

**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 FIFTY-THIRD MEETING
October 10, 2014**

NACCAM Members Present

Dr. Brian Berman, Baltimore, MD¹
Dr. Donald Brater, Indianapolis, IN
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Tracy Gaudet, Washington, DC
Dr. Jane Gultinan, Seattle, WA
Dr. Bin He, Minneapolis, MN²
Dr. Steven Hersch, Charleston, MA
Dr. Janice Kiecolt-Glaser, Columbus, OH
Dr. David Kingston, Blacksburg, VA
Dr. John Licciardone, Fort Worth, TX
Dr. Richard Niemtzwow, Alexandria, VA
Dr. Philippa Marrack, Denver, CO¹
Dr. Lloyd Michener, Durham, NC
Dr. Lynda Powell, Chicago, IL
Dr. Eric Schoomaker, Bethesda, MD
Dr. Chenchen Wang, Boston, MA

¹Telephone

²Ad-hoc

SPEAKER

Dr. Philip Bourne, Bethesda, MD
Dr. Robert Temple, Silver Spring, MD

NACCAM Members Not Present

Dr. David Borsook, Waltham, MA
Dr. Scott Haldeman, Santa Ana, CA
Dr. Frances Henderson, Jackson, MS
Dr. Deborah Powell, Minneapolis, MN

NIH Staff Present

Barbara Sorkin, ODS, NIH

Members of the Public

M.M. Braun
Jason Crosby
JoAnn Yanez

I. Closed Session

The first portion of the fifty-third 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 108 applications were assigned to NCCAM. Of these, 30 were reviewed by NCCAM, 78 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 58 applications, requesting \$19,949,960 in total costs.

II. Open Session—Call to Order

The open session convened at 10:00 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order. The minutes of the June 2014 NACCAM meeting were approved unanimously.

III. NCCAM Director's Welcome

NCCAM Director Dr. Josephine Briggs welcomed attendees and expressed appreciation for the advice of Council. She recognized five members who are completing their terms of service with this meeting: Drs. Brian Berman, Daniel Cherkin, David Kingston, Philippa Marrack, and Lloyd Michener.

IV. NCCAM and FDA Interactions

This session included presentations by Dr. Briggs and Dr. Robert Temple, Deputy Center Director for Clinical Science at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA), and discussion.

Part I. Dr. Briggs identified three major themes for the session: the safety of dietary supplements, their efficacy, and questions surrounding non-mainstream therapies, particularly chelation. NCCAM's scientific findings can be helpful in the regulatory arena, she said, and offered as one example a study by Dr. Robert Saper and colleagues (*JAMA*, 2008, 300(8):915-923). His team purchased an array of Ayurvedic products via the Internet (sourced from inside or outside the United States) and found, through testing, that a number of them contained arsenic, lead, or mercury. This study led to an FDA caution on using Ayurvedic products.

NCCAM has released an initiative to explore potential herb-drug interactions through a methodology center, and CDER staff have advised in that process. Dr. Briggs noted that the databases about these interactions available to pharmacists often rely on rodent studies, which may not accurately predict

interactions in humans. The number of potential interactions is extensive, and prescribing patterns do not appear to follow available guidelines. NCCAM hopes that applicants will propose ways to achieve greater understanding by standardizing methodology, which should improve the ability to sort through the worldwide literature base and prioritize interactions.

Dr. Briggs then presented data on nonvitamin, nonmineral natural products from the National Health Interview Survey, also recapping some results of NCCAM-supported clinical studies on several popular supplements. She suggested—also from data in a major supplement-industry publication—that research results on natural products influence patterns of their sales and use. Before launching any future efficacy study, such as a Phase III trial on a natural product, NCCAM will want to know as much as possible about the compound(s) proposed for study. She invited Council’s comment on this.

The next topic was follow-up to the Trial to Assess Chelation Therapy (TACT; NIH press release November 19, 2013). TACT showed that chelation reduced cardiovascular events in a prespecified diabetic subgroup. No benefit was seen in people who did not have diabetes. Data being gathered by the researchers suggest that cadmium or lead toxicity may be involved, and the impact of heavy metals on cardiovascular injury might play a role in the effect in diabetics. Benefit was also seen in TACT in a subgroup with prior anterior myocardial infarction (MI) compared with other MI locations. NCCAM is currently considering a replication study.

