the placebo response differs greatly among individuals; this difference may correlate with gray matter changes in parts of the brain involved in the reward system as well as with dopamine transmission in the brain.

Another area of interest is comorbidities that may accompany chronic pain, including anxiety, depression, and changes in cognition. Findings from animal studies suggest that brain changes caused by pain may be associated with these comorbidities.

Six new researchers have joined NCCAM's intramural research program, and several projects have been planned. Topics include:

- The effect of social environment and exercise on the development and persistence of chronic pain (an investigation in experimental animals)
- An *in vivo* investigation of pain in rodents using magnetic resonance imaging and positron emission tomography
- Neural mechanisms of placebo analgesia in chronic pain patients
- Longitudinal studies of the effects of yoga, meditation, and aerobic exercise on brain gray matter and pain perception.

NCCAM hopes to hire one or two new principal investigators for the intramural program within the coming year.

Discussion. In response to members' questions, Dr. Bushnell clarified that distraction and mood have different effects on the experience of pain and the accompanying changes in the brain.

When evaluating changes in pain in humans, it is important to distinguish between the perceived intensity of pain and the degree to which the pain bothers the person. Studies have indicated that distraction changes the intensity of pain, whereas changes in emotional state alter bothersomeness.
In response to a question from Dr. Daniel Cherkin about whether the development of the intramural research program would affect NCCAM's extramural research funding priorities, Dr. Briggs explained that continuing dialogue is taking place at NCCAM about how the intramural and extramural programs can complement each other. Guidance from and discussion with Council would be welcome. About one-third of NCCAM's extramural investment is pain-related, and no change in NCCAM's interest in supporting extramural research on pain is anticipated.

Dr. Cherkin commented that both clinicians and patients urgently need summaries of what neuroscience is learning about pain. Dr. David Borsook observed that a disconnect exists between science and patients with regard to pain. Patients do not know what resources are available to them, and better communication is needed. Dr. Briggs commented that NCCAM feels a sense of mission about building an evidence base on nonpharmacological strategies for managing pain.

Dr. Lynda Powell urged that pain studies should compare nonpharmacological approaches with current clinical practice. The standard of care for treating pain emphasizes the use of drugs, which creates a risk of drug dependence.

V. Update on the Patient-Centered Outcomes Research Institute

Dr. Joe Selby, executive director of the Patient-Centered Outcomes Research Institute (PCORI), described PCORI's unique mission and how its research agenda may complement that of NCCAM.

PCORI, authorized by the Patient Protection and Affordable Care Act of 2010, is a nonprofit organization that funds research aimed at providing patients, caregivers, and clinicians with information to make better health care decisions. It will focus on comparative effectiveness research, especially research conducted in typical patients and typical care delivery settings. Differences in treatment effectiveness among patient subgroups are an important emphasis, as is research that can directly influence health care practices. PCORI could fund studies that involve complementary approaches. For example, in instances where usual care is not producing adequate results, it may be appropriate to compare complementary approaches with conventional ones. Research might also examine whether particular population subgroups are especially likely to benefit from complementary approaches for biological or preference reasons.

PCORI is committed to continuously seeking input from patients and a broad variety of stakeholders to guide its work. Patients and other relevant stakeholders must be included as members of research teams and be involved in all aspects of the research project, from planning to dissemination. Grant applications are evaluated for patient-centeredness and stakeholder engagement, and at least 30 percent of the members of the panels that review grant applications must be trained patient or other stakeholder reviewers.

PCORI's priorities are

- Assessing prevention, diagnosis, and treatment options
- Improving health care systems
- Communicating and disseminating research
- Addressing disparities
- Accelerating patient-centered outcomes and methodological research.

PCORI issues both broad and targeted funding announcements. The initial areas for targeted funding are treatment of severe asthma in minorities, treatment of uterine fibroids, and prevention of falls in the elderly. Future topics for targeted funding will be developed in cooperation with the Agency for Healthcare Research and Quality.

PCORI is interested in building infrastructure for patient-centered outcomes research and a health care system that learns from experience. A set of desirable characteristics of a data structure for patient-centered outcomes research has been identified. PCORI sponsored a national workshop in July 2012 to advance use of electronic data. The workshop included discussion of both clinical data networks and patient-powered research networks.

