

**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 EIGHTEENTH MEETING
September 10, 2004**

NACCAM Members Present

*Dr. Samuel Bozzette, La Jolla, CA
Dr. Carlo Calabrese, Portland, OR
Dr. Zang-Hee Cho, Irvine, CA
Dr. Kristina Collins, McLean, VA
Dr. Gerald Cross, Washington, DC
Dr. Jonathan Davidson, Durham, NC
Dr. Jeanette Ezzo, Takoma Park, MD
*Dr. Howard Fields, Emeryville, CA
*Dr. Norman Fleischer, Bronx, NY
Dr. Robert E. Fullilove, New York, NY
Dr. Murray Goldstein, Washington, DC
Dr. Michael Irwin, Los Angeles, CA
Dr. Tieraona Low Dog, Albuquerque, NM
Dr. Bala Manyam, Temple, TX
COL Richard Niemtzw, Clinton, MD
*Dr. Robert Nussenblatt, Bethesda, MD
Dr. Joel Pickar, Davenport, IA
*Dr. Donald Powell, Galveston, TX
Dr. Barbara Timmerman, Tucson, AZ
Dr. Larry Walker, University, MS
Dr. Benjamin Yang, San Francisco, CA

*Ad hoc members

Participated by conference call for the Open Session

Dr. Herbert Pardes, New York, NY
Dr. Ralph Snyderman, Durham, NC

NACCAM Members Absent

Dr. Deborah J. Cotton, West Roxbury, MA
Dr. Haile Debas, San Francisco, CA
Dr. Leslie Hillis, Dallas, TX
Dr. Alan I. Leshner, Washington, DC

NIH Staff Present

National Center for Complementary and Alternative Medicine (NCCAM)

Ms. Sandra Addae	Mr. Peter Kozel
Ms. Willer Batten	Ms. Catherine Law
Dr. Josh Berman	Mr. Qi-Ying Liu
Dr. Dale Birkle	Dr. Patrick Mansky
Ms. April Bower	Dr. Kimberly McFann
Ms. Shea Buckman	Ms. Genevieve Medley
Dr. Craig Carlson	Dr. Heather Miller
Mr. Steve Casady	Ms. Ilze Mohseni
Dr. John Chah	Ms. Barbara Moquin
Dr. Margaret Chesney, Deputy Director	Dr. Richard Nahin
Ms. Alyssa Cotler	Ms. Ellen O'Donnell
Mr. Jimmy Do	Dr. Nancy Pearson
Ms. Karla Ehrler	Ms. Martha Pien
Ms. Linda Engel	Dr. Carol Pontzer
Ms. Carol Fitzpatrick	Ms. Linda Rich
Ms. Anne Frost	Dr. Barbara Sorkin
Dr. Martin Goldrosen	Ms. Kathleen Stephan
Mr. Kevin Green	Dr. Catherine Stoney
Ms. Camille Hoover	Dr. Stephen Straus, Director
Ms. Jeanette Hosseini	Ms. Jennifer Sutton
Dr. Morgan Jackson	Ms. Chris Thomsen
Mr. Mike Kabatt	Mr. George Tucker
Mr. Roald Keith	Ms. Shirley Villone
Dr. Jack Killen	Dr. Shan Wong
Dr. Jane Kinsel	Ms. Angie Wongsam-Nollinger

Other NIH Employees

Ms. Elizabeth Dean-Clower, National Cancer Institute
Ms. Stephanie Hess, National Cancer Institute
Dr. Oluwadamilola Olaku, National Cancer Institute
Ms. Hasnaa Shafik, National Cancer Institute
Dr. Wendy Smith, National Cancer Institute
Dr. Drogen Chen, National Institute of Neurological Disorders and Stroke
Dr. Christine Swanson, Office of Dietary Supplements

Members of the Public

Ms. Pat Anderson	Ms. Amy Hanley
Mr. Stolly Bayne	Ms. Julia Hartley
Ms. Sophie-Kim Bazinet	Ms. Kathleen Hartley
Ms. Michel Belanger	Ms. Bonnie Hillsberg
Mr. William Best	Ms. Laura Honesty
Mr. Leopold Delisle	Mr. Jon Ives
Mr. David Eberts	Dr. David Jodrey
Dr. Christine Goertz	Dr. Wayne Jonas