Part II. Dr. Temple expressed enthusiasm for good studies of complementary treatments and studies on herb-drug interactions. He also expressed concern about whether interactions are being prevented. He is not sure how much health care providers know about what supplements their patients are taking, and whether they consult the existing interaction information, e.g., on St. John’s wort and the CYP450 3A4 enzyme. He observed that various large studies of fish oil have not used populations that are at high risk for health problems or with high triglyceride levels, in contrast to studies of lipid abnormalities.

Some of the products about which the CDER is most concerned, Dr. Temple said, are botanicals/dietary supplements that are actually drugs, although not defined as such under law. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), these supplements become drugs only when claiming to cure or mitigate a disease, not when claiming to maintain health. Whether there is a difference between these two types of claims can be debated, but they are indeed different in terms of regulatory status. Apart from the legalities, sellers of dietary supplements have no obligation to provide data on effectiveness and little obligation to pursue safety issues (although toxicities of which they become aware must be reported). Dr. Temple said that FDA does not have a prejudice that natural products will not work, as many drugs originated from plants.

Dr. Briggs commented that all NCCAM’s studies on natural products have met FDA standards for Investigational New Drug (IND) applications and that NCCAM uniformly encourages this. Dr. Temple said that NIH studies are not required to have INDs, but the FDA always appreciates the opportunity to comment. The FDA considers it valuable to study dietary supplements that people **perceive** as working, to avoid the possibilities of waste and the use of ineffective alternatives.

Dr. Temple added that the FDA is very interested in drug study designs that are efficient and effective. An example is enrichment maneuvers, such as the randomized withdrawal study. In depression, the failure rate for clearly effective agents is about 50 percent, which is not significantly different from the

placebo rate. A randomized withdrawal study of a depression drug would examine the impact of discontinuing the drug in people known to respond to it. Learning whether discontinuation worsens symptoms could provide insight about recurrence. There have been 14 to 16 such trials to date, all of which have been successful.

Often, it is not known why some people respond to an intervention and others do not. One way to address this challenge is by doing a pretreatment study to examine who responds. In symptomatic conditions, failing to distinguish between a drug and a placebo may or may not be informative. The FDA is very interested in consulting on study plans. This is easiest when investigators submit an IND but will be provided in any case.

Dr. Briggs asked Dr. Temple to comment further on how NCCAM's science can make contributions in the safety arena. He responded that, under DSHEA, there is a requirement for manufacturers to report bad news to the FDA about safety—but it is not clear how closely people look for this, and the specific obligations are few, if any. Thus, the FDA would welcome more information in this area. He also mentioned that botanicals/dietary supplements are not labeled in the same way as drugs, and it may be possible to improve the process of disseminating safety information about them.

Dr. Temple said that he would consider the TACT findings, if replicated, to be somewhat surprising and very important (especially concerning the diabetic population). They would suggest a therapy, offer potential environmental insight on the impact of heavy metals on disease, and suggest a more assiduous look at sources of lead in the environment. Dr. Briggs said that NCCAM would probably confine a replication study to subjects with a signal of benefit; may partner with the National Heart, Lung and Blood Institute and the National Institute of Diabetes and Digestive and Kidney Diseases; and would include a large enough population of diabetics. With respect to design, Dr. Temple suggested first determining whether the therapy works, and then, in a subsequent, simplified trial, what the optimal length of therapy is for chelation. Another idea for later followup was an enriched study in the population in which chelation seemed to work.

Discussion. Dr. Temple expressed major concerns about how few data there are on natural products, and how major media, for example, are often too generous in describing the data (versus taking a rigorous approach). Dr. Gaudet asked about dissemination of results on placebos that outperform traditional therapies. Dr. Temple responded that, in his experience, persuasive, well-documented cases for such placebo effects (especially over the long term) have not been frequent; the topic is being studied, with the best place to look probably being pain. Dr. Briggs drew a distinction between pill placebos and expectation placebos. Dr. Temple agreed that the treatment environment can have effects for a variety of reasons, and added that spontaneous improvement can have a bigger effect than a drug.

Dr. Brater asked about the dynamic of uptake of negative results by the public and physicians. Dr. Temple commented that he would like to see NCCAM's negative results more widely publicized so that people will know what does not work, but mission is important. Dr. Briggs noted that when benefit has not been shown, NCCAM's information materials are clear on that point, and the relevance of safety information to the Center's mission is strong.