Discussion. Dr. Gary Curhan commented that PCORI's grants, which are for 3-year projects, may limit researchers' opportunities to assess the long-term outcomes of treatments. Dr. Selby replied that PCORI understands the importance of long-term outcomes but in its very first efforts has placed a priority on some quick results to establish feasibility and credibility in the 2015-2017 timeframe. Going forward PCORI may well fund some studies that will produce both short- and long-term results.

Dr. Philippa Marrack expressed concern about whether patients included in data networks are representative of the overall patient population, particularly in the case of networks initiated by groups of activated patients. Dr. Selby replied that issues exist in this area but are not a crippling problem. Electronic health record data can be used in many ways to identify appropriate patients for inclusion in studies. In some instances, patients with uncertain diagnoses may need to be omitted from analyses.

Dr. Lloyd Michener asked about PCORI's work in developing outcomes that matter to patients and about the relationship between PCORI and Center for Medicare and Medicaid Innovation advanced delivery models. Dr. Selby explained that some of PCORI's current pilot projects relate to patient-centered outcomes and that PCORI currently has a methods-related funding announcement. In the longer term, PCORI would like to align with others, including the Food and Drug Administration and the Patient Reported Outcomes Measurement Information System (PROMIS), to evaluate outcomes more systematically. PCORI has talked with the Center for Medicare and Medicaid Innovation about lending a patient-centered focus to some of their research.

In response to a question from Dr. Cherkin about how NIH and PCORI could guide each other, Dr. Selby explained that PCORI receives ongoing and outstanding support from NIH and that

NIH Director Dr. Francis Collins serves on PCORI's Board of Governors. PCORI used NIH's Center for Scientific Review (CSR) for its first round of grant application reviews and was advised by CSR for the second round. As PCORI learns more about engaging patients and other stakeholders in research, it is likely that PCORI, in turn, will be able to share knowledge with NIH. Cofunding projects is one way in which NIH and PCORI can cooperate and continue to learn from each other.

Dr. Briggs commented that one goal for NCCAM's emphasis on research tools and methods is to facilitate PCORI-type projects; and the research that NCCAM supports is highly patient centered because the practices that NCCAM studies are practices that patients have chosen themselves. There may be some very natural partnerships between the two organizations.

VI. Secondary Studies Associated With the Ginkgo Evaluation of Memory Study

Council member Dr. Steven DeKosky, vice president and dean of the University of Virginia School of Medicine, chaired a minisymposium on the Ginkgo Evaluation of Memory Study (GEMS), focusing on secondary studies and potential future use of the GEMS dataset.

Dr. DeKosky explained that GEMS was a randomized, double-blind, multicenter clinical trial, cofunded by NCCAM and four other NIH agencies, in 3,069 people ages 75 or older who had normal memory or very mild cognitive impairment (MCI) at the time of enrollment in the study. Participants received 120 mg of *Ginkgo biloba* extract or a placebo twice daily and were followed for an average of 6 years. Study participants underwent extensive evaluation at several points in the study, including a 2-hour cognitive assessment, depression assessment, medical history, medication update, functional testing, blood testing, and genetic analyses. The study was conducted primarily to determine whether ginkgo would decrease the incidence of dementia of any type and Alzheimer's disease specifically. The results indicated that ginkgo was ineffective in reducing the development of these conditions. Further analyses indicated that ginkgo also was not effective in reducing coronary heart disease incidence, stroke incidence, or mortality in people over age 75.

Examinations conducted at the end of the trial showed that 50 percent of participants who still had good cognitive function had amyloid plaques in their brains, indicative of the development of Alzheimer's disease. This finding indicates that people may have the disease without showing symptoms.

Dr. Jeff Williamson, chief of gerontology and geriatric medicine at Wake Forest Baptist Health, summarized some of the ongoing uses of GEMS data. He explained that the GEMS dataset is of great value because it is one of the few large datasets on healthy people over age 75. The dataset has been used to:

- Explore potential risk factors for Alzheimer's disease, such as past or coexisting diseases, alcohol use, personality traits, and the use of various medications
- Conduct mechanistic studies on factors that may relate to Alzheimer's disease, such as inflammation, cholesterol metabolism, and red cell membrane protease alterations
- Provide preliminary evidence for Alzheimer's disease prevention strategies

- Evaluate the impact of ginkgo use on other outcomes, such as gait speed, blood pressure reduction, and cancer
- Contribute to the design of other clinical trials in elderly people.

