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# ACCAHC Research Working Group Led Communication with NIH NCCAM on the 2011-2015 Strategic Plan

#### February 2011

The following set of 4 letters sandwiched two conference calls during the development of the NCCAM Strategic Plan. Each letter was developed through the ACCAHC Research Working Group. A draft was then circulated to the ACCAHC Board of Directors and leaders of the 16 ACCAHC member organizations. Amendments and changes were made prior to submission to NCCAM.

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#### Letter #1:

## **Initial Response to NCCAM Request for Stakeholder Comments**

November 18, 2009

Josephine Briggs, MD, Director Members, Strategic Planning Team National Center for Complementary and Alternative Medicine National Institutes of Health 31 Center Drive. Building 31, Room 2B-11 Bethesda, Maryland 20892-2182

Dear Dr. Briggs and Strategic Planning Team Members:

We are writing in response to your October 2009 solicitation of stakeholder input on the next strategic plan for the NIH National Center for Complementary and Alternative Medicine (NCCAM). Thank you for your preliminary work and for this opportunity to respond.

The 12 core ACCAHC member organizations (see left column) serve the distinctly licensed complementary and alternative healthcare disciplines of chiropractic medicine, acupuncture and Oriental medicine, naturopathic medicine, massage therapy and direct-entry midwifery. In addition, ACCAHC's members include 3 organizations from non-licensed Traditional World Medicines fields of yoga and Ayurvedic medicine that are engaging in self-regulatory efforts. The ACCAHC disciplines provide the majority of the complementary and alternative medicine and integrative services for consumers in the United States. Similarly, 187 of our universities, colleges and programs are accredited through specialized U.S. Department of Education-recognized accrediting agencies. These institutions are the educational providers for the vast majority of future integrative practitioners. We view ourselves as a significant NCCAM stakeholder.

We have identified the following three areas as the top, shared priorities for research investment across our licensed professions. We believe that investment in these three areas will have the most potentially positive impact on US healthcare.

- 1. Research on whole practices— We need to learn more about the real world outcomes of these disciplines in order to understand the experience of consumers and the value of these practices in healthcare delivery. We urge the evaluation of the effectiveness of the actual, multi-dimensional practices of the members of these disciplines. A subset of this exploration could include evaluating the preventive outcomes of the clinical approaches that are a common orientation of integrative healthcare practitioners in the ACCAHC disciplines. These whole practices frequently include many of the lifestyle-related interventions that are recommended to combat numerous chronic diseases.
- 2. Costs, cost effectiveness, cost-offsets and cost-savings Cost to consumers and to third-party payers is a critical issue regarding access to integrative healthcare/integrative medical services provided by practitioners from the ACCAHC disciplines. Cost implications of including the services of members of these disciplines are central components of decision-making processes for insurers, employers, legislators and government agencies as well as administrators and medical directors of hospitals and clinics. These stakeholders would find significant, practical value in information on

costs, and particularly cost-offsets, as they continue to expand the integration of the services of these licensed practitioners into payment and delivery systems.

3. Capacity – We urge the expansion of investment in the development of researchers who are graduates of complementary and alternative medicine programs, particularly those who have a continued association with the accredited CAM schools. Our disciplines have gained significant new experience from programs supported by conference grants and by the education awards that assisted the development of evidence-based medicine curriculum, research activity in our faculty and students, and partnerships with conventional academic health centers. Graduates of a growing number of our universities, schools and programs are benefitting from NCCAM's development awards. These have been extremely meaningful, even as NIH investment in conventional academic health centers starting a half-century ago has transformed those institutions. One focus of grants and awards could be on developing expertise in methodologies and practices for evaluations in the areas recommended in #1 and #2, above.

The NCCAM's 1998 mandate from Congress appears to be remarkably supportive of these priorities. We note Congress' prioritization of evaluation of outcomes and health services research. Congress calls repeatedly for the evaluation of each of the licensed CAM disciplines and, specifically, their integration with conventional medicine and into delivery systems. The mandate urges evaluation of preventive approaches, and also notes the importance of investment in personnel as a necessary means to all of these ends.

A number of healthcare trends, beyond the common interests and needs of the ACCAHC disciplines, support these recommendations for NCCAM's strategic plan. Among these are an increased awareness of the multi-factorial nature of care for costly chronic diseases, the heightened focus on healthcare costs and the importance of comparative effectiveness research. In addition, the emergence of "integrative medicine" in conventional medicine has prompted an overlapping interest in the evaluation of whole practices, whole systems, interventions related to wellness and healing, and factors related to their appropriate integration with delivery systems.

Finally, this timing is auspicious for these priorities because a growing number of researchers directly related to these disciplines now have experience of the NIH culture and have participated in the NIH mission as advisers, reviewers, applicants for grants and as funded researchers. Researchers and institutions associated with ACCAHC disciplines are better equipped than they were in 1998 to partner, counsel and lead these evaluations which Congress urges. We anticipate that such a prioritization will continue to excite increasing interest in research endeavors among the students, faculty and clinicians from the ACCAHC disciplines.

Thank you for this opportunity to participate. Please do not hesitate to contact us if we can provide you with further information that will assist NIH NCCAM's strategic planning process.

Elizabeth A. Goldblatt, PhD, MPA/HA	David O'Bryon, JD
ACCAHC Chair	ACCAHC Vice-Chair

Sincerely

# Letter #2 Following a March 2010 call with Briggs, Killen

May 8, 2010

Josephine Briggs, MD, Director
Members, Strategic Planning Team
National Center for Complementary and Alternative Medicine
National Institutes of Health
31 Center Drive. Building 31, Room 2B-11
Bethesda, Maryland 20892-2182

Dear Dr. Briggs:

We thank you and Dr. Killen and the other members of your staff for the March 15, 2010 conference with leaders of the Academic Consortium for Complementary and Alternative Health Care. We circulated notes from the call to our entire group and engaged in follow-up discussions, live and via email, with multiple sub-groups prior to preparing this letter. We hope you will find these additional recommendations and clarifications useful as you move closer to announcing the draft plan.

#### **Principles**

You spoke of organizing the strategic plan around a set of principles. We reiterate the important principle suggested on the call by ACCAHC Research Working Group co-chair, Heather Zwickey, PhD: "Research CAM the way it is practiced." You have articulated an interest in more "real world research" and we encourage NCCAM to focus significant resources on this direction.

A second and related principle is to balance funding between basic science (bench science and efficacy trials to move science forward) and health services research (effectiveness and economics to provide information for health policy). This principle would guide NCCAM toward health services and outcomes research funding to a level that is on par with the levels of resources dedicated to basic research and that dedicated to efficacy trials.