Dr. Guiltinan asked whether DSHEA requires routine testing of dietary supplements for contaminants as part of Good Manufacturing Practices (GMPs). Dr. Temple referred the question to NCCAM, since it is

not his group's area. Dr. Briggs noted that the FDA has been more active in establishing standards for GMPs. NCCAM Program Director Dr. Craig Hopp said that he was not sure whether that testing is required, but, in any case, a segment of companies do not abide by it, unfortunately. He also noted limitations of staff size at the FDA's oversight center. Dr. Temple commented on the history of drug regulation; prior to 1938, the requirements did not require submissions to the FDA. He added that most of what is done for dietary supplements is not submitted to FDA. He has seen some interest in drug claims for botanicals. Dr. Briggs commented that the FDA has developed excellent guidance on how to test natural products as drugs.

Dr. Michener asked to what extent the data being collected about heavy metal exposure and cardiovascular disease suggest crossover to other Federal agencies such as the Environmental Protection Agency. Dr. Briggs said that one of the partners in developing the TACT followup study is the National Institute of Environmental Health Sciences. Dr. Lynda Powell expressed strong support for replication of TACT; discussed use of smaller factorial designs for dose-finding studies; and noted that behavioral treatments are being widely used without regulation or efficacy data. Dr. Temple agreed on the latter point and noted that the laws on well-controlled studies originally did not apply to medical devices, but this has changed. He thought the same standards should apply to behavioral therapies, and that such studies could be done despite challenges with blinding, control groups, etc. In addition, third-party payors could conceivably say that they are not paying for these therapies until such studies are done. Dr. Schoemaker asked who has the responsibility for better educating patients or changing behaviors. Given the heavy use of supplements in the military community and other settings, this is an important concern. Dr. Temple said that he does not think that the FDA could, but it seems plausible that the Department of Veterans Affairs (VA), the Army, the Centers for Medicare and Medicaid Services (CMS), and third-party payors, for example, could educate about the evidence and carry out data reviews.

V. Data Science at NIH

Dr. Philip E. Bourne, Associate Director for Data Science at NIH, gave a presentation on the NIH Big Data to Knowledge (BD2K) Initiative. The current era is an exciting one in which biomedical research is undergoing a large shift, with digital information playing an increasing part. Open access and the democratization of science are also important factors. Dr. Bourne considers NIH to be a digital enterprise.

In October 2014, BD2K launched its first round of funding—consisting of \$32 million for various centers, other training activities, and the creation of an NIH Data Discovery Index Coordination Consortium. With engagement from the broader community, the consortium will study and address problems related to access, discoverability, and citation for all biomedical data. In the big picture, Dr. Bourne sees a need for a “three-legged stool” of community, policies, and infrastructure, all of which move in lockstep and within a “virtuous research cycle.” However, he said, the science must always come first.

Dr. Bourne gave examples of other priorities and initiatives for BD2K in FY 2015. Two major areas are (1) ethics and the legal and sociological aspects of handling clinical data and (2) engagement with an array of communities, from computer science to gaming. A third area is training, e.g., to meet pressing workforce needs in the field of biomedical data science. Among his other topics were data-sharing plans,

data citation, creative use of grant mechanisms to feed the idea of openness, creation of a stronger sharing environment that is also sustainable, and commons as an alternative.

Discussion. Dr. Briggs asked about how to overcome some of the roadblocks pertaining to human studies data, such as privacy. Dr. Bourne responded that indeed there is pressure on the system when trying to have accessibility yet preserve patient anonymity. More experiments, with consideration of emerging methodologies, are needed to see where that boundary is and to understand it better. Scientific advances are driving the thinking, but legislation and technology are needed to back that up, and he thinks the kind of work that BD2K is supporting will help that movement.

Dr. Briggs commented that NCCAM's large trials on dietary supplements have had data-sharing plans for datasets, but the infrastructure has not been there yet to make those plans truly a reality. Dr. Temple discussed some issues related to this in the pharmaceutical field, e.g., concerning proprietary data. Dr. Bourne commented that he thinks there is more openness and willingness currently to share precompetitive information, resources, and infrastructure than there was in the past; new business models as in social media may be having an influence.

In response to a question from Dr. Briggs, Dr. Temple noted that an initial plan was announced in Europe to release all proprietary data after a drug is approved, but it has been put on hold. The speakers discussed increased data openness and sharing as they could aid reproducibility, replication, and publication, and help address inefficiencies that are apparent in the research system and lifecycle.