Ms. Micheline Lacaille
Ms. Amy Lange
Ms. Corey Mackison
Ms. Kate Mazan
Ms. Cheryl McDonnell
Dr. Gastory Naessens
Ms. Jacinte Levesque-Naessens

Ms. Suzanne Niemeyer
Dr. Georgia Persinos
Mr. Bobbie Peterson
Ms. Chris Peterson
Dr. Mary Ann Richardson
Ms. Sara Robinson

I. Closed Session

The first portion of the 18th 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 281 applications were assigned to NCCAM. Of these, 181 were reviewed by NCCAM, 99 by the Center for Scientific Review, and 1 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 9 applications and concurred on 177 applications requesting \$55,336,373 in total costs.

II. Open Session—Call to Order, Meeting Procedures

The open session of the NACCAM meeting convened at 2 p.m. Dr. Jane Kinsel, Executive Secretary, called the meeting to order. The members voted unanimously to approve the minutes of the previous Council meeting, held on June 4, 2004. Dr. Kinsel noted the upcoming Council meeting dates, with the next meeting scheduled for January 28, 2005. Announcing that the afternoon session would include a public comment session, she asked those interested in speaking at that session to sign up in advance.

III. Opening Remarks

Dr. Stephen E. Straus, Director of the National Center for Complementary and Alternative Medicine (NCCAM), began his opening remarks by noting that it was the eve of the anniversary of September 11, 2001. He invited attendees to join him in a moment of silence to remember the losses suffered on that day and since.

Noting that the closed morning session had been very productive, Dr. Straus reported that Council members had reviewed approximately 200 applications for fiscal year (FY) 2005 funding. He then introduced and thanked the following people for joining regular members in this Council meeting: ex officio member Dr. Gerald Cross and ad hoc members Dr. Samuel Bozzette, Dr. Howard Fields, Dr. Norman Fleischer, Dr. Robert Nussenblatt, and Dr. Donald Powell. Dr. Straus also introduced and welcomed invited participants Dr. Ralph Snyderman and Dr. Herbert Pardes, who joined the Open Session discussion by telephone.

Updates on Funding and Training Initiatives

NIH Loan Repayment Program

Dr. Straus announced that NCCAM recently funded seven new applicants under the National Institutes of Health (NIH) Loan Repayment Program. He noted that during the past decade, clinical research has come to be seen as a challenging and arguably endangered discipline. The Loan Repayment Plan is one of the ways NIH helps individuals committed to a research career defray the costs of their education and training. This year, NCCAM funded 7 of the 17 applications (41 percent) it received. Dr. Straus said that three of the individuals receiving funding hold doctoral degrees in complementary and alternative medicine (CAM) fields, while the others are at major integrative CAM programs throughout the United States.

NCCAM Intramural Activities

After 3 years of service as the first Scientific Director for Clinical Research of the Division of Intramural Research, Dr. Marc Blackman has stepped down to concentrate fully on his clinical and basic laboratory research. Dr. Straus is serving as the interim Scientific Director for Clinical Research. At its January 2005 meeting, Council will discuss plans to recruit a new Scientific Director and to further develop the Division.

New Fellowship in Integrative Oncology

Dr. Straus outlined a new clinical research fellowship in integrative oncology, the first of its kind in the United States. Dr. Patrick Mansky, a board-certified oncologist and staff clinician in NCCAM's Division of Intramural Research, developed the program; he also directs several studies on cancer and CAM. In the past year, Dr. Mansky has finalized an NCCAM–National Cancer Institute (NCI) collaboration that allows newly accepted clinical fellows who are board eligible in pediatric or medical oncology to study integrative oncology for 3 years on completion of their clinical training. During the program, participants will fulfill the NCI Medical Oncology clinical fellowship training requirements, including two 6-month rotations in medical oncology at the Clinical Center and at the National Naval Medical Center. In the second and third years, participants will complete four modules designed by NCCAM, which will provide training in research, policy/regulatory affairs, education, and practice. Noting that the program is accepting applications, Dr. Straus congratulated Dr. Mansky and colleagues on their work.