Many of these investigations have produced valuable results. For example, evaluations of the relationship between body mass index (BMI) and dementia risk in the GEMS study participants showed a different pattern than that seen in people ages 40 to 60. Among middle-aged people, high BMI is associated with a greater risk of developing dementia. However, in the elderly GEMS participants, people with higher BMI had a slower trajectory of developing dementia, which may relate to brain pathways that determine appetite.

Many of the secondary analyses of GEMS data are being performed by young scientists who have NIH K grants or other career development awards. Others are being performed by students. For example, the BMI analyses were performed by a group of medical students who worked with statisticians to analyze the data. Thus, in addition to contributing to better understanding of cognitive function and health in older populations, the GEMS dataset is providing meaningful professional development opportunities for researchers in the early stages of their careers.

Dr. Beth Snitz, assistant professor of neurology at the University of Pittsburgh, provided additional details on three investigations conducted using the GEMS dataset. In one, data from the extensive cognitive testing performed on study participants were used to develop an algorithm for the identification of MCI that can be used in future research. Another analysis evaluated whether ginkgo could slow cognitive decline (one of the secondary outcomes of the study); the data indicated that it could not. A third investigation explored the relationship between the presence of amyloid plaques in the brain in nondemented individuals at the end of the study and their performance on cognitive tests conducted at earlier times during the study.

Dr. Kaycee Sink, associate professor of gerontology and geriatric medicine at Wake Forest Baptist Health, summarized the results of studies on the relationships of alcohol and antihypertensive drugs with cognition in the GEMS participants. The alcohol analyses showed that among participants who were cognitively normal at the beginning of the study, moderate alcohol intake (1-2 drinks per day) was associated with a 37-percent decreased risk of dementia over 6 years. However, in participants with MCI at the beginning of the study, alcohol consumption in any amount was associated with greater cognitive decline, with heavy drinkers almost twice as likely as nondrinkers to progress to dementia. Analyses on antihypertensive drugs singled out one class of drugs, the potassium-sparing diuretics, as being linked with better cognitive function and a reduced risk of developing Alzheimer's disease.

Discussion. Dr. Marrack asked whether it would be possible to evaluate the relationship between vaccine use and dementia in the GEMS dataset. Dr. Williamson replied that this could be done for influenza and pneumococcus vaccines and that the topic has not yet been explored. Dr. Scott Haldeman asked whether the GEMS dataset includes any data on chronic pain. Dr. Williamson replied that the dataset includes a good pain questionnaire and that the questionnaire data have not yet been used to investigate the relationship between pain and dementia.

Dr. Briggs commented on the importance of ensuring that resources such as the GEMS dataset are appropriately promoted, and Dr. Williamson noted that the GEMS dataset is in the public domain. Dr. Briggs and Council members discussed current efforts to compile a database of databases and the difficulty of cross-indexing databases, including those from Medicaid and Medicare.

In response to a question from Dr. Lynda Powell about possible confounding of alcohol data by socioeconomic status, Dr. Sink replied that income measures were controlled for, as were measures of social activity, another important potential confounder in alcohol studies. Dr. Stephen Ezeji-Okoye expressed surprise that such a large number of study participants were taking potassium-sparing diuretics and asked whether some might have been taking them for diagnoses other than hypertension. Dr. Sink replied that some could have been treated for heart failure or other conditions. Dr. Williamson added that confounding by indication is a major problem in analyses that relate outcomes to medication use.

In response to a question from Dr. Susan Folkman about personality measures, Dr. Sink replied that people high in neuroticism were found to be more likely to progress to dementia.

Dr. DeKosky concluded the minisymposium by thanking the other participants for their contributions, Council members for their interest and questions, and NCCAM for its support of GEMS. He noted that new ideas for analyses of GEMS data are constantly being generated and that one of the study's greatest legacies will be its contributions to hypothesis generation.

VII. NCCAM Director's Report

Dr. Briggs began her report to Council by explaining that the new NIH logo is now being incorporated into NCCAM public information materials. Dr. Briggs strongly supports the concept of uniform branding that was presented by John Burklow, NIH Associate Director for Communications and Public Liaison, at the October 2012 Council meeting.

Dr. Briggs welcomed new staff members, including several new members of Dr. Bushnell's intramural research program. She explained that NCCAM is operating under a continuing resolution through March 27, 2013. NIH is funding noncompeting grants at 90 percent of the approved level, as is customarily done during a continuing resolution, and does not plan to further ramp down spending in anticipation of a sequester.