VI. Baseline Portfolio Analysis in the Division of Extramural Research

Dr. Emmeline Edwards, Director of NCCAM's Division of Extramural Research, presented a brief look at a portfolio review that has been in progress in the Division since August 2013. The Office of Policy, Planning, and Evaluation and the Office of Communications and Public Liaison have also provided input. The major goals of this review are to create a baseline, encourage staying on-task, and build a rigorous evidence base on the following: what complementary/integrative health approaches NCCAM-funded researchers are studying, the conditions and populations being studied, any longitudinal trends, the kinds of scientific questions being addressed, and gaps and opportunities. The review is already informing funding decisions and the development of initiatives, and will be part of the preliminary work for NCCAM's next strategic plan.

The process uses an organized, phased approach, is driven by scientific content, and is conducted in several contexts: NCCAM, NIH, and the field under review. The process is also seen as dynamic and able to respond to new opportunities as they occur. Program staff initially consult with NCCAM leadership, then refine the process, carry out the analysis, present their findings for further input, and hold a next steps meeting. Tools include NCCAM and NIH databases, and manual analyses and evaluations.

To date, the following reviews have been completed: meditation, acupuncture, movement with meditation, natural products methodology, effectiveness research, the interactions of natural products (at multiple levels, including with drugs and the microbiome), symptom management, pain, and research training. Upcoming efforts include the neuroimaging portfolio.

Dr. Edwards provided snapshots of two completed reviews, on pain and natural product/drug interactions, including investment history from 2000 through 2013, types of studies, several examples of major results, and potential future directions.

For the pain portfolio, investments in recent years reflect the Center's prioritization of that topic. Of a total of 112 grants on a wide range of complementary approaches, more than half were in basic and mechanistic research. Back pain was most represented among diseases and conditions, and 70 to 80 percent of the approaches were mind and body. Future topics holding promise include mechanistic, central nervous system responses to manual therapy; effects of the Diffuse Noxious Inhibitory Controls pathway; ascending inhibitory effects; potentiation of the biological analgesic mechanisms of acupuncture; integration of manual therapy in primary care for reducing transition from acute to chronic low-back pain (LBP); and pragmatic, collaboratory-like study of the benefits of movement-based therapy for reducing LBP-related medical costs.

Natural product/drug interactions are not a new investment area for NCCAM, and the Center is not the only NIH Institute or Center (IC) studying the topic, but NIH's and NCCAM's investments have been relatively modest. Potential future directions offered were the role of transporters in drug interactions (less well understood than Phase I/II metabolizing enzymes), basic pharmacokinetic data (lacking for many commonly consumed natural products), pharmacogenomics of drug interactions, and pharmacodynamic interactions. Overall, these interactions are an area of potential impact for NCCAM. The Center will soon launch a large effort related to them and evaluate other possible followup activities as well in coming months and years.

Navigating research program development with limited resources poses challenges, Dr. Edwards said, and she offered approaches to address these. A major one is leverage—e.g., of existing NIH and/or other Federal agencies' resources, the Patient-Centered Outcomes Research Institute (PCORI), and public-private partnerships. Pooling resources is the optimal path.

Discussion. Dr. Gaudet asked why there is not more research on clinical hypnosis. Dr. Briggs responded that at the time when she arrived at NCCAM, some staff believed that this modality had already been proven to work; since then, she has encouraged pullback from that position. She said that, for her, a major question is why there is so little adoption of hypnosis in the clinical setting, when the evidence is quite clear that hypnosis modifies pain.

Drs. Michener and Brater each commented concerning the fact that dissemination and implementation are already taking place in a number of practice settings because options are badly needed, and questioned whether NCCAM could have a rigorous evaluation framework attached—e.g., by working with a partner like the CMS. Dr. Briggs commented that with complementary approaches, enthusiasm and implementation can leap ahead of the evidence, and people do not always understand the evidence base and its strengths and weaknesses. She agreed with the idea of exploring whether and how NCCAM could have a role in adding rigor to implementation through partnerships.

Dr. Powell described the upcoming strategic plan as an opportunity to develop a vision; encouraged development of the concept of **evidence-based** complementary and integrative medicine (as is being done by PCORI); and supported the study of how to pursue effective integration while keeping a focus on patients' needs. Dr. Schoemaker commented that the grid in the presentation seemed too focused on

modalities rather than problems, and he suggested focusing more on problems—e.g., where currently there are only drugs or potentially damaging interventions available.

VII. Concept Clearance: A Translational Approach to Natural Products

Dr. Wendy Weber, Chief of the Clinical Research in Complementary and Integrative Health Branch, presented a concept for Council's consideration. Its intent would be to encourage new ideas that would cover broad needs existing across the natural products field.