A corollary, given the health orientation of most CAM practitioners, is to focus on the role of CAM therapies and disciplines in prevention and health promotion. One useful step would be the development of reliable, valid and comprehensive outcome measures for health and wellness that can be used in pragmatic studies.

We were pleased to see that our colleagues with the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM) also endorsed both more "real-world effectiveness trials" and a balanced portfolio.\* These principles would also appear to support the outcomes, health services and pragmatic directions of the Congressional mandate you noted in the NCCAM white paper created to shape thinking on the strategic plan. We hope to see these principles at the center of the strategic plan.

#### Capacity

Joe Brimhall, DC, an ACCAHC executive committee member, spoke to the importance of investment in capacity on the call. In the last 11 years, NCCAM's grants have significantly boosted the ability of many of

our institutions and researchers to participate in the research endeavor. We would like to see some key existing programs continued, others expanded and new programs created. We recommend that NCCAM:

- continue and expand R-25 grants relative to evidence-based healthcare and evidence-informed practice in CAM schools and include higher indirect costs, given the experience that the internal costs associated with these grants far exceeds the 8% level;
- work to limit brain drain from the CAM institutions by supporting career development grants for clinicians from the licensed CAM fields who are affiliated with and dedicated to continuing to work in the accredited CAM schools (rather, for instance, than encouraging K-awardees to seek employment at large medical health sciences institutions);
- fund additional stand-alone grants to CAM institutions that already have a strong research foundation, and collaborate with the National Center for Research Resources to create infrastructure in these institutions;
- stimulate a higher percentage of grants to conventional centers to either require or strongly encourage partnership with CAM institutions or CAM researchers on staff at CAM institutions, or award points to those that do;
- fund research conferences, workshops and symposia developed through the accredited CAM schools, including those that explore the best methods for studying the impact of whole disciplines ("whole practice" research); and
- following the present NIH policy of giving points to new researchers, we urge NCCAM to give a
  marginal benefit to grant applications from CAM practitioner-scientists and applications coming
  from CAM academic/research institutions investigators to acknowledge that CAM concepts are
  not necessarily easy to translate to conventional perspectives and pose an extra hurdle in
  articulating a good study.

#### Cost

Adam Burke, PhD, MPH, LAc introduced the topic of cost and cost-effectiveness on the call. Cost questions are critical for government agencies, insurers, employers, health systems and other stakeholders who seek to understand how to integrate licensed CAM disciplines into the delivery system.

We appreciate the challenges involved with cost research, and at the same time urge NCCAM to engage in these challenges. Some are methodological: How do we best evaluate the cost impacts of integrating CAM disciplines into hospitals and payment structures? Another challenge is workforce-related. Past funding priorities have left us with a CAM/IM research community that is somewhat under-developed for either engaging cost questions directly or for employing the best strategies for adding cost components to other research. One compelling tactic will be to announce a scoring benefit to those efficacy and effectiveness trials that include a cost component. An announced NCCAM commitment to elevating research on cost as an ongoing, multifaceted initiative will guide researchers to upgrade their skills in these areas and to develop appropriate collaborations.

We were pleased to hear on the call that NCCAM is seeking to capture more cost-related information regarding covered CAM practice in the next CDC survey and is involved in exploring applications of comparative effectiveness research for CAM treatments. We urge that this include looking at not just therapies but also the cost questions related to the evaluating the care from members of licensed disciplines. We also discussed the possibility of adding CAM-related questions to major longitudinal studies. We support these directions.

#### **Review Processes**

While some members of the ACCAHC research community laud insights gained from NIH reviewers, more often they speak of encountering significant problems with reviewers whose lack of familiarity with CAM or the CAM fields has impeded their ability to appropriately judge the merits of a proposal. Reviewers often do not understand the value of non-RCTs and qualitative research. Presently both R01 and now R21 applications are likely to be reviewed by study sections with little expertise in CAM. The emphasis on significance in these sections with little or no interest in our disciplines means CAM applications face an additional penalty. Concern with the lack of fit or inexperience of reviewers appears to grow in direct correlation with the extent to which the proposal attempts to measure the real world/whole practices of members of these disciplines and investigate innovative concepts from CAM. Experienced biases lead many CAM researchers to frame research questions and methods to satisfy uninformed reviewers rather than in ways which may best advance science and the public health. We recommend that:

- NCCAM should have both basic and clinical science study sections;
- the majority of the assigned reviewers should have the appropriate CAM knowledge and experience;
- the number of CAM reviewers in every study section should be increased; and,
- NCCAM should create educational programs to train CAM school faculty to be trained as reviewers.

#### **Research Stage Guidelines**

NCCAM does not have clear guidelines in place to facilitate development of a program of study and the related appropriate funding mechanisms. This can lead to an expectation of higher level research questions for an exploratory (R21) mechanism, for example. We recommend that NCCAM:

- publish, or borrow from other institutes, a set of principles that underscores the fundamental elements of developing a program of research, and the step-by-step processes involved in building a program of behavioral research that can be used by applicants and reviewers alike (for example NIDA developed the Stage Model set out in Rounsaville & Carroll (2001#); and,
- develop new funding mechanisms that support fundamental questions associated with Stage 1 research questions (that may include qualitative, descriptive and observational studies).

We believe that one of the most significant successes of NCCAM in its first decade was not mentioned in NCCAM white papers for the strategic plan. We refer to the relatively vast expansion of research opportunities during this period for members of the licensed CAM disciplines, for researchers associated with the accredited CAM schools and for the schools themselves. We have had opportunities to participate that were exceedingly rare in the past, or did not exist at all.

We believe that by following these recommendations, NCCAM will allow us to take this involvement in research a next step by engaging research that will improve understanding of the way that CAM practice by licensed CAM practitioners impacts health care delivery. The potential value of the foci we recommended is significant. The licensed CAM disciplines represent over 200 US Department of Education-recognized and accredited schools and programs and more than 350,000 practitioners, some 100,000 of whom are first contact providers.

Thank you again for your time. We look forward to your draft plan and to ongoing dialogue. (Signed by Liza Goldblatt and then RWG Chair Heather Zwickey, PhD)

# Letter #3: Response to NCCAM's Draft Strategic Plan

September 28, 2010

Josephine Briggs, MD, Director
Members, Strategic Planning Team
National Center for Complementary and Alternative Medicine
National Institutes of Health
31 Center Drive. Building 31, Room 2B-11
Bethesda, Maryland 20892-2182

Dear Dr. Briggs:

We thank you and Dr. Killen and your team at NCCAM for the ongoing opportunity to participate in the development of the NCCAM Strategic Plan. These ACCAHC comments offer proposed amendments to the draft of the plan that was released to the public in August 2010. This letter follows our correspondence of November 2009 and May 2010.