NCCAM and NIH Roadmap Initiatives

Dr. Straus co-chairs activities under *Re-engineering the Clinical Research Enterprise*, one of three themes included in the NIH Roadmap for Medical Research. NCCAM is the organizational lead on the Regional Translational Research Centers (RTRC) initiative, a key effort under this theme. Dr. Straus, who also chairs the trans-NIH RTRC Working Group, noted that the group is drafting a request for applications for planning grants to fund RTRCs. In June 2005, Council will provide secondary review to fund planning grants totaling \$3 million. By FY 2006, additional planning grants will be awarded. By

FY 2008, the RTRC program will fund awards totaling \$90 million a year. Dr. Straus stressed that NCCAM is charged with administering the program on behalf of NIH.

Staff News

Dr. Straus welcomed the return to NCCAM of Ms. Anita Greene from a detail at another Federal agency. Ms. Greene will work on expanding NCCAM's outreach efforts to CAM stakeholders, including research organizations, schools, and CAM and minority professional organizations.

IV. Report from the Cancer Working Group

Dr. Straus noted that the Cancer Working Group (CWG) has assumed the role of the former Cancer Advisory Panel for Complementary and Alternative Medicine. He introduced Dr. Tieraona Low Dog, CWG Chair, who reported on the group's September 9, 2004, meeting.

Dr. Low Dog thanked staff from NCCAM and the NCI Office of Cancer Complementary and Alternative Medicine (OCCAM) for facilitating the CWG meeting. She said the group appreciated being given the opportunity to review the Best Case Series presented to OCCAM by manufacturers of 714X, a CAM therapy for cancer. Dr. Low Dog acknowledged the information-gathering efforts of the manufacturer and commended patients for their very moving testimonies before the CWG.

After review of the five detailed case studies in the Best Case Series and thoughtful deliberation, the CWG decided it was premature to recommend that NCCAM or NCI pursue studies of 714X as a priority, Dr. Low Dog reported. She explained that the group concluded that currently available theoretical evidence on 714X's role as an immunomodulator is scientifically weak. Although the cases were intriguing, they were not overly compelling in providing scientific evidence of 714X's effectiveness. The CWG is interested in reviewing results from the University of Montreal's 714X research once they are published. Dr. Low Dog also noted that the CWG encourages the manufacturers of 714X to work with experienced investigators familiar with animal models of cancer to see whether the actions of tumor regression and elimination attributed to 714X can be demonstrated. In conclusion, Dr. Low Dog said that the CWG is willing to reconsider 714X at a later date if new research results make a more compelling case for further study.

Before opening the floor for questions and discussion, Dr. Straus noted that under the leadership of Dr. Jeffrey White, Director of OCCAM, NCI has accrued promising data on CAM for cancer treatment. Over the past 13 years, NCI has developed the Best Case Series to solicit interesting preclinical and clinical data for possible formal research studies of alternative treatments that patients use to treat cancer.

Dr. Joel Pickar asked whether the series ever provided evidence leading to recommendations for using therapies in clinical trials rather than in animal models.

Dr. Low Dog responded that the theory of how 714X works is not now scientifically recognized and that no published information on the product has yet appeared in a peer-reviewed scientific journal. Of the five cases presented, only one featured a patient who had used only 714X and did not receive any conventional therapy. In the other four cases, it was unclear whether conventional chemotherapy or the CAM intervention had produced the curative effect.

Dr. Low Dog reiterated the CWG's belief that the next steps should be review of the University of Montreal research and conduct of research using a mouse model; the CWG has encouraged NCCAM to consider funding investigator-initiated grant applications for research on 714X that are found to be highly meritorious in peer review. Dr. Straus added that NCCAM is always open to investigator-initiated applications with *in vitro* and animal models. He mentioned that two prior Best Case Series have led to clinical studies—a prospective clinical trial of the Gonzalez regimen for pancreatic cancer and a clinical trial of Dr. Alexander Sun's vegetable mixture (also known as "Sun's soup").

V. NCCAM's Second 5-Year Strategic Plan

Dr. Straus provided an update on the status of the second 5-year strategic plan, which was provided to Council members in draft form before the meeting. Noting that the new plan is a work in progress, Dr. Straus stated that the previous 5-year plan articulated a philosophy rather than a detailed approach.