Dr. Briggs mentioned several current NIH-wide initiatives and noted that the issue of a database of databases, which arose during the discussion of the GEMS dataset, is being pursued in the context of informatics resources. Another NIH-wide initiative, this one pertaining to the biomedical research workforce, arose from concerns that the number of biomedical researchers being trained might exceed the number of jobs available. Analyses have shown that the number of tenure-track scientific positions is substantially less than the number of people being trained, but nevertheless a need exists for people with the range of skills that come out of research training. A set of initiatives is being developed to improve training opportunities and mentoring for postdoctoral researchers supported by R01 and other research project grants as well as those supported by training grants.

Dr. Briggs drew Council members' attention to two recently published datasets that may inform decisions about where NCCAM should focus its investments in outcomes and effectiveness research. The first is a comprehensive summary of the worldwide causes of diminished life expectancy and disability that was published in *The Lancet* in December 2012. The data showed that low-back pain is the leading global cause of disability and that neck pain, other musculoskeletal disorders, migraine, and osteoarthritis also rank very high. The causes of worldwide disability map closely with NCCAM's research portfolio.

The second dataset comes from an Institute of Medicine (IOM) report on U.S. health in international perspective. The report compared a variety of health measures in high-income countries and found consistent evidence of poorer health in the United States than in peer nations. The United States fares poorly in terms of life expectancy, mortality from injuries, years of life lost before age 50, obesity, infant mortality, various measures of adolescent health including sexual health, drug-related mortality, heart disease, HIV/AIDS, and several other health domains. For some measures, such as infant mortality and teenage pregnancy, the United States is not merely at the bottom of the pack but is actually an outlier, with dramatically worse statistics than those of many peer countries.

Although aspects of the U.S. health care system, such as the lack of universal health insurance, may explain some of the U.S. health disadvantage, other factors, including individual behaviors and social factors, may also contribute. Americans do not smoke more or drink more alcohol than people in peer countries, but calorie intakes are higher in the United States. U.S. adolescents become sexually active at an earlier age, have more sexual partners, and do not properly use contraceptives and barrier methods. Civilian possession of firearms is higher than in peer countries, and Americans are less likely than people in peer countries to use automobile seat belts and motorcycle helmets. The United States also has the highest level of income inequality among peer countries, the highest relative poverty rate, and the highest rate of child poverty.

Discussion. Dr. Borsook observed that health in the United States has worsened in many domains, including conditions as diverse as opiate addiction and migraine, and that the need for improvement is compelling. Dr. Michener observed that although the general pattern is well known, it is still appalling to see so many indicators of poor health in the United States collected in one place. He pointed out that in some ways, the picture may even be worse than the IOM report indicates because data for population subgroups, such as minority groups, are not presented separately. He recommended that NCCAM focus attention on studies that look at population subgroups and those that investigate barriers to good health.

Dr. Briggs noted that in some other countries, large initiatives to systematically capture data from health care systems are under way. However, in the United States, health care systems do not capture the whole population. In particular, young people often are not engaged with health care systems.

Dr. David Kingston noted that many of the unhealthful behaviors highlighted in the IOM report are socially driven and suggested that efforts might be made to enlist religious organizations to promote healthier behaviors.

Dr. Folkman commented that the study of behaviors that drive unhealthy habits should be legitimized. No NIH agency has made a full-fledged commitment to this topic. In this context, she also raised the issue, discussed several times previously, of changing NCCAM's name to reflect an emphasis on integration rather than alternatives. Dr. Briggs said that she would like to have a subgroup of Council consider the possibility of a name change, perhaps through a series of conference calls. Dr. Cherkin commented that NCCAM's current name separates it from the rest of NIH and that a name involving integrative medicine would be more appropriate. Many of today's health problems are not reducible to simple solutions, and more comprehensive, holistic thinking is needed. Dr. Brian Berman noted that the entity that became NCCAM has already undergone name changes and agreed with other Council members that the time is right to consider an integrative focus.

Dr. John Licciardone commented that the disabling conditions shown to be most prominent in the report from *The Lancet* are conditions that NCCAM already focuses on. Integrative interventions for these conditions are relatively inexpensive and are better accepted internationally than in the United States.