#### Commendation

First, we are very pleased to share that our internal discussions of the draft plan have uniformly included numerous, unsolicited statements of support for key elements of the proposed plan. Most pleasing are the decisions to prioritize "real world research" and the potential value of complementary and alternative medicine therapies and practices as health-promoting and health-enhancing interventions. The draft plan's focus on continued capacity building is also of great interest to the educational institutions associated with the complementary and alternative medicine disciplines that make up ACCAHC's core membership. In each of these areas, our recommendations are reflected. We are pleased with this alignment.

#### Recommendations

Our discussions have also identified areas where changes to this draft will help maximize NCCAM's contributions to the improvement of human health. We offer specific amendments in three thematic areas.

#### Make current Strategic Objective #3 NCCAM's new Strategic Objective #1

Proposed Strategic Objective #3 reads: "Increase understanding of 'real-world' patterns and outcomes of CAM use and its integration into health care and health promotion." This objective encompasses three distinguishing features of complementary and alternative health care as a research endeavor. The first is that, as you note, the leading CAM modalities and disciplines are already in widespread use by consumers and often covered by payers and included in major delivery systems. Second, current Strategic Objective #3 acknowledges that real-world patient use and practitioner delivery of integrative care is typically not via an isolated therapeutic agent or modality but part of multi-modal, whole person care. Reductive, single agent trials do not capture what is practiced. Third, as this draft plan correctly highlights, much of consumer use and practitioner orientation is related to health-promoting and health enhancing outcomes. Engaging these is to engage the defining characteristics of integrative practices. Doing so will align

NCCAM's directions with the top priorities (outcomes/health services) expressed in Section f of the NCCAM enabling legislation. Finally, engaging questions relative to health-enhancement and whole person care will position NCCAM for leadership when this agenda ascends more broadly inside NIH. For all these reasons, Strategic Objective #3 merits positioning as #1.

#### Explicitly include a focus on researching "disciplines"

The document does not at this time mention the importance of focusing on "disciplines" as a unit of research. The critical importance of directly stating this intent is apparent when one considers the choices of citizens and the inclusion decisions of payers and healthcare delivery systems: each frequently includes complementary and alternative medicine through accessing distinctly licensed or trained disciplines such as acupuncturists, chiropractors or massage therapists. To highlight this direction, we recommend some or all of the amendments below. (Additions are in bold.)

Page 1 - The mission of NCCAM is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions **and disciplines** and their roles in improving health and health care.

Page 1: NCCAM defines it simply as a group of diverse medical and health care systems, **disciplines**, practices, and products that are not generally considered to be part of conventional medicine.

Page 2, 4<sup>th</sup> conclusion: Finally, the strategic planning process forged a realization that although half of CAM use by Americans is aimed at improving general health, most CAM research to date has focused on the application of CAM practices **and disciplines** to the treatment of various diseases and conditions.

Page 3, under Goal #1: There is growing evidence that some modalities and disciplines are helpful—

Page 3, under Goal #2: There are also claims and preliminary evidence of success by **members of** CAM **disciplines** and integrative medicine practitioners in motivating people to adopt and sustain health-seeking behavior.

Page 6, under Scientific Promise: Potential application of specific CAM approaches **and disciplines** to comprehensive strategies for management of chronic pain.

Page 10, the 4<sup>th</sup> Guidepost: Fourth, research on the application of CAM modalities **and disciplines** to health care and health promotion requires use of effectiveness and other "real-world" research methodologies.

Page 12 & 23, under Strategic Objective #3: Strategic Objective 3: Increase understanding of "real-world" patterns and outcomes of CAM use of CAM modalities and disciplines and their and its integration into health care and health promotion.

Page 25: One of the defining features of CAM modalities and disciplines is their is its widespread use by the public.

Page 25: Descriptive information examining the frequency of and reasons for **use of** CAM **use modalities and disciplines** in disease and symptom treatment and in promoting improved health and well-being ...

Page 25: "Real-world" outcomes information ... in order to gain insight into the potential or perceived benefits, risks, and comparative effectiveness of **the use of** CAM <del>use modalities and disciplines</del>.

Page 26, Strategy 3.2: Use a range of research methods—for example, epidemiology, surveys, health services research, effectiveness/cost-effectiveness—to study effectiveness (outcomes) and cost-effectiveness of CAM practices **and disciplines** in "real-world" settings.

Page 27, Strategy 3.3: Conduct research on CAM decision making and the role of CAM **modalities and disciplines** in behavior change.

Such inclusion, in these and other places in the Strategic Plan, would mirror the explicit language in the NCCAM enabling legislation which, rather than referencing merely "CAM" or the researching of CAM

"practices" or CAM "modalities," routinely turns NCCAM's attention to focusing on researching the potential of CAM "disciplines" to our payment and delivery system.

#### Explicitly focus on building capacity, including infrastructure, in CAM disciplines and institutions

We strongly support the emphasis on building of capacity in Strategic Objective #4. One of the most significant successes of NCCAM in its first decade was the relatively vast expansion of research opportunities for members of the licensed CAM disciplines and researchers associated with the accredited CAM schools. These opportunities and programs, especially the CAM R-25s, have begun to transform the content and culture of many of our institutions and the continuing education in our professional meetings.

However, present patterns of research investment and available funding mechanisms often foster what our schools experience as a "brain drain." Researchers from CAM disciplines leave our institutions to find employment in conventional academic health centers. While we appreciate the value of collaborating with and connecting to the resources and expertise available in conventional academic health centers, the present pattern has two negative consequences. Our CAM schools are challenged to develop the "intellectual infrastructure" represented by strong cadres of researchers who are onsite, employed, working together, formulating and answering the types of questions that are of greatest significance to our fields. Meantime, the opportunity to impact the educational culture of our institutions is also limited by this exportation of talent. Both, in their ways, have long-term and pervasive effects on appropriate integration of CAM disciplines with mainstream delivery systems.

Investing in this infrastructure development inside our schools and disciplines is critically important to our ongoing research contributions. (One mechanism might, for instance, be funding partnerships in which CAM institutions that have not received R-25 grants could partner with one or more existing R-25 schools in order to take advantage of, and effectively disseminate, the learning from NCCAM's funded programs.) For these reasons, we recommend the following amendments to address the critical importance of building research capacity inside the CAM schools.

#### Page 29, the introductory section:

These efforts have been successful in attracting many conventional, and CAM-trained and CAM discipline scientists into the field of CAM research.