The Planning Process

The strategic plan, near completion, is being developed and implemented in five phases. Phase I included staff meetings, a "think tank" meeting, and stakeholder forums to develop the overarching philosophy and structure of the plan. Phase II involved an intensive workshop to develop recommendations on 10 major topics. The current stage—Phase III—involves soliciting responses to the draft plan through NACCAM meetings and a public comment period. The plan also will be posted on the NCCAM Web site through mid-November 2004. Phase IV culminates in the plan's release in January 2005. Phase V, in winter through spring 2005, will mark the plan's implementation.

Dr. Straus noted that the new 5-year strategic plan would be reviewed regularly, as new implementation approaches are developed and science evolves.

History, Lessons Learned, and Recommendations

History

Offering a snapshot of investments made and lessons learned, Dr. Straus summarized the background to development of the new plan. He emphasized that NCCAM has been entrusted to spend its funds wisely, a responsibility it has successfully fulfilled as its budget has steadily increased. The estimated budget for 2005 is just over \$121 million. Dr. Straus pointed out that CAM research by NIH as a whole has increased as well;

aggregate spending by NIH on CAM is estimated to be about one-third of \$1 billion for FY 2005.

Dr. Straus reviewed how NCCAM allocates its research investments. Hundreds of CAM practices can be divided into four major domains (biologically based practices, mind-body medicine, energy medicine, and manipulative and body-based practices), plus overarching approaches (whole medical systems) that can employ practices in all four domains. Hundreds of CAM modalities fall under the four domains and whole medical systems; deciding how to allocate investments among them is an ongoing effort. Observing that NCCAM has tackled a broad range of health conditions in studying CAM modalities, Dr. Straus reviewed the FY 2003 research portfolio by health condition. The largest investments were made in cancer, mental health, pain management, endocrine conditions, and cardiovascular conditions. He noted that other NIH institutes and centers (ICs) study these same conditions and that NCCAM faces an ongoing challenge in prioritizing its spending on them. Dr. Straus explained that NIH prioritizes its investments by the nature and overall impact of public health conditions and in proportion to scientific opportunities.

Comparing NCCAM's research investments by domains and whole medical systems for FY 1999 and FY 2003, Dr. Straus reported that the majority of funds have supported studies of biologically based practices and whole medical systems. In the past few years, more than half of NCCAM's research budget was spent on biologically based practices; 25 percent was spent on whole medical systems, although much of that targeted only acupuncture. Slightly more than 10 percent was spent on mind-body medicine, 5 percent on manipulative and body-based practices, and 3 to 4 percent on energy medicine.

In addition to funding research projects, NCCAM also has invested substantially in training and career development. Comparing the proportion of its budget allocated for this purpose with that of other NIH ICs, NCCAM ranks between second and fourth place.

A significant proportion of NCCAM's funds support clinical research, Dr. Straus noted. NIH as a whole spends 32 to 35 percent of its research budget on clinical studies, while NCCAM spends about 72 percent. NCCAM's funding of basic research rose from 20 percent in FY 2000 to 28 percent in FY 2003, reflecting the increasing importance of understanding the composition and mechanisms underlying CAM materials and practices. Dr. Straus said that NCCAM has funded a small number of phase III trials, at \$4 million to \$30 million each, accounting for 23 percent of its clinical research spending in FY 2003. Trials completed or under way include large studies of acupuncture, *Ginkgo biloba*, and glucosamine/chondroitin. Dr. Straus noted that a critical part of the Center's mission is to inform the public whether such CAM approaches are safe and effective. Phase III studies build on various tiers of previous preclinical and clinical studies that justify NCCAM's substantial investments in them.

Citing several measures of organizational success, Dr. Straus noted that in its first 5 years NCCAM has (1) built a Center that is responsive to its mission and mindful of its resources, (2) been fully integrated into NIH science and leadership, (3) gained the

respect of CAM and non-CAM communities, (4) created a CAM research and training collective, (5) funded nearly 800 projects at 123 institutions, (6) sponsored research published in more than 700 scientific publications, and (7) worked to inform public policy, patient choice, and clinical practice.