She described some challenges that the Center has had with clinical trials of natural products. One is that applications have not always been aligned with the Center's research priorities. A second is that a trans-NIH concern about reproducibility of preliminary data and animal studies applies to natural products, both preclinically and in small-phase clinical studies. A third is when a trial lacks a biological hypothesis, biological signature, and measurement of the natural product's biological effect. This can lead, for example, to a negative finding being difficult to interpret or to questions about product selection.

Dr. Weber proposed a phased approach that would restrict support of later phase clinical trials to well-characterized agents that have a biological signature (i.e., a biological effect in humans as a measure of the mechanism of action), have a biological hypothesis, and are based on strong preliminary data. To reach this goal, NCCAM would need a solicitation for rigorous preparatory work to speed translation. Studies based on animal findings would require independent replication. Investigators would need to establish the bioavailability, pharmacokinetics, and pharmacodynamics of the natural product, as applicable. They would also need to demonstrate the biological signature of the natural product, reproduce it, and use it to determine dose ranging for future clinical trials. Two potential ideas for future research areas were the impact of prebiotics and probiotics on innate immunity, and natural products of value for symptom management.

Discussion. Drs. Kingston, Hersch, and Powell each expressed support for the concept of a phased approach. Dr. Hersch noted that study sections may not see this kind of work as innovative and pressing; it would be important for NCCAM to be clear about the expectations for a successful application and to communicate them to the sections. Dr. Briggs noted that it is always a question whether to release a funding opportunity so that it uses a standing study section versus a study section set up within the IC. Dr. Powell recommended being specific as to what is meant by "pilot studies." Dr. Briggs responded to a comment from Dr. Brater about explicit validation of surrogate endpoints by noting that the surrogate-endpoint process is very demanding, and NCCAM's trials have tended to be based on hard endpoints instead. Clinical recommendations cannot be based on unvalidated surrogates.

A motion to approve this concept was made, seconded, and passed with 13 affirmative votes.

VIII. How Stress Kills: The Damage and Some Remedies

Council member Dr. Kiecolt-Glaser presented on her team's research at the Ohio State University on how stress and depression modify immune and endocrine function. She has, for example, conducted controlled studies in models of stressed populations such as medical students, caregivers of people with

dementia, and stressed married couples, focusing upon responses to vaccines (as proxies for infectious disease responses) and/or healing of small, standardized wounds.

Her team has found important health consequences from stress, including impaired vaccine responses and slower wound healing, and that chronic stress markedly speeds age-related changes in inflammation. This is linked to a variety of negative health outcomes, including cardiovascular disease, type 2 diabetes, some cancers, osteoporosis, arthritis, and increasing frailty and declining function.

Production of proinflammatory cytokines such as IL-6 is important in acute stress, such as resolving infections and healing wounds, but people also produce them over time under chronic stress, which can lead to deleterious health effects. In a study of caregivers of Alzheimer's disease patients, for example, Dr. Kiecolt-Glaser's team assessed a number of physiological and immunological markers *in vitro*, as well as depressive symptoms, compared with controls. The caregivers had significantly lower T-cell proliferation, higher production of immune-regulatory cytokines, and much greater loss of telomeres than did the controls, as well as significantly higher depressive symptoms.

Higher inflammation levels are also associated with a variety of sickness behaviors (as anyone would have with the flu, for example) and cognitive problems; this actually forms as a cycle, and there are various points in the cycle at which intervention can take place. Interventions that impact stress or depression, such as many being studied by NCCAM, may have physiological consequences downstream. As one example, a recent NCCAM-supported controlled study by her team in a group of breast-cancer survivors found that practice of hatha yoga significantly reduced fatigue and several markers of inflammation (IL-6, TNF- α , and IL-1 β) at 3 months post-treatment, compared with waitlist controls. There was also a dose-response relationship; i.e., women who practiced yoga more obtained more benefit.

Dr. Kiecolt-Glaser then discussed her more recent work in the areas of nutrition, behavior, and immune function. She gave examples of study results indicating that depression and chronic stress alter metabolic responses to food and meals in ways that can promote unhealthy diet patterns, weight gain, and obesity.