NCCAM must continue to ensure that the human talent, resources, and infrastructure **in conventional and CAM institutions** needed to design and carry out the highest quality research are in place,

#### Page 29, paragraph 1 under section 4.1:

A successful and robust CAM research enterprise must draw from two sources of well-trained, skilled, and experienced talent: CAM practitioners and conventional biomedical/behavioral scientists. CAM practitioners are key holders of knowledge related to CAM therapies. NCCAM has always recognized the need for research training and career development efforts targeted specifically toward this diverse community. Over the years the Center has developed a number of programs aimed at enhancing CAM practitioners' abilities to critically evaluate biomedical literature, develop greater knowledge of the therapies prescribed to their patients by allopathic physicians in integrative medicine settings, become better able to participate in clinical research, and, in some cases, be inspired to seek advanced training and career development opportunities in biomedical research. NCCAM programs have led to the development of infrastructure in some CAM institutions that is enhancing the culture of evidence and enabling an expanded engagement in research.

#### Page 30, concluding section 4.1:

... In particular, the Center will focus on:

- Postdoctoral students from conventional and CAM disciplines who are interested in pursuing a career in CAM research.
- CAM practitioners who wish to gain the knowledge and experience needed to engage in rigorous collaborative or independent research in their field.
- Conventional medical researchers and practitioners who need to increase their base of knowledge and experience regarding specific CAM interventions and practices.
- Enabling an expanded engagement in research in CAM institutions.
- Members of populations who are underrepresented in scientific research and are interested in careers in CAM research.

We believe that these recommendations carry the spirit of the Congressional mandate (Section h) to ensure that CAM research centers "shall include accredited complementary and alternative medicine research and education facilities."

Again, we are very pleased with much of the direction in this draft plan and thank you for the work and inclusive process through which it has been engaged. We believe that these additional amendments will allow our graduates, researchers and institutions to significantly enhance their ability to contribute to the understanding of how CAM modalities and disciplines can impact health and healthcare delivery. The ACCAHC CAM disciplines represent roughly 200 US accredited schools and programs accredited by agencies recognized by the U.S. Department of Education-recognized and more than 350,000 practitioners, some 100,000 of whom are first contact providers. Thank you again for your time. We look forward to the final plan.

Sincerely,

Elizabeth Goldblatt, PhD, MPA/HA Chair, ACCAHC Board of Directors

Greg Cramer, PhD, DC Chair, ACCAHC Research Working Group

<sup>(^)</sup> Due to her employment at NCCAM, RWG member Wendy Weber, ND, MPH, PhD abstained from participation in development of the letter.

#### Letter #4:

## Response to a Dialogue with NCCAM Regarding "Disciplines Research"

October 28, 2010

Josephine Briggs, MD, Director
Members, Strategic Planning Team
National Center for Complementary and Alternative Medicine
National Institutes of Health
31 Center Drive. Building 31, Room 2B-11
Bethesda, Maryland 20892-2182

Dear Dr. Briggs:

We are writing to follow-up on the topic of "researching disciplines" which you mentioned in your response to the September 29, 2010 ACCAHC letter on the draft NCCAM Strategic Plan.

Gaining clarity and securing a more significant focus on the topic of "disciplines research" is the highest priority for us, as we believe it must have been for the Congressional architects of NCCAM given the frequency with which the mandate refers to some variant of "researching modalities, **disciplines** and systems." (Appendix A.) Our prior recommendations to NCCAM in the strategic planning process to prioritize investment in research on outcomes, real world settings, whole practices, costeffectiveness/cost-offsets, health-enhancement and on capacity building - can all be folded into the topic of disciplines research. (See ACCAHC letters of November 2009, May 2010 and September 2010.)

As we noted in our September 2010 letter, the draft did not at that time directly focus on the topic of researching disciplines. We would welcome expansive dialogue on a comprehensive NCCAM strategy for disciplines research at your earliest convenience, especially given the status of the strategic plan. An ACCAHC delegation could come to Bethesda. Alternatively, we could discuss the issues further with you and your team via teleconference. We offer these ideas as a further step in a process that we hope will be reflected in changes in the Strategic Plan.

#### The Societal Value of Disciplines Research

The societal value derived from NCCAM focusing on examining "disciplines" is that this reflects the real world choices that stakeholders make when considering use of complementary and alternative medicine practitioners. For instance:

- An individual may ask: Should I see a chiropractic doctor or massage therapist or acupuncturist or naturopathic physician for this condition/disease?
- A hospital administrator or medical director may want to know what happens if massage therapists and/or acupuncture and Oriental medicine practitioners are part of their inpatient teams.
- Insurers and public and private employers typically expand coverage to "CAM" through credentialing panels of members of the distinctly licensed complementary healthcare disciplines.
- Private and public employers may be interested in the value of including a chiropractor or a massage therapist, or an acupuncturist or yoga therapist or naturopathic doctor in their onsite clinic, or via networks of credentialed practitioners in benefit plans.

 Community clinics in such settings as Patient Centered Medical Homes (PCMH) may consider including licensed complementary and alternative healthcare or integrative practitioners. (See Section 3502 of the Patient Protection and Affordable Healthcare Act.)

(While there are no federally-recognized accreditation standards or standardized licensing for "integrative medical doctors," to an extent this group is becoming a "discipline" in the eyes of the public although the present lack of education, credentialing and licensing standards makes this category of providers more challenging to examine as an entity.)

In short, the decision the stakeholder makes to access or include "CAM" is typically about a member of a discipline (if it is an individual) or members of a discipline (if an institution), which is part of a distinct system of care. The institutional purchaser may choose to shape the form of the treatment that the discipline provides. Yet the inclusion decision is ultimately not of needles, or an herb, or manual manipulation, but rather, of a discipline.

#### Heightened Use-Value of Disciplines Following 2010 Federal Health Law

Notably, the value to stakeholders of NCCAM leadership in disciplines research was boosted by changes to federal law in the Patient Protection and Affordable Healthcare Act of 2010 that call for greater integration of the distinctly licensed "CAM" and integrative practice disciplines. These include provisions related to PCMH (noted above, Section 3502), workforce (Section 5101), prevention and health promotion (Section 4001), Patient Centered Outcomes Research Institute (Section 6301) and, most importantly, non-discrimination in payment (Section 2706). This increased inclusion, reflecting changes already in place in many states, creates questions throughout the payment and delivery system for which disciplines research can provide answers.

#### **Definition of "Disciplines Research"**

In our ACCAHC Research Working Group discussion of disciplines research on October 4, 2010, we agreed that it would be useful to offer a definition of "disciplines research" in the context of related research approaches. Appendix B includes our definitions of *real world research*, *whole systems research* (based in part on NCCAM's definition), *whole practice research*, *research into health and health promotion*, and *disciplines research*. We define "disciplines research" in this way:

The most useful form of "disciplines research" is that which responds to Section c of the NCCAM enabling law: "... study the integration of ... disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States." Disciplines research in this context captures the outcomes of members of a given discipline (e.g. chiropractors, licensed acupuncture and Oriental medicine practitioners, massage therapists, naturopathic physicians, integrative MDs, yoga therapists) in such a way as to inform the decisions of third-party payers, health systems, employers and other stakeholders that are considering including new disciplines in healthcare delivery. Key outcome measures again are satisfaction, effectiveness and cost-effectiveness. A supportive and related form of disciplines research is examining practice differences, similarities and outcomes inside a discipline or between different disciplines (e.g. integrative medicine practices by MDs and naturopathic medical practices). More clearly defining the discipline can be useful to all stakeholders in the healthcare delivery systems and also to the profession itself. Such research can also help identify which of multiple modalities may have the most important impacts. Such research can help with the understanding of the "real world patterns and outcomes" noted in the draft Strategic Plan. PBRNs can also be very useful here.