Lessons Learned and Recommendations

Dr. Straus noted that while achieving benchmarks of success, NCCAM has learned some lessons that contribute to useful recommendations to guide its future:

- Some of the Center's early work was built on what Dr. Straus termed assumptions; these include, for example, assumptions that CAM products are safe and pure or that optimal product, dose, and target populations are known, particularly where there are long-standing traditions of using a given treatment. Basing expensive phase III trials on such assumptions could result in a product being prematurely declared ineffective. Recommendations include greater emphasis on preclinical and early-phase clinical investments as crucial preludes to larger scale trials.
- In the past, NCCAM's research portfolio reflected too-modest efforts to understand mechanisms, while addressing a vast range of practices and clinical conditions, and heavy investments in large trials. Recommendations include greater emphasis on basic science, combined with a phased approach to clinical trials and clear priorities.
- The Center has both benefited from and been challenged in efforts to attract experienced scientists and CAM practitioners to CAM research. Dr. Straus noted that it is important for CAM practitioners to know that their participation is key in helping NCCAM succeed in blending these communities. Recommendations include sustaining commitments to training and career development; formalizing investments in health services and international research; and better understanding the ethical, social, and legal contexts that influence prospects for integrating CAM approaches.

The Draft Strategic Plan

Dr. Straus explained that the draft strategic plan is divided in part according to CAM domains and systems, with goals for research, training, and communications components. However, goals and objectives for each area do not map in linear fashion. Some goals are short term, while others are longer term; some priorities require further refinement.

Commenting on the mission statement and vision, Dr. Straus said that the Center's future research will help define what are safe and effective CAM practices and thus make it easier for practitioners and patients to integrate them. He outlined the plan's master health goals, noting the need to increase basic research and enhance partnerships and collaborations. Dr. Straus presented the goals for the four CAM domains and whole medical systems; health services research; ethical, legal, and social implications of CAM research and integrated medicine; training; and outreach.

Investing in Research

Through its research investments, explained Dr. Straus, NCCAM will continue to try to determine *why* a CAM approach works; if mechanisms cannot be readily defined, researchers will attempt to *study* if a CAM approach works. Although not entirely dependent on what NCCAM can provide, resources needed include:

- Powerful scientific tools and models
- Optimal study designs and outcome measures
- Accessible data and samples
- A research community enriched with experienced scientists and practitioners from diverse, relevant fields

CAM Domains and Whole Medical Systems

Mind-Body Medicine. Goals for research in the mind-body medicine domain include correlating mind-body interventions with neurological, psychological, and physiological measures and clinical outcomes. A second goal is studying the effect of placebos and the built environment (how and where we live) as important factors that potentially enhance the healing process. A third emphasis is reducing the burden of stress-related chronic illnesses by studying effects of negative mental states on the brain and body. A fourth goal will examine the mechanisms that link a spiritual orientation and other positive mental states with favorable health outcomes.

Biologically Based Practices. Goals in studying biologically based practices include verifying and identifying the composition of selected botanicals, determining their mechanisms of action, and identifying the pharmacological behavior of CAM products. A major goal is to ensure the safety of CAM products and practices by studying their safety and toxicity and their interactions with conventional drugs and biologicals. Establishing the efficacy of selected therapies to maintain health, prevent disease, and treat conditions of public health importance is another goal, by investing in rigorous, pivotal trials.

Manipulative and Body-Based Practices. Study of manipulative and body-based practices involves understanding mechanisms of action, determining the conditions for which selected practices may offer meaningful benefits, and correlating patient expectations prior to treatment and satisfaction after treatment through the use of physiological changes and other objective indicators.

Energy Medicine. Goals for research in CAM energy medicine call for the application of the research standards and tools used in physics, chemistry, and other quantitative disciplines to accelerate progress in understanding the source and biological effects of putative energy fields and to investigate what transpires in the course of energy healer-patient interactions.

Whole Medical Systems. In acquiring a richer understanding of CAM whole medical systems and how they operate within both their indigenous and dispersed settings,

the benefits of selected whole medical systems for some health conditions will be documented. In addition, the mechanisms underlying successful multimodality treatments in whole medical systems will be studied.

Health Services Research

With its focus on how CAM services affect the marketplace, this aspect of the strategic plan seeks to explore models of health care delivery that integrate CAM with conventional care and to enhance the design of CAM trials by collecting relevant health services research data.

Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine

This set of goals seeks to enhance the understanding of social, cultural, and economic factors relating to the use or rejection of CAM; to describe the framework needed to enable the creation of integrated, multidisciplinary research teams; to facilitate the use of integrated practice communities as environments for research; and to define ethical and legal issues that affect the conduct of CAM trials domestically and internationally.