Discussion. Dr. Schoemaker asked about remedies from complementary approaches. Dr. Kiecolt-Glaser responded that data on yoga and mindfulness, for example, are impressive, but the problem is in getting people to actually practice complementary approaches that would be helpful. She also noted that careful selection is very important for any trial (e.g., studying people who are already at risk, to able to see any changes) and that brain-imaging studies may be more compelling to people than some other kinds of data. Dr. Briggs identified a theme in the meeting: in any design for a randomized controlled trial, it is very important to consider the likelihood of a response in the best-responding group. Dr. Michener asked about use of different language (for example, saying "prayer" instead of "meditation," or "dance" instead of "yoga") in the settings of different communities. Dr. Briggs affirmed that cultural context is important and should be part of the thinking about any trial.

IX. Director's Report

Dr. Briggs opened her report by welcoming Dr. Bin He as an ad hoc Council member. NCCAM staff changes include expansion of the Division of Intramural Research by hiring a tenure-track investigator,

eight other scientists, and a nurse practitioner. Dr. Laura Lee Johnson, statistician in the Office of Clinical and Regulatory Affairs, is departing for the FDA.

NCCAM is operating under a continuing appropriations resolution (P.L. 113-164) that funds the Federal Government through December 11, 2014. It includes a small across-the-board rescission of 0.0554 percent to finance special Federal efforts on Ebola. NCCAM anticipates that Congress will pass, and the President will sign, an omnibus funding bill or another continuing resolution to fund the remainder of the fiscal year. Both the House and Senate have pending appropriation legislation that could be included in an omnibus bill. The provisions of the Senate Appropriations Committee's subcommittee include modest increases for NIH (a \$30 billion budget) and NCCAM (a \$125.8 million budget). Both appropriation bills include a change of name for NCCAM (discussed further below).

Two Senate Appropriations Committee clerks visited NIH and met with IC Directors, and Dr. Briggs presented to them on NCCAM's activities, especially projects on pain with the VA and the Department of Defense. Dr. Briggs was a speaker at a day honoring Senator Tom Harkin, who is retiring at the end of his current term. Dr. Briggs discussed NCCAM's budget from FY 2011 through FY 2015 and presented the current budget mechanism table.

Recent NIH news includes the retirement of Dr. Story Landis as Director of the National Institute of Neurological Diseases and Stroke (NINDS). Dr. Walter Koroshetz has become Acting Director, and Dr. Briggs is a member of the search committee. The NCCAM Division of Intramural Research works very closely with NINDS. Ebola-related issues have had a high impact on NIH. NCCAM's only official role has been to post an advisory on its Web site concerning false "remedies" for Ebola, but Dr. Briggs, as a member of the NIH Steering Committee and the Clinical Center Governing Board, is briefed each week.

A 2-day workshop, "Pathways to Prevention: The Role of Opioids in the Treatment of Chronic Pain," was held at NIH. The workshop's primary sponsor was the National Institute on Drug Abuse (NIDA), but NCCAM provided input. Dr. Briggs commented that she feels strongly that a very vigorous response is needed to what she finds, based on high-impact data, to be a shocking iatrogenic epidemic of opioid overdoses. This situation adds even greater urgency to NCCAM's work on integrative nonpharmacologic approaches.

The NIH Health Care Systems Research Collaboratory recently made three new awards for research on care of people with multiple chronic conditions; NCCAM is the Collaboratory's administrating IC. Dr. Partap Khalsa and NCCAM have had a leading role in the work of the NIH Pain Consortium's Task Force on Research Standards for Chronic Low Back Pain; the Task Force recently released its report and has published related articles in numerous journals. Thirteen new awards to study complementary health approaches for fighting pain in U.S. military personnel and veterans were announced. They involve partnerships between NCCAM, NIDA, and the VA. Other recent events included NIH's initial awarding of \$46 million for BRAIN Initiative research; NCCAM's Integrative Medicine Research Lecture Series; and social media activities.

Dr. Briggs then discussed the potential name change for NCCAM to The National Center for Complementary and Integrative Health. The Center is in the process of exploring two routes, administrative and Congressional, to this change. It submitted an administrative package that was approved by NIH and is with the Department of Health and Human Services. If it is approved by

Secretary Burwell, Congressional notification will be required for 180 days. The potential name change has been included in the Senate appropriations bill; it may also be in an omnibus bill, but that inclusion is not guaranteed.

NCCAM is the lead agency for the 2014 Combined Federal Campaign (CFC) at NIH; Dr. Briggs and NIH Director Dr. Francis Collins are co-chairs. Dr. Briggs described the campaign and some highlights of CFC activities and events involving NCCAM staff.

X. Public Comment and Adjournment

No public comments were offered.

The meeting adjourned at 2:30 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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