One NCCAM mechanism for engaging disciplines research would be to create a multifaceted program that directly highlights this type of research. Elements could include: convening a focused NCCAM workshop on the topic; developing educational materials to elevate the visibility of this type of research; supporting training grants in this area; and developing a program offering that targets the outcomes relative to inclusion of disciplines that will be of use to stakeholders. As part of this multi-pronged effort, NCCAM could reissue variants on the traditional systems, health services, PBRNS, and observational RFAs that have appeared (and lapsed) in the past, with a special focus on the examinations of disciplines.

We recognize that many of these prior program offerings addressing disciplines research did not elicit a large response. Some of these requests for proposals arrived prior to the ability of the ACCAHC fields to respond adequately. We believe the researchers in our fields are better equipped to respond now, in part thanks to the investments of NCCAM over the past decade. We believe that if these programs were emphasized in the strategic plan and offered in the context of NCCAM's real world and health-promotions priority (currently Strategic Objective #3), that the research community would recognize that these programs reflect an ongoing NCCAM interest rather than an aberration from core interests. CAM researchers would respond more vigorously. NCCAM's message would be particularly strong if real world/health-promoting outcomes were elevated to Strategic Objective #1, as we have recommended.

#### Key NCCAM Strategy: CAM-Discipline Practice Based Research Networks (PBRNs)

Chief research strategies are noted in the definitions "disciplines research" and "whole practice research" in Appendix B. A critical mechanism for such research is discipline-specific PBRNs in at least each of the core licensed disciplines of chiropractic, naturopathic medicine, acupuncture and Oriental medicine, massage therapy and MD-led integrative medicine. PBRNs can be a key piece of community-based infrastructure for learning about how the discipline actually practices and also for disseminating quality improvement initiatives, best-practices and guidelines and for acculturating an ethic of self-evaluation in members. PBRNs can be tremendous vehicles for asking questions and generating information. PBRN initiatives are in-place or underway in all 4 fields. NCCAM's role would be to:

- Support the organizing and development of these discipline-specific PBRNs;
- Offer RFAs for outcomes, quality improvement, clinical epidemiology, demonstration projects/evaluations and health-promotion programs through PBRNs of licensed integrative practitioners; and,
- Training of CAM discipline researchers on skill sets in these research environments.

We believe there is a likelihood that each of these disciplines could rally around one or more PBRNs if NCCAM shared an intent for an ongoing use of this structure. Also, expressed intent by NCCAM to support research opportunities that might benefit from the structure of a PBRN would support the organizing and development of these PBRNs.

Note that what we are proposing is to be distinguished from your prior PBRN initiative, which leaned on conventional PBRNs, and is distinct from the HMO network initiative with which you are involved. A discipline-specific PBRN could prove the most significant vehicle for generating real world research; it would also help to increase the participation of these fields in the research endeavor. Partnership with academic health centers or existing PBRNs may also be useful.

#### **Training and Infrastructure Investments**

We believe that top quality disciplines research will require top-quality researchers **from the licensed CAM disciplines.** Scientists from our fields, or those employed by or principally affiliated with CAM schools, will be most likely to frame the questions that capture the disciplines' practices. This focus in no way disregards the value of partnerships with conventional colleagues. To build up the corps of CAM discipline researchers, we urge investment in CAM discipline-focused:

- K grants and support for early stage investigators;
- T32 grants, with at least one per discipline;
- informatics projects, including those that support PBRNs;
- awards for CAM disciplines clinicians or CAM institution-based scientists who will focus on real world, health-promoting, outcomes-oriented and health services research;
- partnerships with other NIH agencies (e.g., NCRR) in bricks and mortar programs;
- training for clinicians who plan to be involved in research while remaining clinicians; and,
- continuing and enhancing the R-25s for CAM colleges.

We view an expanded R25 program as especially useful. These grants have clearly been instrumental in changing the culture of our institutions that have received them. They not only intensify the focus on evidence in the education of new doctors, but they also help educate faculty so the faculty bring research-based content into coursework. Efficient dissemination strategies can be developed and supported by NCCAM through which previously unfunded CAM schools can partner with past recipients to take advantage of the learning of the first R-25s. While nominally education grants, these are critically important in supporting other aspects of disciplines research.

#### **Capacity Building in the ACCAHC Disciplines**

The R-25 programs are a good bridge to the issue at the core of "disciplines research." Examining the social value of the ACCAHC disciplines is closely linked, at every level, with the question of capacity building in these disciplines and in their educational institutions.

Optimal strategic investment in the research capacity in the ACCAHC disciplines requires an understanding of the recent histories of these disciplines relative to the NIH and federal support. For most of the last 60 years of massive growth in federal investment in research, in physical plant and in training of the research workforce, the CAM disciplines were not in the fold. Through 1990, this exclusion was marked by great prejudice. This estrangement restricted development of both the evidence orientation and research involvement of the ACCAHC disciplines. Attitudes began to shift in the last 15 years, though prejudice remains present in many ways and large capacity deficits persist.

In short, the playing field for researchers principally associated with the licensed CAM disciplines and their institutions has not been, nor is it today, level. We believe that **affirmative**, **directive programs from NCCAM** in the period molded by the new Strategic Plan can significantly advance the quality and quantity of CAM research contributions to bettering the public health. NCCAM investment to date has played a significant role in creating a leadership group from the licensed CAM disciplines. We are eager to collaborate with you and your staff and with each other in this work.

We look forward to a meeting, at your earliest convenience, to explore this agenda and securing its place in the Strategic Plan.

Sincerely,

Elizabeth Goldblatt, PhD, MPA/HA
Chair, ACCAHC Board of Directors
On behalf of the Board and ACCAHC
Members (^)

Greg Cramer, PhD, DC
Chair, ACCAHC Research
Working Group

Thank you again for your time. We look forward to the final plan.

(^) Due to her employment at NCCAM, RWG member Wendy Weber, ND, MPH, PhD abstained from participation in development of the letter. RWG member Janet Kahn, PhD, a present member of the NIH National Advisory Council for Complementary and Alternative Medicine, also chose not to participate with this letter.