VIII. Concept Clearance: Strengthening Natural Product Science

NCCAM Program Officer Dr. John Williamson presented a proposed initiative that would use NCCAM's Small Business Innovation Research (SBIR) grant set-aside program to stimulate natural products method development using new or existing technologies. The intent of the initiative would be to encourage new ideas that would cover broad needs across the natural products field. The focus would be on five priority areas, including technologies aimed at:

- Improving field applications for characterizing the best sources and species and their diverse bioactive constituents
- Rapid dereplication of known compounds and removal of nuisance materials from crude extracts
- Development of sensitive phenotypic or high-content bioassays
- Creating expression systems for biosynthetic pathways and their constituents in high-yielding hosts
- Predicting and quantifying risks and benefits associated with natural product–drug interactions.

Discussion. Dr. Kingston expressed strong support for the concept, explaining that natural products research is handicapped by a lack of tools of the types that might be developed under this initiative. He stated that the proposed initiative could be beneficial for the whole field of natural products research.

A motion to approve the concept was made, seconded, and passed unanimously.

IX. 2013 Biennial Advisory Council Report on Research Participant Enrollment

Dr. Catherine Meyers, Director of the Office of Clinical and Regulatory Affairs, presented the 2013 biennial report certifying NCCAM's compliance with NIH policy on inclusion guidelines for women and members of minority groups in clinical research. She explained that the goal of NIH policy is not to satisfy quotas for proportional representation based on census data but to conduct research so that findings will be generalizable to the U.S. population.

In FY 2011, women and minorities represented 52 and 21 percent, respectively, of enrollees in NCCAM-funded clinical research. In FY 2012, women represented 60 percent and minorities 24 percent of enrollees in NCCAM-funded clinical research. Enrollment data are usually presented separately for Phase III trials; however, NCCAM did not fund any Phase III trials in either of these years.

Council unanimously passed a motion approving the biennial report as presented.

Discussion. In response to a question from Dr. Borsook about whether children are a focus of NCCAM research, Dr. Briggs explained that information about children is captured in the National Health Interview Survey. NCCAM Program Officer Dr. Wendy Weber added that NCCAM is funding some small projects that involve adolescents. In response to a question from Dr. Michener about best practices for ensuring inclusion of an appropriate balance of research participants, Dr. Briggs explained that frequent oversight of studies to ensure that they are meeting recruitment targets is important. If targets are not being met, investigators are asked to improve their recruitment strategies.

X. Council Operating Procedures

Dr. Goldrosen reviewed Council operating procedures, including processes for NCCAM reports to Council, secondary review of grant applications, approval of concepts for research initiatives, and handling of appeals from applicants.

Council unanimously passed a motion approving the operating procedures as presented.

XI. The NIH Botanical Research Portfolio

Dr. Paul Coates, Director of NIH's Office of Dietary Supplements (ODS), presented an update on the joint ODS/NCCAM-supported review of the NIH botanical research portfolio by an external expert panel, which Council approved in October 2012.

As background, Dr. Coates explained that when ODS was created in 1994, it was given a mandate to lead the development of a research initiative focused on botanical dietary supplements. Much of this research has been carried out by Botanical Research Centers jointly funded by ODS and NCCAM. The five current Centers are funded until 2015, with a planned recompetition in 2014.

The expert panel will consider the broad picture of NIH-supported botanical research, not just the Centers, and will address the following questions:

1. What are the most critical scientific needs and challenges in research on the role of botanicals in human health?
2. What are key criteria for prioritizing NIH support of research on the role of botanicals in human health?
3. Which of the opportunities and challenges facing the field of botanical research require or are most likely to benefit from an interdisciplinary, multiproject collaborative research program, such as a Centers program?
4. Are there key innovative approaches that NIH should consider that have the potential to enhance the effectiveness of collaborations in advancing botanical research?

The nine-member expert panel includes two Council members, Dr. DeKosky (who is the panel chair) and Dr. Kingston. An in-person meeting is planned for spring 2013, and the target for the panel's report is summer 2013.

XII. Public Comment and Adjournment

Steven Dentali of the American Herbal Products Association announced the upcoming publication of a revised edition of his organization's *Botanical Safety Handbook*. The new edition will include information on pharmacological and toxicological studies, as well as case reports of adverse effects, for approximately 515 botanicals.

No other public comments were offered.

The meeting adjourned at 3:45 p.m.

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

Martin Goldrosen, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Alternative
Medicine

Josephine Briggs, M.D.
Chairperson
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Medicine