Training CAM Researchers

Training efforts will focus on tailoring a portfolio of research training programs that respond to the needs of CAM research and continuing to foster a research culture and resources to enable both CAM-trained and conventionally trained individuals to build successful careers in CAM research.

Expanding Outreach

Outreach activities will be directed toward helping the public and health care professionals make informed decisions about CAM and enriching the pool of multidisciplinary CAM researchers.

Next Steps

Dr. Straus reviewed the next steps in developing and implementing the draft strategic plan. These include producing a finalized plan that incorporates comments from Council members and those submitted from representatives of other NIH ICs, agencies, and diverse stakeholder groups in response to the draft's posting on the NCCAM Web site for public comment through mid-November 2004. The plan will be released in January 2005.

VI. Discussion

After his presentation, Dr. Straus sought comments on the draft strategic plan, asking Council members and participants to concentrate on larger questions and issues. He asked that comments on smaller details be sent to Ms. Linda Engel, NCCAM's Special Assistant to the Director for Program Development.

Overall, Council members praised the draft plan for its ambitious goals and well-defined objectives. They also offered many specific comments and recommendations.

In response to a question on the relationship between the second 5-year plan and NCCAM's funding history, Dr. Straus noted that NCCAM's funding is largely defined by Congress, which expresses interest in certain areas of research. He noted that NCCAM is increasingly funding basic and preclinical research. Most of these grants focus on the domains of mind-body medicine and biologically based practices, areas suggesting the best return on NCCAM's research investments. However, Dr. Straus said that the topic of funding would be revisited frequently in Council discussions. Almost all NCCAM research investments lie in studying interventions for chronic illness; studying wellness will involve determining new measures and interventions.

Dr. Margaret Chesney, Deputy Director of NCCAM, commented that distinguishing between traditional mind-body interventions (such as meditation, yoga, and the placebo effect) and newer CAM practices can be difficult. She also noted that there are important issues in recognizing and measuring responsibility for one's own health or adherence to treatment and asked for guidance on this topic. It was noted that when patients are empowered to take charge of their own health, motivation and self-direction become primary issues and are often more complex than determining interventions alone.

It was observed that documenting a treatment's effectiveness is one of NCCAM's most important issues. The draft document's attention to ethical and legal issues was applauded, despite unease about its focus on medical systems. Dr. Straus responded by saying that NCCAM seeks to determine what works and what does not, while respecting traditions and public use in the context of rigorous science. He said that studying individual components of a treatment, as well as the effects of whole systems, could be useful and productive. One participant suggested that criteria for studying whole medical systems are needed.

Also addressed were measures of effectiveness. Until recently, it was noted that traditional allopathic medicine has focused on the arrest or elimination of pathology or symptoms. CAM research, on the other hand, addresses a phenomenon on which little scientific data exist: quality of life. Council was asked to consider what improves quality of life, as opposed to improving symptoms (such as the pain of rheumatoid arthritis), and what approaches should be used to study quality of life.

Further discussion suggested that having a comprehensive strategy for outcome assessment is key—such as a biological marker or some other measurement, which will likely diverge or vary from measurements of quality of life. It was noted that many patients use a CAM therapy for reasons not always clear to researchers. As an alternative to attempting to measure quality of life, adopting measures of disability or of accomplishment of activities of daily living was suggested. Noted also was the use of measurements of activities of daily living in cerebral palsy research, rather than the quality-of-life scales previously used.

Dr. Straus welcomed guidance in developing strategies for integrating flexible, state-of-the-art outcome measurements in research that would not dominate or overwhelm

NCCAM's research studies. He noted that the NIH Roadmap recently awarded \$5 million to develop new rating instruments.

Council noted that CAM use often is precipitated by patients' subjective responses to health care, such as a perceived lack of response from conventional physicians or the belief that CAM can improve their quality of life. Use of functional imaging as a strategy to document subjective feelings of well-being was suggested, as well as having the study of the neurobiology of well-being be a major part of NCCAM's strategic plan. Members concurred that patients seek something more in turning to CAM, with many CAM traditions incorporating some form of spirituality, noted by one Council member to be a true mind-body connection. It was noted that many patients want to be healed, as opposed to cured. One member queried how investigators could examine such philosophical questions scientifically.