# Appendix to Letter #4: Definitions of Real World, Whole Practice, Whole Systems, "Disciplines Research"

#### Real world research

"Real world research" is research that seeks to capture the outcomes of what is taking place in clinical practice. The phrase embraces the top three priority areas for research in the NCCAM mandate which "the Director of the Center shall conduct or support ...: (1) Outcomes research and investigations; (2) Epidemiological studies and (3) Health services research." From the perspective of the ACCAHC disciplines, this means examining private and group practices, rather than beginning by refracting these practices into procedures to assess in clinical trials. Part of the work here may be viewed as "clinical epidemiology." Significant observational studies can be useful.

#### Whole systems research

"Whole medical systems" are defined on the NCCAM website as "complete systems of theory and practice that have evolved over time in different cultures and apart from conventional or Western medicine." Mentioned are traditional Chinese medicine, Ayurvedic medicine, naturopathic medicine, and homeopathic medicine. However, the term "whole systems research" is frequently used to denote a broader, more complex challenge, particularly since "whole system" is sometimes conflated with the whole system of delivery (access, finance, social support/opprobrium, etc.). For instance, "whole systems research" may mean examining: a hospital system in which reflexology and acupuncture treatments are included in inpatient care; an outpatient system for chronic pain management led by a holistic nurse, in which patients can be referred to chiropractors and massage therapists, be given a relaxation DVD, and also use conventional pain specialists; an integrative medical clinic in which care is organized by an "integrative medical doctor" who provides an integrative consult, offers some therapeutic suggestions or a guided imagery session, then sends patients to receive services from a variety of "CAM" practitioners; and an integrated delivery system that seeks to create an "optimal healing environment" that views physical space, staff communication, process of services, provider-patient relationships, choices of providers and therapies as contributors to healthcare outcomes. Dialogue on assessing these approaches can be extremely challenging and often lead to the field of complexity science.

#### Whole practice research

"Whole practice research" is used when referring to the theories and modalities of a discipline; and specifically, to what the practitioner does and the rules that guide the application. This term is useful in contradistinction to the examination of a broader system of care delivery in a hospital or multi-practitioner environment such as those noted above. The "whole" here is an individual practitioner's typical whole person, multi-variable approach to and interaction with patients. Thus, one refers to the whole practice of, for instance: naturopathic medicine (eclectic mix of botanicals, nutrients, counseling, homeopathic remedies, conventional formulary); acupuncture and Oriental medicine (counseling, practitioner-patient relationship, tui na, herbs, moxibustion, cupping, nutrition, and acupuncture needles): chiropractic health care (counseling, possibly nutrition, self-care methods, exercises, adjustments); Yoga therapy or massage, each of which often includes more than merely the physical intervention; and integrative practice of a medical doctor (botanicals for acute conditions, functional medicine/nutrients, acupuncture needles for limited conditions, plus conventional medical practice). Research on the outcomes of the whole practice can be reasonably captured through strategies of multiple linear outcome measures, e.g. satisfaction, effectiveness, functionality and costs/cost-offsets and comparative effectiveness. Practice-based research networks are effective ways of assessing whole practice research.

#### **Disciplines research**

The most useful form of "disciplines research" is that which responds to Section c of the NCCAM enabling law: "... study the integration of ... disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States." Disciplines research is this context captures the outcomes of multiple members of a given discipline (e.g. chiropractors, licensed acupuncture and Oriental medicine practitioners, massage therapists, naturopathic physicians, integrative MDs, licensed midwives, yoga therapists) in such a way as to inform the decisions of third-party payers, health systems, employers and other stakeholders for including new disciplines in healthcare delivery. Key outcome measures again are satisfaction, effectiveness and cost-effectiveness. A supportive and related form of disciplines research is examining practice differences, similarities and outcomes inside a discipline or between different disciplines (e.g. integrative medicine practices by MDs and naturopathic medical practices). More clearly defining the discipline can be useful to all stakeholders in the healthcare delivery systems and also to the profession itself. Such research can also help identify which of multiple modalities in combination or together, may have the most important impacts. Such research can help with the understanding of the "real world patterns and outcomes" noted in the draft Strategic Plan. PBRNs can also be very useful here.

#### Research on improving health and health promotion

Most practitioners from CAM and integrative care disciplines claim real-world, health-enhancing, outcomes for their patients and clients due to the whole practice of their care. Members of these disciplines view these health outcomes or "positive side-effects" as core values in their health approaches. (For instance, it is not at all surprising for a patient of a whole person-focused integrative practice to find that one or more health issues improves in the course of treatment even if the conditions for which the patient presented has not positively resolved.) Research tools for examining the possible improvement of health and health promotion can include quality of life and functionality measures; however, there is a need for additional outcome measures to fully capture such improvements.

# NCCAM Mandate – Enabling Legislation from US Congress

112 STAT. 2681–387 PUBLIC LAW 105–277—OCT. 21, 1998
TITLE VI—NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
SEC. 601. ESTABLISHMENT OF NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE.

IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—(1) by striking section 404E; and (2) in part E, by adding at the end the following: "Subpart 5—National Center for Complementary and Alternative Medicine

"(a) IN GENERAL.—The general purposes of the National Center for Complementary and Alternative Medicine (in this subpart referred to as the 'Center') are the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention **modalities**, **disciplines and systems**. The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

<sup>&</sup>quot;SEC. 485D. PURPOSE OF CENTER.

- "(b) ADVISORY COUNCIL.—The Secretary shall establish an advisory council for the Center in accordance with section 406, except that at least half of the members of the advisory council who are not ex officio members shall include **practitioners licensed in one or more of the major systems** with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and alternative medicine.
- "(c) COMPLEMENT TO CONVENTIONAL MEDICINE.—In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of alternative treatment, diagnostic and prevention systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States.
- '(d) APPROPRIATE SCIENTIFIC EXPERTISE AND COORDINATION WITH INSTITUTES AND FEDERAL AGENCIES.—The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and alternative medicine are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with appropriate scientific expertise. The Director of the Center shall coordinate efforts with other Institutes and Federal agencies to ensure appropriate scientific input and management.
- "(e) EVALUATION OF VARIOUS DISCIPLINES AND SYSTEMS.—In carrying out subsection (a), the Director of the Center shall identify and evaluate alternative and complementary medical treatment, diagnostic and **prevention modalities in each of the disciplines and systems** with which the Center is concerned, including **each discipline and system** in which accreditation, national certification, or a State license is available.
- "(f) ENSURING HIGH QUALITY, RIGOROUS SCIENTIFIC REVIEW.— In order to ensure high quality, rigorous scientific review of complementary and alternative, diagnostic and **prevention modalities, disciplines and systems,** the Director of the Center shall conduct or support the following activities:
- "(1) Outcomes research and investigations.
- "(2) Epidemiological studies.
- "(3) Health services research.
- "(4) Basic science research.
- "(5) Clinical trials.
- "(6) Other appropriate research and investigational activities.

The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

- "(g) DATA SYSTEM; INFORMATION CLEARINGHOUSE.—
- "(1) DATA SYSTEM.—The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and alternative treatment, diagnostic and **prevention modalities, disciplines and systems**. Such a system shall be regularly updated and publicly accessible.
- "(2) CLEARINGHOUSE.—The Director of the Center shall establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of alternative medical treatment, diagnostic and **prevention practices by health professionals**, patients, industry, and the public.
- "(h) RESEARCH CENTERS.—The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multipurpose centers to conduct research and other activities described in subsection (a) with respect to complementary and alternative treatment, diagnostic and **prevention modalities, disciplines and systems**. The provision of support for the development and operation of such centers shall include **accredited complementary and alternative medicine research and education facilities**.
- "(i) AVAILABILITY OF RESOURCES.—After consultation with the Director of the Center, the Director of NIH shall ensure that resources of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appropriately and effectively carry out its duties as described in subsection (a). The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.
- "(j) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated to carry out this section for fiscal year 1999 are available for obligation through September 30, 2001. Amounts appropriated to carry out this section for fiscal year

2000 are available for obligation through September 30, 2001.".

(k) TECHNICAL AND CONFORMING AMENDMENT.—Section 401(b)(2) of the Public Health Service Act (42 U.S.C. 281(b)(2) is amended by adding at the end the following: 112 STAT. 2681–389 PUBLIC LAW 105–277—OCT. 21, 1998

"(F) The National Center for Complementary and Alternative Medicine."

# ACCAHC Tuesday Letter Special (February 2011): Celebrating Outcomes of Our Collaboration in the NCCAM Strategic Plan

Hello ACCAHC Board Members, WG Members, Organizational Leaders, Advisers, Key Donors:

This Special Tuesday celebrates the very positive impact from our hard work together in collaborating to identify and communicate shared interests. This Letter follows excellent news in the NIH NCCAM 2011-2015 Strategic Plan published last Friday.

# *Credit NCCAM's Responsiveness:* ACCAHC helps focus Strategic Plan on researching impact of "disciplines"

NCCAM's draft plan, released August 2010 had much we liked in it, particularly the focus on the "real world" research and on health outcomes. However, the plan still focused on researching "CAM modalities," "CAM practices" and "CAM therapies." It never directly mentioned the importance of researching the impact of including new "disciplines" in our delivery system.

#### Why the importance of "disciplines" research?

The NCCAM mandate targets such research in its first directive: "... study the integration of ... disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States." (See Section C, bottom of <a href="this article">this article</a>.) The "disciplines" of particular note were the "licensed CAM professions" that constitute ACCAHC's core membership.

Research on the impact of "disciplines" yields the real world outcomes that are most needed to help stakeholders (hospitals, employers, insurers, government payers, community clinics, medical homes, consumers, etc.) know what will happen if they include our disciplines in their care delivery, care or coverage. Such research can include use patterns, effectiveness, functionality, costs and cost-offsets.

#### ACCAHC's work to elevate "disciplines research" in NCCAM's plan

In 2 ACCAHC Research Working Group (RWG)-developed and Board-approved letters (November 2009, May 2010) and a conference call (March 2010) with NCCAM leaders, we focused on the value of looking at whole practices (disciplines) and costs.

But it was in the RWG-developed and Board-approved letter in response to the draft plan (September 2010) that we directly focused on the importance of including "disciplines" language. We recommended 13 specific line-item edits where the plan would be stronger if "disciplines" were included alongside "modalities" or "therapies." (See <u>ACCAHC section of this article</u> for the suggestions.) **Then in October 2010, the RWG developed and Board approved a follow-up letter that specifically focused on "disciplines research," including supplying a definition**. (The definition is attached at the bottom of this letter.)

#### **NCCAM** responds

In a conference call on November 2, 2010, NCCAM Deputy Director Jack Killen, MD referenced our focus on "disciplines" research and our recommendations that "disciplines" be directly noted throughout, saying that these was "a lot of resonance [at NCCAM] with the direction (ACCAHC) recommended." He said he anticipated that there would be multiple references to "disciplines" in the final document. Others were pushing for this real world direction; the disciplines push appeared to be largely ours.

On Friday I skimmed through the plan. **The importance of focusing on "disciplines" is presented in some three dozen places.** In fact, the idea of researching "disciplines" made it into NCCAM's Strategic Objective #1. (See points of inclusion of "disciplines," below.)

#### Value to our colleagues in integrative medicine and holistic nursing

Notably, these changes do not only point toward examining ACCAHC's disciplines. The focus could also be a basis for research on the impact of disciplines such as: holistic nurses in an inpatient environment; integrative medical doctors in cancer treatment; health coaches in secondary prevention; and potentially, of functional medicine-trained practitioners in a clinic that serves the underserved.

Hopefully, our work to highlight "disciplines research" will also assist stakeholders in understanding inclusion of these other disciplines in their payment and delivery.

#### ACCAHC next steps: February 28 delegation to NCCAM

An ACCAHC delegation to NCCAM on February 28 will soon know more about what this means! Deputy Director Killen helped facilitate setting up this meeting. The ACCAHC delegation will include:

- RWG chair Greg Cramer, DC, PhD
- RWG members Carlo Calabrese, ND, MPG, Beau Anderson, PhD, LAc, Martha Menard, PhD, LMT
- ACCAHC vice chair David O'Bryon
- Bill Meeker, DC, MPH (chiropractic researcher, Palmer West president and CWG member) and
- ACCAHC executive director John Weeks.

The ACCAHC team met in a planning session February 7; 2 more calls are booked for later this month. We are looking forward to the dialogue and are appreciative of the open exchange that has characterized our extensive dialogue with NCCAM's leaders during the course of the Strategic Plan process. We are all charged to study the plan more fully before our February 14 call!

### Others who provided significant input

The ACCAHC delegation members have each been instrumental in shaping ACCAHC's work. Others who have been particularly active in forming our response over the last 15 months:

- RWG members Mitch Haas, DC, MA, Patricia Herman, ND, PhD, MA, Iris Bell, MD,
- NCCAM advisory council members Janet Kahn, PhD (also on RWG), Adam Burke, PhD, LAc, MPH
  (also on the EWG) and Tim Birdsall, ND
- Joe Brimhall, DC, Board member
- Heather Zwickey, PhD, ACCAHC past RWG co-chair.

Thanks to all of these (and I am sure I am leaving some out). Thanks to this work, the Strategic Plan is a better platform for research proposals that can advance our collaboratively established priorities to seek to better health care by examining whole systems, costs/cost-offsets and by building capacity in our fields. *Enjoy the moment!* 

John			

#### The "Disciplines" focus in the NCCAM Strategic Plan

As you read, consider the same sentence(s) without the inclusion of "disciplines."