Dr. Straus said that he welcomed comments and suggestions from Council members on rewriting portions of the strategic plan dealing with spirituality and mind-body medicine. In response, it was suggested that the plan specifically mention resilience as a target area for studying CAM use, as CAM is often used for stress-related problems as a way to build biological resilience.

Dr. Chesney thanked Council members for raising issues of patients' sense of healing and resilience. She suggested that studying motivation or efficacy could be productive and would represent an area of research not duplicated by other ICs, such as the National Institute of Mental Health. Dr. Chesney said that she and Dr. Catherine Stoney would revisit portions of the strategic plan in light of Council members' feedback.

In describing the new strategic plan as a potential landmark document, Council noted that it highlighted several areas of study of particular interest to veterans and their clinicians, such as phantom limb pain and post-traumatic stress disorder.

Also suggested was that the strategic plan address the importance of control groups as a crucial part of clinical research design. Massage therapy was noted as unique among CAM interventions as a therapy involving touch; little is known about how much of the benefit massage confers is due to touch alone, as opposed to specialized massage techniques. Remarks concluded with mention of the important implications in studies of massage where the control group treatment consists of touch.

In praising sections of the strategic plan dealing with body-based interventions, Council noted that body-based therapies may achieve their effects through many mechanisms—biological, biomechanical, and placebo, as well as the activation of something inherent in the person who receives the therapy. Observed was the need to indicate desired outcomes in research, such as reduced pain or improved activity levels.

Council also praised the document's vision and expressed the hope that NCCAM would retain its diversity of opinion and approach. It was noted, however, that the draft did not include information on how findings would be transmitted to conventional practitioners.

Dr. Straus responded that NCCAM has funded 15 awards to medical, dental, and nursing schools to introduce CAM information into the curriculum, an award cycle that finishes in FY 2007. He agreed that the draft could more clearly communicate its outreach to conventional practitioners.

One participant recommended that pharmacological interactions receive greater emphasis, as this is an area of great public concern and a research area of interest to other ICs. Suggesting that studies in this area would be moderate in cost, it was then queried whether assessments had been done to determine whether positive and negative research findings were being incorporated into clinical practice. Dr. Straus responded that the draft plan addresses some of these. He also cited the 2002 NHIS study, for which NCCAM funded and developed a supplement on CAM use; the survey tapped CAM use among 31,000 American adults.¹ This major survey of CAM practices and attitudes has inspired additional studies and analyses.

In discussing quality-of-research issues, it was observed that the 2002 NHIS survey found that prayer is the primary form of CAM usage among African Americans. Because the term “prayer” is very general, it was observed, how can researchers ensure that they are using such terms similarly? Definitions of terms, it was noted, would affect how a CAM intervention is quantified and accurately surveyed. Comments on this matter concluded by noting the importance of clarifying practices in CAM institutions in traditional societies versus CAM use in the industrial world, sketching some possibilities for cross-cultural collaborations.

In summing up, Dr. Straus welcomed Council members to make additional comments in the weeks to come. On behalf of NCCAM’s staff, he thanked members for their generous and helpful feedback. The Council will have the opportunity to view a revised version of the draft document at its January 2005 meeting.

VII. Public Comment Session

Dr. Kinsel introduced Julia Hartley, William Best, Sophie-Kim Bazinet, Kathleen Hartley, and Micheline Lacaille, who addressed the Council during the public comment session. Several of these speakers’ cases had been presented to the CWG as part of the Best Case series on 714X. The speakers discussed their or their children’s cancer diagnoses and experiences with conventional medical treatments and 714X. All speakers urged the Council to encourage further research on 714X and to increase public awareness of alternatives to conventional medical therapies for cancer.

Dr. Straus and Dr. Kinsel thanked the participants for their very moving testimonies. Dr. Straus also noted that NCCAM would welcome investigator-initiated applications for funding basic research on 714X. Dr. Low Dog concurred with Dr. Straus’s encouragement of applications for funding to study 714X. She reiterated the CWG’s

¹ Barnes P, Powell-Griner E, McFann K, Nahin R. *Complementary and Alternative Medicine Use Among Adults: United States, 2002*. CDC Advance Data Report No. 343. 2004.

recommendations that manufacturers or other investigators collaborate with experienced researchers, preferably using mouse models, in proposing funding for research studies.

Dr. Straus adjourned the meeting at 4:50 p.m.