## Page 7 – 3<sup>rd</sup> Sentence of the Introduction:

NCCAM defines CAM simply as a group of diverse medical and health care interventions, practices, products, or **disciplines** that are not generally considered part of conventional medicine.

#### Page 11, under Goal #2:

Many CAM and integrative medicine practitioners and **disciplines** employ various CAM-based interventions (e.g., meditation or yoga) to help motivate people to adopt and sustain health-seeking behaviors, or they encourage dietary practices (sometimes grounded in traditional medical systems) that incorporate a healthy food philosophy.

#### Page 14, Under Mind-Body

Exploring the role of specific promising CAM practices or **disciplines** (e.g., meditation, yoga, or acupuncture) in developing better strategies for alleviating symptoms (e.g., chronic pain, stress) or in promoting healthier lifestyles

#### Page 15/9, under Mapping the Path Forward, end of 2<sup>nd</sup> #

It is essential that similar opportunities for investigator-initiated research involving less well-studied or characterized CAM interventions and **disciplines** be preserved.

Page 17/11, top sentence, bolded:

CAM interventions, approaches, and disciplines can and must be studied across the continuum of basic, translational, efficacy, and effectiveness research.

#### Page 19/13, top paragraph:

Most CAM interventions are readily available to the public, and many are used regularly in the health care and health promotion practices of individuals and professions. There are increasingly viable opportunities to take advantage of this fact by employing the methods and tools of clinical outcomes and effectiveness research to develop (1) evidence, based in real-world practices and use, about the potential of CAM interventions, modalities, and **disciplines** to contribute to better treatment and health promotion and (2) data needed to design maximally informative clinical trials.

### Page 19/13, 3<sup>rd</sup> bold heading

Research on the contributions of CAM interventions, practices, and disciplines in promoting or supporting health-seeking behavior is another area of special public health need and scientific opportunity.

#### Page 21/15 In Strategic Objectives

Strategic Objective 1: Advance research on mind and body interventions, practices, and disciplines.

Page 29/23, bolded

Strategy 1.2: Support translational research to build a solid biological foundation for studies of efficacy or effectiveness of mind and body interventions or disciplines.

#### Page 43/37, under Strategic Objective #3, 2<sup>nd</sup> paragraph

CAM's extensive use by both adults and children in the general population presents opportunities to use tools and methods of the disciplines of observational, survey, epidemiology, outcomes, health services, and effectiveness research to help address a number of information needs about CAM interventions, practices, and **disciplines**, including:

#### Page 43/37, bullet point 4 under this heading:

The potential role of CAM interventions, practices, or **disciplines** in supporting healthy lifestyles and wellbeing.

#### Page 44/38, under the IOM's interest in CER for CAM

Information about these and related matters derived from rigorous population-based research has significant potential to help in (1) identifying and shaping research priorities and initiatives, (2) building evidence needed to advance research on specific promising interventions, practices, **or disciplines**, and (3) informing and shaping health care policy.

#### Page 48/42, under Strategic 3.2

The disciplines of observational, outcomes, health services, and effectiveness research offer a number of tools, methods, and pragmatic study designs for gathering useful evidence regarding CAM interventions and **disciplines** on a larger scale than typical clinical trials.

#### Next paragraph, page 49/43

For example, some specific CAM interventions or **disciplines** are covered by some health insurance providers and not covered by others.

#### Page 50/43, Strategy 3.3, bolded:

Strategy 3.3: Conduct research on the potential of CAM interventions, practices, or disciplines to support healthy lifestyle behaviors and behavior change.

#### Next sentence:

Many CAM **disciplines**, systems of traditional medicine, and integrative medicine practices place a strong emphasis on preventive health strategies, including better dietary practices and regular physical exercise.

#### Page 53/47: First paragraph of Strategic Objective #4

When Congress established NCCAM, it recognized the need to build research capacity in the field and authorized NCCAM to undertake various steps to bring together qualified experts from various CAM disciplines and the biomedical sciences to carry out NCCAM's research mission. These efforts have been successful in training and creating a cadre of CAM research scientists from biomedical, behavioral, and CAM backgrounds. A robust and highly collaborative interdisciplinary community of investigators, based in both conventional biomedical and CAM institutions, now employs and develops state-of-the-art research methods and tools in studying the safety and potential application of CAM interventions. [We urged more visible inclusion of our institutions as well as our disciplines.]

#### Below, 2 paragraphs later:

To pursue these questions successfully, NCCAM must continue to ensure that the human talent, resources, and infrastructure needed to design and carry out the highest quality basic, translational, and clinical research are in place; that they involve collaborative, interdisciplinary research partnerships across a spectrum of scientific and **health practice disciplines** and experiences; and that the Center takes advantage of opportunities to leverage national and international scientific resources and experience.

#### Page 54/48, under Strategy 4.1

A successful and robust CAM research enterprise must draw from two sources of well-trained, skilled, and experienced talent: **CAM practitioners expert in their respective disciplines** and biomedical/behavioral scientists expert in cutting-edge scientific methods.

#### Page 55/49, same section, first bullet:

Going forward, NCCAM will continue to support a variety of high-quality research training and career development opportunities aimed at building and maintaining a vibrant, productive, multidisciplinary, and diverse research enterprise and addressing the unique needs for research training in this field. In particular, the Center will focus on:

**CAM practitioners** who wish to gain the knowledge and experience needed to engage in rigorous, collaborative, multidisciplinary research in their field.

\_\_\_\_\_

#### "Disciplines Research" as Defined in ACCAHC October 28, 2010 Letter to NCCAM

The most useful form of "disciplines research" is that which responds to Section c of the NCCAM enabling law: "... study the integration of ... disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States." Disciplines research in this context captures the outcomes of members of a given discipline (e.g. chiropractors, licensed acupuncture and Oriental medicine practitioners, massage therapists,

naturopathic physicians, integrative MDs, yoga therapists) in such a way as to inform the decisions of third-party payers, health systems, employers and other stakeholders that are considering including new disciplines in healthcare delivery. Key outcome measures again are satisfaction, effectiveness and cost-effectiveness. A supportive and related form of disciplines research is examining practice differences, similarities and outcomes inside a discipline or between different disciplines (e.g. integrative medicine practices by MDs and naturopathic medical practices). More clearly defining the discipline can be useful to all stakeholders in the healthcare delivery systems and also to the profession itself. Such research can also help identify which of multiple modalities may have the most important impacts. Such research can help with the understanding of the "real world patterns and outcomes" noted in the draft Strategic Plan. PBRNs [Practice-Based Research Networks] can also be very useful here.